



New to Healthcare Law, Compliance, and Regulations

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Compliance = Doing the Right Thing

- Compliance with Laws and Regulations
 - ***Does it break the law?***
- Compliance with Policies and Procedures
 - ***Does it violate an organizational standard?***
- Compliance with Ethical Guidelines
 - ***Does it make you feel uneasy or nervous?***

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“Compliance” Means...

- Confidentiality (HIPAA)
 - Payments, Discounts, Gifts
 - Patient Referrals
 - Regulatory Programs
 - Federally Funded Programs
 - Scientific Integrity
 - Computer Use
 - Anti-Discrimination
 - Billing, Claims, and Medical Record Documentation
 - Market Competition
 - Purchasing
 - Workplace Safety
 - Waste Disposal
 - Controlled Substances
 - Political Contributions
 - Fundraising
- ...not an exhaustive list!**

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The Medicare Perspective

“Physicians, medical equipment suppliers, clinical laboratories, beneficiaries, and other healthcare providers are all possible candidates for committing Medicare fraud and abuse.”



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What is the “OIG?”

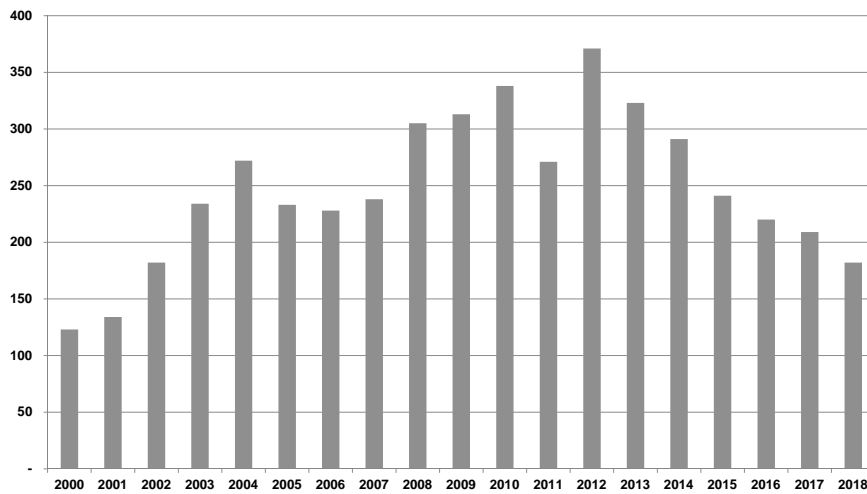
- Department of Health and Human Services Office of the Inspector General (HHS-OIG)
- Established by Congress in 1976
 - To identify and eliminate fraud, waste and abuse
 - To promote efficiency and economy in operations
- Responsible for conducting audits, evaluations, and both criminal and civil investigations for all HHS agencies, including...
 - Centers for Medicare and Medicaid Services (CMS)
 - Public Health Service Agencies
 - Agency for Healthcare Research and Quality (AHRQ)
 - Centers for Disease Control (CDC)
 - Food and Drug Administration (FDA)
 - Health Resources and Services Administration (HRSA)
 - Indian Health Services (IHS)
 - National Institutes of Health (NIH)
 - Substance Abuse and Mental Health Services Administration (SAMHSA)
 - Human Services
 - Administrations for Children & Families, Aging, and Community Living



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Total # of OIG Reports



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~~Seven~~ **Eight Essential Elements of Compliance**

1. Designation of Compliance Officer and Committee
 2. Code of Conduct and Written Policies and Procedures
 3. Conducting Effective Training and Education
 4. Auditing and Monitoring
 5. Developing Effective Lines of Communication
 6. Enforcing Standards Through Well-Publicized Disciplinary Guidelines
 7. Responding to Detected Offenses and Developing Corrective Action Initiatives
 8. Defining Roles and Responsibilities and Assigning Oversight Responsibility
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United States Sentencing Commission, Guidelines Manual, §8A1.2, comment n.3 (2004)

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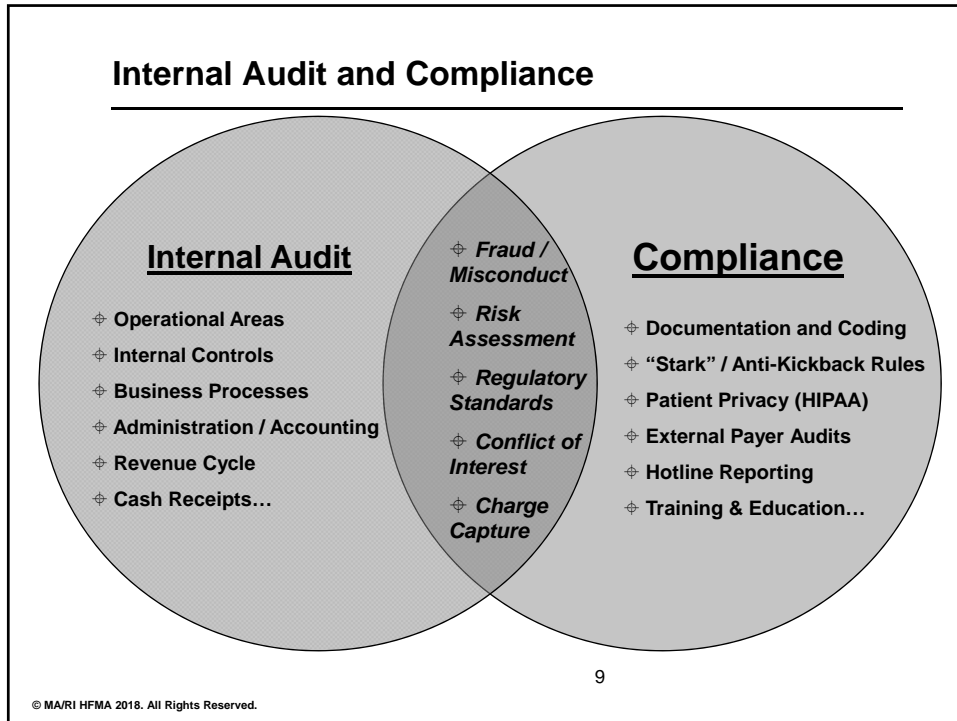
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OIG Compliance Guidance

- Hospitals
- Nursing Facilities
- Individual and Small Group Physician Practices
- Home Health Agencies
- Hospices
- Clinical Laboratories
- DME, Prosthetics, Orthotics, and Supplies
- Ambulance Providers
- Third-Party Medical Billing Agencies
- Pharmaceutical Manufacturers
- Medicare + Choice Organizations
- Recipients of PHS Research Awards

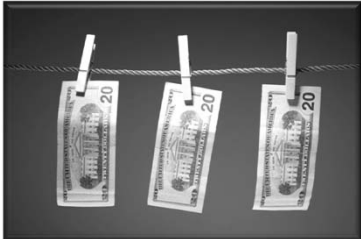
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- ### Key Compliance Risk Areas
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- 1. False Claims**
 - 2. Physician Self-Referral vs. Kickbacks**
 - 3. Privacy / Electronic Security**
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Billing and “False Claims”

- Federal and State law prohibits reimbursement for healthcare services that are not rendered appropriately or documented accurately
- 
- Billing for an inappropriate or inaccurate level of service may be classified as a **false claim** *
 - Violations can result in payment refunds, civil fines, imprisonment, and exclusion from government healthcare programs

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* (Potential) “False Claims”

- Consistently billing for office visits as a **Level 4 or Level 5** regardless of the appropriate level of service
- Routinely **copying-and-pasting** notes from previous patient encounters in order to justify billing for a higher level of service at subsequent visits
- Documenting **inaccurate face-to-face time** spent with a patient during time-based encounters
- Ordering tests or procedures that are **not medically necessary** or are unreasonable for the patient’s treatment

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Causes of Billing Errors

“[T]he statutes and provisions in question, involving the financing of Medicare and Medicaid, and among the most completely impenetrable texts within human experience. Indeed one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making **any solid grasp of the matters addressed merely a passing phase.**”

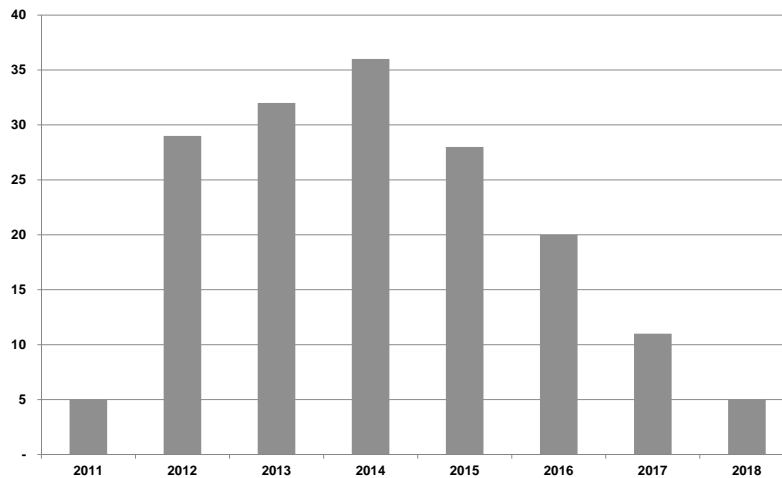


Rehab. Ass'n of Va., Inc. v. Koslowski, 42 F.3d 1444, 1450 (4th Circuit), cert. denied, 516 US 811, 116 S.Ct. 60, 133 L.Ed.2d 23 (1995) Cited in Briggs v. Comm., 429 Mass. 241, 707 N.E.2d 355 (1999).

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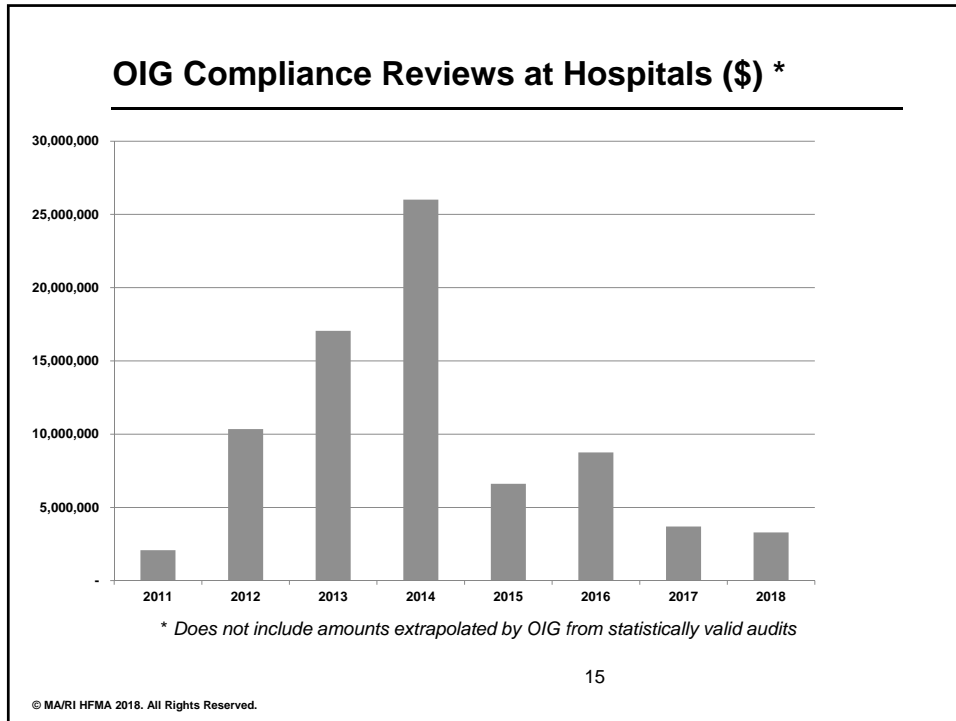
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OIG Compliance Reviews at Hospitals (Reports by FY)



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OIG Compliance Reviews at Hospitals

- **Top 10 Risk Areas: INPATIENT**

1. One-Day and "Short" Stays	\$	36,770,000
2. High Severity Level DRG		5,910,000
3. Claims Paid in Excess of Charges		5,550,000
4. Manufacturer Credits for Medical Devices		4,200,000
5. Inpatient Rehabilitation Facility		3,350,000
6. Transfers		2,550,000
7. Same-Day Discharges and Readmissions		2,510,000
8. Payments Greater than \$150,000		490,000
9. DRG Verification		310,000
10. Kyphoplasty Services		280,000

* Does not include amounts extrapolated by OIG from statistically valid audits

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OIG Compliance Reviews at Hospitals

- **Top 10 Risk Areas: OUTPATIENT**

1. Manufacturer Credits for Medical Devices	\$	5,830,000
2. Lupron Injections		1,850,000
3. Claims Paid in Excess of Charges		1,630,000
4. Claims for Injectable Drugs		1,280,000
5. Dental Services		960,000
6. Surgeries Billed with Units Greater Than One		820,000
7. Payments Greater than \$25,000		790,000
8. Modifiers (-25, -59, -91)		530,000
9. OP Services Provided During an IP Stay		490,000
10. Anti-Cancer Drugs		370,000

** Does not include amounts extrapolated by OIG from statistically valid audits*

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OIG Compliance Reviews at Home Health Agencies

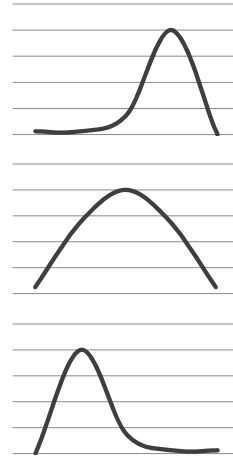
- Improper payment rate for home health claims was approximately 51% (compared to the overall rate of 12.7%) accounting for \$9.4 billion (compared to \$45.8 billion overall)
- The Home Health Prospective Payment System covers intermittent skilled nursing and home health aide visits, covered therapy (physical, speech-language pathology, and occupational), medical social services, and medical supplies
- The OIG commenced auditing home health agencies in 2016, so far there have been three reports issued; and related findings include ...
 - Incorrectly billing for beneficiaries who were not homebound
 - Incorrectly billing for beneficiaries who did not require skilled services
 - Missing or insufficient documentation
 - Improper coding

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Identifying Risk: Internal Data

- Allegations, Complaints, and Questions
- Findings from Previous Audits
- Data Benchmarking
 - Provider by Provider
 - Specialty by Specialty
 - Year by Year

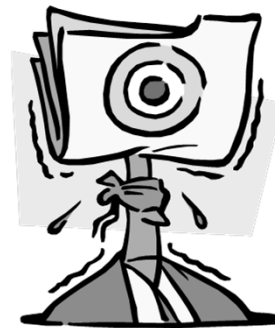


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Identifying Risk: External Data

- OIG Work Plan
- Recovery Audit Contractors (RAC)
“Issues Under Review”
- National Government Services (NGS)
Prepayment Audits for Specific Services
- Centers for Medicare and Medicaid Services (CMS)
Medicare Quarterly Provider Compliance Newsletter
- Publicly Available Data (e.g., MEDPAR)
 - Comprehensive Error Rate Testing (CERT) Reports
 - Medicare Provider Utilization and Payment Data
 - Public Data on Industry-Physician Financial Relationships, i.e., “Open Payments Program” or “The Sunshine Act”
- Proprietary Data (e.g., MGMA, PEPPER)



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Laws Governing Referrals

Stark Prohibition on Self-Referrals

- * A Physician
- * May Not Make Medicare Referrals
- * For “Designated Health Services”
- * If the Physician (or a family member) has a Financial Relationship with the Entity
 - Direct or Indirect
 - Compensation or Ownership

Anti-Kickback Statute (AKS)

- * Knowingly and Willfully
- * Offer, Pay, Solicit, or Receive
- * Remuneration (i.e., “anything of value”)
 - Directly or Indirectly
 - Overtly or Covertly
 - In-cash or In-kind
- * To Induce or Reward the Referral of Items or Services Reimbursable by a Federal Health Care Program

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Laws Governing Referrals – Safe Harbors

- Academic Medical Centers
- Ambulance Replenishing
- Ambulatory Surgery Centers
- Assistance to Compensate a Non-physician Practitioner
- Certain Arrangements With Hospitals
- Charitable Donations by a Physician
- Community-Wide Health Information Systems
- Cooperative Hospital Service Organizations
- Compliance Training
- Discounts
- Electronic Health Records Items and Services
- Electronic Prescribing Items and Services
- Employment Relationships
- EPO and Other Dialysis-Related Drugs
- Eyeglasses and Contact Lens Following Cataract Surgery
- Fair Market Value Compensation
- Federally Qualified Health Centers
- Group Practice Arrangements With a Hospital
- Group Purchasing Organizations
- Investment Interests
 - Publicly-Traded Securities/Large Investment Interest
 - Mutual Funds
 - Invest. Int. Held by Active or Passive Investors
 - Invest. Int. /Joint Ventures in Rural, Underserved Areas
 - Investments in Group Practices
 - Hospital Investment or Ownership
- Implants in an ASC
- Increased Coverage, Reduced Cost-Sharing Amounts, or Reduced Premium Amounts Offered by Health Plans
- Indirect Compensation Arrangements
- In-Office Ancillary Services
- Intra-Family Rural Referrals
- Isolated Transactions
- Medical Staff Incidental Benefits
- Non-Monetary Compensation
- Obstetrical Malpractice Insurance Subsidies
- Payments by a Physician
- Personal Service Arrangements
- Physician Services
- Physician/Practitioner Recruitment
- Preventive Screening Tests, Immunizations, and Vaccines
- Price Reductions Offered by Contractors With Substantial Financial Risk to Managed Care Organizations
- Price Reductions Offered to Eligible Managed Care Organizations
- Price Reductions Offered to Health Plans
- Professional Courtesy
- Referral Agreements for Specialty Services
- Referral Services
- Rental of Office Space and Equipment
- Retention Payments in Underserved Areas
- Risk Sharing Agreements
- Sale of Practice
- Services Furnished by an Organization to Enrollees
- Timeshare Arrangements
- Waiver of Coinsurance and Deductibles
- Warranties

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Enforcement Examples

- A medical laser company agreed to pay **\$126K** to settle allegations of providing physicians an all-expense paid trip to the **Masters Golf Tournament**
- Recent Justice Department complaint alleging that drug company operated multi-million dollar “incentive programs” for doctors who steered patients toward its drugs
 - Payments to doctors for **purported speaker programs** that either did not occur at all or that had few or no attendees
 - Speaker programs held “in circumstances in which it would have been virtually impossible for any presentation to be made” such as **Hooters restaurants or fishing trips off the Florida coast**
- Blood lab bribed a doctor with tickets to see **Justin Bieber, Katy Perry, the Mets, the Knicks and Broadway shows** in exchange for referring his patients' samples to them
 - Physician took \$3,300 a month plus tickets and meals in bribes
 - In exchange, he referred his patients' blood samples to the blood lab
 - The deal generated \$900K in business for the New Jersey-based lab
 - The president of the lab was convicted of bribery and faces 21 years in jail
 - Prosecutors sought \$50M from the physician

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Privacy and Electronic Security

Hhealth
Insurance
Portability
Accountability
Act of 1996



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Privacy and Electronic Security



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HIPAA Breach Notification Regulation

- **Applies to “Protected Health Information”**
 - PHI includes any individually identifiable information relating to provision of health care (including solely demographic or financial information)
- **Following breach of unsecured PHI, notice to:**
 - U.S. Office for Civil Rights
 - Each affected individual
 - In addition, notice to prominent media outlet if more than 500 people affected
- **Notice required “without unreasonable delay”**
 - No later than 60 days of discovery

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Massachusetts Data Breach Notification Statute

- **Applies to “Personal Information”**
 - First and last name or first initial and last name in combination with 1 or more of the following:
 - Social Security Number;
 - Driver's License Number or State-Issued ID; **or**
 - Financial Account, Debit/Credit Card Number (*incl. certain insurance policy numbers*)
- **Following breach of security, notice to:**
 - Mass. Office of Attorney General
 - Mass. Office of Consumer Affairs & Business Regulation
 - Each affected resident of Massachusetts
- **Notice required “as soon as practicable and without unreasonable delay”**

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Privacy / Electronic Security

- **University of Texas MD Anderson Cancer Center *June 2018***
 - **\$4.3M:** loss of USB drives; failure to implement policies on device-level encryption
- **Fresenius Medical Care North America *February 2018***
 - **\$3.5M:** 5 separate breaches; failure to conduct risk analysis
- **Bus. Assoc. – Filefax, Inc. *February 2018***
 - **\$100K:** medical records left in unlocked truck; company closed during investigation
- **21st Century Oncology *December 2017***
 - **\$2.3M:** patient files purchased by FBI informant; failure to conduct risk analysis
- **St. Luke's-Roosevelt Hospital *May 2017***
 - **\$390K:** disclosure of HIV status to employers; failure to implement corrective actions
- **Memorial Hermann Health System *May 2017***
 - **\$2.4M:** impermissible disclosure of patient identity in press release
- **Cardio Net *April 2017***
 - **\$2.5M:** stolen laptop, HIPAA policies were in draft / not implemented

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Privacy / Electronic Security

- **Metro Community Provider Network** ***April 2017***
 – \$400K: email phishing incident; failure to conduct risk analysis
- **Center for Children’s Digestive Health** ***April 2017***
 – \$31K: breach caused by business associate (Filefax); failure to enter BAA
- **Memorial Healthcare System** ***February 2017***
 – \$5.5M: login of former employee used to access ePHI of > 100K individuals
- **MAPFRE Life Insurance Company of Puerto Rico** ***January 2017***
 – \$2.2M: stolen USB drive from IT Department, failure to implement corrective actions
- **UMass Amherst** ***November 2016***
 – \$650K: malware infection, failure to implement technical security measures
- **St. Joseph Health** ***October 2016***
 – \$2.1M: PDF files containing ePHI accessible on the internet via Google search
- **Care New England System** ***September 2016***
 – \$400K: missing unencrypted backup tapes, failure to update BAA

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Privacy / Electronic Security

- **Advocate Health Care** ***August 2016***
 – \$5.55M: 3 separate breaches affecting 4M people, 1 incl. loss of unencrypted laptop
- **University of Mississippi Medical Center** ***July 2016***
 – \$2.75M: no workstation safeguards or unique logins to access ePHI, no risk assess.
- **Oregon Health & Science University** ***July 2016***
 – \$2.75M: stolen unencrypted laptops and thumb drive, cloud storage w/out BAA
- **Bus. Assoc. – Catholic Health Care Svcs of Philadelphia** ***June 2016***
 – \$650K: theft of a company-issued employee iPhone not password protected
- **New York Presbyterian Hospital** ***April 2016***
 – \$2.2M: unauthorized filming of two patients during “NY Med” television show
- **Raleigh Orthopaedic Clinic** ***April 2016***
 – \$750K: transferred x-ray films and PHI to a BA without an executed BAA
- **Feinstein Institute for Medical Research** ***March 2016***
 – \$3.9M: stolen laptop, lacked policies to govern receipt/removal of laptops

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Save the Date!



**MA-RI HFMA
Compliance Update
December 13, 2018**

200 Berkeley Street, Boston, MA

Billing and Coding * Recent Trends in Enforcement *
OIG Work Plan * Privacy and Security Best Practices

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Questions?

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