

Employment Law: An Essential Primer

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Disclosure

Anthony Calamunci is an employee with FisherBroyles, LLP. The conflict of interest was resolved by peer review of the slide content.

Brian Dickerston is an employee with FisherBroyles, LLP. The conflict of interest was resolved by peer review of the slide content.

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Learning Objectives



- Discuss the importance and proper procedures for security and background checks.
- Outline how to develop a program for training and compliance in HIPAA, FWA, and pharmacy audits.
- Discuss best practices for managing Human resources in the pharmacy.

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Pharmacy Employment Best Practices



- Personnel files
- Background checks
- Compliance
- Job descriptions
- Licensure across state lines
- Understanding your contracts and educating your staff

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Personnel Files



- Security:
 - › Maintain files in locked file cabinets. Ensure access to file cabinet keys is managed securely.

- Confidentiality:
 - › Only employees designated by the department head should be allowed access. Ensure contents are not visible to others when reviewing the file.

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Personnel Files



Required File Content:

- Employee Application
- Resume, letters of reference
- I-9 (Can be maintained in a central department file)
- State Oath of Allegiance and Patent Agreement
- W-4 Notice Regarding Overtime Compensation (nonexempt employees only)
- Emergency Contact Information
- Performance Appraisals and Position Description
- Licensure (Pharmacy Tech) (State by State)
- Background Check

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Personnel Files



Additional File Content:

- › Honors and Awards received by the employee
- › Corrective Action/Disciplinary Actions
- › Copies of any performance-related documents to be placed in the personnel file should also be provided to the employee with a Proof of Service form
- An Employee may request removal of corrective action/disciplinary action after two years provided there have been no similar incidents in that period of time (see applicable contract/policy and consult with Labor Relations for guidance).

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Personnel Files



Prohibited File Content:

- Documents related to an employee's medical condition, or a medical condition of the employee's dependents; must be stored separately from the employee's personnel file.
- A separate medical file should be used to store information regarding:
 - › FML forms and supporting documentation
 - › Work-related injury or illness forms and supporting documentation
 - › Disability-related documentation, including any requests for accommodation

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Background Checks

- Use of Counsel - Attorney Client Confidential
- Prior affiliations with illegal healthcare entities
- Banks Actions
- California Workers Comp Statute and Application

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Compliance

- Personnel File Audit
- Personnel Risk Assessment
- Whistle Blower Statute
- Compliance Enforcement by Pharmacy
- Use of Sales Reps
 - › W-2 (Legitimize Reps)
 - › Independent Contractors High Risk

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Licensure Across State Lines



- Employees requiring licensing will require BOP approval in all states doing business.
 - › Non-Resident Permit
 - › License
 - › Timing

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Understanding Contracts and Education



- Employee training (updating Personnel Files with accreditation)
- Employee Certification
- Compliance updates
- Risk Assessments ongoing
- Corrective Action Plans with third party payers and PBMs will require employee assessment(s)

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Health Insurance Portability and Accountability Act of 1996



- Public Law 104-191, included Administrative Simplification provisions that required HHS to adopt national standards for electronic health care transactions and code sets, unique health identifiers, and security, as well as privacy standards.
- HHS published a final Privacy Rule in December 2000, which was later modified in August 2002 to set national privacy standards.
- HHS published a final Security Rule in February 2003. This Rule sets national standards for protecting the confidentiality, integrity, and availability of electronic protected health information.
- The Enforcement Rule provides standards for the enforcement of all the Administrative Simplification Rules.
- HHS enacted a final Omnibus Rule that implements a number of provisions of the HITECH Act to strengthen the privacy and security protections for health information established under HIPAA, finalizing the Breach Notification Rule.

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Topics



Privacy Rule

Security Rule

Breach Notification Rule

Enforcement Rule

OCR Enforcement Actions



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HIPAA Compliance



STEP 1	RISK ASSESSMENT
STEP 2	BUSINESS ASSOCIATE AGREEMENTS
STEP 3	POLICIES AND PROCEDURES
STEP 4	TRAINING
STEP 5	BREACH PLAN
STEP 6	CONTINGENCY PLAN
STEP 7	DOCUMENTATION
STEP 8	PREPARE FOR OCR AUDIT

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Who Does HIPAA Apply To?



HIPAA covers PHI maintained by **Covered Entities** which are:

- Health plans
- Governmental health programs – Medicare, Medicaid, Veterans Health Administration
- Physicians
- Hospitals
- Pharmacies
- Other health care providers and clearinghouses

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Business Associates



- A person or organization, other than a member of a covered entity's workforce, that performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of individually identifiable health information.
- The **HITECH Act of 2009** expanded the responsibilities of business associates under the Privacy and Security Rules.

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Examples of Business Associates



- Billing Services
- Claims Processing
- Utilization Review
- Legal Services
- Management Services
- Third-Party Auditors
- Technology Vendors

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What is Protected Health Information?

- “Individually identifiable health information” is information, including demographic data, that relates to:
- the individual’s past, present or future physical or mental health or condition
- the provision of health care to the individual
- the past, present, or future payment for the provision of health care to the individual
- that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual

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What are PHI Identifiers?

Name

Address

Birth Date

Social Security Number

Other Unique Characteristics



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HIPAA Settlements

February 16, 2017 – Importance of Audit Controls



- Memorial Healthcare System (MHS) agreed to pay HHS-OCR \$5.5 million and implement a robust corrective action plan.
- MHS reported to OCR that the PHI of 115,143 individuals had been impermissibly accessed by its employees and impermissibly disclosed to affiliated physician office staff.

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HIPAA Settlements-Continued

February 16, 2017 – Importance of Audit Controls (cont.)



- OCR determined the login credentials of a former employee of an affiliated physician's office had been used to access the ePHI on a daily basis without detection from April 2011 – April 2012 affecting 80,000 individuals.
- MHS failed to regularly review records of IT system activity on applications that maintain ePHI by workforce users and users at affiliated physician practices despite having identified this risk on several risk analyses conducted by MHS from 2007-2012.

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HIPAA Settlements

January 18, 2017 - Importance of ePHI Safeguards



- MAPFRE Life Insurance agreed to pay HHS-OCR \$2.2 million and adopt a corrective plan.
- MAPFRE filed a breach report in 2011 disclosing that a USB storage device that contained the names, dates of birth and social security numbers of over 2,200 individuals was stolen.
- OCR determined MAPFRE failed to conduct risk analyses, implement risk management plans, or deploy encryption or an equivalent alternative measure on its laptops and removable devices until 2014.

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Business Associate Settlement



- Catholic Health Care Services of the Archdiocese of Philadelphia (CHCS) agreed to settle potential violations of HIPAA for \$650,000 and adopt a corrective plan after the theft of a CHCS mobile device compromised the protected health information (PHI) of hundreds of nursing home residents.
- CHCS provided management and information technology services as a business associate to six skilled nursing facilities. The total number of individuals affected by the combined breaches was 412.

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Business Associate Settlement (cont.)



- OCR initiated its investigation on April 17, 2014, after receiving notification that CHCS had experienced a breach of PHI involving the theft of a CHCS-issued employee iPhone. The iPhone was unencrypted and was not password protected.
- The iPhone contained social security numbers, information regarding diagnosis and treatment, medical procedures, names of family members and legal guardians, and medication information.
- CHCS had no policies addressing the removal of mobile devices containing PHI from its facility or what to do in the event of a security incident; OCR also determined that CHCS had no risk analysis or risk management plan.

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HIPAA Criminal Prosecution



Georgia woman sentenced in 2014 to 27 years in prison and ordered to make restitution of \$493,000 for using identities of nursing home residents to obtain fraudulent income tax refunds.



- The defendant, an employee of Macon Management Health & Rehabilitation Center, netted \$460,000 in the scheme
- Impact on Macon Management is largely dependent upon strength of its compliance program
- Potential civil fines could reach up to \$50,000 per incident or a maximum of \$1.5 million

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Authorized Disclosures

A covered entity *must* receive an individual's permission to use or disclose PHI not for treatment, payment or healthcare operations, including:

- Marketing
- To a life insurer for coverage purposes
- To an employer of the results of a pre-employment physical or lab test;
- Psychotherapy notes (exception for safety)

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Representatives

- Personal Representatives
- Minors

The Privacy Rule requires a covered entity to treat a "*personal representative*" the same as the individual, with respect to uses and disclosures of the individual's protected health information, as well as their rights under the Rule.

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Minimum Necessary Rule

Covered Entity:

- Must make reasonable efforts to use, disclose, and request only the minimum amount of PHI needed to accomplish the intended purpose of the use, disclosure, or request.
- Must develop and implement policies and procedures to reasonably limit uses and disclosures to the minimum necessary.
- Must develop and implement policies and procedures that restrict access and uses of PHI based on the specific roles of the members of their workforce.
- Must establish and implement policies and procedures (which may be standard protocols) for *routine, recurring disclosures, or requests for disclosures*, that limits the PHI disclosed.

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Security Rule



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General Rules

- Requires covered entities to maintain reasonable and appropriate administrative, technical, and physical safeguards for protecting e-PHI.
- Specifically, covered entities must:
 - › Ensure the confidentiality, integrity, and availability of all e-PHI they create, receive, maintain or transmit.
 - › Identify and protect against reasonably anticipated threats to the security or integrity of the information.
 - › Protect against reasonably anticipated, impermissible uses or disclosures.
 - › Ensure compliance by their workforce.

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Physical Safeguards

- Physical Access and Control: Limit physical access to facilities (locked doors, locked cabinets, alarm systems, surveillance, etc.).
- Workstation and Device Security: Secure workstations and electronic devices (Lock computers and iPhones, change passwords regularly, encrypt electronic devices; have a policy on devices leaving the facility, etc.).

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HIPAA and Mobile Devices



HIPAA Rules allow health care providers, other covered entities, and business associates to use mobile devices to access ePHI

AS LONG AS

appropriate physical, administrative, and technical safeguards are in place.

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HIPAA and Mobile Devices



- Use a password or other user authentication
- Install and enable encryption
- Install and activate remote wiping and/or remote disabling
- Disable and do not install or use file sharing applications
- Install and enable a firewall
- Install and enable security software
- Keep your security software up to date
- Research apps before downloading
- Maintain physical control of device
- Use adequate security to send or receive PHI over public Wi-Fi networks
- Delete all stored health information before discarding or reusing the mobile device

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HIPAA and Mobile Devices



If you use a mobile device to access an organization's internal network or system, the policies and procedures of the OWNER of that NETWORK or SYSTEM apply to the use of your personal device.

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Questions to Ask Regarding BYOD



- Does your organization have a mobile device use policy?
- Does your organization allow you to use your personally owned mobile device for work?
- Do you know who your organization's Privacy Officer and Security Officer are?
- Does your organization require you to register your mobile device with the organization?
- Does your organization have a Virtual Private Network (VPN) that allows you to access, receive, or transmit health information securely with your mobile device?

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Questions to Ask Regarding BYOD



- Does your organization have a policy about storing health information on your mobile device?
- Does your organization require you to backup health information from your mobile device to a secure server?
- Does your organization require you to enable remote wiping and/or remote disabling on your mobile device?
- Does your organization offer mobile device privacy and security awareness and training?

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Breach Rule



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Have a Plan



- The Security Rule requires a covered entity or business associate to implement policies and procedures to address security incidents (45 C.F.R. 164.308(a)(6)(i)).
- When developing security incident procedures, consider:
 - › What is considered a “security incident”?
 - › How will incidents be documented and reported?
 - › To whom should incidents be reported?
 - › What are reasonable and appropriate responses to certain types of incidents?

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Have a Plan - Continued



The Breach Notification Rule requires a covered entity or business associate to implement policies and procedures to address the timely reporting of breaches (45 C.F.R.164.414(a)).

- When developing breach notification procedures, consider:
 - › To whom should workforce members report potential breaches?
 - › Who is responsible for completing a risk assessment to determine whether the incident is a reportable breach?
 - › Who is ultimately responsible for ensuring that timely notifications are submitted?
- Training is a **MUST**.

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Document



The Security Rule requires a covered entity or business associate to document security incidents and their outcomes (45 C.F.R. 164.308(a)(6)(ii)).

Document in detail:

- Root cause analysis of incident
- Actions taken to mitigate harm to affected individuals
- Corrective action measures taken, and if certain actions were not taken, the rationale for not taking them



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Document



Important to retain documentation related to:

- Internal investigation into incident
- Risk assessments and submission of notifications pursuant to Breach Notification Rule
- Implementation of corrective action measures

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Breach Notification Rule

Do you need to report?

- Breach involves only *unsecured* PHI
 - › Encrypted (per NIST Standard) or “unusable, unreadable, or indecipherable” PHI is considered “secured” PHI.
- Breach excludes:
 - › Any unintentional acquisition, access, or use of PHI made in good faith and within the scope of authority, or any inadvertent disclosure of PHI by an authorized person to another authorized person at the same entity, provided that the PHI is not further used or disclosed in a manner not permitted under the Privacy and Security Rules.
 - › A disclosure of PHI where a covered entity or business associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

Breach Notification Rule

Breach is presumed, unless the covered entity or business associate demonstrates that there is a low probability that the PHI has been compromised, based on a risk assessment of at least the following:

- The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification.
- The unauthorized person who used the PHI or to whom the disclosure was made.
- Whether the PHI was actually acquired or viewed.
- The extent to which the risk to the PHI has been mitigated.

Breach Notification Rule

- **Breaches affecting 500 or more individuals**
 - › Notices to OCR, affected individuals, and the media must be made without unreasonable delay and no later than 60 days following the discovery of a breach.

- **Breaches affecting under 500 individuals**
 - › Notices to affected individuals must be made without unreasonable delay and in no case later than 60 days following the discovery of a breach.
 - › Notices to OCR must be submitted no later than 60 days after the end of the calendar year.

****Review State Privacy Laws as well.*

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Breach Statistics from OCR

Reports involving a Breach that Impacts	Reporting Period	Number of Reports	Individuals Impacted
500 or fewer individuals	Sept 2009 - 2014	+163,000	+845,000
500 or more individuals	Sept 2009 - 2014	1187	Appx. 41.2 million

Data provided in the Annual Report to Congress on August 30, 2016 – Breaches of Unsecured Protected Health Information For Calendar Years 2013 – 2014

Since compliance was required on Sept. 23, 2009, there have been 2,121 reports involving a breach of PHI impacting 500 or more individuals (Based on data provided by the HHS-OCR as of November 15, 2017).

Type of Breach						Location of Breach					
Theft or Loss Cases		Unauthorized Access Cases		Hacking Cases		Laptop or other PED*		Paper or Films		Network Server	
987	47%	591	28%	394	19%	566	27%	501	24%	402	19%

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Fraud & Abuse Laws and Regulations



Some of the healthcare laws that are being investigated for civil and/or criminal prosecution are as follows:

- False Claims Act (FCA)
- Anti-Kickback Statute (AKS)
- Physician Self-Referral Law (Stark Law)
- 18 USC 1347 (Healthcare Fraud including Private Payors)
- Exclusion Statute
- Civil Monetary Penalties Law

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What is the False Claims Act?



- It is illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent.
- False claims may result in fines up to 3 times the program's loss plus \$11,000 per claim filed.
- Under civil FCA, no specific intent to defraud is required.
- Criminal penalties include imprisonment (up to 10 years) and criminal fines.



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What is the Anti-Kickback Statute?

- Criminal law prohibits the knowing and willful payment of “remuneration” to induce or reward patient referrals.
- Prohibits the payment or receipt of anything of value.
- Criminal penalties and administrative sanctions include fines, imprisonment, and exclusion from participation in Federal health care programs.
- Providers who pay or accept kickbacks also face penalties up to \$50,000 per kickback plus three times the amount of the remuneration.



Physician Self-Referral Law (Stark Law)

Services subject to Stark Law

- Clinical laboratory services
- Physical therapy, occupational therapy, outpatient speech-language therapy
- Radiology and other imaging services
- Radiation therapy services and supplies
- DME and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

What is Title 18 USC Section 1347?



(A) Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice –

- 1) to defraud any health care benefit program.
- 2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services shall be fined under this title or imprisoned not more than 10 years, or both.

(B) With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

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Meals



Occasional modest meals are permissible if:

- They are incidental to a legitimate business, clinical, or educational discussion at which a representative is present.
- They are not intended to induce, reward, or influence ordering of services.
- They are held in an appropriate venue to an appropriate audience.
- They are of modest value in accordance with corporate standards.



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Entertainment Prohibited

Entertainment or recreational items cannot be provided to any health care provider who is not a salaried employee, regardless of the value of the items, whether the health care provider is engaged as a speaker or consultant, or whether the entertainment or recreation is associated with a clinical or educational purpose.



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Speaker Programs

Health care professionals may be engaged to provide educational presentations if:

- There is a bona fide business need.
- The speaker meets the qualifications to speak about the subject matter.
- The program is informative and accurate in content.
- The event is held at a venue that is conducive to educational and informative purposes.
- The event cannot include sponsored entertainment.

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Enforcement Landscape



The **Health Care Fraud Prevention and Enforcement Action Team (HEAT)** is a joint initiative between:

- DOJ
- HHS
- OIG

A key component of HEAT is the **Medicare Fraud Strike Force** – an interagency task force team with the OIG and DOJ.

- **Strike Force Statistics as of January 2018:**

- › **Criminal Actions: 1,938**
- › **Indictments: 2,498**
- › **Money: \$3,005,849,223**

- **Since March 2007, over 3,500 individuals charged with defrauding Medicare of more than \$12.5 billion in fraud.**

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Enforcement Landscape



HCFAC return on investment for FY 2017

- 3 year rolling average on law enforcement activities is \$4.00 for every \$1 spent
- **\$2.6 billion** in tax payer dollars recovered FY 2017
- HCFAC program in total has recovered more than **\$33 billion** since its formation in 1997

HCFAC Funding FY 2017

- Mandatory Resources \$1.27 billion
- Discretionary Resources \$725 million

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Enforcement Landscape



DOJ announced it had recovered \$3.7 billion in civil cases under the False Claims Act for the fiscal year 2017.

- \$2.4 billion came from the healthcare industry alone.
- This \$2.4 billion reflects federal losses only.
- The DOJ was also instrumental in recovering additional millions of dollars for **state Medicare programs**.
- 8th consecutive year the DOJ's civil health care fraud recoveries have exceeded \$2 billion.

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Investigation Triggers



- Use of telemedicine physicians
 - › Government challenges physician-patient relationship status
 - › Doctor is out of state
- No doctor visit is associated with Rx renewal
- Volume of billing to government healthcare programs



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Investigation Triggers



- Sales Representatives and Marketing Company Actions
 - › Direct contact with TRICARE beneficiaries
 - › Remuneration to doctors for Rx referrals
 - › Business arrangements with telemedicine companies to pay for the patient's doctor consultation
 - › Illegal compensation structures

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Investigative Process



- How does the government initiate investigations?
 - › Whistleblowers
 - › Audits
 - › Complaints from citizens/patients
 - › Competition
 - › Other Defendants
 - › Statistics



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Investigative Process

- Other pro-active tools:
 - › Undercover officers or confidential informants
 - › Audio/video recordings
 - › Wiretaps
 - › Trackers and geo-location technology
 - › Sophisticated data analysis



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Enforcement Landscape

- Investigations focused on areas with high volume of TRICARE billings
- We are aware of ongoing investigations against compounding pharmacies in:

- | | | |
|-------------------------------------|--------------------------------------|------------------------------------|
| <input type="checkbox"/> Alabama | <input type="checkbox"/> Louisiana | <input type="checkbox"/> Tennessee |
| <input type="checkbox"/> Arizona | <input type="checkbox"/> Mississippi | <input type="checkbox"/> Texas |
| <input type="checkbox"/> California | <input type="checkbox"/> Nevada | <input type="checkbox"/> Utah |
| <input type="checkbox"/> Florida | <input type="checkbox"/> New Jersey | <input type="checkbox"/> Wisconsin |
| <input type="checkbox"/> Georgia | <input type="checkbox"/> New York | |
| <input type="checkbox"/> Illinois | <input type="checkbox"/> Ohio | |

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Florida 2015 4th Quarter Settlements



- September – Jacksonville Pharmacy (Med Match Pharmacy LLC) Settles False Claim Act Allegations for **\$4.7 million** – through a consultancy company that provided marketing and training services, paid 50-58% commissions based on proceeds of referred Rx's. **TRICARE investigation**
- October – Jacksonville Pharmacy (WELLHealth) Settles False Claims Act Allegations for **\$1.8 million** – third party company made remuneration in the form of research fees to physicians. **TRICARE investigation**
- October – Jacksonville Pharmacy (Durbin Pharmacy) Settles False Claims Act Allegations for **\$2.1 million** – utilized marketers who were compensated with incentive based arrangements. **TRICARE investigation**
- October – Auburndale Pharmacy (OHM Pharmacy) Settles False Claims Allegation for **\$3.1 million** – Submitted a large volume of Rx's from a single physician when the pharmacy should have known the Rx's were not based on a *bona fide* patient/physician relationship. **TRICARE investigation**

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FBI Raids 9 Pharmacies



- January 21, 2016 - FBI Raids 9 Mississippi Pharmacies, Warrants out in Florida, Alabama and Utah
- Multiple agency participation – FBI, DoD, US Postal Inspection Service, Mississippi Bureau of Narcotics
- Raided pharmacies are primarily compounding
- \$15 million in assets seized

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NJ Marketer Admits Bribing Doctor



- January 19, 2016 – Howard Wertheim pled guilty in federal court to an information charging him with one count of paying kickbacks.
- Wertheim worked for compounding pharmacy, Prescription R Us for 6 months in 2013 and earned approximately \$25,000 for his role.
- Wertheim admitted that the pharmacy owner paid him to recruit and pay physicians to refer their Rx's to Prescriptions R Us.
- He paid sports medicine doctor James Morales more than \$60,000 in cash bribes.

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Mississippi Compounding Pharmacy Criminal Investigations



Jason May, of Lamar County, and Gerald Jay Schaar, of Biloxi, both pled guilty on July 25, 2017 after charges were filed in the largest ever health care fraud enforcement action by the Medicare Fraud Strick Force, involving 421 charged defendants in 41 federal districts across the country.

- May, the pharmacist-in-charge of Advantage Pharmacy, **pled guilty to conspiracy to commit health care fraud and money laundering** regarding a scheme to defraud health care benefit programs, including TRICARE, of more than \$190M.
- Schaar, a pharmacy marketer, **pled guilty to conspiracy to commit health care fraud** regarding a scheme to defraud TRICARE of more than \$2.3M.

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Mississippi Compounding Pharmacy Criminal Investigations



10/18/17 – Susan Perry, N.P. of Grand Bay, AL was charged in a **13-count** indictment for her role in a multi-million dollar scheme to defraud TRICARE. **(1 count)**–conspiracy to commit health care fraud and wire fraud, **(4 counts)**–wire fraud, **(1 count)**–conspiracy to distribute and dispense a controlled substance, **(1 count)**–distributing and dispensing of a controlled substance, **(1 count)**–conspiracy to solicit and receive healthcare kickbacks, **(4 counts)**–soliciting and receiving healthcare kickbacks, and **(1 count)**–making a false statement.

10/24/17 – Albert Diaz, M.D. of Ocean Springs, MS was charged in a **16-count** indictment for his role in a similar scheme. **(1 count)**-conspiracy to commit health care fraud and wire fraud, **(4 counts)**-wire fraud, **(1 count)**-conspiracy to distribute and dispense a controlled substance, **(4 counts)**-distributing and dispensing a controlled substance, **(1 count)**-conspiracy to falsify records in a federal investigation, and **(5 counts)**-falsification of records in a federal investigation.

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NJ Doctor Sentenced for Role in Lab Referral Scheme



November 8, 2017 – Ahmed El Soury of Monmouth Junction, NJ received a 33-month prison sentence along with a three year supervised release and a \$7,500 fine. El Soury pled guilty to one count of conspiracy to violate the Anti-Kickback Statute, the Federal Travel Act and the honest services wire fraud statute. Between March 2011 and April 2013, El Soury received more than \$66,000 in referral bribes from Biodiagnostic Lab employees and associates. **El Soury referred patient blood samples that netted more than \$100M in Medicare and private insurance dollars for the lab.** According to the U.S. Attorney’s Office for the District of NJ, El Soury is one of more than four dozen individuals convicted to date in what is believed to be **“the largest number of medical professionals ever prosecuted in a bribery case.”**

June 2016 - Biodiagnostic Lab was ordered to surrender all of its assets after pleading guilty to one count of conspiracy to violate the Anti-Kickback Statute and the Federal Travel Act and one count of conspiracy to commit money laundering.

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The Elements of Effective Compliance



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Compliance Programs



Failing to report any violation of pharmacy policy, regulations, and State or Federal Law, may end in termination of the contract between the pharmacy and the marketing representative.



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FisherBroyles Client Alert - January 16, 2018

The topic of sexual harassment in the workplace (and in some cases all-out sexual assault) has become ubiquitous: From the #MeToo campaign on social media, the “Silence Breakers” featured on the cover of *Time* magazine as “Person of the Year,” to Hollywood’s new effort, the “Time’s Up” legal defense fund, it is impossible to escape the fact that every business across every industry is going to have to undertake a serious evaluation of sexual harassment in their workplace. And while the hammer seems to have fallen hardest thus far in the news and entertainment industries, those in the health care sector should not feel comforted by their current anonymity—the sexual harassment claims are coming to #YouToo as victims are bolstered by the newfound public awareness of the problem and a resolve to hold perpetrators accountable.

The BuzzFeed News website recently posted a [study](#) of the more than 170,000 sexual harassment claims filed with the U.S. Equal Employment Opportunity Commission (EEOC) between 1995 and 2016. For those in health care, the numbers, while not the worst of the lot, are certainly not outstanding. (note that these numbers are only EEOC *reported* claims and don’t include the untold thousands who have remained silent). The EEOC data shows over 3,000 claims at medical and surgical hospitals, over 1,500 at nursing care facilities, nearly 2,000 at miscellaneous ambulatory centers, and thousands more at everything from individual physician’s offices to home health care providers and medical laboratories. This data is backed up by a 2016 Journal of the American Medical Association study ([JAMA](#)), which found that nearly one-third of women in academic medical institutions reported workplace sexual harassment.

Leaders across the health care industry must acknowledge that harassment is happening, probably right under their noses, and resolve to do something about it because it is clear that the dam of silence on this issue has broken. The *how* is going to require positive steps that we plan to discuss in a series of alerts over the coming weeks. We’ll address topics like: Policies and procedures; Effective communication and training; Creating an inclusive environment and spotting red flags; and How to handle complaints, investigations and, if necessary, litigation.

While the stories revealed by the #MeToo movement have been shocking and troubling, they also present an opportunity to seize a teachable moment and set new, clear standards in your workplace.

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FisherBroyles Client Alert - January 22, 2018



As we discussed in our last alert, addressing sexual harassment in the healthcare workspace is no longer optional or something that any business can afford to pay lip service to without serious financial and reputational risk. Payouts and settlements in sexual harassment lawsuits can cost hundreds of thousands of dollars and, in today's highly charged atmosphere, ruin both reputations and careers. [Recent statistics](#) provided by the Equal Employment Opportunity Commission (EEOC) show that in the last seven years alone, U.S. companies have paid out more than \$295 million in public penalties for sexual harassment claims. Note that this figure DO NOT include private settlements, which are normally protected by nondisclosure agreements.

The first line of defense, and one of the best ways to prevent sexual (and indeed any type) of harassment in the workplace is to have a clearly communicated anti-harassment policy. If you already have a policy in place, review it with legal counsel. If you don't have a policy in place, you should. Key components of a workplace harassment policy include:

Harassment Defined. Employees need to know the types of behaviors that are prohibited. As an employer, you will need to know what state and federal laws apply to your business. Your policy will need to take into account those applicable laws, and then communicate clearly the types of conduct that are impermissible and provide examples.

Scope and Application. The policy needs to address behaviors by and toward clients, customers, and coworkers. Make it clear that the policy applies to everyone, regardless of position or level of authority.

Reporting. A robust harassment policy includes a clear and well-communicated reporting procedure. Victims need to know how to report incidents of harassment, whether to a human resources manager, supervisor, or a hotline.

Investigation. The policy should also set forth a process for investigation that includes assurances of promptness, thoroughness and impartiality. Ensure adequate documentation of the process from initial report, through investigation, and to the conclusion of the process – whatever the ultimate outcome. Assure victims and witnesses that they are protected against retaliation.

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FisherBroyles Client Alert - January 22, 2018 (cont.)



Communication. The policy and reporting procedures must be communicated to all employees, generally during onboarding and then ideally at regular intervals thereafter to the entirety of the workforce. The policy should be posted in public areas of the worksite, on company intranet sites, and in policy manuals.

A clearly stated and communicated anti-harassment policy can go a long way toward preventing harassment in the workplace by putting the entirety of the workforce on notice that the matter is taken seriously and that the defined behaviors will not be tolerated.

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FisherBroyles Client Alert - February 19, 2018



Despite your best efforts – you’ve nurtured an inclusive environment, established an effective anti-harassment policy and communicated it across the company, and have provided training to all of your employees, top to bottom – there’s been a complaint of sexual harassment. The basic formula for a sexual harassment investigation, one that will stand up to scrutiny should the allegations lead to an EEOC complaint or lawsuit, is challenging but also fairly straightforward. A meaningful investigation that follows a well-thought-out process can protect a company from both financial and reputational damage.

Act with a sense of urgency. Time can be of the essence in conducting an effective investigation and delay can be costly. While no complainant should be guaranteed immediate results, a failure to pursue matters in a timely manner may lead to the perception that the complaint is not being taken seriously. Delaying an investigation may also lead to the loss of evidence or impair the recollections of witnesses. Continuing misconduct must be halted as soon as possible, with appropriate correct actions taken, while innocent parties should be “cleared” as soon as practicable.

Make a plan. Acting with a sense of urgency does not mean acting in haste. Take the time to assess the situation and establish an order of business. Determine who will conduct the investigation – someone in Human Resources? An outside entity? Your attorney? Be aware of any potential conflicts of interest. Consider what evidence needs to be collected. Must computers or emails be examined? Who will gather that evidence? Who needs to be interviewed beside the complainant and the alleged perpetrator? Are there additional witnesses?

Conduct interviews. Interview the parties in an order that makes sense and in locations that ensure some measure of privacy. Discuss with all interviewees the necessity of maintaining confidentiality in order to protect them and the process. However, do not make any promises regarding the confidentiality of the complaint itself, as it may become necessary to share that information, or parts of it, as the investigation ensues. Explain to all parties concerned that retaliation in any form and by any party is unacceptable and must be reported immediately. Be objective and ask open-ended questions. Avoid aggressive interview tactics. Take comprehensive notes during the interviews and document all findings.

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FisherBroyles Client Alert - February 19, 2018 (cont.)



Construct a report. When the interview/investigative phase is complete, construct a report that includes a description of the incident or incidents being investigated along with relevant dates, the names of the parties, summaries of witness statements or interviews and other evidence, along with any specific workplace policies that may apply. State conclusions and note any actions taken (even if it is determined that no action is to be taken). Notify the relevant parties of the outcome of the investigation and reiterate the non-retaliation policy, if necessary.

A comprehensive sexual harassment investigation can protect a company’s reputation and its finances when done properly. The attorneys at Fisher Broyles are experienced in aiding clients with workplace investigations of all types, including sexual harassment.

The Pharmacy and Health Care Law team welcome your questions. Please contact any of the following attorneys:

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