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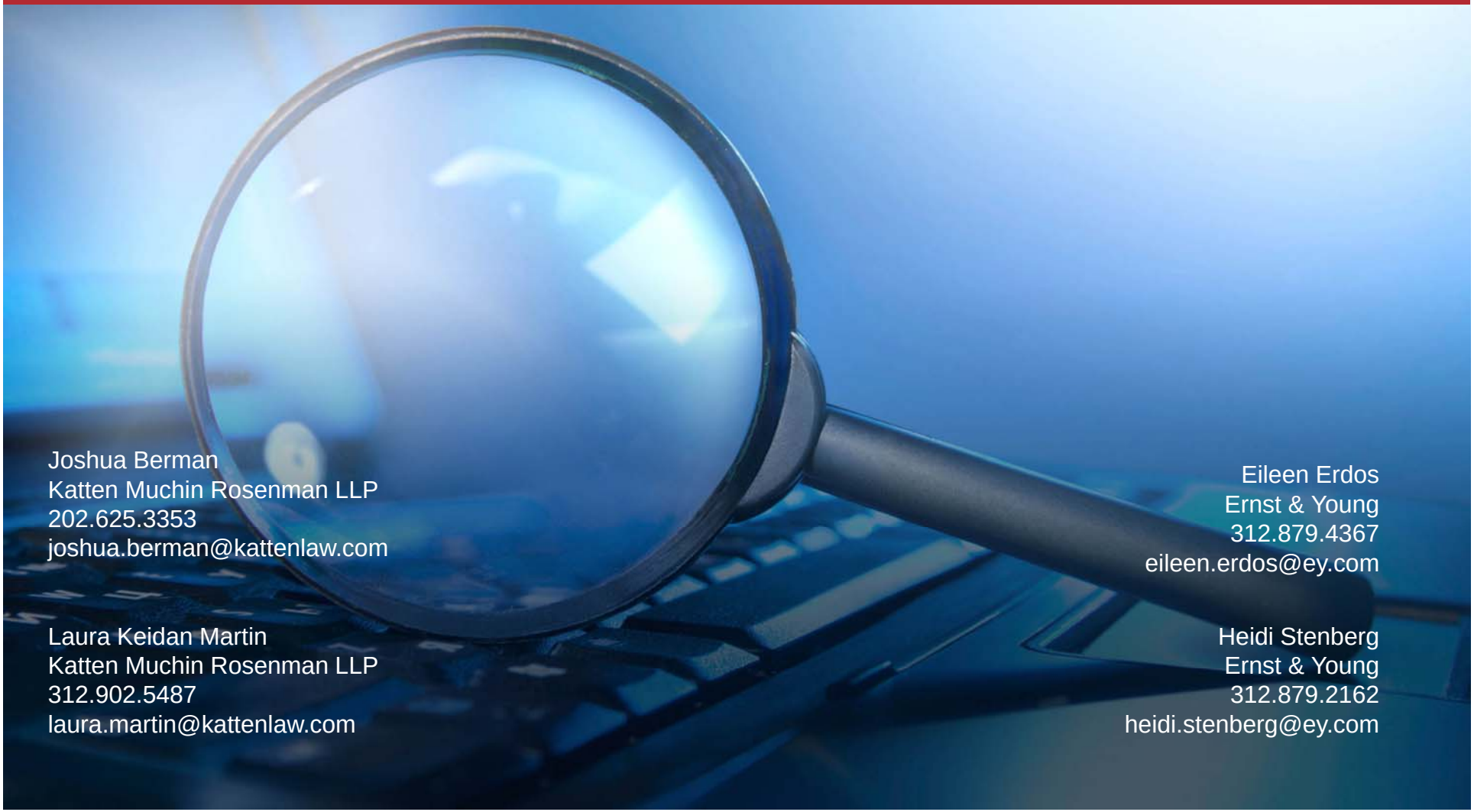
Health Care Industry Government Investigation Preparedness

November 11, 2013



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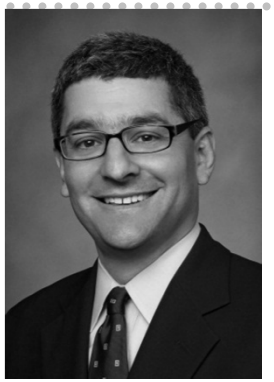
Introductions



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Polling Question

- Who is on the line?
  a) In-house Counsel
  b) External Counsel
  c) Compliance
  d) Internal Audit
  e) Security
  f) Other

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Why this matters

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Resource Allocation

- Health Care Fraud and Abuse Control Account
  - Source for funding health care fraud enforcement efforts
  - 2012: Allocation: $294.8 Million
  - Funds are “available until expended”
- Additional Congressional funding for 2012: $309.7 Million
- Total funding in 2012 for Health Care Fraud and Abuse Control Program: $1.59 Billion

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Results of Enforcement Actions

- $4.2 Billion of health care fraud recovered in 2012
  - Since 1997, $23 Billion returned to the Medicare Trust Fund
- 2,032 pending criminal investigations
- 452 criminal cases filed
  - 826 defendants convicted
  - 329 criminal fraud organizations disrupted
- Disruption / dismantlement of 412 criminal organizations
- 3,131 individuals and entities were excluded from Medicare
- ROI (2010-2012): $7.90 per dollar expended
  - $2.50 higher than the average ROI for the life of the HCFAC

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Be Prepared!

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The Best Preparation for a Government Investigation

Compliance Program Effectiveness Assessment

- Reduces risk of violations
- Promotes reporting
  - Allows for internal investigation and self-reporting before the Government comes knocking
- More lenient treatment under the Federal Sentencing Guidelines in criminal proceedings
- More favorable settlements in civil cases
  - Lesser fines
  - May avoid a Corporate Integrity Agreement

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Compliance Program Effectiveness

Focus and Approach

- Does the organization have an effective compliance function that:
  - Incorporates all seven elements of an effective compliance program?
  - Minimizes enterprise risk by promoting compliance with applicable legal parameters?
  - Enables the organization to proactively identify and address any compliance issues that arise?
- Is there reason to believe that the organization faces material compliance exposure in any regulatory risk area?
- What action steps can be taken to improve compliance program effective and reduce risk?
- Once you review the answers to these question, develop work plan to prioritize and effectuate recommended action steps

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Compliance Program Effectiveness

Effective lines of communication

- Multiple, well-publicized communication channels available to employees, Board and the public
  - Anonymous reporting option available
  - Reporting channels posted in employee areas and on intranet
- Code of Conduct ***requires*** reporting of concerns
  - Code encourages employees/contractors to seek compliance guidance prior to taking action when they are unclear on compliance parameters
- System to track reports and follow up
- Policy or statement of non-retaliation
- Documented hotline testing
- Email blasts, newsletters and other forms of information exchange on compliance issues and developments
- Compliance officer feedback to management on compliance risk areas

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Compliance Program Effectiveness

Training and education

- Develop annual compliance education plan/curriculum
  - All employees educated within 30 days of hire and at least annually thereafter
- Retain training materials, agendas, sign-in sheets
- Track all training (*e.g.,* job-specific, ad-hoc training/coaching, third party conferences, completion of electronic modules
- Document methods to determine effectiveness of training (*e.g.*, tests, surveys, post-training discussions)
- Include compliance training as a documented element of performance reviews
- Educate business leaders on what they ***can*** do – not just what they cannot do
- Focus on "tone at the middle" – not just "tone at the top"

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Compliance Program Effectiveness

Auditing and monitoring

- Risk assessments
- Annual audit work plans and progress tracking
  - Shift from retrospective to concurrent auditing when possible
- Auditing and monitoring results shared with Compliance Officer, CEO, Board, Compliance Committee and key managers
- Work plans for follow up on adverse audit results
- Monthly review of sanctions and exclusions
- Data analysis to identify potential billing/coding errors
- Track auditing and monitoring activities, frequency, systems used
- Annual compliance program effectiveness review

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Compliance Program Effectiveness

Prompt response to suspected non-compliance

- Investigation protocols
- Document holds
- Investigation steps are logged and well documented
  - Retain documentation of interviews and documents reviewed
  - Segregate privileged materials
- Root cause analysis of identified issues
- Corrective action plans designed to correct and prevent future occurrences
  - Monitor corrective action plan implementation and effectiveness/lack of repeat issues
- Policy revisions and education to prevent recurrence of non-compliant behavior
- Reports to government authorities when required or deemed appropriate
  - Compliance with 60-day rule for “identified” overpayments
- Referrals to law enforcement or other agencies

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Emergency Response Plan

- Compliance systems
- Recordkeeping
- Education
- Investigation readiness testing

Preparing personnel removes the sense of panic and empowers employees to obtain the best result possible

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Emergency Response Plan

Compliance systems

- Consider what documentation of compliance an investigator would seek and whether you could provide it
- Generate, train on, and enforce protocols governing how to manage government investigations as part of your compliance system
  - Identify in advance the "control group"/crisis management team that should be notified
    - Designate a senior manager in each practice location as the contact person (*e.g.,* clinical offices, administrative offices, ASCs, etc.)
  - Develop a communication policy
  - Document preservation policies and "back up" procedures for electronic documents should be reviewed and disseminated in advance (see below for more details)
  - Consider a dry-run/"incident response" drill on an annual basis

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Emergency Response Plan

Communication policy

- Outside counsel should be consulted before any communications are made.
  - Counsel should be the first to be called
  - Make office, home, and cell numbers available for both internal crisis management team as well as outside counsel
- DO NOT speak to outside persons or entities
  - While you are permitted to speak to any investigators you do NOT have to do so under any circumstances
  - As to other third parties, including the press, reporters, regulators, creditors, analysts, etc.
- DO NOT speak to internal employees not approved by the “control group”

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Emergency Response Plan

Recordkeeping

- Know what you have
- Know where you have it
- Know what you have to keep
- Know why you have to keep it
- Keep what you have to keep for as long as you have to keep it
- Dispose of everything else

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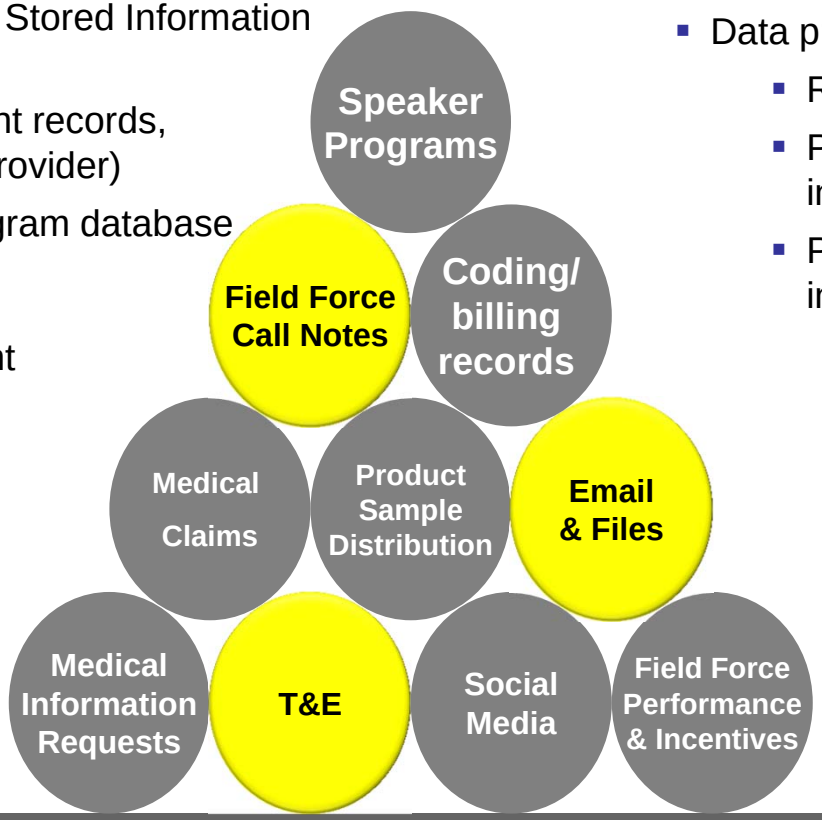
Emergency Response Plan
Considerations for Health Care ESI

- Unique types of Electronically Stored Information (ESI)
  - Clinician notes, treatment records, coding/billing records (provider)
  - Call notes, speaker program database (manufacturer)
- Universe of potentially relevant ESI
  - Mobile, desktop and server
  - Enterprise-wide
  - Cloud and internet



- Data privacy management
  - Region specific
  - Personally identifiable information
  - Protected health information
- Big Data implications
  - High-volume
  - Streaming
  - Semi-structured and unstructured formats

Organizations are using their own data to identify questionable activities, suspected fraud risks, etc.

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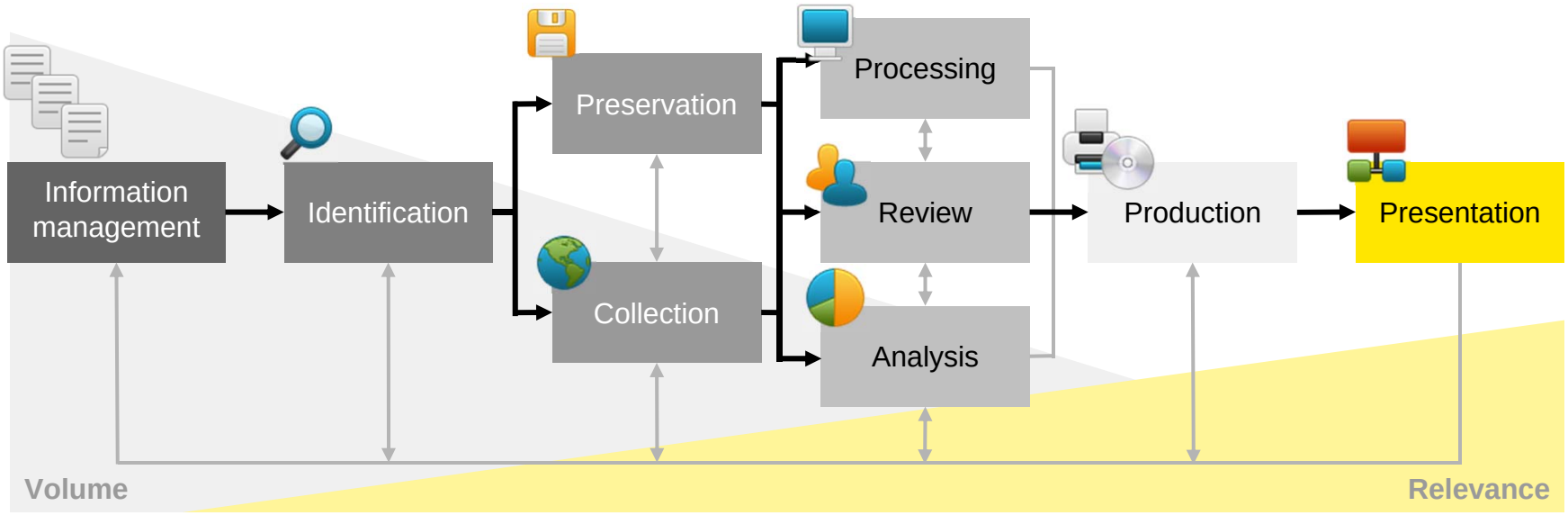
Emergency Response Plan

Addressing the information governance lifecycle



Determine information management policies and identify how ESI is managed in an enterprise

Implement legal holds and other safeguards to ensure that relevant information is preserved and accessible

Confirm which parties to an investigation have access to certain data

Harvest data from servers and other drives while maintaining all relevant metadata

Apply collected data to software that images documents and extracts metadata

Load processed data to a review environment for searching and tagging

Perform additional analytics tools, such as automated review or statistical analysis

Assemble relevant data for review by other parties to a matter

Organize produced data and other data insights for presentations or trial graphics

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Emergency Response Plan

Information governance considerations

Key Goal: Understand data environment

- Establish internal information management procedures
- Review policies dictating information management
- Assess current enforcement of enterprise policies and procedures
- Investigate compliance with data management and preservation policies
- Determine whether data disposition procedures are in line with SEC or other expectations
- Confirm whether enterprise data backup procedures are satisfactory; develop new backup procedures to be prepared for future investigation
- Establish program governance roles and responsibilities

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Emergency Response Plan

Education

- Facility personnel need to understand in advance
  - What to expect in an inspection
  - How the company expects facility personnel to conduct themselves when the inspector(s) arrive
  - How to react if the inspector finds a problem
  - Whom to call and when to call them

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Emergency Response Plan

Investigation readiness testing

- In an advance of an announced inspection, take the opportunity to conduct a pre-audit or inspection, and pursue corrective action
- Can be conducted at the direction of and in consultation with the Company's legal department
- Third-party consultants retained in connection with a pre-audit or inspection can be retained by Company counsel and for the purpose of assisting Company counsel in rendering legal advice to the Company
- Based on the pre-audit or inspection, discuss the need for corrective action in advance of the anticipated audit or inspection, including, but not limited to, tasks related to recordkeeping and housekeeping

Preparing personnel removes the sense of panic and empowers employees to obtain the best result possible

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Polling Question

- Who takes the lead for internal investigation?
  a) Legal
  b) Compliance
  c) Internal Audit
  d) Board of Directors

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Polling Question

- Does your company have an emergency response plan?
  a) Yes
  b) No
- Has your company identified and mapped the location of key information?
  a) Yes
  b) No

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When the government comes knocking

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Polling Question

- Rate your organization's readiness to respond to a government investigation
  a) Informal – no formalized processes or assigned accountabilities
  b) Formal processes in some functional areas (e.g., Legal) and divisions (e.g., US)
  c) Integrated, seamless, company-wide response protocols

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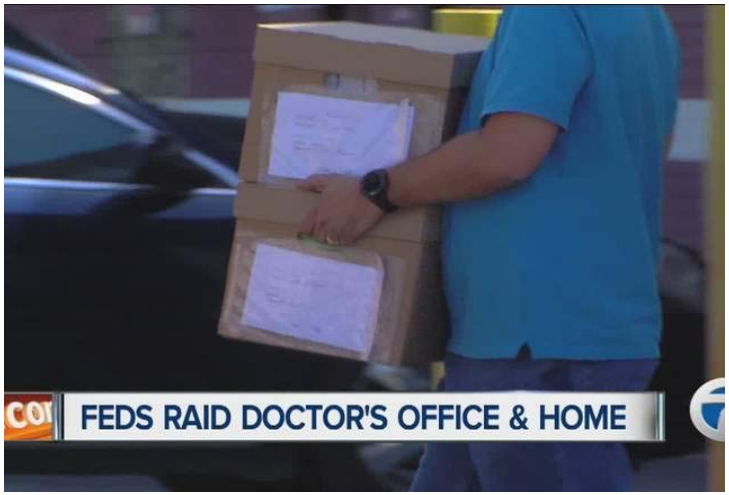
Who is that knocking (or not bothering to knock)?

- Federal and state regulators, law enforcement, prosecutors, whistle-blowers, auditors and inspectors general including
  - Federal: FBI; HHS OIG; DOJ; IRS
  - State: Attorneys General; State OIGs; state law enforcement; medical licensing boards
  - Regulators: CMS; CDC; RAC auditors
  - Undercover agents, confidential sources and whistle-blowers (and their attorneys)

What are they carrying?



- Search warrants
- Subpoenas
- Requests for interviews
- Inspection demands (i.e., medical records; office protocols)
- Books and records audits

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Search Warrant

- Grants law enforcement agents the right to enter a location, search it and seize certain documents, physical items and electronic data and specifies:
  - The location/premises to be searched AND
  - The items to be searched
- Often accompanied by an affidavit
- Unless the affidavit is “sealed,” you have a right to see the document
- Ask for a copy of the affidavit regardless of whether it is offered

Search Warrant

What you can do

- There is very little you can do at the time the search warrant is executed other than contacting counsel immediately
  - You may be able to raise objections to the search warrant at a later date
  - You should request the agents' delay starting the search until counsel arrives BUT the agents are not obliged to do so

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Search Warrant

What NOT to do

- DO NOT volunteer information
  - You do not have to authenticate documents
  - You do not have to respond to any questions except as to the location of documents described in the warrant
  - Provide only truthful information
- DO NOT obstruct the search
  - This can itself be a criminal offense
  - What constitutes obstruction can be at the discretion of the agents conducting the search

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Search Warrant

What you should do

- Call internal crisis management team leader and outside counsel immediately
- Note the area to be searched and try to direct the agents accordingly
- Obtain and keep a copy of the warrant and the receipt for items seized
- Record the identity of every agent involved and his/her agency
  - Ask for credentials/ID and business card
- Politely ask questions about the purpose of the search
- Accompany the agents to the extent permitted to help identify the areas described in the warrant
- Maintain your own inventory of seized items

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Requests for Interviews

What are they?

- Unannounced Surprise! Surprise! Surprise!
- Frequently will contact you at home or in the parking lot outside of work
- Often accompanied by service of subpoena or execution of a search warrant
- It is routine to seek to interview corporate officers and employees when serving a subpoena or executing a search warrant
- Agreeing to an informal interview does not eliminate the possibility of a grand jury subpoena

Requests for Interviews

The basics

- The investigator has a right to contact and to request to speak with any individual
- The individual DOES NOT have to speak to the investigator but may do so if he or she wishes
  - Search warrants do not allow agents to compel employees to grant interviews
- Request a copy of the investigator's notes

Requests for Interviews

What you should do

- Contact internal crisis management team leader and outside counsel immediately
- Identify the lead officer or prosecutor
- Ask for credentials/ID and business card
- Appear friendly and courteous
- Express interest in cooperating with the government
- Try to find out the scope and focus of the government investigation

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Requests for Interviews

What NOT to do

- Employees should understand their right NOT to speak with the agent about anything substantive without counsel present
- Employees DO NOT have to let the agents inside their residences or buildings unless there is a search warrant
- DO NOT destroy or alter documents
- DO NOT lie

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Requests for Interviews

What to advise employees NOW and THEN

- Employees should be advised of these basics and their "rights" now (during training) so that they are aware of it long before the government requests an interview
- Advise employees and executives that the company will make an attorney available to be present during any interviews
  - Employees can be advised that the company requests a company lawyer to be present at any interview
- If they speak with an agent without company counsel, ask them to "de-brief" the company afterward
- If they agree to an interview, they have the right to request a time and place of their own choosing
- They have the right to insist on the presence of counsel
- They should always tell the truth
  - Failing to do so may itself be a violation of law

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Subpoenas and Document Requests

- A subpoena is essentially a formal request for documents
- Can be costly in time and expense to comply
- Typically request production of certain documents by a specific date
- It is routine for subpoenas to request e-mails and voice mail
- Recipients can be the Target, Subject, or a third party witness in an investigation

Subpoenas and Document Requests

What to do

- Forward the subpoena to counsel for review
- Comply with the subpoena
- The response must be coordinated and supervised by counsel
- The medical practice's attorney should contact the government agency issuing the subpoena to discuss its scope
  - A request can be made to modify the subpoena to lessen the burden

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Subpoenas and Document Requests

Inform your employees

- Counsel should review the subpoena with employees and make themselves widely available to answer questions
- Circulate a written set of procedures to employees on how, when, and to whom documents should be sent
- Circulate a timeline of when documents need to be turned over to the company's counsel for review
- Ask each employee to fill out a tracking sheet
- Require employees to sign a declaration that they conducted thorough searches

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Document Preservation Protocol

- Take reasonable steps to preserve relevant evidence from loss or destruction when you know the evidence is relevant to pending investigation or anticipated proceeding
- Suspend otherwise applicable record retention policies and auto-delete functions
- Preserve electronically stored information when you have notice that the evidence is relevant to litigation or future litigation
- Just because electronically stored information is "not reasonably accessible" does not relieve a party's duties to preserve evidence
- Legal Hold: A legal hold notice is a written notice, informing each person that is reasonably likely to have information or documents related to a pending or anticipated proceeding, that they must preserve them
  - Critical to consult counsel immediately upon receipt of subpoena so that counsel can prepare and circulate a Legal Hold Memo promptly

Data Preservation / Holds

Secure data for investigative use

	Data Identification / Preservation	Data Collection
Requisite Actions	▪ Determine priority sources of data across enterprise ▪ Identify the key players in an investigation, and the location of their relevant data ▪ Perform interviews with key players to confirm data locations and preservation practices ▪ Implement a document preservation plan for relevant custodians and applicable data ▪ Create a “litigation hold” that protects potentially relevant information across the enterprise ▪ Enforce policies that maintain the integrity of data, ensuring that data cannot be altered or changed ▪ Confirm that data disposition policies are fully enforced ▪ Further develop a document collection plan, with thought given to custodian and data priority	▪ Perform device imaging procedures to capture all information contained within ▪ Ensure that deleted or modified data is additionally collected ▪ Review hidden locations of a custodian’s devices for additional data for collection ▪ Fully encrypt collected data ▪ Draft full documentation of the “chain of custody” of information, ensuring complete data integrity ▪ Return source devices in the exact same condition as they were received

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Data Processing, Review & Analysis

Enabling review of relevant data

	Data Processing	Data Review	Data Analysis
Requisite Actions	▪ Extract in a forensically secure environment ▪ Utilize tools to process all data, including document metadata ▪ Recover deleted content from imaged sources ▪ Accommodate foreign language data so that all text and metadata are fully searchable ▪ Deduplicate data to ensure a more manageable and consistent review ▪ Assemble data in a manner that allows loading to a database for eventual review ▪ Develop a course of action with encrypted or password-protected data	▪ Load data to a secured review environment ▪ Cull data for review with keyword searches, date restrictions, etc. ▪ Initiate review and train review team ▪ Develop a review mechanism ▪ Communicate with the review team to determine review needs; prepare documents for review accordingly ▪ Scale database access to external parties, including client and outside counsel ▪ Develop strategy for document review procedures and QC protocols	▪ Create models to highlight various data elements or patterns ▪ Assemble reports that detail document search hits or other elements associated with the review ▪ Apply advanced analytics tools to glean deeper insights into the subjective nature of data ▪ Perform analyses to determine when documents were modified, by whom, and how ▪ Initiate predictive coding or other automated review features to reduce the effort associated with document review

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Data Production and Presentation

	Data Production	Data Presentation
Requisite Actions	▪ Assemble data for parties to the engagement to review, including counsel, government entities, or the client ▪ Create document production in accordance with agreed upon or required protocols ▪ Ensure that production efforts capture all potentially relevant data identified during the review phase ▪ Ensure privileged documents are withheld from production or produced in redacted form ▪ Design production to be loaded to any type of database utilized by the receiving party/parties ▪ Provide export of coding fields used to prepare privilege log	▪ Design models to highlight production or document review details ▪ Integrate produced data with other work product to provide further investigation insights ▪ Deliver presentations to client or other parties covering insights gathered from the investigation ▪ Create summary reports that describes the complete discovery process from beginning through the end ▪ Draft reports addressing key investigation matters ▪ Retrieve produced and reviewed data upon request after the investigation has concluded

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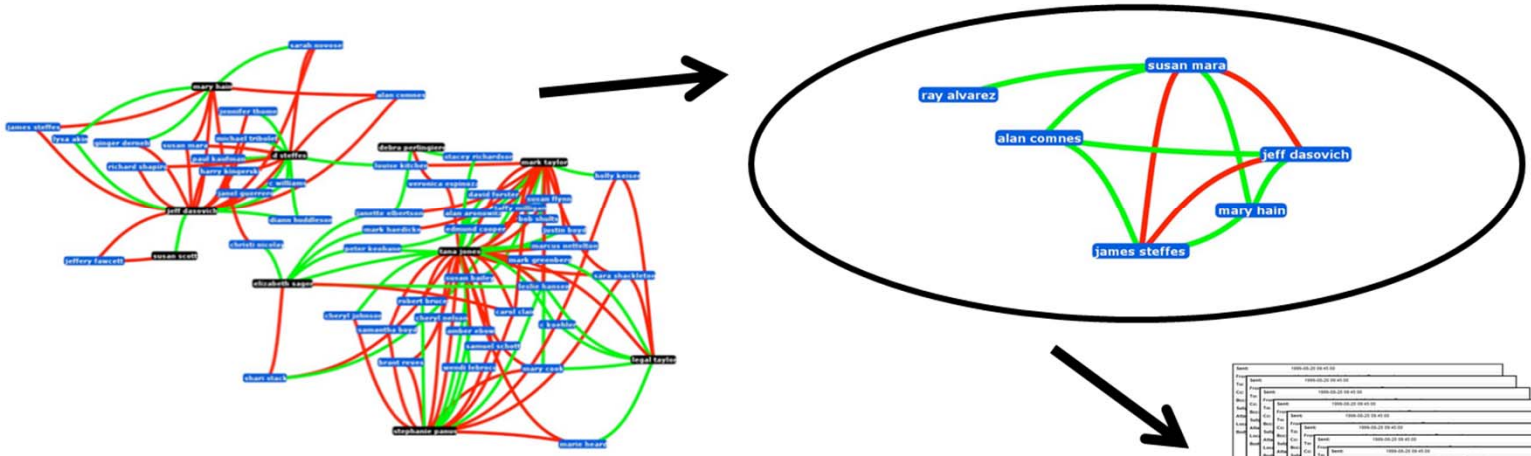
Early Case Assessment

- **The first 48 hours:** Live server log files pulled in quickly for early case assessments
- **Understanding a complex organization's true organization chart:** Identification of relationships, versus activities, amongst actors
- **Triage of custodians and communications for traditional review and additional analytics:** Rapidly identify and point to communications of highest interest



Sample analytics criterion:

1. Private communications, where 90% of all communications is outbound
2. Private Communications where content is FORWARDED Outbound more than 35% of time
3. Private Communications where attachments are sent outbound more that 35% of time

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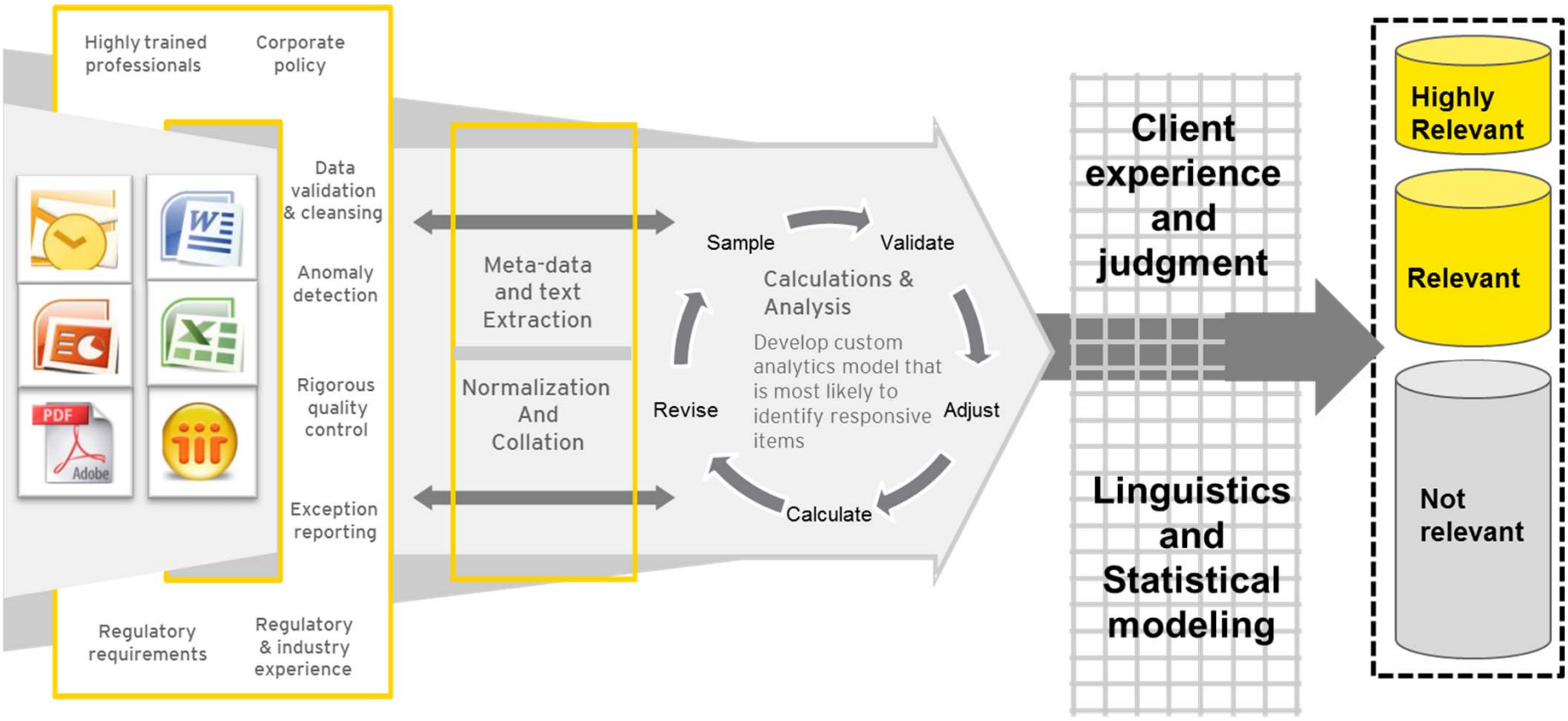
Technology Assisted Review



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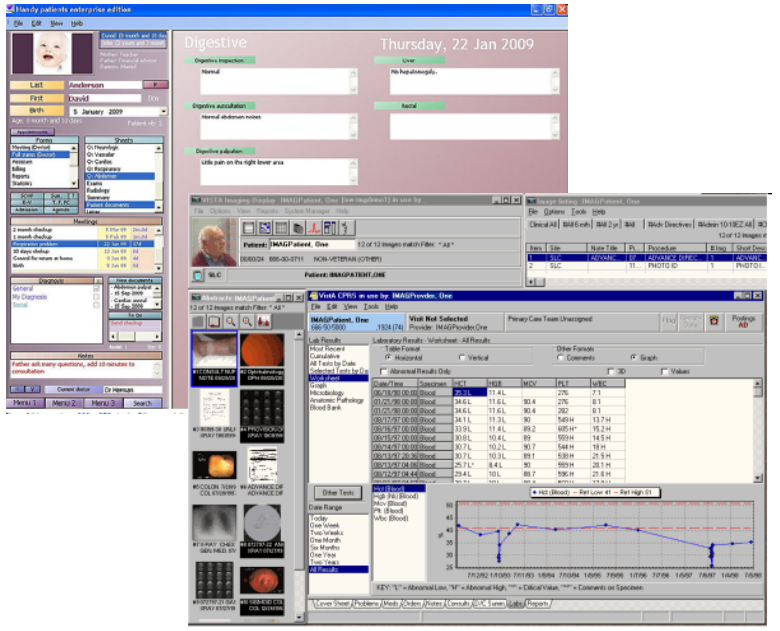
Claims Analytics

- Analyze procedure volume by provider
- Analyze the use of select billing modifiers (e.g. those triggering automatic payment)
- Identify providers billing for high volume of "diagnostic" procedures
- Analyze trends in procedure codes, e.g. compared to provider specialty and peer group
- Identify providers / labs with high frequency of component procedural codes (potential unbundling)
- Look for unusual procedure codes for patient age / DOB
- Identify claims in which no co-pays collected
- Evaluate length of stay for in-patient claims (e.g. look for average length of stay, 1 day length of stay, etc.)
- Pattern detection for rejected claims / re-submissions
- Statistical anomaly detection and predictive modeling to identify suspect claims



Opportunity to "mine" text and link to submitted claims

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Self-Reporting Requirements
Affordable Care Act

- "Overpayment'' means funds received or retained under Medicare or Medicaid to which a person, "after applicable reconciliation," is not entitled
  - Includes payments received for services rendered pursuant to an unlawful referral under the Stark Act
- Providers must report and return overpayments and notify agency of the reason for the overpayment
- Overpayment must be reported and returned within 60 days of the date on which the overpayment was ***identified***, or the date any corresponding cost report is due (if applicable), whichever is later
- Any overpayment retained past the deadline is an "obligation" for purposes of the reverse false claims provision of the False Claims Act (FCA)

Self-Disclosure Options

- Updated OIG Self-Disclosure Protocol (“SDP”)
- CMS Self-Referral Disclosure Protocol (“SRDP”)
- State Provider Self-Disclosure Protocols
- Department of Justice/U.S. Attorney
- Routine Report and Refund Channels

OIG Self-Disclosure Protocol

Potential Benefits of SDP

- Presumption against corporate integrity agreements
- Lower damages multiplier
- Suspends “60-day rule”
- Mitigates FCA exposure
- Nearly always releases parties from permissive exclusion

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OIG Self-Disclosure Protocol

Background

- Conduct that may violate federal criminal, civil or administrative laws for which civil monetary penalties (CMPs) are authorized
  - Does not include matters exclusively involving overpayment or errors
  - Does not include “Stark only” disclosures
- Major changes included in update
  - Expressly applies to entities beyond participating providers such as medical device and pharmaceutical companies
  - Requires additional disclosures
  - Internal investigation and corrective action must be completed within 90 days of submission (subject to extension)
  - Requires disclosing party to screen all current employees and contractors against LEIE before making “excluded persons” disclosures

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OIG Self-Disclosure Protocol

Settlement Parameters

- $10K floor for non-AKS disclosures/$50K floor for AKS disclosures
- 1.5 times multiplier presumed
- Damages in false billing disclosures based on all affected claims or random sample, without “netting” of underpayments
- AKS/Stark settlements typically based on multiplier of remuneration conferred by referral recipient to referral source
- Previously refunded amounts will be credited
- Presumption against corporate integrity agreements
- Criminal matters referred to DOJ for resolution
- Financial inability to pay must be documented with assessment of how much can be paid

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CMS Self-Referral Disclosure Protocol

Background

- CMS traditionally had no authority to compromise or waive Stark Act sanctions
- In March 2009, OIG announced it would no longer take Stark-only disclosures into its SDP
- ACA mandated the establishment of a Stark Act-specific disclosure protocol
- CMS issued the SRDP in September 2010

CMS Self-Referral Disclosure Protocol

Resolution

- CMS has the authority to accept a reduced overpayment (*i.e.*, less than 100%)
- CMS is clear to point out that it is under no obligation to accept the disclosing party's calculation of its financial liability or to compromise the overpayment at all
- There are no limits on the reduction that CMS may make
  - Theoretically, CMS may reduce the overpayment to $0

CMS Self-Referral Disclosure Protocol

Limitations

- Parties have no guarantee of acceptance into the SRDP
- CMS will not waive the "refund to individuals" requirement in section 1877 of the Social Security Act which requires refund of any amounts collected that were billed in violation of the Stark law
- Does not prohibit intervention by law enforcement

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Tips For Handling Self-Disclosures

- Adopt and implement policies to ensure satisfaction of the 60 day rule
- Define “identification” of overpayments to occur following investigation and validation that overpayment was received
- Develop timely investigation and audit plan that avoids need to report and refund on a rolling basis to satisfy the 60 day rule when possible
- Investigate “root cause” of overpayments to determine if they arose from intentional misconduct or reckless disregard of applicable law (ideally before quantifying damages)
- Limit investigation/ audit scope to arrangements/ claims where there is reason to believe that violations may have occurred
- Consider pros and cons of reporting under a protocol v. to USAO or through routine channels
- Ensure that disclosures satisfy all requirements and anticipate Government concerns

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Appendix

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OIG Self-Disclosure Protocol

Baseline disclosure requirements

- Information regarding disclosing party
- Concise statement of conduct disclosed, including conduct giving rise to the matter, time period, and the names of implicated parties, including an explanation of their roles in the matter
- Statement of the federal criminal, civil or administrative laws that are potentially violated by the disclosed conduct
- Federal health care programs affected by the disclosed conduct.
- Damages estimate
- Description of corrective action taken upon discovery of the conduct
- Whether the disclosing party has knowledge that the matter is under current inquiry by a Government agency or contractor
- Name of individual authorized to enter into a settlement agreement on behalf of the disclosing party
- Certification statement

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OIG Self-Disclosure Protocol

Additional disclosure requirements

- New requirements for false billing disclosures, including a minimum sampling requirement of 100 items
- Excluded persons disclosures
- Greater detail regarding why disclosed conduct potentially violated the AKS and Stark Act, if applicable (*e.g.*, why arrangement was not commercially reasonable)
  - Also requires estimate of amount paid by federal health care programs for services associated with and total remuneration paid under unlawful arrangement

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CMS Self-Referral Disclosure Protocol

Requirements

- Thorough description of the parties, financial relationship, time period of non-compliance, DHS at issue, and roles of the individuals involved in the matter
- Analysis of the application of the Stark law to the conduct at issue, including which elements of the relevant exception were met and not met
- Complete financial analysis identifying the 100% overpayment amount
  - Can include alternate theories of the overpayment amount
  - Recent CMS FAQ clarified that the financial analysis should be based on the applicable reopening period
- Description of compliance efforts prior to and since the discovery of the Stark violation
- Agreement to forfeit appeal rights

Disclosures Involving False Billing

- Review Objective: A statement clearly articulating the objective of the review.
- Population: A description of the group of claims about which information is needed, explanation of methodology used to develop population, and basis for this determination.
- Sources of Data: A full description of the data source, including sources of payment data and documents relied upon.
- Personnel Qualifications: The names and titles of the individuals who conducted the review.
- Characteristics Measured: The review report should identify the characteristics used for testing each item.

SDP Sampling Plan Requirement in False Billing Disclosures

- Sampling Unit: Any of the designated elements that constitute the population of interest
- Sampling Frame: The totality of the sampling units from which the sample was selected and the way in which the audit population differs from the sampling frame (and the effect this difference has on conclusions reached as a result of the audit)
- Sample Size: The size of the sample reviewed to reach the estimate of the damages. The sample size must be at least 100 claims
- Source of Random Numbers: The sample must be selected through random numbers (RAT-STATS strongly recommended) and the source must be disclosed
- Method of Selecting Sampling Units: The method for selecting the sample units
- Sample Design: Unless the disclosing party demonstrates the need to use a different sample design, the review should use simple random sampling
  - If necessary, the disclosing party may use stratified or multistage sampling. Details about the strata, stages and clusters should be included in the review report
- Missing Sample Items and Other Evidence: If the review was based on a sample, missing sample items should be treated as errors
- Estimation Methodology: If the review was based on a sample, the methodology to be used must be variables sampling (treating each individual items in the population as a sampling unit) using the difference estimator (estimates of the total errors in the population are made from the sample differences by multiplying the average audited difference by the number of units in the population)