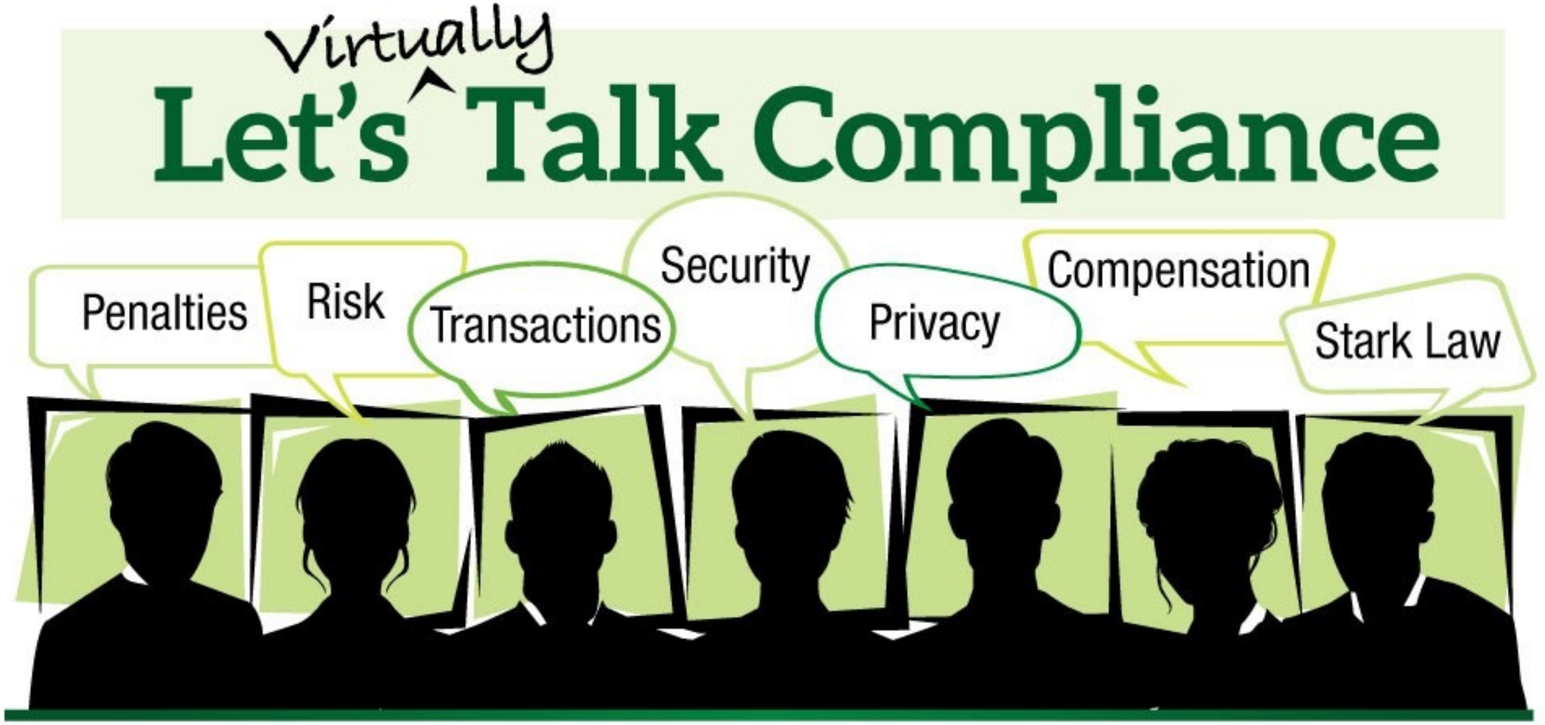
Let's Talk Compliance

One-Day Compliance Master Class



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SESSION #3

Keeping Your House Clean: Data Analytics in Health Car Enforcement and Compliance

Matt Krueger & Valerie Rock

January 20, 2022

Outline

- DOJ/HHS OIG Enforcement Priorities
- Enforcement Agencies’ Use of Data Analytics
- Expectations for Compliance Programs and Due Diligence
- How to Improve Your Use of Data

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DOJ and HHS OIG Enforcement Priorities

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
OIG

Health Care Enforcement in Biden DOJ

- DOJ will continue aggressive enforcement under False Claims Act, Anti-Kickback Statute, Stark Law, Controlled Substances Act, and other criminal statutes.
- **Civil Division:**
  - Over $1.8 billion in False Claims Act recoveries in 2020.
  - Opened a record number (580) of new health care fraud matters in 2020.
- **Criminal Division:**
  - Dedicated Health Care Fraud Unit.
  - Oversees 11 Strike Forces and a National Rapid Response Strike Force.
- 93 U.S. Attorney's Offices, each with Civil and Criminal HCF Coordinators

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Health Care Enforcement in Biden HHS

- HHS OIG imposes Civil Monetary Penalties and exclusions.
- Administers self-disclosure processes.
- Oversees all 50 State Medicaid Fraud Control Units (MFCUs).
- OCR enforces HIPAA compliance.

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DOJ / HHS OIG Enforcement Priorities

- DOJ and HHS OIG leadership have signaled similar priorities:
  - COVID-19 funding, including Provider Relief Funds
  - Telehealth-related fraud and kickback schemes
  - Prescription drugs, including opioid-related cases, kickbacks, and improper coverage of co-pays
  - Electronic health records, such as kickback schemes and misrepresentations of capabilities.
  - Elder care, involving long-term care facilities.
  - Medicare Part C managed care, such as improper diagnosis codes that affect the risk adjustment process.
  - Cybersecurity and data privacy requirements.

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Data Analytics in Enforcement

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DOJ’s Emphasis on Data Analytics

- Deputy Attorney General Monaco:
  - “Data analytics plays a larger and larger role in corporate criminal investigations, whether that be in healthcare fraud or insider trading or market manipulation.” (Oct. 2021).
- DOJ Civil Fraud Section:
  - “Increasingly, [DOJ] has been undertaking sophisticated analyses of Medicare data to uncover potential fraud schemes.” Michael Granston, Dep. Ass’t A.G., DOJ Civil Division (Dec. 2020).

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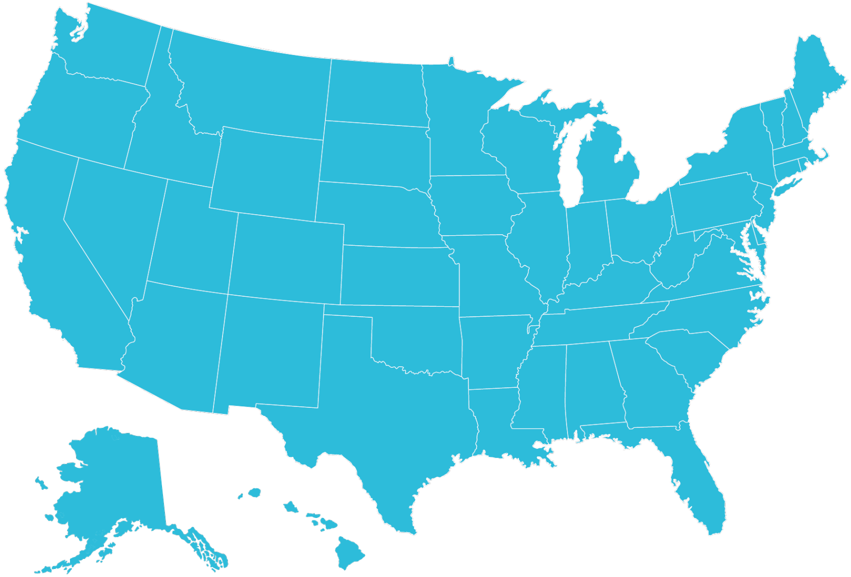
U.S. Attorneys' Offices



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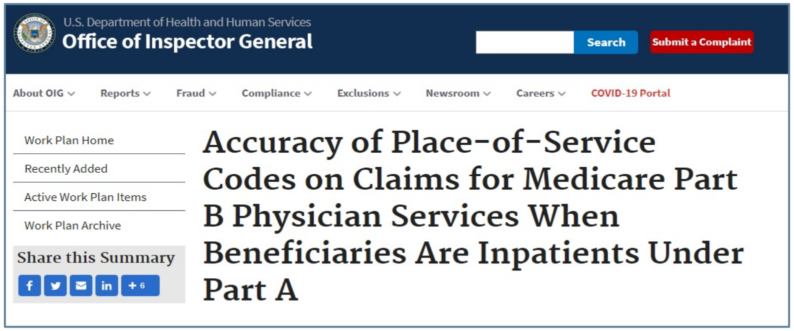
- Each USAO receives customized data analytics packages from DOJ several times per year.
- USAOs have immediate access to aged Medicare claims data and subpoena authority for current claims data.
- USAOs have fraud investigators who work with HHS OIG, FBI, DEA, State MFCUs, other agencies.

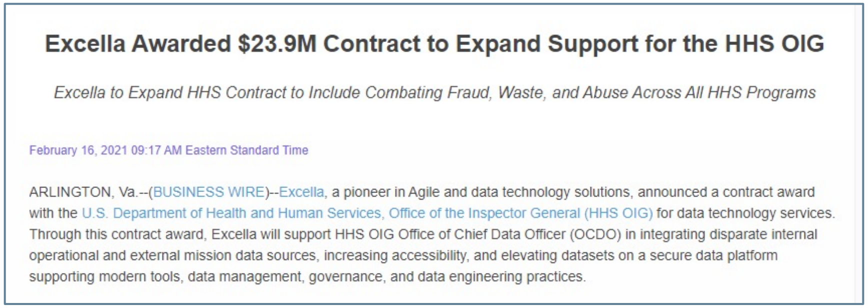
HHS OIG

- Office of Chief Data Officer supports HHS OIG’s work plan, audits and investigations:



Accuracy of Place-of-Service Codes on Claims for Medicare Part B Physician Services When Beneficiaries Are Inpatients Under Part A

- Continually improving:



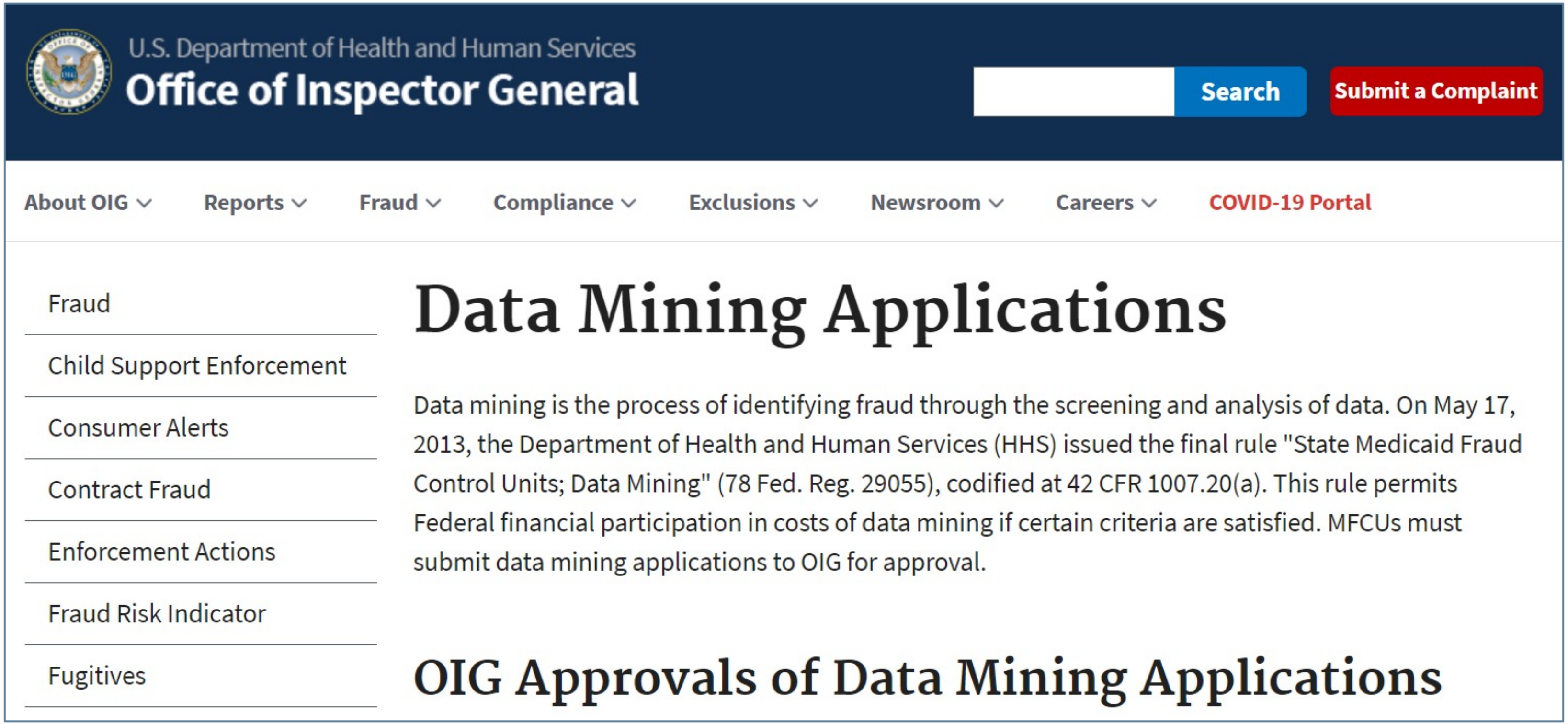
Excella Awarded $23.9M Contract to Expand Support for the HHS OIG

Excella to Expand HHS Contract to Include Combating Fraud, Waste, and Abuse Across All HHS Programs

February 16, 2021 09:17 AM Eastern Standard Time

ARLINGTON, Va.--(BUSINESS WIRE)--Excella, a pioneer in Agile and data technology solutions, announced a contract award with the U.S. Department of Health and Human Services, Office of the Inspector General (HHS OIG) for data technology services. Through this contract award, Excella will support HHS OIG Office of Chief Data Officer (OCDO) in integrating disparate internal operational and external mission data sources, increasing accessibility, and elevating datasets on a secure data platform supporting modern tools, data management, governance, and data engineering practices.

State MCFUs Receive HHS OIG Support for Data Mining



Data Mining Applications

Data mining is the process of identifying fraud through the screening and analysis of data. On May 17, 2013, the Department of Health and Human Services (HHS) issued the final rule "State Medicaid Fraud Control Units; Data Mining" (78 Fed. Reg. 29055), codified at 42 CFR 1007.20(a). This rule permits Federal financial participation in costs of data mining if certain criteria are satisfied. MFCUs must submit data mining applications to OIG for approval.

OIG Approvals of Data Mining Applications

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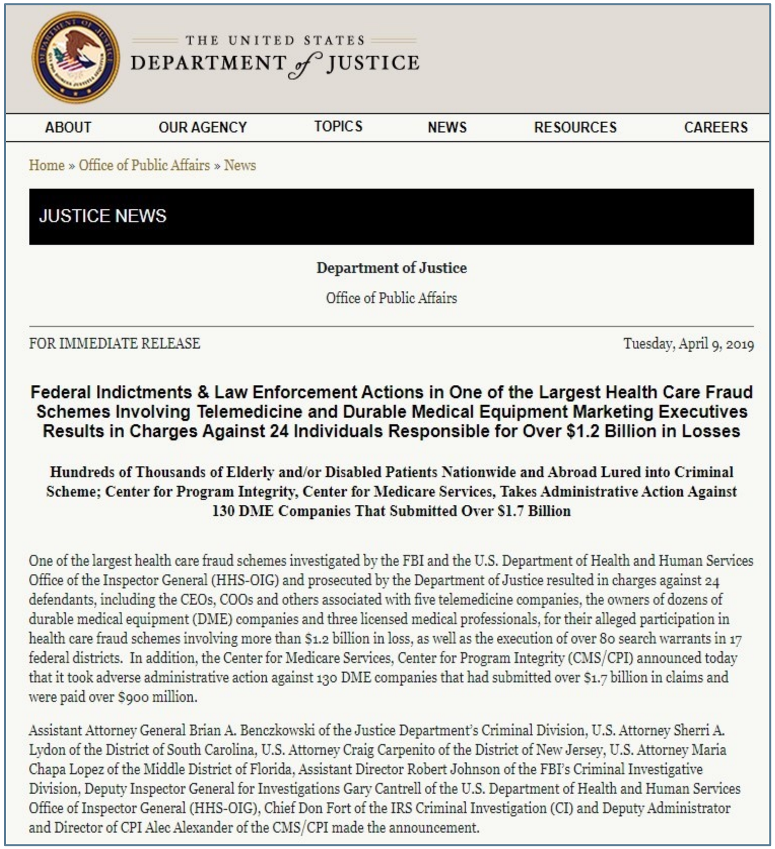
How Do Agencies Use Data Analytics?

- Guide HHS OIG Work Plan
- Generate new investigations / angles on existing investigations.
- Screen *qui tam* complaints and other tips.
- Prioritize cases with higher loss or egregious conduct.
- **Example:** Operation Brace Yourself:
  - Nationwide takedown of scheme involving telehealth visits resulting in orders of DME that were not medical necessary.



Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Tuesday, April 9, 2019

Federal Indictments & Law Enforcement Actions in One of the Largest Health Care Fraud Schemes Involving Telemedicine and Durable Medical Equipment Marketing Executives Results in Charges Against 24 Individuals Responsible for Over $1.2 Billion in Losses

Hundreds of Thousands of Elderly and/or Disabled Patients Nationwide and Abroad Lured into Criminal Scheme; Center for Program Integrity, Center for Medicare Services, Takes Administrative Action Against 130 DME Companies That Submitted Over $1.7 Billion

One of the largest health care fraud schemes investigated by the FBI and the U.S. Department of Health and Human Services Office of the Inspector General (HHS-OIG) and prosecuted by the Department of Justice resulted in charges against 24 defendants, including the CEOs, COOs and others associated with five telemedicine companies, the owners of dozens of durable medical equipment (DME) companies and three licensed medical professionals, for their alleged participation in health care fraud schemes involving more than $1.2 billion in loss, as well as the execution of over 80 search warrants in 17 federal districts. In addition, the Center for Medicare Services, Center for Program Integrity (CMS/CPI) announced today that it took adverse administrative action against 130 DME companies that had submitted over $1.7 billion in claims and were paid over $900 million.

Assistant Attorney General Brian A. Benczkowski of the Justice Department's Criminal Division, U.S. Attorney Sherri A. Lydon of the District of South Carolina, U.S. Attorney Craig Carpenito of the District of New Jersey, U.S. Attorney Maria Chapa Lopez of the Middle District of Florida, Assistant Director Robert Johnson of the FBI's Criminal Investigative Division, Deputy Inspector General for Investigations Gary Cantrell of the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG), Chief Don Fort of the IRS Criminal Investigation (CI) and Deputy Administrator and Director of CPI Alec Alexander of the CMS/CPI made the announcement.

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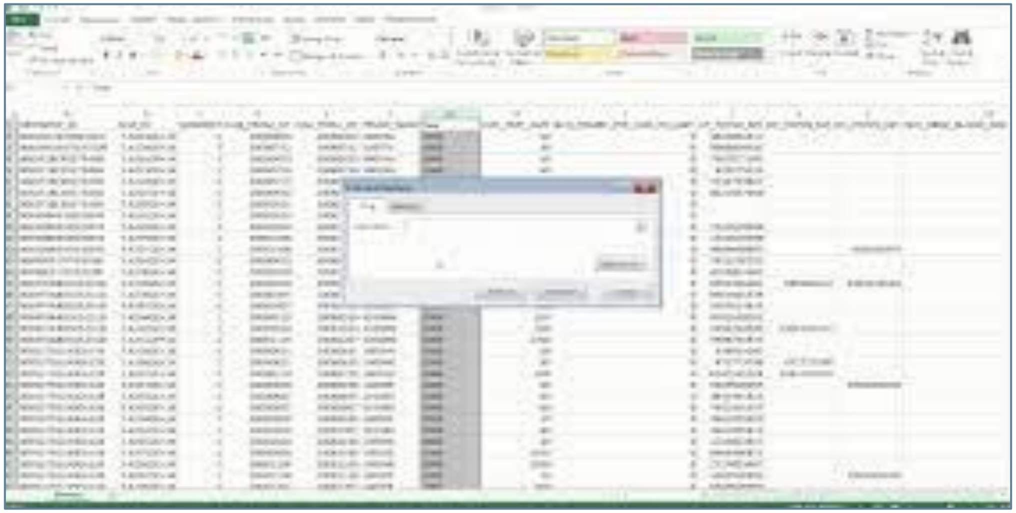
Case Example

- Local AUSA and Health Care Fraud Investigator receive regular data set.
- Lists high-risk physicians based on multiple factors (e.g., costs to Medicare system; red flags).
- One is a pulmonologist employed by hospital and medical director for a clinic.



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Case Example

- Further data mining shows:
  - Doctor is outlier on ordering sleep tests and pulmonary function tests.
  - Dr. also ranks in top quartile for expensive compound pain creams.
  - Particular pharmacy fills most of those prescriptions.

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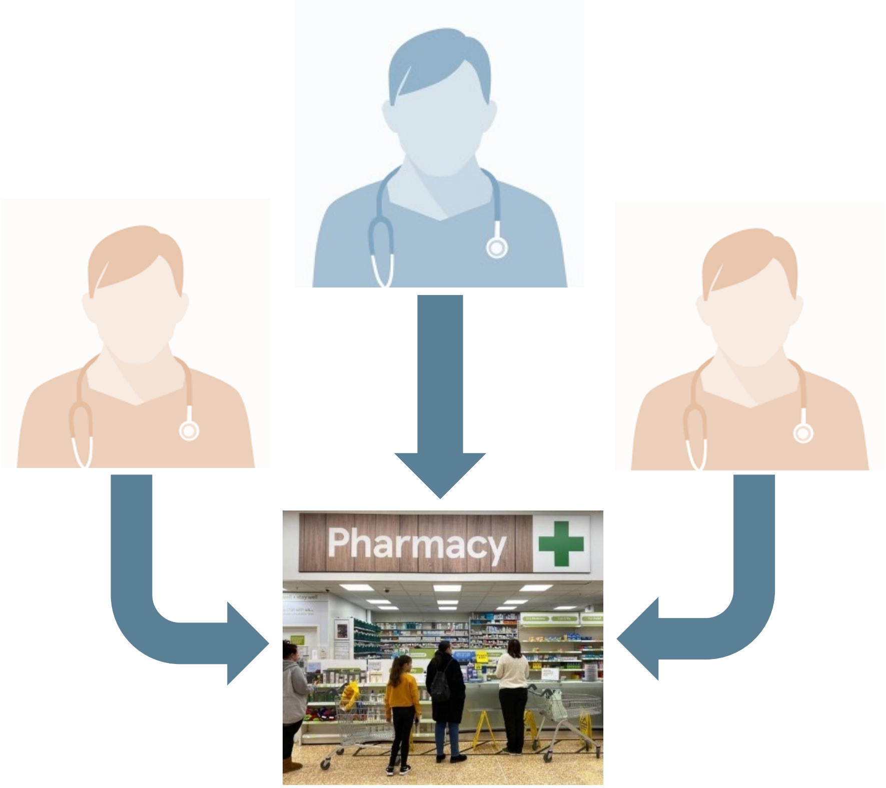
Case Example

- Further data mining shows:
  - Pharmacy receives a high number of similar prescriptions from two other physicians.
  - Physicians ordered high number of prescriptions without E/M.
- AUSA obtains each physicians' claims data.
- Shows all three physicians began writing compound prescriptions around same time.



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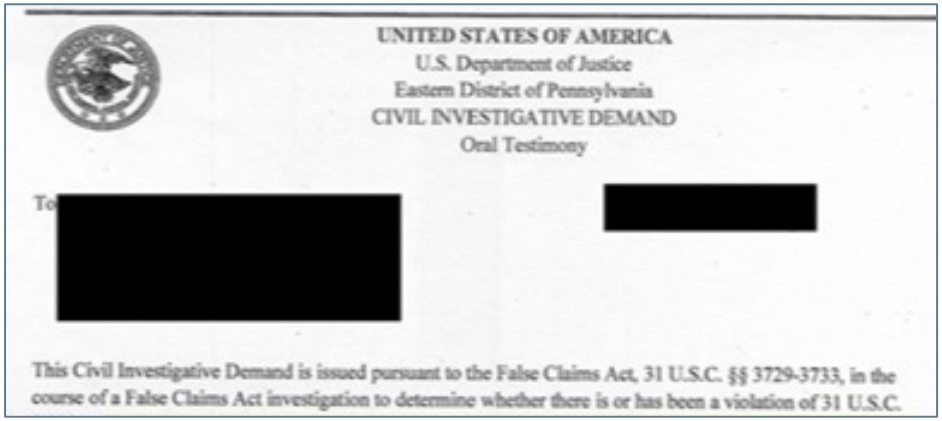
Case Example

- AUSA investigates further:
  - Checks HHS OIG hotline, State MFCU, private payers for complaints.
  - Obtains bank records for clinic, pharmacy, physicians.
  - Obtains state records showing former employees and conducts interviews.
- Only then does AUSA send a CID for medical records, policies, and communications.



UNITED STATES OF AMERICA
U.S. Department of Justice
Eastern District of Pennsylvania
CIVIL INVESTIGATIVE DEMAND
Oral Testimony

To [redacted]

[redacted]

This Civil Investigative Demand is issued pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, in the course of a False Claims Act investigation to determine whether there is or has been a violation of 31 U.S.C.

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What Data Are Analyzed?

- CMS's Integrated Data Repository (IDR) combines multiple data sets:
  - Medicare A, B (including DME), C (MA), D (prescription drug events)
  - Medicare, Medicaid provider and beneficiary information
  - Open Payments.
- Next frontiers:
  - Combining Medicare and Medicaid data
  - Matching with all controlled prescription drugs (not just Medicare/Medicaid)

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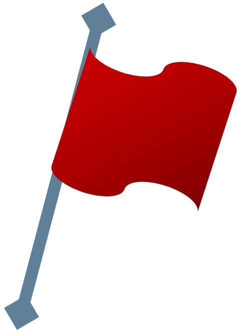
Focus Area: Red Flags



- **Examples:**
  - Geographic distance between patients and provider, or ordering physician and lab.
  - Ordering/referring provider not listed as attending physician or not having other treatment relationship.
  - Physician ordering services outside specialty.
  - Unbundling procedure and E/M service in same day.

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Focus Area: Outliers

- **Examples:**
  - Physician with high number of procedures / claims compared to other physicians in specialty.
  - High number of services billed in 24-hour period or on weekends/holidays.
  - Hospice with long lengths of stay or high number of discharges compared to peers.
  - Lab with larger average panel than peers.

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Focus Area: Relationships

- Major focus on relationships between referring / ordering physician and recipient.
- **Examples:**
  - Physician who orders high amount of particular DME or prescription drug.
  - Lab, pharmacy, home health agency, etc. that receives large percentage of referrals from certain physician.

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Focus Area: Prescription Drugs

- Because of costs and public health risks from ongoing drug epidemic, enforcement agencies focus on prescription drugs.
- **Examples:**
  - Opioids (e.g., high MMEs)
  - Signs of diversion (multiple scripts to same address)
  - Expensive compound drugs
  - Dangerous combinations (e.g., opioids and benzos)

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Data Do Not Tell the Whole Story

- Data need to be validated in context of the potential risk – data prompt further questions.
- Often innocent explanations exist.
- Beware of confirmation biases.
- Government needs witnesses to prove a case.

Expectations for Compliance Programs & Due Diligence

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Expectations for Compliance Programs

- U.S. DOJ’s Evaluation of Corporate Compliance Programs (June 2020) sets standards for effective compliance programs.
- Does not set specific requirements but asks questions to assess whether company is putting reasonable efforts towards compliance program, given its size and operations.
- June 2020 update included multiple new references to use of data in compliance efforts

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Expectations for Compliance Programs

- **Risk Management Process:** What methodology has the company used to identify, analyze, and address the particular risks it faces? What information or metrics has the company collected and used to help detect the type of misconduct in question? How have the information or metrics informed the company's compliance program?
- **Updates and Revisions:** Is the risk assessment current and subject to periodic review? Is the periodic review limited to a "snapshot" in time or based upon continuous access to operational data and information across functions?
- **Data Resources and Access:** Do compliance and control personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing of policies, controls, and transactions? Do any impediments exist that limit access to relevant sources of data and, if so, what is the company doing to address the impediments?

Source: U.S. DOJ's Evaluation of Corporate Compliance Programs (June 2020)

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Improving Your Use of Data Analytics in Compliance

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Take Stock of Current Situation

- Assess:
  - How do you currently use of data in investigations, risk assessments, audits, and monitoring?
  - What data are available?
  - Do you have a data map of your organization?
  - What are current resources in-house and resources to obtain help from outside counsel / consultants?

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Investigations

- Internal investigations
- Responding to inquiries and subpoenas
- Seek to replicate the regulator’s inquiry
- What to do with new information?
- What if you don’t have access to the same data?

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Audits

- Using data for risk-based auditing / sampling
- Best practices
- Pitfalls

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Risk Assessments

- Identify and rank highest risk activities, based on:
  - Enforcement agencies' areas of focus and industry guidance.
  - Prior risk assessments, audits, compliance hotline/reports, etc.
  - Highest revenue / growth service lines, facilities, providers.
  - Your company's particular activities.

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Choosing & Designing Metrics for Monitoring

- Design metrics for high-risk areas, based on:
  - Data available in your organization
  - Data available from third parties (e.g., Open Payments, PEPPER reports).
  - Input from operational leaders
- Iterative process: Test metrics and refine as necessary.

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Plans for Acting on Results

- Develop policies and processes to act on findings.
  - Limit how many reports and metrics are created and designate who is responsible for reviewing.
  - Develop criteria for when to investigate further.
  - Worse to find and ignore issues than not to find them in the first place.
- Document all decisions/efforts so you get credit and can respond to scrutiny.

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Thank you.

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