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What to Do When the Government Comes Calling

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Today's Agenda

- Enforcement Statistics
- Healthcare Regulatory Authorities
- Enforcement Methods
- Recent Settlements
- How to Prepare for an Investigation & What To Do When It Starts

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Enforcement Statistics

Overview of Enforcement Statistics (FY2020)

- DOJ collected **$2.2 B** in False Claims Act Cases
  - **$1.8 B related to matters in the healthcare industry**
  - $1.6 B of these recoveries arose from lawsuits filed through whistleblowers under the qui tam provisions of the False Claims Act
  - These numbers exclude October 2020 unsubordinated general unsecured bankruptcy claim of $2.8 B against Purdue Pharmaceuticals and $225 M from the Sackler Family

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Healthcare Regulatory Authorities

HealthCare Regulatory Authorities

- Department of Justice (DOJ)
- Department of Health and Human Services (DHHS)
- DHHS – Office of Inspector General (OIG)
- DHHS – Office for Civil Rights (OCR)
- Centers for Medicare/Medicaid Services (CMS)
- State Attorneys General
- State Medicaid Agencies

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Enforcement Methods

DOJ Healthcare Fraud (HCF) Units

- DOJ's national HCF unit is comprised of 80 prosecutors solely focused on prosecuting complex health care fraud matters in matters regarding illegal prescription, distribution, and diversion of opioids.
- Many local US Attorney's Offices (e.g., Boston) also have dedicated HCFs that focus on healthcare fraud matters.

DOJ's Primary Enforcement Tool: False Claims Act (FCA)

- The FCA makes liable any person who (i) knowingly submits a false claim to the government, or (ii) causes another to submit a false claim to the government, or (iii) knowingly makes a false record or statement to get a false claim paid by the government
- The FCA provides for ***civil penalties*** between $11,803 and $23,607 (adjusted for inflation annually) per false claim and treble the government's damages, and can extend to ***criminal liability***
- The FCA has ***qui tam ("whistleblower")*** provisions, allowing actions by the government ***or*** private citizen whistleblowers, called ***relators***, who bring suit on behalf of the United States and can share in recovery

- **Note:** Many states have adopted ***state-level FCAs*** that mirror the federal FCA; state attorneys general often pursue theories under state FCAs and/or state consumer protection laws

HHS-OIG

- OIG provides objective and independent oversight of HHS programs – primarily Medicare and Medicaid
- Their #1 priority is to Fight Fraud, Waste & Abuse
  - Prevent, detect, and deter fraud waste and abuse
  - Foster sound financial stewardship and reduction of improper payments
  - Hold wrongdoers accountable and recover misspent public funds
- OIG collaborates with DOJ and HHS agencies on health care fraud and enforcement activities such as the Medicare Fraud Strike Force teams which use data analytics to root out fraud

HHS-OIG

- OIG conducts audits to analyze the validity of healthcare spending
- Between October 1, 2020 and March 31, 2021, OIG issued 75 audit reports, and expects to recover $566.46 M in alleged overpayments
- Expected investigative recoveries for this six month period are $1.37 B
- Civil actions initiated against 272 individuals and entities in that period and excluded 1036 individuals and entities from Federal health care programs

HHS – Office for Civil Rights (OCR)

- OCR is mainly concerned with enforcing the Health Insurance Portability and Accountability Act (HIPAA).
- HIPAA sets a baseline for medical privacy laws – which may be preempted by more stringent state laws
- HIPAA enforcement penalties can be significant:
  - Civil: $100 to $50,000 per violation per person up to a maximum of $1,500,000 per person per year per standard violation
- In addition to traditional misuse of protected information enforcement, the agency has focused over the last 18 months on the HIPAA Right of Access Initiative.
  - There have been 19 settlements to date ranging from $3,500 - $100,000.

State Attorneys General & State Medicaid Authorities

- State Attorneys General often maintain whistleblower portals, and enforce health care fraud laws in collaboration with federal agencies both in civil and criminal courts
- Recent 2021 Settlements
  - Investigation by the CT AG in collaboration with the U.S. Drug Enforcement Administration secured $14,982,081 court judgment against a physician for fraudulent billing under the False Claims Act
  - $678,901 joint state of CT and federal settlement with L.A. Vision for improperly billing medically unnecessary “miscellaneous” items/services

State Medicaid Programs

- State Medicaid agencies may receive allegations of fraud from, among other places: (1) hotlines; (2) claims data mining; (3) patterns from provider audits; and (4) law enforcement investigations
- Procedure:
  1. Determine if an Allegation of Fraud is Credible
  2. Suspend Payments or Document a Good Cause Exception not to suspend
     - The state will completely suspend all Medicaid payments to the provider after it determines there is a credible allegation of fraud
     - This suspension can last indefinitely as they review the allegations
  3. Refer the case to the Medicaid Fraud Control Unit (MFCU) or other appropriate law enforcement agency
  4. Follow up on a quarterly basis and request certification from the MFCU that a referral continues to be under investigation and suspension is warranted

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Recent Settlements

Recent Settlements: Novartis Pharmaceuticals agreed to pay combined $642 M to resolve FCA allegations

- The first settlement pertained to the company's alleged improper use of foundations to cover co-payments for their drugs Gilenya and Afinitor. Novartis agreed to pay $51.25M to resolve these allegations.
  - Gilead Sciences, Inc. maintained a similar foundation support program, and they also agreed to pay $97M to resolve associated allegations.

- The second settlement concerned allegations Novartis paid kickbacks to physicians in return for prescribing their drugs by rewarding physicians through speaking engagements and honoraria. Novartis agreed to pay $591M to resolve these claims.
- Novartis will forfeit an additional $38.4M under the Civil Asset Forfeiture Statute and will pay an additional $48M to resolve allegations related to state Medicaid claims.

Recent Settlements: Practice Fusion, Inc.

- Practice Fusion, Inc. a health information technology developer allegedly solicited and received kickbacks from major opioid company Purdue Pharma in exchange for utilizing its EHR software to influence physicians prescribing opioid pain medications
- This was accomplished by modifying the EHR software so that physicians were given clinical decision support alerts at key points in the prescribing process that encouraged physicians to prescribe opioids.
- Some alerts were directly drafted by pharmaceutical companies.
- Practice Fusion paid $118.6 M to the federal government to resolve FCA allegations in addition to the largest criminal fine in Vermont history of $26M. The Vermont settlement also required an admission of guilt.

Recent Settlements

- Medical Device Company Arthrex agreed to pay $16M to settle allegations that it violated the FCA by paying kickbacks:
  - The payments were allegedly made to a physician under the guise of royalty payments for their contribution to developing Arthrex's orthopedic products.
  - The surgeon had been denied royalty payments between 2006 and 2010 until he allegedly threatened to realign his loyalty to a competitor in 2010. The surgeon then received royalties for both past and future sales of the products at a higher than market rate.
- Texas Pain Management Physicians Agree to Pay $3.9 M to resolve allegations related to unnecessary Urine Drug Testing:
  - Tests were ordered without individualized assessment of need, multiple screenings conducted on every sample and every test was performed at the in-house laboratory.

Recent Settlements: South Bay and Interface

- South Bay Mental Health Center Inc., H.I.G. Growth Partners, LLC, H.I.G. Capital, and executives settle for $25 M regarding allegation of employing unlicensed therapists and counselors:
  - HIG allegedly held the majority of seats on South Bay's board of directors. The AG alleged that the board was aware of violations involving unlicensed therapists and counselors that continued to provide unsupervised care and failed to act.
- Interface Rehab agreed to pay $2 M to resolve allegations they submitted rehabilitation therapy services that were not reasonable or necessary:
  - Interface allegedly pressured therapists to increase the amount of therapy provided in order to meet pre-determined targets for care that would place the facility in the "Ultra High" daily reimbursement level without taking into account patients' individualized needs.

Recent Settlements: Ascension Michigan

- Ascension Michigan and related hospitals agree to pay $2.8 M to resolve claims they submitted false claims for payment related to alleged medically unnecessary gynecological procedures:
  - These allegations related to a specific physician who allegedly claimed reimbursement for medically unnecessary radical hysterectomies, chemotherapy services that were not medically necessary and evaluations of patients that were not actually conducted. There were also concerns about the quality of care that was provided due to complaints and an usually high frequency of medical complications.

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How to Prepare for an Investigation & What To Do When It Starts

How to Prepare

- The best preparation is a culture of compliance
- Prioritize compliance despite competing concerns, disruption, and limited resources (“don’t freeze!”).
- Ensure regular compliance messaging from the top and integrate compliance messaging into high-profile, senior messaging.
- Know your internal audit function, understand its priorities and pay attention to the results!

What to do when the Investigation Begins

- Prepare and issue a document hold notice.
- Engage quickly and meaningfully with the government agency regarding the investigation to establish cooperation.
- Consider an internal investigation to develop your own facts.
- Manage attorney-client privilege carefully.
- Take a step-by-step approach to your response.

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