



Defending a Criminal Health Care Fraud Case

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Recent Activity in Criminal Health Care Fraud Enforcement

- Criminal health care fraud continues to be an enforcement priority for the Department of Justice
- In FY 2017, DOJ:
 - Opened 967 new criminal health care fraud investigations
 - Filed 439 cases involving 720 defendants
 - Convicted 639 defendants



Recent Activity in Criminal Health Care Fraud Enforcement

- September 27, 2018, GIR New York Live Event
 - Deputy Assistant Attorney General Matthew Miner touted the “incredible success” of DOJ’s Health Care Fraud unit, including the June 2018 takedown
 - He also announced an expansion of the Strike Force model into Newark and Philadelphia, facilitating greater cooperation among DOJ, U.S. Attorney’s Offices, HHS-OIG, FBI, and the DEA
- May 18, 2017, ABA Institute on Health Care Fraud
 - Acting Assistant Attorney General Kenneth Blanco: “[L]et me be clear: health care fraud is a priority for the Department of Justice. Attorney General Sessions feels very strongly about this... The investigation and prosecution of health care fraud will continue.”



Recent Activity in Criminal Health Care Fraud Enforcement

- DOJ continues to focus on similar issues
 - Opioids
 - In addition to “pill mills,” recent cases have involved substance abuse treatment centers and kickbacks / false billings
 - Prescription drugs
 - Health Care Fraud Unit’s Chief, Joseph Beemsterboer, said there has been substantial increase in Medicare Part B spending in recent years and his unit is taking “a hard look at if there are fraud indicators in that type of spending.” - August 24, 2018
 - Home health care
 - Emphasis on corrupt medical professionals
 - In the most recent takedown, HHS simultaneously announced stepped-up suspension activity against those suspected of improper opioid activity

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Recent Activity in Criminal Health Care Fraud Enforcement

- Recent cases:
 - October 12, 2018 – the Eastern District of Tennessee indicted four individuals and seven companies in connection with a \$1 billion scheme involving telemedicine and inflated prescription costs
 - June 6, 2018 – CEO of Tri-County Wellness and four physicians charged, in superseding indictment, with \$200 million scheme involving unnecessary prescriptions for controlled substances including oxycodone; CEO pled guilty on October 15, 2018
 - May 14, 2018 – Physician charged in \$240 million scheme related to false diagnoses and chemotherapy
- DOJ and HHS continue to do mass “takedowns,” and they are getting larger
 - June 28, 2018 – DOJ announced enforcement against 601 charged defendants in 58 federal districts for alleged schemes involving more than \$2 billion
 - July 13, 2017 – DOJ executed huge operation, primarily related to opioids, charging over 412 individuals in 41 federal districts responsible for \$1.3 billion in alleged fraud losses

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Preventing a Criminal Case

- Most important part of health care fraud cases is to avoid them
- Standard compliance best-practices, mandated by federal regulations for managed care programs, are essential:
 - Implementing written policies, procedures and standards of conduct
 - Designating a compliance officer and compliance committee
 - Training and education
 - Lines of communication
 - Conducting internal monitoring and auditing
 - Enforcing standards through well-publicized disciplinary guidelines
 - Responding promptly to detected offenses and undertaking corrective action

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Preventing a Criminal Case

- DOJ guidance, Evaluation of Corporate Compliance Programs, should also be taken into account
 - Sufficient Analysis and Remediation of Underlying Misconduct
 - Role of Senior and Middle Management
 - Autonomy and Resources for Compliance Function
 - Policies and Procedures
 - Design and Accessibility
 - Operational Integration

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Preventing a Criminal Case

- Evaluation of Corporate Compliance Programs, ctd.
 - Risk Assessment
 - Training and Communications
 - Confidential Reporting and Investigations
 - Incentives and Disciplinary Measures
 - Continuous Improvement, Periodic Testing, and Review
 - Third Party Management
 - Mergers and Acquisitions

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Preventing a Criminal Case

- Recent focus on the compliance measures of managed care organizations (MCOs)
- July 2018 HHS OIG report: “Weaknesses Exist in Medicaid Managed Care Organizations’ Efforts to Identify and Address Fraud and Abuse”
 - Found that many MCOs were not referring instances of fraud to state Medicaid authorities
 - Not enough MCOs using enough proactive data analysis
 - Many MCOs missing overpayments, which becomes factored into future payments

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Preventing a Criminal Case

- Avoiding personal liability
 - Possible for Chief Compliance Officers to have exposure themselves
 - Example: *U.S. v. Caputo* (N.D. Ill. 2006) – CEO and CCO convicted for scheme involving off label promotion of sterilization devices
 - CCO participated in efforts to misrepresent the very narrow indication approved by FDA when dealing with customers

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Preventing a Criminal Case

- Personal liability generally a worry only in extreme cases
 - CCOs part of a scheme
 - CCOs part of cover up post-scheme
 - CCOs completely ignoring their job and providing only a façade of compliance

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Preparing for a Criminal Case

- Compliance function is often first line of defense when criminal issues arise
 - Have to decide what additional investigation of potential issues is necessary and when
 - Have to decide at what stage to involve both in-house and outside counsel
 - Have to analyze and implement remediation even if allegations about historical practices are unresolved

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Preparing for a Criminal Case

- Ensure company is prepared for criminal investigation
 - Develop instructions for employees regarding what to do if contacted by government agents or if a search occurs
 - Institute document holds, when appropriate, and communicate consequences of obstruction or false statements



Preparing for a Criminal Case

- Need a thorough and independent investigation of facts related to allegations
 - In-depth interviews of current and former employees related to subject of investigation
 - Review and analysis of documents
 - Documents submitted to payers and documents supporting claims
 - Internal records, memoranda, correspondence, reports, and financial data – especially those related to decision-making



Preparing for a Criminal Case

- Anticipate ethical issues
 - Typically, first step is for outside counsel to be hired for the organization
 - Client is the *organization*
 - If executives are targets, have to make clear where counsel's loyalties lie
 - Need an available line of communication from outside counsel directly to board



Preparing for a Criminal Case

- Consider the status of individuals
 - Identify anyone who could become a target / defendant – physicians, nurses, pharmacists, dentists, accountants, business managers, executives, contractors and vendors, etc.
 - Consider separate legal counsel for individual employees
 - Work through indemnification obligations and D&O insurance
 - Consider pool counsel for present and former employees who are not targets
 - Consider a formal joint defense agreement

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Preparing for a Criminal Case

- Consider outside auditors and forensic accountants
 - Many accounting and consulting firms have experience in specialized health care fraud audits
- Consider firms with expertise in reviewing documents
 - Where records are voluminous, can consider alternatives to a full review such as predictive coding and other data analytics

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Litigating a Criminal Case

- All the best practices for litigating any criminal white collar case apply
 - Consider law firms with relevant expertise
 - Want a firm with health care fraud experience and / or strong health care regulatory experience
 - Good local counsel

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Litigating a Criminal Case

- Best practices, ctd.
 - Always be mindful of appellate issues and set them up in briefing or at trial
 - Example: *United States v. Ganji*, 880 F.3d 760 (5th Cir. 2018) – Defendants were able to get the Fifth Circuit to set aside guilty verdicts based on insufficiency of the evidence
 - Allegations concerned false certification for home health care services
 - Court found that there was not enough evidence of an agreement to defraud Medicare to support conspiracy charges
 - Government's key witnesses did not have direct knowledge of defendants' activities and intent, and court found circumstantial evidence of "concerted action" too ambiguous to prove a conspiracy

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Litigating a Criminal Case

- Best practices, ctd.
 - Always be mindful of budget
 - More than one source of costs:
 - Legal fees
 - Medical experts
 - Document review costs
 - Consultants, auditors, and other vendors
 - Depending on resources of client, aggressively litigating a case may be as harmful as losing

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Litigating a Criminal Case

- Best practices, ctd.
 - Public relations
 - Press / media
 - Investors / shareholders

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Litigating a Criminal Case

- Health care fraud cases have particular legal and evidentiary issues that affect litigation tactics
- Two key areas:
 - Statistical sampling
 - Medical necessity

Litigating a Criminal Case

- Statistical Sampling
 - Sampling, in which a smaller subset of records is examined and then extrapolated to estimate the prevalence of an issue in a larger universe, has become key to large cases
 - Methodology of sampling can differ, but may be useful on:
 - Billing Claims Data
 - Patient Charts
 - Personnel Records
 - Provider Business Records

Litigating a Criminal Case

- Many considerations for both sides
 - At the outset, sampling may identify the potentially problematic behavior as related to particular types of services, claims, or locations, or may identify relevant individuals

Litigating a Criminal Case

- Government may use sampling to:
 - Simplify a case and short-circuit the burden of proof by allowing the Government to seek liability / fines based on a larger body of claims
 - Identify specific examples of an issue, to be explored with live witnesses, as a supplement to statistical analysis

Litigating a Criminal Case

- Defense may use sampling to:
 - Reduce the costs of discovery in investigations and litigation by limiting the underlying records that need to be reviewed or produced
 - Cabin or eliminate areas of potential liability
 - Rebut anecdotal evidence of systemic problems

Litigating a Criminal Case

- Regardless of how used, have to aggressively police the methodology of statistical sampling that might be used at trial
 - Defense counsel should move to discover the use of this type of evidence
 - File motions *in limine* to exclude such evidence and request an evidentiary hearing
 - Need own experts to testify regarding validity of analysis suggested by other side and its limitations

Litigating a Criminal Case

- Should not use sampling when...
 - Investigating or litigating incidents that are small in number
 - When claims are not similar enough (in time, type, nature, location, etc.) to allow for extrapolation



Litigating a Criminal Case

- Medical necessity
 - Concept of medical necessity is a key part of theories of liability in which Government alleges providers are habitually giving unneeded treatments or procedures merely to generate revenue
 - Can be complex to litigate because medical necessity is based on judgment of physicians



Litigating a Criminal Case

- Most medical necessity cases are challenging to litigate and for the government to prove beyond a reasonable doubt
- Medical necessity cases will likely involve dueling experts



Litigating a Criminal Case

- Example: *United States v. McLean*, 715 F.3d 129 (4th Cir. 2013).
 - Cardiologist convicted of health care fraud in connection with providing unnecessary stents – Fourth Circuit upheld conviction
 - Evidence showed doctor regularly conducted stent procedures for blockages that were of a low percentage
 - Medical evidence supplemented by statements from doctor, such as an instance in which he told a dissatisfied patient that he put in a stent “because it was easy, why not?”



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Litigating a Criminal Case

- Danger for organizational defendants lies in *why* medically unnecessary services were being provided
 - Most serious cases often tie in to business goals – e.g., a hospital tries to increase in-patient revenue, and there are questions about whether admissions were medically necessary
 - Important to present evidence of independence of health care providers



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Litigating a Criminal Case

- Opportunities for defendants on medical necessity
 - Materiality
 - Argue good faith
 - Argue mere negligence
 - Argue rogue employees



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Settling a Criminal Case

- At all stages of a criminal case, need to determine whether a negotiated resolution is the most rational decision
 - Even if litigation may result in victory, need to account for reputational costs of lingering allegations and ongoing disruption to operations and business planning



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Settling a Criminal Case

- There are many layers to negotiate and consider in health care fraud cases
- Example: In September 2018, Health Management Associates (now owned by Community Health Systems) paid \$260 million to resolve a variety of civil and criminal allegations
 - Corporate criminal guilty plea confined to subsidiary
 - HMA agreed to pay \$35 million as a part of Non-Prosecution Agreement
 - HMA and CHS also agreed to enhanced reporting and compliance obligations for three years under the NPA, replacing a Corporate Integrity Agreement that HMA entered into in 2014
 - 8 *qui tam* actions settled



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Settling a Criminal Case

- Example: In October 2016, Tenet Healthcare Corporation, settled a *qui tam* suit for \$513 million and resolved related criminal allegations
 - Two subsidiaries, connected to specific hospitals, pled guilty to criminal charges in connection with kickbacks and bribes
 - A middle-level subsidiary, one level above the hospitals at issue, entered into a NPA
 - Prosecution of some of the individuals remains ongoing



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Questions?

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