



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.”

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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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