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Litigating and 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 U.S. Department of Justice (DOJ)
- At the end of FY 2020, DOJ announced a nationwide enforcement action (takedown) involving 345 charged defendants across 51 federal districts, including more than 100 licensed medical professionals and alleged fraud losses in excess of \$6 billion
- This enforcement action included cases charged and unsealed since the start of the global pandemic, showing that despite the present circumstances, enforcement has not halted



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Recent Activity in Criminal Health Care Fraud Enforcement

- September 30, 2020, A/AAG Takedown remarks:
 - Acting Assistant Attorney General Brian Rabbitt emphasized, among other things: “Preventing and imposing accountability for healthcare fraud has never been of more critical importance than it is today, and these prosecutions once again show the Criminal Division and its partners efficiently and effectively striking at those who abuse America’s healthcare programs”
 - He also announced creation of the National Rapid Response Strike Force in Washington, DC

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Recent Activity in Criminal Health Care Fraud Enforcement

- DOJ focuses on recurring and emerging fraud trends
 - Opioids – Appalachian Prescription Regional Opioid Strike Forces; Sober Homes Initiative
 - In addition to “pill mills,” recent cases have involved substance abuse treatment centers and kickbacks / false billings – so-called “Sober Homes”
 - Telemedicine Fraud
 - DME
 - Genetic testing
 - Emphasis on corrupt medical professionals
 - In the most recent takedown, HHS simultaneously announced stepped-up suspension activity against those suspected of improper activity

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Preventing a Criminal Case

- From the defense perspective, the most important part of health care fraud cases is to avoid them
- DOJ Criminal Division issued guidance for evaluating corporate compliance programs
 - <https://www.justice.gov/criminal-fraud/page/file/937501/download>
- Standard compliance best-practices, mandated by federal regulations for managed care programs, are essential and include:
 - 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

- Avoiding personal liability
 - Possible for Chief Compliance Officers to have exposure themselves
 - Example: *U.S. v. Caputo* (N.D. II. 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, the 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

- 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



Litigating a Criminal Case

- 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



Litigating a Criminal Case

- 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:
 - Streamline a case and allow the Government to seek liability / fines based on a larger body of claims (more in civil cases)
 - 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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Questions?

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