YOUR HEALTH CARE CASE JUST WENT CRIMINAL: WHY? WHAT SHOULD YOU DO NOW?



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AGENDA

- Identifying Frequently-Used Health Care Fraud Criminal Statutes
- How a Criminal Health Care Case is Initiated
- Comparison of Criminal and Civil Health Care Investigations, Including Parallel Investigations
- Factors Involved with Determination to Go Criminal
- Compelling (and Not-So-Compelling) Defense Arguments
- Additional Strategies and Considerations

FREQUENTLY-CHARGED HEALTH CARE CRIMES

- Health Care Fraud
 - Broad application available to investigate and charge virtually any type of health care fraud scheme
- Anti-Kickback Law
 - Prohibits bribery; recent trend DOJ trend using Travel Act to prosecute kickback transactions involving purely commercial plans
- Controlled Substances Act
 - Increased application in the wake of the opioid epidemic
- Food, Drug, & Cosmetics Act
 - Often used in misbranding, mishandling, and dissemination of certain drugs
- HIPAA
 - Crime for covered entities to use unique health identifier or to obtain or disclose identifiable health information
- False Statements/Obstruction

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HOW CRIMINAL HEALTH CARE CASES BEGIN

A criminal healthcare case can begin at DOJ through numerous avenues:

- Qui Tam Complaints
- Agency Investigations
 - HHS-OIG (HEAT)
 - FBI, FDA, VA, IRS, etc.
 - Data Analytics
- Extraordinary Events
 - e.g., Opioid Epidemic
- News/Press/Politics

CRIMINAL VS. CIVIL INVESTIGATIONS

- Criminal Investigations
 - Undercover informants, electronic surveillance, search warrants
 - Grand jury
- Civil Investigations
 - Civil Investigative Demands
 - Subpoenas
 - Interviews
- Practical Differences
 - Access to information

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PARALLEL PROCEEDINGS

- Encouraged by DOJ
- Beware of the "stalking horse"
- Complications Related to Cross Designating Civil AUSA
- Defense Counsel Must Regularly Seek Clarity

FACTORS LIKELY TO RESULT IN CRIMINAL CHARGES

- Nature and Circumstances of Defendant's Conduct
- Patient Harm
- Substantial Economic Loss
- Whether Defendant Occupies Position of Trust
 - e.g., Doctor, Lawyer, etc.
- Political Pressure
- Media Coverage
- Jurisdiction
- Timing/Resources

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DEFENSE ARGUMENTS

- USAM instructs, if conduct constitutes a federal offense and admissible evidence sufficient to sustain conviction exists, AUSA is directed to pursue criminal prosecution <u>unless</u>:
 - 1. No substantial federal interest
 - 2. Effective prosecution in another jurisdiction
 - 3. Adequate non-criminal alternative to prosecution
- The third exception is the most fruitful avenue for negotiation
 - Prosecutor must consider "all relevant" factors

EXISTENCE OF AN ADEQUATE NON-CRIMINAL ALTERNATIVE TO PROSECUTION

- Non-Criminal Alternative Considerations
 - Civil action under the False Claims Act (USAM specifically identifies as alternative)
 - Collateral consequences (layoffs, etc.)
 - Permanent exclusion vs. Corporate Integrity Agreements
 - Payment
 - Demonstrate corporate changes (enhanced compliance, separate bad actors, etc.)

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ADDITIONAL DEFENSE ARGUMENTS AND MITIGATION STRATEGIES

■ MITIGATION

- Robust Compliance Program
- Internal Investigation
- Use of Experts (e.g., forensic auditor or certified medical biller)

ADDITIONAL DEFENSE ARGUMENTS AND MITIGATION STRATEGIES

■ ADDITIONAL STRATEGIES AND CONSIDERATIONS

- Joint Defense Agreements
- Negotiating Global Settlement
- Deferred Prosecution Agreement

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THANK YOU.

■Any Questions?