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

#### **HOW CRIMINAL HEALTH CARE CASES BEGIN**

A criminal healthcare case can begin at DOJ through numerous

- 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
- Civil Investigations
- Civil Investigative Demands
- Subpoenas
- Interviews
- Practical Differences
  - Access to information

### PARALLEL PROCEEDINGS

- Encouraged by DOJ
- Beware of the "stalking horse"
- Complications Related to Cross Designating Civil
- 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

### **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

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## 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
  - Pavment
  - 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)

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# 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?

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