



# Criminalization of Health Care

## White-Collar Crash Course

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# Presented by

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# Rising Health Care Costs and Heightened Criminal Enforcement

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- As health care costs in the United States continue to grow, fraud enforcement has increased in both scale and severity
- Not only resulting in new anti-fraud programs in recent years, but the federal government has also increasingly sought criminal sanctions for health care non-compliance
- Concerning because the federal government is seeking incarceration for violations of laws and regulations that are complex, technical, and anything but straightforward

# DOJ Now Reviews All *Qui Tam* Complaints through Criminal Lens



- DOJ Criminal Division announced in September 2014 that it is now automatically reviewing all new civil *qui tam* complaints for potential parallel criminal proceedings
- During this initial review, prosecutors consider whether the facts and circumstances support criminal investigation and possible prosecution
  - Among other factors, investigators assess severity/pervasiveness of any compliance failures, involvement and culpability of individuals, and the availability and appropriateness of regulatory or civil enforcement action, as opposed to criminal prosecution
- Criminal prosecution will likely become an even more prominent part of enforcement efforts – federal government is concerned that civil penalties are insufficient to deter fraud

# DOJ's Interest in Healthcare Fraud and Abuse Continues in the New Administration

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- DOJ Staff Under Sessions Have Repeatedly Stated that Healthcare Fraud Remains an Area of Emphasis
- July 2017 Takedown of 412 Individuals Allegedly Responsible for \$1.3 Billion in Healthcare Fraud
- Continued Creation of New Healthcare Fraud Units

# Criminalization of Poor Treatment: Substandard Care and “Worthless Services”



- Over the past several years, the federal government has increasingly sought criminal sanctions for alleged health care violations related to the standard of care provided
- Under the worthless services theory, when a provider bills the federal government for a service that the provider knows, or should know, has no value, the provider has defrauded the government
- The Eleventh Circuit recently issued an opinion in a significant worthless services case in *United States v. Houser*
  - Affirmed the 20-year sentence of a nursing home operator
  - Failure to pay for basic amenities like cleaning supplies and conditions at the nursing homes were—according to witnesses—“barbaric” and “uncivilized”
  - Indictment suggests a development in fraud enforcement that is perhaps even broader than simply the application of the worthless services theory, reflecting federal government’s willingness to craft other theories of criminal liability out of FCA violations

# Criminalization of Medical Necessity: Clinical Decision Making as a Basis for Indictments



- DOJ has also recently used criminal statutes to combat the provision of purportedly medically unnecessary treatments
- **Medical Necessity Standard**: Federal health care programs only reimburse providers for items/services that are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”
- CMS Certification Requirement that items/services are medically necessary
  - Whether an item or service is “medically necessary” for a federal health care program beneficiary is not dependent on a particular provider’s clinical judgment.
  - Decision rests with the Secretary of HHS

# Criminalization of Medical Necessity: Clinical Decision Making as a Basis for Indictments

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- Failure to adhere to medical necessity guidelines may not only constitute a civil FCA violation, but could also be a felony if a provider knowingly and falsely represents the medical necessity of an item or service in the provider's submitted claim
  
- Federal government's *post hoc* medical necessity determination during an audit or investigation can be unsettling
  - CMS has not delineated precisely what constitutes medical necessity or what documentation is required to substantiate it
  - Yet the provider's judgment/determination may be questioned

# Criminalization of Medical Necessity: Clinical Decision Making as a Basis for Indictments



- Despite this lack of clarity, the federal government has moved to criminalize and has obtained significant convictions in several medical necessity cases
  - In *United States v. Patel* (2012), *United States v. McLean* (2013), and *United States v. Chhibber* (2014), the federal government obtained convictions (all affirmed on appeal) in cases where doctors administered tests or treatments that were later deemed medically unnecessary
  - *But See, United States v. Paulus* (2017) (District Court threw out conviction after jury trial).
- With the increased sophistication of CMS's real-time claims data analysis and use of data mining (i.e., where investigators examine claims for clusters of billing anomalies), it is now easier than ever for government prosecutors to target providers and hospitals reporting higher utilization of certain procedures as compared to peers

# Administrative “HIPAA Subpoenas” Blur the Line between Civil and Criminal Investigations



- HIPAA granted DOJ broad investigatory authority to issue administrative “HIPAA subpoenas” in *any* investigation of “a Federal health care offense.”
- Can generally be used in civil or criminal investigations—without specifying if either or both is officially underway—to compel production of documents and testimony
  - Bypasses the grand jury process typically applicable to criminal cases
  - Cannot be used for bank records, but can be used for most kinds of similar materials that a grand jury subpoena would seek
  - The use of HIPAA subpoenas has proven to be a highly effective and expedient investigative tool for parallel investigations
  - Information obtained pursuant to such subpoenas can be shared freely between civil and criminal investigators (and such sharing is encouraged)
  - If a grand jury subpoena is issued, the criminal and civil AUSAs need to set up a wall

# Administrative “HIPAA Subpoenas” Blur the Line between Civil and Criminal Investigations



- If criminal prosecutors utilize the grand jury process to obtain a subpoena, there are restrictions on how information obtained pursuant to that subpoena may be disclosed to civil counterparts
  - Information obtained through the use of HIPAA subpoenas relating to health care offenses is *not subject* to the same disclosure restrictions
  
- Since parallel investigations can exist for the same regulatory violation, and since information disclosed pursuant to a civil investigation may be shared with prosecutors as part of a simultaneous or subsequent criminal investigation, HIPAA subpoenas have a tendency to blur the line between civil and criminal enforcement
  - Responding party wonders whether they are the subject of a criminal investigation and whether their documents and testimony offered under the auspices of a civil investigation will be used against them in a criminal proceeding.

# Questions?



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## White Collar Crash Course Series

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- **Signs You May Have a Problem**  
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Presenter: Richard W. Westling

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