COVID-RELATED HEALTHCARE COMPLIANCE TOPICS

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AGENDA

- FDA Law Overview: EUA & Post-EUA Surveillance
- Fraud & Abuse Law Overview
- Medical Device Case Study (COVID EUA)
- Breakout Discussion
- Full Group Discussion

EMERGENCY USE AUTHORIZATION: OVERVIEW

- FDCA Sections 564, 564A, & 564B
- FDA must make a "declaration of emergency" (Feb. 4, 2020)
- Sponsor can then seek an individual drug, biologic or device EUA if the product qualifies as a medical countermeasure ("MCM")
- Two categories:
  - (1) unapproved MCMS &
  - (2) unapproved uses of approved/cleared MCMs

EMERGENCY USE AUTHORIZATION: CRITERIA

- **(1) Serious or life-threatening disease or condition**
- **(2) No adequate, approved, available alternatives**
- **(3) Evidence of effectiveness**: "may be effective" to prevent, diagnose, or treat the emergency disease or condition
- **(4) Risk/Benefit analysis**: known & "potential" benefits to diagnose, prevent or treat the emergency disease or condition outweigh known & "potential" risks

MEDICAL DEVICES: POST-EUA SURVEILLANCE

- FDA has granted EUA to a number of COVID medical devices that would normally be classified as Class II and subject to 510(k) premarket clearance before sale/distribution
- Ventilators, respirator decontamination devices, diagnostic panels, assays, tests, kits, and reagents
- These devices must comply with the FDCA requirements re: device adulteration and misbranding once *authorized*

MEDICAL DEVICES: ADULTERATION & MISBRANDING

- Primary FDA COVID device warning letters/enforcement actions:
  - Adulterated: satisfies the statutory definition of a medical device but has not been approved, cleared or authorized
    - Section 501(f)(1)(B); 21 U.S.C. § 351(f)(1)(B)
  - Misbranded: no premarket notification as required by 510(k) or EUA
    - Section 502(o); 21 U.S.C. § 352(o)
  - Misbranded: labeling/claims exceed the scope of the EUA
    - Section 564; 21 US.C. § 360bbb-3

Key Fraud & Abuse Statutes

- False Claims Act
- Anti-Kickback Statute (and other anti-corruption statutes)

False Claims Act

- The False Claims Act is designed to recover Govt. money
- Recoveries in FCA cases since 1986 total more than $62 billion
  - $2B more per year in health care recoveries for past decade plus
- Most cases start from *qui tam* actions

False Claims Act

- "knowingly" presenting a false or fraudulent claim for payment
- Claims can be false or fraudulent for a variety of reasons, including:
  - Billing for services not performed
  - Billing for unnecessary services
  - Billing for services where there has been a payment made in violation of Anti-Kickback Statute

Anti-Kickback Statute

- The Anti-Kickback Statute (AKS) prohibits the willful and knowing offer, solicitation, payment, or receipt of any remuneration, directly or indirectly, for
  - Referring or arranging for a referral; or
  - Purchasing, leasing, ordering, etc.

Anti-Kickback Statute

- Only applies if covered by a federal government healthcare program
- "One Purpose Test"
- Both criminal and civil penalties may be imposed
- OIG-HHS has created "Safe Harbors" to protect certain transactions that present a low risk of fraud and abuse

Other Anti-Corruption Statutes

- Stark Law

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…and enforcement has expanded beyond government programs

- Travel Act
- Honest Services Fraud
- Eliminating Kickbacks in Recovery Act (“EKRA”)

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…and beyond the United States

- Foreign Corrupt Practices Act (“FCPA”)

Case Study

CASE STUDY

- Elberg Healthcare, LLC receives an EUA from FDA for it's COVID-19 Test Kit
- **EUA Intend Use**: *"Intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19. This test is for prescription home use with self-collected nasal swab specimens in individuals aged 14 and older who are suspected of COVID-19 by their healthcare provider. This test is also authorized for use at the point of care (POC), in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation, with self-collected nasal swab specimens in individuals aged 14 and older, and in individuals aged 13 and under when the specimen is collected by a healthcare provider at the POC. This test utilizes a molecular amplification technology for the detection of SARS-CoV-2 RNA in individuals with known or suspected COVID-19."*
- This authorization for The Elberg 1000 SuperKit represents the only COVID-19 test kit EUA that Elberg, LLC has sought and received from FDA. Shortly after receiving the FDA authorization, Elberg, LLC created a website, elberg1000superkit.com, via which the company offers three COVID-19 test kits, including the Elberg 100 SuperKit for sale to consumers. The Elberg 1000 SuperKit webpage further states: *"The U.S. Food and Drug Administration has approved the Elberg 1000 SuperKit to mitigate, prevent, treat, diagnose, and cure COVID-19."*

Case Study

- Questions:
  - What concerns do you have about Elberg Healthcare, LLC's marketing of its various COVID-19 test kits to consumers on its website?
  - What concerns do you have about Elberg Healthcare, LLC's Elberg 1000 SuperKit website?

Case Study

As part of its marketing program, Elberg Healthcare, LLC has engaged Dr. Tara Talker to give educational talks to audiences of practitioners about her experience with The Elberg 1000 SuperKit. Dr. Talker refers more of her patients for testing using The Elberg 1000 SuperKit than any other doctor. Elberg Healthcare pays Dr. Talker $1,000 for each presentation she gives. Dr. Talker has been giving an average of three presentations per week since February. Due to COVID, Dr. Talker has been giving her presentations via Zoom. Dr. Talker has stated she prefers presenting over Zoom, and would like to continue presenting via Zoom even when in-person presentations are again possible.

Case Study

- Questions:
  - What concerns do you have about Dr. Talker giving paid presentations? (Put aside, for purposes of this question, any additional concerns you have based on the presentations being via Zoom.)
  - What concerns do you have about Dr. Talker continuing to present via Zoom? What can you do to ensure the presentations are compliant?