AMERICAN HEALTH LAW ASSOCIATION

Enforcement in the COVID-19 Era: The Government's Likely Playbook

May 15, 2020

Jason Mehta, Bradley Arant Boult Cummings LLP

With much fanfare, the Department of Justice (DOJ) has rolled out a series of headlines detailing its enforcement efforts in the wake of COVID-19. At the end of March, the government announced a kickback case against a marketer who allegedly steered patients towards COVID-19 and genetic cancer testing.[1] And, then weeks later, the government announced charges against a duo who allegedly received improper stimulus funds under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).[2] In the midst of this pandemic and unprecedented government spending, DOJ has promised to vigorously pursue cases of alleged fraud. Given this posture, and with the possibility of seemingly unintentional conduct being viewed skeptically, health care practitioners should remain vigilant of conduct that could expose them to potential government scrutiny. This article outlines the expected playbook of DOJ prosecutors in pursuing alleged fraud, with specific examples of cases over the past few weeks, and then concludes with practical advice to help health care practitioners avoid scrutiny.

Government's Likely Arsenal

While most health care attorneys are familiar with the government's traditional arsenal of enforcement tools, a brief recitation of the most common authorities is useful. This article also highlights some of the less well-known statutes that might be triggered by DOJ's scrutiny.

False Claims Act

The government's primary tool in tackling health care fraud has historically been the False Claims Act (FCA). While the statute originally was enacted in response to procurement fraud, the FCA is primarily utilized today in response to allegations concerning health care fraud.[3] In broad strokes, the FCA provides that any person who knowingly submits false claims to the government is liable up to treble the government's damages plus monetary penalties.

As most practitioners are aware, the government's use of the FCA has increased dramatically. However, the FCA only allows the government to tackle alleged fraud involving *federal health care payors* (e.g., Medicare, Medicaid, TRICARE). Where the alleged fraudulent conduct does not affect the federal government, the FCA has no applicability.

If past is any prologue into the future, the FCA will likely be a significant arrow in the government's quiver to recoup allegedly improper use of federal money, particularly funds that flow through the CARES Act. Similar to the government investigations that followed the 2008 Troubled Asset Relief Program (TARP), the playbook for most of the financial recoveries was through the FCA.

Health Care Fraud Statute

On the criminal side, the government's primary tool for health care fraud enforcement is the general health care fraud statute, 18 U.S.C. § 1347. By its terms, the statute punishes anyone who "knowingly and willfully executes, or attempts to execute, a scheme or artifice . . . to defraud any health care benefit program."

While perhaps obvious from the text, the statute requires the government to prove three elements: (1) that the defendant executed a scheme to defraud any health care benefit program (or attempted to do so); (2) that the fraud was in connection with the delivery or payment of health care benefits or services; and (3) that the defendant acted "knowingly and willfully."

Unlike the civil FCA analogue, the general health care fraud statute applies to any "health care benefit program." While DOJ has historically focused its efforts on federal health care payors, DOJ has also applied the general health care fraud statute to conduct affecting private payors.

As it relates to alleged COVID-19 fraud, the government likely will look to the general health care fraud statute as it way to prosecute conduct it believes improper. Given the statute's broad reach, practitioners should tread carefully into conduct that even arguably falls within the statute's gamut.

Anti-Kickback Statute

Another tool used in both the criminal and FCA context, the Anti-Kickback Statute (AKS) prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration, in cash or in kind, to induce or in return for referring an individual for the furnishing or arranging of any item or service for which payment may be made under a federal health care program.[4]

As most health care attorneys know, "remuneration" under the AKS is broadly defined and means anything of value, including gifts, under-market rent, or payments that are above fair market value for the services provided. Criminal penalties for violations are a fine of up to $25,000 and imprisonment for up to five years.

The government has already expressed its willingness to use the AKS to tackle perceived COVID-19-related fraud. In the genetic testing scheme discussed above, the government used the AKS to prosecute someone allegedly steering patients to, at times, unnecessary COVID-19 tests.[5] This statute will likely feature prominently in future prosecutions.

Sale of Fake Drugs/Distribution of Non-Conforming Consumer Goods

Venturing into the lesser known statutes, it is possible—and indeed probable—that the government will bring charges against those who offer fraudulent or false tests, purported preventions, and cures for the COVID-19 epidemic. In this regard, both 15 U.S.C. § 1263 (prohibiting the sale of fake drugs/cures) and 15 U.S.C. § 2068 (prohibiting the distribution of non-conforming consumer goods) are statutes that might be employed in future prosecutions.

In recent months, the government has used civil enforcement tools to take down websites that offer purported COVID-19 cures and vaccines.[6] While civil injunctions can be used to quickly respond to these types of issues, the criminal statutes cited above will likely be used once the government is ready to prosecute individuals.

Statutes Prohibiting Hoarding and Price Gouging

Much ink has already been spilled on individuals' hoarding of personal protective equipment and alleged price gouging and related practices. Criminal prosecutions against these practices have already commenced.[7]

Based on earlier prosecutions, it seems the government will primarily rely on 50 U.S.C. §§ 4512, 4513, which prohibits hoarding and price gouging of designated scarce materials. In relying on these statutes, prosecutors also will likely point to Executive Order 13909 invoking the Defense Production Act making it illegal to acquire medical supplies and devices designated by the Secretary of Health and Human Services (HHS) as scarce to hoard them or sell them for excessive prices.

Practical Tips

Given the breadth of criminal and civil statutes available to the government for enforcement, health care practitioners would be well-served to avoid scrutiny by keeping in mind. a few practical, and perhaps obvious, guideposts:

- As always, practitioners should carefully review all arrangements, contracts, and relationships that involve financial payments related to health care services, particularly those services that might implicate federal moneys. What was once defensible as fitting within safe harbors may no longer be defensible today. And, while normally carving out federal payors could help a provider avoid scrutiny, that practice might be insufficient in today's environment. Therefore, a global review of all financial arrangements is advisable.
- No matter what the statutory vehicle, the government can only bring criminal charges when it can show an improper intent. Therefore, practitioners should contemporaneously document their intentions and purposes *before* entering into new financial arrangements or transactions. This contemporaneous documentation is powerful evidence to negate prosecutors' theories of improper intent.
- While profit motives are not inherently illegal, it does seem that the government is casting a skeptical eye on those seeking to profit off COVID-19-related health

care expenditures. Practitioners should review all agreements and communications to ensure their intentions are clearly stated.

Despite this time of single-minded focus on patient care, the regulatory landscape dictates that health care practitioners continue to be mindful of potential government scrutiny. Those that understand the government's watchful eye will be better positioned to deal with the inevitable questions that arise once this pandemic is behind us. Indeed, as the adage goes, an ounce of prevention is worth a pound of cure.

Jason Mehta is a Partner at Bradley Arant Boult Cummings, LLP in Tampa, FL. He advises clients with respect to criminal and civil law enforcement matters, with a particular emphasis on health care enforcement cases. Jason formerly was a federal prosecutor for the Department of Justice. He may be reached at jmehta@bradley.com or 813-559-5532.

---

[1] *See* DOJ, Press Release, *Georgia Man Arrested for Orchestrating Scheme to Defraud Health Care Benefit Programs Related to COVID-19 and Genetic Cancer Testing*, Mar. 30, 2020, https://www.justice.gov/usao-nj/pr/georgia-man-arrested-orchestrating-scheme-defraud-health-care-benefit-programs-related.

[2] *See* DOJ, Press Release, *Two Charged in Rhode Island with Stimulus Fraud*, May 5, 2020, https://www.justice.gov/opa/pr/two-charged-rhode-island-stimulus-fraud.

[3] *See, e.g.,* DOJ, Press Release, J*ustice Department Recovers Over $2.8 Billion from False Claims Act Cases in Fiscal Year 2018*, Dec. 21, 2018, https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018 (noting that, of the $2.8 billion recovered in 2018 pursuant to the False Claims Act, "$2.5 billion involved the health care industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians"). To be sure, the FCA is still utilized to pursue procurement fraud claims.

[4] 42 U.S.C. § 1320a-7b(b). While the AKS is a criminal statute and contains no private right of action, the government and qui tam plaintiffs have successfully argued that violations of the AKS, a criminal statute, can serve as the basis for a claim under the False Claims Act. Under this theory, a claim to the government is rendered "false" for purposes of the FCA if the medical services or items were furnished in violation of the AKS notwithstanding the fact that the services or items provided were themselves appropriate and proper.

[5] *See supra* note 1.

[6] *See* DOJ, Press Release, *Justice Department Files its First Enforcement Action against COVID-19 Fraud*, Mar. 22, 2020, https://www.justice.gov/usao-wdtx/pr/justice-

department-files-its-first-enforcement-action-against-covid-19-fraud.
[7] *See* DOJ Press Release, *Long Island Man Charged Under Defense Production Act with Hoarding and Price-Gouging of Scarce Personal Protective Equipment*, Apr. 24, 2020, https://www.justice.gov/usao-edny/pr/long-island-man-charged-under-defense-production-act-hoarding-and-price-gouging-scarc-0.