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DO COVID-19 REGULATORY CHANGES POSE AN INCREASED RISK OF FRAUD AND ABUSE LIABILITY FOR HEALTHCARE PROVIDERS?

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If you work in the healthcare industry, you should be generally familiar with laws such as the federal Physician Self-Referral Law ("Stark Law"), the federal Anti-Kickback Statute ("AKS"), and the False Claims Act ("FCA"). The Centers for Medicare & Medicaid Services ("CMS"), Office of Inspector General for Health & Human Services ("OIG"), and the U.S. Department of Justice ("DOJ") commonly rely on these laws to combat healthcare fraud and abuse. The COVID-19 pandemic has modified lots of activities, and regulators modified certain requirements of these laws to enable the healthcare industry to efficiently respond to this global health emergency. This includes the Stark Law blanket waivers previously discussed in this blog.[1]

While healthcare providers certainly welcomed these regulatory changes during a period of crisis, prosecuting healthcare fraud and abuse remains a top priority of the OIG, DOJ, and other regulators. Further, these recent legal changes could provide healthcare regulators with new opportunities to pursue healthcare providers who fail to change practices to comply with the changes to these laws.

What new opportunities could regulators use to prevent, and punish, fraud and abuse?

Recent regulatory developments—such as the Stark Law blanket waivers and the OIG's enforcement deferral for use of the waivers—have helped healthcare providers during the COVID-19 crisis, but healthcare fraud remains a prime target of the DOJ and the OIG (in addition to state regulators). That's not going to change. Between October 2018 and September 2019, the DOJ obtained more than $3 billion in judgments and settlements from fraud claims, a substantial portion of those claims relating to healthcare fraud.[2] The significant increase in qui tam litigation since the 1980s is also notable.[3] With these trends in mind, what fraud and abuse actions could regulators pursue in COVID-19's shadow?

COVID-19 Purposes: Perhaps the most obvious pitfall for a healthcare provider is failing to adhere to the "COVID-19 Purposes" requirement for financial arrangements seeking protection under the Stark Law blanket waivers. Prior blog posts discuss the broad definition of this requirement: COVID-19 Purposes broadly include, e.g., "Diagnosis or medically necessary treatment of COVID-19 for any patient or individual, whether or not the patient or individual is diagnosed with a confirmed case of COVID-19" or "securing the services of physicians and other healthcare practitioners and professionals, to furnish medically necessary services in response to the COVID-19 outbreak in the United States."[4] OIG guidance states that it will exercise enforcement discretion not to impose administrative sanctions under the AKS "for certain remuneration related to COVID-19 covered by the [Stark Law blanket waivers]."[5] This guidance

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[1] *See* https://www.destinationhealthlaw.com/2020/04/cms-issues-covid-19-stark-law-blanket-waivers/
[2] *See* https://www.justice.gov/civil/false-claims-act
[3] *See* https://www.justice.gov/opa/press-release/file/1233201/download
[4] *See* https://www.destinationhealthlaw.com/2020/04/cms-issues-covid-19-stark-law-blanket-waivers/
[5] https://oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf

is in line with CMS guidance for the waiver—"The Secretary will work with the Department of Justice to address False Claims Act relator suits where parties using the blanket waivers have a good faith belief that their remuneration or referrals are covered by a blanket waiver."[6]

Despite this flexibility on the part of regulators, it seems inevitable we will see some prosecution of Stark Law, AKS, or FCA actions for egregious violations of the COVID-19 Purposes requirement. Providers taking advantage of the Stark Law blanket waivers should remain especially vigilant that any financial arrangement that would normally violate the Stark Law complies with the COVID-19 Purpose requirement and any other requirements of the blanket waivers.

Telemedicine: During the COVID-19 emergency, the DOJ has aggressively prosecuted telemedicine fraud schemes, such as one that resulted in 26 people being charged in the Southern District of Georgia in July 2020.[7] As most are aware, patients are driving demand for a significant increase in telemedicine services during the COVID-19 pandemic. In response to that demand, CMS broadened access to telemedicine services in March 2020 by expanding Medicare payment for telemedicine services that would previously have been available only to persons living in certain designated rural areas.[8]

This expansion of payment still carries FCA liability risks if a provider fails to abide by the rules. For example, reimbursement for some services (*e.g.*, "E-Visits" or "Virtual Check-ins") requires that the physician and patient have a prior established relationship.[9] A provider who seeks reimbursement for E-Visits provided to patients with no prior relationship would probably violate the FCA. Although it is too soon to tell how lenient, or aggressive, regulators will be when considering telemedicine requirements as a basis for enforcement actions, prudent providers will scrupulously comply with CMS guidance and rules for expanded telemedicine services.

What are the Stark Law, AKS, and FCA?

While most healthcare providers are familiar with these laws, it is always helpful to have a brief reminder.

Stark Law: The Stark Law generally prohibits physicians from referring Medicare and Medicaid patients to an entity for certain "Designated Health Services" (*i.e.*, lab work, imaging, physical or occupational therapy, hospital services, and numerous other services) if the physician or an immediate family member has a financial relationship with the entity. The Stark Law also prohibits the entity from submitting a Medicare or Medicaid claim if a prohibited referral occurs. As discussed in a prior blog post, CMS issued blanket waivers in March 2020 that temporarily waived sanctions for certain financial arrangements and referrals. Importantly, the blanket waivers apply only to financial arrangements for valid "COVID-19 Purposes."

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[6] https://www.cms.gov/files/document/explanatory-guidance-march-30-2020-blanket-waivers-section-1877g-social-security-act.pdf
[7] https://www.justice.gov/usao-sdga/pr/durable-medical-equipment-company-owner-admits-participation-kickback-scheme
[8] https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet
[9] *Id.*

AKS: The federal Anti-Kickback Statute generally prohibits a healthcare provider from providing something of value to another person in exchange for that person referring a patient whose care will be paid for by a federal program, such as Medicare, Medicaid, or TRICARE. The AKS is a criminal law that provides significant criminal and civil penalties. Conduct that violates the AKS will frequently run afoul of the Stark Law and FCA.

FCA: The federal False Claims Act is a broad statute that prohibits submitting false or fraudulent claims to the federal government for reimbursement. The law has an interesting history in that it was enacted in 1863 in response to defense contractor fraud during the Civil War.[10] Nowadays, regulators use the FCA to combat fraud in numerous industries, most significantly for Medicare and Medicaid fraud in the healthcare industry. For example, a provider who submits a claim for Medicare reimbursement based on a service that was not actually performed, was not medically necessary, or that was "upcoded" (*i.e.*, coded as a more expensive procedure than the procedure actually performed) violates the FCA. The FCA provides for treble damages on each false claim and also incentivizes private citizens (known as qui tam relators) to file whistleblower, or "qui tam," actions on behalf of the government. If the government and the relator prevail in the action, the relator receives a portion of the recovery. Many states have their own versions of the FCA, some of which relate to specifically to the healthcare industry (*e.g.*, Texas's Medicaid Fraud Prevention Act).

[10] *See* https://www.justice.gov/civil/false-claims-act