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Show me the money, and I'll show you whom the government is watching

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Notorious bank robber Willie Sutton's advice was, "Go where the money is...and go there often."[1] And right now, especially in light of the ongoing pandemic, the money is in healthcare. In response to this unprecedent public health crisis, the federal government is spending millions of dollars in support of COVID-19 testing, research, and treatment. As such, it is no surprise that both federal and state authorities are turning their efforts toward combatting fraud related to COVID-19 and those seeking to exploit and profit from the pandemic.

Additional government spending naturally leads to additional government enforcement and oversight.[2] Both federal and state regulators, such as the Department of Justice and state attorneys general, have begun increasing their focus on and even creating multiagency task forces to combat healthcare fraud schemes tied to COVID-19.[3]

In light of this increased oversight, as a result of additional government spending and increasing virus testing and serology testing clinical laboratories, it is a matter of when, not if, the government decides to enforce the legal weapons at their disposal—namely, the federal Anti-Kickback Statute (AKS). However, a more recent act, the Eliminating Kickbacks in Recovery Act (EKRA),[4] may provide government enforcement agencies an additional, more robust and customized means of enforcement. Knowing that they will soon be under a microscope, healthcare professionals should evaluate their marketing and compensation arrangements to ensure compliance with these laws.

Anti-Kickback Statute

Those in the healthcare industry are likely already aware of the AKS. The federal AKS is a healthcare fraud and abuse statute that prohibits the exchange of remuneration—which the statute defines broadly as anything of value—for referrals/kickbacks for services that are payable by a federal program, mainly Medicare or Medicaid. The AKS provides for both criminal and civil penalties. The criminal penalties include fines of up to $25,000 and five years of imprisonment. In addition, the enforcement agencies can pursue civil penalties of up to $50,000 per violation plus three times the amount of any government overpayment. Compliance professionals should reacquaint themselves with the nuances of this law and make sure their current practices are compliant.

Eliminating Kickbacks in Recovery Act

A lesser known but potentially more troublesome means of enforcement authority is the EKRA of 2018. EKRA was

principally enacted to combat abuses arising from the opioid epidemic.[5] However, due to its broad statutory language, EKRA may have a much wider reach than initially anticipated.

EKRA prohibits soliciting, receiving, offering, or paying "remuneration (including any kickback, bribe, or rebate)" in return for referrals to, or in exchange for using the services of, a recovery home, clinical treatment facility, or laboratory. Specifically, EKRA provides that:

> Offense. -Except as provided in subsection (b), whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully-
>
> 1. solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or
>
> 2. pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind-
>
>   A. to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
>
>   B. in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory, shall be fined not more than $200,000, imprisoned not more than 10 years, or both, for each occurrence.[6]
>
> 'Clinical treatment facility' means a medical setting, other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law....'Recovery home' means a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.[7]

Under EKRA, "health care benefit program" includes "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract."[8] Through this all-encompassing definition of healthcare benefit program, EKRA applies to all payers, both private and public. This is unlike the AKS, which applies *only* to services paid for by federal programs. Therefore, a laboratory conducting virus or serology test analysis could be in violation of EKRA for receiving kickbacks for referrals, even if the payments are coming from private insurance companies or from the patient's own wallet. This means that the majority, and potentially all, of COVID-19 virus and serology testing analysis providers are within the scope of EKRA.

Further, while the definitions for "clinical treatment facility" and "recovery home" specifically reference substance use, "laboratory" does not.[9] "Laboratory" is defined to mean "facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological,

pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."[10] Based on this broad definition, both COVID-19 virus test analysis providers as well as serological test analysis providers would fall within EKRA's reach. Therefore, EKRA may be a means of enforcement against all referrals for laboratory tests, regardless of whether the tests relate to substance abuse testing or treatment.

Like the AKS, EKRA statutorily provides for a number of exceptions. However, in some instances, EKRA's eight statutory exceptions and "safe harbors" are lesser in number and scope than the AKS ones. For example, under EKRA, a laboratory may not pay sales or marketing employees if such payments vary by "(A) the number of individuals referred to a particular…laboratory; (B) the number of tests or procedures performed; or (C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular…laboratory."[11] This is unlike the AKS, which generally exempts commissions/payments to bona fide employees of a lab.[12] Therefore, generally accepted clinical laboratory business practices—such as paying sales employees on commission—arguably fall within the scope of EKRA's renumeration prohibition.

Protecting your company from EKRA and promoting compliant practices

Enforcement under EKRA has been limited so far. This is likely due in part to the fact that it was enacted in late 2018 and is still relatively new. However, the time is ripe for the government to tap into this new enforcement mechanism given the government's heightened focus on healthcare providers and the increase in COVID-19 virus and serological testing.

As such, laboratories and other covered providers need to be aware of EKRA and its broad prohibitions when engaging in sales and marketing of their services. All potentially covered providers need to evaluate:

- Whether EKRA applies to their services:
    - Are their services covered by a healthcare benefit program?
    - Are they referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory? (The word patronage in EKRA does not have a defined meaning but is arguably a broader reference than merely "referring a patient" under the federal AKS.)
- Whether any of EKRA's safe harbors are applicable to their organization:
    - For example, do payments to employees not vary regardless of referrals? Do payments fall under defined and approved alternative payment models?
- Could the compensation arrangements for their employees and outside vendors possibly be viewed as payments for referrals under EKRA?
    - Do any of these arrangements amount to remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind?
    - Should they update their policies and procedures related to final arrangements with their employees and vendors?

It is a matter of time before we see fraud prosecution through EKRA, and providers need to act now to prevent themselves from getting trapped in EKRA's wide-reaching net later.

Takeaways

- The federal money allocated in response to the COVID-19 pandemic will mean increased enforcement action and compliance challenges for healthcare organizations.
- The Eliminating Kickbacks in Recovery Act (EKRA), initiated in 2018, is a new enforcement weapon that applies to both private and public payment for healthcare services.
- EKRA is broader than the federal Anti-Kickback Statute and has more limited statutory exemptions or safe harbors and is without protection for bona fide employee compensation based on the volume or value of referrals.
- EKRA applies to COVID-19 virus and serological testing and will present compliance challenges for healthcare organizations.
- EKRA's broad provisions and the scope of federal and private money allocated for pandemic response means it is only a matter of time before its application in criminal and civil enforcement actions.

1 Willie Sutton & Edward Linn, *Where the Money Was: The Memoirs of a Bank Robber* (New York: Viking Press, 1976).
2 U.S. Department of Justice, "Justice Department Files Its First Enforcement Action Against COVID-19 Fraud," news release, March 22, 2020, https://bit.ly/2DsGk5A.
3 Office of the Attorney General, "COVID-19 – Department of Justice Priorities," memorandum, March 16, 2020, https://bit.ly/3aWXp35.
418 U.S.C. § 220 .
5 Bart Daniel, *Health Care Fraud & Collateral Consequences* (Columbia: South Carolina Bar, 2019), 95–96.
618 U.S.C. § 220(a) .
718 U.S.C. § 220(e) .
818 U.S.C. § 24(b).
918 U.S.C. § 220(e) .
1042 U.S.C. § 263a(a).
1118 U.S.C. § 220(b) .
1242 U.S.C. § 1320a-7b(b)(3) .