COVID-19: LABS BEWARE! – EKRA EXPANDS DOJ'S ENFORCEMENT ARSENAL IN THE COVID-19 FRAUD BATTLE

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INTRODUCTION

As discussed in recent alerts, federal and state authorities have focused their enforcement efforts on combatting fraud related to the COVID-19 pandemic. The U.S. Department of Justice ("DOJ"), U.S. Attorneys' Offices, and State Attorneys General are leading these efforts, appointing Coronavirus Fraud Coordinators at each U.S. Attorney's Office and are aggressively pursuing individuals and companies that seek to capitalize from the public crisis.[1] This increased scrutiny may catch clinical laboratories by surprise, as many rush to make much-needed COVID-19 testing available to the public without understanding the applicable enforcement landscape.

When clinical laboratories and health care providers think of kickback enforcement, they often focus on the federal Anti-Kickback Statute ("AKS") codified at 18 U.S.C. § 220. For good reason—DOJ has long relied on the AKS in cracking down on illicit payments in the health care industry. But these companies must be mindful of the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA" or the "Act"), a new and overlooked weapon in the Government's enforcement arsenal. EKRA is part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("Support Act"); a comprehensive body of federal legislation aimed at addressing the opioid crisis.[2] EKRA provides for criminal penalties for anyone who—with respect to services covered by any health care benefit program—knowingly and willfully (1) solicits or receives any remuneration in return for referring a patient to a recovery home, clinical treatment facility, or laboratory or (2) pays or offers any remuneration either to induce such a referral or in exchange for an individual using the services of a recovery home, clinical treatment facility, or laboratory.

While it was enacted to address an entirely different epidemic that has crippled parts of the country, EKRA's scope makes it directly applicable to providers of COVID-19 testing, as it applies to all laboratories and all payors, rather than just substance abuse testing and federal health care programs. Moreover, its employment compensation exception is much narrower than the comparable provision in AKS and, therefore, calls into question common financial relationships between laboratories and referral sources.[3] Given increased enforcement surrounding COVID-19, which will only increase over time, clinical laboratories and health care providers across the U.S. should be aware of EKRA's applicability and take proactive measures to ensure their COVID-19 testing efforts are compliant and do not run afoul of EKRA in light of its broad application.

DIRE NEED FOR COVID-19 TESTING AND MARKET RESPONSE

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In the wake of the COVID-19 crisis, testing availability has been at the forefront of mitigation strategies in quelling the outbreak and "bending" the infection curve nationally. Unfortunately, it has become clear that the national testing supply is significantly below demand. Numerous local and state governments have identified a lack of testing facilities, lack of available testing sites, and extremely restricted test offerings as a serious concern in effectively combating COVID-19.[4] The demand for testing will only increase as states evaluate next steps in the coming months, including the relaxation or elimination of shelter-in-place orders and the use of serology testing, which seeks to identify the presence of antibodies in a population. Serology testing is critical to determine geographical disease spread and is used to isolate and manage the pandemic until a vaccine is available.

To facilitate access to testing, the U.S. Food and Drug Administration ("FDA") has taken a series of steps, including allowing for serological testing without requiring emergency use authorization or prior FDA approval. Many providers are responding to this increase in demand and decrease in access barriers. Clinical laboratories have quickly undergone steps to import, manufacture, distribute, and administer COVID-19 testing. This surge in the testing market coupled with an increased scrutiny into COVID-19 related fraud and a broad enforcement tool such as EKRA, all create a heightened enforcement landscape of which test providers should be cognizant.[5]

APPLICABILITY OF EKRA TO COVID-19 TESTING

EKRA Scope and Definitions

The Support Act, under which EKRA was enacted, was signed into law on October 25, 2018. EKRA was intended to specifically address the opioid epidemic by creating criminal penalties for illegal referrals of patients seeking the services of a recovery home, clinical treatment facility, or laboratory. Congress intended to target kickbacks that had been exploited to keep patients addicted and cycling in and out of the system, thereby allowing providers to profit from a continuous stream of claims. In particular, EKRA provides:

- Offense.-Except as provided in the next subsection, whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully-
  - 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
  - pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind-
    - to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
    - 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]

Under the Act, the term "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." In contrast to the AKS, which only applies to referrals for services payable by a federal program, EKRA expands the government's enforcement arsenal to referrals reimbursed by governmental and commercial

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insurers as well as cash payors. This scope allowed the Government to target addiction referrals that would have otherwise been beyond its reach.

Critically, the term “laboratory” includes all facilities 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. Based on this broad definition, all referrals for clinical laboratory tests, even if the tests do not relate to substance abuse testing or treatment, may implicate EKRA.

It is unclear whether Congress intended for EKRA to apply to all laboratory services and not just those pertaining to drug addiction treatment. Moreover, it is unclear whether Congress intended to criminalize behavior that is allowed under the AKS. Coupled with these uncertainties, there has also been a lack of guidance outlining how the Government plans to utilize the Act. To date there has been minimal use of EKRA,[7] but that may change given DOJ's heightened focus on COVID-19 fraud and how rapidly funds are flowing to COVID-19 testing. The current enforcement climate increases the chances that the Government will turn to EKRA as a prominent enforcement tool for COVID-19 related activity.

EKRA Exceptions

EKRA provides a number of exceptions, including exceptions for payments made under employment arrangements, personal services and management contracts, and waivers or discounts of any coinsurance or copayment, amongst others.[8] EKRA also has an exception for remuneration made pursuant to certain alternative payment models, a parallel of which is not present in AKS exceptions/safe harbors.

The EKRA exception for payments made by an employer is much narrower than the AKS employment safe harbor. Specifically, while the AKS safe harbor permits *any* payments to an employee as long as there is a *bona fide* employment relationship, the EKRA exception requires that the payment not vary based on the number of individuals referred, tests or procedures performed, or amounts billed to or received from health care benefit programs. Accordingly, properly structured employment arrangements, such as W2 commission-based compensation, that would not be prohibited under the AKS appear to be prohibited under EKRA. Moreover, the EKRA employment exception applies to payments made by an employer both to employees and independent contractors rather than only employees.

As noted above, it remains unclear whether these consequences were intended under the Act, but in any event, EKRA provides the Government with an expansive tool to prosecute activity that would have otherwise fallen outside the confines of the AKS. For example, EKRA calls into question diagnostic laboratory compensation of salaried W-2 marketing employees that may be compliant under AKS. The increased attention to fraud and abuse associated with the COVID-19 crisis has led U.S. Attorneys' offices across the country to prioritize the prosecution of criminal conduct related to the pandemic. There is no doubt that the demand for COVID-19 testing and the corresponding surge in supply will garner the government's attention. EKRA may provide the DOJ with a mechanism to prosecute perceived fraud within the laboratory testing industry, thus prompting a wave of enforcement that has not been seen before under the Act.

EKRA COMPLIANCE MEASURES FOR COVID-19 TEST PROVIDERS

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As providers rush to address the severe shortage in testing, they should ensure existing and future compensation arrangements (regardless of payor source) fit within EKRA exceptions. This is particularly true for employment compensation due to the narrower parameters of the EKRA employment exception as compared to the AKS employment safe harbor. Providers should also update policies and procedures related to financial arrangements with referral sources, as related to patient copay and coinsurance waivers, to address compliance with EKRA. Clinical laboratories and referral sources must keep in mind that they are not immune from prosecution even if testing services are not reimbursed through a federal healthcare program or even reimbursed at all.

Entities that are not themselves a recovery home, clinical treatment facility, or laboratory but that do business with a such an entity should evaluate their relationships to ensure that such relationships are in compliance with EKRA. Given that the law applies to parties on both sides of the prohibited arrangement, entities that do business with clinical laborites and referral sources should be particularly mindful of EKRA.

CONCLUSION

As the government allocates 25 billion dollars for testing to try to stem the COVID-19 pandemic, DOJ will direct its attention and resources to stamping out COVID-19 fraud. Clinical laboratories that play a critical role in testing will receive substantial funds from the government and private insurers. Accordingly, some of these laboratories will find themselves in DOJ's crosshairs−before they do, they ought to focus attention on EKRA compliance.

K&L Gates' health care fraud and abuse and investigations, enforcement, and white collar practice groups continue to monitor government enforcement priorities and guidance in light of the COVID-19 pandemic and will continue to provide periodic updates on developments.

FOOTNOTES

[1] *See* Enforcement action against operators of a fraudulent website from DOJ for fraud arising out of the COVID-19 pandemic (March 21, 2020); Memorandum from Attorney General William P. Barr entitled “COVID-19 – Department of Justice Priorities,” directing U.S. Attorneys to prioritize detection, investigation, and prosecution of all criminal conduct related to the pandemic (March 16, 2020); Memorandum from Deputy Attorney General Jeffrey A. Rosen, further directing each U.S. Attorney to appoint a “Coronavirus Fraud Coordinator” to serve as the legal counsel on matters relating to COVID-19, direct the prosecution of COVID-19-related crimes, and increase outreach and awareness (March 19, 2020).

[2] The Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, H.R. 6, 115th Cong. (2018), available here.

[3] EKRA adopts the same approach as the federal Anti-Kickback Statute insofar as targeted conduct and applies to the soliciting or receiving, or paying or offering to pay remuneration, “directly or indirectly, overtly or covertly, in cash or in kind.”

[4] *See* “Sheryl Gay Stolberg, Farah Stockman and Sharon LaFraniere *Testing Remains Scarce as Governors Weigh Reopening States*” N.Y. Times (April 25, 2020).

[5] There has already been a notable increase in scrutiny into price gouging. *See e.g.* State Administration for Market Regulation *Guidance on Investigation and Handling of Illegal Acts of Price Gouging during the Prevention*

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and Control Period of Novel Coronavirus, (February 1, 2020) (setting out detailed guidance on the application of the *Price Law* and the *Provisions on the Administrative Punishment of Price-related Violation* and determination of price gouging offences of epidemic prevention products). Additionally, according to Section 102 of the Defense Production Act, the U.S. President may prohibit the hoarding of needed resources. Pursuant to that act, President Donald J. Trump signed an Executive Order on March 23, 2020 to address hoarding that threatens the supply of necessary health and medical resources, including the hoarding of products to sell above prevailing market prices, Exec. Order No. 13,910, 85 Fed. Reg. at 17001 (Mar. 23, 2020), available here.

[6] The Eliminating Kickbacks in Recovery Act of 2018, H.R. 6, 115th Cong. § 8122 (2018), available here.

[7] *See* Press Release, United States Attorney's Office, Eastern District of Kentucky (January 10, 2020), *available here* (involving an office manager of a substance abuse clinic who allegedly solicited kickbacks from a toxicology lab in exchange for urine drug test referrals).

[8] See 18 U.S.C. § 220(b) for exceptions under the Act: (1) discounts that are disclosed in costs claimed or charges made for the Applicable Services; (2) payments for employment made by employers to employees or independent contractors (under a bona fide employment or contractual relationship), as long as employee payment is not based on the amount of business generated through referrals to the employer, number of services performed by the employer, or amounts billed or received by the employer; (3) a discount of a drug under the Medicare coverage gap discount program; (4) a payment meeting the personal services arrangement safe harbor at 42 C.F.R. § 1001.952(d); (5) a waiver or discount of coinsurance or copayment under 42 C.F.R § 1001.952(h)(5); (6) remuneration between a federally qualified health center (“FQHC”) and any individual or entity providing goods, items, services, donations, or loans to the FQHC under an agreement as long as the agreement contributes to expanding access to or improving the quality of services to a medically underserved population; and (7) any payment made under an alternative payment model as defined in the Social Security Act or other payment arrangement determined to be necessary by the Secretary of Health and Human Services for care coordination or value-based care.

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