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6 Impacts of EKRA on Laboratories, Clinics, and Other Treatment Facilities

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I. What is the Eliminating Kickbacks in Recovery Act ("EKRA")?

The Eliminating Kickbacks in Recovery Act ("EKRA") was enacted by Congress on October 24, 2018 and was a part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act"). EKRA prohibits patient brokers from accepting or paying kickbacks for patient referrals from laboratories, clinics, name="_Hlk56754767">recovery centers, and other clinical treatment facilities.

Its purpose was to address to the growing opioid crisis in the United States by prohibiting patient referrals, kickbacks, or other renumeration for drug recovery centers. However, the text of EKRA goes above and beyond the opioid crisis. First and foremost, EKRA prohibits the solicitation or receipt of any renumeration for referring patients to laboratories, clinics, or recovery homes. Second, EKRA amplifies the already-existing statutory law prohibiting kickbacks by applying to not only government health care programs but also to private health care programs. Third, EKRA forces laboratories and certain healthcare entities to reassess their relationship with their sales and marketing personnel.

II. What is the Text of EKRA?

The text of EKRA is broad. Nevertheless, it carries stiff penalties and lengthy imprisonment terms for each occurrence. The statute, 18 U.S.C. § 220, provides that:

"[W]hoever, 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."

III. EKRA Is Broadly Applicable to Any Laboratory in the Healthcare Industry

EKRA defines certain terms such as clinical treatment facilities and recovery homes specifically, but its definition of laboratory is particularly problematic due, in part, to its broad definition and uncertain application. For instance, "laboratory" is defined as "*a 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*." 42 U.S.C. 263a.

As demonstrated from the text of this definition, "laboratory" can apply to any healthcare entity that uses a lab to carry out its operations. Because of this, many healthcare entities must now make sure they are taking proactive steps to ensure they are compliant with EKRA. To make matters more uncertain, EKRA does not define what constitutes a "referral," providing more leeway for federal agencies when conducting their investigations and prosecutions.

"EKRA is broad both in scope and application. It is important that name="_Hlk56753631">laboratories, clinics, recovery centers, and other clinical treatment facilities understand how to comply with its rules especially because EKRA dramatically changes the status quo of patient referrals and a healthcare entity's relationship with its sales and marketing personnel." – Dr. Nick Oberheiden, Founding Attorney of Oberheiden P.C.

IV. EKRA Imposes Greater Restrictions Than Currently Applicable Statutes Prohibiting Kickbacks

As mentioned, EKRA is both broader and imposes greater restrictions compared to current statutes prohibiting kickbacks, namely the Anti-Kickback Statute. The Anti-Kickback Statute prohibits knowingly and wilfully making a payment to induce patient referrals or generate business in connection with any governmental heath care program. EKRA, on the other hand, is applicable to "services covered by a health care benefit program." The text does not differentiate between governmental programs and private programs. As a result, the federal government is fully within its authority to investigate and prosecute suspicious payments involving services reimbursed by either governmental health plans (e.g., Medicare, Medicaid) and also *private* health plans.

Further, EKRA contains less safe habors compared to the Anti-Kickback Statute. For instance, under the Anti-Kickback Statute, there is an exception for bona fide employees. EKRA, however, does not differentiate between employee-based commissions and independent contractor-based commissions. This means that if a laboratory pays its employee a commission with respect to a referral, the laboratory will be exposed to EKRA liability.

In other words, compliance with the Anti-Kickback Statute no longer assures your compliance with all federal legislation regarding kickbacks. EKRA demands a higher level of compliance to avoid liability.

V. EKRA Modifies Laboratories' Business Relationships with Their Sales and Marketing

Teams

EKRA substantially modifies the relationship that a laboratory maintains with its sales and marketing personnel by limiting the scope of legal activities. Not only does EKRA prohibit certain practices that were traditionally regarded as permissible under other federal statutes (such as paying sales commissions to marketing personnel), but it also creates much uncertainty due to the broad definition of "laboratory" and lack of definition of "referral."

For instance, a laboratory that employs individuals to handle its marketing and sales services may now be at risk of violating EKRA—even if this is a practice it has been utilizing for decades. Now, the act of paying any renumeration in connection with a referral carries the possibility of civil and criminal liability. To avoid these consequences, laboratories must revise, reassess, and continuously monitor their marketing, sales, and patient broker arrangements.

VI. Investigations and Prosecutions for EKRA Violations Have Begun and Are Expected to Continue in 2021

The Department of Justice ("DOJ") has already received pleas from individuals for violations of EKRA. In January 2020, an office manager of a substance abuse treatment clinic pled guilty to soliciting kickbacks from a toxicology lab in exchange for referrals. Specifically, between December 2018 and August 2019, the CEO of the toxicology lab delivered to defendant a $4,000 check, which was a part of "a larger package of promised inducements." After defendant cashed the check, she was asked about it by law enforcement agents. She responded by denying knowledge of it, making an excuse, and then calling the CEO of the lab and requesting that he alter the receipt of the check. Defendant pled guilty to one count of violating EKRA as well as one count of making false statements and one count of attempted tampering with records. On May 11, 2020, she was sentenced to ten months imprisonment for soliciting kickbacks and obstructing justice.

More recently on September 15 of this year, two men admitted to playing a role in a multi-state recovery home patient brokering scheme involving kickbacks. One of the defendants had directed recruiters to bribe individuals suffering from drug addiction to enroll in drug rehabilitation, and the other defendant paid referral fees from his rehabilitation center in exchange for those referrals.

Despite these examples, federal agencies and the courts are still defining the parameters of EKRA. However, this trend of EKRA investigations and prosecutions is expected to increase in 2021, making it incumbent upon laboratories to assess their current business operations for EKRA compliance.

Conclusion

EKRA stands to be one of the most important new pieces of legislation in 2021 due to its ability to encompass not only a broader range of conduct between laboratories, clinics, recovery centers, or other clinical treatment facilities and their marketing personnel but also because such conduct was traditionally viewed as acceptable under the Anti-Kickback Statute. Federal government enforcement and prosecution under EKRA is also likely to increase as the nation copes with COVID-19-related frauds and additional testing and treatment.

It is imperative that laboratories, clinics, recovery homes, and other clinical treatment facilities obtain the advice of an experienced healthcare attorney who fully understands EKRA and how it implicates healthcare entities. This is crucial because EKRA can result in both criminal penalties and imprisonment terms.

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