

The Eliminating Kickbacks in Recovery Act of 2018 (EKRA): A New Federal Kickback Law Applicable to All Payors

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The Eliminating Kickbacks in Recovery Act of 2018 (EKRA) became law on October 24, 2018, and is codified at 18 U.S.C. § 220. As part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, EKRA was enacted in response to a concern that the federal Anti-Kickback Statute (AKS) was not broad enough to cover certain abusive payment arrangements related to opioid addiction treatment centers, since the AKS only applies to federal health care programs. EKRA has considerable similarities to the AKS, but is notably distinct from the AKS in that it applies to all payors rather than just federal health care programs and has an exception for employment compensation that is much narrower than the AKS's employment safe harbor. Further, EKRA relates to arrangements with recovery homes, clinical treatment facilities, and laboratories (the "Subject Entities"). With respect to laboratories, even though EKRA was enacted in response to the opioid crisis, it applies to all laboratories, not just laboratories that perform testing related to substance abuse (e.g., toxicology screening).

We set forth below an overview of EKRA, exceptions to the law's prohibitions, and recommendations to ensure compliance.

Overview

EKRA subjects to criminal penalties anyone who, with respect to services covered by any health care

benefit program (whether federal or private), knowingly and willfully:

1. solicits or receives any remuneration in return for referring a patient or patronage to a Subject Entity; or
2. pays or offers any remuneration:
 - a. to induce a referral of an individual to a Subject Entity; or

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- b. in exchange for an individual using the services of that Subject Entity.

Penalties for each occurrence of violating the law are a fine of not more than \$200,000 (which is double the possible fine per violation of the AKS), imprisonment for not more than 10 years, or both.



EKRA defines the Subject Entities as follows:

- Recovery home: “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.”
- Clinical treatment facility: “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.”
- Laboratories: defined by reference to CLIA, which means that *all* laboratories are subject to EKRA.

EKRA *does not apply to conduct that is prohibited by the AKS*, and EKRA does not “occupy the field” in which any state law may be more stringent related to the same subject matter.

Exceptions

Similar to AKS statutory exceptions and regulatory safe harbors, EKRA provides a number of exceptions to its prohibitions, including exceptions for payments made under employment arrangements, personal services and management contracts, waivers or discounts of any coinsurance or copayment, and certain other exceptions that meet specified parameters (some of which are similar to and some of which are different from the parameters under the parallel AKS exceptions/safe harbors). 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.



Of note, the EKRA exception for payments made by an employer is much narrower than the AKS safe harbor for employment.

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 the health care benefit program from the individuals referred*. This means that employment arrangements that would not be prohibited under the AKS, such as those with sales and marketing personnel that include commission-based compensation, appear to be prohibited under EKRA and thus need to be carefully evaluated for compliance with this new law. (The EKRA employment exception applies to payments made by an employer both to employees and independent contractors (rather than just to employees), even though EKRA has a separate exception for personal services and management contracts.)

EKRA provides that the Attorney General, in consultation with the Secretary of Health and Human Services, may promulgate regulations to clarify the exceptions described in the statute.

Recommendations for Complying with EKRA

The Subject Entities need to:

- Ensure existing and future compensation arrangements fit within EKRA exceptions, particularly for employment compensation due to the narrower parameters of the EKRA employment exception as compared to the AKS employment safe harbor, and to the extent certain of such arrangements would not otherwise be analyzed for compliance with the AKS because they do not involve payment under any federal health care program.
- Update policies and procedures related to financial arrangements with referral sources and related to patient copay and coinsurance waivers to address compliance with EKRA.

Further, entities that are not themselves a Subject Entity but that do business with a Subject Entity should evaluate their relationships with Subject Entities to ensure that such relationships are in compliance with EKRA, since the law applies to parties on both sides of the prohibited arrangement (i.e., the law prohibits both the payment or offering of referral/inducement fees, but also the soliciting or receiving of such remuneration). Policies and procedures of non-Subject Entities who have such business relationships should also be updated to address EKRA compliance.

We will continue to closely monitor the state of EKRA for guidance, revisions to the law and enforcement.

Further, it is important to also understand that several states, such as Florida, Utah and California, have passed their own state level “patient brokering” laws which prohibit similar conduct and arrangements as addressed by EKRA. These laws can also be implicated and we are monitoring their development as well.

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