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Insights

FIVE YEARS ON: EKRA'S LEGACY

Jul 20, 2023

Five years ago Congress enacted the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"). Aimed at combating kickbacks in the addiction treatment industry, EKRA prohibits remunerations in return for patient referrals to recovery homes, clinical treatment facilities, and laboratories. Unique among federal healthcare fraud and abuse laws, EKRA applies to private payors in addition to governmental payors. The law establishes severe criminal penalties for companies who violate its provisions, including a fine of up to $200,000, ten years in prison, or both, per violation.

While the intent behind EKRA was to counter perceived fraud and abuse in the addiction treatment industry, the inclusion of laboratories as a type of entity covered by the law's prohibitions dramatically increased its scope. EKRA covers all laboratory services, whether such services are part of an addiction treatment program or not. Initially, the industry questioned whether the DOJ would pursue enforcement outside the addiction space, but with the advent of the COVID-19 pandemic, the DOJ used EKRA as a tool to combat fraud related to COVID-19 testing. For example, in *United States v. Lepetich*, the DOJ charged the owner of a clinical laboratory after allegedly offering kickbacks for referrals of specimens used in COVID 19 and respiratory pathogen testing.[1]

We anticipate that the DOJ will continue to use EKRA as a tool in its kit to combat fraud and abuse in the laboratory testing space. As such, laboratories should continue to ensure their compensation and business arrangements comply with EKRA. Based on our experience and recent case law, it is important for laboratories to consider the following as they develop compliance plans and risk mitigation measures to comply with EKRA:

EKRA differs from AKS. While the language prohibiting kickbacks in EKRA is similar to the federal Anti-Kickback statute ("AKS"), EKRA's statutory safe harbors are more limited in nature. As such, laboratories must continue to assess relationships under both AKS and EKRA.

Carefully Structure Incentive Compensation for Employees and Independent Contractors. As an example of how EKRA differs from the AKS, the AKS safe harbor for payments made to bona fide employees is quite broad and allows for the payment of compensation based on referrals. EKRA specifically prohibits this type of compensation, excluding from the definition of safe harbored

compensation payment that is determined by, or varies by, the number of individuals referred, the number tests or procedures performed, or the amount billed.

As such, laboratories need to consider whether their current employee compensation structures increase risk under EKRA.

Two courts have wrestled with how to interpret this provision and have reached different conclusions, leaving laboratories without a clear pathway when it comes to structuring employee compensation.

In *S&G Labs Hawaii v. Graves*, a laboratory provided employees with percentage-based compensation that was connected to the net profits in their client accounts.[2] The clients consisted of physicians, substance use disorder counseling centers, and other organizations in the addiction treatment industry. Employees were thus incentivized to bring in business by tying their compensation to the number of tests the clients ordered. The court held that, while EKRA disallows this kind of incentive structure if the underlying value is connected directly to patients themselves, this particular incentive structure did not violate the law because the underlying value was connected to patients only indirectly through their clients. Therefore, the court determined that the indirect nature of the incentive structure was too attenuated to violate EKRA.

On the other hand, in *United States v. Schena*, a medical technology company paid recruiters to reach out to physicians with the goal of convincing them to order allergy tests.[3] The recruiters were paid a percentage-based compensation connected to the number of tests the physicians ordered. Like *S&G*, the physicians served as an intermediary. The compensation was not tied directly to the patients, but indirectly through the physicians' orders. Instead of following the holding in *S&G*, *Schena* critiqued the holding, arguing that the court in *S&G* failed to properly consider the absence of any language in the statute requiring a "direct interaction between the marketer and the individual." Thus, *Schena* held that criminal liability does not hinge on whether recruiters solicited patients directly and that liability can instead attach to indirect solicitations via intermediaries such as physicians.

Improperly Structured Discounts May Give Rise to EKRA Liability. Price discounts may be used for ordinary business purposes, but undisclosed discounts or discounts that do not appropriately reflect the costs claimed or charges made gives the appearance of a kickback. If a healthcare company is to offer price discounts, the discounts should accurately reflect the cost of the goods or services rendered. For example, healthcare companies offering blood tests can likely discount the test if the sample is subject to a limited panel. But, if the blood test is being discounted to encourage doctors to send more samples for testing, this will not accurately reflect the cost of the test and risks violating EKRA. Note that this differs from the AKS in that price discounts under the AKS are allowed if they are disclosed and based on purchases of that same good or services bought within a fiscal year. Thus, the industry a company is in will determine how the company structures discounts.

EKRA Has No Private Right of Action, Limited FCA Claims to Date. Though there is no private right of action under EKRA, the law opens up the door to additional liability through the False Claims Act ("FCA"). Like the AKS, EKRA's criminal penalties may be compounded by the FCA's civil penalties which are tied to inflation and currently range from $13,508 to $27,018 per violation.[4] While conduct that already violates the AKS will not create additional liability under EKRA, there remains space for the FCA to gain a foothold through EKRA's narrower safe harbor provisions. For example, the AKS allows most payments for the recruitment of patients to bona fide employees but, because EKRA disallows these payments if they are based on the underlying value of the referrals, companies engaged in these sorts of incentive structures face potential liability under EKRA and the FCA. EKRA-based FCA claims have yet to show a track record of success and there are a few potential reasons:

- Most EKRA-based FCA claims are also AKS-based FCA claims and are therefore preempted by the earlier law. EKRA's preemption clause states that one will not be liable under EKRA for conduct that already violates either the AKS or state laws on the same subject matter, so liability under the AKS practically eliminates the EKRA-based FCA claim.
- The materiality of the violation acts as a hurdle for EKRA in a way it does not for the AKS. To win an FCA claim, it must be shown that the defendant's false claims were material to the government's payment decision. A 2010 amendment to the AKS effectively made all violations *per se* material, making it significantly easier to win an AKS-based FCA suit. EKRA, on the other hand, does not contain similar language so evidence of materiality must be shown.

Please contact any member of our Healthcare Practice Group to discuss any questions related to EKRA.

*Special thanks to Matthew Steinhaus, a summer associate at BCLP and a rising 2L at UCLA School of Law, for his work on this alert.

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[1] *United States v. Lepetich*, No. 3:21-cr-00032-JWD-SJD (M.D. La. May 20, 2021);

[2] *S&G Labs Haw. LLC. v. Graves*, No. 19-00310 LEK-WRP, 2021 U.S. Dist. LEXIS 200365 (D. Haw. Oct. 18, 2021);

[3] *United States v. Schena*, No. 5:20-cr-00425-EJD-1, 2022 U.S. Dist. LEXIS 96051 (N.D. Cal. May 28, 2022);

[4] As of Jan. 30, 2023.

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