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Fraud and Compliance

First Publicly-Disclosed Prosecution Under EKRA

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Most, if not all, attorneys who represent health care providers in connection with fraud and abuse matters have significant experience with enforcement under the federal Anti-Kickback Statute (AKS), which generally prohibits knowingly and willfully soliciting, receiving, offering, or paying any remuneration in return for federal health care program referrals.[1] Very few of those attorneys have such experience with enforcement under the Eliminating Kickbacks in Recovery Act (EKRA).[2]

EKRA and AKS: Similarities and Differences

EKRA was signed into law in October 2018 as part of the larger Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). Similar to the AKS, EKRA generally prohibits knowingly and willfully soliciting, receiving, paying, or offering any remuneration in order to induce certain referrals. Also similar to the AKS, EKRA is a criminal statute with a maximum term of imprisonment of 10 years. Notwithstanding its similarities to the AKS, however, EKRA is different from the AKS in several very important respects.

In one respect, EKRA is more narrow that the AKS in that it applies only to referrals to certain types of entities--mainly, recovery homes, clinical treatment facilities, and laboratories. In contrast, the AKS does not limit its application to the type of entity to which the referral flows. In two other important respects, however, EKRA is significantly broader than the AKS. First, and perhaps most importantly, whereas the AKS applies only to federal health care programs (with the exception of the Federal Employee Health Benefits Program (FEHBP)), EKRA applies to both federal health care programs and private/commercial health plans.[3]

Second, EKRA's exception for payments by employers to employees is more limited than the AKS employment safe harbor. The AKS makes clear that it does not prohibit payments by an employer to an employee who has a bona fide employment relationship with the employer. [4] Under this safe harbor, any payment by an employer to an employee is exempt from AKS prosecution so long as the employment relationship meets the bona fide employment test. EKRA, on the other hand, exempts payments by an employer to an employee only if the payment "is not determined by or does not vary by" the number of individuals referred to the entity, the number of tests or procedures performed, or the amount billed to or received from the payer based on such referrals.[5]

This limitation on EKRA's employment safe harbor is significant as many entities, including clinical laboratories (which are subject to EKRA), have historically paid their sales force on a percentage-based/commission basis. Under the

AKS, if members of that sales force were bona fide employees, the employment safe harbor would protect the arrangement. Under the language of EKRA, however, such payments might not be protected regardless of whether members of the sales force are W-2 bona fide employees or 1099 independent contractors.

Some commentators have suggested that the Department of Justice (DOJ) would not bring an enforcement action under EKRA in a situation where the arrangement in question would comply with the AKS. EKRA specifically states that it "shall not apply to conduct that is *prohibited* under [the AKS]."[6] Some commentators have suggested that this language is the result of a scrivener's error, and that Congress' intent was to exempt arrangements from EKRA prosecution so long as the arrangement *complies with* the AKS. If that does wind up how regulators interpret EKRA, then entities subject to EKRA might still be able to rely upon the AKS employment safe harbor to protect commission-based payments to W-2 employees. However, thus far, neither the DOJ nor any other federal regulatory agency has adopted this interpretation.

DOJ's First Publicly Disclosed EKRA Prosecution

Although EKRA is now over one year old, until very recently, there have been no publicly disclosed prosecutions under EKRA. That changed in January 2020, when the U.S. Attorney's Office for the Eastern District of Kentucky filed a criminal Information charging Theresa Merced with one count of violating EKRA, along with one count of making false statements and one count of tampering with a financial record.[7] According to the DOJ's press release, Merced, who is 80 years old, was the office manager of a substance abuse treatment clinic in Jackson, KY.[8]

As part of a plea deal, Merced admitted that for a period of approximately nine months in late 2018 and early 2019, she solicited kickbacks from the CEO of a toxicology laboratory in exchange for urine drug test referrals. According to the DOJ, the laboratory CEO delivered a $4,000 check to Merced "as part of a larger package of promised inducements." When she was subsequently questioned about the payment by law enforcement, Merced denied knowledge of it and stated that it "was probably a loan from the lab CEO to her husband." Merced then called the laboratory CEO "and asked that he alter the lab's financial records so that the entry for the $4,000 check would say 'rent/loan,' consistent with the lie she told the agents." Merced's has pled guilty and her sentencing is currently scheduled for May 1, 2020.

Conclusion

Theresa Merced's EKRA conviction may be the first one ever, but it is exceedingly unlikely that it will be the last. Although questions remain regarding the applicability of EKRA and the parameters of future EKRA enforcement, the Merced prosecution makes clear that individuals and entities in the health care industry must remain vigilant and ensure that pertinent arrangements comply not only with the AKS, but with EKRA as well.

[1] 42 U.S.C. § 1320a-7b(b).

[2] 18 U.S.C. § 220.

[3] 18 U.S.C. § 220(e)(3); 18 U.S.C. § 24(b).

[4] 42 C.F.R. § 1001.952(i).

[5] 18 U.S.C. § 220(b)(2).

[6] 18 U.S.C. § 220(d)(1) (emphasis added).

[7] *United States v. Merced*, No. 5:20-cr-00006 (E.D. Ky.).

[8] *See* https://www.justice.gov/usao-edky/pr/jackson-woman-pleads-guilty-soliciting-kickbacks-making-false-statements-law.

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