New Federal Kickback Statute Has Potential to Upend Sales and Marketing Payment Structure for Clinical Labs, Recovery Homes, and Treatment Facilities

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Eliminating Kickbacks in Recovery Act of 2018

In October 2018, the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) became effective. While EKRA was only a small part of the larger Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (better known as the SUPPORT Act), a bipartisan law aimed at addressing the national opioid crisis, EKRA will have an immediate and significant effect on the

marketing and sales activities of clinical laboratories, clinical treatment facilities, and recovery homes.

EKRA, in relevant part, makes it a federal crime to knowingly and willfully:

- solicit or receive 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
- pay or offer 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.[1]

A violation of EKRA is punishable by up to 10 years in prison and a $200,000 fine.

Comparison of EKRA and the Anti-Kickback Statute

Although EKRA uses some of the same language that the existing federal Anti-Kickback Statute (AKS)[2] uses, it is broader than the AKS in at least two very important respects. First, unlike the AKS, which applies only to federal health care programs,[3] EKRA applies to *both* federal health care programs *and* commercial health plans, so long as the latter has a nexus with interstate commerce. This means that the common practice of creating a federal health care program “carve out” to avoid federal liability is no longer a viable option for these types of health care providers.

Second, although EKRA contains an exception for remuneration paid to bona fide employees or independent contractors, that exception is not applicable if the remuneration paid to that employee or independent contractor varies with the number of individuals referred, the number of tests or procedures performed, or the amount billed to or received from a health plan.[4] This provision, related to payments to sales and marketing personnel, is significant in that, before EKRA, such payments were permissible so long as they were made to a “bona fide

employee" as that term is defined by the Internal Revenue Code. Specifically, the AKS employee safe harbor provides:

> As used in section 1128B of the Act, "remuneration" does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.[5]

In other words, under the AKS, so long as the payments were being made to a bona fide W-2 employee, they could not be considered unlawful "remuneration." This safe harbor provided comfort to health care providers that utilize sales or marketing personnel—particularly clinical laboratories—and wanted to make commission-based payments to those employees.

EKRA, however, potentially changes this, at least insofar as it relates to clinical laboratories, recovery homes, and clinical treatment facilities. That is because, as discussed, under EKRA, any such payment would be considered unlawful remuneration if it varied in any way by the number of referrals, the number of tests or procedures, or the amount billed or received from the health benefit program. This is true regardless of whether the recipient of such payments is a bona fide employee or independent contractor. Accordingly, this provision of EKRA potentially eliminates the possibility that clinical laboratories, recovery homes, and clinical treatment facilities may lawfully make any sort of commission-based payment to a sales or marketing employee, even if that employee meets the IRS' bona fide employee requirements.

Unanswered Questions

The EKRA provides that the Department of Justice (DOJ), in consultation with the Department of Health and Human Services, may promulgate regulations to clarify the exceptions contained in the EKRA, including the employee/independent contractor exception discussed above.[6] However, given the relative youth of EKRA, federal regulators have not yet weighed in on its application or issued any sort of guidance or implementing regulations. Therefore, significant questions remain unanswered.

Perhaps the biggest unanswered question relates to a provision of EKRA, which provides that EKRA "shall not apply to conduct that is prohibited under [the AKS]."[7] Many commentators have speculated that this provision was the result of a scrivener's error and that the provision should have stated that EKRA does not apply to conduct that is "*not* prohibited" or that is "*permitted*" under the AKS. If that were what EKRA was intended to say, then providers subject to EKRA might still be able to rely upon the AKS bona fide employment safe harbor to protect commission-based payments to bona fide W-2 employees. However, until Congress fixes this error, or federal regulators issue guidance clarifying this issue, clinical laboratories, recovery homes, and clinical treatment facilities, along with sales or marketing representatives of any such entity, are faced with significant risk of criminal liability for any such payments to employees or contractors.

Another unanswered question is whether DOJ will consider a federal health care program claim that is tainted by an EKRA violation a "false or fraudulent claim" for purposes of the federal False Claims Act (FCA).[8] Congress amended the AKS in 2010 (as part of the Patient Protection and Affordable Care Act) to expressly provide that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]."[9] Under this provision, the DOJ and FCA relators have argued (mostly, although not universally, with success) that when a health care provider submits a claim for reimbursement to a federal health care program, and that claim is tainted by a violation of the AKS, by submitting such a claim, the provider also violates the FCA.

Although, unlike the AKS, EKRA does not contain an express provision making a claim submitted in violation of the EKRA a "false or fraudulent claim" for purposes of the FCA, courts may very well still conclude that submitting a claim to a federal health care program that is tainted by an EKRA violation also constitutes a violation of the FCA. The Stark Law,[10] for example, does not contain an express provision regarding the FCA, but courts have nevertheless held that claims submitted in violation of the Stark Law amount to a violation of the FCA through the implied certification theory of liability, because compliance with

the Stark Law is a Medicare "condition of payment."[11] Attorneys and health care providers will have to wait for EKRA cases to make their way through the courts before obtaining any real clarity on this issue.

Conclusion

Although some health care providers might look at the EKRA as just "another kickback statute," having such a view could be a costly mistake for clinical laboratories, treatment facilities, and recovery homes. In those industries, where commission-based payments to bona fide W-2 employees is extremely common place, ignoring the EKRA could result in significant criminal liability.

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[1] 18 U.S.C. § 220(a).

[2] 42 U.S.C. § 1320a-7b(b).

[3] The AKS applies to all federal health care programs except the Federal Employee Health Benefits Program (FEHB).

[4] 18 U.S.C. § 220(b)(2).

[5] 42 U.S.C. § 1001.952(i).

[6] 18 U.S.C. § 220(c).

[7] 18 U.S.C. § 220(a).

[8] 31 U.S.C. § 3729 *et seq.*

[9] 42 U.S.C. § 1320a-7b(g).

[10] 42 U.S.C. § 1395nn.

[11] *See, e.g., Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 1000-01 (9th Cir. 2010) (holding that the Stark Law "may provide a valid basis from which to imply certification, because it expressly conditions payment on compliance").

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