

How EKRA and AKS Impact Laboratories and Commission-Based Compensation

April 15, 2022 – Dorsey Health Law

by Lillie C. Cox and Ross C. D'Emanuele

With the enactment of the Eliminating Kickbacks in Recovery Act (“EKRA”) in 2018, the permissibility of commission-based compensation to laboratory sales representatives based on volume, revenue, or profit has come under question, and there is still little case law interpreting the Act. Despite EKRA being a relatively newer law, laboratories should remain mindful of how the more established Anti-Kickback Statute (the “AKS”) impacts the permissibility of such commission-based compensation as well. Under current law, commission-based payments (including commission based on volume, revenue, profit, etc.) should be permissible when paid to employee sales representatives. However, labs should be cautious when considering commission-based compensation to independent contractor sales representatives.

I. The Anti-Kickback Statute

The AKS subjects to criminal and civil penalties anyone who knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward the referral of business reimbursable under any federal health care programs. 42

U.S.C. § 1320a-7b(b). Importantly, the AKS extends beyond paying value in exchange for direct patient referrals; it also prohibits paying remuneration intended to induce or reward someone to arrange for or recommend that others purchase, lease, or order any good, facility, service, or item reimbursable by any federal health care program. See *Id.*

The AKS contains numerous safe harbors, the compliance with which protects parties from violation of the AKS. One of these is the employment safe harbor, which permits any payments to an employee if there is a bona fide employment relationship. 42 U.S.C. § 1320a-7b(b)(3)(B). This safe harbor does not extend to independent contractors. *Id.*



Related People

- Lillie C. Cox
- Ross C. D'Emanuele

Related Capabilities

- Healthcare & Life Sciences
- Healthcare Transactions & Regulations
- Healthcare Litigation
- Medical Devices

II. The Eliminating Kickbacks in Recovery Act

EKRA subjects to criminal penalties anyone who, with respect to services covered by certain public health care benefit programs, knowingly and willfully: (1) solicits or receives any remuneration in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or (2) pays any remuneration 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. 18 U.S.C. § 220(a). Laboratory is defined to include all laboratories, not just those that perform testing related to substance abuse. 18 U.S.C. § 220(e)(4). Notably, EKRA's language appears to be limited to paying for direct referrals. Unlike AKS, EKRA does not include language that extends its prohibitions to paying for arranging or recommending others to make referrals or order services.

In addition, EKRA does not have an employee safe harbor analogous to the employee safe harbor under AKS, but rather has a narrower exception permitting payments made under a bona fide employment relationship (including with independent contractors, unlike under the AKS employment safe harbor) where the payment does not vary based on the procedures performed, or amounts billed or received from the health care benefit program from the individuals referred. 18 U.S.C. § 220(b)(2).

In 2021, a federal district court in Hawaii issued the first and, to date, only judicial opinion interpreting EKRA in *S&G Labs Haw., LLC v. Graves*, 2021 U.S. Dist. LEXIS 200365. The district court held that while the employment agreement with Graves (a client account manager) provided for commission-based payments that varied based on the number of tests S&G performed, the arrangement did not violate EKRA since there was only an attenuated connection between the commission-based payments and patient referrals: "Undoubtedly, Graves's commission-based compensation structure induced him to try to bring more business to S&G . . . However, the 'client' accounts they serviced were not individuals whose samples were tested at S&G. Their 'clients' were 'the physicians, substance abuse counseling centers, or other organizations in need of having persons tested.' However, S&G was not compensated by those 'clients'; S&G was 'compensated for the testing services on a 'per test' basis by third party insurers, government agencies under the Medicare and Medicaid programs, and direct self-pay by some individuals.' There is no evidence that Graves's client accounts included individuals who self-paid for S&G to perform urinalysis on their samples." *Id.* at 33-34.

The district court concluded that since "Graves was not working with individuals, the compensation that S&G paid him was not paid to induce him to refer individuals to S&G." *Id.* at 34. In other words, the district court concluded that because Graves was not himself a source of lab referrals, EKRA's prohibitions could not reach the volume-based compensation arrangement between Graves and his laboratory employer.



III. Commissions to Employee Sales Representatives vs. Independent Contractor Sales Representatives

Under current law discussed above, labs should generally be able to make commission-based payments (including commissions based on volume, revenue, profit,

etc.) to employee sales representatives, but should carefully consider the AKS when proceeding with respect to independent contractor sales representatives.

A. Employee Sales Representatives

Commission-based payments, including commission based on volume, revenue, profit, etc., to employee sales representatives are permissible under the AKS. Such payments would fall within the AKS employment safe harbor so long as a bona fide employment relationship exists.

Per the S&G Labs interpretation of EKRA, commission-based payments, including commission based on volume, revenue, profit, etc., to employee sales representatives are also permissible under EKRA, provided that a lab's employee sales representatives have a similar relationship to their client accounts as that described in S&G Labs, wherein sales representatives are working with physician clinics, hospitals, and other organizations and facilities that would utilize the lab, and are not working with individual patients.

B. Independent Contractor Sales Representatives

Based on the only case law to address the issue at this point, so long as independent contractor sales representatives work with organizations and facilities, and are not in a position to refer individual patients, then EKRA should not bar commission-based payments to a lab's independent contractor sales representatives. However, commission-based payments to independent contractor sales representatives remain an issue under the AKS if the laboratory business involves federal health care programs. Such payments fall outside of the employment safe harbor to the AKS, and the broad reach of the AKS prohibition on arranging or recommending that others order items and services could extend to payment arrangements with independent contractor sales representatives. Consequently, laboratories should proceed cautiously when considering compensating independent contractor sales personnel based in whole or in part on a volume- or value-based methodology.

We will continue to closely monitor the state of EKRA and the AKS for guidance, revisions to the law, and enforcement. If you have further questions or need advice on how to restructure compensation arrangements to comply with EKRA and the AKS, please contact the authors or your regular Dorsey attorney.

