In the Absence of Published Guidance or Additional Legislation, Is It Safe for Laboratories to Pay Commissions to Sales Staff?

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In what can only be described as hastily-crafted legislation, Congress passed the Eliminating Kickbacks in Recovery Act of 2018 (EKRA), with an effective date of October 24, 2018.[1] EKRA, from all accounts, was intended to address concerns relating to "body broker" activities observed in patient referrals to substance use-disorder treatment facilities. Because the activities were observed primarily with commercial payors, and thus not prohibited by the federal Anti-Kickback Statute (AKS)[2], Congress quickly passed EKRA in order to fill the perceived commercial payor gap and prevent schemes in which substance use treatment facilities paid third parties a "finder's fee" for patient referrals.

Although not included in the initial draft of the legislation, laboratories were swept up in the legislation so broadly that compensation arrangements expressly permitted by the AKS, such as incentive compensation to bona-fide employees, may very well be prohibited under EKRA. Although legislators and trade associations have long promised a fix, the legislation's effective date is more than a year ago and no changes have been made to the legislation. Nor has any regulatory or other guidance been published by the Attorney General, the person authorized to provide guidance in consultation with the Secretary of Health and Human Services. Moreover, in the current political climate in Washington, no one expects a fix any time soon.

So the question remains: is it safe for a laboratory to pay its sales staff in the form of commissions, if the laboratory does not provide toxicology or other services to the substance use-disorder industry? According to discussion at a recent conference of many leading fraud and abuse lawyers, there is currently no consensus on the answer to this question, and it appears that laboratories are waiting for some type of guidance or the "promised fix," before considering a change in their compensation practices.

To be sure, there are good arguments that EKRA was intended to address a specific concern relating to questionable activities in the substance use-disorder industry. Indeed, EKRA was passed as a late addition to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act designed to address the nation's opioid epidemic.[3] This backdrop would suggest that only laboratories providing toxicology/UDT lab testing should be subject to EKRA's perceived prohibition on commission compensation for sales staff. Notwithstanding, EKRA is written so broadly that all CLIA laboratories, including those that do not provide services solely to the substance use-disorder industry, could be subject to EKRA's significant per occurrence penalties of up to $200,000 in fines and/or 10 years in jail, simply for paying sales staff a commission.

Although EKRA includes a safe harbor designed to protect employee-employer compensation, it does so only if the payment is not determined by or does not vary with (1) the number of individuals referred; (2) the number of tests or procedures performed; or (3) the amount billed to or received from a health care benefit program. Because commission sales are by their very nature volume based, EKRA could be read to prohibit commission payments to W-2 sales staff with bona-fide

1 18 U.S.C. § 220.
2 42 U.S.C. § 1320a-7b(b).
3 2018 Pub. L. 115-271.

employment arrangements, despite the fact that this is a common practice expressly exempted from the AKS and has been repeatedly adopted by the Office of Inspector General in safe harbor regulations, commentary, and other forms of guidance.

It is not only the lack of guidance and the dissimilarity between EKRA and the AKS and its implementing regulations that is creating confusion, however, but the legislation's introduction of new, and as of yet, undefined terms. For example, EKRA prohibits the solicitation, offering, or receipt of remuneration "in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory."[4] What does it mean to refer a patient or patronage? Similarly, EKRA prohibits the payment or offering of remuneration to induce the referral of an individual "in exchange for an individual using the services of [a] recovery home, clinical treatment facility, or laboratory."[5] What is encompassed in providing remuneration "in exchange for an individual" using a service, particularly as it applies to labs? At least some lawyers are interpreting this language as legislative intent that only direct-to-consumer marketing is prohibited and not business-to-business marketing. However, it is far from clear whether the United States Department of Justice or a court would agree with this interpretation.

Unfortunately, at the present, it appears the only guidance the industry is likely to obtain is through an enforcement action. Certainly, commercial payors may feel emboldened to bring an action under EKRA. What seems safe to say is that current sales compensation arrangements used by laboratory companies are in a state of flux with some commission arrangements perhaps no longer considered appropriate, and this is particularly true for laboratories that market to substance use-disorder treatment facilities, clinics, or recovery homes.

Until the "fix" is in, laboratories should discuss the feasibility of alternative compensation arrangements, for example, flat annual salaries based on historical performance, regional budgeting, or other similar factors not tied to specific clients or volumes. Perhaps the bigger question may be who will be the first to change their compensation practices and risk losing their sales staff. Anyone?

4 18 U.S.C. § 220(a).
5 *Id.*

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