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Lab Owners Beware – Conflicting EKRA Opinions Muddy the Landscape on Payments for Physicians' Test Referrals

Authors: Robert E. Mazer, Ty Kelly

June 09, 2022

The Eliminating Kickbacks in Recovery Act (EKRA), a law that became effective in October 2018, extended federal kickback prohibitions to services provided by recovery homes, clinical treatment facilities, and laboratories that were covered by health care benefit plans, including Medicare, Medicaid, and commercial insurers. EKRA's broad prohibition – and narrow exception for payments to employees and independent contractors – put at risk marketing arrangements that had been generally permissible and commonly used in the clinical laboratory industry, particularly commission-based payments to lab-employed sales representatives. However, last October, a dispute between a clinical laboratory and a former employee resulted in an unanticipated EKRA interpretation. A U.S. District Court in Hawaii held that a lab's payments for sales efforts that were directed toward *physicians* and other lab clients did not violate the statute. According to the Court, EKRA prohibited only payments for sales efforts directed at patients who might require lab testing. *S&G Labs Hawaii v. Graves*, Civ. No. 19-00310, 2021 WL 4847430 (D. Haw. Oct. 18, 2021). As discussed below, a recent district court decision, however, disavowed the decision in *S&G Labs*, resulting in conflicting interpretations of EKRA's prohibitions.

Recent EKRA Decision

A federal court in Northern California held recently that laboratories and others involved in commission-based arrangements on behalf of labs relating to marketing physicians and other referral sources may be subject to criminal penalties based on EKRA. *USA v. Schena*, Case No. 5:20-cr-00425-EJD-1, 2022 WL 1720083 (N.D. Cal. May 28, 2022). The decision stemmed from a criminal prosecution of the president of a clinical laboratory who was alleged to have violated various federal laws, including EKRA for paying illegal kickbacks and bribes to individuals and marketing companies hired by the lab to generate physician referrals.

The defendant filed a motion to dismiss three counts of the indictment that were based on EKRA, relying on the decision in *S&G Labs*. He asserted that the law did not prohibit payments to marketers for seeking laboratory referrals from physicians. The Court explicitly disagreed with *S&G Labs*, stating that EKRA clearly prohibits paying remuneration for referrals, including situations where a marketer "causes ... a referral from a physician." According to the Court, the conduct alleged by the government violated EKRA because "the marketers received a kickback to 'influence' the physician's referrals." Therefore, the Court denied the motion to dismiss. Of course, it remains to be seen whether the jury will convict on the charges.

Conclusion

It appears likely that the government will continue to rely on EKRA to pursue participants in arrangements involving payments for marketing lab services to physicians and other referral sources. Application of EKRA to payment arrangements for marketing services may raise difficult issues, including application of the EKRA exception that permits payments that do *not* reflect the number of individuals or tests referred, or the amounts billed or received from lab referrals. Future cases may better define the types of compensation arrangements that may be protected by this exception and those arrangements that will be considered EKRA violations. Accordingly, compensation arrangements demand close attention from all labs that pay for marketing services,

and their exercise of caution until EKRA-compliant payment arrangements for those services are better defined.