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EKRA's Application to Marketing Arrangements: Laboratories and Other Providers

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The Ninth Circuit recently affirmed two decisions that provide additional guidance regarding how arrangements with marketing agents implicate and violate the Eliminating Kickbacks in Recovery Act, 18 U.S.C. § 220(a)(EKRA).

EKRA prohibits a person from soliciting or receiving any remuneration in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory. EKRA also prohibits a person from paying or offering any remuneration either (i) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory, or (ii) in exchange for an individual using the services of a recovery home, clinical treatment facility, or laboratory. The penalties for violating EKRA are severe. Each violation of EKRA could result in a $200,000 fine or a 10-year prison sentence. Like the federal Anti-Kickback Statute (AKS), EKRA is an intent-based statute.

In *United States v. Schena*, the Ninth Circuit affirmed an EKRA conviction involving a laboratory testing company that allegedly engaged in various misleading tactics to encourage health care providers to order laboratory tests that would then be performed by the testing company.

In *Schena*, the owner of the laboratory instructed the company's marketing personnel to advertise certain blood allergy tests to unsophisticated doctors who were not familiar with allergy testing. The marketing personnel, in turn, informed such doctors that the blood allergy tests were highly accurate and far superior to allergy skin tests, even though the blood allergy tests could only assess whether a patient had been exposed to an allergen and could not actually assess whether a patient possessed an allergy.

During the COVID-19 pandemic, the owner of the laboratory instructed the company's marketing personnel to advertise the company's COVID antibody blood test as equal to or superior to COVID polymerase chain reaction (PCR) tests, even though the COVID antibody blood tests could only detect COVID antibodies (and not active COVID infections). Also, the marketing personnel encouraged physicians to bundle COVID blood tests and allergy blood tests by falsely claiming that Dr. Anthony Fauci, the director of the National Institute of Allergy and Infectious Diseases during the COVID-19 pandemic, recommended bundling allergy and COVID tests. The marketing personnel were paid a percentage of the revenue that they generated for the laboratory based on referred testing.

As a result of this conduct, the owner of the laboratory was convicted by the trial court for violating EKRA and other health care fraud statutes. The Ninth Circuit affirmed these convictions and provided additional context regarding what it means to "induce a referral" for purposes of EKRA. In doing so, the court relied on case law interpreting the AKS and aligned its interpretation with those cases.

First, the Ninth Circuit explained that a person could "induce a referral" under the meaning of EKRA by paying someone who could in turn effect a referral (e.g., a marketing agent), even if the person who received the payment did not, on his own, have the ability to order a laboratory test or refer a patient to a treatment facility. The Ninth Circuit observed that this interpretation is both (i) supported by the statutory language of EKRA

which prohibits a person from "indirectly" inducing a referral, and (ii) consistent with decisions from other circuits that have interpreted the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7(b) to prohibit certain arrangements with third party intermediaries when such intermediaries exercise improper influence over health care providers, even though such intermediaries do not have the ability to directly make referrals. *See, e.g., United States v. Schoemaker*, 746 F.3d 614 (5th Cir. 2014); *United States v. Polin*, 194 F.3d 863 (7th Cir. 1999).

Second, however, the Ninth Circuit explained that merely paying a marketing agent a percentage-based compensation structure, without more, would not "induce a referral" in violation of EKRA. Rather, in order to induce a referral, the arrangement must involve undue influence, i.e., an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of federal health care program business. According to the Ninth Circuit, in the context of EKRA, "induce" contemplates not just causation, but wrongful causation.

In *S&G Labs Hawaii, LLC v. Graves*, No. 24-823 (9th Cir. July 11, 2025), an unpublished case decided on the same day as *Schena*, the Ninth Circuit affirmed a trial court's decision to award back pay to a former marketing employee of a clinical laboratory. In *S&G Labs,* the Ninth Circuit cited *Schena* and rejected an argument that the marketing employment agreement violated EKRA, explaining that simply presenting a commission-based employment agreement is not sufficient to show a violation of EKRA.

Important Takeaways

There are several important takeaways from these decisions. First, the decisions clarify that, within the Ninth Circuit, if marketing arrangements do not unduly influence referrals, the payment of a commission-based compensation structure alone does not violate EKRA. Based on this, if the decision is made to implement commission-based marketing arrangements, clinical laboratories, treatment centers, and recovery homes should consider implementing policies and procedures that govern how marketing personnel interact with health care providers and potential referral sources to (i) mitigate the risk of any improper influence on professional clinical decision-making, and (ii) ensure that the marketing-related information that marketing personnel share with health care providers and potential referral sources is accurate and reasonably supported by evidence.

Second, clinical laboratories, treatment centers, recovery homes, and other health care stakeholders should note that EKRA has limited case law precedent and that these opinions only have precedential value for arrangements that operate within the Ninth Circuit's jurisdiction. Due to this, clinical laboratories, treatment centers, and recovery homes that have national operations should continue to be mindful of potential risk and structure their arrangements to mitigate potential risk under EKRA to account for any potential future circuit splits regarding the interpretation of EKRA.

These opinions serve as a reminder that clinical laboratories, treatment centers, and recovery homes should carefully scrutinize their arrangements with marketing personnel to ensure compliance with EKRA.

For more information or assistance on this topic, please contact Alissa Fleming, Bernard Miller, or any member of Baker Donelson's Health Law Team.