Recent Judicial Interpretation of EKRA: Key Implications for Laboratories and Other Health Care Providers

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The Eliminating Kickbacks in Recovery Act of 2018[1] ("**EKRA**"), prohibits knowingly and willfully soliciting or receiving any remuneration in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory.[2] The statute was designed to prevent patient brokering arrangements that involve "taking advantage of individuals with opioid use disorders and referring them to substandard or fraudulent providers in exchange for kickbacks."[3] Prior to EKRA's enactment, no federal law existed to prohibit these types of exploitative arrangements when the services were reimbursed by private health insurers; thus, EKRA – unlike the federal Anti-kickback Statute[4] (the "**AKS**") – applies to items and services reimbursed by federal healthcare programs and private payors.[5]

EKRA specifically 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.[6] Each EKRA violation may result in severe penalties, including fines of up to $200,000 and imprisonment for up to 10 years.[7]

EKRA includes various statutory safe harbor provisions that exempt certain arrangements from its scope.[8] While these arrangements might otherwise implicate EKRA, if the requirements of the safe harbors are met, they are not treated as violations of the statute. There are seven statutory safe harbors that cover the following: certain health care provider discounts, certain payments made to employees and independent contractors, Part D drug discounts, personal services and management contract arrangements that meet the requirements of the AKS safe harbor, 42 C.F.R. § 1001.952(h)(5), remuneration made pursuant to an

alternative payment model, the good-faith and non-routine waiver of co-pays and co-insurance, and certain payments to federally qualified health centers.[9] EKRA contains a preemption provision that states that it does not apply to conduct that is prohibited by the AKS.[10] However, conduct protected by the AKS may violate EKRA if not included in the EKRA safe harbors.

Although EKRA has been in effect since 2018, judicial interpretation of the statute remains limited and has resulted in varying decisions. This lack of clarity has posed challenges for clinical laboratories and other stakeholders seeking to implement arrangements that would allow them to expand patients' access to care and keep pace with the constantly evolving health care industry.

Fortunately, a recent Ninth Circuit decision, *United States v. Schena*,[11] offers valuable guidance on how clinical laboratories may structure arrangements to comply with EKRA. The decision is the first appellate court decision to interpret EKRA and is notable because the Ninth Circuit aligned its interpretation of EKRA with case law interpreting the AKS.

This article (i) discusses the facts and holdings of *Schena*; (ii) examines how the court's reasoning aligns with other cases addressing third-party marketing arrangements under the AKS; and (iii) offers practical guidance for laboratories and other health care providers on structuring their arrangements to comply with EKRA.

Recent Case Law Interpreting EKRA

In *United States v. Schena*,[12] 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. The *Shena* court addressed two key issues:[13]

- Whether EKRA covers payments to marketers designed to induce referrals, or whether the provision is limited to payments made to persons who are doing the actual patient referrals, most typically doctors and other medical professionals; and
- What it means to "induce a referral"[14] under EKRA in circumstances where a party is alleged to have made payments to a marketing agent "to induce a referral of an individual."

The laboratory owner in *Schena* instructed the company's marketing personnel to promote certain blood allergy tests to physicians who were not allergists, did not specialize in allergy testing, and who were unfamiliar with allergy testing, i.e., "naïve doctors."[15] The marketing personnel, in turn, informed such physicians 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. The laboratory could bill third-party payors up to $10,000 for each full suite of tests. Further, the laboratory tested each patient for 120 allergens, not because this was medically necessary, but because the panels included that number of allergens.

Additionally, the evidence revealed that during the COVID-19 pandemic, the laboratory's allergy testing volume substantially decreased because patients stopped seeking care related to allergies which, therefore, resulted in a lower volume of allergy blood tests. In response, the laboratory owner instructed the company's marketing personnel to advertise the laboratory'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). Further, 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 laboratory owner also instructed marketing personnel to misrepresent how quickly the PCR tests could be resulted. Finally, even when physicians only ordered COVID PCR tests, the laboratory owner instructed the laboratory's personnel to run allergy tests on the specimens as well.

At trial, one marketer testified that the marketers "controlled" which laboratory the blood samples would be sent to. Another marketer testified that the laboratory's financial incentives ensured that marketers would "push" the blood allergy tests and not mention the more accurate skin tests. The marketing personnel were compensated based on a percentage of the revenue that they generated for the laboratory based on referred testing.

As a result of this conduct, the Ninth Circuit affirmed the laboratory owners' convictions under EKRA and held that EKRA covers payments to marketers that are intended to induce referrals and "marketing intermediaries who interface with those who do the referrals."[16] "Under EKRA, there is no requirement that the payments be made to a person who interfaces directly with patients."[17] In reaching this decision, the court 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.[18] As discussed below, this interpretation is consistent with decisions from other courts that have interpreted what it means to "induce a referral" under the AKS.[19]

Second, however, the Ninth Circuit explained that percentage-based compensation structures, without more, would not "induce a referral" in violation of EKRA.[20] Rather, to induce a referral, an 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. The *Schena* court relied on its holding in *Hanlester Network v. Shalala*[21] and explained that:

> [t]o induce…connotes an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.[22] Such conduct is not merely influence; we understand Hanlester, based on the facts of the case, to require undue influence.[23]

Thus, according to the Ninth Circuit, in the context of EKRA, "induce" contemplates not just causation, but wrongful causation.

Intent to Induce Referrals Under the Federal Anti-Kickback Statute

The Ninth Circuit's interpretation of EKRA in *Schena* is consistent with decisions from other courts that determined that an arrangement with a third party intermediary could implicate the AKS, even when the intermediary does not have the ability to directly make a referral. Importantly, the court confirmed that EKRA applies not only to health care providers but also to marketers engaged in unlawful referral schemes, even if they have no direct contact with patients. The court's reliance on AKS precedence potentially informs EKRA enforcement. The central question is whether the third-party intermediary exerts undue influence over a health care provider's professional judgment.

For example, in *United States v. Polin*,[24] the Seventh Circuit affirmed an AKS conviction involving an arrangement between a pacemaker monitoring company, the Center for Vascular Studies (the "**Center**") and a pacemaker sales representative. In *Polin*, two key personnel of the Center offered to pay the sales representative for each Medicare patient that the sales representative directed to the Center. The sales representative was in a position to direct patients to the Center because, in his role, he regularly worked with hospitals to ensure that patients who received a pacemaker were properly monitored after the pacemaker was implanted. If a patient's physician decided to use a third-party service to monitor the patient after the procedure, then the sales representative would identify a third-party monitoring vendor to provide such services for the patient. Importantly, the sales representative testified that, though a physician had the right to refuse any monitoring service that he chose, the sales representative stated that "he had never been overruled by a physician during his fourteen year career." [25]

Under the proposed arrangement, however, the sales representative would not receive payment if the patient or the physician declined receiving services from the Center, the patient died before the Center began providing monitoring services, or if the patient was a resident of a nursing home that already had a monitoring contract with the Center.

As a result of this conduct, the key personnel were convicted by the trial court of violating the AKS. On appeal, the defendant-appellants argued, among other things, that the arrangement did not constitute a payment for a "referral" for purposes of the AKS because each patient's physician, not the sales representative, actually referred the patient to the Center to receive monitoring services. The defendant-appellants argued that the alleged conduct constituted a "recommendation" for services because the sales representative's permission was not required for a patient to receive the monitoring services. The defendant-appellants asserted that this distinction was important because the charging documents tracked the language of 42 U.S.C. § 1320a-7b(b)(2)(A) (i.e., the AKS provision that prohibits paying for improper referrals) and not the language of 42 U.S.C. § 1320a-7b(b)(2)(B) (i.e., the AKS provision that prohibits paying for improper recommendations).

The Seventh Circuit rejected this argument and affirmed the AKS convictions, explaining that the sales representative's conduct constituted making referrals (not recommendations) under the meaning of the AKS:

> "We do not believe, as appellants suggest, that 42 U.S.C. § 1320a-7b(b)(2)(A) and (B) are two separate subsections that address 'different and non-overlapping' types of conduct. Counsel for the government aptly summarized the similarities in this situation when he said, '***Refer is to recommend, is to turn over, is to make a selection, is to give the business away; and that's what Mac [sic] Haberkorn was in the position to do***.' The evidence bears this out. Once it was decided that the patient would be sent to an outside service for monitoring, Haberkorn would suggest [the Center] or a similar service to the physician. Never in his fourteen year career was Haberkorn's suggestion rebuked by a physician. Indeed, after his recommendation was made, he would call [the Center] and arrange for the patient's follow-up himself. ***Of course, [the Center] would have to receive the physician's authorization before commencing service, but that permission seemed to be more of a formality or rubber stamping of Haberkorn's referral***."[26]

Similar to Polin, there are several Fifth Circuit cases that have determined that an arrangement with a third party intermediary that exercises undue influence over a health care provider's professional decision-making could implicate the AKS, even when the intermediary does not have the ability to make a referral on its own. For example, in *United States v. Marchetti*,[27] the Fifth Circuit affirmed an AKS conviction related to an arrangement in which Vantari Genetics LLC, a medical laboratory specializing in pharmacogenetic testing, paid a distributor a percentage of its revenue for each Medicare referral that it received. The court held that while much of the conduct at issue did not implicate the AKS, the portion of the arrangement that involved its conduct with one of its distributors violated the AKS because there was evidence that the distributor exercised control over the laboratory that specimen would be sent to, contrary to the directions of the ordering physicians.[28]

In contrast, in *United States v. Miles*,[29] the Fifth Circuit overturned convictions under the AKS involving payments that Affiliated Professional Home Health ("**APRO**"), a Medicare home health agency, made to Premier Public Relations ("**Premier**"), a public relations firm. In *Miles*, Premier delivered promotional materials (e.g., literature, business cards, and plates of cookies) to encourage local physicians to use the services of APRO. In exchange, Premier was paid for each Medicare patient who became a client of APRO.

In distinguishing the facts from *Polin*, the *Miles* court emphasized that payments for advertising services differ fundamentally from payments for referrals to individuals who can influence health care decisions. Specifically, the Fifth Circuit emphasized that Premier merely supplied promotional materials to physicians describing APRO's capabilities. Only after a physician decided to send a patient to APRO would the physician arrange for Premier to send the patient's billing information to APRO. The Fifth Circuit stated that "[t]here was no evidence that Premier had any authority to act on behalf of a physician in selecting the particular home health care provider."[30] The Fifth Circuit in further distinguishing *Miles* from *Polin*, noted that in *Polin* the sales representatives actively recommended monitoring services to physicians, and those recommendations were consistently accepted.[31]

Although not relied upon by the Ninth Circuit in *Shena*, in an April 2025 decision, the Seventh Circuit in *United States v. Sorenson*[32] reversed a conviction under the AKS, finding insufficient evidence that payments made to advertising and marketing companies that worked with a manufacturer to sell orthopedic braces for Medicare patients constituted illegal kickbacks under the AKS. The Seventh Circuit held that the payments "were not made for 'referring' patients within the meaning of the statute."[33] In reaching its decision, the court relied upon *United States v. George*,[34] which holds that a payment is made to induce referrals if the payee can "leverage fluid, informal power and influence over healthcare decisions."[35] The court found that the individuals and businesses paid were advertisers and a manufacturer, not physicians in a position to refer their patients or other decision-makers in a position to exercise power or influence over healthcare decisions.

The arrangement in *Sorenson* was multifaceted. Sorenson owned a durable medical equipment ("**DME**") distributor, SyMed Inc., which contracted with a DME manufacturer and several marketing firms. The marketing firms published advertisements for orthopedic braces for patients. If patients responded to an advertisement providing their names, addresses, and doctor's information, a sales agent would contact the patient and obtain his or her consent to contact their treating physicians. The marketing firm would then fax a pre-filled (but unsigned) prescription

form to the patient's physician. The physicians who received these prescription forms could then choose to sign the form and return the form to SyMed. If the physician signed and returned the form, then SyMed would arrange for the DME manufacturer to ship the braces to the patient and would then submit the claim for reimbursement by Medicare. SyMed paid the manufacturer 79% of the funds reimbursed by Medicare. The manufacturer then paid the marketing firms based on the number of leads they each generated. The evidence at trial demonstrated that the physicians regularly ignored the pre-filled prescription forms that they received from the marketing firms (e.g., 80% of the order forms sent by one of the marketing firms were not returned and the physicians regularly ignored the prescription forms sent by the second marketing firm).[36]

In holding that Sorenson's payments to the manufacturer and marketing firms did not violate the AKS, the Seventh Circuit concluded that there was no evidence that the entities Sorenson paid "leveraged any sort of informal power and influence over healthcare decisions."[37] The "physicians always had ultimate control over their patients' healthcare choices and applied independent judgment in exercising that control."[38] Although the court characterized Sorenson's tactics as "aggressive advertising efforts," such efforts were not equivalent to the unlawful referral of patients.[39]

It is important to note that although the Seventh Circuit analyzed the meaning of induce a referral under Section (b)(2)(A) of the AKS, i.e., the AKS provision that prohibits paying for improper referrals, the court failed to address whether the conduct at issue violated Section (b)(2)(B), i.e., the AKS provision that prohibits the payment for arranging for or recommending items or services reimbursed by federal healthcare programs. The court's failure to directly address whether the conduct involved arranging or recommending items or services reimbursed by federal health care programs cautions against relying on Sorenson to protect similar arrangements.

Important Takeaways

These decisions offer several key takeaways. First, the recent cases clarify that to "induce a referral" under both EKRA and the AKS, the third-party intermediaries' conduct must involve undue influence. When third-party intermediaries improperly influence the medical decision-making of the ordering/referring provider, payments to third-party intermediaries would induce a referral under both EKRA and the AKS. Furthermore, within the Ninth Circuit, a commission-based compensation structure alone does not violate EKRA if the third-party intermediary does not exert undue influence over referrals. Accordingly, when implementing marketing arrangements, clinical laboratories and other affected stakeholders should adopt policies and procedures that (i) minimize the risk of improper influence on clinical decision-making and (ii) ensure that all marketing information shared with health care providers and potential referral sources is accurate and supported by credible evidence. Second, clinical laboratories, treatment centers, recovery homes, and other health care stakeholders should note that EKRA has limited case law precedent and that the *Shena* decision only has precedential value for arrangements 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 these statutes. Health care stakeholders should also monitor and evaluate state laws that are similar to EKRA that also implicate patient-brokering arrangements

that involve clinical laboratories, treatment centers, or recovery homes.[40]

These opinions serve as a reminder that clinical laboratories, treatment centers, and recovery homes should carefully scrutinize their compensation structures and marketing arrangements to mitigate risk under EKRA.

Endnotes

1. 18 U.S.C. § 220.
2. *See* 18 U.S.C. § 220(a).
3. *See* 164 Cong. Rec. H9244 (daily ed. Sept. 28, 2018) (statement of Rep. Pallone).
4. 42 U.S.C. § 1320a-7b(b).
5. *See* 164 Cong. Rec. S6467-73 (daily ed. Oct. 3, 2018) (statement of Sen. Amy Klobuchar).
6. *See* 18 U.S.C. § 220(a).
7. *See id*.
8. *See id.* at § 220(b).
9. *See id.* at § 220(b).
10. *See id.* at § 220(d)(1).
11. 142 F.4th 1217 (9th Cir. 2025).
12. *Id*.
13. *Id*. at 1221-1222.
14. This was a question of first impression as EKRA does not define the word "induce.
15. *See* Schena at 1220.
16. Shena at 1222.
17. *Id*.
18. *See* Schena at 1222 (citing United States v. Prasad, 18 F.4th 313, 325 (9th Cir. 2021)(explaining that the phrasing "directly or indirectly" "reaches broadly")).
19. *See, e.*g., United States v. Marchetti, 96 F.4th 818 (5th Cir. 2024); United States v. Miles, 360 F.3d 472 (5th Cir. 2004); United States v. Polin, 194 F.3d 863 (7th Cir. 1999).
20. Schena, 142 F. 4th at 1224.
21. 51 F.3d 1390, 1398 (9th Cir. 1995)("mere encouragement would not violate the [AKS]").
22. *Id*. (internal quotations omitted).
23. *Id*. at 1224.
24. 194 F.3d 863 (7th Cir. 1999).
25. *See id*. at 865.
26. *See id*. at 866 (emphasis added).
27. 96 F.4th 818 (5th Cir. 2024).
28. *See* Marchetti at 827.
29. 360 F.3d 472 (5th Cir. 2004).
30. *See* Miles at 480.
31. *See id*. at 480-481.
32. 134 F.4th 493 (7th Cir. 2025).
33. *See id*. at 496.
34. 900 F.3d 405, 411 (7th Cir. 2018).
35. *See id*.
36. The court found that the blank prescription forms sent to the physicians were more akin to proposals for care rather than referrals. *See id.* at 502. The court emphasized that the marketers had no direct interaction with the physicians, i.e. no face-to-face contact, other than sending the forms.67. *See id*. at 502.
37. *See id*. at 501.
38. *See id*. at 502.
39. *See id*. at 504. The court distinguished marketing from advertising and found that the two marketing companies provided only advertising services. *See id.* at 501.
40. *See, e.g.,* Ga. Code Ann. § 26-5-80(b).

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