

Publications

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EKRA Gets Teeth: Ninth Circuit Strengthens EKRA Enforcement in Schena Ruling

Key Takeaways

- **First Appellate Interpretation of EKRA:** The Ninth Circuit's decision in *United States v. Schena* marks the first appellate court interpretation of the Eliminating Kickbacks in Recovery Act (EKRA), affirming that the statute applies beyond traditional payors to include private insurers.
- **Scope of EKRA Includes Marketing Intermediaries:** The Court held that EKRA is not limited to payments made directly to referring physicians; it also covers payments to third-party marketers who indirectly influence patient referrals, broadening the statute's reach.
- **Fraudulent Conduct Triggers EKRA Violations:** While percentage-based compensation alone does not automatically violate EKRA, the Court clarified that such arrangements become unlawful when tied to misleading or fraudulent efforts to induce referrals.

On July 11, 2025, the Ninth Circuit Court of Appeals delivered a decision in the case of *United States v. Schena*, marking its first interpretation of the EKRA. This 2018 federal statute specifically targets health care fraud in the laboratory, recovery home, and clinical treatment settings. In *Schena*, the Ninth Circuit affirmed the criminal conviction of a laboratory operator who made payments to marketing intermediaries in return for referrals for allergy tests.¹

Mark Schena operated Arrayit, a medical testing laboratory in Northern California that conducted clinical diagnostics, specifically allergy blood tests that could test up to 120 allergens. Despite blood tests typically being a secondary measure, Schena marketed his as "superior" and often unnecessarily tested for the full 120 allergens. To maintain a steady flow of patients, Schena hired marketers on a revenue-based percentage compensation plan to pitch Arrayit's services. The marketers targeted "naïve" doctors who lacked allergy experience (such as chiropractors and naturopaths) and made misleading statements about the accuracy of Arrayit's tests. In 2020, during the COVID-19 pandemic, Arrayit's testing volume fell significantly, so Schena transitioned to COVID testing. Schena had marketers promote Arrayit's COVID test as equal or superior to PCR tests and had them bundle allergy tests with the COVID tests. Even if a patient only requested a COVID

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test, Arrayit would often run and bill for the allergy test anyway. Ultimately, Arrayit billed more than \$77 million over a three-year period, though only \$2.7 million of those claims were reimbursed. Schena was charged with several counts, including a violation of EKRA.

Schena moved to dismiss the EKRA counts, arguing that he did not violate EKRA because the percentage payments were made to marketers, and not to the referring physicians. The district court denied the motion, and the Ninth Circuit affirmed. In its opinion, the Court stated that EKRA does not require payments to be made to the person interfacing directly with patients and thus covers intermediary marketers. Nothing in EKRA, the Court stated, limits the scope to payments made to people who have the authority to refer or otherwise interface with patients. And, “[w]hile it is true that the doctors’ offices to whom a marketer pitches services to are not ‘individuals’ under the statute, a third-party such as a marketer could still induce a patient referral through a doctor or other medical professional.” Plus, EKRA does not impose a requirement that the recipient of the remuneration directly interact with an individual patient.²

Regarding the connection between the payments and the goal of obtaining referrals, the Court opined that if a payment is made directly to the person making the referral, then such a payment is unlawful under the EKRA. In cases like Schena’s, where the payment was made to a marketing agent, the Court concluded that percentage-based compensation, without more, does not violate the EKRA. However, as was the case in *Schena*, when there is evidence that the defendant paid “remuneration to a marketing agent to have him unduly influence doctors’ referrals through false or fraudulent representations about the covered medical services,” a violation has occurred. Based on the context provided by the Anti-Kickback Statute, the Court stated that the term “induce” implies wrongful causation and the intent to exercise undue influence over the reason of another.

There have not been many cases interpreting or applying EKRA, but the Ninth Circuit’s opinion in *Schena* sets a binding precedent that indirect referral schemes can be found to be a violation under the statute. The Ninth Circuit has opened the door to a broader view of the statute and thus the potential for increased enforcement under the EKRA in addition to other health care fraud statutes. This decision underscores the importance for health care organizations to reassess their compliance practices and review sales and marketing arrangements.

Polsinelli’s Government Investigations attorneys have extensive experience advising on health care compliance and are prepared to assist with any related compliance matter or any potential enforcement action.

[1] Eliminating Kickbacks in Recovery Act of 2018, 18 U.S.C. §229. Notably, unlike other fraud and abuse provisions, the scope of payors to which EKRA applies includes private payors. Additionally, unlike the Anti-Kickback Statute’s broad safe harbor for bona fide W-2 employees, under EKRA, payments to W-2 employees and independent contractors are protected *only* if the payment is not determined by or does not vary by the number of individuals referred, the number of tests or procedures performed, or the amount billed or received from a health care benefit program for referred individuals.

[2] The Ninth Circuit noted that it disagreed with the district court’s opinion in the *S&G Hawaii, LLC v. Graves* case, where the district court interpreted EKRA as requiring interfacing with the patients ultimately being served. *S&G Labs Hawaii, LLC v. Graves*, Case No. 24-823 (9th Cir., July 11, 2025), <https://cdn.ca9.uscourts.gov/datastore/memoranda/2025/07/11/24-823.pdf>. The Ninth Circuit issued the *Graves* opinion in coordination with *Schena*; however, the Court

ultimately concluded there was not an EKRA violation in *Graves* because S&G only showed Graves implemented a percentage-based compensation structure without more illicit conduct beyond that.