

# THE JOURNAL OF FEDERAL AGENCY ACTION

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Victoria Prusen Spears

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# EKRA Heats Up: What U.S. Laboratories and Investors Need to Know

Jennifer Csik Hutchens, Mara Cusker Gonzalez, Sozi Pedro Tulante, Clare Putnam Pozos, and Lindsay N. Zanello\*

*In this article, the authors explain that while the U.S. federal government continues to prioritize healthcare fraud enforcement, the year also brought the first appellate ruling involving the Eliminating Kickbacks in Recovery Act, which scrutinized certain referral practices by a medical testing laboratory.*

Healthcare fraud enforcement remains a top priority of the current Trump administration, with federal agencies ramping up efforts around healthcare fraud and abuse. Notable recent developments include:

- In May 2025, the U.S. Department of Justice (DOJ) unveiled its White-Collar Enforcement Plan, noting, among other things, the continued investigation and prosecution of healthcare fraud.<sup>1</sup>
- In June 2025, the DOJ and other federal agencies reported that the 2025 National Health Care Fraud Takedown brought charges against 324 defendants linked to over \$14.6 billion in alleged fraud schemes, marking one of the largest crackdowns in recent years.<sup>2</sup> Prosecutions involving the federal Eliminating Kickbacks in Recovery Act (EKRA)<sup>3</sup> were included among the charges.
- In July 2025, the DOJ and the U.S. Department of Health and Human Services (HHS) reinvigorated the DOJ-HHS False Claims Act Working Group, signaling a renewed commitment to tackling issues like drug pricing and service fee arrangements, kickbacks, and materially defective medical devices, with an emphasis on collaboration among federal agencies and targeted enforcement.<sup>4</sup>

The focus on healthcare fraud enforcement by federal agencies marks a salient time for private equity, strategics, and other

investors in the healthcare sector—one that rewards informed, proactive engagement. Recent False Claims Act (FCA)<sup>5</sup> matters show that investors with direct operational involvement and actual knowledge of portfolio company misconduct can face increased scrutiny and lawsuits.<sup>6</sup> Even absent direct knowledge, enforcement activity at a portfolio company can have downstream effects for investors, such as reputational harm, legal costs, and financial losses. But with thoughtful structuring, targeted diligence, and proper compliance oversight, investors can pursue opportunities with confidence.

## **The U.S. Government's Approach to Anti-Kickback Enforcement**

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Because the federal government remains focused on investigating and prosecuting kickbacks in healthcare, laboratories and investors should be familiar with the robust set of tools used by the DOJ, including the FCA, the federal Anti-Kickback Statute (AKS),<sup>7</sup> and EKRA. The FCA, enacted in 1863, holds individuals and companies liable for knowingly defrauding the government by submitting false claims for payment. The AKS, adopted as part of the Social Security Amendments of 1972, prohibits remuneration intended to induce services covered by federal healthcare programs and has long been a cornerstone of enforcement. AKS violations can also give rise to FCA claims. During the past five years, EKRA has become part of the DOJ's toolkit for scrutinizing certain referral practices in healthcare, with a particular focus on medical testing laboratories, clinical treatment facilities, and recovery homes.

## **EKRA: Evolving Enforcement Landscape**

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Enacted in 2018 as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), EKRA prohibits the knowing and willful solicitation, receipt, or payment of kickbacks in exchange for referrals to recovery homes, clinical treatment facilities, or medical testing laboratories, regardless of whether the services are reimbursed by federal healthcare programs or private

payors.<sup>8</sup> This broad scope distinguishes EKRA from AKS, which is limited to federal healthcare programs.

Violations of EKRA carry significant penalties, including up to 10 years in prison and fines of up to \$200,000 per violation. EKRA has safe harbor provisions regarding payments to employees or independent contractors, but they are more limited in scope than AKS's safe harbors.<sup>9</sup> In particular, EKRA currently recognizes seven statutory safe harbors and no regulatory safe harbors. The safe harbors cover properly disclosed price discounts, non-referral-based employee compensation, Part D drug discounts, AKS-compliant personal services payments, nonroutine coinsurance/copay waivers, payments to federally qualified health centers, and payments under defined or approved alternative payment models. The statute also includes a "preemption" provision stating that EKRA does "not apply to conduct that is prohibited" under AKS.<sup>10</sup> On the other hand, conduct protected by an AKS safe harbor (and not included in the safe harbor provisions of EKRA) could be subject to EKRA. For example, AKS broadly protects payments to bona fide employees, whereas EKRA's employment safe harbor is narrower and imposes additional conditions, protecting only compensation that does not vary with referral volume, making some arrangements that are protected under AKS potentially risky under EKRA.

Although EKRA was initially enacted to help combat the opioid abuse crisis, recent cases signal that the DOJ is broadening EKRA enforcement beyond the opioid and addiction treatment space to a broader area of diagnostic testing and laboratory activities. For example, in 2021, the owner and operator of a diagnostic testing laboratory in Louisiana enrolled in federal and private healthcare benefit programs was charged with AKS, EKRA, and other healthcare-related violations for soliciting and accepting kickbacks in return for urine specimen referrals for medically unnecessary testing and offering to pay kickbacks for COVID-19 and respiratory pathogen testing referrals.<sup>11</sup>

Despite being in effect since 2018, case law interpreting EKRA remains limited, likely because of its narrower scope, overlap with the better-established AKS, and initial legal uncertainty. However, prosecutions have begun to increase. Importantly, a recent decision by the U.S. Court of Appeals for the Ninth Circuit decision has provided greater clarity on the law.

## Key Takeaways from the Ninth Circuit’s Decision In *Schena*

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In *United States v. Schena*,<sup>12</sup> the Ninth Circuit became the first appellate court to address the reach of EKRA. The decision marks a significant step in defining EKRA’s boundaries and enforcement standards, including as they relate to the dynamics between testing laboratories and their marketing and sales teams. In particular, the decision offers useful guidance to laboratories on how sales, marketing, and referral arrangements will be evaluated, and laboratories and investors should consider EKRA safe harbors when structuring compensation arrangements.

The Ninth Circuit upheld the conviction of Mark Schena, a laboratory executive and operator of a medical testing laboratory, on nine counts of healthcare and securities fraud, including two EKRA violations based on commission-based payments to marketing agents tied to referred testing revenue and misleading claims promoting allergy and COVID-19 antibody tests and bundled offerings.<sup>13</sup> Schena received a 96-month sentence and was ordered to pay more than \$24 million in restitution.<sup>14</sup>

Notably, the court clarified that EKRA applies not only to healthcare providers but also to marketers involved in illegal referral schemes even without direct patient contact.<sup>15</sup> The court drew on AKS case law to interpret EKRA, signaling that established principles under the AKS may inform EKRA enforcement.<sup>16</sup> Importantly, the court held that percentage-based compensation is not a *per se* violation of EKRA, underscoring the need for a fact-specific analysis in each case.<sup>17</sup> Although undefined in the statute, the court clarified that “the term ‘induce’ connotes not mere causation, but wrongful causation,” and requires “undue influence” as opposed to just “influence” or encouragement.<sup>18</sup>

The court left it to future cases “to give content to the specific circumstances in which payments to a marketing agent reflect a wrongful effort to unduly influence the decisions of doctors and medical professionals making referrals,” but suggested that “companies and marketing agents seeking to steer clear of EKRA may consider whether it is preferable to structure their compensation arrangements in accordance with [EKRA’s] safe harbor.”<sup>19</sup> While *Schena* is binding only on the district courts within the Ninth Circuit, courts in other jurisdictions may find this decision persuasive.

## EKRA Considerations for Laboratories and Investors

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As the government continues to prioritize healthcare fraud investigations, we may see more cases addressing EKRA's boundaries, including in connection with laboratories, particularly as the DOJ and other federal agencies broaden EKRA prosecutions beyond addiction treatment.

Given the Ninth Circuit's guidance in *Schena*, to mitigate risk, companies should consider:

- Proactively reviewing their compensation structures and marketing materials;
- Aligning compensation and referral arrangements with EKRA's safe harbor provisions; and
- Adopting more robust compliance programs to address potential vulnerabilities in referral and payment arrangements.

Similarly, private equity firms, strategics, and other investors in laboratories should:

- Conduct thorough due diligence on targets and portfolio companies;
- Assess laboratories' compliance with EKRA and other healthcare statutes; and
- Establish oversight mechanisms to reduce exposure to regulatory enforcement and liability.

## Notes

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1. Memorandum from Matthew R. Galeotti, Head of Crim. Div., U.S. Dep't of Just. on Focus, Fairness, and Efficiency in the Fight Against White-Collar Crime to All Criminal Division Personnel 4 (May 12, 2025), <https://www.justice.gov/criminal/media/1400046/dl?inline>.

2. Press Release, U.S. Dep't of Justice, National Health Care Fraud Takedown Results in 324 Defendants Charged in Connection with Over \$14.6 Billion in Alleged Fraud Schemes (June 30, 2025), <https://www.justice>

.gov/opa/pr/national-health-care-fraud-takedown-results-324-defendants-charged-connection-over-146. By comparison, the 2023 National Health Care Fraud Takedown resulted in charges against 78 defendants committing more than \$2.5 billion in alleged fraud and the 2024 National Health Care Fraud Takedown charged 193 defendants with over \$2.5 billion in alleged fraud. See Press Release, U.S. Dep’t of Justice, National Enforcement Action Results in 78 Individuals Charged for \$2.5B in Health Care Fraud (June 28 2023), <https://www.justice.gov/archives/opa/pr/national-enforcement-action-results-78-individuals-charged-25b-health-care-fraud>; Press Release, U.S. Dep’t of Justice, National Health Care Fraud Enforcement Action Results in 193 Defendants Charged and Over \$2.75 Billion in False Claims (June 27, 2024), <https://www.justice.gov/archives/opa/pr/national-health-care-fraud-enforcement-action-results-193-defendants-charged-and-over-275-0>.

3. 18 U.S.C. § 220.
4. Press Release, U.S. Dep’t of Justice, DOJ-HHS False Claims Act Working Group (July 2, 2025), <https://www.justice.gov/opa/pr/doj-hhs-false-claims-act-working-group>.
5. 31 U.S.C. §§ 3729-3733.
6. See Hannah-Alise Rogers & Alexander H. Pepper, Cong. Rsch. Serv., LSB11215, Private Equity Investments in Health Care: Selected Enforcement Issues 4-5 (2024), [https://www.congress.gov/crs\\_external\\_products/LSB/PDF/LSB11215/LSB11215.1.pdf](https://www.congress.gov/crs_external_products/LSB/PDF/LSB11215/LSB11215.1.pdf) (discussing U.S. and Commonwealth of Massachusetts ex rel. Martino-Fleming v. South Bay Mental Health Centers).
7. 42 U.S.C. § 1320a-7b(b).
8. 18 U.S.C. § 220.
9. 18 U.S.C. § 220(b).
10. 18 U.S.C. § 220(d)(1).
11. Indictment, United States v. Lepetich, No. 3:21-cr-00032-SDD-SDJ (M.D. La. May 20, 2021); Press Release, U.S. Dep’t of Justice, DOJ Announces Coordinated Law Enforcement Action to Combat Health Care Fraud Related to COVID-19 (May 26, 2021), <https://www.justice.gov/archives/opa/pr/doj-announces-coordinated-law-enforcement-action-combat-health-care-fraud-related-covid-19>. The defendant ultimately pled guilty to the conspiracy-related charges and the remaining charges, including the EKRA violations, were dismissed. Judgment, United States v. Lepetich, No. 3:21-cr-00032-SDD-SDJ (M.D. La. March, 22, 2024).
12. United States v. Schena, 142 F.4th 1217 (9th Cir. 2025), petition for cert. filed (U.S. Oct. 9, 2025) (No. 25-447).
13. *Id.* at 1219-20.
14. *Id.* at 1221. By separate order, the Ninth Circuit affirmed the restitution award for the healthcare fraud violations, but it vacated and remanded for redetermination of the award for the securities fraud violations. See United States v. Schena, 2025 WL 1918267, at \*4 (9th Cir. July 11, 2025).
15. *Id.* at 1222-23.

16. Id. at 1223-25.
17. Id. at 1225.
18. Id. at 1224.
19. Id. at 1225.