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Healthcare Compliance Series

Labs & Substance Abuse Providers: EKRA Enforcement Update

Presenters

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Traditional Disclaimers

- This presentation does not constitute legal advice and you cannot rely on it as such.
- If you would like legal advice, a formal engagement is required and individualized advice is provided.

EKRA Background

- In 2018, Congress passed EKRA as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act.
- Similar to the Antikickback Statute (AKS), EKRA imposes criminal penalties for knowing or willful payment of kickbacks to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory - unless a specific exception applies.
- Unlike the AKS, EKRA is an ALL PAYOR STATUTE.
- Although it was enacted in response to the opioid epidemic and to address related misconduct, the inclusion of referrals to laboratories – with no limitation on the type of test or referral source – means that EKRA’s application is **not** limited to substance abuse matters.
- Enforcement actions under EKRA have included areas such as COVID-19 fraud, allergy testing, and genetic testing.

Statutory Language – Prohibited Conduct

Whoever, with respect to services covered by a health care benefit program . . . knowingly and willfully-

- (1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or
- (2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind-
 - (A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
 - (B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory,

Shall be fined not more than \$200,000, imprisoned not more than 10 years, or both, for each occurrence. 18 U.S.C. § 220(a).

Relevant Exceptions to EKRA Liability

- There are seven (7) defined exceptions to EKRA.
- Exceptions not covered today but could be applicable to you: discounts, coinsurance waivers, FQHC, alternative payment model.
- **Most Relevant/Created Most Havoc:**
 - **Compensation Exception** - a payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by—
 - ▶ the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;
 - ▶ the number of tests or procedures performed; or
 - ▶ the amount billed to or received from a health care benefit program;
 - **Personal Services/Management Agreements**: ties in the AKS safe harbor – BUT *only as in effect on the date of enactment of this section and comp based on volume or value prohibited*. No ability to try and use potential benefits of the AKS revisions to this section.

Compensation Exception Issues

- Most laboratories compensate sales / marketing representatives (at least in part) based on a percentage of collections (*i.e.*, the volume or value of referrals).
- Laboratories relied on AKS “Employment” Safe Harbor to support variable compensation:
 - “Remuneration” does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
 - Potential issues with that reliance.
 - Independent Contractor Sales / Marketers – obviously not covered by the employment safe harbor.
- EKRA – upended the ability of laboratories to rely on the AKS Employment Safe Harbor.

Initial Climate Post EKRA

- Laboratories stand firm with little to no adjustment to compensation structure.
- Initial belief that lobbying efforts to amend the law would be successful.
- Hopes were dashed with administration changes.
- “Safety in numbers” mindset.
- Laboratories report unwillingness of sales / marketing reps to agree to change compensation models – fear of losing reps to other labs who maintain status quo.
- No published guidance from the government on EKRA and its application.
- No court opinions.
- Little enforcement activity.

First Court Decision is Lab/Provider Friendly

S&G LABS HAWAII, v. Graves – U.S. District Ct., D. Hawaii Oct. 18, 2021 (2021 WL 4847430).

- Dispute over account manager’s compensation under employment contract. The employment contract provided the account manager a base salary and a percentage of net profit from his own client accounts and from the client accounts managed by the employees that he managed.
- Government not a party to the case.
- Ruling: Payment structure did not violate EKRA.
 - Court said critical issue is whether remuneration was “to induce a referral of an individual.”
 - “Client” accounts serviced were not “individuals” whose samples were tested at the lab.
 - “Clients” were “the physicians, substance abuse counseling centers, or other organizations in need of having persons tested.”
 - Lab was not compensated by those “clients” but on a “per test” basis by third party payors or the individuals.
 - No evidence that manager’s client accounts included individuals who self-paid the lab.
 - Because manager was not working with individuals, the compensation that lab paid him was not paid to induce him to refer “individuals” to lab – EKRA not apply.
 - Because EKRA not apply – Court did not have to consider EKRA Employee Exception.

US v. Schena – Court Rejects S&G Labs Court Decision

U.S. v. Schena, 2022 WL 1720083, 5:20-cr-00425-EJD-1 (N.D. Cal. May. 28, 2022)

- Defendant charged with two counts relating to alleged violations of EKRA and one count of a conspiracy to violate the same statute (*Note: Allergy & COVID Testing!*).
- Defendant filed Motion to Dismiss charges based on the S&G Labs decision.
- The Court denied the motion and rejected the decision in S&G Labs:
 - The plain meaning of the language “to induce” in the EKRA statute, includes indirect efforts by marketers to obtain patient referrals through recruiting physicians.
 - There is no requirement in the EKRA statute that a marketer needs to directly obtain individual patients. A marketer working with physicians who then bring forth referrals is a violation of the statute.
 - EKRA’s safe harbor does not extend to payments made to marketing employees who market to physicians.



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EKRA INVESTIGATIONS AND ENFORCEMENT ACTIONS CONTINUE TO GROW

US v. Schena – Allergy Testing - Criminal Conviction after Trial

- Schena served as the president of Arrayit Corporation. Schena allegedly engaged in a scheme to defraud Arrayit's investors by claiming that he had invented revolutionary technology to test for virtually any disease using only a few drops of blood (we are already far from substance abuse).
- Schena convicted of setting up illegal kickback / health care fraud scheme involving submission of fraudulent claims to Medicare and private insurance for unnecessary allergy testing.
- In order to obtain patient blood specimens, Schena paid kickbacks to marketers (percentage based compensation) in violation of EKRA. Arrayit billed more per patient to Medicare for blood-based allergy testing than any other laboratory in the United States, the evidence at trial showed, and billed some commercial insurers over \$10,000 per test.
- A federal jury convicted Schena on one count of conspiracy to commit health care fraud and conspiracy to commit wire fraud, two counts of health care fraud, one count of conspiracy to pay kickbacks, two counts of payment of kickbacks, and three counts of securities fraud.

US v. Genotox - Settlement – March 30, 2023

- Genotox Laboratories agrees to pay \$5.9M for AKS and EKRA violations – Whistleblower FCA Case.
- Genotox paid commissions to third party marketers and marketing firms based on the volume/value of referrals.
 - Genotox paid 1099 reps almost exclusively on a percentage basis.
 - It “executed contracts in which it committed to pay 1099 representatives a percentage of total revenue associated with medical provider accounts for which each 1099 representative was responsible.”
 - The revenue used to calculate the commission payment was the revenue realized from billings to insurers, including Medicare, TRICARE, and RRB, for services Genotox provided to healthcare providers and patients, including UDT. That revenue was dependent both upon the volume of tests ordered and the type of tests or test panels ordered.
 - Genotox worked to change compensation after EKRA was enacted but was not fully compliant.
 - When it moved to fixed compensation – Genotox tracked and compared the flat rate to the prior percentage based compensation – one purpose was for renegotiation of the flat fee.
 - YOU CANNOT “TRUE-UP” or USE PERCENTAGES AS A METHOD FOR CALCULATING FIXED COMPENSATION.

US v. Lepetich- UDT & COVID-19 Testing

- Nationwide takedown: criminal charges against 14 defendants in seven federal districts across the United States for their alleged participation in various health care fraud schemes that exploited the COVID-19 pandemic and resulted in over \$143 million in false billings.
- Lepetich was charged for an alleged \$15 million scheme to commit health care fraud, to defraud the United States, and to pay and receive health care kickbacks.
- Lepetich, owned MedLogic, LLC, a clinical laboratory allegedly solicited and received kickbacks in exchange for referrals of urine specimens for medically unnecessary testing.
- Lepetich also allegedly offered to pay kickbacks for referrals of specimens for COVID-19 and respiratory pathogen testing.
- Lepetich allegedly caused the submission of over \$10 million in claims to Medicare, Medicaid, and Blue Cross Blue Shield of Louisiana for panels of expensive respiratory testing that was medically unnecessary.
- Last month, filings indicate Lepetich intends to plead guilty.

US v. Mohammed – Patient Brokering

- Dr. Akikur Mohammad of California, sentenced to 15 months for role in patient brokering scheme.
- Dr. Mohammad pleaded guilty, to an information charging him with one count of conspiracy to violate the Eliminating Kickbacks in Recovery Act (EKRA).
- A number of conspirators owned and operated a marketing company in California.
- Marketing companies were used to orchestrate schemes in New Jersey, Maryland, California, and other states involved bribing individuals addicted to heroin and other drugs to enter into drug rehabilitation centers, generating fees from those facilities.
- One facility in California that paid such referral fees was owned and operated by Mohammad.
- Dr. Mohammad's facility and other facilities typically paid the marketing company a fee of \$5,000 to \$10,000 per patient referral.

US v. Merced

- Defendant was the office manager of a substance abuse treatment clinic.
- Between December 2018 and August 2019, she solicited kickbacks from the CEO of a toxicology lab in exchange for urine drug test referrals.
- Merced was paid by lab for sending urine samples to the lab.
- Plead guilty under EKRA.

US v. Ruiz, Frank and Licata: Genetic & COVID-19/Respiratory Tests

- Charged for an alleged \$9.3 million health care kickback scheme.
- EKRA not charged – but could have been
- Licata, owner of the lab Boca Toxicology, LLC, allegedly offered and paid kickbacks to patient brokers, including Ruiz and Frank, in exchange for referring Medicare beneficiaries to his lab for genetic testing and other laboratory testing that they did not need
- Allegations include submission of \$422,748 in claims related to medically unnecessary respiratory pathogen panel testing and genetic testing that was improperly bundled with COVID-19 testing.
- Licata: Plead Guilty - 78 Months - Restitution: \$2,831,632.00
- Eric Frank – 24 Months
- Juan Nava Ruiz - 22 months



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Potential Solutions

Trends in the Cases and What it Means for Sales / Marketing

- Reviewing the cases that are public and understanding what is being investigated, what trends do we see?
 - Compensation focus seems to be on independent contractor relationship
 - Traditional kickbacks being paid
 - Overutilization of tests/medical necessity issues
 - But now - Genotox ...
- So what does this mean for providers and marketers / sales reps?
 - Get rid of all independent contractor relationships – or have counsel prepare compliant fixed fee arrangements meeting applicable EKRA and AKS exceptions/safe harbors.
 - Should all be bona fide employees.
 - Compensation structures need to be changed – and marketing reps need to get on board.

Compensation and the Use of Different Benchmarks / Metrics

- Start with traditional salary - cannot be based on past percentage based compensation.
 - Do NOT track past percentage vs. salary going forward for purposes of renegotiation.
- You can still provide bonus/variable compensation – (not tied to the volume or value of referrals).
- Potential Metrics:
 - Set targets for marketing to potential (and material) new clients or different lines of business to existing clients.
 - Consider provide greater weight to type of client and patient population.
 - Territory expansion.
 - Conduct education and training at clients about compliant ordering and complying with payor requirements and standards (limiting panels, correct DX codes).
 - Identifying problem clients and conducting focused visits to address reoccurring issues and increase clean claims (e.g., clients who consistently fail to input DX codes, fail to sign requisitions, missing demographic for patients).
 - Maintaining (and not losing accounts) – benchmarks for number of service calls to clients to maintain relationships.
 - Retention bonus graded by years with the company.
 - Discretionary year-end bonus that is within the developed bonus structure for all employees.



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THANK YOU!

Thank you for joining us.

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