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EKRA and the Anti-Kickback Statute: Healthcare compliance and risk

by Gabriel Imperato, Esq.

The Eliminating Kickbacks in Recovery Act (EKRA) was enacted rather surprisingly in 2018 and is an obvious overlay of the prohibitions already existing in the Anti-Kickback Statue (AKS), at least as applied to the recovery and laboratory healthcare industries.[1] There has been considerable confusion about the interplay between EKRA and AKS. This article attempts to make some sense of the application of EKRA and AKS to common healthcare referral and payment relationships.

The relevant content of the EKRA Statute prohibits whoever "pays or offers any remuneration":

> "To induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
>
> "In exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory."

This EKRA prohibition does not apply to:

> "(2) 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–
>
> "(A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;
>
> "(B) the number of tests or procedures performed; or
>
> "(C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory."

Notably, there has been only a hand full of identified EKRA criminal enforcement cases (publicized by the U.S. Department of Justice) which have all been based on direct remuneration to a referral source in return for the referral of business. The decision in *S&G Labs Hawaii, LLC v. Graves* was the first of two district court opinions that have interpreted and applied the EKRA statutory provisions to sales and marketing arrangements.[2] The S&G

Labs case held that compensation to the employee (Graves) was "remuneration" under the EKRA Statute; however, the statutory provision prohibited remuneration ". . . to induce a referral of an individual to . . ." the laboratory. The court went on to find that the employee clients were ". . . the physicians, substance abuse counseling centers, or other organizations in need of having persons tested," and there was ". . . no evidence that Graves's client accounts included individuals who self-paid for S&G to perform urinalysis on their samples." Accordingly, the court concluded that since "Graves was not working with individuals, the compensation that S&G paid him was not paid to induce him to refer individuals to S&G"; therefore, the compensation to Graves under his employment agreement did not violate EKRA. The later decision in *United States v. Schena* also applied the EKRA statutory prohibitions to employees of a laboratory engaged in sales and marketing activity and held that: