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Eliminating Kickbacks in Recovery Act: What In-Office Laboratories Need to Know

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To combat the effects of declining reimbursement levels, many physicians and practice groups offer ancillary services to improve patient care and supplement practice revenues. The delivery of these ancillary services, such as laboratory services, is generally made possible by the in-office ancillary services exception found at 42 C.F.R. §411.355(b) (the In-Office Exception) to the Ethics in Patient Referrals Act (the Stark Law).[i] However, the recent passage of the Eliminating Kickbacks in Recovery Act (EKRA),[ii] which directly impacts the profitability of the laboratory industry, has in-office laboratories concerned that their operations may suffer as well. However, as long as these in-office laboratories follow certain guidelines when contracting with outside contractors and employees, EKRA's impact upon them may be minimal.

Client Familiarity:

For the purposes of this article, an "in-office laboratory" is any laboratory owned and operated by, and located at the same location as, the medical practice it exclusively serves. Medical providers who operate in-office laboratories are typically very familiar with the better-known federal laws, such as the Stark Law and the federal Anti-Kickback Statute that regulate their operation, as the feasibility of their practice model relies upon a strong understanding of these statutes.[iii] However, due to its recent passage, EKRA is not as well understood among medical practices operating in-office laboratories, and recent enforcement trends have raised concerns and questions among practitioners and their clients.

EKRA at a Glance:

EKRA was enacted in 2018 as a component of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).[iv] EKRA makes it a federal crime for anyone, with respect to services covered by a health care benefit program, to "knowingly and willfully (1) solicit[] or receive[] any remuneration… directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to… a laboratory, or (2) pay[] or offer[] any remuneration… directly or indirectly, overtly or covertly, in cash or in kind (A) to induce a referral of an individual to a… laboratory or (B) in exchange for an individual using the services of that … laboratory."[v] Violators can "be fined not more than $200,000, imprisoned not more than 10 years, or both, for each occurrence."[vi] Similar to the Anti-Kickback Statute, EKRA requires proof of "knowing and willful" intent of the unlawful behavior and is not a strict liability statute, like the Stark Law.

In years past, stand-alone laboratories (i.e., those not immediately located within a medical practice) sometimes contracted with outside consultants to help drive referrals of specimens to increase revenue. Many of these arrangements risked running afoul of the Anti-Kickback Statute, and the U.S. Department of Justice (DOJ) has an active history of enforcement actions involving such referral schemes. Even under facts where these schemes may have at one point been permissible, the plain language of EKRA now prohibits this practice.

In contrast, in-office laboratories generally only test specimens that are provided by the medical practice in which they are located. As such, EKRA may not be on their immediate radar. Therefore, legal counsel should ensure providers with in-office laboratories are aware of EKRA, as recent enforcement actions, testing trends during the COVID-19 pandemic, and a plain reading of the statute suggests in-office laboratories are also subject to the statute's prohibitions.

What EKRA Covers:

Unlike many federal fraud and abuse statutes, EKRA's prohibitions are applicable to services covered by any "health care benefit program," including those offered by private payors.[vii] The statute expressly adopts this definition from 18 U.S.C. § 24(b), and covers "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract."[viii] Therefore, EKRA's reach is broader than the Anti-Kickback Statute and Stark Law, which only govern federal health care programs like Medicare and Medicaid.[ix]

EKRA's reach also extends beyond large-scale laboratory operations. EKRA derives its definition of "laboratory" directly from 42 U.S.C. § 263a,[x] which defines the term "laboratory" or "clinical laboratory" as "a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."[xi] This broad definition covers laboratories of all types and sizes, including the often smaller in-office laboratories operated by medical practices and providers.

Conflicts and Preemption:

Congress' ambiguous phrasing within the preemption section of the statute opened the door to numerous questions by both experts and providers regarding its scope and interaction with other federal and state health care laws. Section 220(d)(1) of EKRA, which deals with preemption of EKRA by federal law, states that it does "not apply to conduct that is prohibited under" the Anti-Kickback Statute.[xii] Many experts speculate Congress intended to use the term "not prohibited" instead of "prohibited" to bring the two laws into alignment.

If the current phrasing of Section 220(d)(1) was intentional, it is unclear whether Congress merely intended to limit the scope of EKRA so that it would either prevent (1) prosecutors from charging individuals under both Anti-Kickback Statute and EKRA for the same conduct, or (2) to limit enforcement of EKRA to activity involving non-federal payors where an Anti-Kickback Statute violation is also alleged. Regardless of the intent or potential error, the current phrasing is the only authority available at this time, and EKRA should therefore be considered to apply to arrangements otherwise permitted by the Anti-Kickback Statute.

State law preemption under EKRA is much clearer. Section 220(d)(2) of EKRA plainly states "[n]othing in this section shall be construed to occupy the field in which any provisions of this section operate to the exclusion of State laws on the same subject matter."[xiii] Meaning Congress did not intend EKRA to operate to the exclusion of any state laws, and states are free to pass and enforce laws that are more restrictive than their federal counterpart.

EKRA Safe Harbors:

EKRA provides statutory safe harbors similar to the statutory and regulatory safe harbors for the Anti-Kickback Statute. The main difference is that EKRA is limited to only eight, compared to the much lengthier 37 listed in the Anti-Kickback Statute. EKRA's safe harbors include exceptions for (1) properly disclosed discounts or reductions under a health care benefit program, (2) payments made to bona fide employees or independent contractors that are unaffected by patient referral volume, (3) Medicare coverage gap discounts, (4) personal services and management contracts that meet the requirements of the safe harbor to the Anti-Kickback Statute, (5) good faith waivers or discounts by a health care benefit programs, (6) permissive safe harbors for remunerations as listed within the Anti-Kickback Statute, (7) remunerations made pursuant to an alternative payment model or as deemed necessary by the Secretary of the U.S. Department of Health and Human Services (HHS), and (8) any other exceptions as determined by the Attorney General in consultation with HHS.[xiv]

Special attention should be paid to the EKRA safe harbor located at § 220(b)(2) which states that:

"(b) APPLICABILITY. — Subsection (a) shall 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;"[xv]

Similar to EKRA, the Anti-Kickback Statute provides a safe harbor that protects "any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services."[xvi] HHS also promulgated a parallel regulatory safe harbor, which excludes such bona fide employment relationships from the definition of "remuneration."[xvii] In contrast, EKRA's employment safe harbor appears narrower and lists additional conditions that must be met for a bona fide employment relationship to qualify protection.[xviii] As further explained below, these additional criteria may have some impact on in-office laboratory operations and provide useful parameters when contracting with employees, independent contractors, and outside consultants.

Contracting with Outside Consultants:

Generally, medical providers with in-office laboratories rely on outside contractors to provide professional business

guidance, such as assistance with laboratory build out, credentialing, staffing, insurance reimbursement, equipment selection, computer software and support, and regulatory compliance. Although most of these services are provided at the in-office laboratory's earliest stages, additional contracted services may be provided by the contractors on an ongoing basis.

In-office laboratories and their legal counsel should still be mindful not to enter or approve of any agreement with any outside consultants that might reward the value or volume of referrals or take into account the amount of testing being performed, as this would potentially violate EKRA.[xix]

Employee Compensation:

Since in-office laboratories are usually exclusive to the medical practices they serve, there is typically no practical need to compensate employees for increasing the number of outside referrals to the laboratory. However, the COVID-19 pandemic resulted in an increase of applications for low-complexity CLIA Certificates of Waiver and a drastic spike in overall virus testing. It is now more common for medical providers, and their employees, to ask patients whether they would like to be tested for COVID-19, the seasonal flu, or other bacteria and viruses during visits, thus yielding more referrals for laboratory testing. This begs the question: does connecting employee compensation to the revenue yielded from this testing violate EKRA? Recent federal cases indicate that it may.

In *S&G Labs Hawaii, LLC v. Graves*, No. 1:19-cv-310, 2021 WL 4847430 (D. Haw. Oct. 18, 2021), a wrongful termination case, the court held there was a difference between direct and indirect referrals, and that EKRA only prohibited the former.[xx] In *S&G*, the defendant was employed as a manager of a lab and overseeing physician client accounts, where he received a base salary plus a percentage of the monthly net profits generated by his own accounts and those handled by the employees he managed.[xxi] The court held that because these "clients" were physicians and medical practices, the compensation induced him to bring in more business from the providers (indirect referrals) as opposed to referring individual patients (direct referrals).[xxii] Less than a year after this ruling, another court addressed and rejected this "requirement of 'directness.'"[xxiii]

In *USA v. Schena*, No. 5:20-cr-00425-EJD-1, 2022 WL 1720083 (N.D. Cal. May 28, 2022), a criminal case, the court rejected *S&G's* holding, and held that EKRA prohibits both direct and indirect referrals of patients.[xxiv] In *Schena*, the District Court reasoned that the court in *S&G* overlooked the statutory rules of construction and failed to give requisite weight to the plain meaning of the statute and the absence of any language requiring "a direct interaction between the marketer and the individual."[xxv] It further held that the plain meaning of "to induce a referral of an individual" within EKRA included both direct and indirect solicitations of patients [xxvi] Thus, there is no requirement of "directness" in the text of EKRA that would spare certain types of employee compensation arrangements that pay remuneration for the inducement of referrals.[xxvii]

In the context of in-office laboratories, where medical practice employees are often able to solicit laboratory referrals directly from patients, the holding in each federal case indicates that compensation arrangements that take into account the volume of any such referrals would be prohibited under EKRA. As an additional consideration, where the referring practice employees are physicians or their family members, the Stark Law contains its own group practice compensation exception that must be followed.[xxviii] Counsel should therefore consider whether to advise clients with in-office laboratories to pay a flat fee to W-2 employees, or whether any performance bonuses should be based on quality measures instead of the number of individual referrals, the

number of tests or procedures performed, or the amount billed to or received from health care benefit programs.[xxix]

Conclusion:

Attorneys for in-office laboratories should heed the plain reading of the statute when drafting compensation arrangements. As such, regardless of the employee or contractor's level of interaction with patients, such compensation arrangements should avoid considering the volume of referrals to or testing performed.

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[i] 42 U.S.C. § 1395nn and 42 C.F.R. §411.355(b).

[ii] 8 U.S.C. § 220.

[iii] 42 U.S.C. § 1320a-7b(b).

[iv] PL 115-271, October 24, 2018, 132 Stat 3894 (SUPPORT Act).

[v] 18 U.S.C. § 220(a).

[vi] *Id.*

[vii] *Id.*

[viii] 18 U.S.C. § 24(b).

[ix] 18 U.S.C. § 220(e)(3).

[x] 18 U.S.C. § 220(e)(4).

[xi] 42 U.S.C. § 263(a).

[xii] 18 U.S.C. § 220(d)(1).

[xiii] 18 U.S.C. § 220(d)(2).

[xiv] 18 U.S.C. § 220(b).

[xv] 18 U.S.C. § 24(b)(2).

[xvi] 42 U.S.C. 1320a-7b(b)(3)(B).

[xvii] 42 CFR § 1001.952(i),

[xviii] 18 U.S.C. § 220(b).

[xix] 18 U.S.C. § 220(a).

[xx] *S&G Labs Hawaii, LLC v. Graves*, No. 1:19-cv-310, 2021 WL 4847430 (D. HI Oct. 18, 2021).

[xxi] *Id.*

[xxii] *Id.*

[xxiii] *USA v. Schena*, Case No. 5:20-cr-00425-EJD-1, 2022 WL 1720083 (N.D. Cal. May 28, 2022).

[xxiv] *Id.*

[xxv] *Id.*

[xxvi] *Id.*

[xxvii] *Id.*

[xxviii] 42 CFR 411.357(c).

[xxix] 18 U.S.C. § 24(b)(2).

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