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The Eliminating Kickbacks in Recovery Act: A Critical Analysis of an Altered Landscape for Financial Relationships with Clinical Laboratories

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I. Introduction

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the "SUPPORT Act"), passed at the end of October 2018, seeks to prohibit "patient brokering" practices by some recovery homes and treatment facilities. However, in so doing, the SUPPORT Act raises significant challenges and questions for all clinical laboratories, even those not involved in addiction recovery programs. Until Congress amends the law or the Department of Justice issues guidance, clinical laboratories must proceed into 2019 with caution, acknowledging that many if not most of their common arrangements – including ownership, employment, lease, purchasing, independent contracting – likely need to be revisited and may need to be restructured.

II. The SUPPORT ACT and the Eliminating Kickback in Recovery Act of 2018 ("EKRA")

A. EKRA's Prohibition

Section 1822 of the SUPPORT Act, signed into law and effective as of October 24, 2018, contains the "Eliminating Kickbacks in Recovery Act of 2018" ("EKRA"), now codified at 18 U.S.C. § 220. Although EKRA was created to address "patient brokering," the practice by recovery homes and treatment facilities of engaging third parties, or "body brokers," to recruit patients in exchange for kickbacks, *see, e.g.* Energy and Commerce Committee, "How the opioids bill could halt exploitation of addicted Americans" (Oct. 9, 2018), EKRA prohibits a much broader scope of conduct, stating that:

> "whoever, with respect to services covered by a health benefit program… knowingly and willfully (1) solicits or receives 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) pays or offers 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, shall be fined not more than $200,000, imprisoned not more than 10 years, or both, for each occurrence" (emphases added). 18 U.S.C. § 220(a).

Accordingly, EKRA on its face has implications for any financial relationship that a clinical laboratory has with an individual or legal entity that generates business for it.

B. EKRA's Breadth of Scope

Although EKRA's text is similar to the Federal health care program anti-kickback statute, 42 U.S.C. 1320-7b(b) (the "AKS"), it is much broader in scope for a number of reasons.

1. *EKRA Applies to Services Paid for by Any Payor*

First, because EKRA defines "laboratory" to include *any* CLIA-certified laboratory and further defines "health benefit program" to mean "any public or private plan or contract… under

which any medical benefit, item, or service is provided to any individual", EKRA is implicated by any financial relationship that any clinical laboratory may have with respect to services paid for *not just by government-funded plans*, but also by commercial insurance and even self-pay patients – virtually any business conducted by any clinical laboratory.

2. *EKRA Has Few Safe Harbors*

Second, as discussed in further detail below, EKRA contains only a scant list of seven (7) statutory safe harbors, whereas the AKS offers more than three dozen (37) statutory and regulatory safe harbors. As a matter of law, the AKS' safe harbors do not apply to EKRA and, as a matter of practicality, it is far from clear whether practitioners can interpret them as applicable. EKRA authorizes the Attorney General – not HHS-OIG – to promulgate regulatory safe harbors to EKRA.

3. *EKRA Disregards the AKS' Safe Harbors*

Third, subsection (d)(1) of EKRA addresses the law's relationship with the AKS, stating that EKRA "shall not apply to conduct that is prohibited" by the AKS. Read literally, this provision does little to limit the scope of conduct prohibited by EKRA – rather, it seems simply to ensure that a person would not be charged under both the AKS *and* EKRA (since, if conduct were prohibited by the AKS, it could not create liability under EKRA but could, by definition, be pursued under the AKS). While subsection (d)(1) may have been intended to limit EKRA's scope to conduct related to services not payable by the Federal health care programs (since services payable by the Federal health care programs are subject to regulation by the AKS), as written, it does not have this effect. Importantly, conduct that is safe harbored under the terms of the AKS is, by definition, *not* prohibited by the AKS and is thus subject to EKRA. Therefore, the plain language of EKRA leads to the counter-intuitive conclusion that conduct that is safe harbored under the AKS can nevertheless create criminal liability under EKRA.

4. *EKRA Accommodates More Stringent State Kickback Laws*

Fourth, subsection (d)(2) of EKRA addresses the law's relationship with state laws "on the same subject matter", stating that nothing in EKRA "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." In other words, Congress does not intend that federal law exclusively establish the contours of criminally prohibited kickback arrangements for recovery homes, treatment facilities, or clinical laboratories. Instead, the states are free to continue to enforce or to enact more onerous laws limiting these types of arrangements. In particular, conduct could fall within one of EKRA's few safe harbors but still be a criminal offense under state law.

Subsection (d)(2) may have been a response to court decisions like the Florida Supreme Court opinion in *State v. Harden*, 938 So.2d 480 (Fla. 2006). In *Harden*, the Court found that a Florida state law criminalizing kickback arrangements could not be enforced because it: (1) imposed a lesser intent requirement than the AKS; and (2) did not offer safe harbor protection at least equivalent to the applicable AKS safe harbor. According to the Court, the AKS established not only the field of conduct that Congress believed should be illegal, but also the field of conduct that Congress believed should be permitted (for instance, conduct falling within an AKS safe harbor). EKRA's subsection (d)(2) may be Congress' attempt to preempt similar decisions with respect to EKRA. Clinical laboratories, therefore, should assume that they may be subject to both EKRA and any applicable state laws.

III. Limitations of EKRA

A. EKRA Applies Only to Certain Entities

Unlike the AKS, EKRA applies only to arrangements with recovery homes, treatment facilities and clinical laboratories. However, all clinical laboratories are subject to EKRA – not just those that provide services associated with addiction recovery treatment.

B. EKRA Applies Only to "Services", Not to "Items & Services"

Unlike the AKS, EKRA applies only to "services" covered by a health care benefit program, rather than "items and services" payable by Federal health care programs. While this limitation is potentially helpful, clinical laboratories may often find it difficult to identify a service line as relating purely to "items" and not also to "services." While Federal law does not define either "item" or "service", an item is typically tangible and a service typically involves human labor. Whereas a medical device or supply company may sell only tangible items, clinical laboratories typically sell human labor – the performance of laboratory tests and the test results that are the product of that labor. Therefore, the exclusion of "items" from EKRA is unlikely to substantially narrow its scope with respect to clinical laboratories.

C. EKRA Applies Only to "Referrals" and "Use of Services"

EKRA also covers a more limited range of conduct than the AKS, prohibiting remuneration in return for or to induce the "referral" of a patient, or a payment or offer of remuneration in exchange for an individual "using the services" of a clinical laboratory. The AKS more broadly prohibits the offer or payment of remuneration in return for or to induce the "purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering" of items and services. While EKRA on its face appears to focus more narrowly than the AKS on conduct that results in a patient's referral to or use of a clinical laboratory, the scope of the phrase "using the services" is undefined, unclear, and potentially very broad. It is possible, for instance, that at least some payments of remuneration for the purchase or recommendation to purchase a laboratory's services could be construed as remuneration in exchange for an individual "using" a laboratory's services.

IV. Comparing EKRA's Exceptions and the AKS' Safe Harbors

A. EKRA's Exceptions and Their AKS Safe Harbor Correlates

EKRA includes seven (7) statutory exceptions, specifically for certain:

(1) discounts;
(2) payments made to employees;
(3) Part D drug discounts;
(4) personal services arrangements;
(5) coinsurance and copayment waivers;
(6) arrangements with Federally qualified health centers ("FQHCs"); and
(7) remuneration made pursuant to an alternative payment model or similar model.

A few of these exceptions explicitly mirror or are substantively similar to statutory safe harbors to the AKS. In particular, payments made by principals to agents are excepted from EKRA if they meet the requirements of the AKS safe harbor for "personal services and management contracts",

42 C.F.R. § 1001.952(d), and remuneration exchanged with FQHCs is excepted from EKRA if it meets the corollary AKS safe harbor, 42 C.F.R. § 1001.952(w). Likewise, EKRA excepts certain discounts in a manner that tracks the statutory AKS discount safe harbors at 42 U.S.C. § 1320a-7b(b)(3)(A) and (J).

Other EKRA exceptions, however, are dissimilar from AKS safe harbor protection. Most notably, the EKRA exception for payments made by an employer "to an employee… (who has a bona fide employment… relationship with such employer) for employment" is substantially narrower than the AKS safe harbor for payments made to employees. Because the AKS safe harbor immunizes *any* remuneration from an employer to a *bona fide* employee "for employment in the furnishing of any item or service for which payment may be made in whole or in part under [a Federal health care program]", 42 C.F.R. § 1001.952(i), it is broad enough to allow, among other things, employers to compensate their employed salespeople based on their productivity in generating Federal health care program business, *e.g.*, on a commission basis. EKRA's exception, however, is specifically designed to prohibit this form of compensation, as it can be satisfied only if an employee's compensation:

> "is *not* determined by or does *not* vary by…(A) the number of individuals referred to a particular… 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… laboratory." 18 U.S.C. § 220(b)(2).

By effectively excluding any form of productivity-based compensation from EKRA's employment exception, Congress appears to have made it a crime for any clinical laboratory to pay a commission-based payment to a member of its employed sales force.

In contrast, two EKRA safe harbors may provide somewhat more protection than their corollary AKS safe harbors. First, the AKS safe harbor for cost-sharing waivers only applies if a waiver satisfies the definition of "discount" and the requirements of the discount safe harbor, or are offered by particular types of entities. The EKRA coinsurance waiver exception more closely tracks the coinsurance waiver exception to the beneficiary inducement prohibition, 42 U.S.C. § 1320a–7a(i)(6), although it is somewhat less stringent even than that exception. In particular, while both the EKRA and beneficiary inducement coinsurance waiver exceptions require that waivers are not routine, the beneficiary inducement exception also requires that a waiver not be offered as part of any advertisement or solicitation. The EKRA exception contains no such requirement. Additionally, while both exceptions are limited to "good faith" waivers, the beneficiary inducement exception is more explicit as to the types of waivers that may be excepted – specifically, those made after determining in good faith that a patient is in financial need, or after reasonable collection efforts fail. The EKRA exception simply requires that "the waiver or discount is provided in good faith", arguably offering protection to a broader range of waivers without regard to patients' ability or failure to pay. Therefore, clinical laboratories may have more flexibility to waive commercial coinsurance amounts under EKRA than they do to waive Federal health care program coinsurance amounts under the AKS.

Second, EKRA provides an exception for "remuneration made pursuant to an alternative payment model…or pursuant to a payment arrangement used by a State, health insurance issuer, or group health plan if the Secretary of Health and Human Services has determined that such an arrangement is necessary for care coordination or value-based care." 18 U.S.C. § 220(b)(7) (the "APM Exception"). Although OIG has solicited comments regarding how the AKS could be better aligned with current policy shifts away from fee-for-service payment methodologies and toward

alternative payment models, the AKS currently does not have a broad safe harbor applicable to such remuneration. Although the text of EKRA's APM Exception may be a model for future exceptions and safe harbors to other laws – *e.g.*, the AKS, the Stark Law, and the beneficiary inducement prohibition – its usefulness as drafted is uncertain, in particular because it is unclear how or when the HHS Secretary would determine that an arrangement "is necessary" for care coordination or value-based care.

B. AKS Safe Harbors Without Correlate EKRA Exceptions

As noted, EKRA has far fewer exceptions than the combined AKS statutory and regulatory safe harbors. In fact, several fundamental AKS safe harbors have no correlate exception to EKRA – leaving many commonplace arrangements subject to potential scrutiny and liability. For instance, the AKS provides a safe harbor for returns on certain investment interests held by investors – like physicians – who are in a position to refer patients to the entities in which they invest, 42 C.F.R. § 1001.952(a). As there is no correlate investment exception to EKRA, any return on an investment in a clinical laboratory held by someone with the ability to generate business for the laboratory could risk criminal liability under EKRA. Accordingly, any provider – including professionals and facilities alike – might be precluded from investing in a clinical laboratory altogether (although a hospital could send patients to its internal laboratory).

Similarly, EKRA does not include an exception correlative to either of the AKS' safe harbors for returns on investments in group practices or ambulatory surgery centers ("ASCs"), 42 C.F.R. § 1001.952(p), (r), a significant concern for any group practice or ASC that currently owns and operates a clinical laboratory. As it stands, EKRA immediately imperils the viability of any physician practice's in-office clinical laboratory, even though such laboratories can be specifically safe harbored under the AKS and subject to the In-Office Ancillary Services exception to the Stark Law. *See* 42 C.F.R. § 411.355(b).

The AKS provides safe harbors for space and equipment rentals; EKRA does not. Therefore, a clinical laboratory's rental of space or equipment either from or to referral sources such as physicians and hospitals are subject to EKRA without recourse to a safe harbor. Similarly, EKRA contains no exception for agreements with group purchasing organizations ("GPOs"), thus imperiling commonplace agreements by and between clinical laboratories and GPOs that enjoy safe harbor protection from the AKS. Finally, the AKS provides several relatively broad safe harbors for arrangements between providers and managed care organizations ("MCOs"). Many clinical laboratories have arrangements with MCOs that fall within these safe harbors, but which would not be protected under EKRA unless they are determined by the Secretary of HHS to be "necessary" to care coordination or value-based care. As discussed above, it is not clear if or how such determinations would ever be made.

C. Possibility of Regulatory Safe Harbors to EKRA

As alluded to above, the OIG has used authority granted to it under the AKS to promulgate many regulatory safe harbors beyond the safe harbors included in the statute itself. In so doing, the OIG has shielded from AKS liability a great number of arrangements unlikely to pose a risk of fraud and abuse to the Federal health care programs. Under EKRA, the OIG has no power to promulgate any regulatory safe harbors. Instead, EKRA grants authority to promulgate additional exceptions to the Attorney General, in consultation with the Secretary of HHS. Relative to the OIG, the Attorney General has less experience in promulgating regulations providing immunity from health care fraud and abuse prohibitions. Therefore, there is reason for uncertainty as to whether and when any additional regulatory EKRA safe harbors may be forthcoming.

V. Implications

Given the disconnect between Congress' apparent intent in passing the SUPPORT Act (addressing opioid recovery and treatment) and the wide scope of EKRA's operative language, the discordance between EKRA and the AKS, and the practical difficulties that may emerge in developing regulatory safe harbors to EKRA, future prosecutorial discretion will be instrumental to keeping EKRA's new kickback prohibition within a reasonable orbit. It would be odd, for instance, for the DOJ to prosecute as a felony conduct related to services payable by a commercial insurer or a self-pay patient, when Congress or the OIG has deemed that very same conduct to be innocuous when related to Federal health care program business under the AKS. Yet, such a result could occur given the language of EKRA – and perhaps more likely so in the context of a *qui tam* whistleblower suit based on allegations of non-compliance with EKRA. Thus, for many clinical laboratories and their owners and investors, EKRA may require a careful reevaluation and reassessment of the risk of many previously unimpeachable financial arrangements.