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EKRA: Enactment and Implications of the SUPPORT Act's New All-Payor Federal Antikickback Law

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A. Introduction

As part of the federal government's ongoing efforts to combat the nationwide opioid crisis, Congress recently enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). Effective October 24, 2018, the SUPPORT Act reflects a bipartisan, comprehensive legislative initiative comprised of 70 individual bills intended to address the opioid crisis and other substance abuse by enhancing treatment and recovery programs, improving prevention and educational efforts, protecting communities, and fighting deadly synthetic drugs.[1] Under Sections 8121 and 8122 of the SUPPORT Act, Congress enacted the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) with the intent to prohibit individuals from referring substance abuse patients in exchange for kickbacks to recovery homes, clinical treatment facilities, and laboratories.[2] ERKA addresses Congress's concerns regarding the proliferation of patient brokers who profit off of patients seeking substance abuse treatment through "illicit referrals," including "patient brokers who take advantage of patients with opioid use disorders by referring these patients to substandard or fraudulent providers in exchange for kickbacks."[3] As explained below, while EKRA addresses a significant concern in the substance abuse treatment industry, EKRA's broad anti-kickback prohibition appears to exceed its underlying legislative intent to prohibit illicit referrals of substance abuse patients and raises significant questions regarding the applicability of EKRA to unrelated arrangements in the healthcare industry that could otherwise be structured to comply with existing federal law.

B. What is EKRA?

EKRA prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in return for referring a patient to, or in exchange for an individual using the services of, a recovery home, clinical treatment facility, or laboratory with respect to services covered by a health care benefit program.[4] The term "health care benefit program" includes "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."[5] EKRA defines "recovery home" as "a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders."[6] "Clinical treatment facility" is defined as "a medical setting, other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under state law."[7] "Laboratory" is defined to include all clinical laboratories, and thus all referrals for clinical laboratory tests implicate EKRA regardless of whether the tests relate to substance abuse testing or treatment.[8] Importantly, EKRA does not define the term "referral." Because EKRA's prohibition against kickbacks is limited to remuneration paid in exchange for referrals or an individual's use of services, an authoritative interpretation of the term "referral" under EKRA is necessary to determine the scope of the law. Based on these definitions, EKRA establishes a new public and private payor intent-based criminal anti-kickback law that prohibits any form of remuneration in exchange for referrals to, or an individual's use of, all entities that meet the definitions of recovery homes, clinical treatment facilities, and laboratories, including referrals to laboratories unrelated to substance abuse testing or treatment.

EKRA includes eight exceptions to its broad prohibition on the payment of remuneration. Specifically, EKRA provides exceptions for the following types of arrangements, provided that they meet certain enumerated requirements: (1) discounts obtained by service providers; (2) payments made to employees and independent contractors that meet certain structural requirements; (3) drug

manufacturer discounts provided under the Medicare coverage gap discount program; (4) arrangements that meet the personal services and management contracts safe harbor under the federal Anti-Kickback Statute set forth at 42 U.S.C. § 1320a-7b(b) (AKS); (5) waivers or discounts of coinsurance or copayments; (6) remuneration between healthcare entities and an individual or entity pursuant to an agreement that contributes to the availability (or enhances the quality) of services provided to medically underserved populations; (7) remuneration made pursuant to an alternative payment model or other model determined by the Secretary of Health and Human Services (Secretary) to be necessary for care coordination or value-based care; and (8) any other regulatory safe harbor promulgated by the Attorney General in consultation with the Secretary that clarifies the exceptions described in (1) – (7) above.[9] While a few of EKRA's exceptions appear similar to certain exceptions and safe harbors available under the federal AKS, EKRA's exceptions are inconsistent with the corresponding AKS exceptions and/or safe harbors, as discussed in more detail below.

Further, existing federal laws, such as the AKS and the federal Stark law set forth at 42 U.S.C. § 1395nn (Stark) govern the same arrangements implicated by EKRA, and the inconsistencies between EKRA and the AKS and Stark may lead to significant difficulties for healthcare providers and other entities and individuals that must now comply with EKRA in addition to the existing applicable federal laws.[10] In addition, state laws applicable to kickbacks, fee-splitting, and self-referral may also be inconsistent with EKRA. To that end, EKRA includes a confusingly written preemption section that specifies that (i) EKRA does not apply to conduct that is prohibited under the AKS and (ii) EKRA shall not "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."[11]

Similar to certain other federal laws in this area, EKRA is a criminal statute that includes a "knowing and willful" intent requirement. Violators of EKRA will be subjected to a fine of up to $200,000 or imprisonment of 10 years, or both, for each occurrence.[12] In addition, a violation of EKRA could have other collateral consequences such as licensure sanctions, revocation and exclusion from governmental healthcare programs.[13]

EKRA became effective on October 24, 2018 and is broadly drafted in a manner that requires those involved in healthcare arrangements that otherwise comply with federal and state fraud and abuse laws to reassess their compliance. Given the various areas of uncertainty discussed below, healthcare providers and other entities and individuals in the healthcare industry should consider taking a conservative approach when evaluating all relationships with recovery homes, clinical treatment facilities, and laboratories that are governed by EKRA. Until Congress refines EKRA or the Attorney General promulgates regulations or other guidance interpreting EKRA, many existing relationships in the healthcare industry will need to be revised in order to comply with EKRA and avoid risk of criminal liability.

C. Legislative History & Intent

The SUPPORT Act was introduced in the House of Representatives (House) on June 13, 2018. It was passed initially by the House on June 22, 2018, then passed with amendment by the Senate and sent back to the House on September 17, 2018 for the House to resolve differences between its and the Senate's version of the bill, which resolution occurred on September 28, 2018. Notably, the initial version of EKRA was introduced in the Senate as Senate Bill 3254 on July 19, 2018 and was inapplicable to laboratories.[14] A review of the Congressional Record for all House proceedings related to the SUPPORT Act indicates that neither EKRA nor any issues addressed by EKRA were raised in the full House prior to September 28, 2018.

However, three days earlier, on September 25, 2018 EKRA was introduced in the House as H.R. 6878 and referred to the House Committee on the Judiciary, yet it differed from the earlier version in the Senate because it applied to laboratories. The next day, EKRA was introduced again in the House and referred to the House Committee on the Judiciary, but as H.R. 6902 and included almost identical language to H.R. 6878 except that it did not apply to laboratories. Congressional records show that no action on either House bill was taken following their introduction and that they were never released by the House Committee on the Judiciary to the full House for consideration.

On September 28, 2018, the House passed H.R. 1099, which approved the Senate's amendment to the SUPPORT Act and added the version of EKRA presented by H.R. 6878, which included laboratories, to the SUPPORT Act for the first time.[15] Following the addition

of EKRA by the House, the Senate approved H.R. 1099 on October 3, 2018. Although President Trump did not sign the bill enacting the SUPPORT Act until October 24, 2018, EKRA (as it currently reads) was introduced in the House and agreed to by both the House and Senate within a period of eight calendar days as a last-minute addition to the SUPPORT Act.

The Congressional Record illustrates that the legislative intent of EKRA was to prohibit patient brokering of substance abuse patients. For example, the Congressional Record includes a letter signed by representatives of 124 major organizations across all disciplines working on a comprehensive response to address addiction (e.g., AIDS United, Addiction Policy Forum, FedCURE). The organizations' letter, which was submitted "in support of the final conference agreement of the [SUPPORT] Act (H.R. 6) [to] urge for quick passage of this package," describes EKRA as follows:

ENDING ILLEGAL PATIENT BROKERING Criminal penalties (Section 8122)—This provision makes it illegal to pay or receive kickbacks in return for referring a patient to recovery homes or clinical treatment facilities.[16]

Additionally, the Congressional Record shows that EKRA was added to the SUPPORT Act at the last minute and that the lack of consideration given to EKRA could lead to unintended consequences. On September 28, 2018, just prior to the final House vote adding EKRA to the final version of the SUPPORT Act, Congressman Pallone (D-NJ) stated as follows:

[EKRA] did not go through regular order and was not properly vetted. In fact, it was added at the very last minute. That is a proposal by Senator RUBIO to create a new criminal antikickback statute. I know this proposal is well-intentioned in addressing the serious problem of patient brokers who are taking advantage of individuals with opioid use disorders and referring them to substandard or fraudulent providers in exchange for kickbacks. This is an issue, but since the bill was introduced last Tuesday night, multiple stakeholders have raised concerns that the language does not do what we think it does. It may have unintended consequences. Mr. Speaker, I hope this is a good lesson to all of us that passing legislation that has not been properly vetted, and that the public has not had an adequate chance to review, is unwise. I hope to get a commitment from Chairman WALDEN and Chairman GOODLATTE to work to address any technical problems with this provision in the upcoming months.[17]

Accordingly, the legislative intent of the SUPPORT Act and EKRA do not appear to lend support for EKRA's broad application to all laboratories. Thus, the last-minute addition of laboratories to EKRA, when combined with the last-minute addition of EKRA to the SUPPORT Act, indicates that EKRA's widespread impact on the healthcare industry may represent unintended consequences of a rushed legislative process.

D. Preemption

As noted above, EKRA explicitly addresses preemption of state and federal law.[18] With regard to federal law, EKRA does not apply to conduct that is prohibited under the AKS.[19] Accordingly, arrangements prohibited by the AKS are not subject to additional liability under EKRA. However, EKRA's preemption clause does not reference any other federal laws. Specifically, EKRA does not address preemption as it relates to Stark, although both EKRA and Stark may apply to an arrangement involving referring physicians who have financial relationships with entities (e.g., laboratories) subject to EKRA and refer designated health services to these entities.

As it relates to state laws, EKRA provides that, "[n]othing in [EKRA] shall be construed to occupy the field in which any provisions of [EKRA] operate to the exclusion of State laws on the same subject matter."[20] This language is unclear and could possibly be read to mean that EKRA does not preempt state laws on the same subject matter. However, state fraud and abuse laws are often broadly written enough to address the same subject matters as EKRA, and their discrepancies to EKRA may cause additional difficulties in navigating compliance, particularly because EKRA applies to private payors, which have historically been regulated under state but not federal fraud and abuse laws. Due to the potential impact of EKRA's unique preemption clauses, the resulting confusion among stakeholders may increase the likelihood that any future regulations by the Attorney General will include clarifications of EKRA's preemption provisions.

E. What is a "Referral" under EKRA?

EKRA prohibits soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient to a recovery home, clinical treatment facility, or laboratory.[21] Additionally, EKRA prohibits paying or offering remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral to, or in exchange for an individual using the services of, a recovery home, clinical treatment facility, or laboratory.

When compared to the AKS, the AKS's anti-kickback language is broader and applies to a variety of conduct to prohibit soliciting, receiving, offering or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring, purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering of any good, facility, service, or item payable in whole or in part under a federal healthcare program. Importantly, it is this additional conduct – "arranging for" and "recommending" – that has been interpreted by the Department of Health and Human Services' Office of Inspector General (OIG) to implicate commission-based sales agents, marketing firms, and other individuals that may be viewed to engage in patient brokering under the AKS, while the term "referral," although not defined under the AKS statutory language, has been traditionally viewed to apply to provider referrals.[22] Mention of the AKS statutory language and interpretation of such is relevant because of the similarity between the language used in both the AKS and EKRA. However, EKRA omits the statutory language that the federal government has historically used under the AKS to apply that law to marketing and sales activities. The absence of this language in EKRA along with the absence of a statutory definition for "referral" under EKRA unintentionally counteracts the legislative intent of applying EKRA to marketing and sales arrangements. Accordingly, it is possible that the Attorney General will promulgate regulations to clarify the meaning of "referral" under EKRA so that it more clearly applies to marketing and sales agents consistent with its legislative intent.

Aside from the disparity in language between the AKS and EKRA as it relates to referrals, EKRA's prohibition of remuneration solicited, received, offered or paid "in exchange for an individual using the services of a recovery home, clinical treatment facility or laboratory" is notable in that it is broadly enough written to apply not only to third parties, but also to remuneration received by a patient for his/her receipt of services by such an entity. In the absence of any regulatory guidance, EKRA's relationship to the federal Beneficiary Inducement Statute set forth at 42 U.S.C. § 1320a-7a(a) (BIS) and similar state laws should be considered in analyzing any arrangement that could involve remuneration directly or indirectly being paid by recovery homes, clinical treatment facilities, or laboratories to patients.[23]

F. Examples of the Intersection of EKRA with the AKS and Stark[24]

Perhaps the most notable area in which EKRA is currently affecting the healthcare industry relates to sales and marketing relationships that were previously governed under the AKS and are now requiring restructuring in order to comply with EKRA as well. Of these arrangements, those pertaining to laboratories are particularly relevant because of the fact that EKRA applies to all laboratories that meet its broad definition and not only toxicology laboratories that operate in the substance abuse treatment arena.

The personal services and management contracts safe harbor of the AKS applies to sales and marketing arrangements structured as independent contractor (i.e., 1099) relationships and the AKS employees exception and safe harbor applies to such arrangements that are structured as employment (i.e., W-2) relationships. For AKS purposes, distinguishing between employment and independent contractor status has been important because the AKS statutory exception and regulatory safe harbor applicable to employees is more permissive in that it protects all forms of remuneration paid by an employer to a bona fide employee for employment in the furnishing of items or services covered by a federal healthcare program.[25] Conversely, the AKS personal services and management contracts safe harbor contains several elements that must be met in order for remuneration to receive safe harbor protection, including a written agreement with a one year minimum term and aggregate compensation, that is set in advance, consistent with fair market value in arms-length transactions, and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other federal healthcare programs.[26] Thus, commission-based payments that are common in the sales and marketing context will not receive AKS safe harbor protection if they are structured as independent contractor relationships. In light of the more favorable treatment of employees under the AKS, many laboratory and other marketing and sales arrangements have been structured as employment relationships so that commission-based compensation may be paid in compliance with the AKS.

EKRA includes two relevant statutory exceptions. The first protects arrangements that comply with the AKS personal services and management contracts safe harbor.[27] The second protects payments made by employers to employees or independent contractors (who have bona fide employment or contractual relationships with the employer) for employment or independent contractor relationship, if the 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 healthcare benefit program from the individual referred to a particular recovery home, clinical treatment facility, or laboratory.[28] Thus, EKRA's exception for employees is narrower than the AKS exception and safe harbor for employees and, accordingly, it restricts the ways in which employees can be paid if they are governed by both the AKS and EKRA and intend to comply with both laws' statutory exceptions. For example, sales and marketing employees of a clinical laboratory who historically received commission-based compensation tied to the amount billed to or received from federal and private payors in compliance with the AKS employees exception and safe harbor may no longer receive compensation utilizing that methodology if the arrangement is to comply with EKRA's exception. However, independent contractor relationships that are governed by both the AKS and EKRA will largely remain unchanged as the arrangement may be structured to meet either of EKRA's relevant two statutory exceptions, but if the arrangement is to be protected by the AKS personal services and management contracts safe harbor, it must meet the safe harbor's more restrictive "aggregate, set in advance, fair market value" compensation and other requirements. Notably, if an arrangement comes under the ambit of EKRA because it involves private payors, but is not governed by the AKS, it may meet either of EKRA's applicable exceptions and may choose the second, less restrictive, exception discussed above.

Although it is desirable and recommended that an arrangement be structured to meet an applicable AKS exception and/or safe harbor, because the AKS is an intent-based statute, the OIG has clarified that failure to comply with a safe harbor does not make an arrangement per se illegal. Instead, if an arrangement fails to meet an AKS exception or safe harbor, the particular facts and circumstances surrounding the arrangement may be carefully scrutinized by the federal government. In the absence of further guidance or clarifying regulations by the Attorney General, it is unclear as to how the federal government will analyze the intent of, and enforce, arrangements that are governed by EKRA but do not meet any of EKRA's statutory exceptions.

Specifically, the lack of Attorney General guidance at this point in time presents some risks for arrangements that currently meet ownership exceptions and safe harbors under the AKS and Stark, but that have no counterparts under EKRA because EKRA does not contain any ownership exceptions. For example, physician ownership of laboratories that bill Medicare and Medicaid for their services is permissible under Stark if it meets an applicable Stark exception and may also be afforded AKS safe harbor protection.[29] The AKS also extends safe harbor protection to salespersons and marketers who own laboratories.[30] However, despite receiving protection under the AKS and Stark, these two types of ownership relationships are not afforded clear protection under EKRA. No doubt the industry looks forward to further Attorney General guidance in this regard.

G. Conclusion

EKRA became effective and may be enforced as of October 24, 2018. However, the law is broadly drafted in a manner that appears to exceed its initial legislative intent and, thus, may result in unintended consequences. Until Congress refines EKRA or the Attorney General promulgates regulations or other guidance interpreting EKRA, many existing relationships in the healthcare industry will need to be modified in order to comply with EKRA to avoid risk of criminal liability.

1 *See* 164 Cong. Rec. H5512, H5521 (June 22, 2018) (statements of Reps. Walberg, Walden, Bishop).

2 While EKRA was in fact enacted to prohibit patient brokering of substance abuse patients on behalf of substance abuse treatment providers and facilities, EKRA also applies to referrals to laboratories unrelated to substance abuse treatment. *See* 18 U.S.C. § 220(a); *see also* 18 U.S.C. § 220(e)(4).

3 *See* 164 Cong. Rec. H9244, H9249 (September 28, 2018).

4 18 U.S.C. § 220(a); H.R. 6 – 215.

5 18 U.S.C. § 220(e)(3); 18 U.S.C. § 24(b).

6 18 U.S.C. § 220(e)(5).

7 18 U.S.C. § 220(e)(2).

8 *See* 18 U.S.C. § 220(e)(4); 42 U.S.C. 263a(a). For purposes of EKRA, the term "laboratory" means "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." 42 U.S.C. § 263a(a).

9 18 U.S.C. §§ 220(b), (c).

10 As an example of other federal laws that govern arrangements now subject to EKRA, the beneficiary inducement provisions of the federal Civil Monetary Penalties (CMP) law include requirements for waivers or discounts of coinsurance and copayments. *See* 42 U.S.C.§ 1320a-7a(a)(4); *see also* 42 C.F.R. § 1003.1000(a). EKRA includes an exception for waivers or discounts of coinsurance or copayments; however, EKRA's exception differs from the beneficiary inducement provisions of the federal CMP laws by, for example, not requiring a pre-waiver or pre-discount determination of financial need or failure to collect after making reasonable collection efforts. *See* 18 U.S.C. § 220(b)(5); *see also* 42 C.F.R. § 1003.1000(a).

11 18 U.S.C. § 220(d).

12 18 U.S.C. § 220(a).

13 *See e.g.,* 42 U.S.C. 1320a-7(a)(1).

14 *See Senate Bill* S. 3254 (July 27, 2018).

15 *See* H.R. 1099. The Senate's amendments to the SUPPORT Act related to issues such as the labeling of prescription opioids and elimination of time restrictions for non-physician practitioners (NPPs) to become "qualifying practitioners" under the Support Act. *See* 164 Cong. Rec. S6193 (September 78, 2018).

16 *See* 164 Cong. Rec. H9253 (September 28, 2018).

17 *See* 164 Cong. Rec. H9244 (September 28, 2018).

18 18 U.S.C. § 220(d).

19 *See* 18 U.S.C. § 220(d)(1) ("This section shall not apply to conduct that is prohibited under section 1128B of the Social Security Act (42 U.S.C. 1320a–7b)").

20 18 U.S.C. § 220(d)(2).

21 18 U.S.C. § 220(a).

22 *See* 56 Fed. Reg. at 35974; OIG Advisory Opinion 98-1 (March 19, 1998).

23 Under Section 1128A(a)(5) of the Social Security Act (the Act), a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties (CMPs) of up to $10,000 for each wrongful act. Under the Act, "remuneration" is defined to include, without limitation, waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value (e.g., free transportation).

24 In general, the AKS has statutory exceptions and regulatory safe harbors that specify certain types of remuneration that do not violate the AKS; however, failure to meet an exception or safe harbor does not make an arrangement per se illegal under the AKS because the AKS is an intent-based law. In contrast, because Stark is a strict liability statute, if Stark is implicated, an exception to Stark must be met.

25 42 U.S.C. § 1320a-7b(b)(3)(B); 42 C.F.R. § 1001.952(i).

26 42 C.F.R. § 1001.952(d).

27 18 U.S.C. § 220(b)(4).

28 18 U.S.C. § 220(b)(2). Notably, the statutory language is confusingly written and seems to blur the lines between a contractual and employment relationship.

29 For example, physician ownership of a laboratory may be permissible under Stark's in-office ancillary services exception (*see* 42 C.F.R. § 411.355(b), as well as protected under the investments in group practices safe harbor available under the AKS (*see* 42 C.F.R § 1001.952).

30 For example, salespersons and marketers may structure investments in laboratories to meet the investment interests safe harbor available under the AKS. *See* 42 C.F.R. § 1001.952(a).

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