EKRA COMPLIANCE: QUESTIONS AND IMPLICATIONS RAISED BY NEW FEDERAL LAW

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Healthcare providers and other individuals and entities engaged in the healthcare industry must now comply with a new all-payer federal anti-kickback law applicable to recovery homes, clinical treatment facilities, and laboratories.[1] Effective October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) represents the culmination of the federal government's year-long comprehensive, bipartisan, and bicameral legislative effort to both turn the tide of the tragic opioid epidemic and improve treatment options for individuals battling substance-use disorders.[2]

The SUPPORT Act includes 70 separate acts introduced by Congress to advance treatment and recovery initiatives, improve prevention and educational efforts, protect and provide resources to communities, and bolster efforts to fight deadly synthetic drugs.[3] As part of the SUPPORT Act, Congress enacted the Eliminating Kickbacks in Recovery Act of 2018 (EKRA). The intent of EKRA is to prohibit referrals of substance abuse patients in exchange for kickbacks from recovery homes, clinical treatment facilities, and laboratories.[4] The term "referral" is not defined under EKRA, however the Congressional Record indicates that EKRA is intended to apply to illicit referrals that include, but are not limited to, patient brokering by lay individuals who seek to profit by taking advantage of patients with opioid use disorders by referring these patients to substandard or fraudulent providers in exchange for kickbacks. 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 clinical laboratories unrelated to substance abuse treatment.

What is EKRA?

According to the Congressional Record, EKRA was added to the SUPPORT Act in order to prohibit patient brokers who profit from 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."[5] As explained below, although EKRA addresses a significant issue harming the substance abuse treatment industry,

EKRA's broad anti-kickback law appears to exceed its legislative intent and raises significant questions regarding EKRA's implications on unrelated, common, and otherwise compliant arrangements in the healthcare industry.

Prohibition and definitions

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 healthcare benefit program.[6] EKRA uses the following definitions:

- ***Recovery home*** means "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."[7]
- ***Clinical treatment facility*** means "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."[8]
- ***Laboratory*** means "a facility for the biological, microbiological, serological, chemical, immunohematological, 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."[9] Thus all referrals for clinical laboratory tests implicate EKRA regardless of whether the tests relate to substance abuse testing or treatment.[10]
- ***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."[11]

As explained above, EKRA does not define the term "referral." Since 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 federal public and private payer 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.

Exceptions, preemption, and penalties

EKRA provides exceptions to its broad prohibition on payments of remuneration for the following types of arrangements that meet certain enumerated requirements: (1) discounts obtained by service providers; (2) payments made to employees and independent contractors that meet certain requirements; (3) drug manufacturer discounts provided under the Medicare coverage gap discount program; (4) arrangements that meet the personal services and management contracts federal Anti-Kickback Statute (AKS)[12] safe harbor; (5) waivers or discounts of coinsurance or copayments; (6) remuneration between health care 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 any of the seven exceptions described above.[13]

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Despite the similarities between EKRA's exceptions and certain exceptions and safe harbors available under the AKS, EKRA's exceptions contain inconsistencies when compared to the corresponding AKS exceptions and/or safe

harbors.[14] Accordingly, healthcare providers and other individuals that enter into arrangements with, or on behalf of, recovery homes, clinical treatment facilities, and laboratories must not rely on compliance with an exception or safe harbor under the AKS in order to meet a similar exception under EKRA. Instead, the nuances of each law must be considered separately.

Additionally, existing federal and state laws govern the same arrangements now subject to EKRA's prohibition on remuneration in exchange for referrals to recovery homes, clinical treatment facilities, and laboratories. Specifically, the AKS, the federal Stark Law set forth at 42 U.S.C. § 1395nn (Stark), and state laws applicable to kickbacks, fee-splitting, and self-referrals apply to the same relationships implicated by EKRA. Due to the inconsistencies between EKRA and the AKS, Stark, and these state laws, arrangements subject to EKRA must account for the varying requirements and interpretations of each law, and the healthcare providers and other individuals involved may experience significant difficulties when revising existing relationships or structuring future arrangements to also comply with EKRA.

EKRA recognizes the overlap between EKRA and existing federal and state laws through a preemption section that specifies that: (1) EKRA does not apply to conduct that is prohibited under the AKS; and (2) 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."[15]

In light of the similar yet inconsistent requirements of EKRA and existing federal and state laws governing the same arrangements, as well as the uncertainty raised by EKRA's confusingly written preemption language, healthcare providers and other individuals subject to EKRA should consult experienced legal counsel to determine the federal and state laws applicable to each arrangement. As many arrangements in the healthcare industry are structured to comply with the AKS, Stark, and state fraud and abuse laws, well-known and otherwise compliant arrangements will need to be restructured to meet an exception to EKRA and remain in compliance with existing laws.

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.[16] A violation of EKRA could have other collateral consequences, such as licensure sanctions, revocation, and exclusion from governmental healthcare programs.[17]

Legislative history

EKRA was intended to prohibit patient brokering in the substance abuse arena. A review of the Congressional Record shows that EKRA was introduced in the U.S. House of Representatives and approved by both the House and Senate within only eight calendar days and after both the House and Senate had already initially voted to approve the SUPPORT Act. When EKRA was introduced in the House as H.R. 6878 on September 25, 2018, it differed from an earlier version in the Senate introduced on July 19, 2018, because it applied to laboratories.

Further, the next day, EKRA was re-introduced to the House as H.R. 6902 and included almost identical language to H.R. 6878 except that it did not apply to laboratories. On September 28, 2018, the House passed H.R. 1099, which added the version of EKRA that included laboratories to the SUPPORT Act for the first time.[18] Accordingly, the Congressional Record demonstrates EKRA was a last-minute addition to the SUPPORT Act and, further, EKRA's applicability to clinical laboratories was a last-minute change to EKRA. The legislative intent of the SUPPORT Act and EKRA do not support EKRA's broad application to all laboratories, including those outside of toxicology and other laboratories operating in the substance abuse arena. 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 laboratories and thus the healthcare industry may represent unintended consequences of a rushed legislative process.

Impact of EKRA

Given EKRA's broad application to the healthcare industry, EKRA requires healthcare providers, compliance professionals, and other individuals involved in healthcare arrangements that currently comply with federal and state fraud and abuse laws to reassess their compliance under EKRA. In light of the various areas of uncertainty, healthcare providers, compliance professionals, and other entities and individuals in the healthcare industry should engage experienced legal counsel and take a conservative approach to 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, a review of existing relationships in

the healthcare industry is necessary to determine whether any such arrangement need to be revised in order to comply with EKRA and avoid risk of criminal liability.

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.[19] EKRA also 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.

Similar to other federal and state fraud and abuse laws, EKRA requires an interpretation of the term "referral" in order to understand the full scope of the law. When compared to EKRA, 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 Office of Inspector General (OIG) to implicate commission-based sales agents, marketing firms, and other individuals who may be viewed to engage in patient-brokering under the AKS, while the term "referral," although not defined under the AKS, has been traditionally viewed to apply to provider referrals.[20]

The AKS statutory language and the federal government's interpretation of such language is relevant due to the similarities between the statutory language used in the AKS and EKRA. However, because EKRA only prohibits remuneration in exchange for referrals to providers or in exchange for an individual using the services of providers, 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 lack of a statutory definition for "referral," could have unintended consequences that counteract the legislative intent of applying EKRA to marketing and sales arrangements. Accordingly, the Attorney General may promulgate regulations to clarify the meaning of "referral" under EKRA so that it more clearly applies to marketing and sales agents.

Aside from the disparity in language between the AKS and EKRA pertaining to referrals, EKRA's applicability to remuneration solicited, received, offered, or paid "in exchange for an individual using the services of a recovery, clinical treatment facility or laboratory" is notable in that it is broad enough 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 (BIS) set forth at 42 USC 1320a-7a(a) and similar state laws should be considered by legal counsel in analyzing any arrangement that could involve remuneration directly or indirectly being paid to patients by recovery homes, clinical treatment facilities, or laboratories.

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How does EKRA relate to existing laws?

EKRA's statutory language results in significant overlap between EKRA and existing federal and state laws including, but not limited to, the AKS, Stark, and state laws applicable to kickbacks, fee-splitting, and self-referrals. Accordingly, when evaluating an arrangement now subject to EKRA, it is necessary for healthcare providers, compliance professionals, and other individuals engaged in the healthcare industry to consider the impact of existing federal and state laws that govern arrangements with recovery homes, clinical treatment facilities, and laboratories.

Because EKRA appears to not preempt existing federal and state laws that govern arrangements subject to EKRA, healthcare providers must revise current relationships and structure future arrangements to comply with both EKRA and all other applicable

federal and state laws. Most notably, EKRA will alter the healthcare industry as it relates to sales and marketing relationships that were previously governed under the AKS and now must be restructured in order to comply with EKRA. Of these arrangements, sales and marketing involving laboratories are particularly relevant because of the fact that EKRA applies to all laboratories that meet its broad definition, regardless of whether the laboratories perform toxicology testing or other services for substance abuse patients.

The personal services and management contracts safe harbor under the AKS applies to sales and marketing arrangements structured as independent contractor (i.e., 1099) relationships, whereas the employees exception and safe harbor under the AKS applies to such arrangements structured as employment (i.e., W-2) relationships. Under the AKS, 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 health care program.[21]

On the other hand, the AKS personal services and management contracts safe harbor contains multiple 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 arm's-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.[22]

Thus, commission-based payments that are common in the sales and marketing context will not receive AKS safe harbor protection if the arrangements 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 previously been structured as employment relationships so that commission-based compensation may be paid in compliance with the AKS.

EKRA includes two relevant statutory exceptions. First, EKRA protects arrangements that comply with the AKS personal services and management contracts safe harbor.[23] The second exception protects payments made by employers to employees or independent contractors (who have bona fide employment or contractual relationships with the employer) for employment, 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. Notably, the statutory language is confusingly written and seems to blur the lines between a contractual and employment relationship.[24]

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 the employment relationships 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 payers in compliance with the AKS employees exception and safe harbor may no longer receive compensation using that methodology if the arrangement is to comply with EKRA's exception for employees. 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. Alternatively, if an arrangement comes under the ambit of EKRA because it involves private payers, 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 advisable 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 scrutinized by the federal government. However, 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.

The lack of Attorney General guidance pertaining to EKRA also 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 a laboratory that bills Medicare and Medicaid for its services may be permissible under Stark if it meets an applicable Stark exception and may also be afforded AKS safe harbor protection. In addition, the AKS extends safe harbor protection to salespersons and marketers who own laboratories. However, despite receiving protection under the AKS and Stark, these two types of ownership relationships are not afforded clear protection under EKRA and, thus, require Attorney General guidance in this regard.

Conclusion

Healthcare providers, compliance professionals, and other individuals and entities engaged in the healthcare industry must evaluate whether all indirect or direct, current, and future arrangements with recovery homes, clinical treatment facilities, and laboratories comply with EKRA. EKRA became effective on October 24, 2018, and 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 revised in order to comply with EKRA to avoid risk of criminal liability. CT

Endnotes

1. *See* 164 Cong. Reg. H9244, H9249 (September 28, 2018).
2. *See* 164 Cong. Reg. H9244 (September 28, 2018) (statement of Rep. Pallone)
3. *See* 164 Cong. Rec. H5512, H5516, H5521 (June 22, 2018) (statements of Reps. Walberg, Walden, Bishop).
4. *See* 18 U.S.C. § 220(a)
5. *See* 164 Cong. Rec. H9244, H9249 (September 28, 2018).
6. 18 U.S.C. § 220(a)
7. 18 U.S.C. § 220(e)(5)
8. 18 U.S.C. § 220(e)(2)
9. 18 U.S.C. § 220(e)(4)
10. 42 U.S.C. 263a(a).
11. 18 U.S.C. § 220(e)(3); 18 U.S.C. § 24(b).
12. 42 U.S.C. 1320a–7b(b) Federal Anti-Kickback Statute.
13. 18 U.S.C. §§ 220(b), (c).
14. *See* 42 U.S.C. § 1320a-7b(b)
15. 18 U.S.C. § 220(d).
16. 18 U.S.C. § 220(a).
17. *See e.g.*, 42 U.S.C. 1320a-7(a)(1).
18. *See* H.R. 1099.
19. 18 U.S.C. § 220(a).
20. *See* 56 Fed. Reg. at 35974
21. 42 U.S.C. § 1320a-7b(b)(3)(B)
22. 42 C.F.R. § 1001.952(d).
23. 18 U.S.C. § 220(b)(4).
24. 18 U.S.C. § 220(b)(2).

Takeaways

- EKRA creates a new public and private payer federal anti-kickback law that criminalizes remuneration in exchange for referrals to recovery homes, clinical treatment facilities, and laboratories.
- EKRA's application to laboratories, regardless of whether the laboratory provides substance abuse testing or other services, appears to exceed EKRA's legislative intent and may represent an unintended consequence of a rushed legislative process.
- Due to inconsistencies between EKRA and existing federal and state fraud and abuse laws, such as the federal Anti-Kickback Statute, traditional arrangements in the healthcare industry will need to be restructured to comply with EKRA.
- Specifically, absent further action by Congress or regulations promulgated by the Attorney General, EKRA effectively prohibits commission-based sales arrangements for recovery homes, clinical treatment facilities, and all laboratories.
- Healthcare providers and other parties to arrangements governed by EKRA should consult experienced legal counsel to ensure compliance with EKRA and all existing applicable federal and state fraud and abuse laws.