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EKRA compliance: Questions and implications raised by new federal law

By Reesa N. Benkoff, Esq. and Dustin T. Wachler, Esq.

Reesa N. Benkoff (rbenkoff@wachler.com) is a Partner and **Dustin T. Wachler** (dwachler@wachler.com) is an Associate Attorney at Wachler & Associate PC in Royal Oak, Michigan.

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, 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." [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]

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]