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CLIENT ALERT

The SUPPORT for Patients and Communities Act:

Part 1: New Federal Anti-Kickback Law—Eliminating Kickbacks in Recovery Act of 2018

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President Trump recently signed sweeping bipartisan legislation to combat the opioid epidemic. The Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, or the SUPPORT for Patients and Communities Act ("the SUPPORT Act"),[1] aims to "reduce access to the supply of opioids by expanding access to prevention, treatment, and recovery services." Congress has already appropriated $8.5 billion to implement this "landmark legislation" in 2018 and 2019.

Section 8122 of the SUPPORT Act includes the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"),[2] which amends title 18 of the *United States Code* ("U.S.C.") to add criminal anti-kickback provisions that address patient brokering activities associated with substance abuse treatment and recovery efforts.[3] Specifically, EKRA makes it illegal to knowingly and willfully (1) solicit or receive remuneration for referring a patient to a "recovery home, clinical treatment facility, or laboratory" or (2) pay or offer remuneration to either "induce a referral of an individual to" or "in exchange for an individual using the services of" a "recovery home, clinical treatment facility, or laboratory."[4] Violators are

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[1] The Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, H.R. 6, 115th Cong. (2018), *available at* https://www.congress.gov/bill/115th-congress/house-bill/6/text.

[2] The Eliminating Kickbacks in Recovery Act of 2018, H.R. 6, 115th Cong. § 8122 (2018), *available at* https://www.congress.gov/bill/115th-congress/house-bill/6/text#toc-HB10AD8D0FD9C456F81EE0083634020CB.

[3] "Patient brokering" is the practice of third parties ("body brokers") recruiting patients for recovery and/or treatment homes in exchange for kickbacks from the facility that received the referral. In a Congressional hearing on September 28, 2018, to add several bills to the SUPPORT Act (including EKRA), representatives and stakeholders discussed combating "patient brokering" and "patient brokers." 164 Cong. Rec. H9244, H9247, H9253 (daily ed. Sept. 28, 2018), *available at* https://www.gpo.gov/fdsys/pkg/CREC-2018-09-28/pdf/CREC-2018-09-28.pdf.

[4] EKRA adopts the same broad approach as the federal Anti-Kickback Statute ("AKS"), and applies to the soliciting or receiving, or paying or offering to pay remuneration, "directly or indirectly, overtly or covertly, in cash or in kind."

subject to fines and imprisonment up to $200,000 and 10 years, respectively, for each occurrence.

The changes made by EKRA, which took effect on October 24, 2018, affect three specific type of providers: clinical laboratories (and their compensation with sales and marketing personnel[5]), substance use recovery homes, and clinical treatment facilities. These parties should examine their compliance policies carefully to avoid significant problems in the future.

This Client Alert, which is the first part of a series of publications that analyze the SUPPORT Act, summarizes EKRA's differences from—and similarities to—the federal Anti-Kickback Statute ("AKS").[6]

How Does EKRA Compare to the AKS?

Although the language in EKRA has similarities to that of the AKS, EKRA is an entirely new offense with several notable differences from the AKS:

First, EKRA applies to *all* improper referrals to recovery homes, clinical treatment facilities, or laboratories—regardless of whether the referred service relates to substance use disorder treatment. This difference is particularly significant for health care providers who have existing arrangements with these facility types; these previously allowable arrangements must now be reevaluated under EKRA.[7] "Laboratories" have a broad definition under EKRA, and it includes physician-owned laboratory arrangements.[8]

Second, EKRA applies to *all payors*; this is more expansive than the AKS, which applies only to federal health care programs.[9] This enables the federal government to monitor payment arrangements related to items and services that may be reimbursed by either private health plans or government health programs.

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[5] Charles C. Dunham, IV, "Sales and Marketing Compliance: New Federal Anti-Kickback Law May Alter How Clinical Laboratories Compensate Sales Personnel," *Health Law Advisor* (blog), Nov. 20, 2018, https://www.healthlawadvisor.com/2018/11/20/sales-and-marketing-compliance-new-federal-anti-kickback-law-may-alter-how-clinical-laboratories-compensate-sales-personnel/.

[6] 42 U.S.C. 1320a-7b, *available at* https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap7-subchapXI-partA-sec1320a-7b.htm.

[7] For example, arrangements that fell within federal AKS safe harbors must also now be assessed in light of EKRA.

[8] Under EKRA, a "laboratory" is defined 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." This incorporates the definition of "laboratory" in 42 U.S.C. 263a(a).

[9] EKRA applies to services covered by a "health care benefit program," which is defined as having its meaning under 18 U.S.C. 24(b): "any public or private plan . . . 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."

Third, EKRA applies to specific entities—recovery homes, clinical treatment facilities, and clinical laboratories. These entities were apparently targeted in EKRA in an effort to address the opioid crisis.

Finally, EKRA contains eight statutory exceptions; some track the existing AKS safe harbors and some are new.[10] These exceptions are listed below:

Exceptions that Track AKS Safe Harbors
Personal Services and Management Contracts: Payment made by "a principal to an agent as compensation for the services of the agent under a personal services and management contract" under section 1001.952(d) of title 42 of the *Code of Federal Regulations* ("C.F.R."),[11] "as in effect on the date of enactment of this section"
Medicare Coverage Gap Discounts: Discount in the price of an applicable manufacturer's drug that is furnished to an applicable beneficiary under the Medicare coverage gap discount program[12]
Federally Qualified Health Center: Transfer of goods, items, services, donations, or loans set out in writing that are medical or clinical in nature and contribute meaningfully to the health center's ability (among other requirements) to serve a medically underserved population[13]
Coinsurance/Copayment Waiver or Discount: If (1) not routinely provided and (2) provided in good faith (similar to AKS exception 42 C.F.R. 1001.952(k)[14] and civil monetary penalty exception 42 U.S.C. 1320a–7a(i)(6)[15])

[10] For a full list of AKS safe harbors, *see* 42 C.F.R. 1001.952.
[11] 42 C.F.R. 1001.952(d), *available at* https://www.gpo.gov/fdsys/pkg/CFR-2001-title42-vol3/xml/CFR-2001-title42-vol3-sec1001-952.xml.
[12] 42 U.S.C. 1395w–114a(g), *available at* http://uscode.house.gov/view.xhtml?req=(title:42%20section:1395w-114%20edition:prelim).
[13] 42 U.S.C. 1320a–7b(b)(3)(I), *available at* https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap7-subchapXI-partA-sec1320a-7b.htm.
[14] 42 C.F.R. 1001.952(k), *available at* https://www.gpo.gov/fdsys/pkg/CFR-2016-title42-vol5/xml/CFR-2016-title42-vol5-sec1001-952.xml.
[15] 42 U.S.C. 1320a–7a(i)(6), *available at* https://www.govinfo.gov/content/pkg/USCODE-2017-title42/html/USCODE-2017-title42-chap7-subchapXI-partA-sec1320a-7a.htm.

New Exceptions
Standard Discount: Reduction in price if "properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity"
Employee *and* Independent Contractor Compensation (AKS applies only to employees): Bona fide employment or a contractual relationship with such employer; payment not determined/varied by the (1) number of individuals referred to the facility, (2) number of tests/procedures performed, or (3) amount billed to the health care benefit program (*all* payors)
Alternative Payment Models: Remuneration made pursuant to (1) an alternative payment model or (2) a payment arrangement deemed necessary by the Secretary of the U.S. Department of Health and Human Services ("HHS") for "care coordination or value-based care"
Other Exceptions: Authority given to the U.S. Attorney General, in consultation with the Secretary of HHS, to determine other exceptions ("payment, remuneration, discount, or reduction")

EKRA establishes a *new* federal offense that is distinct from the AKS. Although EKRA states that it does not apply to prohibited conduct under the AKS, it is unclear how federal agencies will enforce these two federal offenses when there is overlap.[16] A literal interpretation of this EKRA preemption provision could indicate that potential defendants cannot be charged under both EKRA and the AKS; however, as discussed in a recent post,[17] we do not think it has, or was intended to have, this meaning.

Particular attention to compensation arrangements with sales and marketing employees is necessary given the substantial differences between the AKS's exception for bona fide employees and the parallel provision of EKRA. Because EKRA's bona fide employee

[16] EKRA includes a section entitled "Preemption" that states, "This section shall not apply to conduct that is prohibited under [the AKS]."
[17] Charles C. Dunham, IV, "Sales and Marketing Compliance: New Federal Anti-Kickback Law May Alter How Clinical Laboratories Compensate Sales Personnel," *Health Law Advisor* (blog), Nov. 20, 2018, https://www.healthlawadvisor.com/2018/11/20/sales-and-marketing-compliance-new-federal-anti-kickback-law-may-alter-how-clinical-laboratories-compensate-sales-personnel/.

carve-out does not permit compensation that is determined by, or varies with, the number of individuals referred, the number of tests or procedures performed, or the amount billed to or received from a payor, existing employee compensation arrangements that comply with the AKS may run afoul of EKRA.

The scope of EKRA and the related enforcement risk are still unknown. While these issues become clearer, recovery homes, clinical treatment facilities, and laboratories should examine their policies and practices to determine if changes are necessary to comply with the new law.

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