

# Differences and Similarities Between - Federal Anti-Kickback Statute and the 2018 Eliminating Kickbacks in Recovery Act

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**PRACTICES** Healthcare and Life Sciences, Healthcare Transactions and Regulatory, False Claims Act and Qui Tam Defense

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The Eliminating Kickbacks in Recovery Act of 2018 (“EKRA”) marks a significant shift in federal oversight of the healthcare industry, applying the general rule against paying remuneration related to referrals of patients for items or services regardless of payor. For a specific—but broad—subset of providers, paying any remuneration to induce referrals now carries significant potential criminal and civil liability under EKRA and the False Claims Act.

EKRA went into effect October 24, 2018, and contains a broad prohibition on receiving or offering remuneration in exchange for referrals to a recovery home, clinical treatment facility, or laboratory, regardless of payor type. EKRA complicates compliance efforts for these providers by implementing an additional statutory prohibition on referrals that is broader than the federal Anti-Kickback Statute (“AKS”) with exceptions that are not entirely consistent with the safe harbors currently found in the AKS.

EKRA was passed as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (the “SUPPORT Act”). Although the SUPPORT Act was primarily intended to address the opioid crisis, EKRA applies to any item or service covered by any healthcare benefit program (*i.e.*, governmental or commercial insurance), not just those items or services relating to substance abuse disorders and not just those covered by federal healthcare programs.

EKRA’s far reaching scope means that recovery homes, clinical treatment facilities, and laboratories must evaluate their current arrangements for compliance, and potentially restructure them. For example, while the AKS contains a safe harbor that generally permits compensation as part of a bona fide employment arrangement, EKRA permits payments to an employee only if the payment is not determined by, or does not vary by, (1) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory; (2) the number of tests or procedures performed; or (3) the amount billed to, or received from, in part or in whole, the healthcare benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory. Thus, certain common arrangements between recovery homes, clinical treatment facilities, and laboratories and their employees (such as marketers) that involve variable compensation (such as commission) may need to be evaluated and potentially restructured to comply with EKRA.

A chart comparing some of the key similarities and differences between EKRA and the AKS is included below:

## **Key Differences and Similarities between the Federal Anti-Kickback Statute (AKS) and the Eliminating Kickbacks in Recovery Act of 2018 (EKRA)**

**AKS**

**EKRA**

**Statutory Prohibition**

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind —

(A) In return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal healthcare program, or

(B) In return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal healthcare program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal healthcare program, or

(B) To purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal healthcare program,

(1) OFFENSE — Except as provided in subsection (b), whoever, with respect to services covered by a healthcare benefit program, in or affecting interstate or foreign commerce, knowingly and willfully —

(A) Solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory or

(B) Pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind —

(i) To induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or

(ii) In exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory,

— shall be fined not more than \$200,000, imprisoned not more than 10 years, or both, for each occurrence.

— shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both

**Scope/Applicability**

<b>Services Covered by...</b>	<b>Federal healthcare programs</b> – Any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government or a State healthcare program (42 U.S.C. 1320a–7b(f))	<b>Healthcare benefit programs</b> – 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 (18 U.S. Code § 24(b)) <i>*Note that the prohibition applies to all services, not just those relating to substance abuse disorders</i>
<b>Referrals to...</b>	Any healthcare entity (that offers services covered by federal healthcare programs)	Recovery homes, clinical treatment facility, laboratory  <b>Recovery home</b> – 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  <b>Clinical treatment facility</b> – 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  <b>Laboratory</b> – 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

**Exceptions [The following are not “remuneration” under the applicable Statute]**

<b>General Discounts</b>	Discount or other reduction in price obtained by a provider of services or other entity under a Federal healthcare program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal healthcare program	Same <sup>1</sup>
<b>Bona Fide Employment Relationship</b>	<b>Any amount</b> paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services	A payment made by an employer to an employee <b>or independent contractor</b> (who has a bona fide employment <b>or contractual relationship</b> with such employer) for employment, <b>if the employee's 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 individuals referred to a particular recovery home, clinical treatment facility, or laboratory</b>
<b>Group Purchasing Organizations</b>	Any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal healthcare program if (i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and (ii) in the case of an entity that is a provider of services (as defined in section 1395x (u) of this title <sup>2</sup> ), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity	
<b>Patient Copayments</b>	A waiver of any coinsurance under part B of subchapter XVIII of this chapter by	A waiver or discount (as defined in 42 CFR § 1001.952(h)(5)) of any

<b>or Coinsurance</b>	a Federally qualified healthcare center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act [42 U.S.C. 201 et seq.]	coinsurance or copayment by a healthcare benefit program if (A) the waiver/discount is not routinely provided, and (B) the waiver/discount is provided in good faith
<b>Risk-Sharing Arrangements</b>	Any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1395mm of this title or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide	See Alternative Payment Model exception
<b>Pharmacy Waivers/ Part D Cost-Sharing</b>	The waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of subchapter XVIII of this chapter, if the conditions described in clauses (i) through (iii) of section 1320a–7a (i)(6)(A) of this title are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1395w–114 (a)(3) of this title), section 1320a–7a (i)(6)(A) of this title shall be applied without regard to clauses (ii) and (iii) of that section)	
<b>FQHCs &amp; MA Organizations</b>	Any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1395w–23 (a)(4) of this title	
<b>FQHCs &amp; Donors</b>	Any remuneration between a health center entity described under clause (i) or (ii) of section 1396d (l)(2)(B) of this title and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health	Same <i>[Direct cross-reference to the AKS exception]</i>

center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity

**Medicare Coverage Gap Discounts** A discount in the price of an applicable drug (as defined in paragraph (2) of section 1395w–114a (g) of this title) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1395w–114a of this title Same

**Organizational Compensation** No exception that mirrors the EKRA exception here, but Personal Services & Management Contracts Safe Harbor A payment made by a principal to an agent as compensation for the services of the agent under a personal services and management contract that meets the requirements of 42 CFR § 100.952(d), as in effect on the date of enactment of this Section

**Alternative Payment Models** ***\*If within the AKS Personal Services & Management Contract Safe Harbor, it is excepted under EKRA*** Payments made as part of an alternative payment model (the shared savings program under Section 1899 of the Social Security Act (“SSA”), a model created by the Center for Medicare and Medicaid Innovation other than a healthcare innovation award, a demonstration under the Health Care Quality Demonstration Program (Section 1866C of the SSA), or a demonstration required by federal law), or any alternative payment model used by a state, health insurance insurer or group health plan if approved by the U.S. Department of Health and Human Services (“HHS”) as necessary for care coordination and value-based care

**Subsequently Enacted Regulations** Any other payment, remuneration, discount, or reduction as determined by the Attorney General, in consultation with HHS, by regulation

For more information about EKRA, the AKS, or other healthcare regulatory and compliance questions, please contact the Haynes Boone [Healthcare Practice Group](#) members below.

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<sup>1</sup> This means the EKRA exception is the same as the AKS exception, notwithstanding the distinctions already discussed, *e.g.*, that the AKS exception refers to “discount[s] [] obtained ... under a **federal healthcare program**,” whereas EKRA’s exception refers to “discount[s] [] obtains ... under a **healthcare benefit program**.”

<sup>2</sup> As used here, “this title” refers to 42 USC § 1320a-7b.