Eliminating Kickbacks in Recovery Act:

Practical Guidance for Laboratories, Treatment Centers, and Other Providers

May 2026

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ROADMAP

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THE HISTORY AND PURPOSE OF EKRA

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THE HISTORY AND PURPOSE OF EKRA

- The Eliminating Kickbacks in Recovery Act, 18 U.S.C. § 220 ("**EKRA**"), is a health care fraud and abuse statute established to prohibit certain types of patient brokering arrangements related to services provided to vulnerable individuals with substance use disorders during the opioid epidemic.
- Prior to EKRA, there was concern that no federal law existed to prohibit exploitative patient brokering arrangements for services reimbursed by commercial health insurance programs.

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THE STATUTE, EXCEPTIONS, AND PENALTIES

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THE ELIMINATING KICKBACKS IN RECOVERY ACT

- EKRA makes it unlawful to knowingly and willfully, with respect to services covered by a **health care benefit program**:
  - (1) **solicit or receive 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
  - (2) **pay or offer 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**.

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THE ELIMINATING KICKBACKS IN RECOVERY ACT

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Definitions:

- "**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.

- "**Health Care Benefit Program**" means commercial health insurance programs (e.g., BCBS, Aetna, etc.) and federal health care programs (e.g., Medicare, Medicaid, TRICARE, etc.).

- "**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.

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THE ELIMINATING KICKBACKS IN RECOVERY ACT

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- **"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.

Violations:

- Each violation or EKRA could result in fines of up to $200,000 and imprisonment for up to 10 years.

Example:

- A company operates a recovery home. The company agrees to pay a local hospital $500 each time the hospital refers a patient to the recovery home. Some of the referred patients are beneficiaries of a commercial health insurance plan.

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EKRA STATUTORY EXCEPTIONS

- EKRA contains seven statutory exceptions promulgated at 18 U.S.C. § 220(b). The exceptions are listed below:
  - Discounts
  - Certain payments made to an employee or independent contractor
  - Personal services and management contracts
  - Waiver of beneficiary copayment, coinsurance and deductible amounts
  - Drug discounts provided to Medigap program beneficiaries
  - Certain arrangements with Federally Qualified Health Centers
  - Certain payments made associated with Alternative Payment Models

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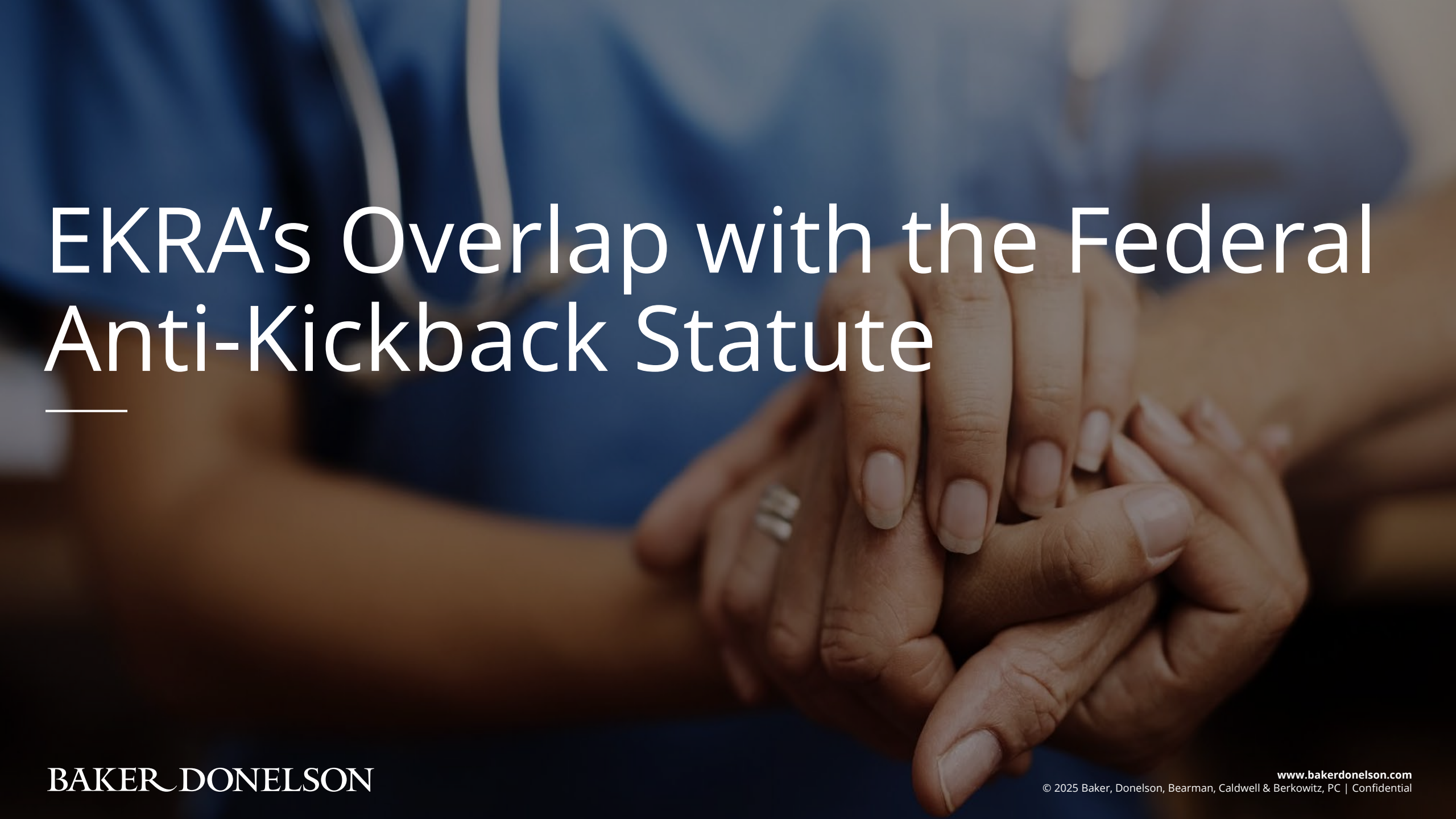
EKRA's Overlap with the Federal Anti-Kickback Statute



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EKRA AND THE FEDERAL ANTI-KICKBACK STATUTE

- EKRA has some structural overlap with the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1)-(2) (the "**AKS**"):

EKRA	The AKS
EKRA makes it unlawful to knowingly and willfully, with respect to services covered by a **health care benefit program**: (1) solicit or receive 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 (2) pay or offer 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**.	The AKS makes it unlawful to knowingly and willfully offer, pay, solicit or receive **remuneration**, overtly or covertly, in cash or in kind to **induce such person** to: (1) **refer** an individual to a person for the provision of an item or service for which payment may be made in whole or in part under a **federal health care program**; or (2) **arrange** for or **recommend** that someone purchase, lease or order a good, facility, service or item covered under a **federal health care program**.

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EKRA AND THE FEDERAL ANTI-KICKBACK STATUTE

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- Both EKRA and the AKS are intent based statutes.
- EKRA relates to arrangements that involve laboratories, treatment facilities, and recovery homes. The AKS is not limited to any particular type of provider.
- EKRA is an all-payor statute. The AKS relates to items and services reimbursed by a federal health care program.
- EKRA has seven (7) exceptions. The AKS has thirty-seven (37) safe harbors. Many of the EKRA exceptions overlap structurally with AKS safe harbors, but **be careful**:
  - E.g., EKRA includes an exception for "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 section 1001.952(d) of title 42, Code of Federal Regulations, ***as in effect on the date of enactment of this section***". *See* 18 U.S.C. § 220(b)(4) (emphasis added).
- EKRA is a relatively new law so there is limited case law interpreting the statute and its exceptions.

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United States v. Schena

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UNITED STATES V. SCHENA

Overview:

- In *United States v. Schena*, 142 F.4th 1217 (9th Cir. 2025), the Ninth Circuit affirmed an EKRA conviction involving a laboratory testing company that allegedly engaged in various misleading tactics to encourage health care providers to order laboratory tests that would then be performed by the testing company.

Key Facts:

- The laboratory owner in *Schena* instructed the company's marketing personnel to promote certain blood allergy tests to physicians who were not allergists, did not specialize in allergy testing, and who were unfamiliar with allergy testing.
- As a result, the marketing personnel informed such physicians that the blood allergy tests were "highly accurate" and "far superior" to allergy skin tests, even though the blood allergy tests could only assess whether a patient had been exposed to an allergen and could not actually assess whether a patient possessed an allergy.

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UNITED STATES V. SCHENA

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- During the COVID-19 pandemic the laboratory's allergy testing volume substantially decreased.
- In response, the laboratory owner instructed the company's marketing personnel to advertise the laboratory's COVID antibody blood test as equal to or superior to COVID polymerase chain reaction ("**PCR**") tests, even though the blood tests could only detect COVID antibodies (and not active COVID infections).
- The marketing personnel encouraged physicians to bundle COVID blood tests and allergy blood tests by falsely claiming that Dr. Anthony Fauci recommended bundling allergy and COVID tests.
- The laboratory owner also instructed marketing personnel to misrepresent how quickly PCR tests could be resulted.

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UNITED STATES V. SCHENA

CONTINUED

- There was also evidence of inappropriate utilization.
  - Even when physicians only ordered COVID PCR tests, the laboratory owner instructed the laboratory's personnel to run allergy tests on the specimens as well.
  - The laboratory tested each patient for 120 allergens, not because this was medically necessary, but because the panels included that number of allergens. The laboratory could bill third-party payors up to $10,000 for each full suite of tests.
- The marketing personnel were compensated based on a percentage of the revenue that they generated for the laboratory based on referred testing.
  - One marketer testified that the marketers "controlled" which laboratory would receive the blood samples.
- The trial court convicted the laboratory owner for violating EKRA.

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UNITED STATES V. SCHENA

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Key Issues:

- Whether EKRA covers payments to marketers designed to induce referrals, or whether the provision is limited to payments made to persons who are doing the actual patient referrals, most typically doctors and other medical professionals?
- What it means to "induce a referral" under EKRA in circumstances where a party is alleged to have made payments to a marketing agent "to induce a referral of an individual"?

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UNITED STATES V. SCHENA

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The Decision:

- The Ninth Circuit affirmed the laboratory owners' convictions under EKRA and held that EKRA covers payments to marketers that are intended to induce referrals and "marketing intermediaries who interface with those who do the referrals."
  - "Although the doctors may have nominally referred patients to [the laboratory], a jury could have found that [the laboratory owner] directed marketers to engage in deceitful conduct that gave the marketers undue influence over the referrals. In that sense, [the laboratory owner] paid marketing agents to induce referrals to his lab." *Schena* at 1226.
  - "Under EKRA, there is no requirement that the payments be made to a person who interfaces directly with patients." *Schena* at 1222.

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UNITED STATES V. SCHENA

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- The Ninth Circuit provided additional context regarding what it means to "induce a referral" for purposes of EKRA and aligned its interpretation of EKRA with applicable case law interpreting the AKS.
- First, the Ninth Circuit explained that a person could "induce a referral" under the meaning of EKRA by paying someone who could in turn effect a referral (e.g., a marketing agent), even if the person who received the payment did not, on his own, have the ability to order a laboratory test or refer a patient to a treatment facility.
  - This is consistent with decisions from other courts that interpreted what it means to induce a referral in the context of the AKS. *See, e.g., United States v. Marchetti*, 96 F.4th 818 (5th Cir. 2024); *United States v. Miles*, 360 F.3d 472 (5th Cir. 2004); *United States v. Polin*, 194 F.3d 863 (7th Cir. 1999).
- Second, the Ninth Circuit explained that implementing a percentage-based compensation structure, without more, would not "induce a referral" in violation of EKRA. To induce a referral, an arrangement must involve undue influence.
  - "[t]o induce . . . connotes an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business." *Schena* at 1224.

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Key Takeaways

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EKRA – Key Takeaways

After Schena:

- In order for a third-party intermediary to "induce a referral" for purposes of EKRA, the third-party intermediary's conduct must involve undue influence.
  - Either (i) some control over the medical decision-making of the ordering/referring provider, or (ii) dishonest marketing tactics that influence the ordering/referring provider's decisions.
- A commissions based compensation structure with a third-party intermediary alone does not violate EKRA, if the third-party intermediary does not exercise undue influence over referrals.
- Schena is limited to the Ninth Circuit.
- Potential overlap with AKS legal precedent. But be careful!

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EKRA – Key Takeaways

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Next Steps:

- Laboratories, treatment centers, and recovery homes should establish policies and provide training for their marketing personnel.
- Laboratories, treatment centers, and recovery homes should develop consistent processes to review marketing materials and related communications to ensure that clinical claims included in such materials and communications are supported by clinical evidence.
- Health care providers more broadly should review agreements with laboratories, treatment, centers, and recovery homes to ensure compliance with EKRA.

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