



## EKRA: New Kickback Law Creates Risk for Common Medical Lab Marketing Practices

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As in the healthcare industry generally, many, or even most, lab companies compensate an employee salesforce based on a range of commission structures (“base plus bonus”). The Eliminating Kickbacks in Recovery Act of 2018 (EKRA), a law recently passed by Congress, creates new and material risk around this long-standing incentive compensation structure. EKRA is part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the Support Act), a comprehensive federal legislative initiative aimed at addressing the opioid crisis, which was signed into law on October 25, 2018. EKRA was a last minute addition to the Act and was introduced in the House and agreed to by both the House and Senate in just over a week.

The intent of EKRA is to address the opioid crisis by penalizing patient brokers who seek profits off of illegal referrals of patients seeking the services of a recovery home, clinical treatment facility, or laboratory. Importantly, the term “laboratory” includes all facilities 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.<sup>1</sup> Based on this broad definition, all referrals for clinical laboratory tests, regardless of payor source, potentially implicate EKRA, even if the tests do not relate to substance abuse testing or treatment. Therefore, clinical laboratories should be aware of EKRA, as there are hefty penalties associated with noncompliance.

### The Act

EKRA prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in return for the referral of a patient to, or in exchange for an individual using the services of, a recovery home, clinical treatment facility, or laboratory if the services are covered by a health care benefit program.<sup>2</sup> The term “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.”<sup>3</sup> Therefore, in contrast to the federal Anti-Kickback Statute (“AKS”), which applies to referrals for services payable by a federal program, EKRA extends to referrals reimbursed by both governmental and commercial insurers. Violators of EKRA may be subject to hefty penalties, including a fine of up to \$200,000 or imprisonment of 10 years, or both, for each occurrence.<sup>4</sup>

EKRA includes eight exceptions, including an exception for payments made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, but only if the employee’s 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;

<sup>1</sup> 18 U.S.C.A. § 220.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

2. the number of tests or procedures performed; or
3. the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory.<sup>5</sup>

Notably, the EKRA exception for employees is narrower than the AKS safe harbor for employees and would further restrict the ways in which employees can be paid, *i.e.*, compensation may not vary by the volume or value of referrals, if both the AKS and EKRA apply.

## Critics of EKRA

EKRA has been criticized as being overly broad and exceeding its legislative intent, as its applicability arguably extends to arrangements in the healthcare industry that are widespread and legal under similar federal laws, and to arrangements that do not involve substance abuse treatment. EKRA has also been criticized for containing a number of ambiguities. For instance, the bill does not include a definition of “referral,” although the prohibition hinges on whether any remuneration is paid in exchange for a referral. The statute includes a preemption clause related to conduct that is prohibited by the AKS Statute. The preemption clause states, “This section shall not apply to conduct that is prohibited under [the Anti-Kickback Statute].” While it is possible that the inclusion of this clause was Congress’s attempt to ensure that kickbacks under the current AKS regime continue to be governed by the AKS Statute, several legal analysts have questioned whether the word “not” should have been inserted before “prohibited,” or if prohibited was intended to be the word “permit.” If the word “not” had been included, EKRA’s reach would not prohibit the payment of employed salesforce based on commissions.

## Complying with the Law

A variety of approaches are being taken in terms of compliance with EKRA. Some laboratories may take the aggressive approach that the law does not apply if the laboratory does not perform toxicology testing. Given its status as a last-minute and rushed addition to the SUPPORT Act, there may be some rationale for this position. However, this is not a conservative approach and it does carry with it some regulatory risk of willful noncompliance with EKRA. Other laboratories are moving towards different payment structures (*i.e.*, paying employed salesforce based on a performance metric), at least on a temporary basis until the Attorney General issues further guidance as to how EKRA should apply.

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<sup>5</sup> *Id.*

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