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New All-Payor Anti-Kickback Law in Opioid Bill Impacts Clinical Laboratories

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The Eliminating Kickbacks in Recovery Act (the "EKRA") was passed on October 24, 2018 as part of the SUPPORT Act, Congress's effort to address the current opioid epidemic in our nation.[i] The EKRA is a separate provision within the Act which criminalizes "any solicitation or payment of remuneration in exchange for patient referrals or to induce the referral of an individual to a recovery home, clinical treatment facility, or laboratory."[ii] Violations of the EKRA can result in fines up to $200,000, 10 years in jail, or both.

The EKRA is extremely broad in its application. Unlike other federal health care fraud and abuse laws, the EKRA's prohibitions are related to services covered by any "health care benefit program," which includes not only government insurance programs but also private payors. The term "laboratory" is broadly defined under the act.[iii] Therefore, *any* referral to *any* laboratory, clinical treatment center or recovery home is potentially implicated, whether or not the referral is opioid-related. This is not in line with the intent of the EKRA, which was added into the SUPPORT Act last-minute with the intended purpose of addressing "patient brokering" in exchange for kickbacks of individuals with substance abuse disorders.[iv]

The EKRA contains several exceptions that track certain Anti-Kickback statute ("AKS") safe harbors, but which contain fundamental differences. In doing so, the EKRA appears to prohibit conduct that is currently permissible under the federal AKS safe harbors. While the AKS employment safe harbor excludes from the definition of remuneration "any amount paid by an employer to a bona fide employee for employment in the furnishing of any item or service," the payment of which may be made in whole or in part under a federal or state health care program,[v] the EKRA on its face appears to make commission-based payments to W-2 employees a criminal act.

The exception under the EKRA for "payments made by an employer or independent contractor" applies only if the employee's payment is not determined 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 health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory.

This would appear to prohibit commission-based payments or bonuses to any employees, which has been historically legal under the well-established AKS safe harbor and heavily relied upon by laboratories and the health care industry.

The EKRA is currently in effect. It may bring laboratories, clinical treatment centers and recovery homes under scrutiny and may expose them to potential criminal penalties. Congress has recognized potential unintended consequences of the EKRA and may pass clarifying language, but this will likely not occur until the next legislative session. While we await legislative clarification, and until the promulgation of formal regulatory guidance and judicial interpretation, it is important for these potentially affected entities to evaluate current compensation arrangements with all referral sources, including marketing and sales representatives, to ensure they do not involve any exchange of remuneration in exchange for patient referrals. Since it is a widespread practice for laboratories to employ or contract with sales personnel or marketing agents who generate referrals, it is wise to consider alternative payment structures for these individuals that is compliant under both the AKS and this new EKRA.

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[i] H.R. 6, 115th Cong. (Oct. 24, 2018) (titled the Substance Abuse Use-Disorder Prevention that Promotes Opioid Recovery for Patients and Communities Act).
[ii] Subtitle J of the SUPPORT Act, to be codified at 18 U.S.C. § 220.
[iii] "Laboratory" means a facility for the biological, microbiological, serological, chemical, immune-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.
[iv] *See* Congressional Record H9244, U.S. House of Representatives, 115th Cong. (Sept. 28, 2018) (Statements of Congressman Frank Pallone, Jr. (D-NJ)).
[v] 42 C.F.R. § 1001.952(i); see also OIG Adv. Op. 12-08 (2012); OIG Adv. Op. 04-09 (2004); OIG Adv. Op. 00-02 (2000); OIG Adv. Op. 98-9 (1998).

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