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EKRA is Creating Uncertainty and Potential Criminal Liability for Clinical Laboratories: What Can Laboratories Do Now?

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In late 2018, as a part of federal efforts to combat the ongoing American opioid crisis, Congress passed 70 bills designed to address the crisis in a comprehensive manner that includes the regulation of substance abuse providers and others. These bills are referred to as the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).

In the SUPPORT Act is EKRA, which stands for the Eliminating Kickbacks in Recovery Act of 2018. EKRA makes it a crime to knowingly and willfully solicit, receive, offer or pay remuneration directly or indirectly, in return for referring a patient to, or in exchange for an individual using the services of a recovery home, clinical treatment facility, or clinical laboratory.[1] It is an "all payor" statute, meaning that it applies to any kind of payors and not just government payors which trigger the similar but not identical prohibition under the federal anti-kickback law. Those who violate EKRA could be subjected to a fine of $200,000 and/or 10 years of prison for each violation.[2]

EKRA has eight exceptions that are similar to but not identical to the federal anti-kickback law and has a confusingly drafted preemption law which states that EKRA shall not "be construed to occupy the field in which any provisions of [EKRA] operate to the exclusion of state laws on the same subject matter."[3] Does EKRA preempt state laws on the same subject matter, is it an additional violation, or does the state regulation preempt EKRA? These are questions that will need to be resolved state by state and statute by statute.

Interestingly, although EKRA and the entire SUPPORT Act are focused on drug abuse treatment providers, it does not limit the regulation to toxicology laboratories. This means that all clinical laboratories are affected by the new law however and from whomever they receive payment. It also directly targets their marketing arrangements which may have been legally acceptable under pre-EKRA fraud and abuse laws. For example, EKRA prohibits compensation paid from laboratories to employees or contractors that is based on the number of individuals referred to the clinical laboratory, the number of tests or procedures performed, or the amount billed or received from payors.[4] This can create liability for laboratories because prior to EKRA, health lawyers may have opined that under the federal anti-kickback law exception and safe harbor for employees, marketing employees could be paid by clinical laboratories based on the business generated for the laboratories.[5]

Clinical laboratories should review all of their financial relationships with a health lawyer now for EKRA compliance—and not just limited to their marketing arrangements. This, however, is a confusing time because EKRA is so broadly drafted and the federal government has not issued clarifying regulations as of the date of this publication. Hopefully, the federal government will come out soon with EKRA regulations to clarify some of these questions and concerns. However with the serious criminal penalties under EKRA, clinical laboratories should tread very carefully and conservatively in their financial arrangements with third parties and monitor closely the promulgation of EKRA regulations.

If you have any questions, please contact Erin S. Aebel at eaebel@shumaker.com or 813.227.2357.

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[1] 18 U.S.C. § 220(a).

[2] 18 U.S.C. § 220(a).

[3] 18 U.S.C. § 220(d)(2).

[4] 18 U.S.C. § 220(b).

[5] See, 42 USC § 1320a-7b(3)(B); 42 CFR § 1001.952(i).