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A New Anti-Kickback Law Targets Clinical Lab Marketing Arrangements

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Some very important and potentially game-changing legislation was recently passed. On Oct. 24, 2018, Congress enacted the Eliminating Kickbacks in Recovery Act of 2018 (or EKRA) – a statute that potentially eliminates legal protections (i.e., "safe harbors") used by clinical laboratories to market their services. EKRA is part of the "Support for Patients and Communities Act," comprehensive legislation designed to address the opioid crisis. The Act is clearly aimed at the use/abuse of opioids and the business practices of recovery centers.

EKRA has several potentially game-changing provisions. The first big development is EKRA's definition of "clinical labs." The definition of clinical labs used by EKRA is the extremely broad definition contained in 42 USC 263a. Rather than confining the definition of "clinical lab" to toxicology labs, which would satisfy the legislative purpose of the opioid crisis and business practices of recovery centers, the definition covers ALL clinical labs. Consequently, the reach of the definition of "laboratory" is significantly broader than the purpose of the Support for Patients and Communities Act.

Another important provision of EKRA is the statute is an "all-payor" statute. This means it applies to services that are paid by commercial insurers in addition to services paid by Medicare and Medicaid. Unlike the Anti-Kickback Statute ("AKS") that only applies to federal payors, EKRA applies to commercial payors as well. This

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is obviously more expansive than the AKS and may require many clinical labs to examine their business practices as they relate to commercial payors if the labs have carved out arrangements specifically to commercial payors

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