A New Anti-Kickback Law Targets Clinical Lab Marketing Arrangements

By James A. Hoover March 2019

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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 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.

Finally and most substantively, EKRA prohibits certain business practices that some clinical labs currently use. EKRA defines payment practices that violate the statute to include compensation to *employees* or contractors that is based on: the number of individuals referred to a particular recovery home, clinical treatment facility or laboratory; the number of tests or procedures performed; or 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 change is important because under the AKS, clinical laboratories and other providers are permitted to pay bona fide employees compensation based on revenues generated from their marketing activities. The OIG has even indicated in several Advisory Opinions that providers could pay independently-contracted sales agents percentage-based compensation so long as the arrangement contained adequate safeguards to address so-called "suspect factors." The prohibition of paying an *employee* based on some type of formula that takes into account the amount of business generated by the employee should cause laboratories to review their compensation practices because these compensation arrangements used by any clinical laboratory may no longer be protected.

While there is a possibility the definition of clinical lab will be interpreted to apply only to toxicology labs, it is far from certain. Consequently, any/every clinical laboratory needs to be aware of the new legislation and examine its business practices immediately.

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