Clinical Labs Beware: Review Your Marketing Arrangements

By James A. Hoover

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On October 24, 2018, Congress enacted the Eliminating Kickbacks in Recovery Act of 2018 (EKRA). EKRA is part of the "Support for Patients and Communities Act," comprehensive legislation designed to address the opioid crisis. Although the Act is aimed at the use/abuse of opioids and the business practices of recovery centers, it contains some very important and potentially game changing legislation.

The most substantive change brought about by EKRA relates to certain business practices that some clinical labs currently use. EKRA prohibits certain compensation arrangements with employees and contractors. The statute prohibits a clinical lab from paying compensation to employees or contractors that is based on: (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. Thus, compensation formulas for employees that use a percentage of collections or number of specimens are now prohibited. 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 employees based upon a formula that takes into account the amount of business generated by the employee should cause laboratories to review and change their compensation practices since these compensation arrangements are widely-used, and now are no longer protected.

Another game changing provision of EKRA is that the statute applies to all payors. 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. Obviously this is much more expansive than the AKS and may have a significant impact on clinical labs if a lab carves out arrangements for federal healthcare benefit programs. Clinical labs should examine their business practices as they relate to commercial payors if the labs have carved out arrangements specific to commercial payors.

Finally, EKRA currently applies to all clinical laboratories. The definition of "clinical labs" used by EKRA is the definition contained in 42 USC 263a, which is extremely broad. 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 actually includes 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 and, as currently drafted, applies to every clinical laboratory. Accordingly, all clinical laboratories are subject to EKRA's reach.

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 and compensation arrangements immediately.

For more information, please contact:

James A. Hoover
Partner, Birmingham
P. (205) 458-5111
E. jhoover@burr.com

James (Jim) Hoover is a Partner with Burr & Forman LLP practicing in the firm's Health Care Industry Group.