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Health Care Alert: EKRA Enforcement in an Era of Minimal Regulatory Guidance

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On January 10, 2020, the Department of Justice announced that a Kentucky woman admitted in federal court that she solicited kickbacks from a toxicology laboratory in exchange for urine drug testing referrals, lied to law enforcement agents about the kickback she received, and then attempted to cover up the kickback by requesting the alteration of certain financial records. Theresa C. Merced, 80, pleaded guilty to one count of violating the Eliminating Kickbacks in Recovery Act (EKRA); one count of making false statements; and one count of attempted tampering with records. Merced, the office manager of a substance abuse treatment clinic in Jackson, Kentucky, admitted that between December 2018 and August 2019, she solicited kickbacks from the CEO of a toxicology lab in exchange for urine drug test referrals. According to the plea agreement, in August 2019, the CEO delivered to Merced a $4,000 check as part of a larger package of promised inducements. Merced cashed the check. When Merced was later questioned by law enforcement agents about the check in September 2019, she denied knowledge of it, and stated that the $4,000 was probably a loan from the lab CEO to her husband. Shortly after her interview with the agents, Merced called the lab CEO and asked that he alter the lab's financial records so that the entry for the $4,000 check would say "rent/loan" to align with what she told the agents. This conviction of an individual pursuant to EKRA is notable as HHS has promulgated no regulatory or sub-regulatory guidance since enactment of the statute.

EKRA was enacted in October 2018 as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. EKRA created criminal penalties for any individual who "solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory" or "pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory or in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory."

Furthermore, EKRA prohibits payments made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer), if the employee or contractor’s payment is determined by or varies by any of the following:

1. The number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory.
2. The number of tests or procedures performed.
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.

EKRA was a response to the concern that the federal Anti-Kickback Statute (AKS) was not broad enough to cover certain unethical payment arrangements related to opioid addiction treatment centers as AKS only applies to federal health care programs. Thus, unlike AKS, ERKA applies to services covered by government *or* private payors. Furthermore, EKRA goes beyond the prohibitions under AKS and directly prohibits certain arrangements that are expressly permitted under AKS, such as the bona fide employee safe harbor under AKS, which grants employers wide discretion in how employees are paid, including permitting percentage-based compensation.

Merced is scheduled to be sentenced on May 1, 2020. She faces up to 20 years in prison and a maximum fine of $250,000. Merced’s EKRA conviction is believed to be the first in the nation. Laboratories and other implicated providers should review their compensation arrangements for compliance with both AKS and EKRA, as well as other potentially applicable federal and state fraud and abuse laws. As EKRA prohibitions are broader than those under AKS, it is unclear whether arrangements that comply with AKS, but are prohibited under EKRA, would be protected from enforcement under EKRA. Until clarifying guidance is issued, laboratories and substance use disorder providers should review all payor arrangements, not only those payable by a Federal Healthcare Program payor, and should ensure that their arrangements comply with EKRA’s stringent requirements.

If you have questions about the EKRA or the impact on your organization, please contact Jonathan Ishee, Nita Garg, Liam Gruzs, Suzanne Scrutton, Jolie Havens, or your regular Vorys attorney.