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New Federal Law Targets Referrals to Substance Abuse Treatment Providers and Labs

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The federal government as well as many states are enacting legislation to address growing concerns over referrals for substance abuse treatment stemming from the increasing prevalence of opioid abuse. Tennessee, for example, enacted a substance abuse treatment Anti-Kickback Statute that took effect July 1, 2018. On October 24, 2018, President Trump signed into law the new Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. The SUPPORT Act contains a number of provisions aimed at addressing the opioid crisis. Section 8121 of the SUPPORT Act, separately referred to as the Eliminating Kickbacks in Recovery Act of 2018 (Act), contains a provision (to be codified at 18 U.S.C. § 220) that prohibits the payment of remuneration for referrals to certain providers.

Specifically, the Act prohibits any person, with respect to services covered by a health care benefit program, from paying, offering to pay, soliciting or receiving any remuneration (1) to induce a referral of an individual to a recovery home, clinical treatment facility, or a laboratory or (2) in exchange for an individual using the services of a recovery home, clinical treatment facility or a laboratory. The Act does not offer a specific definition of remuneration, but it likely will be interpreted to be the same or substantially similar to the broad definition of remuneration provided in the federal Anti-Kickback Statute (AKS), which includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

Importantly, the Act applies to kickbacks related to services covered by a "health care benefit program," which is defined as "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract." The definition of health care benefit program sets the Act apart from other notable federal health care fraud and abuse laws in that it applies to services reimbursable by private insurers and not just governmental insurance programs. Because of that, the Act likely applies to virtually all substance abuse treatment facilities and laboratories.

The Act targets three types of providers whose involvement triggers application: (1) recovery homes, (2) clinical treatment facilities, and (3) laboratories. Recovery homes and clinical treatment facilities are specifically defined as facilities providing services related in some way to substance abuse treatment (though hospitals are excluded from the definition). However, laboratory is not defined by reference to substance abuse treatment, but applies broadly to facilities for "the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." The broad definition of the types of entities covered, specifically labs, means that the Act has application beyond opioid-related treatment (or even other substance abuse treatment) because any referrals to these types of entities are potentially implicated, whether opioid related or not.

There are eight exceptions to the general prohibition, and although no interpretative guidance has yet been issued under the Act, AKS guidance is likely instructive given the similarity between the laws. The following exceptions are of particular note:

- 1. An exception for discounts that is largely similar to the AKS safe harbor for discounts.
- 2. An exception for certain bona fide employment arrangements. Importantly, this exception deviates significantly from the AKS safe harbor for employees. The employee exception under the Act does not apply to remuneration paid for "(A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory, (B) the number of tests or procedures performed, or (C) 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." The AKS, on the other hand, does not contain those additional requirements, stating "'remuneration' does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs." So while the AKS has traditionally been interpreted to allow compensation paid to employees even when that compensation varies with the volume or value of referrals (e.g., commissions), the Act explicitly prohibits commission-based compensation paid to employees.
- 3. An exception for independent contractors that specifically references, and is coextensive with, the AKS.
- 4. An exception for waivers and discounts of coinsurance and copayments that cross references the similar AKS safe harbor and adds two additional requirements that the waiver or discount not be routinely provided and be provided in good faith.

The Act explicitly states that the kickback section neither supersedes the AKS nor preempts similar state laws. However, the Act clearly and explicitly goes beyond the AKS in certain ways - e.g., less protection for employment relationships. Therefore, it is very likely that the purpose of the Act is to be more restrictive than the AKS both in its application to payments from private payors and in its more restrictive exceptions.

In light of its greater restrictions, all providers covered by the Act should review arrangements with referral sources, specifically those that involve commissions or other incentive-based compensation. Compliance with existing fraud and abuse laws will not necessarily ensure compliance with the Eliminating Kickbacks in Recovery Act.