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Client Alert: Congress Adds New Criminal Kickback Prohibition that Includes Services Covered by Private Health Plans

INDUSTRY SECTOR

Health Care

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Against the backdrop of an unprecedented opioid epidemic claiming the lives of an estimated 130 Americans each day, Congress passed the federal Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("**SUPPORT Act**"), which became law on October 24, 2018. The SUPPORT Act is the result of a bipartisan effort to address the opioid crisis in a variety of ways.

While the SUPPORT Act is intended to increase the likelihood that drug-addicted patients will get needed help, it also adds new criminal penalties applicable to certain payments made to drug treatment facilities, recovery homes, and laboratories. The "Eliminating Kickbacks in Recovery Act of 2018" ("**EKRA**") prohibits kickbacks for referrals to these entities if the services are covered by a "health care benefit program", which includes public and private health plans. The penalties included in EKRA aim to deter dishonest providers engaged in "patient brokering" or "junkie hunting" scams, in which some unscrupulous drug rehabilitation centers pay brokers, often the operators of recovery homes, to send them patients with insurance coverage. The rehabilitation centers in turn bill for drug addiction treatments and tests, typically including a high volume of urine tests – often two or three per week – which can be reimbursed thousands of dollars each time they are ordered. Disreputable rehabilitation centers sometimes will even directly recruit drug addicts by offering gift cards and other incentives.

To address this problem, EKRA:

- Prohibits paying, offering, soliciting, or receiving cash or remuneration of any kind in exchange for a patient referral or to induce an individual to receive services from a lab, a recovery home, or clinical treatment center;

- Applies to substance abuse treatment services covered under any public or private health plan;
- Includes criminal penalties of up to $200,000, and 10 years imprisonment, or both, per occurrence; and
- Delegates rulemaking authority to the U.S. Attorney General.

The Law's Expansive Scope

Enacted in 1972, the federal Anti-Kickback Statute ("AKS") generally prohibits health care providers from offering, soliciting or accepting anything of value in exchange for referrals for federal health care program business, but EKRA casts a wider net capturing referrals involving patients covered by any "health care benefit program." This expanded scope includes patients who are enrolled in either a ***public*** or ***private*** health plan and includes group or individual commercial health insurance, ERISA plans, and any public or private insurance affecting interstate or foreign commerce.

Impacted Providers

The law applies to: 1.) laboratories, 2.) all recovery homes (often referred to as residential treatment centers), regardless of their state licensure status, and 3.) clinical treatment centers (excluding hospitals) that are state-licensed or state-certified to provide substance abuse services in a medical setting. Because EKRA expressly states that it does not preempt any other federal or state law, its application to state-licensed or state-certified clinics means that the very purpose Congress intended to serve by this change—to penalize bad actors who prey on drug addicted patients with insurance coverage– will not be served if the actors involved in "patient brokering" are operating without a state license.

EKRA would also affect clinical research laboratories having no association with substance abuse treatment, since it is applicable to all 'laboratories' as described in Section 353 of the Public Health Service Act, which broadly defines a "laboratory" as a facility engaging in the "examination of materials derived from the human body for the purpose of providing information for the diagnoses, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." The prohibition applies whether or not the referral is related to lab services for substance abuse disorders.

Substance Abuse Treatment Not Required

In addition, EKRA does not specify that a patient must actually receive substance abuse treatment services in order for the law to apply to an unlawful referral arrangement, nor does it require laboratories or clinics to provide substance abuse treatment services in exchange for prohibited kickbacks. Instead, the statute covers ***any*** kickback arrangement involving a recovery home, clinical treatment facility, or laboratory, regardless of whether the services obtained from the provider relate to substance abuse treatment.

Exceptions

EKRA carves out seven exceptions similar to those contained in the AKS. EKRA does not apply to:

- Discounts disclosed and reflected in costs claimed or charges made by the provider;
- Payments made to a bona fide employee or independent contractor if the payment does not vary by

the number of individuals referred, the number of tests performed, or the amounts billed or received by the provider;

- Drug discounts under the Medicare Coverage Gap Discount Program;
- Payments made that meet the personal service and management contracts safe harbor under the AKS;
- Waiver or discounts of co-insurance or co-payments that satisfy AKS definition if the waiver or discount is not routinely provided and is provided in good faith;
- Federally Qualified Health Clinic payments under agreements that satisfy AKS requirements; and
- Payments made pursuant to an alternative payment model or pursuant to payment arrangements used by a state, health insurance issuer, or group health plan if the Secretary of Health and Human Services determined such payment is necessary for care coordination or value-based care.

The law provides that the U.S. Attorney General, in consultation with the Secretary of Health and Human Services, may issue regulations clarifying the statutory exceptions.

In light of weighty criminal penalties, labs, recovery homes, and clinical treatment centers should carefully scrutinize existing compensation arrangements, particularly those with employees and independent contractors. EKRA allows payments to employees or independent contractors if the payment is not determined on the basis of the number of individuals referred, the number of tests performed, or the amounts billed or received by the provider. Accordingly, EKRA would appear to exclude any kind of productivity or incentive payments. With respect to bona fide employees, this is notably a more narrow protection than what the AKS employment safe harbor provides, since the AKS protects *any amount* paid by an employer to an employee for furnishing a service that is payable, in whole or in part, under a federal health care program.

EKRA also includes an exception for payment arrangements that satisfy the AKS safe harbor for personal service and management contracts. Under the AKS safe harbor, compensation must be "set in advance," which is construed to mean that the total aggregate compensation to be paid over the term of the contract must be determined at the inception of the arrangement. Accordingly, arrangements with individuals who provide services on an hourly, per diem, or other variable basis would not meet the requirements of the EKRA exception because the AKS safe harbor would not be satisfied.

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