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OPIOID LEGISLATION ESTABLISHES NEW ALL-PAYOR ANTI-KICKBACK PROVISION

by Darrell Armer and Evie Lalangas Gray Reed November 1, 2018



On Oct. 24, 2018, President Trump signed into law the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, or the SUPPORT for Patients and Communities Act (the "SUPPORT Act"). The SUPPORT Act aims to generally reduce the use and supply of opioids, among several other goals. It is a 600 plus-page law that likely has a far-reaching impact, including major changes to the healthcare regulatory landscape.

Section 8122 of the SUPPORT Act lays out the Recovery Kickback Prohibition (RKP), which makes it a federal offense to pay for referrals to recovery homes, clinical treatment facilities and laboratories. The RKP structurally mirrors the Federal Anti-Kickback Statute (AKS) but has some extremely important differences. Generally, the RKP aims to curtail patients' brokering with opioid treatment centers and slow the overutilization of laboratory toxicology screenings by closing a loophole remaining under the AKS.

The RKP states:

a) OFFENSE — Except as provided in subsection (b)[, which establishes certain exceptions to the prohibition], whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully —

- (1) 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
- (2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind
 - (A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or
 - (B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory,

shall be fined not more than \$200,000, imprisoned not more than 10 years, or both, for each occurrence.

The terms "recovery home", "clinical treatment facility", and "laboratory" are defined as follows:

- Recovery Home a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote 16 sustained recovery from substance use disorders.
- Clinical Treatment Facility a medical setting, other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under state law.

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 Laboratory – a facility for the biological, microbiological, serological, chemical, immuno-hematological, 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 RKP operates parallel to the AKS, in that it neither amends nor supersedes it when the AKS is otherwise applicable.

The RKP is wider in scope than the AKS because it applies to both federal health care programs and commercial programs. However, the RKP is narrower than the AKS in one regard because it only applies to referrals to recovery homes, clinical treatment facilities, and laboratories. Given the general definition of "laboratory" outlined above, the RKP appears to apply to any laboratory – not only those producing opioid-related toxicology test results.

Like the AKS, the RKP includes several enumerated exceptions, each with its own specific components that must be met. Some of these exceptions include (but are not limited to):

- 1. Payments to bona fide employees and independent contractors; and
- 2. Payments for services that meet the AKS safe harbor for personal services and management contracts;

Importantly, the first exception listed above – payments to bona fide employees and contractors – is more narrow than the AKS "employees" exception. The AKS exception applies to any "bona fide employment relationship". In the RKP exception, a bona fide employment relationship is only protected if the employee's payment is not determined by or does not vary by:

- (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 resulting effect is that the RKP creates a much stricter environment for how even *bona fide* employees can be paid – seemingly eliminating the option to pay percentage-based compensation to such employees.

It remains unknown as to how the relevant federal agencies will interpret and enforce this new law, including whether they will rely on existing guidance by the OIG. Stay tuned for further updates from Gray Reed with respect to the RKP.

ABOUT THE AUTHORS



Darrell Armer, Partner

An experienced dealmaker and strategic advisor for a diverse group of healthcare clients, Darrell Armer focuses his practice on structuring complex commercial transactions that not only achieve his clients' business goals, but also minimize risk within strict regulatory frameworks. Darrell has over 20 years of experience managing all aspects of the organization, reorganization, funding, operation and merger/acquisition of a variety of providers, including hospitals, ambulatory surgery centers, physical therapy companies, diagnostic imaging centers, medical and dental practices and home health agencies, as well as various provider networks. He is Board Certified in Health Law by the Texas Board of Legal Specialization.



Evie Lalangas, Associate

Evie Lalangas brings an insider's perspective to the firm's health care and business services expertise. Having worked for health-related nonprofits and the U.S. Department of Health and Human Services, she not only understands the legal issues surrounding the health care industry, but also the policy and business concerns. Evie's unique vantage point gives her an intimate understanding of her clients' perspectives, and enables her to help them achieve their goals in the health care field and beyond.

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