Report on
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Opioid Law Creates New Kickback Penalties for Some Provider Types

New penalties for kickbacks that were customized for the opioid crisis are part of the bipartisan legislation to address opioid abuse that passed Congress on Oct. 3 and was signed by President Trump on Oct. 24.

The SUPPORT for Patients and Communities Act (HR 6), which synthesized dozens of bills introduced by various members of Congress, is designed to increase access to prevention, treatment and recovery services. For example, the legislation broadens the use of telehealth in Medicare for treating opioid and other substance use disorders and requires Medicare coverage of certain services provided by opioid treatment programs. It also expands the Physician Payments Sunshine Act.

Breadth of Law Is Unclear

Section 8121 of the law, the Eliminating Kickbacks in Recovery Act of 2018, makes it a crime to solicit or receive "remuneration" (e.g., kickbacks, bribes) for patient referrals to a recovery home, clinical treatment facility or laboratory. The term "clinical treatment facility" specifically refers to a medical setting "other than a hospital that provides detoxification, risk reduction, outpatient treatment and care, residential treatment or rehabilitation for substance abuse pursuant to licensure or certification under State law."

For those types of providers, the new anti-kickback law is broader than the existing Anti-Kickback Statute for federal health care programs, says Jonathan Diesenhaus, an attorney with Hogan Lovells US LLP in Washington, D.C. The new statute applies to referrals for "services covered by a health care benefit program." The definition of benefit program encompasses government and private payers, he says, "adding a new layer of regulation for providers who already serve government program beneficiaries and already comply with the Medicare Anti-Kickback Statute and Stark Law."

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Another attorney believes the new law is targeted at private payers. Because the Anti-Kickback Statute is limited to federal health care programs and only some state kickback laws apply to private payers, there's an enforcement gap, says Scott Memmott, with Morgan Lewis in Washington, D.C. The new law "is meant to address that gap," he says.

New Kickback Law Has Exceptions

Like the Stark Law and Anti-Kickback Statute, the new law has exceptions. Some reference the safe harbor regulations to the Anti-Kickback Statute and others that seem to borrow terms from the Stark Law, Diesenhaus says. For example, in the new legislation, payments from employers to employees and independent contractors are not kickbacks if they don't vary according to the number of people referred for treatment, the number of tests or procedures performed, or the amount paid by benefit programs to labs, clinical treatment facilities or recovery homes.

There's also an exception for a discount or other reduction if it's "properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity," the law states.

Diesenhaus says the exceptions aren't a natural fit with the safe harbors or Stark Law exceptions, and that could complicate compliance. "Today, it is the exceptions and the safe harbors in the Medicare Anti-Kickback Statute that drive compliance," he contends. For example, the broad exception for bona fide employees in the Medicare Anti-Kickback Statute "is the touchstone for employment compensation," he says. "The exception seems to recognize that employees under the control of their employer pose little risk of fraud and abuse." The Stark Law has tighter controls, but only when the employee is a referring physician. To qualify for the Stark employment exception, physicians can't be compensated based on the volume or value of their referrals. "The opioid statute changes the formulation and seems to shift Stark-like controls on employment compensation to all types of non-physician employees," Diesenhaus says.

The SUPPORT Act also extended the reporting requirements of the Physician Payments Sunshine Act to allied health professionals -- physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives and certified registered nurse anesthetists, Memmott says.

The Physician Payments Sunshine Act, which CMS refers to as the open payments program, requires pharmaceutical and device manufacturers to report payments and other "transfers of value" that they give physicians and teaching hospitals annually to CMS, which makes the payment information public in a searchable online database. With the new law's addition of the clinicians, drug and device manufacturers "will have to expand their internal data capture and data aggregation to cover these other provider categories," he notes.

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