

New anti-kickback prohibition in opioid bill creates tangled web of compliance obligations

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On October 3, the U.S. Congress passed [H.R. 6](#), the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the SUPPORT Act), a wide-reaching bill that aims to combat opioid abuse. One largely overlooked but significant provision of the bill, section 8122, would make it a federal crime to receive or offer remuneration for referrals to a recovery home, clinical treatment facility, or laboratory, regardless of whether the referred patients are covered under a federal health care program or privately insured.

The new kickback prohibition

If signed into law in its current form, the SUPPORT Act creates a parallel statutory kickback prohibition that is simultaneously narrower and broader than the federal health care program Anti-Kickback Statute (AKS). The SUPPORT Act and the AKS feature similar language: both prohibitions make it a crime to offer, pay, solicit, or receive remuneration (including any kickback, bribe, or rebate) in connection with referrals. The SUPPORT Act does not redefine "remuneration," so it will likely be read to follow the government's broad interpretation under the AKS to include "anything of value." Violations of the new kickback prohibition are punishable with criminal penalties, including monetary fines up to US\$200,000, imprisonment up to 10 years, or both, for each occurrence.

Unlike the federal AKS, which applies only to referrals reimbursed by federal health care programs, the new kickback prohibition would apply to referrals to a "health care benefit program," defined as "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual." This all-payer prohibition is likely to cover a much larger array of relationships and referrals than are covered under the federal AKS.

At the same time, the new kickback prohibition is narrower than the federal AKS because it applies only to referrals to certain entities designated under the law: recovery homes, clinical treatment facilities, and laboratories. Despite this narrower scope, the law as currently drafted could apply to remuneration paid for *any* referral to these entities, regardless of whether the referral is for the purpose of substance abuse or addiction treatment. The SUPPORT Act's kickback prohibition contains no limitation on the *purpose* of the remuneration or the type of

referral and therefore ostensibly applies to all remuneration and referrals to a recovery home, clinical treatment facility, or laboratory.

Notably, the SUPPORT Act explicitly states that the kickback section neither supersedes the federal AKS nor preempts similar state laws. However, it is not yet clear whether compliance with a federal AKS exception or safe harbor will, in and of itself, protect an entity from prosecution under the new kickback statute.

The exceptions

The prohibition includes seven statutory exceptions and delegates authority to the attorney general, in consultation with the secretary of Health and Human Services (HHS), to promulgate regulations to create new exceptions or to clarify the statutory exceptions. Thus the secretary of HHS, who has statutory powers to create safe harbors to the AKS, merely consults on exceptions under the SUPPORT Act, potentially leading to differing protections under each statute.

Indeed, although the seven exceptions to the SUPPORT Act's kickback section appear to be modeled on the statutory exceptions and regulatory safe harbors to the federal AKS, most are not identical. While the SUPPORT Act simply cross-references the regulatory safe harbor for personal services and management contracts, the other SUPPORT Act exceptions contain subtle but important differences from the AKS exceptions. In particular

- the SUPPORT Act's exception for employment relationships is narrower than the equivalent AKS exception, meaning that the new law does not clearly allow typical forms of incentive compensation arrangements for bona fide employees of laboratories, recovery homes, and clinical treatment facilities, most notably including sales commissions. Many employment relationships include responsibilities that involve facilitating or encouraging referrals, with compensation that, as a result, implicates the AKS and thus makes clear protections necessary to avoid the threat of investigation or prosecution. However, the new law's employee exception does not extend to compensation that varies based on (1) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory, (2) the number of tests or procedures performed, or (3) the amount billed to or received from the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory. While the exception does extend to compensation of independent contractors, which is not expressly protected by the AKS employment safe harbor, compensation for independent contractors would be subject to the same narrower protection as compensation for employees; and
- the SUPPORT Act models its protection of discounts on the AKS statutory exception, which protects any discount or other price reduction that is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity. The Office of Inspector General (OIG) of HHS has long maintained that the AKS statutory exception protects price reductions only if they also comply with the more complex regulatory safe harbor for discounts. At least until interpretive rules are promulgated, the SUPPORT Act's use of the statutory AKS language may make it easier for a discount to comply with the new kickback prohibition than with the AKS.

Other exceptions created by the SUPPORT Act include

- a discount in the price of an applicable drug furnished to an applicable beneficiary under the Medicare coverage gap discount program;
- a waiver or discount of any coinsurance or copayment by a health care benefit program if it is not routinely provided and is provided in good faith;

- remuneration provided to a federally qualified health center pursuant to an agreement that contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population; and
- remuneration made pursuant to an alternative payment model or other payment arrangement that HHS has determined is necessary for care coordination or value-based care, as we recently discussed [here](#).

Expansion of "Sunshine" transparency law to other practitioners

In addition to the new kickback prohibition, the SUPPORT Act also includes a provision that expands the scope of the "Sunshine" (Open Payments) law, which currently requires drug and device manufacturers to publicly report payments and transfers of value that they make to physicians and teaching hospitals. The SUPPORT Act would extend this obligation to require manufacturers to report payments that they make to (1) physician assistants, (2) nurse practitioners, (3) clinical nurse specialists, (4) certified registered nurse anesthetists, and (5) certified nurse-midwives. The expanded reporting obligation would take effect beginning with "information required to be submitted on or after January 1, 2022," which suggests that manufacturer reports for calendar year 2021 (which will be due March 31, 2022) will be the first to include the expanded set of covered recipients.

Conclusion

The SUPPORT Act features a potentially wide-ranging kickback prohibition. It remains to be seen whether the attorney general will go beyond the statute's intent to curb opioid abuse and use the statute to reach all manner of activities related to recovery homes, clinical treatment facilities, or laboratories. The SUPPORT Act also offers broad, undefined exceptions, but no guidance on whether OIG interpretations of analogous AKS exceptions and safe harbors will also apply to the SUPPORT Act or whether the attorney general will create a unique enforcement scheme.

President Trump is expected to sign H.R. 6 into law soon. We also expect an effort to get technical corrections passed in the new Congress, which may provide additional clarity. If you have concerns that may be addressed by technical corrections, please contact us for assistance in making the appropriate comments to Congress.

If you have any questions about the impact of this new anti-kickback prohibition or on the expansion of the Sunshine law, please contact any of the authors or the Hogan Lovells lawyer with whom you regularly work.

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