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Practice Update

New Federal Legislation Regarding Substance-Use Disorder Treatment

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On October 24, 2018, the federal government enacted comprehensive, bipartisan legislation intended to address America's pandemic of opioid abuse. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act combines a broad array of policy initiatives taken from more than 60 pieces of legislation previously passed by the U.S. House of Representatives into a single bill that was approved by nearly every member of both chambers of Congress. The SUPPORT Act includes several anti-fraud provisions which, unlike many federal anti-fraud statutes, are directly applicable to private health plans as well as federal programs. Additionally, the SUPPORT Act provides a host of new programs and policies that range from a pilot program of electronic health record use for behavioral health professionals to provisions expanding the availability of medication-assisted treatment for Medicare beneficiaries.

The Act also incorporates various measures aimed at preventing and combating fraud in connection with addiction treatment. Subtitle B of the SUPPORT Act, also known as the Opioid Addiction Recovery Fraud Prevention Act of 2018, is one such provision. Section 8023 makes it unlawful to engage in an unfair or deceptive act or practice with respect to any substance use disorder treatment service or

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product. As used in the Act, a "substance use disorder treatment service" is any service that purports to provide (i) referrals to treatment, (ii) treatment, or (iii) recovery housing for people who have or purport to have a substance use disorder. Similarly, a "substance use disorder treatment product" is any product "for use or marketed for use in the treatment, cure, or prevention of a substance use disorder[.]" Section 8023 provides for enforcement by the Federal Trade Commission.

The Eliminating Kickbacks in Recovery Act of 2018, incorporated as Subtitle J of the SUPPORT Act, is another example of anti-fraud provisions in the new law. Like the federal Anti-Kickback Statute set forth at 42 U.S.C. § 1320a–7b ("AKS"), the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) is intended to prohibit the referral or exchange of substance use disorder patients or patronage for financial gain. EKRA makes it a federal crime to receive or offer remuneration for referrals to clinical treatment facilities, laboratories, and recovery homes.

While EKRA has many similarities to the AKS, it also contains a number of significant differences from prior federal prohibitions on kickbacks. Perhaps the most notable departure from the AKS, which only applies in cases involving federal health care programs, is that the SUPPORT Act's kickback prohibition expressly applies to services covered by "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual." By expanding the kickback prohibition to private health plans (and non-federal public plans), the EKRA covers a much broader spectrum of relationships and referrals than are covered under the federal AKS.

The EKRA incorporates eight enumerated exceptions to its prohibitions. Like the AKS, the EKRA also includes an express delegation of authority to create new exceptions and/or clarify the

statutory exceptions through regulations. Unlike the AKS, the EKRA delegates rulemaking authority to the United States Attorney General, not the Secretary of Health and Human Services (HHS), whom the AKS tasks with creating safe harbors to the AKS. Although the new law requires the Attorney General to consult with the Secretary of HHS on exceptions, it still creates the possibility that different agency prerogatives may lead to differences between the AKS and EKRA exceptions and safe harbors.

SUPPORT Act Statutory Exceptions

The statutory exceptions to the new anti-kickback provisions in the SUPPORT Act are:

> (i) discount or price reduction under a health care benefit program if properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity;
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> (ii) a payment to a bona fide employee or independent contractor, if the payment is not tied to the number of individuals referred, number of tests or procedures performed, or amount billed to or received from the referred individual's health care benefit program;
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> (iii) a discount in the price of an applicable drug furnished to an applicable beneficiary under the Medicare coverage gap discount program;
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> (iv) a payment made as compensation under a personal services and management contract that meets the requirements of 42 C.F.R. § 1001.952(d);
>
> (v) 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;
>
> (vi) 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;

(vii) 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; and

(viii) any other payment, remuneration, discount, or reduction as determined by the Attorney General, in consultation with the Secretary of HHS, by regulation.

Although several of these exceptions closely resemble or simply cross-reference exceptions and safe harbors found in the AKS and its accompanying regulations, there are several important distinctions to be aware of with respect to the way the SUPPORT Act exceptions treat remunerations to employees and price reductions, as these may differ from the way the AKS treats these issues.

Of particular note, there are several differences between the EKRA's exception for employment relationships and its AKS equivalent. The new law excepts certain compensation of independent contractors, which is not expressly protected by the AKS employment safe harbor. However, the EKRA exception does not clearly exempt certain types of incentive-based compensation, like sales commissions, which employers may pay to bona fide employees under the AKS. Specifically, the bona fide employee exception in the SUPPORT Act 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. Notably, while a payment made to a bona fide employee

based on the amount collected from a referred patient's health care benefit plan would not be protected by the EKRA's exception, the statute is silent with respect to employee compensation based on copayments, coinsurance or deductibles collected from patients.

Also noteworthy in the SUPPORT Act's exceptions is that the SUPPORT Act relies on the statutory language from the AKS with respect to discounts. Under the AKS, HHS has adopted the view that the statutory exception protects price reductions only if the discount also complies with the regulatory safe harbor for discounts (set out in 42 C.F.R. § 1001.952(h)). The regulatory safe harbor is generally more restrictive and contains complex provisions for determining when a discount or price reduction is "properly disclosed and appropriately reflected in the costs claimed or charges made[.]" Thus, the use of the language from the AKS statutory exception in the EKRA (without incorporating the safe harbor language in 42 C.F.R. § 1001.952(h)) may mean particular discounting practices could satisfy the EKRA exception that would not be protected under the AKS – at least until the Attorney General promulgates regulations or formally adopts HHS's position under the AKS framework. For example, the discount safe harbor applicable to the AKS excludes cash payments (except for a narrow class of rebates paid by check) from the definition of "discount." While this potential conflict remains unresolved, clinical treatment facilities, laboratories, and recovery homes will need to exercise caution when structuring "discounts" as the requirements of EKRA and the AKS may differ.

Possible Impact on Florida Law

By its own terms, the SUPPORT Act's new kickback prohibition is not intended to preempt state laws prohibiting the exchange of remuneration for patient referrals like Florida Statutes § 817.505 ("Patient Brokering Statute") and Florida Statutes § 456.054 ("Florida Anti-Kickback Statute"). Although the

Patient Brokering Statute and the EKRA have considerable overlap, there are several key differences that may impact how particular conduct by a provider or other entity should be analyzed for compliance. For instance, the Patient Brokering Statute incorporates an exemption for "[a]ny discount, payment, waiver of payment, or payment practice not prohibited by 42 U.S.C. s. 1320a-7b(b) or regulations promulgated thereunder." Because this exemption expressly references the AKS and its regulations, but not the SUPPORT Act, there are unresolved questions concerning conduct that falls within, for example, an EKRA exception, but not an AKS safe harbor.

A further point of differentiation between the state and federal statutes is that the Patient Brokering Statute explicitly prohibits split-fee arrangements. The Florida Anti-Kickback Statute, which prohibits health care providers and providers of health care services from exchanging remuneration for referring or soliciting patients, was recently amended to add broad prohibitions for any person or any entity to pay or receive remuneration for referring patients to a clinical laboratory. Unlike the Patient Brokering Statute, the Florida Anti-Kickback Statute does not provide any exceptions or safe harbors. Thus, care must be taken in any analysis to ensure all statutory exceptions are reviewed in detail and considered in conjunction with other laws that provide no exceptions or slightly different exceptions.

Conclusion

The SUPPORT Act features a potentially wide-ranging kickback prohibition with the capacity to impact all manner of activities related to recovery homes, clinical treatment facilities, and laboratories. Consequently, there will be considerable interest in seeing what approach the Attorney General ultimately takes in developing interpretive regulations under the EKRA to curb fraud and abuse in the context of substance abuse disorder treatment

programs. The SUPPORT Act also offers broad, undefined exceptions, but little in the way of guidance as to whether HHS's 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. Regardless, it is clear that the SUPPORT Act's anti-kickback section is an important new tool to curb fraud and abuse in connection with substance use disorder treatment. Of course, we will continue to monitor developments in this area and provide further updates.

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