

Publications

OIG Releases Advisory Opinion 22-04 Approving Arrangement that Provides Cash Equivalents to Patients

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On March 2, 2022, the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services published Advisory Opinion 22-04 (the Opinion). The Opinion approves a program through which the requestor provides certain individuals who suffer from a substance use disorder (SUD) access to digital contingency management and related tools, including cash equivalents, to motivate behavioral health changes.

The Proposed Arrangement

The requestor, a digital health company, uses smartphone and smart debit card technology to implement contingency management (CM) for individuals with SUD. The requestor certified that its CM program is a highly effective, cost-efficient treatment that uses incentives to motivate and sustain positive behavioral changes in these individuals. The program is evidence-based, protocol-driven, and consistent with the National Institute on Drug Abuse's principles for effective SUD treatment. Although the requestor is not enrolled as a provider or supplier in any federal health care program, it contracts with customers (including health plans, addiction treatment providers, other treatment providers, and employee assistance programs) that may be enrolled in a federal health care program.

The program's services include appointment reminders with attendance verification, cognitive behavioral therapy, certified recovery coaching, and virtual support groups. Although the program is entirely digital, incentives may be tied to in-person services furnished by the requestor's customers (such as group counseling). Some of the requestor's customers may bill federal health care programs for the in-person services they provide.

The program provides incentives when individuals complete certain events, such as attending a treatment session, or achieve certain behavioral goals, such as a negative substance test. The requestor provides the incentives via a smart debit card that includes abuse and anti-relapse protections (*i.e.*, it cannot be used at bars, liquor stores,

casinos, or certain other locations nor can it be used to convert credit to cash at ATMs or gas stations). Additionally, the requestor can monitor use of the smart debit cards, allowing coaches and providers to be signaled of the possible need for intervention in the event of a blocked purchase. Each incentive offered in connection with the program is relatively small; however, the requestor provides incentives more frequently in the initial phase of treatment, when the member is subject to more frequent substance testing. Incentives are capped at \$200 per month and \$599 per individual per year.

Although individuals may self-enroll in the program, the requestor typically contracts with customers that pay for the program. Customers may either pay a flat monthly fee for each eligible member or select a pay-for-performance model under which they pay the requestor for achieving certain agreed-upon targets for abstinence. The requestor certified that the fees are consistent with fair market value and do not vary based on the volume or value of referrals.

OIG Analysis

The requestor inquired whether the program would run afoul of the federal Anti-Kickback Statute (AKS) or the civil monetary penalty prohibition on federal beneficiary inducements (CMP). OIG observed there are two streams of remuneration that could potentially implicate AKS and CMP. First, OIG noted that the customers pay the requestor a fee to provide the program's services, some of which could incentivize a member to receive a federally billable service. Second, OIG also noted that some of the fees customers pay to the requestor get passed on to members as CM incentives for achieving certain behavioral goals, some of which may involve services that are billable to a federal health care program by a customer.

OIG expressed its longstanding concerns about incentives provided to beneficiaries to obtain federally reimbursable services, as such incentives could corrupt medical decision-making and lead to overutilization, patient steering, and increased costs. Although neither remuneration stream satisfies the requirements of a safe harbor to the AKS or an exception to the CMP, OIG ultimately concluded that the arrangement poses a minimal risk of fraud and abuse for several reasons, including the following:

- The CM incentives are part of a protocol-driven, evidence-based treatment program rather than an inducement to seek, or a reward for having sought, a particular federally reimbursable treatment.
- While OIG made clear that any amount of remuneration can implicate AKS, the program's incentives are relatively low in value, a substantial portion of the CM incentives is not associated with federally payable services, and the requestor was not enrolled as a provider or supplier in any federal health care program. Therefore, the risk of overutilization of federally reimbursable services is low.
- The requestor's customer base is varied, with many of the customers being individuals or entities that do not have an incentive to induce a member to receive federally reimbursable services.
- While the incentives are cash equivalents because they are provided via a smart debit card, the card has anti-relapse protections and the lack of any incentive on the requestor's part to overutilize federally reimbursable services mitigated the risks of fraud and abuse.

As with all OIG Advisory Opinions, this Opinion is limited in scope to the specific arrangement described in the Opinion. Each situation is fact specific, and providers should review their current CM arrangements to ensure compliance with applicable law. In addition to federal law, providers should also consider the legal implications of such arrangements under any applicable state "mini-AKS" laws applicable to Medicaid and/

or private payor arrangements.

Takeaways

Over the past few years, we have seen a significant uptick in interest surrounding CM, and we have assisted a number of clients with implementing compliant CM programs. As the OIG recognized, protocol-driven and evidence-base CM programs, while highly effective, have posed significant fraud and abuse compliance challenges. This Opinion provides welcome guidance for both the CM technology industry and also providers seeking to implement a compliant CM program. As a more general matter, this Opinion is notable because the proposed program involves the award of cash equivalents, about which OIG has longstanding concerns. Moreover, the total value of those cash equivalents may exceed the \$500 cap that OIG imposed in the new safe harbor for patient engagement and support.

If you have any questions about this Opinion as to how it may impact your operations, please contact Liam Cruzs, Suzanne Scrutton, Jolie Havens, Nita Garg, or your regular Vorys attorney.