FRAUD AND ABUSE IN SUBSTANCE USE TREATMENT

LEGAL UPDATE - OIG ADVISORY OPINION, MARCH 2, 2022

HHS OIG Issues Fraud and Abuse Advisory Opinion on Contingency Management/Patient Incentive Program

At long last, health care providers and suppliers seeking to use patient incentives for contingency management to support evidenced based treatment for substance use disorder patients have guidance on how to minimize risk of fraud and abuse. Advisory Opinion, Office of Inspector General (OIG), posted March 2, 2022.

Background:

On March 2, 2022, Office of Inspector General for the Department of Health and Human Services (OIG) issued Advisory Opinion No. 22-04 concluding that a digitally managed substance use disorder treatment program offering direct incentives to patients presents a low risk of fraud and abuse to Medicare and Medicaid. The OIG limited its favorable opinion to the evidenced based and technology enabled program (the "CM Program") operated DynamicCare Health, Inc., a digital therapeutics company, on behalf of a broad group of fee-based customers, including health plans, healthcare providers and employee assistance programs.

The OIG warned providers and suppliers that cash and cash equivalent remuneration to patients raises substantial risk of fraud and abuse, explaining that:

> *"[w]e have longstanding concerns relating to the offer of incentives intended to induce beneficiaries to obtain federally reimbursable items and services, as such incentives could present significant risks of fraud and abuse."*

In the Opinion, the OIG outlined the specific characteristics of a compliant contingency management program for treatment of patients with substance use disorders.

Contingency Management Programs

Contingency management is a behavioral therapy that uses motivational incentives to reinforce positive behaviors and tangible rewards to sustain treatment adherence. The COVID-19 pandemic has exacerbated certain substance use disorders and limited treatment options. Substance use disorder treatment providers have been haunted by the risks associated with offering contingency management programs for patients despite evidence that such treatment is highly effective for some patients, especially those with stimulant use disorder.

Why Are Contingency Management Programs a Fraud and Abuse Risk?

As part of the CM Program, Medicare and Medicaid patients receive cash or in-kind compensation in exchange for engaging in certain behaviors including substance use disorder treatment therapies. The OIG has historically warned against offering or paying cash

incentives to program beneficiaries and was therefore asked whether the digitally operated CM Program violated the Anti-Kickback Statute and Beneficiary Inducement Civil Monetary Penalty laws.

The **Anti-Kickback Statute (AKS)**, 42 U.S.C. Section 1320a-7b(b), makes it a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration directly or indirectly to induce or reward patient referrals or to generate business involving any item or service reimbursable by a Federal health care program. When a provider offers, pays, solicits, or receives unlawful remuneration, the provider violates the AKS. Remuneration includes anything of value, such as cash, free rent, hotel stays, meals, and excessive compensation for services.

The **Beneficiary Inducements Civil Monetary Penalty Laws** provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. 42 U.S.C. § 1320a7a(a)(5).

The OIG has issued repeated alerts against providers or suppliers giving gifts to beneficiaries as such gifts might influence their choice of provider or service. New or amended safe harbors finalized in 2020 protect certain patient engagement incentives but only when the incentives are capped and associated with value-based payment arrangements, Accountable Care Organization beneficiary incentive programs, or when the incentive is in the form of limited local transportation services. Even the new safe harbors don't protect cash, gift cards, waivers or reductions in cost-sharing amounts and cap the in-kind benefits to $500 per patient per year as part of any value-based-payment arrangement.

As part of the review of the CM Program, the OIG examined:

> 1) the fee arrangement between the digital CM Company and its customers for appropriate safeguards and 'fair market value' compensation; and
>
> 2) the relationship between all participants and the beneficiaries receiving incentives to determine overall program compliance.

Based on the specific facts of the digital CM Program for substance use disorder patients, the OIG concluded that while the CM Program implicates the Anti-Kickback Statute and the Beneficiary Inducement Civil Monetary Penalty laws and ***no*** regulatory safe harbor applies, the specific arrangement as operated would not result in enforcement action.

Why Did the OIG Approve This Contingency Management Program?

The OIG highlights the following characteristics of the CM Program that drives the "won't impose administrative sanctions" opinion:

- **A digital company operates the CM Program**: The CM Program is operated by DynamicCare Health and uses smartphone and smart debit card technology to

implement contingency management and administer the incentives for individuals. DynamicCare Health is not enrolled in Medicare or Medicaid;

- **The digital company operating the CM Program contracts with "customers" at fair market value**: DynamicCare Health, Inc. contracts with treatment providers and health plans to offer the CM Program to individuals who need substance use disorder treatment and the fee is "fair market value" not based on volume or value of referrals;
- **The CM Program is protocol driven and evidenced based**: The CM Program is "evidence-based, protocol-driven and consistent with principles for the effective treatment of substance use disorders published by the National Institute on Drug Abuse (NIDA)." The OIG concluded that the CM Program incentives are not "an inducement to seek, or a reward for having sought, a particular federally reimbursable treatment."
- **The CM Incentives are low value, capped and not related to reimbursable services**: The incentives are low value and administered entirely by the CM digital company consistent with detailed protocols set forth in the opinion. Incentives are typically $5 per successful test or achievement and are capped at $200/month and $599/year. A substantial portion of the CM Program incentives are **not associated** with federally payable services and the digital CM company is not an enrolled provider or supplier.
- **Health care professionals and entities are minimally involved in the CM Program**: DynamicCare Health's customer base is "varied" and many have no incentive to induce patients to receive reimbursable services. In addition, the OIG noted that when customers are professionals or entities that treat Medicare and Medicaid patients, these customers are not administering the CM Program, although the incentives may be tied to the patient attending treatment sessions which are verified via GPS for in-person visits or electronically for virtual visits. The fees paid by customers do not vary based on the volume or value of any federally reimbursable services, and the CM Program is protocol-driven and set by CM Program, not the customers.

While the OIG continues to be suspicious that cash and cash equivalent remuneration to beneficiaries raises a substantial risk of fraud and abuse, the OIG confirmed it would not impose administrative sanctions on the CM Program as operated by the DynamicCare Health.

Specific Facts and Protocols of the Approved CM Program

As always, the OIG limited its review and favorable opinion to the specific facts of the CM Program. The facts and details below are quoted directly from the Advisory Opinion, pp 3-6 and therefore material to the opinion.

Enrollment

An individual may seek the CM Program's services via referral from a customer or self-referral. The CM Program certified that its enrollment team follows a formal protocol with training and

ongoing supervision by licensed clinical supervisors. Pursuant to the protocol, the CM Program obtains enrollment information from the following sources:

(i) the referrer, if available;
(ii) a structured interview of the individual;
(iii) an open-ended discussion with the individual; and
(iv) input from support persons, e.g., a significant other and family members, if available.

The structured interview uses the American Society of Addiction Medicine Continuum Triage tool, which CM Program certified various public entities (e.g., county health departments) use to determine, among other things, whether the interviewee has a substance use disorder.

In particular, the tool prompts the enrollment specialist to obtain information that enables a branching algorithm to determine if the interviewee:

(i) has a substance use disorder;
(ii) requires treatment, and if so, for which priority substance(s); and
(iii) requires a specific level of care.

Type of Services

The enrollment specialist, under the guidance of a licensed clinical supervisor, determines the type of services (e.g., alcohol, drug, or nicotine testing, or medication administration reminders) and amount of services appropriate for each individual enrolled in the Program (each, a "Member"). The frequency of any Member's recovery coaching is determined by CM Program's algorithm using baseline Member data. Once the Member begins the Program, its algorithm continuously varies the frequency of testing according to the Member's performance (e.g., results of substance testing or participation in recovery coaching), with additional tests added "for cause" by the Member's recovery coach.

The CM Program's services are set according to an evidence-based, automated algorithm over a 12-month period, which is divided into 3 phases of approximately 4 months each:

(i) the anchor phase, during which the Member will have frequent substance testing and active CM Incentives for achieving specified behavioral health goals (e.g., a negative substance test);
(ii) the build phase, during which the substance testing frequency decreases and CM incentives begin phasing out; and
(iii) the maintenance phase, during which the CM Program reinforces the behavioral health goals through non-incentive community reinforcers, such as employment and relationships.

The CM Program technology establishes the schedule of expected target health behavioral events, objectively validates whether each expected event has occurred, and if it has, promptly disburses the exact, protocol-specified CM incentive to the Member, using (where appropriate) a progressive reinforcement schedule.

The CM Program includes a wide variety of features that vary by Member, including, but not limited to:

- Automated appointment reminders, with both GPS (for in-person) and electronic (for virtual) attendance verification;
- Medication reminders and self-administration verification via self-video;
- Saliva drug testing, breathalyzer alcohol testing, Smokerlyzer CO testing for tobacco, and saliva cotinine testing for e-cigarettes, all verified via self-video;
- Cognitive Behavioral Therapy ("CBT"), which includes 90 modules, on a variety of topics, each 2-5 minutes in length, with effort validation through exercises, comprehension questions, and detection of actual reading duration;
- Various surveys and assessments;
- Certified recovery coaching offered weekly via video link or telephone call plus unlimited texting during business hours, with addiction specialist expert clinical supervision;
- Certified family partners for significant others and family members, with community reinforcement and family training, which consists of video training in an evidence based support model; and
- Daily virtual support groups moderated by certified recovery coaches (for Members) or certified family partners (for support persons).

Patient Incentives

The CM Program is digital and does not include any in-person elements. The CM Program's incentives, however, may be tied to certain services furnished in-person by another provider—which could include a customer—such as attending a treatment session (which is verified via GPS for in-person visits or electronically for virtual visits).

While most of the CM Program's current customers are entities that do not bill Federal health care programs, some current customers do bill, and other potential future customers may bill, Federal health care programs for services that they provide (e.g., group therapy sessions).

The CM Program provides CM incentives via a smart debit card. While the smart debit card looks like a typical debit card, the CM Program certified that it includes abuse and anti-relapse protections (e.g., 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).

The CM Program can monitor Members' 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. As stated above, the CM Program furnishes members with CM Incentives for achieving specified behavioral health goals.

The CM Program's protocol allocates 70 percent of the potential CM incentives for verified, consistent substance tests (i.e., consistent with medical expectations) and medication adherence, 20 percent for treatment attendance, and 10 percent for self-guided CBT modules and other features, such as follow-up self-assessments.

The CM incentives are capped at $200.00 per month, with an annual maximum of $599.00 per Member per year. Individual CM incentives typically are relatively small (e.g., $1.00-$3.00), but a particular CM Incentive could be slightly larger if a member has a progressive reinforcement schedule.

The CM Program certified that it is authorized by the customer for 1 month and then must be reauthorized each subsequent month, for up to 12 months. The CM Program's 2021 data (as of September 2021) show that 86 percent of Members who start the CM Program are still active in their third month.

Customer Payment Contracts

Typically, the CM Program contracts with customers that pay for the CM Program. Members and their families also have the ability to self-refer and pay for the CM Program, in which case the member or family member is the customer.

The CM Program receives fees from customers on: (i) a flat monthly basis per eligible, active Member; or (ii) a pay-for-performance model, in which the CM Program is paid upon a Member achieving certain agreed-upon targets for abstinence. In the pay-for-performance model, Customers pay a lower flat rate per active Member but a substantially higher rate for each Member who achieves clinical success in a given month.

CM Program certified that the aggregate fees are consistent with fair market value and do not vary based on the volume or value of business generated under Federal health care programs. Instead, fees vary based on the service configurations being purchased and the intensity of behavioral targets that are planned for each member.

Fees include the costs of the application, any substance testing equipment that is shipped to the member, test monitoring, medication self-administration monitoring, appointment attendance monitoring, recovery coaching, and CM incentives. The fees also may vary based on whether members are considered low-risk or high risk, and whether they are in treatment or out of treatment.

CM incentives are held in reserve until the Member is verified by the system as having successfully completed each expected behavioral health goal. CM Program detects Member activity month-by-month; in a given month, if a member does not engage in using the application, the member is detected by the system as "inactive" for the month. When a member is inactive, the customer is not billed any fees and the unspent CM Incentive fees continue to be held in reserve for the member.

Conclusion

The OIG Advisory Opinion offers hope to those seeking to support substance use disorder patients with evidenced based contingency management or motivational incentive programs. However, due to the risks of fraud and abuse, and the specific details of the approved digital CM Program, any entity, provider or supplier seeking to offer a program to patients should consult legal counsel.

Please send questions or concerns to:

Lucy C. Hodder, JD
Director of Health Law and Policy
Professor of Law
UNH Franklin Pierce School of Law
Institute for Health Policy and Practice
Lucy.Hodder@unh.edu
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