



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information, unless otherwise approved by the requestor(s).]

Issued: February 25, 2022

Posted: March 2, 2022

[Name and address redacted]

Re: OIG Advisory Opinion No. 22-04

Dear [Name redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of [name redacted], (“Requestor”), regarding a program through which Requestor provides certain individuals access to digital contingency management and related tools to treat substance use disorders (the “Program”), where the Program is funded by customers, which could include individuals’ health care providers or suppliers (the “Arrangement”). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the “Act”), as that section relates to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Arrangement, and we have relied solely on the facts and information Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG

will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) although the Arrangement may generate prohibited remuneration under the Beneficiary Inducements CMP, the OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

This opinion may not be relied on by any person¹ other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Requestor is a privately held digital health company that uses technology to provide a comprehensive personalized support program that individuals with substance use disorders can access at any time or location. Requestor is not enrolled as a provider or supplier in any Federal health care program and, therefore, does not bill any Federal health care program for items or services furnished through the Program.

Requestor's Program uses smartphone and smart debit card technology to implement contingency management ("CM") for individuals with substance use disorders (including disorders involving opioids, stimulants, alcohol, and nicotine). Requestor certified that substance use disorders are known to impair the brain reward mechanisms responsible for healthy motivational drive. Requestor further certified that CM is a highly effective, cost-efficient² treatment approach that uses incentives ("CM Incentives") to motivate and sustain behavioral health efforts in people who suffer from substance use disorders. Requestor certified that this treatment approach addresses the brain's reward response in ways that conventional counseling and medications often cannot.

As described in more detail below, Requestor contracts with a variety of entities, including but not limited to, health plans, addiction treatment providers, employee assistance programs, research institutions, and other treatment providers ("Customers") to offer the Program to individuals who meet certain requirements. The Program integrates remote tools and services that utilize CM Incentives, along with supportive tools. Requestor certified that the Program is

¹ We use "person" herein to include persons, as referenced in the Federal anti-kickback statute and Beneficiary Inducements CMP, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

² Requestor cited to research showing that CM provides one of the largest returns on investment of any of the studied evidence-based practices for treating substance use disorders in adults, with a 77 percent chance that the treatment will produce benefits greater than costs. *See, e.g.,* Washington State Institute for Public Policy, *Benefit-Cost Results: Substance Use Disorders* (Dec. 2019), <http://www.wsipp.wa.gov/BenefitCost?topicId=7Contingency> (last visited February 14, 2022).

evidence-based, protocol-driven, and consistent with the principles for the effective treatment of substance use disorders published by the National Institute on Drug Abuse (“NIDA”).³

A. Program Enrollment and Operation

An individual may seek Requestor’s services via referral from a Customer or self-referral. Requestor certified that its enrollment team⁴ follows a formal protocol with training and ongoing supervision by licensed clinical supervisors. Pursuant to the protocol, Requestor 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 Requestor 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. 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”).⁵ The frequency of any Member’s recovery coaching is determined by Requestor’s algorithm using baseline Member data. Once the Member begins the Program, Requestor’s 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.

Requestor’s services under the Program 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

³ Specifically, Requestor certified that the protocols are based upon 50 years of research funded by the National Institutes of Health (“NIH”) as well as numerous peer-reviewed scientific publications and meta-analyses. Requestor’s platform has received three NIH grants, including Phase I and Phase II grants from the National Institute on Alcohol Abuse and Alcoholism and a Phase I grant from NIDA. It also has been used as the research platform by 18 funded research groups affiliated with various universities.

⁴ Requestor’s enrollment team is comprised of certified recovery coaches and enrollment specialists who are trained and supervised by a licensed Clinical Psychologist (Ph.D.), a Board Certified Addiction Psychiatrist (M.D.), and a counselor licensed to treat addiction and mental health disorders.

⁵ Some individuals will not be eligible for the Program (e.g., if they score as needing residential care or if they score as not needing substance use disorder treatment).

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 Program reinforces the behavioral health goals through non-incentive community reinforcers, such as employment and relationships. The 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 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).

The Program is digital and does not include any in-person elements with Requestor. Requestor’s CM 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 the majority of Requestor’s current Customers are entities that do not bill Federal health care programs, some current Customers bill, and other potential future Customers may bill, Federal health care programs for services that they provide (e.g., group therapy sessions).

Under the Program, Requestor provides CM Incentives via a smart debit card. While the smart debit card looks like a typical debit card, Requestor 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). Requestor 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 Program furnishes Members with CM Incentives for achieving specified behavioral health goals. Requestor’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. 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.⁶ Requestor certified that the Program is authorized by the Customer for 1 month and then must be reauthorized each subsequent month, for up to 12 months. Requestor's 2021 data (as of September 2021) show that 86 percent of Members who start Requestor's Program are still active in their third month of the Program.

B. Customer Payment for the Program

Typically, Requestor contracts with Customers that pay for the Program. Members and their families also have the ability to self-refer and pay for the Program, in which case the Member or family member is the Customer. Requestor receives fees from Customers on: (i) a flat monthly basis per eligible, active Member; or (ii) a pay-for-performance model, in which Requestor 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.

Requestor 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.⁷ 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.⁸ CM Incentives are held in reserve until the Member is verified by the system as having successfully completed each expected

⁶ For example, a CM Incentive might start at \$2.00 per successful breathalyzer test for 5 tests per week and potentially reach \$3.50 per successful test for 3 tests per week later in the Program. Similarly, for drug saliva testing a CM Incentive may start at \$5.00 per successful test for 2 tests per week and progress to \$10.50 per test once a week.

⁷ Requestor certified that the enrollment team assesses each new Member's needs and charges a lower monthly fee for individuals enrolled for smoking cessation or alcohol moderation, and a higher fee for those who have alcohol or other substance use disorders. While the same CM Incentive schedule generally applies to all Members, Requestor primarily applies text-based coaching for smoking cessation and alcohol moderation, and video-, voice-, and text-based coaching for Members with alcohol or other substance use disorders leading to the cost differential.

⁸ Requestor certified that an individual is considered to be "out of treatment" if the individual: (i) is not involved in substance use disorder specialty services; and (ii) either is referred to Requestor by a payor or managed care organization manager or contacts Requestor directly for assistance with a substance use disorder.

behavioral health goal. Requestor 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.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.⁹ The statute’s prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.¹⁰ For purposes of the Federal anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a Federal health care program.¹¹ Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program 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. The OIG also may initiate administrative proceedings to exclude such person from

⁹ Section 1128B(b) of the Act.

¹⁰ Id.

¹¹ E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

Federal health care programs. Section 1128A(i)(6) of the Act defines “remuneration” for purposes of the Beneficiary Inducements CMP as including “transfers of items or services for free or for other than fair market value.”

B. Analysis

Under the Arrangement, there are two streams of remuneration that potentially implicate the Federal anti-kickback statute and the Beneficiary Inducements CMP. First, Customers pay Requestor a fee to provide services, some of which could incentivize a Member to receive a federally billable service. Second, some of the fees Customers pay to Requestor get passed on to Members as CM Incentives for achieving certain behavioral health goals, some of which may involve services that could be billable to Federal health care programs (e.g., a counseling session) by a particular provider or supplier, which could be a Customer. We 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 particular, programs that involve giving remuneration to beneficiaries can corrupt medical care decision-making, which could result in overutilization, increased costs, steering to particular providers or suppliers, or inappropriate medical choices.

Neither remuneration stream satisfies the requirements of a safe harbor to the Federal anti-kickback statute or an exception to the Beneficiary Inducements CMP. Arrangements that implicate these statutes and are not protected by a safe harbor or exception are evaluated on a case-by-case basis, based on the totality of the facts and circumstances. For purposes of this advisory opinion’s analysis, we assess the Arrangement in its totality, inclusive of the aforementioned remuneration streams. Based on this assessment, and for the combination of the following reasons, we conclude that the Arrangement presents a minimal risk of fraud and abuse under the Federal anti-kickback statute, and we would not impose sanctions under the Beneficiary Inducements CMP in connection with the Arrangement.

First, Requestor certified that the Program, including the provision of CM Incentives, is protocol-driven and is consistent with evidence-based research funded by NIH and principles for the effective treatment of substance use disorders published by NIDA. Moreover, the Program has been funded by multiple government-sponsored grants and has been used as a research platform by research groups affiliated with various universities. In addition, Requestor cited to various sources that state that CM is a highly effective, cost-efficient treatment for individuals with substance use disorders. Taken together with the safeguards present in the Arrangement, the CM Incentives in Requestor’s Program 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.

Second, while any amount of remuneration can implicate the Federal anti-kickback statute, the individual CM Incentives given to Members under the Program have a relatively low value (typically under \$5.00 per successful test or achievement of other specified behavioral health goal) and are capped at a maximum of \$200.00 per month and \$599.00 per year. Moreover, a substantial portion of CM Incentives is not associated with federally payable services (e.g., participating in self-guided CBT modules or self-administered breathalyzer or saliva drug testing). Further, Requestor certified that it is not enrolled as a provider or supplier in any

Federal health care program and, accordingly, does not bill any Federal health care program for the services furnished through the Program. Therefore, the risk of the CM Incentives encouraging overutilization of federally reimbursable services is low.

Third, 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. We recognize that there may be circumstances where the Customer is an entity that bills Federal health care programs and that a CM Incentive might be given for receiving a federally billable service (e.g., attending a federally reimbursable counseling session) rendered by that Customer. However, the fees paid by Customers do not vary based on the volume or value of any federally reimbursable services, and the Program is protocol-driven and set by Requestor, not the Customers. Moreover, Requestor does not bill Federal health care programs. Therefore, we believe the risk is low that a Customer would pay Requestor's fees to generate business or reward referrals of federally reimbursable services.

Finally, we recognize that the CM Incentives, which are loaded onto a smart debit card, are cash equivalents, and our enforcement experience suggests that cash and cash-equivalent remuneration given to beneficiaries may raise substantial fraud and abuse risks. However, this particular Arrangement includes certain safeguards that mitigate the risk of fraud and abuse. For example, Requestor—an entity that does not bill Federal health care programs and does not have an incentive to induce overutilization—determines what types of services each member needs and what CM Incentives will be attached to those services. In addition, the smart debit card has anti-relapse protections (e.g., 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). Under the particular facts of this Arrangement, we conclude that remuneration in the form of the smart debit card is sufficiently low risk.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) although the Arrangement may generate prohibited remuneration under the Beneficiary Inducements CMP, the OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.

- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.
- This advisory opinion may not be introduced into evidence by a person other than Requestor to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against Requestor with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against Requestor with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs