



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: April 22, 2022

Posted: April 27, 2022

[Name and address redacted]

Re: OIG Advisory Opinion No. 22-08

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 an arrangement whereby certain existing patients of Requestor use limited-use smartphones that Requestor loaned to such patients to facilitate access to telehealth services (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 could 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

A. The Arrangement

Requestor is a federally qualified health center that serves predominantly low-income individuals, including Federal health care program beneficiaries.² Requestor offers telehealth services to its patients through a telehealth application that can be downloaded on a smartphone. Requestor loaned approximately 3,000 limited-use smartphones and chargers on a first-come first-served basis to existing patients³ who did not have a device capable of running the telehealth application required to access telehealth services from Requestor.⁴ The patients currently in possession of a loaned smartphone are the only patients who are or will participate in the Arrangement, and the smartphones currently being used by those patients are the only smartphones involved in the Arrangement (i.e., the Arrangement is not available to new patients, and Requestor will not loan any additional smartphones). The smartphones Requestor loaned under the Arrangement are “locked,” meaning they restrict use to making and receiving telephone calls, sending and receiving text messages, using the telehealth application used by

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 certified that 94 percent of its patients report incomes at or below 200 percent of the relevant federal poverty guideline established by the U.S. Department of Health and Human Services.

³ Requestor considered existing patients to be patients who, regardless of insurance status, have received at least one service furnished by Requestor in the prior 24-month period.

⁴ Prior to loaning the smartphones, Requestor screened patients to determine whether they already possessed a device capable of running the telehealth application. For patients who could visit one of Requestor’s physical locations, Requestor determined whether a patient possessed a phone capable of running the telehealth application by examining the patient’s existing phone. For patients who could not visit one of Requestor’s locations but who had made only audio calls to Requestor in the past, Requestor relied on a patient’s statement that the patient did not have a phone with the requisite functionality to join a telehealth appointment with Requestor.

Requestor, and viewing the respective patient’s medical records.⁵ Requestor certified that the purposes of the Arrangement are to enable patients to access health care services via telehealth and to combat social isolation by allowing patients to talk and text with others, including during the coronavirus disease 2019 (“COVID-19”) public health emergency (the “PHE”). Requestor certified that the telehealth services it offers to patients via the limited-use smartphones are medically necessary services that are currently covered by Medicare and the State Medicaid Program.⁶

A patient can keep the smartphone under the Arrangement as long as Requestor has furnished at least one service to the patient in the prior 24-month period (regardless of whether it was a telehealth service). As a condition of lending the smartphone, Requestor asked patients to return the smartphones if they are no longer receiving services (e.g., they have relocated from the Requestor’s service area).⁷ Requestor does not prohibit patients from using the smartphones for telemedicine visits with other health care providers; however, given the smartphones’ use limitations, the only telemedicine application patients can use is the one used by Requestor.

B. Funding for the Arrangement

In connection with the PHE, Requestor received grant funding from the Federal Communications Commission (the “FCC”) and [Name redacted] (the “Local Charity”), a charitable organization in Requestor’s community,⁸ to purchase the smartphones. Around 15 percent of the smartphones Requestor purchased were funded by the Local Charity, and around 85 percent were funded by the FCC under the FCC’s COVID-19 Telehealth Program, which permits eligible providers to obtain eligible telecommunications services, information services, and connected devices that

⁵ The smartphones cannot be used, for example, to download applications (other than the telehealth application) or browse the internet.

⁶ The Centers for Medicare & Medicaid Services (“CMS”) and the [State redacted] Medicaid Program (the “State Medicaid Program”) have temporarily expanded the scope of the telehealth services for which those programs will reimburse providers during the PHE. See CMS, COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers (May 24, 2021), <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>; [State redacted] Department of Health, [State redacted] Department of Health Informational Bulletin 20-5 (May 29, 2020), [link redacted].

⁷ Requestor remotely disables any smartphones that patients report lost or stolen.

⁸ The grant funding from the Local Charity was transferred to Requestor through a private foundation. Requestor certified that both the Local Charity and the private foundation support a wide range of charitable causes and are not limited to supporting health care-related causes. Requestor also certified that it has no knowledge of the individuals or entities that funded the grant Requestor received from the Local Charity.

they need to provide telehealth services in response to the PHE.⁹ Requestor also certified that it has used the funding in compliance with all requirements imposed by the FCC and the Local Charity (e.g., restricting purchases to specified technologies) in connection with the purchase of smartphones. Although the grant funding for the smartphones became available to Requestor during the PHE, the Arrangement is not limited to the PHE. Therefore, Requestor will permit patients to continue using the smartphones after the PHE,¹⁰ but Requestor certified that it has not and will not use its own funds to purchase smartphones or chargers as part of the Arrangement, and it does not anticipate receiving any further funding to purchase additional smartphones.

The grant funding Requestor received from the FCC and the Local Charity covered the voice and data services required to operate the smartphones for the first 12 months that each smartphone was in use, but Requestor certified that the voice and data plans for all loaned smartphones have since expired. While Requestor used its own funds to provide voice and data service for 2 months after the initial voice and data services funding expired, Requestor certified that it does not independently have the financial ability to cover voice and data services for the loaned smartphones in the longer term and will not use its own funds to purchase voice and data services in the future. Therefore, patients participating in the Arrangement must secure their own voice and data services; patients who fail to do so are not able to utilize the smartphones. Requestor has instructed patients on how to apply for voice and data services funding under the FCC's Affordable Connectivity Program and encourages individuals who do not qualify for such program to identify similar programs that may fund the voice and data services for the patient's loaned smartphone.

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.¹¹ 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.¹² For purposes of the Federal anti-kickback

⁹ See Promoting Telehealth for Low-Income Consumers; COVID-19 Telehealth Program, 85 Fed. Reg. 19,892 (Apr. 9, 2020).

¹⁰ Requestor certified that neither the FCC nor the Local Charity precludes Requestor from permitting patients to use the smartphones after the PHE.

¹¹ Section 1128B(b) of the Act.

¹² Id.

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.¹³ 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 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.” Section 1128A(i)(6) of the Act contains an exception to the definition of “remuneration” that may apply in the context of the Arrangement. Section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term “remuneration” does not include “remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs” (the “Promotes Access to Care Exception”). We have interpreted this provision to apply to:

[i]tems or services that improve a beneficiary’s ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—(i) [b]eing unlikely to interfere with, or skew, clinical decision making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns¹⁴

¹³ 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).

¹⁴ 42 C.F.R. § 1003.110 (defining “remuneration”).

B. Analysis

The Arrangement implicates the Federal anti-kickback statute because Requestor permits patients to whom it has already loaned limited-use smartphones and chargers to continue using the smartphones and chargers free of charge, and this could induce those patients to receive items and services from Requestor that are reimbursable by a Federal health care program. Likewise, the Arrangement implicates the Beneficiary Inducements CMP because the Arrangement may be likely to influence those patients to select Requestor for the receipt of items and services that are reimbursable by Medicare or Medicaid.

1. Beneficiary Inducements CMP

For the following reasons, we conclude that Requestor’s provision of limited-use smartphones and chargers to patients satisfies the Promotes Access to Care Exception during the PHE. We cannot opine on the application of the Promotes Access to Care Exception to the Arrangement after the PHE because that exception applies to items or services that improve a beneficiary’s ability to obtain items and services payable by Medicare or Medicaid, and we do not know, at the time of the issuance of this opinion, whether the telehealth services to which the smartphones are promoting access will be covered by Medicare or the State Medicaid Program following the PHE. However, to the extent Medicare or the State Medicaid Program covers telehealth services that Requestor is offering to patients via the smartphones after the PHE, the analysis below would apply.

The first step in an analysis under the Promotes Access to Care Exception is to determine whether the remuneration promotes access to care, *i.e.*, whether it improves a beneficiary’s ability to obtain items and services payable by Medicare or a State health care program. Because 94 percent of Requestor’s patients report incomes at or below 200 percent of the relevant federal poverty guideline established by the U.S. Department of Health and Human Services, the Arrangement may remove socioeconomic barriers to accessing telehealth services. As the FCC recognized, “[w]ith remote patient monitoring and mobile health applications that can be accessed on a smartphone or tablet, health care providers now have the technology to deliver quality health care directly to patients, regardless of where they are located.”¹⁵ Additionally, Requestor permits use of the smartphones only for patients who do not already have a device capable of running the telehealth application required to access telehealth services from Requestor. For these reasons, we conclude that, since the telehealth services Requestor offers to patients via the limited-use smartphones are currently covered by Medicare and the State Medicaid Program, the smartphones and chargers improve the ability of patients who are Medicare or Medicaid beneficiaries to access telehealth services that are payable by Medicare or Medicaid during the PHE.

The second step is to determine whether the remuneration poses a low risk of harm by: (i) being unlikely to interfere with clinical decision making; (ii) being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and

¹⁵ Promoting Telehealth for Low-Income Consumers; COVID-19 Telehealth Program, 85 Fed. Reg. 19,892, 19,904 (Apr. 9, 2020).

(iii) not raising patient safety or quality-of-care concerns. We conclude that Requestor’s provision of the limited-use smartphones and chargers to eligible patients would satisfy these requirements.

The Arrangement does not appear likely to interfere with clinical decision-making. While the Arrangement may help patients access telehealth services offered by Requestor that they otherwise may not have received, nothing in the facts suggests that Requestor permitting patients to use the smartphones and chargers skews the clinical decision-making of medical professionals affiliated with Requestor who provide services to patients via telehealth visits.

Further, the risk that the Arrangement increases costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization is low. While the Arrangement may result in increased utilization of telehealth services, there is nothing in the Arrangement to suggest that any such increase in utilization would be inappropriate. The Arrangement is limited to existing patients who: (i) already have the smartphones (*i.e.*, no new patients may participate in the Arrangement); and (ii) only must receive one service from Requestor within the preceding 24-month period to remain eligible to continue using a loaned smartphone. These facts, in combination with the limited functionality of the smartphones and the requirement for patients to secure funding for voice and data services through a source other than Requestor, reduce the risk that patients will seek out services from Requestor solely to maintain use of a loaned smartphone under the Arrangement and thus mitigate the risk of overutilization or inappropriate utilization.

Finally, we do not believe that the Arrangement poses patient safety or quality-of-care concerns. The use of telehealth services during the PHE may promote patient safety by allowing patients to seek health care services without coming into physical contact with providers, staff, and other patients. Notwithstanding the importance of telehealth during the PHE, we understand that, in some circumstances, an in-person visit may result in a higher quality of patient care due to a provider’s ability to physically examine a patient, among other potential reasons. However, nothing in the Arrangement suggests that Requestor would provide telehealth services when doing so could pose patient safety or quality-of-care concerns.

Even if the Arrangement does not meet the Promotes Access to Care Exception after the expiration of the PHE, for the reasons set forth in this advisory opinion, we conclude that we would not impose administrative sanctions under the Beneficiary Inducements CMP.

2. Federal Anti-Kickback Statute

The Arrangement does not satisfy a safe harbor to the Federal anti-kickback statute. However, based on the combination of safeguards present in the Arrangement, we conclude that the Arrangement presents no more than a minimal risk of fraud and abuse under the Federal anti-kickback statute. In addition to the analysis of the safeguards above, which also applies to our assessment of the Arrangement under the Federal anti-kickback statute, certain additional features of the Arrangement reduce the risk of fraud and abuse. For example, Requestor received funding from the FCC and the Local Charity—both entities with no financial interest in patients receiving services from Requestor—to purchase smartphones needed to provide telehealth services in response to the PHE. Further, Requestor certified that it has used the funding in compliance with all requirements imposed by the FCC and the Local Charity in

connection with receiving the funding. Even though Requestor will continue permitting patients to use the smartphones under the Arrangement after the PHE, there is nothing in the facts to suggest that—after the PHE has ended—Requestor will use the smartphones as a way to inappropriately increase utilization of federally reimbursable services from Requestor.

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 could 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