



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 associated with the individual or entity, unless otherwise approved by the requestor.]*

**Issued:** December 23, 2020

**Posted:** December 30, 2020

[Name and address redacted]

### **Re: OIG Advisory Opinion No. 20-08**

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a federally qualified health center's proposal to offer gift cards to incentivize certain pediatric patients to attend rescheduled preventive and early intervention care appointments (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed Arrangement could potentially generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General (“OIG”) would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

## **I. FACTUAL BACKGROUND**

[Name redacted] (“Requestor”) is a 501(c)(3) nonprofit community health center with eight sites located in the metropolitan area of [city redacted, state redacted]. Requestor participates in Federal health care programs and receives Federal grants to deliver health care services as a federally qualified health center (“FQHC”). Consistent with its mission and status as an FQHC, Requestor serves predominantly low-income individuals. Requestor certified that 96 percent of its patients report incomes at or below 200 percent of the Federal poverty level, and 65 percent of its patients receive coverage under either Medicaid or the Children’s Health Insurance Program (“CHIP”).

### **A. Parameters of the Proposed Arrangement**

Under the Proposed Arrangement, Requestor seeks to incentivize pediatric patients who have previously missed two or more preventive and early intervention care appointments (“Care Appointments”) with Requestor to attend such appointments. More specifically, under the Proposed Arrangement, Requestor would: (i) contact by telephone patients or their parents or guardians, as applicable, who are under the age of 19 and have missed two or more previously scheduled Care Appointments<sup>1</sup> with Requestor in the past six months

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<sup>1</sup> Requestor certified that, under the Proposed Arrangement, Eligible Patients or their parents or guardians would have scheduled the previous Care Appointments. That is, Requestor would not have scheduled the Care Appointments automatically.

(each an “Eligible Patient”); (ii) notify such Eligible Patients of the opportunity to receive a \$20 gift card<sup>2</sup> from Requestor upon rescheduling and attending a Care Appointment; and (iii) furnish the gift card at checkout after the Eligible Patient attends the Care Appointment and a Requestor staff member has verified the patient’s eligibility.<sup>3</sup>

The gift card would be offered and furnished to an Eligible Patient irrespective of his or her health insurance status or ability to pay for services. Each Eligible Patient could receive only one \$20 gift card over the course of the Proposed Arrangement. To ensure adherence to this requirement, Requestor stated that it would document and track the offer and receipt of gift cards under the Proposed Arrangement.

Requestor certified that it would not advertise the Proposed Arrangement, other than by notifying Eligible Patients or their parents or guardians of the Proposed Arrangement by telephone. Requestor further certified that while all items and services furnished during the Care Appointments would be medically necessary, some items and services would not meet the definition of “preventive care” described in the current U.S. Preventive Services Task Force’s Guide to Clinical Preventive Services. For any Eligible Patient with Medicaid coverage, however, all Care Appointments would be covered by the Medicaid Early and Periodic Screening, Diagnostic, and Treatment (“EPSDT”) benefit.<sup>4</sup>

## **B. Goals of the Proposed Arrangement**

Requestor’s stated goal for the Proposed Arrangement is to improve the attendance rate for Eligible Patients. According to Requestor, it developed the Proposed Arrangement in response to internal data indicating that, on average, 30 percent of its pediatric patients

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<sup>2</sup> Eligible Patients or their parents or guardians would choose one \$20 gift card from four select retailers, one of which is a “big-box” store, *i.e.*, it sells a wide variety of items. The gift cards would not be redeemable for items or services provided by Requestor.

<sup>3</sup> If a patient has missed two or more previously scheduled Care Appointments in the past six months and, prior to Requestor notifying the patient of the Proposed Arrangement, the patient reschedules and attends one of the appointments, the patient would not be considered an Eligible Patient for purposes of the Proposed Arrangement.

<sup>4</sup> The EPSDT benefit is “designed to assure that children receive early detection and care, so that health problems are averted or diagnosed and treated as early as possible.” Centers for Medicare & Medicaid Services, [EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents](https://www.medicare.gov/medicaid/benefits/downloads/epsdt_coverage_guide.pdf) (2014), available at [https://www.medicare.gov/medicaid/benefits/downloads/epsdt\\_coverage\\_guide.pdf](https://www.medicare.gov/medicaid/benefits/downloads/epsdt_coverage_guide.pdf).

missed one or more Care Appointments.<sup>5</sup> During each Care Appointment, in addition to providing medically necessary services, Requestor intends to: (i) educate Eligible Patients or their parents or guardians on the importance of primary care and, in particular, attending Care Appointments; and (ii) inform such Eligible Patients or their parents or guardians of options Requestor offers that could facilitate attendance at future Care Appointments, e.g., back-to-back scheduling of sibling appointments.

Requestor certified that it intends to track whether the Proposed Arrangement improves attendance rates at Care Appointments for Eligible Patients. Requestor would calculate, at least once per calendar year, the Proposed Arrangement’s “success rate,” defined as the number of Eligible Patients who attended a rescheduled appointment and received a gift card under the Proposed Arrangement in the applicable calendar year, divided by the total number of Eligible Patients contacted by Requestor regarding the Proposed Arrangement in that calendar year. Requestor stated it would consider modifying or discontinuing the Proposed Arrangement if the success rate were to fall below 50 percent.

## **II. LEGAL ANALYSIS**

### **A. Law**

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program.<sup>6</sup> The anti-kickback statute specifically prohibits the offer, payment, solicitation, or receipt of any remuneration to induce or reward referrals for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or the purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.<sup>7</sup> Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the

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<sup>5</sup> To support its internal findings, Requestor cited to a 2010 OIG report highlighting underutilization of EPSDT well-child visits across state Medicaid programs. Department of Health and Human Services, Office of Inspector General, Most Medicaid Children in Nine States Are Not Receiving All Required Preventive Screening Services (2010), available at <https://oig.hhs.gov/oei/reports/oei-05-08-00520.pdf>.

<sup>6</sup> See section 1128B(b) of the Act.

<sup>7</sup> Id.

anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the 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 was to obtain money for the referral of services or to induce further referrals.<sup>8</sup> Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to ten years, or both. Conviction also will lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

Section 1128A(a)(5) of the Act (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 (including Medicaid) beneficiary that the benefactor 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 (including Medicaid). The OIG also may initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines “remuneration” for purposes of section 1128A(a)(5) of the Act as including “transfers of items or services for free or for other than fair market value.”<sup>9</sup> The OIG has taken the position that incentives that are only nominal in value (other than cash or cash equivalents) are not prohibited by the statute and currently interprets “nominal value” to mean no more than \$15 per item or \$75 in the aggregate per patient on an annual basis.<sup>10</sup>

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<sup>8</sup> See, 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).

<sup>9</sup> See also 42 C.F.R. § 1003.110 (defining “remuneration,” for purposes of the regulations implementing the Beneficiary Inducements CMP, to be consistent with the definition of “remuneration” set forth at section 1128A(i)(6) of the Act).

<sup>10</sup> See, e.g., 81 Fed. Reg. 88,368, 88,394 (Dec. 7, 2016); Office of Inspector General Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries,

Because one of the gift cards is a cash equivalent and all such gift cards would exceed the current per item threshold, this guidance would not apply.

The definition of “remuneration” in section 1128A(i)(6) of the Act includes a number of exceptions that are potentially applicable to the Proposed Arrangement. For example, section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term “remuneration” does not apply to “remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations)” (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 . . . .”<sup>11</sup>

The definition of “remuneration” in section 1128A(i)(6) of the Act also contains an exception for incentives given to individuals to promote the delivery of preventive care (the “Preventive Care Exception”).<sup>12</sup> The regulations interpreting the Preventive Care Exception define “preventive care” as:

any service that (1) [i]s a prenatal service or a post-natal well-baby visit or is a specific clinical service described in the current U.S. Preventive Services Task Force’s Guide to Clinical Preventive Services, and (2) [i]s reimbursable in whole or in part by Medicare or an applicable State health care program.<sup>13</sup>

## **B. Analysis**

Under the Proposed Arrangement, Requestor would offer a \$20 gift card to Eligible Patients. Because Requestor certified that 65 percent of its patients are covered under Medicaid or CHIP, it is likely that at least some Eligible Patients would be Federal health care program beneficiaries. The \$20 gift card would constitute remuneration offered by Requestor to Eligible Patients, designed to influence such patients to select Requestor for

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available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf>.

<sup>11</sup> 42 C.F.R. § 1003.110 (defining “remuneration”).

<sup>12</sup> Section 1128A(i)(6)(D) of the Act.

<sup>13</sup> 42 C.F.R. § 1003.110 (defining “remuneration”).

future items or services (e.g., attending their rescheduled Care Appointment or selecting Requestor in the future for other federally reimbursable items or services). Thus, the Proposed Arrangement would implicate the Beneficiary Inducements CMP and the Federal anti-kickback statute.<sup>14</sup>

Upon determining that the Proposed Arrangement would implicate the Beneficiary Inducements CMP and the Federal anti-kickback statute, we first analyze the Beneficiary Inducements CMP and assess whether an exception applies. We conclude that neither the Promotes Access to Care Exception nor the Preventive Care Exception would protect the Proposed Arrangement. The Promotes Access to Care Exception would not protect the gift cards that Requestor would offer because the gift cards would reward Eligible Patients who access care; they would not, as the Promotes Access to Care Exception requires, improve Eligible Patients' ability to access items and services payable by Medicare or Medicaid. In addition, one of the gift cards offered under the Proposed Arrangement would be to a retailer that is a big-box store, *i.e.*, it sells a wide variety of items; as we have explained, such gift cards are not "items or services" and are considered cash equivalents that are not protected by the exception.<sup>15</sup> Similarly, the gift cards would not satisfy the Preventive Care Exception because, among other issues, some services furnished during Care Appointments would not meet the applicable definition of "preventive care," which means the gift card would not, in all instances, promote the delivery of "preventive care," as the exception requires.

Although we conclude that the Proposed Arrangement would not satisfy the Promotes Access to Care Exception or the Preventive Care Exception, in an exercise of our discretion we would not impose sanctions under the Beneficiary Inducements CMP for the combination of the following reasons.

First, we believe the risk of inappropriate patient steering would be minimized under the Proposed Arrangement due to the narrowly defined pool of Eligible Patients, *i.e.*, those

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<sup>14</sup> The OIG recently published regulations amending certain safe harbors and promulgating new safe harbors to the Federal anti-kickback statute. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684 (Dec. 2, 2020). Although the new safe harbor for patient engagement and support, 42 C.F.R. § 1001.952(hh), could potentially apply (as of the regulations' effective date of January 19, 2021), the facts presented to us do not demonstrate that the Proposed Arrangement would satisfy all conditions of that safe harbor.

<sup>15</sup> 81 Fed. Reg. 88,368, 88,397 (Dec. 7, 2016).

patients who have scheduled but missed two or more Care Appointments with Requestor in the past six months. While Eligible Patients would not have attended these missed Care Appointments, they nonetheless would have an established relationship with Requestor by virtue of previously contacting it to schedule the Care Appointment. Accordingly, while the gift card could induce Eligible Patients to select Requestor and attend their rescheduled Care Appointment, we believe the risk that the gift card would induce Eligible Patients to select Requestor for future Care Appointments or other federally reimbursable items and services is low because the Proposed Arrangement would: (i) be available only to a patient who has previously scheduled his or her Care Appointment at least twice with Requestor and then missed such appointments; and (ii) entail the offer and furnishing of a one-time \$20 gift card, even if an Eligible Patient continues to miss Care Appointments in the future.

Second, the Proposed Arrangement would be unlikely to lead to increased costs to Federal health care programs or patients through overutilization or inappropriate utilization. While we acknowledge that the Proposed Arrangement would increase utilization of health care services by incentivizing Eligible Patients to attend their next scheduled Care Appointment with Requestor, we believe any resulting increase in costs to Federal health care programs would reflect appropriate utilization. By design, the Proposed Arrangement targets chronic underutilization of preventive and early intervention items and services for low-income, pediatric patients.<sup>16</sup> In addition, all items and services furnished to such patients during Care Appointments would be medically necessary, and for any such patient with Medicaid coverage, the Care Appointment would be covered by the Medicaid EPSDT benefit.

Third, the Proposed Arrangement is unlikely to harm competition. While one of the types of gift cards offered would be a cash equivalent, the remuneration would be of modest value and could only be furnished once during the Proposed Arrangement. In addition, and of import, while Requestor would notify patients or their parents or guardians of the ability to earn a gift card by telephone, all such outreach would be limited to a narrowly defined pool of Eligible Patients, *i.e.*, those patients who have previously scheduled and missed two Care Appointments with Requestor. Requestor certified that it otherwise would not advertise the Proposed Arrangement.

Lastly, the scope of the Proposed Arrangement appears reasonably tailored to accomplish Requestor's goal of improving attendance rates at Care Appointments. The following parameters evidence such tailoring: (i) Requestor relied on internal data to identify a policy

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<sup>16</sup> Requestor certified that 96 percent of its patients report incomes at or below 200 percent of the Federal poverty level, and 65 percent of its patients receive health care coverage under either Medicaid or CHIP.

concern and potential solution;<sup>17</sup> (ii) the Proposed Arrangement is focused on a targeted subset of patients to address this policy concern; (iii) the offer and provision of the gift card would be paired with patient education, an eligibility verification process, documentation requirements, and an annual effectiveness review; and (iv) the reward for attending a Care Appointment consists of a one-time \$20 gift card, even if an Eligible Patient continues to miss Care Appointments in the future.

We believe these safeguards, in combination, distinguish the Proposed Arrangement from problematic programs that offer free goods or other remuneration to beneficiaries merely as an incentive for those patients to obtain federally reimbursable items and services. Thus, in an exercise of our discretion, we would not subject Requestor to sanctions under the Beneficiary Inducements CMP in connection with the Proposed Arrangement. For the same reasons, we also would not subject Requestor to sanctions under the Federal anti-kickback statute in connection with the Proposed Arrangement.

### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that although the Proposed Arrangement could potentially generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. In addition, the OIG would not impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

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<sup>17</sup> We have not performed a review of the data and rely upon Requestor's certifications with respect to its validity.

- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied 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 Proposed 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.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party 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 [name redacted] with respect to any action that is part of the Proposed 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 Proposed 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 [name redacted] with respect to any action that is part of the Proposed 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