



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:** August 16, 2022

**Posted:** August 19, 2022

[Address block redacted]

**Re: OIG Advisory Opinion No. 22-16**

Dear [redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of [redacted] (“Requestor”), regarding its provision of a gift card to certain Medicare Advantage (“MA”) plan enrollees who complete specific steps in an online patient education program (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 would 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) the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

This opinion may not be relied on by any person<sup>1</sup> 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 Program**

Requestor operates a shared decision-making, online learning tool that educates patients on potential risks, benefits, and expectations relating to surgeries (the “Program”). The Program consists of two modules, each with three components. The first module aims to: (i) help patients understand their diagnosis (or diagnoses) and explain their symptoms; (ii) educate patients on discussing their diagnosis (or diagnoses) with their primary care providers; and (iii) educate patients on non-surgical treatment options. The second module is for patients who choose a surgical treatment option and is designed to: (i) educate patients on the various types of surgical facilities that exist (e.g., hospitals and ambulatory surgery centers); (ii) help patients prepare for surgery by, for example, creating a pre-operation “to-do” list; and (iii) reduce the chance of complications and facilitate recovery by providing information on post-operative care. The Program’s content is customized to the individual user.<sup>2</sup>

Requestor stated that the Program is designed to enhance the patient experience, increase patient literacy about surgery, reduce the incidence of inappropriate surgeries, and mitigate complications, errors, and infections for those surgeries that do occur.<sup>3</sup>

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<sup>1</sup> 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.

<sup>2</sup> The Program asks the user a series of questions and uses those responses to tailor the information it provides to the user. These questions address both clinical information (e.g., whether the user has received a diagnosis, what the user’s symptoms are, the user’s personal risk factors and comorbidities, whether the user has already decided to have surgery, etc.) as well as information regarding the user’s values, beliefs, and circumstances (e.g., is the user inclined to follow a doctor’s suggestion, social and environmental factors that may contribute to care or outcomes, etc.). Users will have a unique experience with the Program depending on their specific diagnosis and responses to these questions. For example, for users that indicate they have already opted for surgery, the Program would not provide alternatives to the selected procedure, but would instead jump to the preparing for surgery section of the Program.

<sup>3</sup> In [redacted], the Centers for Medicare and Medicaid Services (“CMS”) granted Requestor a Health Care Innovation Award, which provided Federal funding to implement the Program. [Redacted]. As part of this award, CMS—through its contractors—conducted an evaluation of

Requestor certified that the Program does not refer to or recommend any provider, practitioner, supplier, or service; indeed, the Program contains no information about particular providers, practitioners, suppliers, or services. Instead, the Program directs patients to contact their primary care provider for additional information.

## **B. The Arrangement**

Requestor contracts with certain Medicare Advantage Organizations (each, an “MAO”) to offer the Program to enrollees in their MA plan(s) (each an “Enrollee”) and charges each MAO on a per-member, per-month basis for its services.<sup>4</sup> Under the Arrangement, Enrollees who complete the first module of the Program, along with a survey, receive a \$25 gift card to a retailer.<sup>5</sup> The gift cards may be for a big-box store or a retailer that is an online vendor that sells a wide variety of items. Requestor awards the gift card after completion of the first module (and survey) because that module is broadly applicable to all patients who may face a decision regarding surgical versus non-surgical treatment options now or at some future time. The second module is designed for patients who have opted to undergo surgery.

While Enrollees may use the Program multiple times during their period of enrollment, each Enrollee may only receive one \$25 gift card annually. The gift card is not contingent on the Enrollee undergoing surgery, pursuing a non-surgical treatment option, receiving any additional treatment, or demonstrating surgery literacy on the survey.

Use of the Program by Enrollees is voluntary, and any Enrollee may use the Program and earn a gift card under the Arrangement. Requestor makes the Program and gift cards available to all Enrollees, regardless of whether they are facing an immediate decision regarding surgery. According to Requestor, they make the Program available to all Enrollees because there is value in having an understanding about surgical decision-making even in the absence of an imminent decision regarding surgery, and, more broadly, the Program teaches core health care literacy skills for making treatment decisions and preparing for medical procedures.

Requestor sends direct mailings and email correspondence with information about the Program and the Arrangement to Enrollees.<sup>6</sup> Some of these communications are sent to all Enrollees, and

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the Program and determined that the Program was associated with statistically significant decreases in certain utilization and cost measures related to surgery. [Redacted].

<sup>4</sup> We have not been asked to opine on, and express no opinion regarding, Requestor’s agreements with MAOs relating to the Program or the Arrangement.

<sup>5</sup> The survey consists of 17 questions and is designed to: (i) assess the participant’s understanding of, and literacy with respect to, the participant’s surgical and non-surgical treatment options; (ii) gather preliminary self-reported outcomes; and (iii) measure satisfaction with the Program.

<sup>6</sup> Requestor certified that all MAOs must obtain CMS approval of all materials that Requestor uses to promote the Program and the Arrangement. This advisory opinion is limited to the Federal anti-kickback statute and the Beneficiary Inducements CMP. Whether the Arrangement

others are sent only to a subset of Enrollees who are identified as being more likely to be facing a decision regarding surgery. Requestor does not advertise, market, or promote the Program or the Arrangement to individuals who are not Enrollees. In addition, the standard contract governing the Arrangement between Requestor and each MAO prohibits the MAO from including information about the gift cards offered under the Arrangement in the MAO's marketing communications to prospective enrollees.

Requestor operates the Program with policies and procedures in place that are designed to ensure that only Enrollees who complete the first module of the Program receive a gift card and that no Enrollee receives more than one gift card annually. Specifically, Requestor conducts regular audits that include verifying Enrollee eligibility, ensuring Program and survey completion, and confirming that each eligible Enrollee receives only one gift card in a single year period.

## 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.<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup> 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

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meets the requirements set forth at 42 C.F.R. § 422.134 pertaining to MAO rewards and incentive programs is outside the scope of the OIG advisory opinion process.

<sup>7</sup> Section 1128B(b) of the Act.

<sup>8</sup> Id.

<sup>9</sup> 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).

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."

### **B. Analysis**

#### 1. Federal Anti-Kickback Statute

The Arrangement implicates the Federal anti-kickback statute because the \$25 gift card that Requestor provides to Enrollees, each of whom is a Federal health care program beneficiary, is remuneration that could induce the Enrollees to self-refer to a particular MA plan offered by an MAO that arranges for the provision of federally reimbursable items or services. In addition, in at least some instances, the gift cards will be a cash equivalent because they are for a big-box store or a retailer that is an online vendor that sells a wide variety of items. Nonetheless, for the combination of reasons discussed below, we conclude that the Arrangement presents a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute.

First, the Arrangement is unlikely to increase costs to Federal health care programs or result in inappropriate utilization and could potentially have the opposite effect. The Program is designed to improve patient literacy regarding surgery, reduce the incidence of medically inappropriate surgeries, and mitigate complications, errors, and infections for the surgeries that do occur. These aims may have the effect of improving patient safety and reducing inappropriate utilization, and they could also decrease Federal health care program costs if the Program works as intended.<sup>10</sup>

Second, we believe the likelihood that the Arrangement would meaningfully influence a beneficiary's selection of a particular MA plan is low because Requestor does not advertise the Program or the Arrangement to beneficiaries who are not Enrollees, and Requestor's standard contract with MAOs prohibits the MAO from including information about the gift cards offered under the Arrangement in the MAO's marketing communications to prospective enrollees. While we acknowledge that the Arrangement may influence Enrollees to re-enroll in an MAO in

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<sup>10</sup> This conclusion is bolstered by the finding of CMS's contractor that the Program was associated with statistically significant decreases in certain utilization and cost measures related to surgery. See note 3, supra.

subsequent plan years, we believe there is a broad range of other factors that may be more likely to influence a Medicare program beneficiary when making a re-enrollment decision (e.g., the MAO's scope of benefits, premiums, cost-sharing amounts, provider network, and customer service). We also believe that any risk of influence is reduced by the limited frequency and modest value of the reward (i.e., once per year and \$25), and we note that Requestor has implemented various safeguards to monitor and ensure compliance with these features of the Arrangement.

Lastly, the Arrangement is unlikely to impact competition among health care providers, practitioners, or suppliers. While the Program describes the various types of surgical facilities that are available for surgical procedures, Requestor certified that the Program does not refer to or recommend—or even include any information about—any particular provider, practitioner, supplier, or service.

## 2. Beneficiary Inducements CMP

In evaluating the Arrangement under the Beneficiary Inducements CMP, we consider whether Requestor would know or have reason to know that the remuneration it provides to beneficiaries is likely to influence their 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. Here, we conclude that, although the provision of a gift card under the Arrangement is clearly remuneration to a Medicare program beneficiary, the Arrangement would not implicate the Beneficiary Inducements CMP.

The remuneration to Enrollees under the Arrangement (i.e., the gift card) is provided upon completion of the first module of the Program. Because the Program does not refer to or recommend any provider, practitioner, supplier, or service (the Program contains no information about particular providers, practitioners, or suppliers), the remuneration provided to Enrollees is not likely to influence an Enrollee's selection of a particular provider, practitioner, or supplier. To the extent the remuneration has the potential to influence a beneficiary's selection of a particular MA plan, we note that an MA plan is not a provider, practitioner, or supplier for purposes of the Beneficiary Inducements CMP.

## 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 would 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) the Arrangement does not constitute grounds for the imposition of sanctions under 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