



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 27, 2022

**Posted:** May 2, 2022

[Address block redacted]

### **Re: OIG Advisory Opinion No. 22-10**

Dear [redacted]:

The Office of Inspector General (“OIG”) is writing in response to a request from [redacted] (“Requestor”) for OIG to: (i) modify OIG Advisory Opinion 15-14 (“AO 15-14”), issued to Requestor on November 13, 2015, to include within the scope of that opinion, Requestor’s proposal to provide financial assistance for certain past magnetic resonance imaging (“MRI”) tests (the “Proposed Modification”); and (ii) opine on a second arrangement regarding the distribution of certain cooling and mobility items, ancillary to the arrangement addressed in AO 15-14 (the “Distribution Program”). Specifically, you have inquired whether the Proposed Modification, if undertaken, would constitute, and whether the Distribution Program 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 Proposed Modification and the Distribution Program, 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 Proposed Modification and the Distribution Program. 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 Proposed Modification, if undertaken, and the Distribution Program 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 Proposed Modification or the Distribution Program 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 Proposed Modification, if undertaken, would generate, and the Distribution Program generates, prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed Modification or the Distribution Program 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 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**

Requestor is a non-profit organization dedicated to providing resources, services, and support to individuals with [redacted] (the “Disease State”).<sup>2</sup> In AO 15-14, the OIG opined favorably on an arrangement whereby Requestor assists low-income individuals with obtaining an MRI for the diagnosis or ongoing evaluation of the Disease State (the “Current Arrangement”). The Current Arrangement is limited to financial assistance for future MRIs, *i.e.*, MRIs that have been ordered but not yet administered.

### **A. Proposed Modification**

Under the Proposed Modification, Requestor would expand the Current Arrangement to cover the cost of an individual’s MRI (up to a specified monetary cap), provided: (i) the date of service of the MRI is within 6 months prior to the individual’s application to Requestor; and (ii) the individual met the Current Arrangement’s eligibility criteria on the date of service. Requestor certified that, apart from the Proposed Modification, all material information it furnished to the

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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> As specified in AO 15-14, the Disease State is defined in accordance with widely recognized clinical standards, without reference to specific symptoms, severity of symptoms, the stage of the Disease State, type of drug treatment or method of administration, type of items or services required to alleviate symptoms, or any other way of narrowing the definition of the widely recognized underlying Disease State. Requestor certified that no donor of Requestor or affiliate of any donor of Requestor, directly or indirectly, influenced the identification or delineation of the Disease State. Multiple items or services made, marketed, or provided by a number of different suppliers or manufacturers are available to treat the Disease State or alleviate symptoms.

OIG in connection with AO 15-14, including all supplemental submissions, remains true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

## **B. Distribution Program**

### 1. Overview

Ancillary to the Current Arrangement, and pursuant to the Distribution Program, Requestor distributes certain cooling and mobility items to low-income individuals diagnosed with the Disease State.<sup>3</sup> Under the Distribution Program, qualifying individuals are eligible to receive, free of charge: (i) a cooling vest or a cooling accessory to alleviate Disease State symptoms (each a “Cooling Item”); (ii) equipment designed to improve safety, mobility, activities of daily living, and wellness, e.g., a grab bar, shower chair, walker, a wide-grip utensil set, or yoga mat (each a “Mobility Item”); or (iii) both (collectively, the “Cooling and Mobility Items”). As a general matter, individuals may receive only one Cooling Item and one Mobility Item.<sup>4</sup>

Individuals seeking assistance pursuant to the Distribution Program must submit an application to Requestor that includes proof of both the individual’s Disease State diagnosis and income and that identifies the individual’s desired Cooling Item, Mobility Item, or both, as applicable. Requestor certified that it makes all eligibility determinations consistently and uniformly, on a first-come, first-served basis, without influence from any Donor, and without regard to the identity of: (i) an individual’s health care provider, practitioner, supplier, prescribed drugs, or insurance plan; or (ii) the party that referred the individual to the Distribution Program, if applicable.

### 2. Distribution

To distribute the Cooling and Mobility Items selected by individuals, Requestor contracts with manufacturers and suppliers of the Cooling and Mobility Items (“Suppliers”). Requestor certified that the selection of Suppliers is an objective process that does not account for—or otherwise consider—whether a Supplier donates (or how much a Supplier donates) to Requestor. Suppliers are responsible for shipping such items directly to qualifying individuals.

Requestor does not bill qualifying individuals for any Cooling Item or Mobility Item furnished pursuant to its Distribution Program. Rather, it compensates Suppliers, in full, for the cost of

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<sup>3</sup> The Distribution Program’s income requirements are identical to those of the Current Arrangement.

<sup>4</sup> Individuals are eligible to receive a new Cooling Item and a new Mobility Item once every 5 and 3 years, respectively.

such items.<sup>5</sup> Requestor certified that Suppliers' compensation under the Distribution Program is consistent with fair market value.<sup>6</sup>

Some of the Cooling and Mobility Items may be reimbursable by a Federal health care program. However, Requestor certified that, because it is not a provider or supplier, it does not bill, directly or indirectly, any payor, including Federal health care programs. Similarly, Requestor certified that, as a condition of participation in its Distribution Program, Suppliers may not bill any payor or qualifying individual for the Cooling and Mobility Items.

### 3. Donors

The Distribution Program is funded by individuals and entities that contribute to Requestor (collectively, and including any affiliates of such individuals or entities, "Donors").<sup>7</sup> Donors are corporations, individuals, and foundations, and include individuals or entities that manufacture, supply, or furnish items or services reimbursable by a Federal health care program, e.g., pharmaceutical and durable medical equipment manufacturers. Donors may be Suppliers or affiliates of Suppliers.

According to Requestor, Suppliers (or their affiliates) that are Donors may not earmark their contributions to the Distribution Program; rather, they may make only unrestricted donations to Requestor, such that Requestor is afforded complete discretion as to how the donation may be spent. All other Donors may provide either unrestricted donations or elect to earmark their contributions to the Current Arrangement or the Distribution Program (although such Donors may not earmark their donations by any other criteria, e.g., for individuals requiring certain treatments or items or services; for specific items or research; or for cost-sharing assistance for drugs). Requestor certified that, other than through the Distribution Program, it does not refer individuals to, recommend, or arrange for the use of: (i) any particular practitioner, provider, insurance plan, manufacturer, or supplier that is a Donor; or (ii) any item or service manufactured, distributed, supplied, or furnished by a Donor.

As with the Current Arrangement, Requestor certified that it maintains a conflict-of-interest policy for its board of directors and that the board operates independent of any Donor.

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<sup>5</sup> We have not been asked to opine on, and express no opinion regarding, such financial arrangements between Requestor and its Suppliers.

<sup>6</sup> We are precluded by statute from opining on whether fair market value shall be, or was, paid for goods, services, or property. Section 1128D(b)(3)(A) of the Act. For purposes of this advisory opinion, we rely on Requestor's certification regarding fair market value.

<sup>7</sup> The term "affiliate" includes any parent, subsidiary, employee, agent, officer, shareholder, immediate family member, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager) of a Donor.

## 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>8</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>9</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>10</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 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.”

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<sup>8</sup> Section 1128B(b) of the Act.

<sup>9</sup> Id.

<sup>10</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).

## **B. Analysis**

### 1. Proposed Modification

Considering Requestor's certification that the Proposed Modification would constitute the only material change to the information furnished to the OIG in connection with AO 15-14, including all supplemental submissions, we conclude that the Proposed Modification would not materially change the risk level of the Current Arrangement. Accordingly, we believe the Proposed Modification would present a minimal risk of fraud and abuse under the Federal anti-kickback statute. In an exercise of our discretion, we would not impose sanctions under the Beneficiary Inducements CMP. We reach this conclusion for the same reasons set forth in AO 15-14.

### 2. Distribution Program

#### *i. Federal Anti-Kickback Statute*

There are two streams of remuneration under the Distribution Program that require analysis: first, Donors' contributions to Requestor, and second, Requestor's use of such donations to furnish free Cooling and Mobility Items to qualifying individuals. Such streams of remuneration may induce Requestor to recommend, or eligible individuals to self-refer to, items or services manufactured, distributed, supplied, or furnished by a Donor that are reimbursable by a Federal health care program, potentially implicating the Federal anti-kickback statute. However, for the following reasons, we conclude that the Distribution Program presents a minimal risk of fraud and abuse under the Federal anti-kickback statute.

First, the Distribution Program is unlikely to result in increased costs to Federal health care programs or Federal health care program beneficiaries because the Cooling and Mobility Items that Donors fund, and that Requestor arranges for the provision of, are not billed to any Federal health care program. Indeed, Requestor certified that, irrespective of whether an item is federally reimbursable, it cannot bill any payor, and it does not bill any qualifying individual for the Cooling and Mobility Items. Requestor further certified that it does not permit Suppliers to bill any payor or qualifying individual as a condition of participation in its Distribution Program.

Second, the Distribution Program is unlikely to steer or otherwise influence individuals to self-refer to a Supplier in the future for other federally reimbursable items or services manufactured, distributed, or supplied by the Supplier. In particular, nothing from a clinical perspective would require individuals to order such items or services. For example, if, under the Distribution Program, a qualified individual receives a Mobility Item that is potentially reimbursable by a Federal health care program, such as a walker, there is no clinical reason that would require the individual to order a second walker or, alternatively, preclude the individual from switching to a different walker manufactured by another entity. Such facts mitigate the risk that the Distribution Program would be used as a seeding program.

Third, the Distribution Program is sufficiently independent of Donors' financial interests. Although Requestor arranges for the use of Cooling and Mobility Items from Suppliers that may be Donors, Requestor certified that: (i) no Supplier (or affiliate of a Supplier) may earmark its donation to the Distribution Program; and (ii) Requestor's selection of a Supplier under the

Distribution Program is an objective process that does not account for, or otherwise consider, whether a Supplier donates (or how much a Supplier donates) to Requestor. While Donors other than Suppliers (or affiliates of Suppliers) may elect to earmark their donations to the Current Arrangement or the Distribution Program, Donors may not earmark their donations by any other criteria, e.g., for individuals requiring certain treatments, items, or services; for specific items or research; or for cost-sharing assistance for drugs.

In addition, and further evidencing Requestor's and the Distribution Program's financial independence from Donors, with the exception of the Distribution Program, Requestor does not refer individuals to, recommend, or arrange for the use of: (i) any particular practitioner, provider, insurance plan, manufacturer, or supplier that is a Donor; or (ii) any item or service manufactured, distributed, supplied, or furnished by a Donor. Moreover, Requestor certified that it pays each Supplier fair market value for the Cooling and Mobility Items it purchases.

Fourth, individual eligibility determinations under the Distribution Program are based on objective, uniform criteria. Cooling and Mobility Items are furnished to applicants on a first-come, first-served basis, based on two criteria: (i) a Disease State diagnosis, with the Disease State defined in accordance with widely recognized clinical standards, without influence from any Donor; and (ii) financial need. Furthermore, eligibility determinations are made without regard to the identity of an individual's health care provider, practitioner, supplier, prescribed drugs, insurance plan, or the party that referred the individual to the Distribution Program, if applicable. Employing objective, uniform criteria in eligibility determinations ensures that donations do not favor: (i) individuals using only Donors' items or services; or (ii) only Federal health care program beneficiaries.

*ii. Beneficiary Inducements CMP*

With respect to the Beneficiary Inducements CMP, Donors' contributions to Requestor and Requestor's use of such contributions to furnish free Cooling and Mobility Items to qualifying individuals could influence a beneficiary to select a provider, practitioner, or supplier for items or services for which payment may be made in whole or in part by Medicare or a State health care program. However, for the reasons stated above, in an exercise of our discretion, we would not impose sanctions under 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 Proposed Modification, if undertaken, and the Distribution Program 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 Proposed Modification or the Distribution Program 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 Proposed Modification, if undertaken, would generate, and the Distribution Program generates, prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed Modification or the Distribution Program 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 Proposed Modification and the Distribution Program 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 Proposed Modification or the Distribution Program, 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 Proposed Modification or the Distribution Program 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 Modification and the Distribution Program 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 Proposed Modification or the Distribution Program 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