



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: November 13, 2015

Posted: November 20, 2015

[Name and address redacted]

Re: OIG Advisory Opinion No. 15-14

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a non-profit, tax-exempt, charitable organization's program to help financially needy patients, including Medicare and Medicaid beneficiaries, obtain magnetic resonance imaging for the diagnosis or ongoing evaluation of [disease state redacted] (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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 Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Arrangement could potentially generate prohibited remuneration under the 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”) will 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 Arrangement. This opinion is limited to the 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) charitable organization dedicated to providing resources, services, and support for patients with a single disease, [disease state redacted] (the “Disease State”). Requestor operates the Arrangement to help financially needy patients, including Medicare and Medicaid beneficiaries, obtain magnetic resonance imaging (“MRI”) for the diagnosis or ongoing evaluation of the Disease State by fully subsidizing the costs the beneficiary would otherwise incur for the MRI.

Patients learn about the Arrangement through a variety of sources, including Requestor,¹ health care professionals (e.g., primary care doctors, neurologists, and nurse practitioners), social workers, other healthcare charities, and others within the community serving individuals with the Disease State. To be eligible to receive assistance under the Arrangement, a patient must have a physician’s order for an MRI for diagnosis of the Disease State or, if already diagnosed with the Disease State, have a physician’s order for an MRI for ongoing evaluation of the Disease State.

Requestor assesses a patient’s financial eligibility for assistance based on the Federal poverty guidelines. Requestor determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. Requestor will employ a process for screening all applicants for compliance with designated financial eligibility criteria prior to enrolling applicants or within a reasonable

¹ Requestor publicizes the Arrangement via its website, social media platforms, national magazines, in-person educational programs, conferences, seminars, workshops, brochures, and other publications.

time thereafter. Such screening process will be applied uniformly and involve: verifying each applicant's financial resources through information provided by a third party service, collecting documentation of financial need from the applicant, or some combination thereof.

Financial assistance is awarded on a first-come, first-served basis to any financially qualified patient who has not received a Requestor-subsidized MRI within the previous 24 months, to the extent funding is available. Requestor does not make eligibility determinations based in whole or in part on: the interest of any person or entity who contributes to Requestor's grant program funds ("Donor") or affiliate(s) of Donors,² including the amount of contributions made by any Donor whose drugs or services may be used by the patient; the patient's choice of provider, practitioner, supplier, drug, or insurance plan; or the identity of the referring person or entity (including whether the referring person or entity is a Donor). Patients are eligible for one Requestor-subsidized MRI within a 24-month period and must re-apply for assistance each time they seek financial assistance for an MRI through the Arrangement.

Requestor uses preset criteria to determine the most cost-effective means to assist patients in obtaining an MRI. Under such criteria, patients are categorized as either "Co-Pay" or "Full-Pay" patients based on their insurance status and, if applicable, their deductible balance and cost-sharing obligations. Co-Pay patients are insured patients (including those insured through Federal health care programs) whose combined deductible balance and cost-sharing obligations are less than the average charge for an MRI that Requestor is able to negotiate with contracted MRI providers in the patient's geographic region. A Co-Pay patient chooses an MRI provider in his or her insurer's network and Requestor remits payment directly to the MRI provider to cover the patient's applicable deductible and/or cost-sharing obligation. Co-Pay patients are able to choose their MRI providers subject only to the requirements of the individual patient's insurance plan.

Full-Pay patients are those who are either (i) uninsured or (ii) insured with a combined deductible balance and cost-sharing obligation that exceeds the average charge for an MRI that Requestor is able to negotiate with contracted MRI providers in the patient's geographic region. In such circumstances, Requestor matches the patient with a local contracted MRI provider based on pre-determined criteria such as cost, service, and proximity to the patient. Accommodations may be made for patients who request different MRI providers due to their particular needs, such as a need for access to an open MRI machine or a need for service in a specific geographic location. Payment is remitted

² The term "affiliate" of any Donor includes, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager) of a Donor.

directly from Requestor to the contracted MRI provider at a discounted rate.³ Requestor certified that it contracts with any willing MRI provider that meets Requestor's quality and cost criteria.

Requestor certified that the Disease State is defined in accordance with widely recognized clinical standards, without reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of the Disease State, type of drug treatment, or any other way of narrowing the definition of the widely recognized underlying disease state.⁴ Requestor further certified that no Donor or affiliate of any Donor directly or indirectly influenced the identification or delineation of the Disease State fund.

Requestor certified that it does not refer patients to, recommend, or arrange for the use of any particular practitioner, provider, supplier, or insurance plan that is a Donor or affiliate of a Donor, or refer patients to, recommend, or arrange for the use of any product or service of a Donor or affiliate of a Donor, and that patients have complete freedom of choice in such matters.⁵ Assistance is provided without regard to a patient's choice of provider, practitioner, supplier, drug, or insurance plan, and while receiving Requestor's financial assistance, patients remain free to change their health care providers, practitioners, suppliers, drugs, or insurance plans.

Requestor solicits donations from its regular donor sources, which include corporations (primarily pharmaceutical manufacturers), individuals, and foundations. All donations are in the form of cash or cash equivalents. Donors are able to change or discontinue their contributions to Requestor at any time. Donors are permitted either to provide unrestricted donations to Requestor or to earmark their contributions for the

³ We have not been asked to opine on, and we express no opinion regarding, Requestor's arrangements with contracted MRI providers. Requestor certified that no contracted MRI provider is a Donor or an affiliate of a Donor.

⁴ Requestor certified that multiple drugs made or marketed by a number of different pharmaceutical manufacturers are available to treat the Disease State. While some manufacturers of such drugs are Donors to the Arrangement, the Arrangement is limited to financial assistance to support patients in obtaining MRIs. It does not provide financial assistance for drugs or any other product or service of any Donor. Requestor does not maintain any disease funds that provide assistance for drugs.

⁵ Outside of the Arrangement, Requestor engages in certain educational activities, which may include the provision of information regarding Disease State treatments to patients diagnosed with the Disease State. Requestor certified that its internal policies require educational activities to be objective and free from bias. We have not been asked to opine on, and we express no opinion regarding, Requestor's educational activities.

Arrangement, but may not earmark their donations by any other criteria (e.g., they may not earmark funds for patients requiring certain treatments). Requestor's discretion to use the donations is absolute, independent, and autonomous.

Requestor is governed by an independent Board of Directors (the "Board"). No Donor, or affiliate of a Donor, exerts any direct or indirect influence over Requestor or Requestor's Arrangement. No person who is a Donor, or immediate family member, director, officer, employee, or person otherwise affiliated with a Donor, currently serves on Requestor's Board.⁶ Requestor further certified that no former director, officer, or employee of a Donor who maintains an ongoing relationship with the Donor (via consulting or otherwise), or immediate family member of such former director, officer, or employee of a Donor currently serves on the Board. Requestor certified that it maintains a conflict of interest policy for its Board to ensure independence in the Board's decision-making.

As a courtesy, Requestor may give Donors aggregated data, such as the number of MRIs provided through the Arrangement and certain other aggregated data obtained through patient surveys, including data regarding patients' use of Disease State treatments approved by the Food and Drug Administration (but not specific to any particular Disease State treatment). Requestor certified that it does not provide Donors with any individual patient information or any information that would enable a Donor to correlate the amount or frequency of its donations with the amount or frequency of the use of its drugs or services. While the identities of multiple pharmaceutical manufacturer Donors are disclosed on Requestor's website and on the Arrangement application for assistance, the Arrangement does not provide financial assistance for drugs or any other product or service of any Donor.

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

⁶ While Requestor's policies do not prohibit a Donor from serving on the Board, Requestor certified that it would permit such Board service only if a majority of disinterested Board members determined that the individual's contribution was critical to the achievement of Requestor's overall mission. Moreover, Requestor certified that it requires recusal of a Board member from consideration of any matter involving any entity in which a Board member has an interest, through ownership, employment, or otherwise, in accordance with Requestor's conflict of interest policy. Requestor's conflict of interest policy requires Board members to disclose potential conflicts of interest and includes a process for resolving any potential conflict of interest.

reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the 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. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); 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), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also 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 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 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 may also 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) as including “transfers of items or services for free or for other than fair market value.”

B. Analysis

Two aspects of the Arrangement require scrutiny: the Donors’ contributions to Requestor and Requestor’s assistance to patients. We address them in turn.

1. Donors’ Contributions to Requestor

Long-standing OIG guidance makes clear that industry stakeholders can contribute effectively to the health care safety net for financially needy patients, including Federal health care program beneficiaries, by contributing to independent, bona fide charitable

assistance programs. For the combination of the following reasons, we believe that the Arrangement entails minimal risk of Donors' contributions influencing direct or indirect referrals by Requestor.

First, no Donor or affiliate of any Donor exerts direct or indirect control over Requestor or its program. Requestor is an independent, non-profit, tax-exempt charitable organization that operates with absolute, independent, and autonomous discretion as to the use of Donors' contributions. No Donor, or immediate family member, director, officer, employee, or person otherwise affiliated with a Donor (including any former director, officer, or employee who maintains an ongoing relationship with a Donor or his or her immediate family members), currently serves on Requestor's Board. Although such individuals are not prohibited from serving on Requestor's Board, safeguards are in place to appropriately identify and screen potential conflicts of interest.

Second, while Requestor matches Full-Pay patients with contracted MRI providers for MRIs covered under the Arrangement, all patients otherwise remain free, while receiving Requestor's assistance, to change their health care providers, practitioners, suppliers, drugs, and insurance plans. Requestor does not refer patients to, recommend, or arrange for the use of any practitioner, provider, supplier, or insurance plan that is a Donor or affiliate of a Donor, or refer patients to, recommend, or arrange for the use of any product of a Donor or affiliate of a Donor.⁷

Third, Requestor does not provide Donors with any data that would facilitate a Donor in correlating the amount or frequency of its donations with the amount or frequency of the use of its drugs or services. No individual patient information is conveyed to any Donor. Some aggregated data may be provided to Donors as a courtesy. While the identities of certain pharmaceutical manufacturers that are Donors are disclosed on Requestor's website and the application for assistance under the Arrangement, the Arrangement does not provide financial assistance for drugs or any other product or service of any Donor. While we might view the identification of Donors as problematic in other circumstances, we do not view it as problematic in the instant case because the Arrangement does not support the Donors' products.

Finally, the fact that Requestor permits Donors to earmark donations to the Arrangement should not, on the facts presented, significantly raise the risk of abuse. In this case, Requestor certified that no Donor or affiliate of any Donor (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) directly or indirectly influenced the identification or delineation of the Disease State fund. Requestor further certified that: (i) it defines the Disease State fund in accordance with widely recognized

⁷ Although Requestor refers Full-Pay patients to contracted MRI providers, Requestor certified that no such provider is a Donor or an affiliate of a Donor.

clinical standards; and (ii) the Disease State fund is not defined by reference to specific symptoms, severity of symptoms, the method of administration of drugs, stages of the Disease State, type of drug treatment, or any other way of narrowing the definition of the widely recognized underlying disease state. Moreover, in this case, the Arrangement is limited to the provision of financial assistance to offset patient costs associated with MRIs. The Arrangement does not provide assistance to support the products or services of any Donor or affiliate of any Donor. Donors are permitted to earmark contributions for the Arrangement, but not with any greater specificity (*e.g.*, not for patients requiring certain treatments). For the combination of reasons described above, it is unlikely that such earmarking would result in the Arrangement serving as a disguised conduit for financial assistance from a pharmaceutical manufacturer Donor to induce patients to use its drugs.

In sum, Requestor is a 501(c)(3) charitable entity that must use its donated funds in a manner that maximizes its charitable mission. Requestor's design and administration of the Arrangement as described herein provide sufficient insulation so that Requestor's assistance to patients should not be attributed to, or influenced by, any of its Donors. In these circumstances, for the combination of reasons described above, we do not believe that the contributions Donors make to Requestor can reasonably be construed as payments to Requestor to arrange for referrals.⁸

2. Requestor's Assistance to Federal Health Care Program Beneficiaries

In the circumstances presented by the Arrangement, Requestor's provision of financial assistance with deductible and cost-sharing obligations for certain eligible, financially needy patients, including Federal health care program beneficiaries, presents a low risk of fraud and abuse and is not likely to influence any beneficiary's selection of a particular 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. We reach this conclusion based on the following factors.

First, while Requestor matches Full-Pay patients with contracted MRI providers, Requestor reimburses the contracted provider in full for the MRI in such circumstances. Because Requestor is paying the full fee, those MRI costs are not services reimbursable by the Medicare or Medicaid programs. For Co-Pay patients, Requestor has certified

⁸ This conclusion is consistent with the OIG's November 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70623; Nov. 22, 2005) and the OIG's May 2014 Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs (79 Fed. Reg. 31120; May 30, 2014), in which the OIG made it clear that, in the circumstances described in the bulletins, cost-sharing subsidies provided by bona fide, independent charities should not raise anti-kickback concerns.

that, aside from directing a patient to obtain an MRI within the patient's insurance network, Requestor does not otherwise refer Co-Pay patients to, recommend, or arrange for the use of any particular practitioner, provider, supplier, drug, or insurance plan.

Second, Requestor's determination of a Disease State patient's qualification for assistance is based solely on his or her financial need, without considering the identity of any of his or her health care providers, practitioners, suppliers, drugs, or insurance plans; the identity of any referring party; or the identity of any Donor that may have contributed to the Arrangement or the amount of the donation. Requestor determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. Requestor will verify applicants' financial need before providing assistance or within a reasonable period of time after assistance is initiated.

Third, Requestor assists all eligible, financially needy patients on a first-come, first-served basis, to the extent funding is available. Patients are not eligible for assistance unless they meet Requestor's financial need eligibility criteria. As explained above, all patients already have selected a provider, practitioner or supplier, and have a treatment regimen in place that includes a physician's order for an MRI for diagnosis or ongoing evaluation of the Disease State. Eligibility determinations are not based, in whole or in part, on whether a patient's provider, practitioner, or supplier has made contributions to Requestor's support program. Requestor does not refer patients to, recommend, or arrange for the use of any practitioner, provider, supplier, or insurance plan that is a Donor or affiliate of a Donor, or refer patients to, recommend, or arrange for the use of any product or service of a Donor or affiliate of a Donor. While the identities of certain pharmaceutical manufacturers that are Donors are disclosed on Requestor's website and the Arrangement application for assistance, the Arrangement does not provide financial assistance for drugs or any other product or service of any Donor. While we might view the identification of Donors as problematic in other circumstances, we do not view it as problematic in the instant case because the Arrangement does not support the Donors' products.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG will 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 Arrangement. This opinion is limited to the 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.
- 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 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 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 [name redacted] 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General