



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: June 18, 2018

Posted: June 25, 2018

[Name and address redacted]

Re: OIG Advisory Opinion No. 18-05

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding an arrangement under which a hospital has established a caregiver center that provides or arranges for free or reduced-cost support services to caregivers in the local community (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, 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. In addition, the OIG will not impose administrative sanctions on [name redacted] under section 1128A(a)(5) 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 nonprofit medical center located in [state redacted] (the “State”), whose mission includes caring for the sick and enhancing the health of the communities it serves. Citing to a published report,¹ Requestor stated that many caregivers who provide unpaid care and daily living assistance to persons with debilitating chronic conditions (“Care Recipients”) experience high levels of physical strain from caregiving, and some also express concern about financial strain. Caregivers often are family members or friends of Care Recipients and, citing again to the published report, Requestor stated that caregivers spend an average of 24.4 hours per week assisting Care Recipients, with nearly 25 percent of caregivers providing 41 or more hours of assistance per week. Requestor noted that same report found that more than 80 percent of caregivers stated that they could use more information or help in various caregiving areas, such as keeping the Care Recipient safe at home, managing their own stress, and making end-of-life decisions.²

¹ National Alliance for Caregiving and AARP Public Policy Institute, *Caregiving in the U.S. 2015* (June 2015), available at <https://www.aarp.org/content/dam/aarp/ppi/2015/caregiving-in-the-united-states-2015-report-revised.pdf>.

² Id.

In furtherance of its mission, Requestor established the [name redacted] (the “Center”) as a department of the medical center to provide or arrange for certain support services for individuals in Requestor’s community who care for adults with chronic medical conditions (“Caregivers”). The Center’s leadership is the same as Requestor’s. Requestor certified that the vast majority of the Center’s staff are unpaid volunteers who receive volunteer training through Requestor.³ The Center’s operating budget is funded by the [name redacted] (the “Foundation”), which is a nonprofit corporation organized and operated exclusively to foster support for Requestor’s mission and activities. Requestor certified that private donations fund, and will continue to fund, all of the Center’s operating costs and that none of the Center’s costs are or would be shifted to any Federal health care program.

Requestor stated that the Center’s primary role is to advocate and provide care coordination for Caregivers. To that end, the Center—either directly, or by collaborating with other local nonprofit organizations—provides a number of free and fee-based services to Caregivers. Free services include, but are not limited to, access to a resource library, various educational sessions (such as care coaching by volunteers), support groups, and an equipment lending program under which Caregivers may borrow a personal listening device (e.g., an Apple iPod shuffle or MP3 player) or adaptive equipment such as spoons and pill-minders to try for a short period of time before purchasing elsewhere. In addition, the Center provides free on-site respite care during Center-sponsored events attended by Caregivers. The Center also offers, or partners with community providers to offer, fee-based services such as stress reduction workshops (e.g., music, art, or massage therapy), low-cost ride-share programs, and additional respite care resources. If a Caregiver expresses a need for financial assistance for fee-based services, a volunteer at the Center tries to identify local community resources available for the Caregiver. If no such resources are available, or if the Caregiver expresses needs that require financial assistance beyond what is available in the community, the volunteer provides the Caregiver with Requestor’s application for financial assistance.

All Caregivers are eligible to access the Center’s services. Neither the Center, nor any volunteer, collects or tracks data related to a Caregiver’s or Care Recipient’s health care providers or insurance plan. Likewise, any financial assistance that Requestor awards is based solely on the Care Recipient’s financial need⁴ and is applied in an objective and standardized manner to all applicants seeking financial assistance. Requestor’s financial

³ Only the Center’s receptionist is a paid employee; all other Center staff are unpaid volunteers.

⁴ Requestor noted two exceptions to this financial need policy: (1) if the Caregiver is the Care Recipient’s spouse, then the household income is considered; and (2) if the Care Recipient is listed as a dependent on the Caregiver’s tax return, then the Caregiver’s income is considered.

need application does not request any information regarding health care providers or payors. However, Requestor is aware that many Care Recipients, and some Caregivers, likely are Federal health care program beneficiaries.

Requestor does not pay specifically to market the Center's services, but information about the Center is available on Requestor's website, on its social media pages, and in brochures. Any such information includes a statement that the Center provides certain services for all Caregivers, regardless of the Caregivers' or Care Recipients' ability to pay or the identity of their health care providers or insurance plans. Center staff do not market, promote, or make referrals for any medical items or services that are reimbursable by Federal health care programs, nor does the Center provide any items or services that are reimbursable by Federal health care programs. Requestor certified that volunteers are trained to redirect Caregivers to the Caregivers' (or, if applicable, the Care Recipients') health care providers for information about any medical needs. Volunteers may provide referrals for non-medical items or services (e.g., respite care, adult day care, elder abuse intervention, safety services), but any such referrals are made by providing a comprehensive list of service providers in the area who provide the requested services, without recommending one service provider over another.⁵ All Caregivers who come to the Center must sign a consent form that informs them that the Center does not provide medical care, make recommendations related to health care items or services, or recommend any particular health care or other service provider.

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. 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

⁵ Although most of the non-medical items and services for which the Center might, upon request, provide a comprehensive list of service providers are not reimbursable by a Federal health care program, Requestor acknowledged that respite care and adult day care services may be payable by the State Medicaid program when provided to beneficiaries who are eligible for certain State Medicaid waivers. However, the overnight respite care that Requestor directly provides is not billable to any Federal health care program because the facility in which Requestor offers overnight respite care is a private-pay senior residence that does not accept Federal health care funds, and the on-site respite care Requestor offers during programs at the Center is free to all Care Recipients.

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. 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), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to ten 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 (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 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 the Beneficiary Inducements CMP as including “transfers of items or services for free or for other than fair market value.” Section 1128A(i)(6) of the Act includes two exceptions that could apply to remuneration offered in the Arrangement. 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 by — (i) [b]eing unlikely to interfere with, or skew, clinical

decision making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns[.]⁶

In addition, Section 1128A(i)(6)(H) of the Act (the “Financial Need-Based Exception”) provides that, for purposes of the Beneficiary Inducements CMP, the term “remuneration” does not apply to the offer or transfer of items or services for free or less than fair market value if the items or services: are not advertised, are not tied to the provision of other reimbursable items or services, are reasonably connected to the medical care of the individual, and are provided only after a good faith determination that the recipient is in financial need.

B. Analysis

Under the Arrangement, the Center provides or arranges for a wide range of services for Caregivers in its local community. We must consider whether Requestor’s role in providing or arranging for these services to Caregivers, which also can benefit Care Recipients, is likely to influence them to select Requestor for items or services reimbursable by Medicare or State health care programs in the future. If so, we must analyze whether an exception to the Beneficiary Inducements CMP applies. In addition, we must consider whether Requestor’s role in providing or arranging for services to Caregivers implicates the anti-kickback statute.

At a minimum, all of these services have intangible, psychological value to Caregivers and also can indirectly benefit Care Recipients. Some of these support services, particularly the fee-based services for which Requestor offers financial assistance, relieve Caregivers or Care Recipients who qualify for financial assistance of an expense they otherwise might have incurred. In addition, many of the support services take place at the Center, which is located on Requestor’s campus. Therefore, it is possible that offering free services, and financial assistance for fee-based services, could influence Caregivers or Care Recipients to select Requestor for federally reimbursable items or services in the future.

Because the Beneficiary Inducements CMP is implicated with respect to certain services, we next analyze whether an exception applies. We conclude the Arrangement is not protected by either the Promotes Access to Care Exception or the Financial Need-Based Exception. To be protected under the Promotes Access to Care Exception, the remuneration must improve a beneficiary’s ability to obtain items and services payable by Medicare or

⁶ 42 C.F.R. § 1003.110 (2017) (defining “remuneration”).

Medicaid. Here, most of the items or services offered under the Arrangement⁷ do not necessarily improve a beneficiary's ability to obtain federally reimbursable items or services; in fact, Center staff do not collect any information about Caregivers' or Care Recipients' health care providers, do not provide medical services, and do not recommend any particular health care providers. Similarly, the Financial Need-Based Exception requires the remuneration to be reasonably connected to the individual's medical care. Although many of the services Requestor offers under the Arrangement may relate to Caregivers' general health and well-being, the services are not connected to either the Caregivers' or the Care Recipients' medical care.

Even though the Arrangement does not meet the requirements of either the Promotes Access to Care Exception or the Financial Need-Based Exception, in an exercise of our discretion, we will not impose sanctions under the Beneficiary Inducements CMP for the combination of the following reasons.

First, the services offered under the Arrangement primarily benefit the Caregivers (rather than Care Recipients), who are not necessarily in need of any particular health care provider, practitioner, or supplier. Although Requestor certified that Caregivers may experience physical strain from caregiving, eligibility for the Arrangement is unrelated to any physical conditions or health needs a Caregiver may experience. All Caregivers who participate in any program at the Center must sign a consent form that specifies that the Center does not provide medical care, make recommendations related to health care items or services, or recommend any particular health care or other service provider. Because the services provided under the Arrangement have little, if any, tie to federally reimbursable services, and because the Center does not recommend any particular service providers who provide medical services, the risk that the Arrangement would influence a Caregiver to choose Requestor for federally reimbursable services is low.⁸

⁷ It is possible that a Caregiver who is a Medicare or Medicaid beneficiary and who uses the Center's services could more easily access health care services (e.g., financial assistance provided for respite care could promote access to care because the Care Recipient would be safe while the Caregiver attends an appointment). However, as a whole, the Arrangement does not meet the terms of the exception.

⁸ We recognize that Care Recipients also indirectly benefit from the Arrangement. While we cannot conclude that the Arrangement poses no risk of influencing a Care Recipient's choice of a provider or supplier, we find the risk to be low for the same reasons set forth herein with respect to Caregivers.

Second, the Center's services are available to all Caregivers. Requestor certified that the Center does not track or request information about Caregivers' or Care Recipients' health care providers or insurers. To the extent a Caregiver seeks financial assistance to obtain services, such assistance is awarded on the basis of objective, standardized financial criteria. Thus, the Arrangement does not take into account whether Caregivers or Care Recipients are Federal health care program beneficiaries or whether they have or will seek federally reimbursable services from Requestor.

Third, Requestor certified that it does not actively market the Arrangement. Requestor provides information about the Center on its website, on its social media pages, and in brochures but does not advertise in the media or on billboards and does not engage in other active advertising. Further, to the extent that a Caregiver requests information about health care items, services, or providers, the volunteers at the Center redirect the Caregiver to the Caregiver's (or Care Recipient's, if applicable) own health care providers for information about any medical needs. If the Caregiver's request relates to non-medical items or services, the volunteers provide a list of all known providers of the requested service in the area.⁹ Thus, although Caregivers or Care Recipients could ultimately select Requestor as their provider of reimbursable services in the future, the Center refrains from recommending Requestor for any kind of item or service, whether or not the item or service is reimbursable by a Federal health care program.

Fourth, the Arrangement is unlikely to increase costs to Federal health care programs. The Center staff is comprised primarily of unpaid volunteers. Requestor certified that all costs of operating the Center come from private donations and would not be shifted to any Federal health care program.

The support services that are provided under the Arrangement are designed to help Caregivers in Requestor's community reduce stress and maintain or promote health. The combination of safeguards described above reduces the risk that offering free or reduced-cost services will influence Caregivers or Care Recipients to choose Requestor for federally reimbursable items or services in the future. Therefore, in an exercise of our discretion, we will not subject Requestor to sanctions under the Beneficiary Inducements CMP in connection with the Arrangement. For the same reasons, we conclude that we also would

⁹ We do not believe the fact that the respite care or adult day care services may be reimbursable by the State Medicaid program when provided to certain beneficiaries increases the risk because: (a) the volunteer provides a list of all available service providers in the area; (b) the volunteer does not know whether the Care Recipient would qualify for a Medicaid waiver; and (c) if the Caregiver selects Requestor's facility for respite care, the respite care service could not be billed to Medicaid.

not subject Requestor to sanctions under the anti-kickback statute in connection with the Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, 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. In addition, the OIG will not impose administrative sanctions on [name redacted] under section 1128A(a)(5) 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,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs