



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 2, 2012

Posted: November 9, 2012

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-17

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal for a hospice to establish a volunteer program to provide non-skilled services to terminally ill patients who do not qualify for hospice care (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the “Act”), or under the exclusion authority at section 1128(b)(7) of the Act, or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

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

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

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

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

I. FACTUAL BACKGROUND

[Name redacted] (the “Requestor”) is a non-profit, hospital-based hospice agency that offers skilled services as well as bereavement and education programs to its hospice patients’ families, friends, co-workers, caregivers, and the community-at-large. The Requestor’s eligibility requirements for hospice services are consistent with those for the Medicare hospice benefit: patients must be diagnosed with a terminal illness and have a prognosis of no more than six months to live if the illness runs its normal course. The Requestor provides hospice care to eligible patients, regardless of their ability to pay; however, the hospice care services are funded largely through Medicare, Medicaid, and private insurance.

Under the Proposed Arrangement, the Requestor would offer a community services program to provide non-skilled services at no charge to terminally ill patients who have one year or less to live if the illness runs its normal course, but who do not qualify for hospice services either because they are projected to have more than six months to live or because they do not wish to renounce curative treatment. The services offered under the Proposed Arrangement would be available only to patients who live in their homes, as defined under the Medicare Home Health benefit; the services would not be available to patients residing in skilled nursing facilities. These non-skilled services would include, but would not be limited to: companionship, visitation, transportation in the volunteers’ personal automobiles, running errands, food preparation, respite for caregivers, and assistance with reading and writing.

The individuals providing the non-skilled services would be unpaid volunteers; they would not receive any compensation or other remuneration from the Requestor or its base hospital (the “Hospital”) for services provided under the Proposed Arrangement or for any other services. The Requestor would employ a volunteer coordinator to oversee the volunteers and communicate with the patients receiving the non-skilled services to ensure that the resources and needs of those patients are identified. The expenses of the Proposed Arrangement, including the volunteer coordinator’s salary, would be maintained separately from the Requestor’s and the Hospital’s expenses and would not be included on the Hospital’s or the Requestor’s cost reports. The Hospital’s foundation would help the Requestor raise funds for the Proposed Arrangement’s first year of operation. After that, if the Hospital determines that the Proposed Arrangement has fulfilled an unmet need in the community, the Hospital would fund the Proposed Arrangement going forward.

The Requestor anticipates that it would receive referrals for the services provided under the Proposed Arrangement from three primary sources: (1) the Hospital and other hospitals in the community; (2) physician offices; and (3) directly from patients’ family members. The Requestor would not actively market the Proposed Arrangement to the community. However, the Requestor would educate local hospital case managers about the purpose of services provided under the Proposed Arrangement, including an explanation about the eligibility criteria, one of which is that the patient has been diagnosed with a terminal illness but does not qualify for or does not desire hospice or home care services. The Requestor would explain the program to physician offices and family members upon request (*i.e.*, if a physician office or family member contacts the Requestor seeking information about community resources for services that could be available to patients). If a patient decides to receive the services available under the Proposed Arrangement, the Requestor would give the patient a packet that would include a letter explaining the patient’s right to choose a provider if the patient should need home health or hospice services in the future and a list of known agencies within the patient’s service area.

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 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

Under the Proposed Arrangement, the Requestor would coordinate free, non-skilled services for patients, including Federal health care program beneficiaries, who may require Federally reimbursable hospice services in the near future. At minimum, these services would have intangible, psychological value to patients. However, in some cases, patients would be relieved of a financial expenditure that the patient might have incurred to engage a person or entity to provide similar services to those that would be offered under the Proposed Arrangement (such as doing errands, driving to appointments, etc.). Thus, we must consider whether the Requestor's role in providing these free services to potential hospice patients would be likely to influence the patients to select the Requestor as their provider of hospice services in the future. Although we believe that the Proposed Arrangement could influence the patients to select the Requestor as their provider of hospice services in the

future,¹ we find that the following factors adequately protect Federal health care programs against the risk of fraud and abuse. For the reasons elaborated below, we would not subject the Requestor to sanctions under section 1128A(a)(5) of the Act or the anti-kickback statute.

First, the Requestor certified that it would not market the Proposed Arrangement in the community, other than explaining the purpose of the program and its eligibility criteria to local hospital case managers, and to others upon request. Further, the Requestor would provide patients receiving services under the Proposed Arrangement with information about all known home health and hospice providers in the patient's geographic area. Thus, although patients could ultimately select the Requestor as their provider of hospice services in the future, the Requestor would have given the patients information to exercise their freedom of choice in selecting a provider.

Second, the Proposed Arrangement would be unlikely to increase costs to Federal health care programs. The services would be provided to patients by unpaid volunteers. The Requestor certified that the costs associated with the Proposed Arrangement would be maintained separately from the Requestor's hospice program and from the Hospital's expenses and would not be passed on to Federal health care programs.

Third, to be eligible for hospice care, a patient must have a prognosis of no more than six months to live if the illness runs its normal course, and the patient also must renounce coverage for curative medical treatment for the terminal condition. A patient's decision to elect hospice care, once qualified, is likely to be based on the patient's comfort with rejecting curative treatment and not based on the availability (or unavailability) of services under the Proposed Arrangement. We note, however, that our recognition that hospice care may appeal only to a subset of qualifying patients—those patients who are comfortable renouncing coverage for curative medical treatment for a terminal condition—does not mean that hospice providers can offer patients inducements to elect hospice. We mean only that in the particular circumstances here, *i.e.*, services of relatively small monetary value provided by unpaid volunteers, the requirement that hospice patients forego curative care for their underlying terminal illnesses provides a safeguard against the overutilization often associated with such inducements.

The non-reimbursable services that would be provided under the Proposed Arrangement would be designed to help vulnerable patients adjust to their illnesses by assisting with day-

¹ We recognize that the Requestor is a hospital-based hospice, and that patients receiving services under the Proposed Arrangement could also require inpatient or outpatient services. However, we believe that the services offered under the Proposed Arrangement—non-skilled services, provided to a patient at the patient's residence, through the Requestor—would be unlikely to influence patients to choose the Hospital for medical care.

to-day tasks without increased cost to the Federal health care programs. In these circumstances, with the combination of factors and safeguards detailed above, we would not subject the Requestor to sanctions under section 1128A(a)(5) of the Act or the anti-kickback statute in connection with the Proposed Arrangement.

III. CONCLUSION

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

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestor with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestor with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General