

[Posted November 13, 1998]

[Issued November 6, 1998]

[Names and addresses redacted]

Re: Advisory Opinion No. 98-17

Dear [Names redacted]:

We are writing in response to your request for an advisory opinion, in which you ask whether donations by Company X ("Company X") to Organization A ("Organization A") (an independent, 501(c)(3) charitable organization) for the purpose of funding a program to pay for Supplementary Medical Insurance ("Medicare Part B") or Medicare Supplementary Health Insurance ("Medigap") premiums for financially needy Medicare beneficiaries with end-stage renal disease, where some or all of the beneficiaries may be receiving treatment from Company X (the "Proposed Arrangement"), would constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Social Security Act (the "Act").

You have certified that all of the information you provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the material facts and agreements among the parties regarding the Proposed Arrangement. In issuing this opinion, we have relied solely on the facts and information you presented to us. We have not undertaken any independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and subject to the conditions described below, we conclude that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act.

This opinion may not be relied on by any person other than the requesters and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. End-Stage Renal Disease and Medicare's Dialysis Benefit

End-stage renal disease ("ESRD") is a chronic disease that requires routine dialysis, as well as regular monitoring of laboratory values, diet, and medication. In addition to chronic renal failure, ESRD patients commonly suffer from certain co-morbid conditions, such as diabetes, anemia, hypertension, and congestive heart failure.

In 1972, Congress created a special Medicare benefit for all individuals with ESRD who are eligible for Social Security benefits (or are dependents of those who are eligible). Eligible persons are entitled to benefits under Medicare Part A and are eligible to enroll in Medicare Part B. Medicare Part B payments generally cover eighty percent of the composite rate for Medicare-covered maintenance dialysis services, as well as eighty percent of physician services and certain ancillary services, with the patient responsible for the remaining twenty percent.⁽¹⁾ Medigap insurance can be purchased to cover a patient's annual Medicare coinsurance obligations for Medicare-covered services.

B. The Parties

Company X owns twelve renal dialysis facilities in State Z and is a wholly-owned, direct subsidiary of Company Y. Organization A is an independent, 501(c)(3) charitable organization providing financial support to needy persons in State Z with ESRD for items such as transportation, medication, and other living expenses. Organization A is governed by a board of directors comprised of health professionals, community volunteers, and persons with kidney disease. No

employee or affiliate of Company X or Company Y, serves on the Organization A board. The Organization A board is not directly or indirectly controlled by Company X, Company Y, or any of its subsidiaries or affiliates. It has been the policy of the Organization A board not to have any employees of dialysis programs serve on the board.

Organization A provides financial support to financially needy ESRD patients through a general fund and an emergency fund. Grants from the general fund require a patient to fill out an application providing detailed financial information for the applicant's entire household.⁽²⁾ Eligibility for the general fund is based on guidelines measuring monthly income and family size and a demonstration that the applicant is unable to pay his or her monthly expenses. Individuals who meet the guidelines are eligible to receive \$500 per calendar year from the general fund. A social worker submits the applications to the Organization A board, which gives approval and distributes the funds. Individuals receiving assistance from the emergency fund must show a demonstrated need and receive approval by a social worker. Emergency funds do not require an individual to fill out a financial application. Requests from the emergency fund are limited to \$35, four times a year, or a maximum of \$140 per year per individual.

C. The Proposed Arrangement

Organization A wishes to extend the general fund assistance program to include financial assistance to financially needy ESRD patients for the costs of health insurance premiums, including Medicare Part B and Medigap premiums. Social workers will assist patients in identifying all available sources of assistance for which they qualify, including assistance for health insurance premiums and, if appropriate, will refer financially needy patients to Organization A for such assistance. Although most, if not all, patient contact with Organization A is through a provider's social worker, if a patient who does not already have a provider contacts Organization A to inquire about dialysis facilities, Organization A will provide the patient with a complete list of all dialysis facilities in the area and will not express any preference among facilities.

Organization A will continue to use its current financial assistance application in assessing the financial need and eligibility of all patients, whether self-referred, referred by Company X, or referred by other non-donor dialysis providers. In most cases, an ESRD social worker, employed by the dialysis provider, will submit a completed application to Organization A. Approval of the health insurance premium application will be made by the Organization A board's executive committee comprised of the president, vice president, secretary, treasurer, and two "at-large" board members. Determinations will be based solely on Organization A's good faith assessment of a patient's financial need. Organization A will not take the identity of the referring facility or the amount of any provider's donation into consideration when assessing patient applications or making grant determinations. Any qualified person will be free, and encouraged, to apply for grants under the expanded program. The patient can re-apply at any time his or her financial or family situation changes. All grants will be reviewed on an annual basis for eligibility. Organization A will send all premium payments directly to the insurance company.

Under the Proposed Arrangement, funding for the expanded program will be primarily donated by Company X. Company X will make contributions to Organization A without any restrictions or conditions placed on the donation. Company X has acknowledged that "contributions . . . will be gifts without any guarantee or promise on the part of Organization A that patients referred to Organization A for possible financial assistance with their insurance premiums will receive such assistance. Organization A's discretion as to the uses of contributions will be absolute, independent, and autonomous."

Company X will not track the amount that Organization A pays on behalf of patients dialyzing at its facilities in order to calculate future contributions. However, in calculating its contributions to Organization A, Company X has indicated that it may consider what it would have otherwise paid on behalf of financially needy patients. Company X will not advertise the availability of possible financial assistance to the public and will not disclose directly or indirectly to individual patients it refers to Organization A that Company X has donated to Organization A.

II. LEGAL ANALYSIS

Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who:

"offers to or transfers remuneration to any individual eligible for benefits under subchapter XVIII of this chapter, or under a State health care program (as defined in section [1128(h) of the Act]) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under subchapter XVIII of this chapter, or a State health care program (as so defined)."

Section 1128A(i)(6) defines "remuneration", in relevant part, as "transfers of items or services for free or for other than fair market value."⁽³⁾

A. Donations by Company X Do Not Constitute Remuneration to an Eligible Beneficiary

Company X's contributions to Organization A would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act, because the contributions are not made to, or on behalf of, an individual eligible for Medicare or State health care program benefits. Organization A is an independent, 501(c)(3) charitable organization whose charitable purposes include aiding ESRD patients and their families and is not subject to control, directly or indirectly, by Company X, Company Y, or any of its subsidiaries or affiliates. Under the Proposed Arrangement, Organization A will have absolute discretion regarding the use of provider contributions made to Organization A.

In addition, eligibility for Organization A's health insurance premium assistance is available to any financially needy ESRD patient regardless of the provider; it is not limited to patients of Company X. Organization A will make all health insurance premium eligibility determinations using its own criteria, and Organization A will not take into account the identity of the referring provider or the amount of the provider's donation to Organization A.

As an additional safeguard, Company X has represented that it will not track the amounts that Organization A pays on behalf of patients dialyzing at its facilities in order to calculate amounts of future contributions, although donations may take into account the amounts that Company X would have otherwise expended on financially needy patients. Contributions will not be earmarked for the use of particular beneficiaries or groups of beneficiaries. Company X may change the amount of its contributions or discontinue contributing to Organization A at any time. Company X has represented that it will determine the amount of its contributions without consulting any other dialysis providers.

In sum, Organization A's status as an independent, 501(c)(3) charitable organization and its administration of the Proposed Arrangement provides sufficient insulation so that the premium payments should not be attributed to Company X. Company X's contributions to Organization A will not assure that the amount of health insurance premium assistance its patients receive bears any relationship to the amount of its donations. Indeed, Company X is not guaranteed that beneficiaries it refers to Organization A will receive any assistance at all. In these circumstances, we do not believe that the donations by Company X to Organization A can reasonably be construed as payments to eligible beneficiaries of Medicare or a State health care program.

B. Organization A's Purchase of Premiums Is Not Likely to Influence a Beneficiary's Choice of a Particular Provider

Section 1128A(a)(5) of the Act prohibits payments to, or on behalf of, Medicare or State health care program beneficiaries only if the payments are likely to influence such beneficiaries to use a particular provider. In the circumstances presented by the Proposed Arrangement, we believe that Organization A's payments of premiums on behalf of financially needy beneficiaries are not likely to influence a beneficiary's selection of a particular provider.

As part of the application process for health insurance premium assistance, Organization A requires certain financial information from the applicant, as well as additional information from the social worker. While patients may apply directly to Organization A, more commonly the dialysis provider's social worker refers the application to Organization A on the patient's behalf. Thus, a patient will often have selected a provider prior to submitting his or her application for assistance or prior to the initial Organization A premium payment. Moreover, Company X will not publicly advertise the availability of possible financial assistance. This should reduce the probability that a beneficiary would select a

Company X facility based on its participation in the health insurance premium program. Most importantly, once in possession of Medicare Part B or Medigap coverage, a beneficiary will be able to select any provider of his or her choice. Simply put, Organization A's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice of providers.

III. CONCLUSION

We conclude that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act. A violation of section 1128A(a)(5) of the Act requires that something of value be given to a beneficiary, either directly or on his or her behalf. The contributions to Organization A by Company X are not made to or on behalf of beneficiaries.⁽⁴⁾ Moreover, while the premium payments by Organization A may constitute remuneration to beneficiaries, they are not likely to influence patients to order or receive services from particular providers. To the contrary, the insurance coverage purchased by Organization A will follow a patient regardless of which provider the patient selects, thereby enhancing patient freedom of choice in health care providers.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- o This advisory opinion is issued only to Organization A and Company X, the requesters of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.
- o This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requester to this opinion.
- o This advisory opinion does not address any other current or past arrangement for the payment of Part B or Medigap premiums by any dialysis provider or any other charitable or non-profit organization. The U.S. Department of Health and Human Services does not accept or acquiesce in any characterizations of the propriety of such arrangements in the materials submitted by the requesters.
- o This advisory opinion is applicable only to the statutory provision specifically noted above. No opinion is herein expressed or implied 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.
- o This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- o This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.
- o 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.

The Office of Inspector General ("OIG") will not proceed against the requesters 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, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the requesters with respect to any action 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,

/s/

D. McCarty Thornton

Chief Counsel to the Inspector General

FOOTNOTES:

¹The composite rate is a prospective payment system for outpatient maintenance dialysis services to Medicare beneficiaries. We note that Medicare reimbursement for some medical services provided to ESRD patients, such as certain lab services, are not covered under the composite rate.

² The information required includes: assets held in checking, savings, and CD accounts; monthly income (which is made up of the take-home pay of the patient and spouse, social security, retirement income, etc.); and monthly expenses for rent, mortgage, food, utilities, transportation, medical expenses, insurance, charge accounts, and loans.

³ This definition of remuneration also provides an exception, not applicable here, for certain waivers of coinsurance and deductible amounts.

⁴ The Proposed Arrangement differs from an arrangement where a renal dialysis provider directly pays premiums for beneficiaries, thus potentially influencing them to continue to use that particular dialysis provider in order to ensure continuing payment of premiums.