

[Names and addresses of Requestors have been redacted]

Re: Advisory Opinion No. 97-1

Dear [Names have been redacted]:

We are writing in response to your request for an advisory opinion, which we accepted pursuant to 42 C.F.R. § 1008.41 on April 11, 1997. Your request asks whether donations by renal dialysis providers to an independent 501(c)(3) charitable organization for the purpose of funding a program to pay for Supplementary Medical Insurance Program ("Medicare Part B") or Medicare Supplementary Health Insurance ("Medigap") premiums for financially needy Medicare beneficiaries with end-stage renal disease where such beneficiaries may be receiving treatment from the donor-dialysis providers (the "Proposed Arrangement") would constitute grounds for the imposition of a civil monetary penalty under Section 231(h) of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

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 facts and agreements among the parties regarding the Proposed Arrangement. You have also certified that upon our approval of the Proposed Arrangement, you will undertake to effectuate the Proposed Arrangement.

In issuing this opinion, we have relied solely on the facts and information you 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, this opinion is without force and effect.

Based on the information provided and subject to certain conditions described below, we have determined that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under Section 231(h) of HIPAA. This opinion may not be relied on by any person other than the addressees and is further qualified as set out in Part III below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

The American Kidney Fund and Company A, Company B, Company C, Company D, Company E, and Company F, (collectively the "Companies") have made the following representations with respect to the Proposed Arrangement. The American Kidney Fund and the Companies are collectively the "Requestors".

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

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

In 1972, Congress created a special Medicare ESRD benefit. This benefit is for all individuals with ESRD who have earned a certain level of eligibility for Social Security benefits (or are dependents of those who have attained that level). People in this category are entitled to benefits under Medicare Part A and are eligible to enroll in Medicare Part B. Medicare Part B payments on behalf of ESRD patients 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.¹ Medigap insurance can be purchased to cover a patient's annual Medicare coinsurance obligations for Medicare-covered services.

B. Parties to the Proposed Arrangement

1. The Companies

[Material redacted] [The companies have formed an association] to address issues that affect the dialysis industry and to improve the way the renal dialysis industry performs as a whole. While the Companies [as an association] have worked with the American Kidney Fund to develop the proposed arrangement, the individual providers have applied for the advisory opinion in their separate capacities.

2. American Kidney Fund

The American Kidney Fund ("AKF") is a bona fide, 501(c)(3) charitable and educational organization that has been in existence for over twenty-five years. AKF, a public charity, is governed by a board of twenty-five members. The board bylaws provide that membership on the board should be comprised of representatives involved with ESRD issues, including nephrology physicians, nephrology nurses, nephrology social workers, patients or family members of ESRD patients, and community leaders. Vacancies on the board are filled by vote of the remaining board members. Although two members of the current board are employees of subsidiaries of one Company, the AKF board is not directly or indirectly

¹ 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.

controlled by any Company or Companies. AKF has established a subcommittee of the board's Program and Grant Committee to have primary oversight authority for the Health Insurance Premium Program; membership on such subcommittee will be restricted to exclude any employees, officers, shareholders, or owners of any dialysis provider.

In addition to its educational efforts on behalf of those suffering from renal failure, AKF provides direct financial support in the form of grants to needy persons with ESRD for items such as transportation, medication, and insurance premiums. In the past, AKF has funded 100 percent of all eligible grant requests from ESRD patients. In 1995, AKF assisted over 12,000 patients with ESRD and received over \$5 million in donations. Of that amount, less than ten percent was contributed by the Companies. The largest percentage of AKF's funds was directed towards patient aid. AKF disseminates information about its patient assistance and other programs throughout the national dialysis provider community, especially to social workers who work with ESRD patients.

C. Health Insurance Premium Program

AKF's Health Insurance Premium Program ("HIP") provides financial assistance to financially needy ESRD patients for the costs of medicine, transportation, and health insurance premiums, including Medicare Part B and Medigap premiums. Assistance is available to all eligible patients on an equal basis. In general, eligibility for participation in AKF's assistance programs requires a physician certification, a referral letter signed by a social worker or administrator at a dialysis provider, and an individual Patient Grant Application. The Patient Grant Application requires patients to provide detailed financial information for their entire household.² While a patient can apply directly to AKF for a grant, most applications are submitted on the patient's behalf by dialysis providers or social workers employed by a dialysis provider.

Upon receipt of a patient's application, a member of AKF's staff reviews the application, gathers additional information, if necessary, and makes an initial recommendation as to the disposition of the application based upon AKF's needs assessment and eligibility criteria. A senior staff employee reviews the recommendation and makes a final determination. All

² The information required includes: assets held in checking and savings accounts; the value of a home, stocks and bonds, and automobiles; monthly income (which is made up of take-home pay of the patient and spouse, social security, welfare, retirement income, veterans benefits, etc.); and monthly expenses for rent, mortgage, food, utilities, transportation, medical expenses, insurance, charge accounts, and loans. AKF further requires that the patient disclose all sources of alternative assistance available, such as Medicare, Medicaid, and state renal programs.

determinations are made by AKF employees who have no financial interest in the Companies or other dialysis providers and are based on their good faith assessment that the applicant is in financial need and eligible for assistance. If AKF determines that a patient is eligible for assistance, AKF notifies the dialysis provider's social worker that the insurance premium has been paid in order to ensure that the patient's billing information is accurate.

Because of AKF's limited financial resources, an AKF patient assistance grant is provided for a specific time period. Upon expiration of the period, the patient must submit another grant application. Grant requests are reviewed on a first-come, first-served basis to the extent funding is available.

D. The Proposed Arrangement

AKF proposes to expand significantly its patient assistance grants to financially needy ESRD patients for payment of medical insurance premiums through HIPP. Additional funding will be donated primarily by the Companies. Medical social workers at each Company's dialysis facility will assist patients in identifying all available sources of assistance for which they qualify, which may include assistance from HIPP, and if appropriate, will refer financially needy patients to AKF for such assistance. However, the Companies will not advertise the availability of possible financial assistance to the public and will not disclose directly or indirectly to individual patients they refer that such members have contributed to AKF to fund the grants.

AKF will continue to use its current procedures in assessing the financial need and eligibility of all patients, whether self-referred or referred by the Companies, or other non-donor dialysis providers. Determinations will be made solely on AKF's good faith assessment of a patient's financial need. AKF staff involved in awarding patient grants 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.

Under the Proposed Arrangement, the Companies will be free to determine whether to make contributions to AKF and, if so, how much to contribute. All the Companies have certified that they will not track the amount that AKF pays on behalf of patients dialyzing at their facilities in order to calculate future contributions. However, in calculating their contributions to AKF, the Companies have indicated that they may consider what they would have otherwise paid on behalf of financially needy patients utilizing their facilities. The Companies will not disclose to each other, or other dialysis providers, the amount or method of calculating their respective contributions to AKF, and AKF will not disclose one Company's contribution to another Company or to other dialysis providers.

Contributions will be made without any restrictions or conditions placed on the donation. The Companies have acknowledged that "contributions . . . will be gifts without any guarantee or promise on the part of AKF that patients referred to AKF for possible financial assistance with their insurance premiums will receive such assistance. AKF's discretion as to the uses of contributions will be absolute, independent, and autonomous."

II. LEGAL ANALYSIS

Section 231(h) of HIPAA, effective January 1, 1997, provides for the imposition of civil monetary penalties against any person who:

offers or transfers remuneration to any individual eligible for benefits under [Federal health care programs (including Medicare or Medicaid)] 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, [by a Federal health care program].

Section 231(h) defines "remuneration", in relevant part, as "transfers of items or services for free or for other than fair market value."³

We conclude that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under Section 231(h) of HIPAA. A violation of Section 231(h) requires that something of value be given to a beneficiary, either directly or on his or her behalf. Simply put, the contributions to AKF by the Companies are not made to or on behalf of beneficiaries.⁴ Moreover, while the premium payments by AKF 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 AKF will follow a patient regardless of which provider the patient selects, thereby enhancing patient freedom of choice in health care providers.

A. Donations By The Companies Do Not Constitute

³ The statutory definition of remuneration 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.

Remuneration To An Eligible Beneficiary

The Companies' contributions to AKF would not constitute grounds for the imposition of civil monetary penalties under Section 231(h), because such contributions are not made to or on behalf of an individual eligible for Federal health care program benefits. AKF is a bona fide, independent, publicly-funded, 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 any Company or Companies. Under the Proposed Arrangement, AKF will have absolute discretion regarding the use of provider contributions made to AKF.

Moreover, eligibility for HIPP assistance is available to any financially needy ESRD patient regardless of provider; it is not limited to patients of the companies. AKF will make all AKF eligibility determinations using its own criteria, and AKF staff will not take into account the identity of the referring provider or the amount of any donation to AKF by such provider.

Finally, as an additional safeguard, the Companies have represented that they will not track the amounts that AKF pays on behalf of patients dialyzing at their facilities in order to calculate amounts of future contributions, although donations may take into account the amounts that the Companies would have otherwise expended on financially needy patients. Contributions will not be earmarked for the use of particular beneficiaries or groups of beneficiaries. The Companies may change the amount of their contributions or discontinue contributing to AKF at any time. The Companies have represented that they will individually determine the amount of their contributions without consulting with the other Companies or other contributing dialysis providers.

In sum, the interposition of AKF, a bona fide, independent, charitable organization, and its administration of HIPP provides sufficient insulation so that the premium payments should not be attributed to the Companies. The Companies who contribute to AKF will not be assured that the amount of HIPP assistance their patients receive bears any relationship to the amount of their donations. Indeed, the Companies are not guaranteed that beneficiaries they refer to HIPP will receive any assistance at all. In these circumstances, we do not believe that the donations by the Companies to AKF can reasonably be construed as payments to eligible beneficiaries of a Federal health care program.

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

Section 231(h) prohibits payments to or on behalf of Federal 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 AKF's payments of premiums on behalf of financially needy beneficiaries is not likely to influence a beneficiary's selection of a particular provider.

As part of the application process for HIPP, AKF requires certain medical and financial certifications from the applicant's physician and social worker. While patients may apply directly to AKF, more commonly, the dialysis provider makes the application on behalf of the patient. Thus, a patient will often have already selected a provider prior to submitting his or her application for assistance or the initial payment of premiums by AKF. As an additional safeguard, HIPP will not be advertised to the public by the Companies; this should reduce the probability that a beneficiary would select a Company based on its participation in HIPP. 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, AKF's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice.

III. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to AKF, Company A, Company B, Company C, Company D, Company E, and Company F, which are the Requestors of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.
- 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 Requestors.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a Requestor to this opinion.
- 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, including any laws relating to insurance or insurance contracts.

- 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 prospective only. It has no application to conduct which precedes the date of this opinion.
- 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.

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 Requestors with respect to any action 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, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the requestors 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.

Sincerely,

/S/

D. McCarty Thornton
Chief Counsel to the Inspector General