DEPARTMENT OF HEALTH AND HUMAN SERVICES **Office of Inspector General**

Washington, D.C. 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: January 18, 2007

Posted: January 25, 2007

[Name and Address Redacted]

Re: OIG Advisory Opinion No. 07-01

Dear [names redacted]:

We are writing in response to your request for an advisory opinion regarding a hospital's proposal to provide free acute dialysis treatment services to chronic dialysis patients unable to obtain dialysis in their community, some of whom may be Medicare or Medicaid beneficiaries (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 ("CMP") for violations of the prohibition against inducements to beneficiaries under 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 CMP 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.

You have certified that all of the information provided in your request, including all supplementary letters, 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 the Proposed Arrangement could potentially constitute prohibited remuneration within the meaning of section 1128A(a)(5) of the Act, and 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, but that the Office of Inspector General ("OIG") would not impose administrative sanctions on [name redacted] under section 1128A(a)5 of the Act, or 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 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 large, public health system with a state statutory obligation to provide health care to the residents of [county and state redacted]. See [state law citation redacted]. Requestor's mission is to serve underserved populations, and a high proportion of its patients are indigent. Requestor operates an acute care hospital known as [name redacted] (the "Hospital").

The Hospital has a dialysis unit, which is operated by the non-profit [name redacted] (the "Management Company"), to serve Hospital inpatients. This dialysis unit is licensed by [state agency redacted] to provide dialysis services for two patients simultaneously. The Hospital only offers dialysis services to inpatients and emergency department patients in an emergency condition. The Hospital does not offer chronic dialysis services for outpatients.

Patients who need chronic dialysis treatments three times per week, but who do not have access to an outpatient dialysis chair in the community ("Chronic Dialysis Patients"), routinely present to the Hospital's Emergency Department or the Hospital's Outpatient Renal Clinic. The Hospital's Outpatient Renal Clinic provides care for patients in all stages of chronic kidney disease, up to the point when dialysis is started; it does not offer dialysis, and once a patient has started dialysis, that patient is no longer treated at the Outpatient Renal Clinic. According to Requestor, Chronic Dialysis Patients may lack access to dialysis for a variety of reasons: no payment source for dialysis (e.g., no health insurance); lack of open dialysis chairs in [county redacted] and the surrounding areas; inability to transfer and sit in a dialysis chair for the four hour treatment; or behavioral or psychiatric issues that make the patient undesirable to receive dialysis in one of the

privately-owned dialysis units in the area.[1] Chronic Dialysis Patients frequently include individuals who are Medicare or Medicaid beneficiaries, individuals whose applications with those programs are pending, or individuals who will become Medicare eligible in a short period of time.[2]

Since Chronic Dialysis Patients are unable to obtain dialysis in the community, many of them forego treatment until their conditions become urgent, at which point they present to the Hospital's Emergency Department and are admitted as inpatients to receive emergency dialysis treatment. Other Chronic Dialysis Patients present to the Hospital's Outpatient Renal Clinic, and to prevent their condition from developing into an emergency situation, the Hospital admits them as inpatients so dialysis can be provided in the Hospital's dialysis unit. At any given time, the Hospital has ten to fifteen Chronic Dialysis Patients occupying inpatient beds who have been admitted under these circumstances. The Hospital does not bill anyone for these admissions; rather, the Hospital absorbs all costs associated with these services.[3]

According to Requestor, the current arrangement limits other patients' access to the Hospital's inpatient unit, because Chronic Dialysis Patients are occupying inpatient beds

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[1]Medicare and Medicaid providers are required to comply with certain civil rights requirements as a condition of participation in those programs. 42 CFR 489.10(b). To the extent that a Medicare or Medicaid provider either excludes a qualified beneficiary, or denies the benefits of participation to a qualified beneficiary, on the basis of handicap, it may be in violation of its provider agreement.

[2]Requestor has certified that patients with end stage renal disease ("ESRD") may be eligible for Medicare benefits if they meet certain criteria, but Medicare benefits typically begin after a three-month waiting period, unless the individual receives a kidney transplant or participates in a self-dialysis training program during the waiting period. See Section 226A of the Act. Unlike Medicare beneficiaries entitled to Social Security benefits, who are automatically enrolled in Medicare Part A, most ESRD patients must submit an application for enrollment in Medicare Part A before they can receive any benefits. All potential Medicaid beneficiaries must submit an application so that their state of residency can determine whether they meet applicable criteria for Medicaid eligibility.

[3]Neither the Management Company nor the Hospital bills anyone for these services. Requestor has certified that the Hospital pays the Management Company fair market value for the services it renders to Chronic Dialysis Patients. We have not been asked, and we express no opinion, about the arrangement between the Hospital and the Management Company.

solely to receive thrice weekly dialysis, even though they appropriately could receive outpatient dialysis if they had access to it. As a result, acute patients in the Emergency Department have to wait for an inpatient bed to become available, which in turn causes the Emergency Department to reach capacity, necessitating diversion of patients to other emergency rooms.

Under the Proposed Arrangement, the Hospital would admit Chronic Dialysis Patients for dialysis treatment, and then immediately discharge them following treatment.[4] Instead of essentially living in the Hospital, as is currently the case, the Chronic Dialysis Patients would be admitted to the Hospital and discharged three times per week. The Hospital would not bill these patients or any third party payor, including Medicare or Medicaid, for these admissions. The Hospital would not advertise the availability of these services. The Hospital expects that some patients would be directed to the Hospital for these services by its Outpatient Renal Clinic, its Emergency Department, or local dialysis facilities that are unable or unwilling to provide them with services.

According to Requestor, the outpatient dialysis clinics in the area will not accept patients who have Medicare or Medicaid applications pending. The Hospital is attempting to bridge this gap. As part of the Proposed Arrangement, the Hospital's Renal Case Manager/Social Worker would assist any Chronic Dialysis Patients who became eligible for Medicare or Medicaid in finding an outpatient dialysis chair in the community. Since the Hospital does not offer outpatient dialysis services, Medicare and Medicaid beneficiaries treated under the Proposed Arrangement would not return to the Hospital for such services.

II. LEGAL ANALYSIS

A. Law

Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or Medicaid program 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 Medicaid. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(a)(5) of the Act defines "remuneration" for

[4]Requestor has certified that this would mirror the standard of care for routine outpatient dialysis patients.

purposes of section 1128A(a)(5) as including "transfers of items or services for free or for other than fair market value."

The anti-kickback statute makes it a criminal offense knowingly and willfully to 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. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), 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.

B. Analysis

With respect to Medicare and Medicaid beneficiaries, the Proposed Arrangement, under which the Hospital would admit Chronic Dialysis Patients for treatment and would not bill them or any third party for the admissions, could potentially implicate both the CMP prohibiting beneficiary inducements, as well as the anti-kickback statute. The Hospital would confer a benefit on individuals who are Federal health care program beneficiaries that, if the requisite intent were present, could potentially violate the two statutes discussed above. However, for the reasons set forth below, we conclude that the Proposed Arrangement presents a minimal risk of Federal health care program abuse, while providing significant benefits to an underserved patient population, and we would not seek to impose administrative sanctions under the statutes discussed above.

1. The CMP

We begin with the application of the CMP to the facts presented. The threshold question is whether free chronic dialysis treatments constitute remuneration to the patient who receives them. Since the dialysis treatments, which are being provided for free, have more than nominal value, they would constitute remuneration for purposes of the CMP.

The next question under the CMP is whether the free chronic dialysis treatments would be likely to influence patients to select the Hospital as their provider of items or services payable by Medicare or Medicaid. On the facts presented, we believe this is unlikely. The free dialysis treatments would not precipitate an ongoing relationship between Medicare or Medicaid patients and a service offered by the Hospital, because the Hospital does not offer outpatient dialysis services, and patients who have started dialysis are no longer treated at the Outpatient Renal Clinic. The Hospital will take affirmative steps to locate an available chair for patients requiring dialysis at a local outpatient dialysis facility. In this way, the Proposed Arrangement is distinct from other arrangements where a provider or supplier provides free items or services to patients with Medicare or Medicaid coverage, with the knowledge and expectation that the patients are likely to continue to utilize its items or services. Importantly, the Proposed Arrangement will not be advertised; rather, patients presenting for services will more likely be influenced by extreme illness that drives them to the Hospital's Emergency Department or Outpatient Renal Clinic, or by local dialysis facilities that steer them to the Hospital. While we recognize that the free dialysis treatments could give some patients a generalized feeling of goodwill toward the Hospital, which could potentially influence them to choose the Hospital for non-dialysis services in the future, we believe any such influence would be speculative and attenuated by circumstances beyond the Hospital's control (e.g., whether the patient would ever require services offered by the Hospital). Accordingly, we conclude that it is not probable that the Proposed Arrangement would influence beneficiaries to select the Hospital.

Having determined that the Proposed Arrangement is unlikely to influence patients to select the Hospital as their provider of items or services payable by Medicare or Medicaid, we do not reach the third issue under the CMP (i.e., whether the Requestor knows or should know that the Proposed Arrangement would be likely to influence beneficiaries' selection of the Hospital for future services). For the reasons noted above, we would not impose sanctions on Requestor under the CMP.

2. The Anti-kickback Statute

For the reasons set forth above, and for the reasons discussed below, we also conclude that the Proposed Arrangement poses a minimal risk of Federal health care program or patient fraud or abuse, and would therefore not impose administrative sanctions on Requestor arising in connection with the anti-kickback statute.

First, under the Proposed Arrangement, the Hospital would absorb all costs associated with providing dialysis services to Chronic Dialysis Patients. No Federal health care programs would be billed for these services.

Second, the Proposed Arrangement is expressly designed to discourage Chronic Dialysis Patients from self-referring back to the Hospital for dialysis, by providing the assistance of the Hospital's Renal Case Manager/Social Worker to help place them in local outpatient dialysis chairs as soon as possible.

Third, the Proposed Arrangement is designed to treat efficiently Chronic Dialysis Patients so that the inpatient beds that they currently occupy can be made available to other patients who require inpatient care, and for whom the Hospital likely can bill for services. Thus, the Hospital has a legitimate business purpose for participating in the Proposed Arrangement unrelated to the provision of services to the Chronic Dialysis Patients, namely freeing up inpatient beds so that they can accommodate paying and other patients who the Hospital currently must turn away when its Emergency Department reaches capacity.

Finally, the provision of free dialysis treatments to the Chronic Dialysis Patients is consistent with the Hospital's statutory duty to provide health care to the residents of [county redacted], and its mission to serve underserved populations (e.g., the uninsured and those suffering from behavioral or psychiatric issues that cause other providers to turn them away). We note that the Proposed Arrangement would help bridge a coverage gap, and in so doing would provide a substantial benefit to a vulnerable patient group.

For the foregoing reasons, we conclude that the Proposed Arrangement poses a minimal risk of Federal health care program or patient fraud or abuse, and would therefore not impose sanctions on Requestor in connection with the anti-kickback statute.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under Section 1128A(a)(5) and the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on [name redacted] for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Act or for violations of the anti-kickback statute 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.

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 in any matter involving an entity or individual that is not a requestor of this opinion.
- 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.
- 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 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 [name redacted] 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/

Lewis Morris
Chief Counsel to the Inspector General