



[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.]

Issued: March 19, 2003

Posted: March 26, 2003

[names and addresses redacted]

Re: OIG Advisory Opinion No. 03-7

Dear [names redacted]:

We are writing in response to your request for an advisory opinion regarding a proposed arrangement pursuant to which a renal dialysis facility will provide acute hemodialysis services to a hospital district's inpatients, provide outpatient chronic hemodialysis services to some of the hospital district's indigent patients, and purchase certain hemodialysis equipment from the hospital district (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (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.

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 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 [Entity A] or [Entity B] 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, absent any undisclosed aggravating factors (including, but not limited to, overutilization or inappropriate higher costs to the federal health care programs). 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 letter or supplemental submissions.

This opinion may not be relied on by any persons other than [Entity A] and [Entity B], the requestors of this opinion (the “Requestors”), and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

1. FACTUAL BACKGROUND

[Entity A] (the “Hospital District”) and [Entity B] (the “Contractor”) propose to enter into a written agreement regarding the provision of hemodialysis services and the purchase of the Hospital District’s hemodialysis machines.

A. The Parties

The Hospital District, a political subdivision of the State of [state redacted], owns and operates a large health system in [county redacted] (the “County”), including three hospitals. The Hospital District’s hospitals provide services to most of the indigent patients within the Hospital District’s service area. Prior to 1995, the Hospital District offered at its facilities both acute hemodialysis services (*i.e.*, immediate or emergency dialysis services furnished on a temporary inpatient basis due to a rapid deterioration in kidney function) and chronic hemodialysis services (*i.e.*, a regular course of dialysis administered on a routine basis – usually several times per week on an outpatient basis).¹ In 1995, the Hospital District’s governing body instructed the Hospital District to cease providing chronic hemodialysis services, in part because of funding problems resulting from an increase in the number of indigent patients and the severe shortage of hemodialysis nurses. However, the Hospital District continued to provide chronic hemodialysis services to established patients who were unable to obtain chronic services elsewhere and who met the Hospital District’s indigence requirements (the

¹Hemodialysis services are only provided at two of the Hospital District’s three hospitals, and any hemodialysis services provided in connection with the Proposed Arrangement will be limited to those two hospitals.

“Grandfathered Patients”). Currently, the Hospital District provides chronic hemodialysis services to approximately nineteen Grandfathered Patients. Moreover, the Hospital District continues to provide acute hemodialysis services to all patients needing such services.

The Contractor is a Medicare-certified end stage renal dialysis (“ESRD”) provider that has several ESRD facilities. The Contractor has entered into contractual arrangements or agreements with other community Medicare-certified ESRD facilities (the “Community ESRD Facilities”) that have agreed to assist the local community by providing some chronic hemodialysis services to indigent patients. Although a few of the Community ESRD Facilities are direct or indirect affiliates of the Contractor, most are independent, unrelated facilities.

B. The Proposed Arrangement

In light of the financial and staffing difficulties in providing even acute hemodialysis, the Hospital District issued a request for proposals (the “RFP”) seeking to: (i) subcontract the delivery of acute hemodialysis services in its hospitals; (ii) arrange for the provision of chronic hemodialysis services within the Hospital District’s service area at no cost to the Hospital District; and (iii) sell the Hospital District’s ten hemodialysis machines at fair market value. The Hospital District received several responses to its RFP, including the Contractor’s response. The Hospital District awarded the contract to the Contractor, and the Proposed Arrangement sets forth the terms and conditions of that contract.²

Under the Proposed Arrangement, the Hospital District and the Contractor will enter into a one-year written agreement pursuant to which:³

- the Contractor will provide acute hemodialysis services at the Hospital District’s hospitals, and the Hospital District will pay the Contractor [amount redacted] per treatment. The Requestors have certified that the foregoing fee represents fair market value in an arms’-length transaction. The Hospital District will have the exclusive right to bill patients and their third-party payors for acute hemodialysis services provided by the Contractor under the Proposed Arrangement;

²The Hospital District has certified that it employed an open competitive bidding process consistent with the relevant government contracting laws and that it selected among bids based on price and other features contained in the bids.

³The one-year term of the agreement is renewable in separate one-year increments for up to a maximum of three years.

- the Contractor will purchase the Hospital District's ten hemodialysis machines. The Requestors have certified that the purchase price represents fair market value in an arms'-length transaction;
- the Contractor will provide chronic hemodialysis services to any Grandfathered Patient without regard to the Grandfathered Patients' ability to pay. The Contractor will either provide services for such patients at its own facilities or arrange for services to be provided by the Community ESRD Facilities. Neither the Contractor nor the Community ESRD Facilities will bill the Hospital District or the Grandfathered Patients for chronic hemodialysis services provided to Grandfathered Patients; and
- the Contractor will accept all referrals from the Hospital District of other patients needing chronic hemodialysis services.⁴ The Contractor will either provide services for such patients at its own facilities or arrange for services to be provided by the Community ESRD Facilities. While it must provide, or arrange for the provision of, services initially, neither the Contractor nor the Community ESRD Facilities are required to provide continuing chronic services to any patients, other than the Grandfathered Patients. Moreover, the Hospital District is not required to refer any patients to the Contractor or the Community ESRD Facilities.

The Hospital District will cease providing chronic hemodialysis services to the Grandfathered Patients upon implementation of the Proposed Arrangement.

Under Medicare, ESRD services are usually covered as outpatient services, but may under certain circumstances be covered as inpatient services. Medicare reimbursement for facilities furnishing outpatient ESRD services to Medicare beneficiaries is based upon a prospective payment system that establishes a composite rate of payment per dialysis session. There are two base composite rates: one for Medicare-certified, hospital-based ESRD facilities and a separate, lower one for independent, Medicare-certified facilities. Items and services related to the treatment of ESRD are covered under the composite rate, unless specifically excluded. The Contractor has certified that under the Proposed Arrangement utilization of items and services that are not included in the composite rate will be comparable to utilization of such items and services by its existing patients with similar medical circumstances.

⁴Notwithstanding, each patient needing chronic hemodialysis services, including each Grandfathered Patient, is free to use a provider other than the Contractor.

II. LEGAL ANALYSIS

A. Law

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.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Proposed Arrangement. The personal services and management contracts safe harbor requires, in part, that the aggregate compensation paid over the term of the agreement must be set in advance and must not take into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any federal health care program.

B. Analysis

The Requestors have certified that, under the Proposed Arrangement, the amounts that the Contractor will both receive for providing acute hemodialysis services and pay for the hemodialysis machines represent fair market value in arms'-length transactions.⁵ The transaction will be memorialized in a written agreement with a one-year term. However, the aggregate compensation for the acute hemodialysis services will not be fixed in advance and will fluctuate based on the volume of services provided. Fluctuating fee arrangements cannot qualify for protection under the personal services and management contracts safe harbor. Depending on the circumstances, such arrangements may increase the risk of abuse. However, given the nature of acute hemodialysis (i.e., acute emergency or inpatient dialysis) and the Requestors' fair-market-value certifications, we believe the risk of overutilization or increased costs to the federal programs in these circumstances is minimal.

Given this, our primary concern with the Proposed Arrangement is the Contractor's agreement to provide free chronic hemodialysis services to the Hospital District's Grandfathered Patients and other indigent patients. In other words, the Proposed Arrangement implicates the anti-kickback statute because the Hospital District could be referring federal health care program business to the Contractor in exchange for services to the indigent -- that is, services the Hospital District might otherwise have to fund.

With respect to the possible tying of referrals of indigent business to referrals of paying business (i.e., the acute hemodialysis business, as well as the potential referral of insured chronic business), we have repeatedly expressed our concerns with arrangements involving the provision of free or discounted goods or services by a vendor in exchange for the opportunity to provide services reimbursable by federal health care programs. Notwithstanding, a number of factors under the Proposed Arrangement mitigate the risk of fraud or abuse or otherwise merit consideration.

First, in the circumstances presented, the Proposed Arrangement appears unlikely to increase costs to federal health care program costs appreciably.⁶ The criteria for

⁵We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). For purposes of this advisory opinion, we rely on the Requestors' certifications of fair market value. If the fees paid are not fair market value, this opinion is without force and effect.

⁶We express no opinion regarding the appropriate billing of any particular claims or the liability of any party under the False Claims Act or any other legal authorities for improper billing, claims submission, cost reporting, or related conduct.

qualifying for chronic hemodialysis are well established and generally sufficient to deter unnecessary services. Medicare reimbursement for chronic dialysis is set prospectively and includes all items and services, except for certain specifically excluded items and services. Accordingly, federal payment will be approximately the same amount per dialysis service, regardless of the Proposed Arrangement. Thus, there is little risk of additional costs to the Medicare program. We are concerned that utilization of other separately reimbursable items or services (*i.e.*, items and services not included in the dialysis composite rate) are potentially subject to abuse. However, the Contractor has certified that utilization of other, non-composite rate items and services will be comparable to utilization of such items and services by its existing patients with similar medical circumstances.

Second, it is unclear whether, under these circumstances, the Hospital District will receive the putative remuneration, since it has no obligation to provide chronic hemodialysis services to the indigent or others. However, to the extent it did receive remuneration (*i.e.*, the Hospital District's avoided costs for the indigent and uninsured patients), such remuneration inures to the public, not private, benefit. One of the core evils addressed by kickback or bribery statutes, whether involving public or private business, is the abuse of a position of trust, such as the ability to award contracts or business on behalf of a principal for personal financial gain. Here, the public receives the financial benefit of the arrangement.

Third, the Proposed Arrangement will not have an adverse impact on competition. The Hospital District employed an open competitive bidding process consistent with the relevant government contracting laws. The Proposed Arrangement is limited to a one-year period. Public policy favors open and legitimate price competition.⁷

Fourth, the Hospital District's ability to influence referrals of insured patients for chronic hemodialysis is unclear, since insurance typically gives patients the ability to choose from many different providers. Insured patients will usually choose the providers recommended by their physicians. Conversely, the Hospital District's ability to influence referrals is likely to be greatest for indigent patients, since such patients have little choice.

Fifth, some free chronic hemodialysis services will be provided by Community ESRD Facilities that are not otherwise involved in the Proposed Arrangement. Thus, the free services to be provided to Grandfathered Patients and other indigent patients could be characterized as an effort by the local community of ESRD facilities to share

⁷The Hospital District has certified that it selected among bids based on price and other features contained in the bid.

responsibility for indigent care.

In light of these factors and absent any undisclosed aggravating factors (including, but not limited to, overutilization or inappropriate higher costs to the federal health care programs), the possible tying of referrals of indigent business to paying business in the Proposed Arrangement poses a minimal risk of federal health care program fraud or abuse.

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 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 [Entity A] or [Entity B] 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, absent any undisclosed aggravating factors (including, but not limited to, overutilization or inappropriate higher costs to the federal health care programs). 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 letter or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Entity A] and [Entity B], the requestors 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 the Requestors 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 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. 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