[*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: July 30, 2002

Posted: August 7, 2002

[name and address redacted]

Re: OIG Advisory Opinion No. 02-10

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding your proposal to offer discounts to customers based on their purchases of dialysis equipment and supplies, some of which may be reimbursed under different Medicare Part B methodologies (the "Proposed Discounts"). Specifically, you have inquired whether the Proposed Discounts 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 Proposed Discount A (as defined below) 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 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 Proposed Discount A.

However, with regard to Proposed Discount B (as defined below), we conclude that the OIG could potentially impose administrative sanctions on [name redacted] related to the commission of acts described in section 1128B(b) of the Act. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

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.

1. FACTUAL BACKGROUND

A. Proposed Discounts

[Name redacted] manufactures and distributes dialysis equipment and supplies. Through one of its subsidiaries, [name redacted] (the "Requestor"), the company sells its equipment and supplies to providers and suppliers of dialysis services throughout the country. The equipment and supplies include equipment and supplies for both hemodialysis and peritoneal dialysis. The hemodialysis equipment and supplies are used primarily in dialysis facilities and other institutional settings, while the peritoneal dialysis equipment and supplies are used almost exclusively by self-dialyzers in the home or at work. Some supplies are used in both hemodialysis and peritoneal dialysis.

Under the Proposed Discounts, the Requestor would offer the following discount arrangements to purchasers of dialysis equipment and supplies:

- A uniform discount based on the aggregate annual purchases by the purchaser of any and all dialysis equipment and supplies sold by the

Requestor ("Proposed Discount A").

- A discount based on total annual purchases of certain designated or all items if the purchaser buys a minimum quantity of one or more certain items ("Proposed Discount B").

Regarding the Proposed Discounts, the Requestor has certified that it will fully and accurately report any such awarded discounts on the invoice, coupon, or statement submitted to the buyer; inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discounts and to provide information about the discounts to payors upon request; and refrain from doing anything that would impede the buyer from meeting these obligations. In addition, where the value of the particular Proposed Discount is not known at the time of sale, the Requestor has certified that it will fully and accurately report the existence of a discount program on the invoice, coupon, or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discounts and to provide information about the discounts to payors upon request; when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and refrain from doing anything which would impede the buyer from meeting its obligations.

Further, the Requestor has certified that the Proposed Discounts are not dependent upon and do not operate in conjunction with (either explicitly or implicitly) any other arrangement or agreement between or among the Requestor, Requestor's parent or other corporate affiliates, Requestor's customers, or any other party with respect to the items subject to the Proposed Discounts.[1]

B. Applicable Medicare Reimbursement

Medicare Part B reimburses outpatient maintenance dialysis under three methodologies – one is for dialysis in a facility (mainly hemodialysis) and the other two are for dialysis at home (mainly peritoneal dialysis). While different, all three methodologies are

[1]The Proposed Discounts comprise the complete and entire arrangement that is the subject of this advisory opinion. The Proposed Discounts may become illegal when considered in the context of other related conduct or arrangements. In such circumstances, this advisory opinion is without force and effect.

capped at approximately the same amount. As explained below, the in-facility method and one of the at-home methods are composite rate payments that are equivalent in most circumstances. The other at-home method is based on reasonable costs or reasonable charges (depending on whether the patient's back-up facility is hospital-based or independent), but also caps the payment at a level that reflects Medicare's payments under the composite rate system.

More specifically, the three reimbursement methodologies are as follows. For dialysis in a facility, Part B pays a composite rate for each treatment that a patient undergoes in the facility. See 42 C.F.R. § 413.170. In-facility hemodialysis patients generally dialyze three times per week. The composite rate payment includes, among other things, payment for the equipment and supplies used in furnishing the treatments. The rate varies, in part, according to the facility's wage index.

End-stage renal disease ("ESRD") patients who dialyze at home (e.g., peritoneal dialysis) must elect annually the methodology under which Medicare Part B pays for their dialysis services. If a patient elects Method I (also known as the "composite rate"), Medicare pays the patient's dialysis facility once a month based on the same composite rate paid for in-facility treatment. See 42 C.F.R. § 414.330, referencing 42 C.F.R. § 413.170. The facility is responsible for providing the beneficiary with all home dialysis equipment and supplies.

If the beneficiary chooses Method II (also known as "direct dealing"), he or she is responsible for making his or her own arrangements directly with a supplier of home dialysis equipment and supplies. The supplier must have a written agreement with a Medicare-approved dialysis facility to provide all necessary support, backup, and emergency dialysis services (collectively, "support services"). Id. Under Method II, Medicare makes separate payments to the supplier for home dialysis equipment and supplies and to the dialysis facility for the support services.[2] The payment to the supplier is capped at an amount designed to approximate the national average monthly payment for such supplies and services provided by hospital-based facilities. Id. Payment to the dialysis facility for support services is also capped so that monthly payments do not exceed the national average payment for home dialysis support

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

services, including laboratory tests included in the composite rate.[3]

Although there are three different payment methodologies (the in-facility composite rate, Method I, and Method II), they are designed to generate substantially the same payment. Under the first two payment methodologies, payment is made to a single entity, while under the third payment methodology (Method II), payment is made to two separate entities. Even so, the total Method II payment could be less than the composite rate and, in any event, is capped in such a way that it should not exceed the composite rate paid under the first two payment methods.[4]

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

---

[3]If the dialysis facility is hospital-based, the Method II monthly payment to the dialysis facility for support services is made on a reasonable cost basis; if the dialysis facility is instead an independent facility, the payment is made on the basis of reasonable charges related to reasonable costs and allowances.

[4]Method II seeks to "provide equal payment for equal services since payment for these services would also be derived from the Method I composite rate." See Medicare Program; Payment Change for Home Dialysis, 57 Fed. Reg. 54179, 54183 (November 17, 1992) (final rule). A relatively rare exception exists in the case of continuous cycling peritoneal dialysis ("CCPD"), used by fewer than three percent of ESRD patients.

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.

Initially created by statute, the safe harbor for discounts is potentially applicable to the Proposed Discounts. This safe harbor protects "a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." Section 1128B(b)(3)(A) of the Act. This discount exception reflects Congress' intent to encourage price competition that benefits the Federal health care programs. The requirements of the safe harbor are further enumerated at 42 C.F.R. § 1001.952(h).

The discount safe harbor regulation contains different requirements for sellers, purchasers, and offerors of discounted items and services, as well as distinctions among providers reimbursed under charge-based, cost-based, or composite rate systems. The Requestor would have to comply with the requirements for sellers. See 42 C.F.R. § 1001.952(h)(2).

In 1999, we clarified that a "discount" for purposes of the discount safe harbor does not include:

> Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same

> methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology. [Emphasis added.]

See 42 C.F.R. § 1001.952(h)(5)(ii); Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63530 (Nov. 19, 1999) (final rule). Accordingly, the discount safe harbor does not apply in circumstances in which the goods or services that are subject to the discount are reimbursed under different methodologies.

B. Analysis

As stated above, the Requestor proposes to offer the following arrangements to purchasers of dialysis equipment and supplies:

- A uniform discount based on the aggregate annual purchases by the purchaser of any and all dialysis equipment and supplies sold by the Requestor ("Proposed Discount A").

- A discount based on total annual purchases of certain designated or all items if the purchaser buys a minimum quantity of one or more certain items ("Proposed Discount B").

The Proposed Discounts are remuneration to encourage the Requestor's customers to purchase goods for which payment may be made in whole or in part under a Federal health care program. Thus, the Proposed Discounts implicate the anti-kickback statute.

By its terms, the discount safe harbor does not protect bundled goods discounts where the bundled goods are reimbursed under different payment methodologies. Such discounts may permit parties to shift costs among reimbursement systems, distort the true costs of items, or lead parties to order more goods than necessary when the cost can be passed onto the Federal health care programs. Since Medicare reimburses some of the Requestor's customers or their subsidiaries for dialysis equipment and supplies under two or even three of the above-described methodologies, discounted sales to those customers would not qualify for the discount safe harbor.

However, while the payment methodologies applicable to the discounted equipment and supplies in this case differ, they result in almost identical payments for such equipment and supplies. Under two of the three methods (in-facility composite rate and Method I), Part B pays the same composite rate on a per treatment basis. Although Method II uses two different payment methodologies (reasonable cost and reasonable charges related to costs), the Method II reimbursement caps substantially equalize the reimbursement for all three methodologies. In addition, in spite of the Proposed Discounts' ineligibility for the discount safe harbor, the Requestor has certified that it would meet all of the discount safe harbor's requirements for sellers.

In light of these two safeguards, we do not think that Proposed Discount A, as applied in these facts and circumstances, presents a substantial risk of program abuse. Accordingly, we would not impose administrative sanctions on the Requestor in relation to Proposed Discount A.

However, Proposed Discount B raises an additional concern. Rather than a discount applied equally to all products on the basis of sales price, Proposed Discount B requires the purchaser to buy a minimum quantity of one or more of certain items (hereafter, "Product X"). The identity of Product X is variable and, thus, we do not know the payment methodology for Product X. We also do not know whether the discounts would be "tiered" so that greater levels of Product X purchases would lead to greater percentage discounts. Accordingly, we cannot determine whether dialysis goods would be supplied at a reduced charge in order to induce the purchase of Product X nor can we determine whether the Federal health care programs would share appropriately in the discounts. See 64 Fed. Reg. at 63530. Bundled discounts are problematic because they may potentially shift costs among reimbursement systems, distort the true costs of items, lead to overutilization, and make it difficult for Federal health care programs to determine proper reimbursement levels. Id., citing 56 Fed. Reg. at 35987.

Given the potential for abuse inherent in supplying goods at a reduced charge in order to induce the purchase of other goods under the Federal health care programs, we cannot be confident that Proposed Discount B poses no more than a minimal risk of fraud or abuse.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental

submissions, we conclude that Proposed Discount A 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 [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 Proposed Discount A.

However, with regard to Proposed Discount B, we conclude that the OIG could potentially impose administrative sanctions on [name redacted] related to the commission of acts described in section 1128B(b) of the Act. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

Furthermore, we wish to make clear that the specific arrangement approved in this advisory opinion (Proposed Discount A) may become illegal when considered in the context of other related conduct or arrangements. Moreover, this advisory opinion is without force and effect if any discount provided under Proposed Discount A is dependent on or operates in conjunction with (either explicitly or implicitly) any other arrangement or agreement between or among the Requestor, Requestor's parent or other corporate affiliates, Requestor's customers, or any other party with respect to the items subject to Proposed Discount A.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], which is 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

Discounts, 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 Proposed Discount A 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 Proposed Discount A 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\

D. McCarty Thornton
Chief Counsel to the Inspector General