DEPARTMENT OF HEALTH & 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: May 14, 2002

Posted: May 22, 2002

[name and address redacted]

Re: OIG Advisory Opinion No. 02-6

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding your proposal to offer a refund program to hospital customers who purchase your blood-filtering device for treatment of rheumatoid arthritis (the "Refund Program"). Specifically, you have inquired whether the Refund Program 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 Refund Program 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 the Refund Program.

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] (the "Requestor") has developed and sells to health care providers a Protein A column for the filtering of blood in the treatment of rheumatoid arthritis (the "Column"). In a process similar to kidney dialysis, a rheumatoid arthritis patient's blood is filtered through the Column, which removes anti-platelet antibodies from the patient's plasma. A course of treatment typically consists of twelve blood-filtering sessions (one Column per session), given at weekly intervals.

The Centers for Medicare and Medicaid Services ("CMS") (formerly the Health Care Financing Administration) issued a National Coverage Decision ("NCD") that extracorporeal immunoadsorption using Protein A columns is a reasonable and necessary treatment for rheumatoid arthritis that is covered if the following two criteria are met:

- the patient has severe rheumatoid arthritis; and
- the disease has failed to respond to an adequate course of a minimum of three disease-modifying drugs.

See Medicare Coverage Policy – National Coverage Decisions, CAG-00057N (HCFA April 27, 2000).

The Requestor has represented that some hospitals have been reluctant to purchase Columns because of the high cost of the Columns for a course of treatment and uncertainty regarding coverage, notwithstanding the NCD. In such circumstances, the Requestor proposes to refund the full purchase price of any Column to a purchasing hospital if a fiscal intermediary denies payment for treatments with the Column, subject to the following limitations and restrictions:

- The treatments must meet the coverage criteria of the NCD;
- The payment denial must be sustained through the first level of appeal;[1]
- Medicare must be the primary insurer of the patient for whom payment is denied;
- The patient for whom payment is denied must be a registered outpatient of the hospital;
- The hospital must have maintained and submitted all documentation to Medicare necessary to establish the Medicare conditions of coverage;
- In the event that the Requestor provides a refund under the Refund Program, the hospital must agree to: (1) report the refund to the appropriate government payor (e.g., the Medicare contractor) and any secondary insurer; (2) return any collected deductibles and copayments to the patient and/or adjust the statement submitted to the government payor or any secondary insurer to reflect the return of any collected cost-sharing amounts; (3) upon request, provide the Requestor with proof of such reports, refunds, or adjustments; and (4) upon request, provide all information related to the Refund Program to Federal and state health care officials.

The Requestor will report the existence of the Refund Program on invoices to each hospital. For each hospital, the refund offer would be for a limited time and would expire on the earlier of (i) the one-hundred and twentieth (120^{th}) day after the first delivery to the hospital of purchased Columns, or (ii) the hospital's first receipt of notice of a denial by the fiscal intermediary for a patient qualified for the treatment under the NCD. In other words, the Refund Program would be limited to the period of the Column's initial introduction in each hospital.

Virtually all of the hospitals that are potential purchasers of the Columns participate in Medicare. Therefore, it is expected that at least some of the Columns sold to hospitals will be used to provide services reimbursed by Medicare.

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[1]In connection with the first level of appeal at which the denial is upheld, the hospital must have submitted all relevant portions of the patient's medical records necessary to demonstrate that the patient met Medicare standards for coverage of treatments with the Column.

II. LEGAL ANALYSIS

B. 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 warranties, 42 C.F.R. § 1001.952(g), is potentially applicable to the Refund Program.

B. Analysis

Extracorporeal adsorption using Protein A columns is a Medicare-covered service for treatment of rheumatoid arthritis, and the hospitals that purchase the Columns are expected to use them to provide treatment to some Medicare patients. Therefore, the

Refund Program is an offer of remuneration to induce the hospitals to purchase items indirectly reimbursable by a Federal health care program. Accordingly, the Refund Program implicates the anti-kickback statute.

The Refund Program would not be protected under the warranty safe harbor to the anti-kickback statute. See 42 C.F.R. § 1001.952(g). For purposes of the safe harbor, the warranty must be related to product failure.[2] By contrast, the Refund Program does not relate to product failure, but to the purchaser's resale of the product. Thus, the Refund Program does not meet the definition of warranty and cannot fit in the safe harbor.

Nevertheless, the Refund Program contains a number of safeguards that reduce the risk of fraud and abuse. First, the reimbursement guarantee for each hospital is limited in time with reference to the initial delivery of purchased Columns or the initial payment denial. Second, the guarantee is limited in scope to treatments that meet the conditions of coverage in the NCD. Given the constraints on coverage in the NCD, this limitation should reduce the risk of improper utilization. Third, the guarantee is also limited to Medicare claims denied through the first level of appeal. Fourth, the guarantee is limited to a refund of the purchase price of the Columns. The Requestor will not reimburse the purchasers for any patient care expenses (i.e., medical, surgical, or hospital expenses) or for any other costs that the hospital may have incurred related to the therapy. Fifth, the Requestor will report the existence of the Refund Program on invoices to each hospital and, as a condition of participation in the Refund Program, will require each hospital to uphold its regulatory obligations related to the Refund Program, including (1) reporting the refund to the appropriate government payor and secondary insurer, (2) returning any collected deductibles and copayments to the patient, and/or adjusting the statement submitted to the government payor or any secondary insurer to reflect the return of any collected cost-sharing amounts, and (3) providing all information related to the Refund Program to Federal and state health care officials upon request.

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[2]The safe harbor incorporates the definition of warranty in 15 U.S.C. § 2301(6), namely:

> any undertaking in writing in connection with the sale by a supplier of a consumer product to refund, repair, replace, or take other remedial action with respect to such product in the event that such product fails to meet the specifications set forth in the undertaking, which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a supplier and a buyer for purposes other than resale of such product.

See 15 U.S.C. § 2301(6)(b).

These safeguards and the limited nature of the Refund Program serve to reduce the risk of fraud or abuse related to the anti-kickback statute. In particular, the Refund Program presents a low risk of fraud and abuse because it is not open-ended and is restricted to a time limit that is tied to the initial introduction and product launch of the Column within each hospital.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Refund Program 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 the Refund Program.

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 Refund Program, 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 Refund Program 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 Refund Program 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,

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D. McCarty Thornton
Chief Counsel to the Inspector General