[September 25, 1997]

[name redacted]

Re: [name redacted]
Advisory Opinion No. 97-4

Dear [name redacted]:

We are writing in response to your request for an advisory opinion, in which you ask whether declining to pursue collection of copayments from certain patients who have employer-sponsored Medicare complementary coverage constitutes grounds for imposition of sanctions under Section 231(h) of the Health Insurance Portability and Accountability Act ("HIPAA") [42 U.S.C. § 1320a-7a(a)(5)] or under Sections 1128B(b) (the anti-kickback statute) or 1128A(7) (relating to payment of kickbacks) of the Social Security Act [42 U.S.C. §§ 1320a-7b(b) and 1320a-7(b)(7)].

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.

In issuing this opinion, we have relied solely on the facts and information you presented to us. We have not undertaken any 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 conclude that the proposed arrangement may constitute grounds for the imposition of civil monetary penalties under Section 231(h) of HIPAA. We further conclude that the proposed arrangement may constitute grounds for the imposition of criminal penalties under 1128B(b) and for exclusion under 1128(b)(7) (as it relates to kickbacks) of the Social Security Act. This opinion may not be relied on by any person other than the addressee and is further qualified as set out in Part III below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Company A (the "Requestor") is a Michigan limited liability company doing business as Center B. Center B is a Medicare-certified ambulatory surgical center ("ASC") licensed by the State of Michigan Department of Community Health and accredited by the Accreditation Association for Ambulatory Health Care. Center B limits the scope of its

services to the provision of endoscopy services. Center B believes that it provides endoscopy services to patients in a manner that is more convenient, cost-effective, and of higher quality than the provision of comparable services in a hospital inpatient or outpatient setting.

Medicare payment for ASC services consists of a facility fee and a professional fee. The facility fee is a prospectively determined rate; the professional fee is based on the Medicare physician fee schedule. Both fees are subject to Medicare Part B coinsurance and deductible amounts (collectively, the "Medicare Copayment").

Certain current and prospective Center B patients are retirees who have Medicare complementary coverage furnished by their former employer to cover the cost of the Medicare Copayment. The employer contracts with Company X to administer the complementary coverage. In administering the complementary coverage, Company X pays the Medicare Copayment attributable to the professional fee to the physician who performs the endoscopy services, but declines to pay the Medicare Copayment attributable to the facility fee to Center B. Company X denies payment of the facility fee copayment on the ground that Center B is not an ambulatory surgical facility participating with Company X.[1] Center B has represented that this policy adversely affects Medicare beneficiaries and the Medicare program, because beneficiaries are denied the choice of receiving health care services at Center B. Center B asserts that receiving services at its facility is more convenient and less costly than receiving comparable services in a hospital setting.

The Proposed Arrangement that is the subject of Center B's request for an advisory opinion is as follows. Center B would pursue payment of the facility fee Medicare Copayment exclusively from Company X, including any appeal rights within Company X. Center B has provided a copy of a proposed form of appeal letter that would be sent in response to each denied claim. However, if Company X were to continue to deny payment, Center B would not pursue payment from the covered beneficiaries. Center B is concerned that this Proposed Arrangement may constitute a prohibited waiver of the Medicare Copayment in violation of Section 231(h) of HIPAA and the anti-kickback statute.

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[1] Center B contends that Company X's denial of the facility fee copayment is contrary to Medicare payment principles. In support of this view, it has submitted an Order from the Wayne County (Michigan) Circuit Court in the matter of Greater Lansing Ambulatory Surgery Center Company et al. v. Blue Cross and Blue Shield of Michigan, No. 96-635927-CZ (March 1, 1997).

II. LEGAL ANALYSIS

The Proposed Arrangement May Constitute a Violation of Section 231(h) of HIPAA.

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" as including, inter alia, the waiver of coinsurance and deductible amounts (or any part thereof). Waivers of coinsurance and deductible amounts are excepted from the definition of remuneration if:

(i) the waiver is not offered as part of any advertisement or solicitation;

(ii) the person making the waiver does not routinely waive coinsurance or deductible amounts; and

(iii) the person making the waiver

(I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or

(II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts.

See 42 U.S.C. § 1320a-7a(i)(6), as amended by section 4331 of the Balanced Budget Act of 1997, P.L. 105-33.[2] Subsections (i), (ii), and at least one prong of subsection (iii) must be satisfied for the exception to apply.

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[2] The statute, as amended, contains three further exceptions, not applicable here, for: (i) certain permissible waivers specified in section 1128B(b)(3) of the Social Security Act or in regulations issued by the Secretary; (ii) certain differentials in coinsurance and deductible amounts as part of a benefit plan design; and (iii) certain incentives given to individuals to promote the delivery of preventive care.

Based on our review of the Proposed Arrangement as represented in the request letter, we first conclude that the Proposed Arrangement may fall within the general proscription against inducements to Federal health care program beneficiaries set forth in section 231(h) of HIPAA. Prohibited "remuneration" for purposes of section 231(h) specifically includes a waiver of coinsurance and deductible amounts that a provider knows or should know is likely to influence a beneficiary's choice of a particular provider. Medicare beneficiaries are obligated to pay Medicare Copayments; therefore any waiver of that obligation constitutes remuneration to the beneficiary. According to the request letter, Center B's proposal to refrain from pursuing collection of the Medicare Copayment from beneficiaries is intended, at least in part, to encourage covered beneficiaries to obtain services at Center B's facility. The Proposed Arrangement would therefore potentially be subject to sanction under section 231(h).

We further conclude that the Proposed Arrangement does not meet the criteria for the exception under section 231(h), because it does not satisfy either prong of subsection (iii) of the exception. The Proposed Arrangement does not satisfy the first prong, because it does not provide for individualized determinations of financial hardship. The only remaining issue is whether the Proposed Arrangement satisfies the second prong by constituting "reasonable collection efforts."

Reasonable collection efforts are those efforts that a reasonable provider would undertake to collect amounts owed for items and services provided to patients. These efforts should include a bona fide attempt to bill and collect from the patient if the patient's insurer refuses to pay.[3] When an insurer has taken a consistent position with the provider that a category of claims are not covered, the provider's continued submission of such claims, including subsequent appeals, is not a bona fide collection effort. In such circumstances, the provider must make reasonable efforts to collect the Medicare Copayment from the patient.

In the absence of reasonable collection efforts or individualized determinations of financial need, the Proposed Arrangement fails to meet either prong of subsection (iii) of § 1320a-7(i)(6). Thus, the Proposed Arrangement may constitute unlawful remuneration for the purpose of influencing beneficiaries to select Center B as their provider in contravention of section 231(h) of HIPAA.

The Proposed Arrangement May Constitute a Violation of the Anti-Kickback Statute.

The anti-kickback statute, 42 U.S.C. §1320a-7b(b), makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce the

[3] See, e.g., 42 C.F.R. § 413.80; Prov. Reimb. Man., Part I, §§308, 310.

referral of business that may be paid for by a Federal health care program. Specifically, the statute provides that

> Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony.

42 U.S.C. § 1320a-7b(b). In other words, the statute prohibits payments made purposefully to induce referrals of business paid for by a Federal health care program. The statute ascribes liability to both sides of an impermissible "kickback" transaction. 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). "Remuneration" for purposes of the anti-kickback statute includes the transfer of any thing of value, in cash or in-kind, directly or indirectly, covertly or overtly.

We have said previously that providers who routinely waive Medicare Copayments may be held liable under the anti-kickback statute. See Special Fraud Alert, 59 Fed. Reg. 242 (1994).[4] When providers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they unlawfully may be inducing the patient to purchase items or services in violation of the anti-kickback statute's proscription against offering or paying something of value as an inducement to generate business payable by a Federal health care program. Thus, except in those special cases of financial hardship, providers must make a good faith effort to collect Medicare Copayments. One indicator of a suspect waiver is the failure to collect Medicare Copayments for a specific group of Medicare patients for reasons unrelated to indigency.

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[4] Although the Special Fraud Alert addressed charge-based providers, we expressly stated that the Special Fraud Alert should not be interpreted to legitimize routine waiver of Medicare copayments with respect to providers paid under prospective payment or cost-based systems.

Here, the Proposed Arrangement is suspect because it would effectively waive the Medicare Copayment for the specific group of Medicare patients covered by the Company X complementary coverage, if Company X continues to deny payment. Moreover, an inference can be drawn that the Proposed Arrangement's waiver of the Medicare Copayment for reasons unrelated to individualized financial hardship may unlawfully induce patients to purchase services from Center B that are reimbursable by Medicare. For these reasons, the Proposed Arrangement may be subject to sanction under the anti-kickback statute, 42 U.S.C. § 1320a-7b(b).

III. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Company A, which is the Requestor of this opinion. This advisory opinion has no application, 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 to this opinion.

- This advisory opinion is applicable only to the statutory provisions 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 Arrangement.

- 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.

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 Requestor 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 Requestor 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,

D. McCarty Thornton
Chief Counsel to the Inspector General