

[We have redacted specific information regarding the requester and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise specified by the requester.]

Issued: October 25, 1999

Posted: November 1, 1999

[Name & Address Redacted]

Re: OIG Advisory Opinion No. 99-11

Dear [Name Redacted]:

We are writing in response to your request for an advisory opinion concerning an arrangement sponsored by Coalition A (the "Coalition") to provide psychotherapy services at free or reduced prices using residents from local teaching facilities as clinicians (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for sanctions under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), or under section 1128A(a)(5) of the Act, which prohibits the offering of inducements to beneficiaries in order to influence their selection of a provider for Medicare or Medicaid covered services.

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 information provided, we conclude (i) that the Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that, based on the totality of the facts present in the Arrangement as described and certified in your request letter and supplemental submissions, the Office of Inspector General ("OIG") will not subject the Coalition to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act; and (ii) that the OIG will not subject the Coalition to sanctions under section 1128A(a)(5) of the Act in connection with the Arrangement as described and certified in your request letter and supplemental submissions.

This opinion may not be relied on by any persons other than the Coalition, the requester 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

The Coalition is a State X nonprofit organization formed by Foundation B, a 501(c)(3) charitable organization that operates for the benefit and in support of the Coalition; Entity C; and Entity D. Pursuant to the Arrangement, the Coalition provides psychodynamically-oriented psychotherapy at free or reduced prices to individuals who meet financial and clinical criteria. The therapy is typically provided by advanced psychiatric residents from local teaching facilities.⁽¹⁾ The residents donate their time and services to the Coalition, as do members of the teaching faculties who provide clinical training and supervision.

The teaching facilities involved in the Arrangement are Hospital E, Hospital F, and Hospital G (collectively, the "Participating Institutions"). The Arrangement enables the Participating Institutions to provide training to their residents in psychodynamically-oriented psychotherapy (a less time-intensive and less costly form of talk therapy than psychoanalysis) which they are not currently providing. A total of 45 to 50 residents provide services under the Arrangement. Prior to the Arrangement, these residents had to arrange and pay for supervised training in this form of therapy outside their residency programs.

The Coalition handles all billing and collections; neither the clinicians, nor their supervisors, bill for services provided under the Arrangement. Although some services that the Coalition provides may be covered by insurance, including Medicare or Medicaid, the Coalition does not bill Medicare, Medicaid, or any other third party insurer. In addition, the Coalition notifies patients that they are ineligible for Coalition services if they seek third-party reimbursement.

The Coalition screens prospective patients based on financial and clinical criteria. Most of the Coalition's patients self-pay for the therapy sessions on a sliding fee schedule based on income and family size. However, the Coalition does not charge Medicare beneficiaries for any Medicare-covered services. The Coalition anticipates that no more than ten percent of its total patient population will be Medicare beneficiaries.

If a clinician determines that a patient is not suitable for long-term psychoanalytic treatment after a four to six session evaluation (e.g., the patient needs hospitalization or treatment for drug or alcohol addiction), the Coalition suggests that the patient obtain services from an alternative treatment resource. The Coalition provides the patient with a list of such resources, but does not take further steps to refer the patient (the Coalition does make a follow-up phone call to the patient to try to ensure that the patient contacts an alternative treatment provider). The top resource on the list is the community mental health clinic for the catchment area in which the patient resides. The list does not include any Participating Institutions, unless the patient was originally referred to the Coalition from a Participating Institution, in which case the list may include the Participating Institution.⁽²⁾

The Coalition anticipates making an average of two alternative treatment referrals each year, even if the patient enrollment in the Arrangement is at capacity.⁽³⁾ The alternative treatment services are provided outside the scope of the Arrangement, and providers of such services may bill third-party insurers, including Medicare and Medicaid.

Currently, there are no more than twenty patients enrolled on an on-going basis. The Coalition estimates that it will serve approximately forty to fifty patients each year.⁽⁴⁾ The Coalition publicizes the availability of the Arrangement (primarily through word-of-mouth) to prospective patients and to other programs that may be interested in the Arrangement, such as university counseling centers, research programs, and employee assistance programs. Services are provided to patients at the clinicians' own offices.

The Coalition's costs of administering the Arrangement are funded through a mix of patient fee payments, various grant sources, and funding from its supporting foundation. Even at full capacity, the Coalition projects an operating loss for the Arrangement of approximately \$[Y] per month.

II. LEGAL ANALYSIS

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by any Federal health care program. See section 1128B(b) of the Act. 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."

Id. Thus, where remuneration is paid purposefully to induce referrals of items or services for which payment may be made 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, in cash or in-kind, directly or indirectly, covertly or overtly.

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. The OIG may also initiate administrative proceedings to exclude persons from Federal and State health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.⁽⁵⁾

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 regulatory safe harbor potentially applicable to the Arrangement protects certain referral services, 42 C.F.R. § 1001.952(f). However, based on the facts presented, the Arrangement is not a referral service; rather, through the Arrangement, the Coalition provides clinical services for which it collects fees from patients.

The Arrangement raises concerns under the anti-kickback statute to the extent that the Participating Institutions may be providing free clinical services to the Coalition as a means of generating referrals of alternative treatment mental health business that they can bill to a Federal health care program. The OIG's position on the provision of free or below market value goods or services to potential referral sources is longstanding and clear: the provision of free goods or services to an actual or potential referral source may violate the anti-kickback statute, depending on the circumstances. For example, the preamble to the 1991 safe harbor regulations explains that giving free goods that have an independent value to a physician may violate the anti-kickback statute. See 56 Fed. Reg. 35978 (July 29, 1991); see also Special Fraud Alert, 59 Fed. Reg. 65372, 65377 (Dec. 19, 1994); OIG Advisory Opinion 98-16. This analysis generally applies to the provision of any free or below market value goods or services to actual or potential referral sources. If the requisite intent to induce or reward referrals of Federal health care program business is present, the anti-kickback statute is violated.

In addition, we generally have heightened concerns about abuses in the area of mental health services, where medical necessity determinations are often subjective and the risk of overutilization is substantial. See, e.g., Review of Partial Hospitalization Services Provided Through Community Mental Health Centers (A-04-98-02146; 10/98).

Notwithstanding, based on the totality of the facts presented, we conclude that the Arrangement poses a minimal risk of Federal health care program or patient fraud or abuse given the small number of patients enrolled at any given time, the limited number of anticipated alternative treatment source referrals, and the fact that no Federal health care programs are billed for services provided under the Arrangement. Moreover, the Participating Institutions have a legitimate business purpose for participating in the Arrangement, namely that the Arrangement affords them additional training opportunities for their advanced psychiatric residents. Finally, the Arrangement potentially offers a significant community benefit through increased access to mental health services for lower income community residents.

For these reasons, we would not impose sanctions on the Coalition for violations of the anti-kickback statute in connection with the Arrangement. In addition, we would not impose sanctions arising under section 1128A(a)(5) of the Act (the civil money penalty provision prohibiting inducements to beneficiaries to influence their selection of providers of Medicare or Medicaid covered services), because the Coalition does not provide any services for which it -- or anyone else -- bills Medicare or Medicaid.

III. CONCLUSION

Based on the information provided, we conclude (i) that the Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that,

based on the totality of the facts present in the Arrangement as described and certified in the request letter and supplemental submissions, the OIG will not subject the Coalition to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act; and (ii) that the OIG will not subject the Coalition to sanctions under section 1128A(a)(5) of the Act in connection with the Arrangement as described and certified in the request letter and supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to the Coalition, the requester 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 requester to this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above in the first paragraph of this opinion. 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 that 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 requester with respect to any action that is part of the 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 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, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the requester 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

FOOTNOTES:

1. Any qualified psychiatrist may participate in the Arrangement, although most clinicians are expected to be psychiatric residents.

2. The Coalition discloses to patients the Participating Institutions' affiliation with the Arrangement and makes the five disclosures to patients enumerated in 42 C.F.R. § 1001.952(f)(4). Although disclosures of this type are insufficient to guard against Federal health care program abuses, effective disclosures offer some protection against possible abuses of patient trust.
3. Any substantial increase in the number of referrals, particularly referrals to the Participating Institutions, could constitute a material change of fact and render this advisory opinion without force and effect.
4. If the Coalition perceives that the community's needs exceed its twenty-patient capacity, the Coalition may consider expanding the Arrangement. Any substantial increase in enrollment could constitute a material change of fact and render this advisory opinion without force and effect.
5. Because both the criminal and administrative sanctions related to the anti-kickback implications of the Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.