

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: June 17, 2004

Posted: June 24, 2004

[name and address redacted]

Re: OIG Advisory Opinion No. 04-07

Dear [name redacted]:

We are writing in response to your request for an advisory opinion about an arrangement between a health system and school-based clinics (the "Arrangement"). Specifically, you have inquired whether a health system's provision of professional consultative services to low-income schoolchildren in predominantly rural areas through a sponsored telemedicine network constitutes 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 Arrangement may 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 [requestor's 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 Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any other agreements or any other arrangements disclosed or referenced in your request letter or supplemental submissions.

This opinion may not be relied on by any persons other than [requestor's name redacted] and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. THE ARRANGEMENT

[requestor's name redacted] (the "Health System") is an integrated nonprofit health care delivery system that includes a tertiary care facility (the "Hospital), several general acute care hospitals, a number of nursing homes, a home care service, a behavioral health center, a cancer center, and a hospice program, as well as 40 family medical clinics. The Health System serves a three-state area covering 22 predominantly rural counties with approximately 650,000 residents.

In 1992, the Health System began a school-based health center program for low-income children that now operates at 18 locations in rural counties. The Health System has enhanced the school-based health center program by constructing a telemedicine network (the "Telemedicine Network")¹ to link school-based health centers (the "spokes") with various departments of the Health System, a family medicine residency training program, a behavioral health center, a community health department, and school-based health centers (the "hub sites"). Many of the children receiving services in the school-based health centers may be Medicaid or [state redacted] Children's Health Insurance Program ("CHIP") beneficiaries or eligible for such benefits.

Nurses located at the school-based health center "spoke" facilities see students on site, conduct basic screening tests, and consult with physicians or specialists at the "hub" sites regarding appropriate treatment and follow-up care. Health System staff assist with scheduling tele-consultations. If, as a result of the screening tests and any tele-consultations conducted at the school-based centers, a student requires a referral to a physician, the student is referred to his or her regular primary care provider. If the student has no regular primary care provider, the nurse provides a list of the primary care providers in the student's community.

The [state redacted] Medicaid/CHIP programs do not currently provide any reimbursement for telemedicine services. Neither the Health System, nor any of the consulting professionals, receives any reimbursement from any Federal health care program for teleconsultations or other services provided through the Telemedicine Network.

II. LAW AND ANALYSIS

¹The Telemedicine Network is not a separately incorporated legal entity. The participants of the Telemedicine Network or their affiliates may be engaged in, or contemplating, other joint business relationships. Those relationships are outside the scope of this advisory opinion.

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 <u>one</u> purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. <u>United States v. Kats</u>, 871 F.2d 105 (9th Cir. 1989); <u>United States v. Greber</u>, 760 F.2d 68 (3d Cir.), <u>cert. denied</u>, 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.

B. Analysis

By developing, operating, administering, and funding the Telemedicine Network, the Health System confers benefits on three potential referral sources: (i) the school-based health center "spoke" facilities that obtain free telecommunications equipment and subsidized line charges necessary for operation; (ii) the consulting practitioners at the "hub" sites, who might receive additional opportunities to earn professional fees; and (iii) the patients. In short, there is remuneration.

For purposes of this advisory opinion, the core issue is whether the remuneration is likely to generate Federal health care program business for the Health System or any of its affiliated providers or practitioners. Since the tele-consultations are not reimbursable by the state Medicaid or CHIP or any other relevant Federal health care program, the only possible Federal health care program business would be potential follow-up care. In effect, the Health System is providing the schools and students with a screening service. The Health System has certified that, if a student requires a referral to a physician, the student is referred to his or her regular primary care provider. If the student has no regular primary care provider, the school nurse provides the student or parent or guardian with a list of the primary care providers in the student's community. In similar circumstances, we have determined that the provision of non-reimbursable screening services that are not tied in any way to the provision of services that are reimbursable by a Federal health care program will not generally implicate the separate prohibition on inducements to Federal health care beneficiaries,

section 1128A(a)(5) of the Act. See 65 Fed. Reg. 24400 at 24408, 24410 (April 26, 2000).

In short, as structured, the Arrangement appears to contain safeguards sufficient to reduce the risk that the remuneration would generate appreciable referrals of Federal health care program business. Moreover, the Arrangement promotes the obvious public benefit in facilitating better access to screening services for low-income children in rural areas. In light of the totality of facts and circumstances presented, we conclude that we would not subject the Health System to administrative sanctions 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 Arrangement.²

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the 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 [requestor's 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 Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any other agreements or any other 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 [requestor's name redacted], 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 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.

²We note that for the same reasons we would not impose sanctions under section 1128A(a)(5) of the Act.

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 [requestor's name redacted] 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 [requestor's 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/

Lewis Morris Chief Counsel to the Inspector General