DEPARTMENT OF HEALTH AND 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: October 26, 2006

Posted: November 2, 2006

[Name and address redacted]

Re: OIG Advisory Opinion No. 06-18

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding your Outreach Volunteer Services Program – a volunteer services program for the provision of specialty medical care and professional development in rural areas, through which you cover volunteers' travel costs (the "Program"). Specifically, you have inquired whether the Program 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 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") will 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 Program. This opinion is limited to the Program and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

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

[Name redacted] (the "Requestor") is a limited liability company owned by [name redacted] d/b/a [name redacted] ("Parent Company A"), a nonprofit corporation, and certain affiliates of [name redacted]. The Requestor is the largest health care provider in the [location redacted] area, operating six acute care hospitals, one specialty rehabilitation hospital, and numerous outpatient clinics. Through the Program, the Requestor facilitates the delivery of volunteer specialty medical and community services and professional development in rural communities by covering travel costs for volunteers. Specifically, under the Program, a network of volunteer physicians and other health care professionals who regularly practice in the [location redacted] area travel to rural communities to provide: (i) specialty medical care to local residents; (ii) health screening and other health-related community service activities; and (iii) educational activities and collaboration with local health care professionals, such as lectures, "shadowing" a local practitioner, providing hands-on demonstrations, or engaging in substantive discussions of clinical issues or specific patient cases.

The Requestor states that the Program is needed to address the following problems specific to the rural areas served under the Program: (i) shortages of health care professionals, especially specialists; (ii) the barriers to care presented by distance and transportation issues; (iii) the likelihood that rural residents will delay or forego care due to items (i) and (ii); (iv) rural area practitioners' lack of access to educational materials and services and opportunities for professional collaboration; and (v) vulnerable patient populations, such as migrant workers, low-income and uninsured individuals, and the elderly. The Program currently serves more than [number redacted] rural communities in [number redacted] states and utilizes the volunteer services of more than [number redacted] health care professionals.

The Program is administered by the Requestor's employees. The Requestor receives requests from rural providers and communities that have identified a need for specialty medical care

or professional development and collaboration.[1] The Requestor conducts a needs assessment, reviewing information from various assessment forms and interviews of providers and patients in the requesting community, to determine whether the community qualifies for assistance under the Program. A community must satisfy at least one of five criteria that the Requestor has identified to ensure that credible, objective evidence supports the need for the requested services. These criteria relate to shortages of health care professionals, the unavailability of specialty care in the area, and the need for professional development services.[2] Once the Requestor determines that the community is eligible, it determines the scope of services to be provided to the community.[3] Local health care entities or other providers in the recipient communities are responsible for providing adequate space and equipment for the volunteers to deliver the Program services.

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[1]The Program is not advertised. Most of the participating communities and providers have been participating in the Program for several years. An outreach program offering volunteer services has been in operation in one form or another in the area for at least 25 years. Prior to the Requestor's formation in 1995, Parent Company A operated a similar outreach program for many years. New participants may hear about the Program through word-of-mouth; through an independent, nonprofit, state-affiliated rural health organization; or when the coordinator of the Program travels to rural communities that have been identified as having a potential need for Program services.

[2]Specifically, the criteria are: (i) objective data supports the need to recruit physicians in a particular specialty to the requesting community, and the distance to currently available specialty care of that type is at least 60 miles; (ii) the requesting community has no providers practicing within a particular specialty or subspecialty and the nearest available specialty care of that type is at least 60 miles away; (iii) the requesting community qualifies as a health professional shortage area as determined by the United States Department of Health and Human Services or holds a similar designation issued by a state entity; (iv) published health policy data or medical literature supports the need for professional development services or specialty care in the requesting community, or in communities substantially similar to the requesting community, to prevent adverse health outcomes due to lack of access to educational resources or medical care; and (v) the requesting community demonstrates that it is experiencing a shortage of a particular type of health care professional, such that the absence of these professionals from the community for purposes of attending off-site educational programs would adversely affect the level of care available to local residents.

[3]Communities selected for participation in the Program must be able to demonstrate the need for services on an ongoing basis. The Requestor conducts annual surveys to determine whether the scope of the services provided under the Program remains appropriate.

The Requestor matches volunteers for the recipient communities according to the identified community needs and volunteer qualifications. Volunteers are required to spend at least 20% of their time during a volunteer trip, not including travel time, on Program activities (the "20% requirement"). The volunteer trips are scheduled as day trips not requiring overnight stays. Volunteers may receive either a no-cost flight arranged by the Requestor or mileage reimbursement up to [amount redacted], the Requestor's approximation of the value of the Requestor-arranged flights.[4] Volunteers are not paid by the Program, although they may bill for services rendered to patients with insurance coverage, including Medicare. Time spent on billable services for insured patients does not count toward the 20% requirement. Volunteers must provide patient care services to any individual presenting for care without regard to the patient's ability to pay for such services. The Program does not provide free or discounted care to Federal health care program beneficiaries, however. Such patients are entitled to receive care only under the same terms and conditions with respect to payment for services that would apply if they sought care in the Requestor's metropolitan area.

To be eligible for travel assistance, a volunteer must enter into a written agreement with the Requestor, document all time spent on Program activities, submit such documentation within a specified period upon return, comply with all Program policies, and, if requesting mileage reimbursement, supply documentation of the mileage. If a volunteer does not satisfy the 20% requirement or does not submit the required time log, the volunteer will not be eligible to receive travel assistance and will be required, if applicable, to reimburse the Requestor for the flight.

To prevent a volunteer from inappropriately benefitting from the travel assistance, volunteer health care professionals must not have an office or practice in the community to which they will travel. To ensure the quality of the outreach services, volunteers must be credentialed as active members of the medical or allied health professional staff at one of the Requestor's facilities.[5] In addition, volunteers must not have been subject to disciplinary action by any regulatory agency or hospital.

The Requestor has certified that the processes for identification of community needs and volunteer matching are based solely on a particular community's needs and volunteer qualifications and do not include any consideration of the potential for referrals or other

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[4]The Requestor has certified that, to the extent the assumption of travel expenses represents a value to the volunteer, such value represents the fair market value for the Program services performed.

[5]In limited circumstances, when there is a community need that cannot be met by an employee or active staff member, the Program will accept the volunteer services of a licensed, qualified health care professional who does not meet this requirement.

business generated for the volunteers or the Requestor's facilities. Volunteers are not required or encouraged to refer patients to the Requestor's facilities and are free to refer patients to local providers or suppliers where available. The Requestor notes that the provision of services under the Program may, in fact, reduce the need for more expensive tertiary care of preventible conditions. The Requestor has certified that Program personnel do not track or review referrals to any of the Requestor's facilities on the basis of admissions from rural communities served, admissions from volunteers, or on any other basis related to Program activities.

With regard to the Program's professional development services, the Requestor has certified that it does not influence or control the content of the services; the scope, nature, and content of the educational services are dictated by the needs of the recipient rural community. The Requestor acts as a coordinator in selecting volunteers who are qualified to provide the requested educational services, and does not actually provide the services or control the volunteers' provision of the services. When providing Program services, the volunteer acts as an independent health care professional, not as a representative of the Requestor or the Requestor's views. Furthermore, the Requestor has certified that most of the professional education provided is not comparable to the type of continuing medical education that is available for commercial purchase, but rather is informal and collaborative in nature.

The Requestor states that it is only able to accommodate about 30 percent of the requests for Program services it receives each year due to the limited number of health care professionals willing to volunteer to provide services under the Program. The Requestor states that it is difficult to recruit volunteers for the Program because of the substantial commitment of time and resources required for the volunteers to travel to the remote locations and the loss of income associated with spending time away from their usual practices. The Requestor further states that, without the travel assistance, it anticipates that it would be even more difficult to find volunteers to fulfill the needs of the communities served under the Program.

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 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.

B. Analysis

By paying volunteer travel costs and bringing specialty care and professional education and collaboration to rural communities under the Program, the Requestor arguably confers benefits on two potential referral sources: (i) the volunteer health care professionals; and (ii) the health care professionals and patients in the recipient communities. In short, there is remuneration that implicates the anti-kickback statute. For purposes of this advisory opinion, the core issue is whether the remuneration is likely to be an improper payment to generate Federal health care program business for the Requestor.

For the reasons set forth below, we conclude that the facts and circumstances of the Program, in combination, adequately reduce the risk that the remuneration under the Program could be an improper payment for referrals or the generation of Federal health care program business.

First, with regard to the volunteer health care professionals, the Program's structure ensures that the volunteers will not unduly profit from the trip. Volunteers do not receive payment from the Requestor for Program-related activities. They must see any patient who requests care, regardless of ability to pay. While volunteers may bill for services provided to insured patients, including Federal health care program beneficiaries, the time spent on billed services does not count toward the requirement to spend at least 20% of the time in the remote location on Program activities. Thus a volunteer is almost certain to generate less income on a Program trip than when practicing at his or her own medical office.

In these circumstances, the provision of travel assistance has little or no value to the volunteers, aside from facilitating the volunteers' own community service, which they are under no obligation to undertake. It is worth noting that, despite the travel assistance, the Requestor has certified that it has been able to recruit volunteers to accommodate less than a third of the requests for services it receives each year.

Second, the Program's structure makes it unlikely that the volunteers will generate appreciable referrals as a result of the Program. Participation in the Program is initiated by rural communities, rather than the Requestor. Community need is assessed, and volunteers are selected, without regard to the potential for referrals or other business generated for the volunteers or the Requestor's facilities. Volunteers are not required or encouraged to refer patients to the Requestor's facilities and are free to refer patients to local providers or suppliers where available. Program personnel neither track nor review referrals to any of the Requestor's facilities on the basis of admissions from rural communities served, admissions from volunteers, or on any other basis related to Program activities. Program services are documented, and the Program is audited annually to ensure compliance with laws, regulations, and Program policies.

Third, with regard to the health care professionals in the recipient communities, while they may benefit from the opportunity to enhance their professional skills, in the circumstances presented, the primary beneficiaries of any education or collaboration are the patients and residents of the recipient rural community. Furthermore, as noted, most of the training provided is not comparable to the type of continuing medical education that the health care professionals would otherwise pay for. For example, when the volunteer discusses individual patient cases with a local practitioner to assist that practitioner in understanding and treating the patient's condition, the volunteer is providing a service that is more akin to mentoring than to continuing medical education that may be counted toward any state licensing requirements. Furthermore, the scope, nature, and content of the professional development services are dictated by the needs of the recipient rural community and not by the Requestor. Volunteers providing Program-related educational services do not act as representatives of the Requestor or the Requestor's views, but as independent health care professionals. While the Requestor selects volunteers who are qualified to provide the requested services, the Requestor simply acts as a coordinator or liaison in this role, and does not actually provide the services or control the volunteers' provision of the services.[6]

Fourth, the Program contains no indicia of remuneration to the Federal health care program beneficiaries who use Program services. Under the Program, these beneficiaries do not receive free or discounted care. They receive Program services only under the same terms and conditions with respect to payment that would apply if they sought care in the

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[6]The educational services provided in the particular circumstances presented here differ substantially from those provided in other contexts that pose greater risk of fraud or abuse, such as continuing medical education services sponsored or funded by pharmaceutical manufacturers. See, e.g., OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) available at http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf.

Requestor's metropolitan area. Thus, apart from the convenience of locally available services, beneficiaries are offered no particular incentive to use the services of the volunteers or the Requestor's facilities. Program volunteers are free to refer locally for additional care, and, according to the Requestor, the Program may, in fact, reduce the need for patients in rural communities to seek additional care.

Finally, the Program offers significant community benefits. The Program is primarily designed to benefit residents of rural areas where there is a documented lack of necessary specialty care or consultation or where the local health care professionals have limited opportunities for the continuing education necessary to provide high quality, up-to-date services to their patients. The areas served by the Program are characterized by inadequate access to medical specialists – both for patient care and for the professional collaboration that can enhance the quality and efficacy of patient care – and vulnerable patient populations, for whom any access barriers are harder to overcome. Recipient communities must have documented needs for Program services on an ongoing basis. The Program design is targeted to help rural communities and their residents who are faced with significant barriers to obtaining necessary care and the most up-to-date information for providing quality health care services.

In short, as structured, the Program appears to contain sufficient safeguards to reduce the risk that the Program would result in improper payments for referrals of Federal health care program business for the Requestor and its volunteers. Moreover, the Program promotes the obvious public benefit in facilitating better access to specialty care and professional development in rural areas. In light of the totality of facts and circumstances presented, we conclude that we would not subject the Requestor 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.[7]

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the 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 will 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 Program. This opinion is limited to the

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

Program and, therefore, we express no opinion about any ancillary agreements or 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 [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 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 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 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General