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: September 2, 2004

Posted: September 9, 2004

[name and address redacted]

Re: OIG Advisory Opinion No. 04-11

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposed arrangement to subsidize malpractice insurance expenses for four community-based obstetricians (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement 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 Proposed 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 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

Proposed Arrangement. This opinion is limited to the Proposed Arrangement 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 "Medical Center"), a tax-exempt organization under section 501(c)(3) of the Internal Revenue Code, operates a hospital and integrated health care delivery system in a largely rural section of [state name redacted] (the "State"). The U.S. Department of Health and Human Services (the "Department") has designated the county in which the Medical Center is located as a health professional shortage area ("HPSA") with respect to its low income, migrant farm worker, and homeless populations.

The Medical Center includes a 142-bed hospital that provides services without regard to a patient's ability to pay. The hospital is designated as a Level III Trauma Center, a Level II Pediatric Trauma Care Service, and a Level II Adult Trauma Rehabilitation Service. In addition to traditional hospital care, the Medical Center also operates a transitional care unit, an urgent care and occupational medicine center, and a family birth center. The Medical Center also provides various community outreach programs.

Labor and delivery services at the Medical Center are currently provided by four community-based obstetricians who hold staff privileges at the Medical Center, but are not employees or contractors of the Medical Center (the "Obstetricians"); several family medicine physicians and a nurse midwife who are employed by the Medical Center; and several emergency medicine physicians who are under contract with the Medical Center. The Obstetricians routinely assist the physicians and midwives at the Medical Center with particularly high-risk or complicated cases; at least one of the four Obstetricians is available at all times to provide back-up obstetrical services. In addition, the Obstetricians provide back-up obstetrical services for nurse midwives who furnish labor and delivery services at a local migrant health clinic unaffiliated with the Medical Center. The Obstetricians are routinely engaged in the full-time practice of obstetrics in the county served by the Medical Center.

From 2002 to 2003, the Obstetricians' malpractice insurance premiums increased by more than $36,000 per physician. The Medical Center asserts that the increased premium expenses derive in part from the special nature of services the Obstetricians render to the Medical Center and the community, in particular their back-up services in high-risk and

complicated deliveries.[1] The Medical Center anticipates that the Obstetricians' malpractice expenses will continue to rise, which could cause the Obstetricians to cease providing obstetrical care in the community. In that event, the Medical Center estimates that the community will experience a thirty percent decrease in access to obstetrical care.

To preserve access to obstetrical care, the Medical Center proposes a malpractice insurance subsidy program. Under the Proposed Arrangement, the Medical Center would partially subsidize the Obstetricians' malpractice insurance expenses for two years.[2] The subsidy would be calculated as fifty percent of the increase in premium expenses for the current year from the premiums paid in 2002, with the subsidy capped at $25,000 per Obstetrician per year. The Medical Center expects the actual subsidy to be well below the cap; in the first year of the Proposed Arrangement, the subsidy would approximate $18,000 per Obstetrician. The Medical Center has certified that the subsidy will not vary based on the volume or value of any previous or expected referrals to, or business otherwise generated for, the Medical Center.

The Medical Center and each subsidized Obstetrician will enter into a written agreement that sets forth the terms and conditions of the subsidy. The Medical Center has certified that the subsidized malpractice insurance will be a *bona fide* malpractice insurance policy with a premium calculated based on a *bona fide* assessment of the liability risk covered under the insurance. The malpractice insurance will cover services provided by the Obstetricians at sites other than the Medical Center, including facilities that are not affiliated with the Medical Center, such as the migrant health clinic. The Medical Center will pay the subsidy amount directly to the insurer.

Under the Proposed Arrangement, each Obstetrician would be obligated to: (i) abide by the rules and regulations, and remain a member in good standing, of the Medical Center's medical staff; (ii) provide back-up obstetrical services for the Medical Center and the migrant health clinic; (iii) notify the Medical Center of any changes in scope of practice or other changes that would materially affect the obstetrical services provided by the Obstetrician; and (iv) notify the Medical Center of any reductions in malpractice insurance premiums so that the subsidy could be reduced or eliminated as appropriate. The Obstetricians will not be required to make referrals to, or otherwise generate

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[1]The Medical Center additionally attributes the increased premiums to broader insurance market trends in the State.

[2]This advisory opinion is limited to the Proposed Arrangement and has no application to any payments outside the Proposed Arrangement or to any potential use of malpractice insurance subsidies in connection with recruitment or retention of health care professionals other than the four Obstetricians.

business for, the Medical Center, and will be permitted to establish staff privileges at, refer patients to, and otherwise generate business for, any other entities of their choosing.

The Medical Center expects that, in each year of the Proposed Arrangement, at least ninety-five percent of the obstetrical patients treated by the Obstetricians will reside in a HPSA or medically underserved area ("MUA") or be part of a medically underserved population ("MUP"). Prior to making the first subsidy payment, the Medical Center will obtain a certification from each subsidized Obstetrician that he or she reasonably expects that at least seventy-five percent of his or her obstetrical patients will belong to these populations. The Obstetricians will make patient demographic information available to the Medical Center to the extent necessary for the exclusive purpose of verifying the accuracy of these certifications. The Medical Center has certified that the Obstetricians currently treat, and will continue to treat, Federal health care program beneficiaries in a nondiscriminatory manner.

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.

The Department 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. Arrangements that do not fit squarely in a safe harbor are evaluated on a case-by-case basis.

The safe harbor for obstetrical malpractice insurance subsidies, 42 C.F.R. § 1001.952(o), is potentially applicable to the Proposed Arrangement.[3] The safe harbor protects payments that are: (i) made by a hospital or other entity to a hospital or other entity that is providing malpractice insurance; and (ii) used to pay all or part of the costs of malpractice insurance premiums for practitioners engaging in obstetrical practice in a primary care HPSA, if the following seven standards are satisfied:

- The payment is made in accordance with a written agreement between the entity paying the premiums and the practitioner, which sets out the payments to be made by the entity, and the terms under which the payments are to be provided.

- The practitioner must certify that: (i) for the initial coverage period (not to exceed one year) the practitioner has a reasonable basis for believing that at least seventy-five percent of the practitioner's obstetrical patients treated under the coverage of the malpractice insurance will either reside in a HPSA or MUA or be part of a MUP; and (ii) thereafter, for each additional coverage period (not to exceed one year), at least seventy-five percent of the practitioner's obstetrical patients treated under the prior coverage period (not to exceed one year) must have resided in a HPSA or MUA or been part of a MUP.

- There is no requirement that the practitioner make referrals to, or otherwise generate business for, the entity as a condition for receiving the benefits.

- The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

- The amount of payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare, Medicaid, or any other Federal health care programs.

- The practitioner must treat obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

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[3]Depending on the circumstances, some premium support arrangements may fit into other safe harbors, such as the employee safe harbor at 42 C.F.R. § 1001.952(i).

- The insurance is a *bona fide* malpractice insurance policy or program, and the premium, if any, is calculated based on a *bona fide* assessment of the liability risk covered under the insurance. For practitioners who practice obstetrics full-time, costs of malpractice insurance premiums means any costs attributable to malpractice insurance.[4]

42 C.F.R. 1001.952(o)(1)-(7).

The safe harbor requires that the subsidized practitioners routinely practice obstetrics in a "primary care" HPSA. Pursuant to regulations contained in 42 C.F.R. Pt. 5, the Department designates areas as various types of HPSAs based on shortages of particular types of health care professionals or based on shortages of health care services available to particular populations residing in the area. For primary care HPSAs, the HPSA designation is based on a shortage of primary medical care professionals. For homeless, migrant agricultural worker, and low income HPSAs, each HPSA designation is based on the shortage of health care services available to the local homeless, migrant agricultural worker, or low income population, respectively. Defined geographic boundaries demarcate the territories included in areas designated as primary care HPSAs, homeless population HPSAs, migrant agricultural worker HPSAs, and low income HPSAs.

B. Analysis

The OIG historically has been concerned that a hospital's subsidy of malpractice insurance premiums for potential referral sources, including hospital medical staff, may implicate the anti-kickback statute, because the payments may be used to influence referrals. There is a particular concern where subsidies are offered in a conditional or selective manner that reflects current or anticipated referrals from the subsidized practitioners. At the same time, the OIG has recognized the importance of ensuring access to obstetrical care in underserved areas and for underserved populations by establishing the safe harbor for obstetrical malpractice premium subsidies.

The Proposed Arrangement meets all but one of the conditions of the safe harbor for obstetrical malpractice subsidies. Specifically, the subsidized Obstetricians do not practice in a "primary care" HPSA; rather, they practice in a community with three other HPSA designations based on health care shortages for: (i) low income populations; (ii) migrant agricultural workers; and (iii) homeless individuals. Accordingly, because

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[4]For practitioners who practice obstetrics on a part-time or sporadic basis, the costs of malpractice insurance premiums means the costs attributable exclusively to the obstetrical portion of the practitioner's malpractice insurance and related exclusively to obstetrical services provided in a primary care HPSA. 42 C.F.R. § 1001.952(o)(7)(ii).

safe harbor protection is only available when all conditions of a safe harbor are squarely met, the Proposed Arrangement cannot qualify for protection.

Failure to fit in a safe harbor is not fatal. Non-conforming arrangements must be evaluated on a case-by-case basis for compliance with the anti-kickback statute. In the context of this advisory opinion, we assess the potential risk of patient or program fraud or abuse that might arise from the Proposed Arrangement.

In the particular circumstances presented, where all other terms and conditions of the obstetrical malpractice insurance subsidy safe harbor will be met, we conclude that the fact that the subsidized Obstetricians will practice obstetrics in a low income, migrant agricultural worker, and homeless population HPSA, instead of a primary care HPSA, does not result in any increased risk of fraud or abuse. Our conclusion is consistent with the intent of the safe harbor to ensure access to needed obstetrical care – including expert care for high-risk and complicated deliveries – in places and for populations that do not have sufficient access to such care,[5] while at the same time protecting the Federal health care programs and beneficiaries from fraud and abuse. Accordingly, we would not subject the Proposed Arrangement to sanctions arising from the anti-kickback statute.

We note that any residual risk from the Proposed Arrangement is further mitigated by its structure, which combines all of the conditions of the obstetrical malpractice insurance subsidies safe harbor (except the primary care HPSA requirement) with several significant additional safeguards. First, the insurance subsidies will be provided in response to sharply escalating premiums on a temporary, interim basis for a fixed period. Second, the subsidies will not create a windfall for the Obstetricians, as the program is structured to cover only part of the Obstetricians' increased insurance expenses and each subsidized Obstetrician will pay at least as much for malpractice insurance as he or she paid prior to participating in the subsidy program. Third, the subsidized insurance will cover the Obstetricians regardless of the site where they perform services, even if the services are performed at facilities unaffiliated with the Medical Center. In addition, we note that the potential community benefits of the Proposed Arrangement are substantial, as the Obstetricians will largely treat underserved obstetrical patients in a rural area, including patients of a clinic for migrant farm workers unaffiliated with the Medical Center.

[5]By contrast, the result might be different if the subsidy were provided to an obstetrical practitioner furnishing services in an unrelated type of HPSA, for example, a HPSA for mental health or dental services.

III. CONCLUSION

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