



*[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:** December 27, 2007

**Posted:** January 3, 2008

[Name and address redacted]

**Re: OIG Advisory Opinion No. 07-20**

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal to establish an imaging center in the same building as your medical practice in a hurricane-devastated area (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, the Federal anti-kickback statute.

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 while 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, the Office of

Inspector General (“OIG”) would not impose administrative sanctions on you 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 may not be relied on by any persons other than you, the requestor 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**

You have certified that you are a physician practicing in [name redacted] Parish, Louisiana (the “Parish”). The Parish is in the area hardest hit by Hurricane Katrina in August 2005. Shortly before Hurricane Katrina struck, you had opened [type redacted] clinic in the Parish. That clinic was completely destroyed in the aftermath of the hurricane. You have since opened [name redacted] (the “Medical Practice”), also in the Parish. You are the sole physician employee of the Medical Practice, which you co-own with your wife. You have certified that most of your patients reside in the Parish.

In July 2005, the U.S. Census Bureau officially estimated the population of the Parish to exceed [number redacted]. The Census Bureau’s July 2006 estimate for the Parish, however, was less than one-quarter of the 2005 number. While the Census Bureau has not issued an updated population estimate since that for 2006, a recent private study indicates that the population of the Parish remains well below 50 percent of its pre-Katrina level, and that the Parish’s population recovery rate lags behind that of other nearby jurisdictions affected by hurricane damage in 2005.<sup>1</sup>

The sole hospital in the Parish was destroyed by Hurricane Katrina and has not reopened. You have certified that there were approximately [number redacted] physicians practicing in the Parish prior to Hurricane Katrina and that you are one of fewer than [one-sixth the previous number] physicians now practicing there.

You have certified that, at the present time, there are no medical imaging services available in the Parish. Patients who need such imaging services are required to travel outside the Parish. As a result of hurricane damage, however, the healthcare infrastructure of the entire region has been significantly reduced, making it also more difficult to obtain services in the immediate area outside the Parish.

You propose to establish a medical imaging center (the “Imaging Center”) in the same building as your Medical Practice. You have certified that you and your brother will each

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<sup>1</sup> [Citation redacted.]

contribute 50 percent of the capital necessary to fund the Imaging Center and will each own 50 percent of it.

Your brother will be employed as business manager of the Imaging Center. You have certified that he will be a bona fide employee and will be paid a salary that will be fair market value for actual and necessary services rendered and will not take into account the volume or value of business generated for the Imaging Center. Your brother has not previously been employed or invested in the health care industry.

You have certified that: (1) both you and your brother will be active investors in the Imaging Center; (2) the terms on which an investment interest is offered to you and your brother will not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from either of you to the Imaging Center; (3) the Imaging Center will be located in a Medically Underserved Area, as designated in accordance with regulations issued by the Department, and at least 75 percent of the dollar volume of the Imaging Center's business will be derived from the service of persons who reside in a Medically Underserved Area or are members of a Medically Underserved Population, in accordance with regulations issued by the Department; (4) neither the Imaging Center nor any investor (or other individual or entity acting on behalf of the Imaging Center or any investor in the Imaging Center) will loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the Imaging Center if the investor uses any part of such loan to obtain the investment interest; and (5) the amount of payments to each investor in return for the investment interest will be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

You state that the Imaging Center will be available to provide services to patients other than those of the Medical Practice. You estimate that initially about 35 percent of the patients receiving services from the Imaging Center will be referred by you,<sup>2</sup> and 65 percent will come from outside referrals. As more physicians return to or establish new medical practices in the Parish, you expect that the percentage of patients referred by other physicians will increase.

The building in which the Medical Practice is located and the Imaging Center is proposed to be located is owned by [name redacted], which you co-own with your wife. You have

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<sup>2</sup> You have certified that the Proposed Arrangement will comply with the requirements of the Physician Self-Referral Law, Section 1877 of the Act, 42 U.S.C. § 1395nn and with the billing requirements of the Center for Medicare and Medicaid Services. We express no opinion with regard to these issues.

certified that the Imaging Center will lease space from [name redacted] in compliance with each of the conditions of the space rental safe harbor to the anti-kickback statute, 42 C.F.R. § 1001.952(b).

## 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 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 safe harbor for investment in small entities in underserved areas, 42 C.F.R. § 1001.952(a)(3), is potentially applicable to the Proposed Arrangement. This safe harbor applies to an investment entity located in an underserved area, if all of the following eight standards are met: (1) No more than 50 percent of the value of the investment interests of

each class of investments may be held in the previous fiscal year or previous 12-month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity; (2) the terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors; (3) the terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity; (4) there is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor; (5) the entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross-referrals agreement) to passive investors differently than to non-investors); (6) at least 75 percent of the dollar volume of the entity's business in the previous fiscal year or previous 12-month period must be derived from the service of persons who reside in an underserved area or are members of medically underserved populations; (7) the entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for a investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest; and (8) the amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

## **B. Analysis**

The Proposed Arrangement does not qualify for protection by the safe harbor for investment in small entities in underserved areas, because it does not meet the first condition of the safe harbor, that no more than 50 percent of investment interests in an entity may be held by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity. In the Proposed Arrangement, 100 percent of the investment interests are to be held by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the Imaging Center. You, who will own 50 percent of the Imaging Center, are a physician who is in a position to refer patients. Your brother, who will also own 50 percent, will be employed as the Imaging Center's business manager, and thus provide services to it. In addition, your brother, through his family relationship with you, may be in a position to influence patient referrals.

The fact that the Proposed Arrangement does not fit in the safe harbor does not end the inquiry, and we must examine the totality of facts and circumstances to determine the extent of the risk posed by the Proposed Arrangement. In the singular circumstances presented here, the fact that 50% of the venture is owned by your brother who will be employed as the Imaging Center's business manager – rather than by a wholly disinterested investor -- does not materially increase the risk of fraud and abuse, particularly when viewed in light of the Proposed Arrangement's substantial potential community benefits.

Your brother is not currently in the health care business, will not be compensated as business manager in any manner that depends on his generating business for the Imaging Center, and will receive a fair market value salary for actual and necessary services rendered to the Imaging Center.<sup>3</sup> This latter fact reduces a usual risk that arises when an investor provides items or services to a venture, namely that the investor will charge the venture below market rates in order artificially to boost the profitability of the venture and the size of returns available to investors who are referral sources. In addition, your brother, like you, will put up real capital and receive returns that are proportional to his capital contributions. You have certified that the terms the investment will not be related to the previous or expected volume of referrals, items or services furnished, or amount of business otherwise generated by an investor for the Imaging Center.

We recognize that, as the relative of a physician, your brother may be in a position to influence referrals. He can do so, however, only through his relationship with you, who are also an investor in the Imaging Center. Because you already have substantial independent reasons to refer patients to the Imaging Center, on the facts presented your family relationship should not increase the capacity of the investors, as a whole, to influence referrals.<sup>4</sup>

Finally, any residual risk posed by the Proposed Arrangement is offset by the special conditions in which the Proposed Arrangement is to be implemented. As noted in the preamble to the safe harbor for investment in entities in underserved areas, “[p]aramount among OIG’s concerns is that beneficiaries have adequate access to quality health care.” 64 FR 63518, 63532 (Nov. 19, 1999).

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<sup>3</sup>We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). For purposes of this advisory opinion, we rely on your certifications of fair market value. If the compensation is not fair market value, this opinion is without force and effect.

<sup>4</sup>We are mindful that unscrupulous parties sometimes use family members as fronts to funnel money to referral sources. Here, however, we are persuaded, based on the totality of facts and circumstances – including your certification that your brother will invest his own capital in the venture -- that such subterfuge is unlikely.

The devastation to health care services in the area to be served by the proposed Imaging Center is well-known. Two years after Hurricane Katrina, the one hospital that had operated in the Parish has not reopened. You have certified that fewer than [number redacted] physicians now practice in the Parish, which previously was served by approximately [number redacted] practitioners. It is possible – even likely – that the limited availability of health care services discourages the return of some former residents and the rebuilding of the community as a whole.

For all of these reasons, we conclude that the risk of fraud and abuse posed by the Proposed Agreement is relatively low and offset by potential improvements in access to care in an area still recovering from catastrophic damage to its healthcare infrastructure.

### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while 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, the OIG would not impose administrative sanctions on you 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 you, [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 you 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 you 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