

*[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:** May 3, 2001

**Posted:** May 10, 2001

[name and address redacted]

**Re: OIG Advisory Opinion No. 01-4**

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposed arrangement between [name of hospital redacted] (the “Hospital”) and a new physician whom the Hospital would like to recruit to practice within its service area (the “Proposed Arrangement”). Specifically, the question raised by your request is 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. You have also certified that, upon our approval, you will undertake to effectuate the Proposed Arrangement.

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 would 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 the Hospital 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 the Hospital, 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

The Hospital is a tax-exempt organization under section 501(c)(3) of the Internal Revenue Code. It operates an acute care hospital in the city of [city redacted] (the “City”) which is located in rural eastern [state redacted]. A large percentage of the Hospital’s revenues is derived from Federal health care program business. The Hospital’s service area includes [county redacted] County (the “County”) and several other surrounding counties. The County is not designated as a health professional shortage area (“HPSA”), as defined in regulations issued by the Department of Health and Human Services (the “Department”), for any medical specialty. However, the Hospital has certified that the County and all other counties within the Hospital’s service area are currently designated as medically underserved areas (“MUAs”), as defined in regulations issued by the Department, and that, based upon a *bona fide* needs analysis that the Hospital conducted using objective criteria, there is a shortage of otolaryngologists and head and neck surgeons within its service area.<sup>1</sup>

The Hospital would like to recruit [name redacted] (the “Physician”), a recent medical school graduate who has agreed to relocate to the City upon completion of a five-year residency program for otolaryngology and head and neck surgery (collectively, the “Specialties”). The Physician’s residency program, which began on July 1, 2000, is at an

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<sup>1</sup>The Hospital has presented a copy of its needs analysis to the OIG. We express no opinion regarding whether the Internal Revenue Service (“IRS”) would deem the Hospital’s needs analysis to be “objective evidence of a demonstrable community need” for purposes of determining whether the Proposed Arrangement would jeopardize the Hospital’s tax-exempt status.

unaffiliated institution located more than 100 miles from the Hospital. The Hospital has certified that it expects that the shortage of otolaryngologists and head and neck surgeons within its service area will not be alleviated prior to the Physician's completion of his five-year residency program.<sup>2</sup>

Under the Proposed Arrangement, the Hospital would loan the Physician [amount redacted] dollars (\$[X]) annually during the five years of his residency training, for an aggregate principal amount of [amount redacted] dollars (\$[5X]). The Hospital has certified that the loan amount is equal to the aggregate monthly payments (i.e., \$[M] per month for 60 months) that the Physician is required to make on his medical school loans during his residency program, plus an additional \$[N] per year during each year of his residency program to be used for any other educational expenses. Interest on the loan would accrue from the date of each annual disbursement and would continue to accrue on the outstanding loan balance until paid or forgiven in the manner described below. The interest rate applicable to the loan would be the prime rate, as determined by a designated local bank, plus one percent (1%), with the rate being adjusted semi-annually.

The Physician's obligations under the Proposed Arrangement would begin upon completion of his residency training, but not later than August 1, 2005, and continue for three consecutive years. Those obligations include: (i) establishing and maintaining a full-time private practice of the Specialties within a three-mile radius of the City; (ii) acquiring and maintaining active professional staff privileges in the Specialties at the Hospital; (iii) accepting patients referred by the Hospital's emergency room while on-call, regardless of the patients' ability to pay; (iv) assisting the Hospital in its educational programs; (v) upon request, assisting the Hospital in fund-raising efforts in order to promote the charitable and educational purposes of the Hospital; (vi) providing reasonable assistance to the Hospital in its physician recruitment programs; and (vii) agreeing to treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner. In no event will the number of hours that the Physician spends fulfilling the obligations listed under subsections (iv), (v), and (vi) above exceed twenty hours per month.

The Physician would agree to repay the loan, together with accrued interest, in three equal annual payments, with the first installment becoming due on August 1, 2006.

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<sup>2</sup>The Hospital's certification is based upon several factors, including difficulties associated with recruiting physicians to the City and the announced plan of one of the otolaryngologists currently practicing at the Hospital to retire upon the Physician's arrival.

However, the Hospital would incrementally forgive the Physician's obligation to make installment payments by forgiving one-third of his payment obligations for each year that the Physician fulfills the obligations listed above. If the Physician were to default on any of his obligations, the outstanding balance (i.e., the principal and accrued interest minus all amounts forgiven in the manner described above, if any) would become immediately due and payable. For example, if the Physician were to cease his practice within the City after one year of his three-year commitment, he would repay the entire outstanding balance which would be approximately equal to two-thirds of the original principal together with the accrued interest.

The Hospital has certified as follows:

- The Proposed Arrangement would not be renegotiated in any substantial aspect during its term;
- The Proposed Arrangement would not be conditioned upon the Physician making referrals to, or being in a position to make or influence referrals to, or otherwise generating business for the Hospital;
- The Physician would not be restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his choosing;
- The amount or value of the remuneration provided under the Proposed Arrangement would not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to, or business otherwise generated for, the Hospital by the Physician for which payment may be made in whole or in part under any Federal health care program;
- At least seventy-five percent (75%) of the revenues of the Physician's new practice will be generated from patients residing in a HPSA or a MUA or who are part of a Medically Underserved Population ("MUP"), as defined in regulations issued by the Department; and
- The Proposed Arrangement would not directly or indirectly benefit any person (other than the Physician and his patients) or entity in a position to make or influence referrals to the Hospital of items or services payable by a Federal health care program.

## II. THE ANTI-KICKBACK STATUTE

### A. Law

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 Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services paid for 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. 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 arrangements that are not subject to the anti-kickback statute because such arrangements 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 OIG promulgated a new safe harbor for certain payments or benefits offered by hospitals and other entities to attract physicians and other practitioners to HPSAs. See 42 C.F.R. § 1001.952(n). The safe harbor is designed to facilitate recruitment of needed health care professionals to rural and urban underserved areas, without protecting "recruitment" payments that are really camouflaged kickbacks for referrals of Federal health care program business to recruiting hospitals and entities. The safe harbor protects newly-minted practitioners, as well as practitioners relocating to underserved geographic

areas and starting new practices. The safe harbor does not protect recruitment arrangements in areas that are not HPSAs.

To achieve safe harbor protection, a recruitment arrangement must satisfy nine express conditions enumerated in the safe harbor regulation. More specifically, the practitioner recruitment safe harbor protects any payment or exchange of anything of value by an entity in order to induce a practitioner who has been practicing within his or her current specialty for less than one year to locate, or to induce any other practitioner to relocate, his or her primary place of practice to a HPSA for his or her specialty area, as long as all of the following nine standards are met:

- the arrangement is set forth in a written agreement signed by the parties that specifies the benefits provided by the entity, the terms under which the benefits are to be provided, and the obligations of each party;
- if the practitioner is leaving an established practice, at least seventy-five percent (75%) of the revenues of the new practice must be generated from new patients not previously seen by the practitioner at his or her former practice;
- the benefits are provided by the entity for a period not in excess of three years, and the terms of the agreement are not renegotiated during that three-year period in any substantial aspect;
- there is no requirement that the practitioner make referrals to, be in a position to make or influence referrals to, or otherwise generate business for the entity as a condition for receiving the benefits; provided, however, that for purposes of this paragraph, the entity may require as a condition for receiving benefits that the practitioner maintain staff privileges at the entity;
- 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 or value of the benefits provided by the entity may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any 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 any Federal health care program;

- the practitioner agrees to treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner;
- at least seventy-five percent (75%) of the revenues of the new practice must be generated from patients residing in a HPSA or a MUA or who are part of a MUP; and
- the payment or exchange of anything of value may not directly or indirectly benefit any person (other than the practitioner being recruited) or entity in a position to make or influence referrals to the entity providing the recruitment payments or benefits of items or services payable by a Federal health care program.

See 42 C.F.R. § 1001.952(n). These conditions are designed to ensure that the payments are genuine recruitment payments, rather than retention payments or payments to lock up existing streams of referrals, and that the payments further the primary goal of the safe harbor: improving access to needed health care services for underserved patients.

## **B. General Observations About Practitioner Recruitment Arrangements**

It is not uncommon for a rural tax-exempt hospital to provide incentives to recruit a physician to join its medical staff and provide medical services to the surrounding community, but not necessarily for, or on behalf of, the hospital. Pursuant to the IRS's Revenue Ruling 97-21, such recruitment activities would not jeopardize the hospital's status as a tax-exempt organization, if there is objective evidence demonstrating a need for the physician's medical services within the hospital's service area and if certain other conditions are met. See Rev. Rul. 97-21, 1997-1 C.B. 121.

Notwithstanding, such arrangements may be unlawful under the anti-kickback statute. When a hospital provides remuneration to a physician in exchange for relocating or establishing his or her medical practice within the hospital's service area, an inference may be drawn that one purpose of the remuneration is to generate referrals for the hospital, including referrals of Federal health care program beneficiaries.

While practitioner recruitment is an area that is subject to abusive practices, the OIG recognizes that: (i) many rural and urban underserved communities have difficulty attracting medical professionals, and may need to offer additional financial incentives to acquire needed staff; and (ii) when payments are made to new or relocating physicians who do not have an established patient base in the new area, the risk of kickbacks is more

attenuated. However, even if an arrangement is crafted under the foregoing circumstances, it may not qualify for safe harbor protection.

Practitioner recruitment arrangements that implicate the anti-kickback statute, but do not qualify for the practitioner recruitment safe harbor, must be evaluated on a case-by-case basis. In evaluating the risks posed by a specific arrangement, the OIG looks to a number of factors, including, but not limited to, the following:

- **Whether there is documented evidence of an objective need for the practitioner's services.** Generally, recruitment activities based upon documented evidence of an objective need for the practitioner's services are less suspect than recruitment activities used to attract a practitioner to an area which has no practitioner shortages for his or her specialty. For purposes of our analysis, the fact that the area to which a practitioner is recruited is a HPSA for the practitioner's particular specialty will, in most cases, represent documented evidence of an objective need for the practitioner's services. We recognize, however, that even when an area is not designated as a HPSA, the area may be deficient with respect to a particular specialty.<sup>3</sup> In such cases, we would consider the validity of other documented evidence of an objective need on a case-by-case basis.
- **Whether the practitioner has an existing stream of referrals within the recruiting entity's service area.** The risk of kickbacks is mitigated when payments are made to new or relocating practitioners who do not have established referral streams that can be locked up through inappropriate incentives and loyalties. Practitioners in urban areas who relocate their offices short distances to underserved areas could still have an existing stream of referrals, and therefore inducements offered to such practitioners could be suspect if patients residing in the nearby urban area continue to represent a large percentage of the practitioner's practice.

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<sup>3</sup>In fact, an area can only be designated as a HPSA for one or more of seven health professional types (i.e., primary medical care, dental, mental health, vision care, podiatric, pharmacy, and veterinary). See 42 C.F.R. pt. 5. Moreover, the definition of primary medical care is limited to doctors of medicine or osteopathy who practice primarily in one of four primary care specialties -- general or family practice, general internal medicine, pediatrics, and obstetrics and gynecology. See 42 C.F.R. pt. 5 app. A.

- **Whether the benefit is narrowly tailored so that it does not exceed that which is reasonably necessary to recruit a practitioner.** Whether the value or duration of a benefit is indicative of abusive practices varies based upon a number of factors including, for example, whether there is a reasonable and documented basis for the benefit's value and duration. Generally, benefits of greater value and benefits provided over longer durations (i.e., more than three years) are more suspect.<sup>4</sup>
- **Whether the remuneration directly or indirectly benefits other referral sources.** Remuneration is more suspect if it directly or indirectly benefits actual or potential referral sources, other than the recruited practitioner, or if it is directly or indirectly related to broader arrangements that the entity has with the recruited practitioner or other actual or potential referral sources. For example, we are aware of many joint recruitment arrangements between hospitals and other referral sources (e.g., solo practitioners, group practices, or managed care organizations) pursuant to which the hospital makes payments directly or indirectly to the other referral source to assist the referral source in recruiting a new practitioner. Such arrangements are subject to a higher degree of scrutiny to ensure that the remuneration is not a disguised payment for past or future referrals.

We emphasize that these factors are not indicative or necessarily probative of whether a practice, in fact, actually violates the anti-kickback statute. Rather, we weigh these factors, as well as other relevant concerns, in assessing the level of risk presented by a practitioner recruitment arrangement. These factors are not exhaustive, and the presence or absence of any one factor is not determinative of whether, in our discretion, the OIG would subject the parties involved in a practitioner recruitment arrangement to administrative sanctions for violating the anti-kickback statute.

### **C. Application of the Anti-Kickback Statute**

In the instant case, the Hospital would provide remuneration (i.e., a loan subject to favorable terms, together with conditional loan forgiveness) to the Physician, a potential

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<sup>4</sup>Generally, the three-year period begins on the earlier of (i) the date of the first payment or transfer of anything of value to the recruited practitioner or (ii) the date that the practitioner begins his or her new practice in, or relocates his or her practice to, the area.

referral source, to relocate to, and practice medicine within, the Hospital's service area.<sup>5</sup> Since such an arrangement gives rise to an inference that one purpose of the remuneration is to induce or reward referrals of Federal health care program business, the anti-kickback statute is implicated. Moreover, the Proposed Arrangement does not qualify for safe harbor protection because it fails to satisfy two of the requirements of the practitioner recruitment safe harbor (i.e., the Physician is not relocating to a HPSA and the benefit is not limited to three years).<sup>6</sup>

Notwithstanding, we would not subject the Hospital to administrative sanctions for violations of the Federal anti-kickback statute in connection with the Proposed Arrangement for the following reasons. First, consideration of the factors listed above suggests that the Proposed Arrangement would pose a minimal risk of Federal health care program fraud and abuse. Specifically, in addition to servicing a rural area which has a documented shortage of health care services generally,<sup>7</sup> the Hospital has certified that its service area has a specific, documented shortage of physicians practicing the Specialties. Moreover, upon relocation, the Physician would not have a ready stream of referrals. Although the duration of the Proposed Arrangement (i.e., eight years) would exceed the three-year threshold, the repayment period, the only period of the Proposed Arrangement during which the Physician could make referrals to the Hospital, is limited to three years. In addition, there is a reasonable, documented basis for both the monetary value of the original loan amount and the duration over which it is paid. Moreover, the Hospital has certified that the benefit would be provided directly to the Physician and it would not directly or indirectly benefit any other potential or actual referral source.

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<sup>5</sup>In the instant case, the limited additional services that the Physician would provide to the Hospital (e.g., assisting the Hospital in its educational programs) do not materially impact our analysis.

<sup>6</sup>We recognize that even if there were a dire shortage of physicians practicing the Specialties within the County, the County could not be designated as a HPSA for the Specialties, because HPSA designations are only available for certain limited primary care specialties. See supra note 3.

<sup>7</sup>The fact that the Hospital's service area consists exclusively of areas designated as MUAs is not determinative and is only one of many factors that we consider. In fact, in revising the practitioner recruitment safe harbor, we considered whether we should protect arrangements where practitioners relocate to a MUA, but we rejected the use of MUAs, because unlike HPSAs, which target practitioner shortages, MUAs only measure shortages of health care services generally. See 64 Fed. Reg. 63,518, 63,542 (Nov. 19, 1999).

Second, the Proposed Arrangement would contain the following safeguards that would further reduce the risk of fraud and abuse:

- The Proposed Arrangement would not be renegotiated in any substantial aspect during its term;
- The Proposed Arrangement would not be conditioned upon the Physician making referrals to, or being in a position to make or influence referrals to, or otherwise generating business for the Hospital;
- The Physician would not be restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his choosing; and
- The amount or value of the remuneration provided under the Proposed Arrangement would not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to, or business otherwise generated for, the Hospital by the Physician for which payment may be made in whole or in part under any Federal health care program.

In light of the foregoing, the Physician would be free to make referrals based upon clinical judgment without fear of reproach from the Hospital.

Third, because all of the counties in the Hospital's service area have been designated as MUAs by the Department, the Proposed Arrangement will benefit the public by increasing access to health care services in medically underserved areas.

### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would 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 the Hospital 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.

#### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name of hospital redacted], who is the requestor of this opinion. This advisory opinion has no application, 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 to this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. 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 Proposed 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 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 the Hospital 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, rescind, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Hospital 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