

[Posted December 3, 1998]

[Issued November 25, 1998]

[Name and address redacted]

Re: Advisory Opinion No. 98-18

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding whether an ophthalmologist's proposed sublease to an optometrist of certain imaging equipment (the "Sublease") would meet the criteria of the equipment rental safe harbor, 42 C.F.R. § 1001.952(c). The imaging equipment may be used by the ophthalmologist to conduct telemedicine consultations relating to the optometrist's patients. The Sublease and the telemedicine consultation arrangement are referred to in this opinion letter collectively as the "Proposed Arrangement".

You have certified that all of the information provided in the request letter, including all supplementary submissions, 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, this opinion is without force and effect.

Based on the facts certified in the request for an advisory opinion (including the certification of fair market value), we conclude that the Sublease satisfies the criteria of the equipment rental safe harbor, 42 C.F.R. § 1001.952(c). We further conclude that the arrangement for the provision of telemedicine consultations may involve prohibited remuneration if the requisite intent to induce referrals is present, but would not be subject to Office of Inspector General ("OIG") sanctions arising under the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), based on the facts presented.

This opinion may not be relied on by any persons other than the requestor and is further qualified as set out in Part IV below and in 42 C.F.R. § 1008.

I. FACTUAL BACKGROUND

A. The Parties

Dr. Y (the "Requestor") is an ophthalmologist licensed to practice medicine in State A. He is a participating provider in the Medicare and Medicaid programs. Dr. X is an optometrist licensed to practice optometry in State A. Dr. X is a Medicare provider who performs Medicare-covered services. She has several office locations. The office location relevant to the Proposed Arrangement is located approximately twenty miles from Dr. Y's office.

B. The Proposed Arrangement

Dr. Y wishes to conduct telemedicine consultations for patients in remote locations. To this end, Dr. Y intends to lease from a third-party equipment leasing company (the "Lessor") certain telemedicine equipment (the "Leased Equipment") that will enable him to view images of a patient's eye transmitted from such locations. Dr. Y proposes to enter into an arrangement with Dr. X to locate in Dr. X's office the components of the Leased Equipment that transmit the images to Dr. Y's office. These components can also be used by Dr. X as a fundus photography system to document a patient's ocular disease. Dr. Y will retain in his office the components of the Leased Equipment that allow him to view the transmitted images. This arrangement will enable Dr. Y to consult with Dr. X in connection with those of her patients who may require ophthalmologist services beyond the scope of her optometry practice. If, after such consultation, Dr. Y determines that a patient requires services beyond the scope of Dr. X's practice, Dr. X may refer the patient to Dr. Y, although the patient will be free to select any ophthalmologist. Neither Dr. Y nor Dr. X will bill the patient or any

insurer for the telemedicine consultation.

Dr. Y proposes subleasing the equipment to Dr. X pursuant to a written sublease ("Sublease"). The Sublease will describe the subleased equipment with specificity and will cover all of the equipment leased between Dr. Y and Dr. X for the twelve-month term of the Sublease. The Sublease will provide for monthly rent of \$[redacted], an amount determined by multiplying the cost associated with purchasing a fundus photography unit from the Lessor by a rental factor of [redacted]. This rental factor is ordinarily applied by the Lessor to equipment leases of the length involved here for the equipment. The rent to Dr. X amounts to a direct "pass through" of the rent being paid by Dr. Y to the Lessor for the same equipment. Dr. Y has certified that the rental amount under the Sublease constitutes fair market rent for the subleased equipment. The Sublease will prohibit Dr. X from advertising or marketing in any respect her ability to provide telemedicine consultation services. The only arrangement between Dr. Y and Dr. X is the Sublease and there are, and will be, no oral or written collateral agreements or understandings between them, including agreements or understandings regarding the referral of patients from either party to the other.

II. LEGAL ANALYSIS

A. The Anti-Kickback Statute

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 any Federal health care program. See 42 U.S.C. § 1320a-7b(b). 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 is 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, 476 U.S. 988 (1985). Violations of the statute constitute 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. This Office may also initiate administrative proceedings to exclude persons from the Federal and State health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under 42 U.S.C. §§ 1320a-7(b)(7), 1320a-7a(a)(7).⁽¹⁾

We have previously stated our view that a gift to an existing or potential referral source that has independent value to such source implicates the anti-kickback statute and may be unlawful if the donor of the gift has the requisite intent to induce Federal health care program referrals. For example, in the preamble to the 1991 safe harbor regulations, we stated that giving a physician who is a referral source a free computer that has independent value to the physician may violate the statute. See 56 Fed. Reg. 35978 (July 1991); see also, e.g., OIG Special Fraud Alert, 56 Fed. Reg. 65377 (Oct. 1994) (explaining that the anti-kickback statute is implicated where a clinical laboratory provides a phlebotomist to a physician to perform tasks normally the responsibility of the physician's office staff).

A number of statutory and regulatory "safe harbors" protect certain arrangements that might otherwise technically violate the anti-kickback statute from prosecution. See 42 U.S.C. § 1320a-7b(b)(3); 42 C.F.R. § 1001.952. The safe harbor potentially applicable to the Sublease is the equipment rental safe harbor at 42 C.F.R. § 1001.952(c). This safe harbor protects equipment rental payments if:

- there is a written lease signed by the parties;
- the lease specifies the equipment covered by the lease;
- where the lease is intended to provide the lessee with the use of the equipment for periodic intervals, rather than full-time for the term of the lease, the lease specifies the exact schedule, length, and rent for the intervals;
- the term of the lease is for at least one year; and

-- the aggregate rental charge is set in advance, consistent with fair market value in an arms-length transaction, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

42 C.F.R. § 1001.952(c). For purposes of the equipment rental safe harbor, "fair market value" means the value of the equipment when obtained from a manufacturer or professional distributor, provided that the value is not adjusted to reflect any additional value one party would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare or a State health care program. Strict compliance with all safe harbor elements is required in order to receive safe harbor protection. See 56 Fed. Reg. 35952, 35954 (July 29, 1991).

B. The Proposed Arrangement

Dr. Y and Dr. X are potential sources of referrals of Federal health care program business for one another and therefore anything of value exchanged between them potentially implicates the anti-kickback statute. In this regard, there are two aspects of the Proposed Arrangement to be analyzed: the Sublease for the fundus photography equipment and the arrangement for free telemedicine consultations.

1. The Sublease

The Sublease will be in writing and will specify the exact equipment subleased. The Sublease will cover all of the equipment subleased between Dr. Y and Dr. X for its twelve-month term.⁽²⁾ The Sublease will provide for a fixed rental payment of \$[redacted] per month, resulting in an annual aggregate rental payment fixed in advance of \$[redacted]. The rent to be paid under the Sublease, presumed to be fair market value for purposes of this advisory opinion,⁽³⁾ is based on the equipment's value to Dr. X as a fundus photography unit. The rental charge has been determined by multiplying the supplier's purchase price for a fundus photography unit by a rental factor ordinarily applied by the supplier for leases of the duration of the Sublease. Thus, the rental charge will not be determined in a manner that takes into account the volume or value of any referrals or business generated between the parties. In sum, because all safe harbor elements are satisfied (assuming fair market value), the rent paid under the Sublease would not constitute prohibited remuneration under the anti-kickback statute.

2. The Telemedicine Consultations

The Sublease will only cover the rental of a fundus photography system to be used for producing images of the eye in Dr. X's office. However, the arrangement for telemedicine consultations itself may have value to Dr. X. When connected to the receiving components retained by Dr. Y (for which Dr. X will not be paying under the Sublease), the subleased equipment will enable Dr. X to access telemedicine consultations with Dr. Y. This may enable Dr. X to expand her business or to earn additional fees associated with her role in performing the consultations. However, based on the facts submitted by Dr. Y, Dr. X will not advertise or market her access to telemedicine consultations and will not charge a fee in connection with such consultations. Therefore, the telemedicine consultations will have minimal, if any, value to Dr. X.

Conversely, the arrangement for telemedicine consultations may have value to Dr. Y. Dr. X's referral of a patient to Dr. Y in conjunction with a telemedicine consultation will provide Dr. Y the opportunity to generate Federal health care program business. However, the Proposed Arrangement permits Dr. X's patients the freedom to choose any ophthalmologist. In addition, Dr. Y has certified that the only arrangement between Dr. Y and Dr. X is the Sublease and that there are, and will be, no oral or written collateral agreements or understandings between them, including agreements or understandings regarding the referral of patients from either party to the other. Based on these representations, any opportunity for Dr. Y to generate business from telemedicine consultations will not be an inducement for Dr. Y to refer patients to Dr. X.

Accordingly, although the telemedicine consultation arrangement may constitute prohibited remuneration under the anti-kickback statute if the requisite intent is present, the OIG will not subject it to sanctions arising under the anti-

kickback statute.⁽⁴⁾

III. CONCLUSION

Based on the facts as certified by Dr. Y (including Dr. Y's certification that the rental amount to be paid under the Sublease constitutes fair market value in an arms-length transaction) and subject to the conditions stated in this opinion letter, we conclude that the Sublease would meet the criteria of the equipment rental safe harbor at 42 C.F.R. § 1001.952(c). We further conclude that the arrangement for the provision of telemedicine consultations may involve prohibited remuneration if the requisite intent to induce referrals is present, but would not be subject to OIG sanctions under 42 U.S.C. §§ 1320a-7(b)(7) & 1320a-7a(a)(7), based on the facts presented.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Dr. Y, 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 that 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 Requestor 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, the compensation under the Sublease represents fair market value in accordance with the requirements of 42 C.F.R.

§ 1001.952(c), 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 Requestor 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, where the compensation under the Sublease represents fair market value pursuant to 42 C.F.R.

§ 1001.952(c), 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

FOOTNOTES:

1. Because both the criminal and administrative sanctions related to the Proposed Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same for both.
2. The Sublease agreement provides for early "for cause" termination by Dr. Y, if Dr. X fails to perform any conditions or covenants of the Sublease or removes, or attempts to remove, the subleased equipment from her office without Dr. Y's consent. For purposes of this advisory opinion, termination of the Sublease prior to the end of the initial one-year term would be deemed to be a material change in the facts presented and result in this advisory opinion being without force and effect.
3. 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).
4. This advisory opinion will be without force and effect if Dr. X charges a fee for the telemedicine consultations or does not comply fully with the prohibition on marketing her access to telemedicine consultations.