



[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 30, 2011

Posted: October 7, 2011

[Name and address redacted]

Re: OIG Advisory Opinion No. 11-14

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal for ophthalmologists in a group practice to co-manage cataract surgery patients, including Medicare beneficiaries, with optometrists external to that group practice who would separately charge the beneficiaries for services related to premium refractive intraocular lenses that are not covered by the Medicare program (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 supplemental submissions, 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 would not generate prohibited remuneration under the anti-kickback statute. Accordingly, 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 for an advisory opinion 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.

I. FACTUAL BACKGROUND

[Name redacted] (the “Requestor”) is a physician group practice that specializes in ophthalmic care. The practice’s four shareholders are ophthalmologists, and it also employs optometrists. One of the Requestor’s specialties is cataract surgery. A cataract is a clouding of the eye’s crystalline lens, which causes progressive vision loss. Patients typically present first to their optometrist with complaints of decreased vision. If an optometrist diagnoses cataracts that may have progressed to the point of requiring surgery, the optometrist discusses treatment options and refers the patient to a cataract surgeon for evaluation.

Cataract surgery involves removing the cloudy lens and replacing it with a permanent prosthetic intraocular lens (“IOL”). The typical IOL (“Conventional IOL”) provides patients with clear distance vision but does not correct any pre-existing refractive problems that may have been causing the patient to have difficulty seeing at near or intermediate distances. Patients receiving a Conventional IOL would still require glasses or contact lenses to correct these vision problems. Newer types of IOLs can correct vision at multiple ranges or correct astigmatism (collectively, “Premium IOLs”). Patients opting for a Premium IOL may no longer require glasses or contact lenses after surgery.

The Medicare program covers Conventional IOLs when reasonable and necessary for a patient. In addition, even though glasses and contact lenses generally are excluded from Medicare coverage, Medicare does cover one pair of glasses or contact lenses following cataract surgery. Cataract surgery is a global surgical procedure, which means that Medicare pays the physician one global fee for the pre-operative care, the surgery, and the post-operative care for 90 days following the surgery. Payment for the Conventional IOL implant is bundled into the facility fee for the surgery. When a physician transfers care to

another health care professional during the global surgical period (e.g., the surgeon transfers the patient back to his or her optometrist for post-operative care), the health care providers bill Medicare using the -54 (surgical care only) and -55 (post-operative management only) modifiers.¹

Premium IOLs cost significantly more than Conventional IOLs. In addition to the implant itself being more costly, the facility and physician may require additional resources for fitting and inserting the Premium IOL. Additional visual acuity testing may also be necessary in connection with Premium IOLs. The Centers for Medicare & Medicaid Services (“CMS”) considered how to cover Premium IOLs and ultimately issued two rulings explaining that both the professional fee and the facility fee are partially covered by the Medicare program.² Correction of refractive errors does not fall into a covered benefit category. If a Medicare beneficiary elects to receive a Premium IOL rather than a Conventional IOL, Medicare pays for the medically necessary cataract surgery when a Premium IOL is inserted, as well as the covered aspect of the IOL. However, the beneficiary is responsible for the professional and facility fees associated with increased testing and other services related to the correction of refractive errors, as well as the difference in cost between the Premium IOL and the Conventional IOL.

The Requestor offers all cataract surgery patients the opportunity to return to their referring optometrist for post-operative care, as long as the optometrist is comfortable completing the post-operative care and the surgeon believes that such a transfer is clinically appropriate. The referring optometrists may also advise their patients of this choice when referring the patients for cataract surgery. Except as specified below, the Requestor currently co-manages patients receiving Conventional IOLs and patients receiving Premium IOLs who choose to return to their referring optometrists for post-surgical care. The Requestor certified that it follows all applicable Medicare billing and coding requirements for those co-managed patients. The Requestor also certified that it does not have any written or unwritten agreements with optometrists regarding co-management; however, the Requestor requires that all patients who choose to return to their optometrists sign an informed consent memorializing this decision.

The Requestor certified that it has a broad referral base of optometric and ophthalmic primary eye care professionals in the surrounding communities, many of whom have begun discussing Premium IOLs with their patients. When a patient elects to receive a Premium IOL, the Requestor charges a flat fee of \$[amount redacted] per eye for the additional

¹ The sharing of a cataract patient’s care between the surgeon and primary eye care professional is known as “co-management.”

² See Medicare Ruling CMS-05-01 and Medicare Ruling CMS-1536-R.

testing and related physician services.³ When the Requestor co-manages these patients with an optometrist external to the Requestor's practice, the Requestor bills Medicare with the -54 modifier, as it does with the Conventional IOL, but continues to charge the \$500 flat fee. The Requestor does not reduce this fee if a patient elects to return to his or her referring optometrist for post-operative services, because the Requestor does not typically perform additional non-covered services for patients who received a Premium IOL after the point at which it would be clinically appropriate to transfer the patient back to the optometrist. In other words, the Requestor performs all non-covered services associated with a Premium IOL during the timeframe in which the patient is under the Requestor's care, whether or not that patient is co-managed. The Requestor cannot certify as to what additional services an optometrist might perform after the transfer. The Requestor has not asked us to opine on its current co-management practices.

According to the Requestor, some optometrists have announced their intention to charge Premium IOL patients for non-covered, post-operative services that are not required in connection with Conventional IOLs and that the optometrist determines are necessary in connection with the Premium IOLs. The Requestor does not yet co-manage any patients receiving Premium IOLs with optometrists who have proposed to charge patients separately for services related to the Premium IOLs; co-management of these patients constitutes the Proposed Arrangement.

The Requestor would not have any written or unwritten agreements with optometrists for the co-management of patients receiving Premium IOLs. Under the Proposed Arrangement, the Requestor certified that it would: (1) notify all patients, whether they are receiving a Conventional IOL or a Premium IOL, of their option to return to their optometrists for post-operative care if such a transfer would be clinically appropriate; and (2) notify patients receiving a Premium IOL that their optometrists may charge additional fees for the post-operative services that the patients would not incur if the Requestor furnished the care. This latter notification would be incorporated into the informed consent process.

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

³ Patients also pay an additional fee to the facility where the surgery is performed for the non-covered portion of the Premium IOL and facility resources.

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. 1985), 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

The Requestor has posed a very narrow question: whether the Proposed Arrangement, pursuant to which the Requestor would co-manage a Medicare beneficiary with an optometrist who would charge the beneficiary for the additional testing and services related to the Premium IOLs, would constitute remuneration to a referral source in the form of an opportunity to earn a fee. The Requestor has not asked whether the opportunity to earn a fee through the co-management of Medicare beneficiaries may be prohibited remuneration under the anti-kickback statute when the optometrist charges no fee in excess of the Medicare fee schedule, and we express no opinion on that separate question.⁴ Rather, the

⁴ In the preamble to the final regulation for the safe harbor relating to referral arrangements for specialty services, we addressed a comment about potentially abusive referral arrangements between optometrists and ophthalmologists who split a global fee through co-management. 64 Fed. Reg. 63,518, 63,548-63,549 (Nov. 19, 1999). As we explained in the preamble, not all referral arrangements that involve splitting global fees are illegal under the anti-kickback statute. Instead, they must be examined on a case-by-case basis. There, we expressed concern about an example provided by a commenter who claimed that an optometrist/ophthalmologist network referred patients for cataract surgery only to ophthalmologists who would agree to refer the patient back and split the global fee, often without regard to clinical appropriateness. Although we note that the Requestor has certified these factors are not present in its current operations and would not be present in the Proposed Arrangement—the Requestor does not agree to refer patients back to optometrists, nor would the Requestor make such a transfer unless it was clinically

Requestor has asked us whether the opportunity for the optometrist to earn a fee for services not covered by the Medicare program in connection with post-operative management of Premium IOL patients may constitute prohibited remuneration. Under the facts present in the Proposed Arrangement, we conclude that it would not.

Several policies that the Requestor certified it would follow under the Proposed Arrangement lead us to the conclusion that the Proposed Arrangement does not involve prohibited remuneration.

First, the Requestor would have no written or unwritten agreements to co-manage patients with optometrists. Instead, the Requestor would explain to all patients that they may receive their post-surgical care from the Requestor or from their referring optometrist, following a determination of clinical appropriateness—an option that the referring optometrist may have already presented to the patient.

Second, the Requestor would inform patients receiving Premium IOLs that, if they choose to return to their optometrist for post-operative care, the optometrist may charge them for any services related to the Premium IOL that the optometrist may deem necessary. By informing the patient of potential additional charges that the patient would not incur by receiving follow-up care with the Requestor, the Requestor actually reduces the likelihood that the patient will choose to return to the referring optometrist.

Third, the increased costs associated with a Premium IOL are not covered by the Medicare program. Although the Medicare program does cover the cost of medically necessary cataract surgery (including facility and physician services) up to the cost of, and for services associated with, a Conventional IOL, as noted above, we have relied on the Requestor's certification that it complies with all applicable Medicare billing and coding requirements, including requirements regarding splitting the global fee. Thus, the fact that the Requestor would co-manage a beneficiary receiving a Premium IOL with an optometrist who may charge the beneficiary for additional, non-covered services provided would not increase costs to the Medicare program.

Finally, the Requestor also certified that it would transfer a patient back to his or her optometrist only upon the patient's request. Explaining a patient's options for post-surgical treatment providers, including the potential for incurring additional fees by returning to the optometrist, and complying with the patient's decision, would not constitute prohibited remuneration to induce the optometrists' referrals under the anti-kickback statute.

appropriate—the question presented in the request did not ask about the existing operations, and therefore we did not evaluate such operations.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute. Accordingly, 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 for an advisory opinion 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General