



[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 3, 2010

Posted: September 10, 2010

[Name and address redacted]

Re: OIG Advisory Opinion No. 10-16

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a cochlear implant manufacturer that seeks to compensate certain providers for the provision of otherwise unreimbursable services rendered in connection with faulty external components of a cochlear implant while the product is still under warranty (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of 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: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; but (ii) the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the Office of Inspector General (“OIG”) could potentially 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. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties’ intent, which determination is beyond the scope of the advisory opinion process.

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] (“Requestor”) manufactures cochlear implants, which are medical devices used to assist in restoring hearing for patients. The devices are covered by the Medicare and Medicaid programs for eligible individuals. Cochlear implants include both internal and external components. The internal component is implanted surgically either in a hospital outpatient department or in an ambulatory surgery center. Following implantation of the internal component, an audiologist must program the external sound processor. This programming process takes place in either an audiologist clinic or in an otolaryngology physician’s office (collectively, “Clinic(s)”). The patient has a choice of competing cochlear implant devices, and this choice could be influenced by the patient’s audiologist or surgeon.

If an external component of the cochlear implant fails, Requestor’s warranty generally covers replacement of the component. The customer must complete a return material authorization (“RMA”) and ship the component back to Requestor. Requestor maintains a customer service department with a toll-free line to assist customers with this process. Customers can contact Requestor directly for troubleshooting services related to malfunctioning components (other than programming sound processors, which must be done by audiologists) and can process RMAs in a direct transaction with Requestor.

Despite Requestor’s efforts to make the RMA process easier for customers, Requestor asserts that its customers often seek support from the Clinics when the device malfunctions rather than follow the warranty procedures. At the Clinics, audiologists, technicians, and/or administrative staff provide troubleshooting services, which potentially involve scheduling the patient, testing the device, recording results, and, if the malfunction is due to the failure

of an external component of the device, shipping the device to Requestor (collectively, “RMA Services”). Requestor either repairs or replaces the device in accordance with the warranty. Requestor has certified that third-party payors do not provide reimbursement for RMA Services associated with troubleshooting faulty external components, such as a broken cable or bad headpiece microphone, if the customer does not require sound processor programming services.¹ Requestor has certified that it has received requests for reimbursement from multiple providers for RMA Services, but that at this point, Requestor does not reimburse providers for these services.

Under the Proposed Arrangement, Requestor would reimburse Clinics for RMA Services. Each time one of Requestor’s customers seeks and receives RMA Services from a Clinic (rather than following the warranty instructions and submitting the RMA directly to Requestor), Requestor would reimburse the Clinic \$37.00. Requestor conducted a survey of nine Clinics to determine who performed each part of the RMA Services at the Clinics (an audiologist or technician/administrator) and how much time each step of the process took. Based on the varying responses from the survey, Requestor arrived at an estimated average time allocation for each step in the RMA Services process. Requestor then looked at the average salaries for audiologists, estimated the salaries for technicians and administrators, and assigned those rates to each step of the RMA Services process using the estimated average time allocations from the survey results. Based on those results, Requestor asserts that \$37.00 is fair market value² for the RMA Services.

Under the Proposed Arrangement, Requestor would enter into written agreements with Clinics, which would be for a period of at least one year. Clinics would submit monthly invoices to Requestor indicating the dates of RMA Services and the serial numbers of the sound processors that the Clinics submitted to Requestor on behalf of patients for repair or replacement. Requestor would confirm that the serial numbers on the invoice submitted by a Clinic correspond with Requestor’s records of returned sound processors. The agreements between Requestor and the Clinics would prohibit the Clinics from charging any patient or third-party payor for RMA Services billed to Requestor. Moreover, Requestor would not advertise or promote the availability of RMA Services at the Clinics to beneficiaries.

¹ According to Requestor, these non-programming RMA Services do not satisfy the Current Procedural Terminology (“CPT”) descriptor for programming services or other reimbursable services. Although third-party payors will reimburse for RMA Services associated with reprogramming or adjusting the programs on the sound processor, the RMA Services discussed in this advisory opinion are limited to non-programming RMA Services.

² 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).

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. 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.

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 personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Proposed Arrangement. One requirement to qualify for protection under the personal services safe harbor is that the aggregate compensation paid for services under the agreement is set in advance. This condition is not met here.

Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or state health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of any

item or service for which payment may be made, in whole or in part, by Medicare or a state health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines “remuneration” for purposes of section 1128A(a)(5) as including “transfers of items or services for free or for other than fair market value.” The OIG has previously taken the position that “incentives that are only nominal in value are not prohibited by the statute,” and has interpreted “nominal value to be no more than \$10 per item, or \$50 in the aggregate on an annual basis.” 65 F.R. 24400, 24410 – 24411 (April 26, 2000).

B. Analysis

Under the Proposed Arrangement, Requestor seeks to compensate Clinics for services provided to Requestor’s customers. Although the Proposed Arrangement would not result in impermissible beneficiary inducements, the remuneration involved would implicate the anti-kickback statute.

The Proposed Arrangement presents more than a minimal risk of fraud and abuse under the anti-kickback statute for the following reasons.

First, several Clinics have expressly sought remuneration from Requestor for RMA Services that Requestor already makes available to its customers through the warranty process. If Requestor were to pay the Clinics for warranty-related services, including RMA Services, the Clinics could be influenced to recommend Requestor’s product over a competitor’s product. One purpose of the anti-kickback statute is to protect patients from inappropriate referrals (or recommendations) by providers and suppliers that may be unduly influenced by financial incentives. The statute seeks to ensure that referrals will be based on sound medical judgment and that providers and suppliers will compete for business based on quality and convenience, instead of paying for it. Requestor has not proposed any safeguards to deter such steering of patients arising from the financial incentives built into the Proposed Arrangement. Moreover, there appears to be no compelling need to pay the Clinics to perform these services, because Requestor has taken measures to ensure that it has a process in place for customers to complete this transaction directly with Requestor, including establishing a toll-free line for troubleshooting services and for assisting customers with the RMA process.

Second, under the Proposed Arrangement, Requestor would pay the Clinics for RMA Services on a per-occurrence basis at a rate that Requestor certified to be fair market value. We are not confident that, in these circumstances, Requestor’s survey method for establishing fair market value is sufficient to ensure that Requestor will not be overpaying a

referral source for the RMA Services.³ Requestor's survey only took into account time spent by and average salaries for audiologists, technicians, and administrative staff of the Clinics, who are actual or potential referral sources. It is not clear that the survey captures amounts commensurate with what it would cost the Requestor to obtain comparable services from individuals or entities that are not potential referral sources.

In sum, the Proposed Arrangement would result in Requestor paying the Clinics, which have solicited compensation from Requestor (by requesting reimbursement for RMA Services) and are referral sources for products reimbursable under Federal health care programs, on a per-occurrence basis, for a warranty service that Requestor itself provides to its customers at no additional cost. For the combination of the foregoing reasons, we cannot be confident that there is no more than a minimal risk of fraud or abuse under the Proposed Arrangement. Therefore, we conclude that the Proposed Arrangement may involve prohibited remuneration under the anti-kickback statute and thus potentially be subject to sanction 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). Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

We note, however, that the Proposed Arrangement to pay the Clinics to furnish RMA services would not violate the beneficiary inducement prohibitions found in section 1128A(a)(5) of the Act. The Proposed Arrangement would be essentially invisible to the beneficiary. Customers using Requestor's products receive a warranty. If an external component of the cochlear implant fails during the warranty period (the only circumstance applicable to the Proposed Arrangement), the customer does not expect to have to pay for a replacement or for remedial services. Further, Requestor has certified that it would not market this program to beneficiaries. For these same reasons, there also appears to be no unlawful remuneration from Requestor to beneficiaries under the anti-kickback statute.

³ Although, as noted above, we are precluded from opining on whether fair market value shall be or was paid for goods, services, or property, we must evaluate whether the method used to determine that a fee represents fair market value appears reliable. For example, we explain in various guidance documents that "fair market value" must represent an arm's-length transaction (e.g., what would a provider or supplier pay a non-referral source?). See, e.g., Supplemental Hospital Compliance Program Guidance, 70 Fed. Reg. 4858, 4866 (January 31, 2005); Special Fraud Alert, "Arrangements for the Provision of Clinical Lab Services," 59 Fed. Reg. 65372, 65377 (Dec. 19, 1994).

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; but (ii) the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

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 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.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General