DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

[*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 28, 2015

Posted: June 4, 2015

[Name and address redacted]

Re: OIG Advisory Opinion No. 15-07

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding subsidies a medical device manufacturer provides to certain patients participating in a clinical research study (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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 the 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, but that the Office of Inspector General ("OIG") will 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 Arrangement. In addition, the OIG will not impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act in connection with the Arrangement. This opinion is limited to the 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] ("Requestor") manufactures the [system name redacted] (the "System"), a set of specialized instruments designed to perform minimally invasive direct decompression of the lumbar spine in patients with lumbar spinal stenosis. This procedure is also known as percutaneous image-guided lumbar decompression ("PILD").

In January 2014, the Centers for Medicare & Medicaid Services ("CMS") issued a Medicare National Coverage Determination ("NCD") and supporting Decision Memorandum (the "Coverage Decision") stating that it had determined that PILD for lumbar spinal stenosis is not "reasonable and necessary" under section 1862(a)(1)(A) of the Act, but that it will allow for coverage of PILD for lumbar spinal stenosis under certain conditions.[1] Specifically, CMS stated that PILD will be covered by Medicare under the Coverage with Evidence Development ("CED") Program when PILD is provided pursuant to a clinical study performed in accordance with section 1862(a)(1)(E) of the Act for beneficiaries with lumbar spinal stenosis.[2] For an entity to be eligible for Medicare reimbursement under the CED Program, patients must be enrolled in a clinical study that satisfies criteria established by CMS, and the study itself must be approved by CMS. As specified in the Coverage Decision, an approved study must be a prospective, randomized, controlled design using current validated and reliable measurement instruments and clinically appropriate comparator treatments, including appropriate

[1] Decision Memo for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433N), Jan. 9, 2014, available at http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=269.

[2] Id.

medical or surgical interventions or a sham controlled arm, for patients randomized to the non-PILD group.[3]

In consultation with CMS, Requestor developed a clinical research study (the "Study") intended to evaluate the effectiveness of PILD using the System compared to a sham procedure in the Medicare population. The Study is a prospective, multi-center, randomized, controlled, double-blind trial, the principal purpose of which is to test whether PILD using the System meaningfully improves health outcomes of patients with lumbar spinal stenosis.

The Study is open to individuals who meet the enrollment criteria set forth in the Study protocol and is not limited to Medicare beneficiaries. The Study protocol calls for 120 patients, with a 2:1 randomization, meaning that 80 patients are assigned to the treatment group and 40 patients are assigned to the control group. In the treatment group, patients receive PILD using the System. In the control group, patients receive a sham surgery that includes the same anesthesia and skin incision that is used for patients receiving PILD; however, patients in this group do not receive any therapeutic treatment (i.e., no PILD), and the incision is closed.[4] Requestor selected sham surgery as the control treatment for the Study to control for the placebo effect, which can have a meaningful impact on the interpretation of results in studies of interventions for back pain. By controlling for the placebo effect, the Study design is intended to produce findings that specifically address the impact of PILD using the System on patient health outcomes.

PILD typically is performed in a hospital outpatient department or ambulatory surgical center ("ASC"). Requestor has entered into written agreements with several Study sites ("Sites"). Each Site may consist of multiple persons or entities. For each Site, Requestor has entered into a written agreement with the principal investigator and the principal investigator's medical practice, and also may have written agreements with associated hospitals or ASCs. Each agreement sets forth both Requestor's and the person or entity's responsibilities with respect to the conduct of the Study at the Site and the compensation that Requestor will pay for the services the person or entity provides in connection with the Study. Requestor certified that the compensation is fair market value for necessary Study-related services, including costs for Institutional Review Board review, monitoring visits, and investigator meetings.

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[3] Id.

[4] Requestor certified that it is conducting the Study consistent with the requirements in Federal regulations at 45 C.F.R. Part 46 and 21 C.F.R. Parts 50 and 56 regarding the protection of human subjects which requires, among other things, oversight and monitoring by an Institutional Review Board.

Any qualified physician who is willing to follow the Study protocol is eligible to participate in the Study as an investigator, subject to the overall Study enrollment target, which includes caps on the numbers of sites and patients. Physician investigators for the Study are interventional spine physicians who have: experience conducting clinical research and the appropriate research infrastructure in place; prior experience in minimally invasive decompression procedures or similar invasive interventional spine procedures; and privileges at a suitable hospital or ASC where the procedure can be performed.

Consistent with the Coverage Decision and pursuant to CMS's approval of the Study, CMS will provide coverage for Medicare beneficiaries enrolled in the Study. Medicare beneficiaries typically would be charged copayments for the facilities' services and the physicians' professional services. For beneficiaries who receive the sham surgery—in which no therapeutic treatment is performed—it would be inappropriate to collect copayments from the beneficiaries or their Medicare supplement payors, as no items or services are rendered with therapeutic intent. However, Requestor states that failing to charge patients who receive the sham surgeries copayments for the facilities' and physicians' services, while charging patients assigned to the treatment group of the Study copayments for these same services, would compromise the Study design because patients who are not charged copayments would be made aware they are in the control group.

Requestor certified that it consulted with CMS regarding this issue and that the parties concluded that the optimal solution is for a third-party sponsor, such as Requestor, to pay the applicable copayments for all Medicare beneficiaries enrolled in the Study. Accordingly, under the Arrangement, Requestor pays the copayments associated with the Study for such individuals.[5] Requestor pays the applicable copayments to the person or entity to whom the patient otherwise would owe the copayment (or their designee).

The Study protocol requires evaluating each patient's response to the procedure over time. The primary endpoint is six months post-procedure. At this time, each patient will be evaluated to identify clinically significant improvements in outcomes and determine whether he or she has required any additional interventions during the six-month period. Patients who fail to meet the evaluative criteria set forth in the Study protocol at the primary endpoint will be deemed failures for purposes of the analysis.

Patients who are deemed failures at the primary endpoint may be unblinded to determine whether they are in the treatment group or the control group. Under the Arrangement,

[5] For patients with private insurance that denies coverage for sham procedures, Requestor covers all of the costs for which the third-party payor does not provide coverage. Requestor states that this approach is necessary because, without such support, only Medicare beneficiaries would be able to enroll in the Study.

once unblinded, patients who are failures and who are in the control group will have the opportunity to undergo PILD using the System if they desire. Requestor will pay all of the costs of the PILD procedure using the System for any control group patient who either: (1) is deemed a failure and elects to have the procedure at the primary endpoint, or (2) must exit the Study within one year of enrolling because he or she requires a secondary intervention and elects to have the procedure.[6] As with the copayment subsidies, Requestor pays these amounts directly to the person or entity to whom the patient otherwise would owe the copayment. Requestor does not pay for any other treatments under the Arrangement. Patients are made aware of the potential availability of an additional subsidized procedure in the informed consent document they execute prior to participating in the Study.

Requestor states that the purpose of subsidizing the PILD procedure for patients in the control group is to encourage patients to enroll in the Study, as individuals otherwise might be reluctant to participate in a research study known to include a sham, or placebo control group. Requestor certified that the Arrangement is not dependent upon, and does not operate in conjunction with, either explicitly or implicitly, any other arrangement or agreement between or among Requestor, the participating physician investigators, the Sites, any patient who enrolls in the Study, or any other party in a position to refer or arrange for the referral of items or services reimbursable by any Federal health care program.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully 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.

[6] Requestor states that Medicare will not cover the costs associated with PILD for control group patients who are deemed failures because Medicare coverage for PILD is governed by the terms of the NCD and Coverage Decision, which provide coverage under the CED Program only for beneficiaries who are enrolled in an approved research study and who receive PILD in accordance with the terms of the approved study.

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. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); 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.

Section 1128A(a)(5) of the Act (the "CMP") provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration 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 the CMP as including "transfers of items or services for free or for other than fair market value."

B. Analysis

Under the Arrangement, Requestor pays both the applicable copayments for all Medicare beneficiaries enrolled in the Study and all of the costs of the PILD procedure using the System for certain control group patients (the "Subsidies"). Requestor certified that the purpose of the Subsidies is to encourage patients to enroll in the Study. Because Medicare provides reimbursement for the PILD procedure using the System under the CED Program when the procedure is performed in accordance with the Study, the Arrangement implicates both the anti-kickback statute and the CMP. Nevertheless, for the combination of the following reasons, we conclude that the Arrangement presents a minimal risk of fraud and abuse under the anti-kickback statute.

First, CMS issued a Medicare NCD and Coverage Decision allowing for Medicare reimbursement of PILD for lumbar spinal stenosis through the CED Program under certain conditions. Requestor designed the Study in consultation with CMS. Published data generated by the Study will eventually assist CMS in determining whether PILD is reasonable and necessary for broader Medicare payment. The Arrangement is therefore consistent with CMS policy objectives.

Second, according to Requestor, the Subsidies are necessary to enable a randomized, controlled, double-blind study with appropriate comparator treatments. Requestor's assertion is consistent with CMS's requirement, specified in the Coverage Decision, that studies be designed using appropriate comparator treatments, including appropriate medical or surgical interventions or a sham controlled arm for patients randomized to the non-PILD group. The Arrangement is a reasonable means of achieving the Study's goals because it both encourages necessary patient enrollment in the Study and allows for the true impact of PILD using the System on patient health outcomes to be isolated and assessed.

Third, Requestor certified that the Arrangement is not dependent upon, and does not operate in conjunction with, either explicitly or implicitly, any other arrangement or agreement between or among Requestor, the participating physician investigators, the Sites, any patient who enrolls in the Study, or any other party in a position to refer or arrange for the referral of items or services reimbursable by any Federal health care program.[7] Furthermore, Requestor certified that the compensation it pays in connection with the Arrangement is fair market value for necessary Study-related services.[8] The Arrangement therefore does not appear to be designed to induce the physician investigators or any other person or entity to use, or to arrange for the use of, the System except for purposes of conducting the Study.

Finally, patients must satisfy the enrollment criteria set forth in the Study protocol and execute an informed consent document to be eligible to participate in the Study. Participating physician investigators must comply with the Study protocol and are subject to oversight and monitoring by an Institutional Review Board. These factors, combined with the fact that the Subsidies may be provided only to the small, predetermined number of patients enrolled in the Study, reduce the risk that the Arrangement will result in overutilization or increased costs to the Federal health care programs.

For the combination of reasons described above, we conclude that the Arrangement presents a minimal risk of fraud and abuse under the anti-kickback statute. For the same

[7] The Arrangement is the complete and entire arrangement that is the subject of this advisory opinion. We rely on this certification regarding the lack of any tie between the Arrangement and any other arrangement or agreement between Requestor and its referral sources. If this certification is incorrect, this opinion is without force and effect.

[8] We are precluded by statute from opining on whether fair market value shall be, or was, paid for goods, services, or property. 42 U.S.C. § 1320a-7d(b)(3)(A). For purposes of this advisory opinion, we rely on the Requestor's certification of fair market value. If the compensation under the Arrangement is not fair market value, this opinion is without force and effect.

reasons, in an exercise of our discretion, we choose not to impose sanctions under the CMP as a result of the Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the 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, but that the Office of Inspector General ("OIG") will 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 Arrangement. In addition, the OIG will not impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act in connection with the Arrangement. This opinion is limited to the 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 by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- 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 Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) 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 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 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 that is part of the Arrangement 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General