



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, unless otherwise approved by the requestor(s).]

Issued: June 24, 2021

Posted: June 29, 2021

[Name and address redacted]

Re: OIG Advisory Opinion No. 21-06

Dear [Name redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of [name redacted] (“Requestor”), regarding a proposal under which a spinal implant manufacturer would offer its products to hospitals at a reduced price if the hospitals agree to assume certain duties related to the products (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under: (i) the civil monetary penalty provision for a hospital’s payment to a physician to induce the reduction or limitation of medically necessary services to Medicare or Medicaid beneficiaries under the physician’s direct care, sections 1128A(b)(1)–(2) of the Social Security Act (the “Act”); or (ii) 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”).

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangement, and we have relied solely on the facts and information you provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Proposed Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement, if undertaken, would not involve an improper payment to physicians to induce the reduction or limitation of medically necessary services under sections 1128A(b)(1)–(2) of the Act, and the OIG would not impose sanctions on

Requestor in connection with the Proposed Arrangement. In addition, we conclude that the Proposed Arrangement, if undertaken, would not generate prohibited remuneration under the Federal anti-kickback statute, and therefore, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute.

This opinion may not be relied on by any person¹ other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Requestor designs and manufactures spinal implants and devices (the “Products”) and sells them, directly or indirectly, to hospitals. Requestor typically sells the Products through its traditional distribution system, which includes Requestor’s sales representatives, distributors, or both (“Intermediaries”). Intermediaries perform a number of services, described below, before, during, and after the surgeries in which the Products are used. Some of the services the Intermediaries provide are intermittent, while other services are performed in connection with each surgery. Requestor certified that it typically compensates Intermediaries for their services and that these services are included in the Product prices Requestor charges to hospitals.

Hospitals that choose to participate in the Proposed Arrangement (“Participating Hospitals”) would enter into an agreement with Requestor that has an initial 3-year term. Under the Proposed Arrangement, Participating Hospitals would purchase the Products directly from Requestor with no Intermediary assistance or involvement; rather, Participating Hospitals would assume all of the duties that otherwise would have been performed by the Intermediaries in connection with the Products. Specifically, Participating Hospitals would assume the following duties, usually performed by Intermediaries prior to surgery: (i) training all appropriate surgical staff on how to use the Products in the set or kit (a “Product Kit”); (ii) packing the Products into a Product Kit needed for a particular surgery and sterilizing the Product Kit; (iii) taking the proper Product Kit to the appropriate operating room on the day of surgery; (iv) inspecting the Product Kit to ensure that each part is in perfect condition; and (v) making sure that all needed Products, parts, and instruments for the particular surgery are present and that no additional or special Products are needed. After a surgery, a Participating Hospital would: (i) wash and repack the reusable parts of the Product Kit; (ii) determine if the Product Kit is missing any parts and order any necessary replacement parts from Requestor; and (iii) receive and restock the replacement parts so that they are ready to be packed into Product Kits for future surgeries.

In exchange for a Participating Hospital agreeing to assume Intermediaries’ duties, Requestor would offer the Products to the Participating Hospital at a reduced price. Requestor certified that this reduction would be approximately equal to the compensation otherwise paid to the Intermediaries. The Proposed Arrangement would be optional; a hospital would have the ability

¹ We use “person” herein to include persons, as referenced in the Federal anti-kickback statute, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

to choose to participate in this program as a Participating Hospital or to continue purchasing the Products through traditional channels where Intermediaries would perform their usual duties. If a Participating Hospital fails to comply with the terms of the Proposed Arrangement, Requestor would revert to selling the Products at the then-current price and using Intermediaries to perform all associated duties and would not renew the agreement with the hospital. After the initial 3-year term, any renewal agreement would be based on Requestor's own assessment and discretion.

II. LEGAL ANALYSIS

A. Law

Section 1128A(b)(1) of the Act prohibits a hospital or critical access hospital from knowingly making payments, directly or indirectly, to a physician to induce the physician to reduce or limit medically necessary services to Medicare or Medicaid beneficiaries who are under the physician's direct care. Hospitals and critical access hospitals that make (and physicians who receive) payments prohibited by this provision are liable for civil money penalties of up to \$5,000 for each patient for which the prohibited payment was made.²

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.³ The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.⁴ For purposes of the Federal 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 is to induce referrals for items or services reimbursable by a Federal health care program.⁵ Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to

² Sections 1128A(b)(1)–(2) of the Act (the "Gainsharing CMP").

³ Section 1128B(b) of the Act.

⁴ Id.

⁵ E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); 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).

impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

B. Analysis

1. Gainsharing CMP

The Gainsharing CMP prohibits a hospital or critical access hospital from knowingly making a payment directly or indirectly to a physician (and any physician from receiving such payment) to reduce or limit medically necessary items or services to Medicare or Medicaid beneficiaries under the physician’s direct care. The Proposed Arrangement does not involve any payments from a hospital or critical access hospital to physicians; therefore, the Proposed Arrangement does not implicate the Gainsharing CMP.

2. Federal Anti-Kickback Statute

Under the Proposed Arrangement, Requestor would offer a lower price on the Products to Participating Hospitals that assume responsibility for duties otherwise performed by Intermediaries. Offering a lower price on a product could be remuneration to induce referrals of items or services reimbursable by a Federal health care program and thus could implicate the Federal anti-kickback statute. However, the price Requestor currently charges hospitals includes not just the price of the Product but also the cost of the Intermediaries’ services associated with the Product. The Products would be available either through: (i) traditional distribution channels at one price that would include the Intermediaries’ services; or (ii) the Proposed Arrangement at a lower price, where the price reduction would be approximately equal to the compensation otherwise paid to the Intermediaries. Thus, under the Proposed Arrangement, Participating Hospitals would be purchasing only a Product rather than a “package” of a Product plus the Intermediary’s services. Rather than bestowing something of value, the reduction in price simply would reflect the reduction in services the Participating Hospital would be purchasing. We therefore conclude that, under the circumstances described above, the lower price⁶ that Requestor would offer to Participating Hospitals for the Products without the Intermediaries’ services would not constitute remuneration and would not implicate the Federal anti-kickback statute.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement, if undertaken, would not involve an improper payment to physicians to induce the reduction or limitation of medically necessary services under the Gainsharing CMP, and the OIG would not impose sanctions on Requestor under the Gainsharing CMP in connection with the Proposed Arrangement. In addition, we

⁶ Despite language suggesting that the Products would be offered at a “reduced” or “lower” price, the Proposed Arrangement does not involve a “discount” that would be analyzed under the discount safe harbor at 42 C.F.R. § 1001.952(h) for the reasons described herein.

conclude that the Proposed Arrangement, if undertaken, would not generate prohibited remuneration under the Federal anti-kickback statute, and therefore, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.
- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.
- This advisory opinion may not be introduced into evidence by a person other than Requestor to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion 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 (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.
- We express no opinion herein regarding the liability of any person 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 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, 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 Requestor with respect to any action that is part of the Proposed 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,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs