



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: May 22, 2026

Posted: May 28, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-12 (Favorable)

Dear [redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of [redacted] (“Requestor”), regarding Requestor’s proposed warranty program pursuant to which Requestor would refund certain concierge fees to patients who require revision surgery within 2 years of an initial surgery (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the “Act”), as that section relates to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

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 Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This advisory 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, have been misrepresented, or change, then this advisory 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 generate prohibited remuneration under the Federal anti-kickback statute or Beneficiary Inducements CMP. Accordingly, OIG would not impose administrative sanctions on Requestor in connection

with the Proposed Arrangement under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute; the Beneficiary Inducements CMP; or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

This advisory opinion may not be relied on by any person¹ other than Requestor, has no applicability to any arrangements other than the Proposed Arrangement, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Requestor, an orthopedic surgery provider, offers a voluntary concierge program (the “Concierge Program”) pursuant to which patients pay fees to access certain concierge items and services for 1 year following the date of a surgical procedure. Requestor certified that none of the items or services provided as part of the Concierge Program are covered by insurance, including Federal health care programs, although the surgeries may be covered by Federal health care programs. Requestor certified that the items and services provided as part of the Concierge Program are designed to support the patient’s recovery and ensure optimal post-surgical outcomes. Examples of these items and services include personalized coaching and education sessions from a wellness coach, a peri-operative nutritional supplement program, a wellness application membership that includes health data monitoring, and products, such as a leg elevator and compression garments. Requestor certified that the concierge fees are consistent with the fair market value of the items and services and are 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 a Federal health care program.

To participate in the Concierge Program, prior to the date of the surgery, patients would enter into a Membership Agreement with Requestor that sets forth the terms of the Concierge Program. Patients would be able to participate in the Concierge Program for any surgery. For example, a patient receiving a right-knee replacement could enter into a Membership Agreement with Requestor and participate in the Concierge Program, and then if the patient receives a left-knee replacement at a later time, they could enter into a new Membership Agreement with Requestor and pay to participate in the Concierge Program again (with the Concierge Program running for 1 year from the date of the surgery in each case).

For patients electing to participate in the Concierge Program for an initial surgery, Requestor would warrant in the Membership Agreement that a patient’s substantial compliance with the Concierge Program following the initial surgery will result in the patient not requiring revision surgery within 2 years of the date of the initial surgery (the “Warranty”). If a patient requires revision surgery within 2 years from the date of the initial surgery, then Requestor would refund the concierge fees that the patient paid to access the Concierge Program in connection with the

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

initial surgery.² Requestor would not refund any other patient costs or give patients anything else in connection with the Warranty. Requestor would not require patients to select Requestor for revision surgery. Requestor certified that only 1-2 percent of its patients have required revision surgery at the 2-year mark.

Requestor certified that it would not condition the Warranty on patients' exclusive use of, or a minimum purchase of, any of Requestor's items or services. Requestor further certified that it would fully and accurately report any refund it would issue as part of the Warranty to patients on an invoice or statement submitted to the patients. Additionally, the Membership Agreement patients and Requestor would sign when patients elect to participate in the Concierge Program for an initial surgery would obligate patients to provide such information upon request by the Secretary or a State agency.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

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

² Although patients could sign up for the Concierge Program in connection with revision surgery, those concierge fees would not be part of the Proposed Arrangement (*i.e.*, Requestor proposes only to refund concierge fees that a patient pays in order to participate in the Concierge Program in connection with an initial surgery but not concierge fees that a patient pays in connection with a revision surgery).

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).

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

Congress has developed several statutory exceptions to the Federal anti-kickback statute.⁶ In addition, the U.S. Department of Health and Human Services has promulgated safe harbor regulations that specify certain practices that are not treated as an offense under the Federal anti-kickback statute and do not serve as the basis for an exclusion.⁷ However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Compliance with a safe harbor is voluntary. Arrangements that do not comply with a safe harbor are evaluated on a case-by-case basis.

The safe harbor for warranties potentially applies to the Proposed Arrangement.⁸ Under that provision, safe harbor protection is available to a manufacturer or supplier offering a “warranty” (as defined by the safe harbor)⁹ on an item, a bundle of items, or a bundle of one or more items and related services. The safe harbor for warranties includes the following conditions:

- (1) The buyer (unless the buyer is a Federal health care program beneficiary) must fully and accurately report any price reduction of an item or service (including a free item or service) that was obtained as part of the warranty in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.
- (2) The buyer must provide, upon request by the Secretary or a State agency, information provided by the manufacturer or supplier as specified in paragraph (g)(3) of this section.
- (3) The manufacturer or supplier must comply with either of the following standards:
 - (i) The manufacturer or supplier must fully and accurately report any price reduction of an item or service (including free items and services) that the buyer obtained as part of the warranty on the invoice or statement submitted to the buyer and inform the buyer of its obligations under paragraphs (g)(1) and (2) of this section.
 - (ii) When the amount of any price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under

⁶ Section 1128B(b)(3) of the Act.

⁷ 42 C.F.R. § 1001.952.

⁸ 42 C.F.R. § 1001.952(g).

⁹ 42 C.F.R. § 1001.952(g)(7).

paragraphs (g)(1) and (g)(2) of this section, and when any price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.

(4) The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty.

(5) If a manufacturer or supplier offers a warranty for more than one item or one or more items and related services, the federally reimbursable items and services subject to the warranty must be reimbursed by the same Federal health care program and in the same Federal health care program payment.

(6) The manufacturer or supplier must not condition a warranty on a buyer's exclusive use of, or a minimum purchase of, any of the manufacturer's or supplier's items or services.¹⁰

2. Beneficiary Inducements CMP

The Beneficiary Inducements 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 beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value." The definition of "remuneration" includes an exception for "[a]ny permissible practice as specified in section 1128B(b)(3) of the Act or in regulations issued by the Secretary."¹¹

B. Analysis

The Proposed Arrangement implicates the Federal anti-kickback statute. Requestor would offer patients a refund on concierge fees paid to access the Concierge Program if the patient requires revision surgery within 2 years of the initial surgery. The offer of the refund under Requestor's Warranty could induce patients to choose Requestor for their surgery, which may be reimbursable in whole or in part by Federal health care programs. However, for the following reasons, we conclude that the Proposed Arrangement would be protected by the safe harbor for warranties.

The safe harbor for warranties defines "warranty" in three ways, including:

¹⁰ 42 C.F.R. § 1001.952(g)(1)-(6).

¹¹ 42 C.F.R. § 1003.110 (defining "remuneration").

Any undertaking in writing in connection with the sale by a manufacturer or supplier of an item or bundle of items, or services in combination with one or more related items, to refund, repair, replace, or take other remedial action with respect to such item or bundle of items in the event that such item or bundle of items, or services in combination with one or more related items, fails to meet the specifications set forth in the undertaking which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a seller and a buyer for purposes other than resell of such item or bundle of items.¹²

The terms of Requestor's proposed Warranty meet this definition. Pursuant to the Warranty, Requestor would warrant that a patient's substantial compliance with the Concierge Program following an initial surgery will result in the patient not requiring revision surgery within 2 years of the date of the initial surgery, and Requestor would refund the concierge fees in the event a patient substantially complied with the Concierge Program following an initial surgery and still required revision surgery within 2 years following the date of the initial surgery. The Warranty would be included in the Membership Agreement patients sign prior to undergoing an initial surgery and participating in the Concierge Program. Therefore, the Warranty would be an undertaking in writing for Requestor to take remedial action with respect to a bundle of items and related services, which undertaking would form part of the basis of the bargain between Requestor and the patient.

In order to be protected by the safe harbor for warranties, both the buyer (*i.e.*, the patient) and the supplier (*i.e.*, Requestor) must comply with all of the applicable elements set forth in the safe harbor. Because none of the items or services provided as part of the Concierge Program are covered by insurance, including Federal health care programs, and because Requestor would offer a warranty remedy only to patients, only certain elements of the safe harbor apply.¹³

Based on Requestor's factual certifications, the following conditions of the safe harbor for warranties would apply to the Proposed Arrangement, and all of the conditions would be satisfied:

- Requestor certified that it would fully and accurately report the refund it would issue to patients as part of the Warranty on an invoice or statement submitted to the patients, and

¹² 42 C.F.R. § 1001.952(g)(7)(ii).

¹³ Some conditions of the safe harbor are not applicable to the Proposed Arrangement like the safe harbor condition prohibiting a manufacturer or supplier from paying any remuneration to an individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty. This condition does not apply to the Proposed Arrangement because: (i) Requestor would pay remuneration only to patients, and the patients relevant to our Federal anti-kickback statute analysis would be Federal health care program beneficiaries; and (ii) the remuneration is not for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty.

Requestor would inform patients—through the Membership Agreement—of their obligation to provide such information upon request by the Secretary or a State agency.

- With respect to patients who are Federal health care program beneficiaries, their only obligation under the safe harbor would be to provide, upon request by the Secretary or a State agency, the information provided by Requestor with respect to any refund Requestor issued to the patients, and through the Membership Agreement, patients would agree to fulfill this requirement.
- Requestor certified that it would not condition the Warranty on patients' exclusive use of, or a minimum purchase of, any of Requestor's items or services.

Based on the foregoing, we conclude that the Proposed Arrangement would be protected by the safe harbor for warranties and therefore would not generate prohibited remuneration under the Federal anti-kickback statute.¹⁴ Additionally, because the Proposed Arrangement would comply with a safe harbor to the Federal anti-kickback statute, the Proposed Arrangement would not constitute remuneration under the Beneficiary Inducements CMP.¹⁵

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 generate prohibited remuneration under the Federal anti-kickback statute or Beneficiary Inducements CMP. Accordingly, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute; the Beneficiary Inducements CMP; or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

¹⁴ We distinguish the items and services provided under the Proposed Arrangement through the Concierge Program, for which patients must pay prior to undergoing surgery to the extent the patients want to participate in the Concierge Program, from the offer and provision of free concierge or other items and services in connection with surgery. Such free items and services would not be protected by the safe harbor for warranties, and we have longstanding and continuing concerns regarding the provision of free items or services by individuals and entities, including physicians, to patients that could lead to the ordering and provision of an item or service payable by Federal health care programs.

¹⁵ 42 C.F.R. § 1003.110 (defining “remuneration” as not including “[a]ny permissible practice as specified in section 1128B(b)(3) of the Act or in regulations issued by the Secretary.”).

IV. LIMITATIONS

The limitations applicable to this advisory opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement. This advisory opinion has no applicability to any other arrangements, including, without limitation, any 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 advisory opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

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. 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, 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 OIG.

Sincerely,

/Susan E. Gillin/

Susan E. Gillin
Assistant Inspector General for Legal Affairs