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: September 10, 2021
Posted: September 15, 2021

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 21-12

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 to implement a program offering certain free items and services to patients who experience specific complications after undergoing certain joint replacement procedures (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 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 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: (i) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, 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; and (ii) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

This opinion may not be relied on by any person[1] 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 is a not-for-profit critical access hospital located in [city and state redacted] that serves a rural, eight-county region across two states, and the next nearest hospital is more than 40 miles away. Under the Proposed Arrangement, Requestor would offer an arrangement similar to a warranty[2] applicable to specific joint replacement procedures performed by Requestor's two employed orthopedic surgeons (the "Surgeons"). Specifically, for patients who meet the qualifying criteria described below, Requestor would not bill the patient or the patient's insurer, including Federal health care programs, for certain items and services provided to treat complications that occur within 90 days of a qualifying joint replacement procedure.

A. Eligibility Requirements

The Proposed Arrangement would apply only to patients who: (i) undergo a certain type of surgical procedure; (ii) experience a certain type of complication; and (iii) meet specific clinical criteria (each a "Qualifying Patient"). First, the Proposed Arrangement would apply only to patients receiving primary[3] total knee, total hip, or partial knee arthroplasty procedures from one of the Surgeons (the "Covered Surgeries"). Patients who receive procedures similar to the Covered Surgeries—for example, revision surgery, conversion of a previous hip surgery to a total hip

[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.

[2] As noted in Part II below, the Proposed Arrangement would not meet the definition of "warranty" as set forth in 42 C.F.R. § 1001.952(g)(7).

[3] A "primary" procedure means the procedure is the patient's first total knee, total hip, or partial knee arthroplasty surgery on a particular joint.

replacement, and non-elective total hip replacement for a fracture—would not be eligible for the Proposed Arrangement.

Second, the Proposed Arrangement would apply only to a patient who develops certain complications within 90 days of receiving a Covered Surgery at Requestor's facility. Requestor selected 60 diagnosis codes that represent the universe of complications that could trigger the Proposed Arrangement (each, a "Covered Complication"), based on what Requestor believes to be the most common complications resulting from Covered Surgeries. These Covered Complications include the following: (i) peri-prosthetic infection (infection related to the replacement joint); (ii) peri-prosthetic fracture (fracture related to the replacement joint); (iii) mechanical loosening of prosthesis components; (iv) dislocation or instability of a prosthesis; and (v) other mechanical complications of a prosthesis.

Third, the Proposed Arrangement would be available only to patients who meet the following clinical criteria, which Requestor developed in collaboration with the Surgeons: (i) the patient's body mass index, hemoglobin A1c, and albumin level are within a defined range on the date of surgery and upon diagnosis of a Covered Condition; (ii) the patient is nicotine free for 2 weeks prior to the date of surgery and 6 weeks after the date of surgery; and (iii) the patient adheres to Requestor's post-surgical follow-up appointment schedule.

According to Requestor, prior to undergoing a Covered Surgery, Qualifying Patients would receive and would be asked to sign a detailed disclosure of the terms and conditions of the Proposed Arrangement, in addition to the customary surgical informed consent. All Qualifying Patients would be eligible to participate in the Proposed Arrangement.

B. Implementation of the Proposed Arrangement

For any Qualifying Patient, Requestor would furnish items and services, worth up to $50,000 in total charges, to treat the Covered Complication(s) within 90 days after the diagnosis of a Covered Complication—without billing the Qualifying Patient or the insurer ("Covered Items and Services").[4] Covered Items and Services would include, for example, revision surgery, a replacement prosthesis, anesthesia and associated services, drugs, operating room fees, supplies, an inpatient stay, physical therapy, and occupational therapy. Requestor generally would absorb the full cost of any Covered Items and Services provided to treat Covered Complications under the Proposed Arrangement, subject to the $50,000 cap. Requestor would, however, exercise its rights,

[4] According to Requestor, the $50,000 limit would be sufficient to include all Covered Items and Services provided by Requestor in the vast majority of cases, including those requiring revision surgery. In the event the Covered Items and Services exceed the $50,000 limit, if a patient has insurance, Requestor would apply the contractual rate for the items and services and bill the insurer for any amount in excess of $50,000, less any cost sharing the patient would owe (calculated based on charges in excess of $50,000). If the patient is uninsured, Requestor would apply an uninsured discount first and bill the patient for any amount in excess of $50,000.

if any, under an agreement with a manufacturer (for example, a manufacturer's warranty) or supplier to obtain a replacement implant or other medical device in the event the Covered Items and Services include a replacement implant or other medical device.[5] Charges for items or services for which Requestor receives a warranty remedy from a manufacturer or supplier would not count toward the $50,000 limit. Under the Proposed Arrangement, the Covered Items and Services must be furnished by Requestor; items and services furnished by other providers or suppliers would not be covered under the Proposed Arrangement.

C. Additional Features of the Proposed Arrangement

Requestor certified that it would not shift the burden of financial losses stemming from the Proposed Arrangement to either payors or patients. To ensure this, Requestor would allocate the costs of the Covered Items and Services as a separate line item under non-allowable costs on its Federal and State cost reports so that they would not be reimbursed and would not affect the hospital's cost-to-charge ratio but still would be auditable. Requestor certified that it would take similar actions to ensure the financial losses are not shifted to commercial payors. Also, for Qualifying Patients who are Federal health care program beneficiaries, Requestor certified that it would submit no-pay claims for Covered Items and Services.

Requestor would inform current and prospective patients about the Proposed Arrangement through various methods, including, but not limited to: (i) one-on-one discussions with prospective patients and referring providers; (ii) community education sessions; (iii) service line brochures; (iv) newspaper articles; (v) television commercials; (vi) newsletters; and (vii) its website. Each communication would note the limited nature of the Proposed Arrangement, and it would include the specific details within the actual communication, if practicable. Each communication also would state that additional information can be obtained from Requestor and the Surgeons upon request.

Requestor certified that it would defer to the Surgeons for all clinical decisions relating to orthopedic surgical patients or potential orthopedic surgical patients and that it would rely on the Surgeons' determination, in their independent medical judgment, that the Covered Surgery is medically necessary. The Surgeons are compensated through five-year employment agreements, with productivity incentives based on personally performed work relative value units. The Surgeons would be compensated for performing Covered Items and Services in the same way they are paid for other services provided at Requestor's facility.

Requestor certified that it would implement a number of measures intended to monitor and ensure the quality of care provided to patients undergoing joint replacement procedures—including Covered Surgeries—at Requestor's facility. For example, Requestor would implement evidence-based, professionally recognized standards of practice and pathways, protocols, order sets, and

[5] We express no opinion on any arrangements between Requestor and manufacturers or suppliers, such as warranty arrangements covering surgical devices.

processes to ensure appropriate identification, evaluation, and treatment of all joint replacement patients. Requestor also would implement a quality assurance and performance improvement

program to address priorities for improving quality of care and patient safety and to ensure that corrective and preventive actions are implemented. In addition, Requestor would convene an interdisciplinary team to conduct monthly reviews of joint replacement procedures that involve complications, readmissions, and returns to the operating room. The interdisciplinary team also would conduct a quarterly review of joint replacement quality data.

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.[6] 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.[7] 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.[8] 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 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.

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[6] Section 1128B(b) of the Act.

[7] Id.

[8] 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).

Congress has developed several statutory exceptions to the Federal anti-kickback statute.[9] 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.[10] 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[11] potentially relates to the Proposed Arrangement. Under that provision, safe harbor protection is available to a "manufacturer or supplier" offering a warranty on an item, a bundle of items, or a bundle of one or more items and related services, and the safe harbor sets forth disclosure and reporting obligations that apply to the manufacturer or supplier and the "buyer." The warranties safe harbor also contains a definition of the term "warranty" specific to that safe harbor.[12]

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. The 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."

B. Analysis

Under the Proposed Arrangement, Requestor would offer potential surgical patients and give Qualifying Patients, some of whom may be Federal health care program beneficiaries, something of value—free Covered Items and Services in the event of a Covered Complication—that could induce such patients to have a Covered Surgery performed at Requestor's facility or to receive other items and services at Requestor's facility. As a result, the Proposed Arrangement would implicate both the Federal anti-kickback statute and the Beneficiary Inducements CMP. The Proposed Arrangement also would constitute remuneration to payors—including, for example, Medicare

[9] Section 1128B(b)(3) of the Act.

[10] 42 C.F.R. § 1001.952.

[11] Id. § 1001.952(g).

[12] Id. § 1001.952(g)(7).

Advantage plans—in the form of costs avoided because Requestor would not bill for Covered Items and Services furnished following a Covered Complication (up to the $50,000 limit). The offer of such potential remuneration could induce a payor to refer beneficiaries to Requestor to receive Covered Surgeries (e.g., by including Requestor within its preferred provider network), which would implicate the Federal anti-kickback statute.

We first consider whether the Proposed Arrangement would be protected by any safe harbor to the Federal anti-kickback statute or exception to the definition of "remuneration" for purposes of the Beneficiary Inducements CMP. The warranties safe harbor protects certain remuneration provided by manufacturers and suppliers to address products that fail to meet bargained-for requirements. Because the warranties safe harbor protects only remuneration offered by a "manufacturer or supplier," the remuneration that would be provided under the Proposed Arrangement would not meet the safe harbor. The Medicare regulations and common industry understanding categorize critical access hospitals as "providers," not manufacturers or suppliers.[13] Accordingly, the remuneration provided under the Proposed Arrangement by Requestor, a critical access hospital, is not eligible for protection under the warranties safe harbor.[14] The Proposed Arrangement also is not eligible for protection under any of the exceptions to the definition of "remuneration" for purposes of the Beneficiary Inducement CMP. Arrangements that do not fit in a safe harbor or exception must be evaluated on a case-by-case basis, based on the totality of the facts and circumstances.

For the combination of reasons set forth below, we conclude that the Proposed Arrangement would present a minimal risk of fraud and abuse under the Federal anti-kickback statute and, in an exercise of our discretion, we would not impose sanctions under the Beneficiary Inducements CMP.

First, the Proposed Arrangement seems designed to promote quality of care and better outcomes with respect to the Covered Surgeries by providing an incentive for Requestor to reduce its financial exposure by attempting to prevent Covered Complications. To the extent the Proposed Arrangement achieves this purpose, it also has the potential to benefit patients, Federal health care programs, and other payors. In addition, it is possible that the Proposed Arrangement could result in decreased costs to Federal health care programs and beneficiaries because Requestor would not bill for otherwise billable Covered Items and Services up to the $50,000 cap in the event of a Covered Complication.

Second, the safeguards in the Proposed Arrangement reduce the risk that the Proposed Arrangement would interfere with or skew clinical decision making or result in reductions in medically necessary care. Arrangements akin to warranties have the potential to influence physician judgment by, for example, providing incentives for "cherry picking" only the healthiest patients for Covered

[13] Id. § 400.202.

[14] In addition, the definition of "warranty" for purposes of the warranties safe harbor applies only to remuneration offered by a "manufacturer or supplier." 42 C.F.R. § 1001.952(g)(7). Therefore, the Proposed Arrangement would not be considered a "warranty" under the safe harbor.

Surgeries and "lemon dropping" or referring more complicated (and potentially more costly) patients to other hospitals. The Proposed Arrangement also has the potential to create an incentive for Requestor to discourage the diagnosis of Covered Complications because Requestor would not bill for Covered Items and Services provided as the result of a Covered Complication (up to the $50,000 limit).

These risks are mitigated, in part, by the Surgeons' independent exercise of their medical judgment. Under the Proposed Arrangement, clinical decisions relating to patients or potential patients would be made exclusively by the Surgeons. Requestor certified that—due to their compensation structure as salaried employees—the Surgeons do not have a direct financial stake in the program, and the Surgeons' compensation would not be negatively impacted in the event the hospital provides Covered Items and Services under the Proposed Arrangement. These features serve as a check on Requestor's ability to influence patient selection in a way that might result in cherry picking or lemon dropping. In addition, there appears to be no direct financial incentive for the Surgeons to stint on medically necessary follow-up care because the Surgeons would be compensated for performing Covered Items and Services in the same way they are paid for other services provided at Requestor's facility. Requestor also would implement a number of oversight mechanisms—evidence-based protocols, a quality assurance and performance improvement program, and periodic review of joint replacement procedures by an interdisciplinary team—that reduce the likelihood that the Proposed Arrangement would result in diminished quality of care.

Third, the Proposed Arrangement is unlikely to lead to overutilization or inappropriate utilization of items or services reimbursable by Federal health care programs. Although Requestor would advertise the Proposed Arrangement to prospective surgical patients, patients would be eligible for surgery only if the Surgeons, in their independent medical judgment, determine that surgery is medically necessary. Moreover, Requestor's oversight protocols, in particular the adoption of professionally recognized standards of practice and pathways, protocols, order sets, and processes, are intended, in part, to ensure appropriate identification of potential joint replacement patients, which further reduces the risk of overutilization of Covered Surgeries.

Finally, although the Proposed Arrangement could result in steering of potential orthopedic surgical patients to Requestor to receive Covered Surgeries, we believe the potential for inappropriate steering is reduced by mitigating factors. In particular, because Requestor is a critical access hospital serving a rural, eight-county region across two states, and the nearest hospital is more than 40 miles from Requestor, a potential patient's options of health care providers may be limited, which would make it less likely that the Proposed Arrangement would inappropriately influence a patient's choice of provider.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, 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; and (ii) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

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