



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: April 26, 2021

Posted: April 29, 2021

[Name and address redacted]

Re: OIG Advisory Opinion No. 21-02

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] (the “Health System”) and [name redacted] (the “Manager,” and together with the Health System, “Requestors”) regarding an investment by the Health System, the Manager, and certain surgeons in an ambulatory surgery center (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (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”).

Requestors have 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 Requestors. This opinion is limited to the relevant facts presented to us by Requestors 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, 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 Requestors 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 Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Parties

Under the Proposed Arrangement, the Health System, certain orthopedic surgeons and neurosurgeons employed by the Health System (the “Physician Investors”), and the Manager would invest in a new ambulatory surgery center (the “New ASC”).² The Physician Investors would consist of five orthopedic surgeons and three neurosurgeons.

The Manager develops and manages ambulatory surgery centers (“ASCs”) nationwide and would provide management, consulting, administrative, and other services to the New ASC. The Manager certified that it would not make or influence referrals, directly or indirectly, to the Physician Investors or to the New ASC. Additionally, no physician has or would have ownership in the Manager.

B. New ASC Ownership

Under the Proposed Arrangement, the Health System would own 46 percent of the New ASC, the Physician Investors collectively would own 46 percent, and the Manager would own 8 percent. The Physician Investors individually would own interests in the New ASC ranging from 4 percent to 8 percent.³ All New ASC investors would invest directly in the New ASC (i.e., no investor would invest through a pass-through entity). Neither the New ASC nor any investor would loan funds to, or guarantee a loan for, any investor to obtain ownership in the New ASC. Ownership in the New ASC was not offered, and would not be offered in the future, to any potential investor based on the previous or expected volume or value of referrals made by the potential investor. Capital contributions and profit distributions would be made in proportion to an investor’s ownership in the New ASC.

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 We have no facts, and express no opinion, with regard to any existing or future financial arrangements between or among these parties other than the proposed offer of ownership in, and profit distributions from, the New ASC under the Proposed Arrangement.

³ While the aggregate ownership by the Physician Investors would be 46 percent, each Physician Investor would determine the percentage ownership he or she holds in the New ASC. Neither the Health System, the Manager, nor the New ASC would participate in any investment decision made by a Physician Investor.

The Health System and physicians affiliated with the Health System, including Physician Investors, would be in a position to make or influence referrals of Federal health care program beneficiaries to the New ASC. To limit the ability of such physicians to make or influence referrals, the Health System would refrain from any action requiring or encouraging physicians who are its employees, independent contractors, or medical staff members (“Affiliated Physicians”) to refer patients to the New ASC or to the Physician Investors. The Health System certified that it would not track referrals made to the New ASC by Affiliated Physicians. In addition, the Health System certified that no Affiliated Physician arrangement with the Health System, including any Physician Investor employment arrangement, would require the Affiliated Physician to refer to the New ASC. Further, any compensation for services furnished that would be paid by the Health System to Affiliated Physicians, including employee compensation that would be paid to Physician Investors, would be consistent with fair market value and would not be related, directly or indirectly, to the volume or value of referrals Affiliated Physicians may make to the New ASC or its Physician Investors.

C. Physician Investor Procedures and Income

The Health System certified that at least one-third of procedures performed by Physician Investors each year that would be payable by Medicare when performed in an ASC (“ASC-Qualified Procedures”) would be performed at the New ASC. It further certified that each orthopedic surgeon Physician Investor would receive at least one-third of his or her medical practice income for the previous fiscal year or previous 12-month period from ASC-Qualified Procedures. The Manager would monitor each Physician Investor’s compliance with these procedure and medical practice income requirements under the Proposed Arrangement.

However, not all neurosurgeon Physician Investors would derive one-third of their medical practice income for the previous fiscal year or previous 12-month period from the performance of ASC-Qualified Procedures. According to the Health System, neurosurgeon Physician Investors primarily derive their medical practice income from inpatient hospital procedures and would continue to do so following their investment in the New ASC. Nonetheless, the Health System certified that neurosurgeon Physician Investors would use the New ASC on a regular basis as part of their medical practices (e.g., to personally perform neuroplasty procedures). The Health System also certified that the Physician Investors rarely would refer patients to each other for ASC-Qualified Procedures; in fact, the Health System estimated that the number of procedures referred by Physician Investors that would be performed at the New ASC by other Physician Investors (i.e., procedures that would not be performed personally by the referring Physician Investor) would be less than 1 percent of the aggregate number of ASC-Qualified Procedures performed at the New ASC each year.

D. Additional Program Parameters

The New ASC would operate in a newly constructed medical facility owned by a real estate joint venture that is owned by the Health System, the Physician Investors, and the Manager (the “Real Estate Company”). The New ASC would enter into space and equipment leases as well as services arrangements with the Health System and the Real Estate Company. The Health System certified that any space or equipment leased by the New ASC from the Health System or the

Real Estate Company, and any services performed by the Health System or Real Estate Company for the New ASC, would comply with the Federal anti-kickback statute safe harbors for space rental, equipment rental, or personal services and management contracts and outcomes-based payment arrangements, as applicable.⁴

According to the Health System, the New ASC, on behalf of its investors, would provide written notice to patients referred to the New ASC by any investor of such investor's ownership in the New ASC. Additionally, the Health System certified that the New ASC and its Physician Investors would treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

The Health System certified that all ancillary services provided to Federal health care program beneficiaries at the New ASC would be related directly and integrally to primary procedures performed at the New ASC and would not be billed separately to any Federal health care program. In addition, the Health System would not include on any cost report or any claim for payment from a Federal health care program any costs associated with the New ASC, unless such costs are required to be included by a Federal health care program.

II. LEGAL ANALYSIS

A. Law

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.⁵ 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.⁶ 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.⁷ 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

⁴ See 42 C.F.R. §1001.952 (b), (c), and (d), respectively.

⁵ Section 1128B(b) of the Act.

⁶ Id.

⁷ 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).

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.

Congress has developed several statutory exceptions to the Federal anti-kickback statute.⁸ In addition, the U.S. Department of Health and Human Services has promulgated safe harbor regulations that, if met, would protect persons from sanctions under the Federal anti-kickback statute.⁹ 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 provision for ASCs (the “ASC Safe Harbor”)¹⁰ is potentially applicable to the Proposed Arrangement. Under the ASC Safe Harbor, remuneration does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor, as long as the investment entity is a certified ASC and meets certain additional safeguards that vary based on the type of investors that own the ASC. One purpose of the ASC Safe Harbor is to protect payments of investment returns by an ASC to owners who refer patients to the ASC. In particular, the ASC Safe Harbor contemplates surgeon-owners referring patients to the ASC and personally performing surgical procedures on those patients.¹¹

Under the ASC Safe Harbor provision applicable to ASCs jointly owned by hospitals and physicians, paragraph (r)(4) (the “Hospital-Physician ASC Safe Harbor Provision”), there must be at least one hospital investor, and all physician investors must meet the requirements of paragraph (r)(1), (r)(2), or (r)(3) of the ASC Safe Harbor (*i.e.*, physician owners must be all surgeons, all physicians of the same specialty, or multi-specialty physicians, each of whom would be in a position to refer and perform surgeries at the ASC). Paragraph (r)(3)—incorporated as a condition of paragraph (r)(4)—includes certain requirements related to medical practice income and procedures; in particular, under (r)(3)(ii), at least one-third of each physician investor’s medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician’s performance of ASC-Qualified Procedures, and under (r)(3)(iii), at least one-third of the procedures performed by each physician investor for the previous fiscal year or previous 12-month period must be performed at the investment entity. Paragraph (r)(4) also contains additional requirements, including a requirement that the terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise

⁸ Section 1128B(b)(3) of the Act.

⁹ 42 C.F.R. § 1001.952.

¹⁰ 42 C.F.R. § 1001.952(r).

¹¹ *Id.*

generated from that investor to the entity. Compliance with a safe harbor is voluntary. Arrangements that do not comply with a safe harbor are evaluated on a case-by-case basis.

B. Analysis

Under the Proposed Arrangement, the Health System, the Physician Investors, and the Manager would invest in the New ASC. The offer or payment of investment returns from an ASC to an investor constitutes remuneration under the Federal anti-kickback statute.

With respect to the Manager's investment interest, although the Manager may be in a position to directly or indirectly influence referrals of items or services reimbursable by a Federal health care program to the New ASC, thereby implicating the Federal anti-kickback statute, it certified that: (i) it would not make or influence referrals, directly or indirectly, to the Physician Investors or to the New ASC; and (ii) no physician has or would have ownership in the Manager. These safeguards mitigate the risk that the offer or payment of investment returns by the New ASC to the Manager would be problematic under the Federal anti-kickback statute.

Second, with respect to the Physician Investors' and the Health System's investment interest, we likewise conclude that both parties would be in a position to make or influence referrals for items and services reimbursable by a Federal health care program furnished by the New ASC, implicating the Federal anti-kickback statute. In particular, the Health System would be in a position to influence referrals to the New ASC through its financial arrangements (e.g., employment agreements) with Affiliated Physicians, and Physician Investors could profit from their referrals to other Physician Investors who perform procedures at the New ASC. Any payments that are a return on the Health System's or Physician Investors' investment interest in the New ASC would fail to qualify for protection under the ASC Safe Harbor because, among other reasons: (i) the Health System would be in a position to make or influence referrals directly or indirectly to the Physician Investors and the New ASC; and (ii) certain Physician Investors would fail to meet the requirements set forth in paragraph (r)(3)(ii)-(iii), which are incorporated as a condition of the Hospital-Physician ASC Safe Harbor Provision, namely, not all of the neurosurgeon Physician Investors would derive at least one-third of his or her medical practice income from all sources for the previous fiscal year or previous 12-month period from the neurosurgeon Physician Investor's performance of ASC-Qualified Procedures. However, for the combination of the following reasons, we conclude that the Proposed Arrangement presents a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute, and we would not impose administrative sanctions on the Health System or the Manager, the requestors of this advisory opinion, in connection with the Proposed Arrangement.

First, although one or more of the neurosurgeon Physician Investors would fail to meet the Hospital-Physician ASC Safe Harbor Provision requirement that a physician investor derive at least one-third of his or her medical practice income for the previous fiscal year or previous 12-month period from the performance of ASC-Qualified Procedures, the Health System certified that neurosurgeon Physician Investors would use the New ASC on a regular basis as part of their medical practices. Additionally, the Health System certified that Physician Investors would rarely refer patients to each other for ASC-Qualified Procedures. In fact, the Health System estimated that the number of procedures referred by Physician Investors that would be performed

at the New ASC by other Physician Investors (i.e., procedures that would not be performed personally by the referring Physician Investor) would be fewer than 1 percent of the aggregate number of ASC-Qualified Procedures performed at the New ASC each year. In other words, the Physician Investors would personally perform almost all ASC-Qualified Procedures he or she refers to the New ASC. Based on these facts, the Physician Investors would not be significant sources of cross-referrals to other Physician Investors to generate New ASC profit distributions.

Second, the Proposed Arrangement would contain certain safeguards to reduce the risk that the Health System would make or influence referrals to the New ASC or the Physician Investors. For example, the Health System certified that any compensation paid by the Health System to Affiliated Physicians for services furnished, e.g., an employee or personal services arrangement, would be consistent with fair market value and would not be related, directly or indirectly, to the volume or value of referrals Affiliated Physicians may make to the New ASC or its Physician Investors. In addition, the Health System certified that it would refrain from any action to require or encourage Affiliated Physicians to refer patients to the New ASC or to its Physician Investors and would not track referrals made to the New ASC by Affiliated Physicians.

Third, certain factors in the Proposed Arrangement reduce the risk that investors who are referral sources for the New ASC would be rewarded for their referrals through: (i) the offer of ownership based on past or future referrals; or (ii) New ASC profit distributions that are disproportionate to their ownership in the New ASC and are tied to referrals. For example, neither the New ASC, nor any investor, would loan funds to or guarantee a loan for any investor to obtain ownership in the New ASC. The New ASC would not offer ownership to any party based on the previous or expected volume or value of referrals made by any party to the Proposed Arrangement. In addition, capital contributions and profit distributions would be made in proportion to an investor's ownership in the New ASC. Further, all New ASC investors would invest directly in the New ASC (i.e., no investor would hold any ownership through a pass-through entity, which could be used to redirect revenues to reward referrals or otherwise erode the safeguards provided by direct investment).

Fourth, certain safeguards within the Proposed Arrangement reduce the risk that the New ASC's investors would receive profit distributions for referrals of patients to the New ASC. The Health System certified that any space or equipment leased by the New ASC from the Health System or the Real Estate Company would comply with the Federal anti-kickback statute safe harbors for space rental and equipment rental, as applicable, and any services performed by the Health System or the Real Estate Company for the New ASC would comply with the safe harbor for personal services and management contracts and outcomes-based payments. In addition, the New ASC and its investors would provide written notice to patients referred by New ASC investors to the New ASC of the referral source's investment interest in the New ASC.

Finally, the Proposed Arrangement contains other safeguards designed to reduce fraud and abuse risks (e.g., improper billing). The New ASC, the Health System, the Physician Investors, and the Manager would treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner. Further, the Health System certified that all ancillary services provided to Federal health care program beneficiaries performed at the New ASC would be related directly and integrally to primary procedures performed at the New ASC

and would not be billed separately to Medicare or any Federal health care program. The Health System also certified that it would not include on any cost report or any claim for payment from a Federal health care program any costs associated with the New ASC, unless such costs are required to be included by a Federal health care program.

For all of the foregoing reasons, we conclude that the Proposed Arrangement is sufficiently low risk under the Federal anti-kickback statute, and we would not impose administrative sanctions on the Health System or the Manager in connection with the Proposed Arrangement.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, 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 Requestors 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 Requestors. 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 Requestors 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 Requestors 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 Requestors 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