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(s).*]

Issued: November 17, 2021

Posted: November 22, 2021

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 21-18

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 proposed joint venture for the provision of therapy services (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").

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 opinion is limited to the relevant facts presented to us by Requestor in connection with the Proposed Arrangement.

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 generate prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act.

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 contract therapy services company that provides management of day-to-day operations and therapy staffing for rehabilitation programs in long-term care communities, including skilled nursing facilities, assisted living facilities, and full-service continuing care retirement communities (collectively, "Facilities"). Under the Proposed Arrangement, Requestor would enter into a joint venture with a company that directly or indirectly owns Facilities (the "JV Partner"), and the joint venture entity ("Newco") would provide contract therapy services to rehabilitation programs in Facilities.

Requestor would form Newco and enter into a management services agreement ("MSA") with Newco to provide the clinical and back-office employees, space, and equipment necessary for Newco's operations in exchange for a fee that is consistent with fair market value.[2] Thereafter, the JV Partner would purchase a 40 percent interest in Newco, resulting in Requestor owning a 60 percent interest in Newco. Requestor certified that the purchase price for the JV Partner's investment interest in Newco would be based on a third-party valuation and would be consistent with fair market value.

Distributions from Newco to Requestor and the JV Partner would be proportional to their respective ownership interests in Newco. Newco's board of directors would consist of members appointed by both Requestor and the JV Partner, but the JV Partner would not be involved in the day-to-day operations of Newco. Newco would not have any employees; it would lease all clinical and back-office staff from Requestor through the MSA.

Requestor certified that the JV Partner's investment in Newco would be based, in part, on Newco's expected business with Facilities that the JV Partner owns either directly or indirectly ("Affiliated Facilities"). Though the JV Partner would not be obligated to contract with or otherwise make or direct referrals to Newco for therapy services, either directly or through Affiliated Facilities, Requestor expects that the JV Partner would do so. Specifically, as the owner of the Affiliated Facilities, the JV Partner would be in a position to control or influence the amount of business the Affiliated Facilities direct to Newco, and Requestor stated that it is likely that the JV Partner would terminate its current therapy services contracts (or direct its Affiliated Facilities to terminate their current therapy services contracts), which may or may not be with Requestor, and enter into therapy services contracts with Newco. Under these new contracts, Newco would furnish the same contract therapy services that Requestor (or the

[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.

[2] We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. Section 1128D(b)(3)(A) of the Act.

Affiliated Facility's current therapy services provider) currently provides to the Affiliated Facilities.

Requestor further certified that, during the initial phases of the joint venture, Requestor would likely only contract with Affiliated Facilities, and therefore all of Newco's revenues would likely be generated by therapy services agreements with Affiliated Facilities. However, Newco would not limit its operations to Affiliated Facilities and would, over time, seek to expand its business beyond Affiliated Facilities.

Consistent with Requestor's current business practice, Newco would not bill Federal health care programs directly for its services. Newco would bill the Facilities it contracts with for its services (including Affiliated Facilities), and those Facilities would pay Newco a fair market value fee for Newco's services. The Facilities would be responsible for billing and collecting from payors, including Federal health care programs, for services provided by Newco.

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.[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 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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[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).

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.

Because the Proposed Arrangement would involve ownership of a non-public entity by interested investors, the small entity investment safe harbor is potentially applicable (the "Small Entity Investment Safe Harbor").[8] This safe harbor requires that, among other things: (i) no more than 40 percent of an entity's investment interests are held by investors in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity (the "Investor Test"); (ii) no more than 40 percent of an entity's gross revenues come from referrals or business otherwise generated from investors (the "Revenue Test"); and (iii) the terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity are not related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity (the "Investment Offer Test").[9] With respect to the Investor Test, investors who provide items and services are classified together with investors who make or influence referrals to the entity. We have observed that this safeguard "is necessary to preclude a supplier, such as a DME company, from forming a joint venture with referring physicians, giving them a 39 percent interest in the entity," concluding, "[i]t would be inappropriate to grant safe harbor protection to such an entity because all of the owners would be doing business with the joint venture by either furnishing items or making referrals."[10]

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

[7] 42 C.F.R. § 1001.952.

[8] See 42 C.F.R. § 1001.952(a)(2).

[9] 42 C.F.R. § 1001.952(a)(2)(i) and (iii)-(vi).

[10] Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,968 (Jul. 29, 1991); see also Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,523 (Nov. 19, 1999) ("We continue to believe that the appropriate focus under this safe harbor is the status of the investors and the ability of the investors to make or influence the investment entity's referral stream or level of business activity. Investors that furnish items or services to the entity, as well as investors that refer patients or otherwise generate business for the entity, are 'tainted' investors doing business with the entity for purposes of the [Investor Test]. Thus, to iterate the example provided in the preamble to the 1991 final rule, if a durable

B. Analysis

The Proposed Arrangement would implicate the Federal anti-kickback statute because it would involve a joint venture for the furnishing of items and services that are reimbursable by a Federal health care program between a party in a position to refer, arrange for, or recommend those items and services and a party that currently provides those covered items or services. OIG has longstanding and continuing concerns about these types of joint venture arrangements, especially where all or most of the business from the joint venture is derived from one of the joint venture investors.[11] Consistent with these concerns, and for the reasons set forth more fully below, we conclude that the Proposed Arrangement presents more than a minimal risk of fraud and abuse.

1. No Safe Harbor Protection

As a threshold matter, we conclude that the remuneration exchanged under the Proposed Arrangement would not qualify for protection under any safe harbor.

The Small Entity Investment Safe Harbor would not protect any payments that are a return on an investment interest in Newco because several aspects of the Proposed Arrangement conflict with the safe harbor's requirements. For example, more than 40 percent of Newco would be owned by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for Newco, which fails the Investor Test. Likewise, Newco would be expected to derive more than 40 percent of its revenues from referrals from Affiliated Facilities, which would fail the Revenue Test. Requestor also certified that the JV Partner's investment in Newco would be based, in part, on Newco's expected business with Affiliated Facilities, which fails the Investment Offer Test.

The Proposed Arrangement could also include other remuneration for which no safe harbor protection would be available, such as the opportunity for the JV Partner to generate a profit through the difference between the fees the Affiliated Facilities pay Newco for the provision of therapy services and the reimbursement the Affiliated Facilities receives from Federal health care programs and other payors for such services.

Because the Proposed Arrangement would not qualify for a safe harbor, we next consider the totality of the facts and circumstances to assess the relative risk of fraud and abuse it presents.

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medical equipment (DME) supplier and hospital enter into a joint venture to furnish DME to patients when they leave the hospital, both the DME supplier and the hospital fit within the category of investors doing business with the entity (56 FR 35968). We are not persuaded that hospitals, nursing homes, skilled nursing facilities, or other institutions are incapable of influencing referrals of Federal health care program business. To the contrary, we are aware of instances of referrals that are in fact controlled by these institutions' employees or agents.").

[11] See, e.g., OIG 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted in the Federal Register in 1994, 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994).

2. Significant Risk of Fraud and Abuse

The Proposed Arrangement presents a host of concerns, including patient steering, unfair competition, inappropriate utilization, and increased costs to Federal health care programs. Indeed, the Proposed Arrangement exhibits many attributes of the problematic contractual joint ventures identified by the OIG in its 2003 Special Advisory Bulletin on Contractual Joint Ventures (the "2003 SAB").[12] The following description from the 2003 SAB is instructive:

> [A] health care provider in one line of business (hereafter referred to as the "Owner") expands into a related health care business by contracting with an existing provider of a related item or service (hereafter referred to as the "Manager/Supplier") to provide the new item or service to the Owner's existing patient population, including [F]ederal health care program patients. The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier—otherwise a potential competitor—receiving in return the profits of the business as remuneration for its Federal program referrals.[13]

In the Proposed Arrangement, the JV Partner would be in the same position as the "Owner," and Requestor would be in the same position as the "Manager/Supplier." For example:

- Like the "Owner," the JV Partner would be expanding into a related line of business—therapy services for patients of Facilities—that would, at least in the near term, be dependent on referrals and business generated, directly or indirectly, by the JV Partner through its Affiliated Facilities.

- The JV Partner would not actually participate in the operation of Newco but would instead contract out substantially all of Newco's operations to Requestor. Like the "Owner," the JV Partner's actual financial and business risk would be minimal or nonexistent because the JV Partner is in a position to control or influence the amount of business its Affiliated Facilities direct to Newco.

- Requestor, like the "Manager/Supplier," is an established provider of the same services that Newco would provide. In other words, absent the Proposed Arrangement, Requestor would be a competitor to Newco, providing items and services in its own right.

- By creating a joint venture with the JV Partner, Requestor effectively would be agreeing to forego a portion of the profit that it would realize if it provided those services directly

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[12] OIG Special Advisory Bulletin on Contractual Joint Ventures (reprinted at 68 Fed. Reg. 23,148 (Apr. 30, 2003)).

[13] Id.

(as it currently does), while providing the JV Partner the opportunity to share in those profits.

Based on the facts presented here, we are unable to exclude the possibility that the Proposed Arrangement is designed to permit Requestor to do indirectly what it cannot do directly: pay the JV Partner a share of the profits from the JV Partner's referrals (whether directly or through its Affiliated Facilities) to Requestor for therapy services that are reimbursable by a Federal health care program. Indeed, there is a significant risk that the Proposed Arrangement could be used as a vehicle to: (i) reward the JV Partner for directing Federal health care program and other business to Requestor; (ii) lock in that referral stream to Requestor; and (iii) block out potential competitor therapy services providers.

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 generate prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act.

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 or entity other than Requestor 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 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 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.

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs