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: August 15, 2023

Posted: August 18, 2023

[Address block redacted]

Re: OIG Advisory Opinion No. 23-05 (Unfavorable)

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 a proposed arrangement in which Requestor would assist physicians who perform surgeries for which intraoperative neuromonitoring ("IONM") is used with the formation and operation of a turnkey physician-owned entity that would perform IONM 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

A. The Services and Parties

IONM is used to observe a patient's neurological functions during certain surgeries in which the patient's neurological structures are at risk. IONM services have a technical component and a professional component. The technical component of IONM involves a neurophysiologist, located in the operating room of a hospital or ambulatory surgical center ("ASC") while a surgery takes place, setting up the IONM equipment and ensuring it works properly. The professional component of IONM involves a neurologist, typically located in a remote location, monitoring the test results and waveforms generated by the IONM equipment during the surgery in real time using a dedicated internet connection.

Requestor contracts with various hospitals and ASCs under an IONM services agreement to: (i) perform the technical component of IONM services for surgeries at such facilities through its employed neurophysiologists; and (ii) arrange for the performance of the professional component of IONM services for the same surgeries through neurologists employed or engaged as independent contractors by [redacted], a physician practice that has a management services agreement with Requestor ("Practice"). Specifically, when surgeons wishing to schedule IONM services for one of their surgical cases at a hospital or ASC make a referral to Requestor for such services, they first contact Requestor. Requestor then schedules one of its neurophysiologists to perform the technical component for the surgery and contacts Practice to arrange for Practice to assign a neurologist to perform the professional component for the surgery. Generally, Requestor bills the hospital or ASC for the technical component, and Practice bills the surgical patient or insurer, as applicable, for the professional component.[2]

B. The Proposed Arrangement

Under the Proposed Arrangement, Requestor proposes to assist physicians who perform surgeries for which IONM is used, and who currently make referrals to Requestor for IONM services, with the formation and operation of a turnkey entity that would perform IONM services ("Newco") and that would be owned by such physicians (the "Surgeon Owners"). Neither Requestor nor Practice would have an equity interest in Newco. The Surgeon Owners would be responsible for forming Newco and for preparing Newco's internal governance documents.

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[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 have not been asked to opine on, and we express no opinion regarding, the arrangements between and among: Requestor; Practice; the owners, employees, or contractors of each of Requestor and Practice; and the hospital and ASC clients of Requestor and Practice.

While the Surgeon Owners ultimately would set the terms of their respective investment interests in Newco and the methodology for the distribution of Newco's profits amongst themselves, Requestor anticipates that the Surgeon Owners would receive distributions of Newco's profits in return for their investment interests in Newco.

After formation, the Surgeon Owners would have limited participation in Newco's day-to-day business operations and would instead contract with Requestor and Practice for the performance of these operations through the following contracts:

- Pursuant to a billing services agreement between Requestor and Newco, Requestor would provide to Newco billing, collection, and certain other administrative services in exchange for a fee from Newco (the "Billing Services Agreement").

- Pursuant to a personal services agreement between Practice and Newco, Practice would provide to Newco the services of its neurologists and the services of neurophysiologists (which Practice would lease from Requestor under the management services agreement between Requestor and Practice) in exchange for a fee from Newco (the "Personal Services Agreement").

Requestor certified that the services provided by Requestor and Practice under these contracts would constitute virtually all of the day-to-day requirements of an IONM business. Requestor does not expect that Newco would need to hire any dedicated employees because Requestor and Practice would provide all necessary services for Newco.

Newco would contract with various hospitals and ASCs under an IONM services agreement that would govern Newco's provision (or arranging for the provision) of the technical and professional components of IONM services for surgeries at such facilities. Generally, Newco would bill the hospital or ASC for the technical component and would bill the surgical patient or insurer, as applicable, for the professional component. Although Newco's billing would be handled by Requestor under the Billing Services Agreement, Requestor would take direction from the Surgeon Owners regarding the amounts to be billed for services.

Requestor certified that it would enter into the Proposed Arrangement for competitive reasons because existing surgeon clients of Requestor are continually approached by other IONM companies that are encouraging the surgeons to enter into similar arrangements, and Requestor seeks to retain business from its existing surgeon clients that otherwise would be lost to these competing IONM companies. Requestor further certified that it would adopt the Proposed Arrangement only as required in specific situations where its existing surgeon clients wish to own their own IONM company and may not continue to do business with Requestor otherwise.

Although Newco would pay a fee to Requestor under the Billing Services Agreement and would pay a fee to Practice under the Personal Services Agreement, Requestor anticipates that Newco would achieve substantial profits from the Proposed Arrangement (i.e., the difference in fees paid to Requestor and Practice under the services agreements and reimbursement received from third parties) and anticipates that Requestor and Practice would earn substantially less profits under the Proposed Arrangement than under their current business model. This is primarily because, as Requestor certified: (i) reimbursement for the professional component of IONM can

far exceed the cost of providing the service; and (ii) Practice would charge Newco less than it could bill a third-party payor for the same services under Requestor's and Practice's current business model because competing IONM companies marketing similar arrangements to surgeons have aggressively discounted their charges for such services.

Under the Proposed Arrangement, the Surgeon Owners would refer the patients of their own surgical practices to Newco for IONM services when a surgery requires IONM, as determined in the discretion of the referring surgeon. Requestor certified that it would attempt to ensure that the Surgeon Owners would not refer their Federal health care program surgical patients to Newco for IONM services. However, as a practical matter, Requestor certified that it would not be able to enforce restrictions regarding where the Surgeon Owners refer their patients for IONM services. Although Newco's billing would be handled by Requestor under the Billing Services Agreement, a patient's insurance carrier may not be known at the time the IONM services would be scheduled, and IONM services reimbursable by a Federal health care program could be performed and billed through Newco unintentionally from time to time. Requestor certified that, if the Surgeon Owners do not refer their Federal health care program patients to Newco for IONM services, it is likely that the Surgeon Owners would instead refer these patients directly to Requestor (for the technical component of IONM) and Practice (for the professional component of IONM).

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

[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).

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.

B. Analysis

The Proposed Arrangement would implicate the Federal anti-kickback statute. It would involve several forms of remuneration, including, but not limited to: (i) discounts under the Personal Services Agreement provided by Practice to Newco; (ii) the opportunity for Newco to generate a profit through the difference between the fees paid by Newco to each of Requestor and Practice under the services agreements and the reimbursement Newco would receive for such services from third parties; and (iii) returns on investment interests in Newco to the Surgeon Owners. These streams of remuneration could induce the Surgeon Owners to make referrals of IONM services for which payment could be made by a Federal health care program.

For the reasons set forth below, we conclude that the risk of fraud and abuse presented by the Proposed Arrangement is not sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion. Indeed, as described more fully below, the Proposed Arrangement would have many of the indicia of suspect contractual joint ventures, about which OIG has longstanding and continuing concerns.[6]

1. No Safe Harbor Protection

As a threshold matter, we conclude that at least some remuneration that would be exchanged under the Proposed Arrangement would not qualify for protection under any safe harbor. For the Proposed Arrangement to have safe harbor protection, each stream of remuneration would have to squarely satisfy one or more safe harbors. We conclude that, based on the facts certified by Requestor, safe harbor protection would not be available to all of the Proposed Arrangement's streams of remuneration. For example, the opportunity for Newco to generate a profit—through the difference between the fees paid by Newco to each of Requestor and Practice under the services agreements and the reimbursement Newco would receive for such services—would not be protected by any safe harbor. Because the Proposed Arrangement would not qualify for safe harbor protection, we next consider the totality of the facts and circumstances to assess the risk of fraud and abuse the Proposed Arrangement would present.

2. Significant Risk of Fraud and Abuse

The Proposed Arrangement would present a host of risks of fraud and abuse under the Federal anti-kickback statute, including patient steering, unfair competition, inappropriate utilization, and increased costs to Federal health care programs. Based on the facts presented here, we are

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[6] See, e.g., OIG, Special Fraud Alert: Joint Venture Arrangements (1989), https://oig.hhs.gov/documents/special-fraud-alerts/876/121994.html.

unable to exclude the possibility that the Proposed Arrangement could enable Requestor and Practice to do indirectly what they could not do directly: pay the Surgeon Owners a share of the profits from their referrals for IONM services that could be reimbursable by a Federal health care program. As stated above, the Proposed Arrangement would exhibit many attributes of problematic contractual joint ventures, about which OIG has longstanding and continuing concerns. The following description from OIG's 2003 Special Advisory Bulletin on Contractual Joint Ventures (the "2003 SAB")[7] 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 [F]ederal program referrals.[8]

First, there is a risk that the Proposed Arrangement could be used as a vehicle to induce referrals of Federal health care program business from the Surgeon Owners to Newco.[9] According to Requestor, the Surgeon Owners would have limited, if any, participation in the operation of Newco and instead would contract out substantially all of Newco's operations to Requestor and Practice. Like the "Owner" in the description from the 2003 SAB excerpted above, the Surgeon Owners' actual financial and business risk would be minimal or nonexistent because the Surgeon Owners would be in a position to control or influence the amount of business that they direct to Newco. Also, like the "Owner" in the 2003 SAB, the Surgeon Owners would be expanding into a related line of business—IONM services—that would be dependent on referrals and business generated by the Surgeon Owners. Requestor and Practice, like the "Manager/Supplier" in the 2003 SAB, are each an established provider of the same services that Newco would provide and would be competitors to Newco absent the Proposed Arrangement. By entering into the Proposed Arrangement with the Surgeon Owners, Requestor and Practice effectively would be

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[7] OIG, Special Advisory Bulletin: Contractual Joint Ventures (2003), https://oig.hhs.gov/documents/special-advisory-bulletins/885/042303SABJointVentures.pdf.

[8] Id. at 2.

[9] We recognize that Requestor certified that it would attempt to ensure that the Surgeon Owners would not refer their Federal health care program surgical patients to Newco for IONM services. This does not alleviate our concerns because Requestor also certified that, as a practical matter, it would not be able to enforce restrictions regarding where the Surgeon Owners refer their patients for IONM services, and IONM services reimbursable by a Federal health care program could be performed and billed through Newco unintentionally from time to time.

agreeing to forego a portion of the profits that they would realize if they provided those services directly (as they currently do), while providing the Surgeon Owners the opportunity to share in those profits. The financial incentives inherent in the Proposed Arrangement could corrupt the Surgeon Owners' medical decision-making and result in overutilization or inappropriate utilization of IONM services and improper steering to Newco.

Second, there is a risk that the Proposed Arrangement could be used as a vehicle to induce referrals of Federal health care program business from the Surgeon Owners to Requestor and Practice. Requestor certified that, if the Surgeon Owners do not refer their Federal health care program patients to Newco for IONM services, it is likely that the Surgeon Owners would instead refer these patients directly to Requestor (for the technical component of IONM) and Practice (for the professional component of IONM). Accordingly, even if Requestor could ensure that the Surgeon Owners would not refer their Federal health care program patients to Newco, this "carve out" of Federal health care program business would not be dispositive with respect to whether the Proposed Arrangement would implicate, and potentially violate, the Federal anti-kickback statute. OIG has longstanding and continuing concerns about arrangements under which parties carve out referrals of Federal health care program beneficiaries or Federal health care program business from otherwise questionable financial arrangements.[10] Such arrangements implicate, and may violate, the Federal anti-kickback statute by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business.

Here, even if Requestor could ensure that no IONM services reimbursable by a Federal health care program would ever be referred to Newco, the remuneration to Newco under the Proposed Arrangement could induce the Surgeon Owners to refer their IONM services reimbursable by a Federal health care program to Requestor and Practice, thereby disguising remuneration for Federal health care program beneficiary referrals through the payment of amounts purportedly related to non-Federal health care program business. This conclusion is consistent with, and supported by, Requestor's certifications that it is under competitive pressures to enter into the Proposed Arrangement and that it seeks to retain business from its existing surgeon clients that otherwise would be lost to competing IONM companies. This, too, would present some of the risks against which the Federal anti-kickback statute is designed to protect, including unfair competition and improper steering.

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.

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[10] See, e.g., OIG, Special Fraud Alert: Laboratory Payments to Referring Physicians 5 (2014), https://oig.hhs.gov/documents/special-fraud-alerts/866/OIG_SFA_Laboratory_Payments_06252014.pdf.

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. 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,

/Susan A. Edwards/

Susan A. Edwards
Acting Assistant Inspector General for Legal Affairs