



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: December 14, 2022

Posted: December 19, 2022

[Address block redacted]

Re: OIG Advisory Opinion No. 22-20

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 the utilization of its employed nurse practitioners to perform services that traditionally have been performed by a patient’s attending physician in certain medical units of one of its hospital campuses, [redacted] (the “Arrangement”). Specifically, you have inquired whether the Arrangement constitutes 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 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 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 Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor in connection with the 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 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 an acute-care hospital comprised of two campuses that provide a range of inpatient and outpatient hospital-based services. Under the Arrangement, for physicians who choose to participate (“Participating Physicians”), Requestor utilizes its employed nurse practitioners (“NPs”) to assist in rendering certain care to those patients of the Participating Physicians who are inpatients or in observation status in two designated medical units. The NPs perform a wide range of tasks, some of which the Participating Physicians otherwise would perform, including:

- promptly initiating plans of care through existing protocols;
- implementing any applicable care protocols instituted by Requestor (e.g., stroke or community-acquired pneumonia protocols);
- making rounds on assigned units, during which the NPs address concerns of patients, their families, nurses, and other clinicians (e.g., physical therapists and speech therapists);
- responding to laboratory or imaging studies, including arranging prompt follow-up testing and attending to abnormal results as needed;
- addressing rapid changes in patient condition, including adjusting care plans and ordering imaging, laboratory tests, or other diagnostic tools or interventions in real time;
- educating and supporting patients and families;
- coaching, educating, and otherwise supporting nurses on the unit, including providing certified continuing education;
- overseeing and supporting unit-based quality improvement projects; and
- discharge planning, which at times includes obtaining insurance authorizations for post-acute care (such as for home health care, skilled nursing, or acute inpatient rehabilitation) and scheduling follow-up testing and appointments.

Requestor certified that the two medical units subject to the Arrangement are general care units and are neither surgery nor specialty care units (e.g., critical care, cardiology), and the Participating Physicians are predominantly primary care physicians.² According to Requestor, patients in the medical units covered by the Arrangement are undergoing active evaluation to determine the cause and extent of their illnesses and often require ongoing attention throughout the day, including real-time responses to changes in patient condition. From Requestor’s experience, having the NPs readily available in these medical units improves patient care by

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 While it is possible that a patient receiving care under the Arrangement ultimately may need surgery (e.g., a consulting surgeon may determine that surgery is advised for a patient presenting with gallstones), the surgical consult and procedure are outside the scope of the Arrangement and are billed by the surgeon as separate and distinct services.

allowing patients to be evaluated more quickly and efficiently so that they can receive diagnoses and treatments as soon as practicable.

Requestor certified that all of the duties performed by the NPs are done in communication and collaboration with the Participating Physician treating the patient. The Participating Physician (or other qualified physician designated by the Participating Physician if the Participating Physician is unavailable) must still round daily, and Participating Physicians maintain the same accountability for patient care as physicians not participating in the Arrangement. Requestor certified that it prohibits Participating Physicians from billing for the services furnished by the NP. According to Requestor, consistent with Medicare guidelines,³ Participating Physicians must conduct their own patient assessments and generate their own documentation in order to bill for their services, and they are prohibited from relying on the NPs' services or documentation to bill for any services.⁴ Requestor certified that it pays for all services rendered by NPs under the Arrangement, and it does not separately bill any payor, including Federal health care programs, for the NPs' services.

Each year, Requestor sends an educational letter to all physicians with privileges at Requestor who regularly admit patients to the two designated medical units, including physicians employed by affiliates of Requestor and physicians employed by independent physician groups, informing them of the Arrangement. Requestor certified that it does not take into account a physician's volume or value of expected or past referrals, nor does it target any particular referring physicians, when offering (and providing NPs' services under) the Arrangement. Requestor certified that it does not make payments to Participating Physicians under the Arrangement and that it has no ancillary agreements with Participating Physicians that would otherwise induce or reward referrals to Requestor. Requestor also certified that any compensation it pays to Participating Physicians outside of the Arrangement does not reflect or take into account any services performed by the NPs under the Arrangement.

³ See, e.g., Centers for Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual Ch. 12, § 30.6.1, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf>; CMS, Evaluation and Management Services Guide (Jan. 2022), <https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/eval-mgmt-serv-guide-icn006764.pdf>.

⁴ Requestor certified that these services are not "split (or shared) visits" as defined by CMS. See CMS, Medicare Claims Processing Manual Ch. 12, § 30.6.18, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf>. Additionally, for an inpatient, Medicare permits a physician to bill for only one evaluation and management service per patient per day, regardless of whether the physician sees a patient more than once in a day. See CMS, Medicare Claims Processing Manual Ch. 12, § 30.6.9., <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf>.

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 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.

B. Analysis

The OIG's position on the provision of free or below-market-price goods or services to actual or potential referral sources is longstanding and clear: such arrangements are suspect and may violate the Federal anti-kickback statute, depending on the circumstances. When a party in a position to benefit from referrals provides remuneration to an existing or potential referral source, there is a risk that at least one purpose of providing the remuneration is to influence referrals.

For example, OIG's Supplemental Compliance Program Guidance for Hospitals explains that:

[t]he general rule of thumb is that any remuneration flowing between hospitals and physicians should be at fair market value Arrangements under which hospitals . . . provide physicians with items or services for free or less than fair

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).

market value . . . [or] relieve physicians of financial obligations they would otherwise incur . . . pose significant risk.⁸

The Arrangement implicates the Federal anti-kickback statute because Requestor is providing remuneration in the form of NP services to Participating Physicians that could induce such physicians to make referrals to Requestor for items and services reimbursable by a Federal health care program. Under the Arrangement, Requestor assigns its employed NPs to perform a range of tasks that Participating Physicians otherwise would have to perform as part of their responsibilities to care for their patients appropriately from the time of admission to Requestor to the time of discharge. Under the Arrangement, services performed by Requestor's NPs on behalf of any Participating Physician potentially relieve the Participating Physician of a range of tasks and services for which they otherwise would have to expend their time and resources. For example, an NP performing services on behalf of a Participating Physician might save that physician the time and costs associated with having to return to the hospital or taking calls from the hospital to make treatment decisions. These services also might allow Participating Physicians to use the time they would have spent performing these tasks to perform other separately billable services. The NPs' services may be particularly valuable to a Participating Physician where the physician can bill Medicare for only one evaluation and management service per day, regardless of whether the physician sees a patient more than once in a day. For these reasons, using NPs to take on patient care duties for which Participating Physicians otherwise are responsible constitutes remuneration to such Participating Physicians, and at least one purpose of providing such remuneration may be to induce them to make referrals to Requestor for items and services reimbursable by a Federal health care program. However, for the combination of the following reasons, we believe the Arrangement presents a minimal risk of fraud and abuse under the Federal anti-kickback statute.

First, the Arrangement is restricted to two non-surgical, non-specialty units at one of Requestor's hospital campuses. We might reach a different conclusion if, for instance, the Arrangement was offered on surgical or specialty units where specialist physicians typically make more lucrative referrals to Requestor. In addition, the Arrangement does not target any particular referring physicians, and Requestor certified that Participating Physicians are predominately primary care physicians, as opposed to specialist physicians who could be in a position to make more lucrative referrals to Requestor. Requestor also certified that any compensation it pays to Participating Physicians outside of the Arrangement does not reflect or take into account any services performed by the NPs under the Arrangement. Finally, Requestor certified that it does not take into account a physician's volume or value of expected or past referrals when offering the Arrangement. These facts mitigate the risk that the Arrangement is used to induce or reward valuable referrals from any physicians, including specialist physicians.

Second, the Arrangement contains safeguards that lower the risk of fraud and abuse under the Federal anti-kickback statute. For example, Requestor certified that all of the duties performed by the NPs are done in communication and collaboration with the Participating Physician treating the patient. The Participating Physician (or other qualified physician designated by the Participating Physician if the Participating Physician is unavailable) still must round daily, and

⁸ OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4,858, 4,866 (Jan. 31, 2005).

Participating Physicians maintain the same accountability for patient care as physicians not participating in the Arrangement. Additionally, Requestor certified that it does not make any payments to Participating Physicians under the Arrangement, and there are not any ancillary agreements with the Participating Physicians that otherwise induce or reward referrals.

Requestor also certified that Participating Physicians in the Arrangement can bill for services only where they have documentation supporting the work they actually have performed, and they are prohibited from billing for services performed by the NPs. We believe the specific facts of the Arrangement are distinguishable from suspect arrangements where, for example, hospitals permit their employed NPs to provide services to physicians' patients at no cost to the physicians, and the physicians then bill payors, including Federal health care programs, for the services performed by these NPs.

Finally, the design of the Arrangement appears unlikely to increase costs to Federal health care programs and may ensure an appropriate level of care for patients in these units. Requestor certified that it does not bill any payor, including Federal health care programs, for the services performed by the NPs. The fact that Requestor does not bill for NPs services—even when the NPs' services performed under the Arrangement would otherwise be separately reimbursable--mitigates the risk of inappropriately increased costs to Federal health care programs from additional claims for reimbursement. Moreover, according to Requestor, patients in the medical units covered by the Arrangement are undergoing active monitoring and evaluation to determine the cause and extent of their illness, and they often require ongoing attention throughout the day, including real-time responses to changes in a patient's condition. Accordingly, Requestor certified that having the NPs available in these medical units improves care for patients by allowing them to be evaluated more quickly and efficiently so that they can receive diagnoses and treatments as soon as practicable. The services performed by the NPs under the Arrangement appear reasonably designed to address these objectives.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor in connection with the 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 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 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 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 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 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