

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: November 5, 2021

Posted: November 10, 2021

[Name and address redacted]

Re: OIG Advisory Opinion No. 21-15

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 its proposal to retain net profits from services provided by an employed certified registered nurse anesthetist (the "CRNA") pursuant to a reassignment of billing rights (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. 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 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.

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, a pain management practice that is solely owned by [name redacted] (the "Physician"), employs [name redacted], the CRNA, on a part-time basis to provide anesthesia services² at two locations where Requestor provides pain management services: the pain management practice office (the "Office") and [name redacted], an ambulatory surgical center (the "ASC"). Requestor certified that the CRNA is a bona fide employee in accordance with the definition of the term "employee" set forth at 26 U.S.C. § 3121(d)(2).

Pursuant to the CRNA's employment agreement, the CRNA reassigned the right to receive reimbursement for the anesthesia services he performs, whether at the Office or the ASC, to Requestor and receives a salary from Requestor. Requestor bills for all separately billable anesthesia services that the CRNA provides at the Office and the ASC.⁴ Requestor certified that, pending the issuance of a favorable advisory opinion, it is holding all net profits from the CRNA's provision of anesthesia services in escrow and, upon the issuance of a favorable advisory opinion, it would collect and retain the net profits from the escrow account and future net profits generated from services the CRNA performs.

Requestor certified that it assumes responsibility for the CRNA's performance of anesthesia services. For example, Requestor pays the CRNA's salary; performs the billing for all of the CRNA's anesthesia services; performs all tasks associated with hiring other CRNAs; and provides human resources services. Additionally, Requestor certified that it carries liability insurance that covers Requestor's vicarious liability with respect to the CRNA.

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 Requestor certified that, in accordance with the applicable scope of practice for CRNAs in Florida, the CRNA orders items and services and furnishes services related to the provision of anesthesia.

³ The Physician owns 80 percent of the ASC, and another physician owns the remaining 20 percent. We have not been asked to opine on, and express no opinion regarding, any existing or future remuneration exchanged between the ASC and either Requestor or the CRNA.

⁴ Requestor certified that it follows all applicable rules and regulations with respect to the reassignment of billing rights and billing and payment for the CRNA's provision of anesthesia services at both the Office and the ASC. Requestor also certified that the ASC does not bill for or receive any payment from Requestor or any other party for the CRNA's performance of anesthesia services.

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. 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.

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 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. ⁹ 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 statutory exception and regulatory safe harbor for employees are potentially applicable to the Proposed Arrangement. The statutory exception protects "any amount paid by an employer to an

⁵ Section 1128B(b) of the Act.

⁶ <u>Id.</u>

E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey,
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⁸ Section 1128B(b)(3) of the Act.

⁹ 42 C.F.R. § 1001.952.

employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services." The safe harbor regulations provide that the term "remuneration," as used in the Federal anti-kickback statute, does not include "any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs." For purposes of the employees safe harbor, the term "employee" has the same meaning as it does for purposes of 26 U.S.C. § 3121(d)(2). 12

B. Analysis

The Proposed Arrangement implicates the Federal anti-kickback statute in two ways. First, Requestor pays the CRNA remuneration in the form of salary payments in exchange for the CRNA furnishing anesthesia services. This remuneration implicates the Federal anti-kickback statute because the CRNA orders and arranges for items and services related to the provision of anesthesia, some of which may be reimbursable by Federal health care programs. Second, the CRNA's reassignment of billing rights to Requestor gives Requestor the opportunity to earn a profit from the CRNA's performance of services because, under the Proposed Arrangement, Requestor would retain net profits from the escrow account and future net profits. This remuneration implicates the Federal anti-kickback statute because Requestor arranges for the purchase of or refers patients for anesthesia items and services furnished by the CRNA, where some items and services may be reimbursable by a Federal health care program.

The first stream of remuneration under the Proposed Arrangement—salary payments from Requestor to the CRNA for the ordering and furnishing of anesthesia items and services—is protected by the employment safe harbor because: (i) Requestor certified that the CRNA is a bona fide employee according to the definition of the term "employee" set forth at 26 U.S.C. § 3121(d)(2); ¹³ and (ii) salary payments from Requestor to the CRNA for the ordering and furnishing of anesthesia items and services constitute amounts paid by an employer to an employee for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

With respect to the second remuneration stream under the Proposed Arrangement—the opportunity for Requestor to earn a profit from the CRNA's performance of services as a result of the CRNA's

¹⁰ Section 1128B(b)(3)(B) of the Act.

¹¹ 42 C.F.R. § 1001.952(i).

¹² <u>Id.</u>

¹³ Advisory opinions do not address whether an individual is a bona fide employee. Section 1128D(b)(3)(B) of the Act. Thus, for purposes of this advisory opinion, we rely on Requestor's certification that the CRNA is a bona fide employee in accordance with the definition of the term set forth at 26 U.S.C. § 3121(d)(2).

reassignment of billing rights—the safe harbor would not offer protection because it protects remuneration only in one direction: from "an employer to an employee." Nevertheless, employment arrangements in which a health care professional who is a bona fide employee reassigns billing rights to an employer in exchange for salary payments are a commonplace practice in the health care industry, explicitly authorized by the laws and regulations governing the Medicare program. The Proposed Arrangement appears to be a straightforward employment arrangement involving the reassignment of billing rights by the CRNA, where Requestor assumes certain duties that may be typical of an employer and where Requestor certified that the CRNA is a bona fide employee. We therefore conclude that the Proposed Arrangement would present a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute.

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 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.

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

¹⁴ See, e.g., "No payment under this part for a service provided to any individual shall (except as provided in section 1870) be made to anyone other than such individual or (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) the physician or other person who provided the service, except that (A) payment may be made (i) to the employer of such physician or other person is required as a condition of his employment to turn over his fee for such service to his employer" Section 1842(b)(6) of the Act.

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