



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: August 3, 2021

Posted: August 6, 2021

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 21-10

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 an arrangement whereby Requestor would provide free routine and emergency dental services to certain indigent residents of skilled nursing facilities and nursing facilities in [state redacted] (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the “Act”), as that section relates to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

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 you 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 the Proposed Arrangement, if undertaken, would not generate prohibited remuneration under the Federal anti-kickback statute or Beneficiary Inducements CMP. Accordingly, the OIG would not impose administrative sanctions on Requestor in

connection with the Proposed Arrangement under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute; the Beneficiary Inducements CMP; or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

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

A. The Parties

[Name redacted] (the “Company”) offers a commercial dental insurance program for routine and emergency dental services for residents of skilled nursing facilities and nursing facilities (referred to collectively herein as a “Facility” or “Facilities”) in [state redacted] (the “State”) known as the [name redacted] (the “Program”).² All Facility residents in the State are eligible to enroll in the Program, and residents who enroll pay a monthly premium to the Company.

Requestor is a professional corporation with a sole shareholder who is a licensed dentist in the State (the “Owner”). Requestor is a preferred provider in the Program, and the Company pays Requestor a capitated per-member, per-month fee for all dental services that Requestor provides to individuals enrolled in the Program. Requestor contracts with dental professionals (“Contracted Providers”) to provide dental services on-site to Facility residents enrolled in the Program.³

B. The Proposed Arrangement

Under the Proposed Arrangement, Requestor would provide free routine and emergency dental services to indigent Medicaid beneficiaries who are not enrolled in the Program but who reside in Facilities where Program enrollees receive services from Requestor. The routine dental services that Requestor would furnish under the Proposed Arrangement include dental exams, cleanings, extractions, and denture fitting and alignment. The emergency dental services that Requestor would furnish under the Proposed Arrangement are dental services that treat a dental

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 The Company is not a party to this advisory opinion, and we express no opinion regarding any insurance program offered by the Company that may cover federally reimbursable items or services. Arrangements between Requestor and the Company are also outside the scope of this advisory opinion.

³ The Contracted Providers are not parties to this advisory opinion, and arrangements between Requestor and the Contracted Providers are outside the scope of this advisory opinion.

condition of an unforeseen nature that requires immediate dental treatment. Requestor would furnish the free dental services under the Proposed Arrangement through the Owner and the Contracted Providers.

Requestor certified that any resident of a Facility who is a Medicaid beneficiary and whose eligibility for Medicaid under State law is based on the fact that they “would be eligible for [Social Security Income] or Optional Supplementation but for the fact that they are residents of a Title XIX institution” would be eligible to receive free dental services under the Proposed Arrangement.⁴ Requestor also certified that it would develop, implement, and uniformly apply a written policy that uses the aforementioned criteria to determine whether an applicant is eligible to participate in the Proposed Arrangement. As part of that policy, Residents would be required to complete an eligibility application prior to receiving free dental services under the Proposed Arrangement. Requestor would offer the free dental services to eligible residents of all Facilities with at least one resident already enrolled in the Program. Requestor would not advertise or market the Proposed Arrangement.

Requestor certified that: (i) none of the items or services that Requestor, the Owner, or the Contracted Providers furnish under the Program or would furnish under the Proposed Arrangement are, or would be, paid for, in whole or in part, by a Federal health care program; (ii) neither Requestor nor the Owner provides any items or services outside of the Program, or would provide any items or services outside of the Proposed Arrangement, that may be paid for, in whole or in part, by a Federal health care program; (iii) the Owner does not have an ownership or investment interest in any other entity that provides any items or services that are paid for, in whole or in part, by a Federal health care program; and (iv) the Facilities may influence or direct referrals for commercially insured Program services to the Company and Requestor, but the Facilities do not and would not make any referrals to Requestor, the Owner, or any Contracted Providers for any items or services paid for, in whole or in part, by a Federal health care program.

C. Summary of Medicare and Medicaid State Plan Coverage for Dental services and Requirements for Participation

Except for certain circumstances involving patients who require inpatient hospitalization, Medicare Part A and Part B do not cover routine or emergency dental services, and the Medicaid State Plan in the State (the “Medicaid State Plan”) does not provide coverage for routine or emergency dental services.⁵ Requestor further certified that Medicaid does not reimburse Facilities in the State for routine or emergency dental services. Requestor also certified that, under the Medicaid State Plan, Medicaid pays for Facility care for Medicaid beneficiaries under a formula that first requires the Medicaid beneficiary to apply his or her personal resources to the allowable facility charge, and then Medicaid pays the difference between a Medicaid beneficiary’s personal resources and the allowable facility charge. In computing personal resources, dental insurance premiums are considered an allowable deductible expense under the

⁴ See [citation redacted].

⁵ See section 1862(a)(12) of the Act; [citation redacted].

Medicaid State Plan. As a result, the relative amount that Medicaid pays for the care of Facility residents who are Medicaid beneficiaries and who purchase dental insurance using their personal resources (including, for example, through the Program) is increased by the amount of the dental insurance premium.

Requestor certified that Facilities contract with Requestor to arrange for the provision of dental services for their residents, including residents enrolled in the Program and residents who are not enrolled in the Program, to meet their obligations under pertinent Medicare and Medicaid requirements for participation.⁶ Requestor further certified that, under the Proposed Arrangement, Requestor and the Facilities would enter into written agreements that reflect that Requestor will furnish free dental services to indigent Medicaid beneficiaries who are Facility residents, consistent with applicable regulatory requirements.⁷

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

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.⁸ 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.⁹ 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.

⁶ To participate in the Medicare and Medicaid programs, skilled nursing facilities are required to provide or obtain from an outside resource, in accordance with 42 C.F.R. § 483.70(g), routine and emergency dental services to meet the needs of their residents, and nursing facilities are required to provide or obtain from an outside resource, in accordance with 42 C.F.R. § 483.70(g), routine dental services (to the extent covered under the State plan) and emergency dental services. See 42 C.F.R. § 483.55(a)-(b). The Centers for Medicare & Medicaid Services ("CMS") State Operations Manual also states, "[a] dentist must be available for each resident. . . . If any resident is unable to pay for dental services, the facility should attempt to find alternative funding sources or delivery systems so that the resident may receive the services needed to meet their dental needs and maintain his/her highest practicable level of well-being." CMS, State Operations Manual, Appendix PP, section 483.55.

⁷ See 42 C.F.R. § 483.70(g).

⁸ Section 1128B(b) of the Act.

⁹ Id.

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.¹⁰ 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.

2. Beneficiary Inducements CMP

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value."

B. Analysis

Arranging for free dental services on behalf of Facilities with Medicaid residents and offering free dental services to Medicaid beneficiaries could potentially implicate the Federal anti-kickback statute and the Beneficiary Inducements CMP. However, for the reasons set forth below, we conclude that the Proposed Arrangement would not result in prohibited remuneration under the Federal anti-kickback statute or the Beneficiary Inducements CMP.

1. Federal Anti-Kickback Statute

As a preliminary matter, it is not clear from the certifications Requestor provided that the Proposed Arrangement confers anything of value on the Facilities, such as reducing the Facilities' administrative burden. However, we need not reach the question of remuneration where, as is the case here, there would be no referrals for any items or services for which payment may be made by a Federal health care program in connection with the Proposed Arrangement. In support of this conclusion, we rely on Requestor's certifications that: (i) none of the items or services that Requestor, the Owner, or the Contracted Providers furnish under the Program or under the Proposed Arrangement are or would be paid for, in whole or in part, by a Federal health care program; (ii) neither Requestor nor the Owner provides any items or services outside of the Program or would provide any items or services outside of the Proposed

¹⁰ 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).

Arrangement that may be paid for, in whole or in part, by a Federal health care program; (iii) the Owner does not have an ownership or investment interest in any other entity that provides any items or services that are paid for, in whole or in part, by a Federal health care program; and (iv) the Facilities do not and would not make any referrals to Requestor, the Owner, or any Contracted Providers for any items or services paid for, in whole or in part, by a Federal health care program.¹¹ The fact that the Facilities may refer Medicaid beneficiaries to the Program and that, according to Requestor, those referrals could result in Medicaid paying a larger portion of the Facilities' allowable charges for care furnished to residents who are Program enrollees does not, in and of itself, implicate the Federal anti-kickback statute. The referral to enroll in the commercial Program is not a referral for, or arranging for, an item or service that may be payable, in whole or in part, by a Federal health care program.

In addition, although the free dental services furnished under the Proposed Arrangement clearly would have value to the indigent Medicaid beneficiaries who receive them, and therefore would constitute remuneration under the Federal anti-kickback statute, this remuneration stream would not implicate the Federal anti-kickback statute because there is no nexus between the remuneration and any referrals for items or services for which payment may be made by a Federal health care program. Except for certain circumstances involving patients who require inpatient hospitalization, Medicare Part A and Part B do not cover routine or emergency dental services, and the Medicaid State Plan does not provide coverage for routine or emergency dental services. Thus, even though the free dental services may lead the beneficiary to obtain further dental services from Requestor, the Owner, or one of the Contracted Providers, Requestor certified that: (i) none of the items or services that Requestor, the Owner, or the Contracted Providers furnish under the Program or would furnish under the Proposed Arrangement are or would be paid for, in whole or in part, by a Federal health care program; and (ii) neither Requestor nor the Owner provides any items or services outside of the Program or would provide any items or services outside of the Proposed Arrangement that may be paid for, in whole or in part, by a Federal health care program. We distinguish this arrangement from the types of seeding arrangements about which the OIG has consistently expressed concerns, where a party offers an item or service for free to induce a patient to obtain future supplies of such item or future services that would be billed to a Federal health care program.

2. Beneficiary Inducements CMP

We conclude that the Proposed Arrangement would not generate prohibited remuneration under the Beneficiary Inducements CMP. Although the Facilities provide items and services for which payment may be made, in whole or in part, by Medicare or a State health care program, the facts

¹¹ We contrast the facts here with arrangements where parties “carve-out” Federal health care program beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. We reiterate OIG’s longstanding position that such arrangements implicate and may violate the anti-kickback statute by disguising remuneration for Federal business through the payment of amounts purportedly related to non-Federal business. Unlike these questionable arrangements, the Proposed Arrangement does not purport to carve-out such referrals. Instead, Requestor has certified that no such referrals exist between or amongst Requestor, the Owner, the Contracted Providers, or the Facilities.

certified by Requestor do not suggest that the free dental services would be likely to influence a beneficiary's selection of a particular Facility for such services. Requestor certified that, under the Proposed Arrangement, it would make the free dental services available to qualifying residents of any Facility with at least one resident enrolled in the Program, and it would not advertise or market the Proposed Arrangement. Requestor further certified that the Program is itself available to residents of any Facility in the State. Thus, the free dental services offered under the Proposed Arrangement would not influence a beneficiary to select one Facility over another. For this reason, and those described above, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the Beneficiary Inducements CMP.

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 not generate prohibited remuneration under the Federal anti-kickback statute or Beneficiary Inducements CMP. Accordingly, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute; the Beneficiary Inducements CMP; or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

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 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