



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: April 28, 2026

Posted: May 1, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-09 (Favorable)

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 its proposal to offer free orthodontic treatment to certain patients (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 Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This advisory 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, have been misrepresented, or change, then this advisory 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: (i) although the Proposed Arrangement, if undertaken, would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, 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; and (ii) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

This advisory opinion may not be relied on by any person¹ other than Requestor, has no applicability to any arrangements other than the Proposed Arrangement, 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 exclusively pediatric dental and orthodontic services provider that operates practices in three cities in [redacted].² Under the Proposed Arrangement, Requestor would provide free, comprehensive orthodontic treatment (the “Free Service”³) to up to one of Requestor’s existing patients per year at each of Requestor’s three locations for a potential total of three new recipients of the Free Service each year.⁴ Requestor certified that orthodontic treatment typically spans 12 to 24 months and is valued at approximately \$4,725 per patient. Requestor certified that it would not bill any Federal health care programs for the Free Service. Requestor certified that the Proposed Arrangement is intended solely to provide charitable care to underserved pediatric patients and to highlight the impact of orthodontic treatment on oral and mental health.

Under the Proposed Arrangement, Requestor’s treating dentists or orthodontists could nominate Requestor’s existing patients to receive the Free Service pursuant to the following guidelines. Patients eligible for nomination must be [redacted] residents between the ages of 10 and 14, have

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 Requestor is affiliated with [redacted], a dental support organization that provides non-clinical administrative services. [Redacted] is not a party to this advisory opinion request.

³ The Free Service would include post-treatment orthodontic services following the removal of orthodontic appliances. These services include two sets of retainers as well as periodic retainer check appointments for up to 1 year after appliance removal.

⁴ A location’s orthodontic practice must be accepting new orthodontic patients at the time of selection for that location to participate in the Free Service that year.

clinical necessity for orthodontics,⁵ and have financial need and the potential for community impact as described below. Patients with any type of health insurance, including Medicaid, or no insurance at all would be eligible; however, if a nominated patient is insured, then Requestor would require documentation that orthodontic treatment had been denied by their insurer. Patients cannot nominate themselves for the Free Service.

Prospective recipients of the Free Service must meet basic oral health requirements prior to starting orthodontic care. Specifically, a licensed dental provider must determine that the patient is cavity-free and demonstrates good oral hygiene (“cavity clearance”). Requestor certified that there would be no obligation to receive cavity clearance or any other general dentistry services from Requestor; patients may obtain cavity clearance, any necessary restorative care, and oral hygiene education from a dental provider of their choosing prior to initiating orthodontic treatment.

The process for selecting patients to receive the Free Service would work as follows. Each year in December, Requestor would select from among the nominated patients one recipient per practice,⁶ utilizing a consistently administered, weighted scoring system that would consider clinical need (40 percent), financial hardship (40 percent), and community impact (20 percent). Requestor would evaluate clinical need based on a thorough review of a nominee’s dental and orthodontic records to assess the severity of the child’s need for treatment. Requestor would evaluate financial hardship by assessing a nominee’s household income and assigning greater weight—and a higher likelihood of selection—to lower household income. Requestor would consider community impact by assessing factors that would include, for example, whether the patient was in foster care status or lived in a single-parent household. Requestor certified that it would maintain thorough records of nominations and decisions and would conduct periodic audits of the selection process.

Requestor certified that it would not promote the Proposed Arrangement in a manner intended to attract or induce new patients. Specifically, Requestor certified that it would neither publicize that the Proposed Arrangement selects from among Requestor’s patient population nor that Requestor selects recipients each year or otherwise presents an ongoing opportunity for selection. Requestor further certified that it would neither advertise the Proposed Arrangement in its offices nor target messages (for example via email, SMS, or direct communication) to patients or potential patients about the availability of the Free Service.

Requestor may make limited public reference to the Proposed Arrangement—such as on its website or social media platforms or in relevant community or professional settings—for the sole purpose of highlighting the community service aspect of the Free Service and its positive impact on recipients. These references may include general descriptions of the Proposed Arrangement’s

⁵ Requestor defines “clinical necessity” as the presence of at least two qualifying orthodontic conditions, such as crossbite, crowding or spacing, missing teeth, or significant malocclusion, as supported by the patient’s dental or orthodontic records.

⁶ Due to the variable duration of orthodontic treatment, Requestor notes that more than one patient per practice may be receiving free orthodontic care at a given time.

charitable purpose, summaries of patient outcomes, and testimonials from selected patients (with their consent) but would not include any solicitation or promotional language.⁷

Requestor certified that there would be no requirement or expectation that recipients of the Free Service would obtain any future services from Requestor or that they otherwise would have any future business relationship with Requestor.

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.

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, 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.

⁷ Requestor would communicate internally within its practices more detailed information about the operational aspects of the Proposed Arrangement for the purpose of ensuring consistent administration.

⁸ Section 1128B(b) of the Act.

⁹ Id.

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).

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. 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

1. Federal Anti-Kickback Statute

The Federal anti-kickback statute is implicated because, under the Proposed Arrangement, Requestor would offer remuneration in the form of free orthodontia to patients, including Federal health care program enrollees, who could self-refer to Requestor for services billable to a Federal health care program. We have longstanding and continuing concerns regarding the provision of free items or services by individuals and entities, including dentists and orthodontists, to patients that could lead to the ordering and provision of an item or service payable by Federal health care programs. However, for a combination of the following reasons, we believe the risk of fraud and abuse presented by the Proposed Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

First, the Proposed Arrangement has features that reduce the risk that it would steer patients to Requestor. The Free Service is available only to existing patients of Requestor and, as such, those individuals already have selected Requestor for their dental or orthodontic care. Importantly, Requestor would publicize neither the fact that it selects from among its patient population nor that it selects recipients each year or otherwise presents an ongoing opportunity for selection. Additionally, patients cannot nominate themselves for the Free Service. These safeguards significantly reduce the risk that new patients would be steered toward Requestor in the hopes of being selected to receive the Free Service.

Second, the Proposed Arrangement is unlikely to lead to inappropriate utilization or increased costs to Federal health care programs. Requestor would offer the Free Service free of charge and would not bill any Federal health care program for it. A treating dentist or orthodontist would nominate potential Free Service recipients, who would be selected pursuant to a consistently administered scoring system that is based upon clinical need, financial hardship, and community impact—factors that do not incentivize patients to increase utilization of services. Furthermore, Requestor would not require recipients of the Free Service to obtain any additional services from Requestor: recipients may receive any required dental services, such as cavity clearance, from any provider of their choosing and would not be obligated to obtain any future services from Requestor.

Third, the Proposed Arrangement has additional features that reduce its risk under the Federal anti-kickback statute. The Proposed Arrangement contemplates the Free Service being provided in modest numbers: up to one patient per practice per year. Requestor has certified that it would make limited public reference to the Proposed Arrangement for the sole purpose of highlighting the community service aspect of the Free Service and its positive impact on recipients. We rely on Requestor's certifications that these references would be limited to general descriptions of the Proposed Arrangement's charitable purpose, summaries of patient outcomes, and consensual testimonials from selected patients and would not include any solicitation or promotional language. We likely would reach a different conclusion for an arrangement where a provider publicizes the fact that it selects from among its patient population to receive free services or that it selects recipients for free services on an ongoing basis, as such actions would present a higher risk of patient steering and unfair competition.

2. Beneficiary Inducements CMP

With respect to the Beneficiary Inducements CMP, we conclude that the Proposed Arrangement could influence beneficiaries to select Requestor for the receipt of dental or orthodontic services that could be reimbursable by a Federal health care program, and therefore the Proposed Arrangement would implicate the Beneficiary Inducements CMP. The Proposed Arrangement does not satisfy any exceptions to the definition of remuneration in the Beneficiary Inducements CMP. For the reasons stated above, however, in an exercise of our enforcement discretion, we would not impose sanctions under the Beneficiary Inducements CMP in connection with the Proposed Arrangement.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Proposed Arrangement, if undertaken, would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, 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; and (ii) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this advisory opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement. This advisory opinion has no applicability to any other arrangements, including, without limitation, any 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 advisory opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

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. 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 advisory opinion. In the event that this advisory opinion is modified or terminated, 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 OIG.

Sincerely,

/Spencer K. Turnbull/

Spencer K. Turnbull
Acting Assistant Inspector General for Legal Affairs