Gentlemen:

We are writing in response to your request for an advisory opinion regarding payment of certain compensation owed by the organizer of a dental preferred provider organization to a dental network marketing and management company in connection with the use of the dental network by a Federal employee health benefits plan (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.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward
referrals were present, but that the Office of Inspector General (“OIG”) will not impose administrative sanctions on [name redacted] or [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted] and [name redacted], the requestors of this opinion (the “Requestors”), and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

1. FACTUAL BACKGROUND

[Name redacted] (the “Network Organizer”) has developed a dental preferred provider organization (the “Network”), consisting of dentists who agree to accept discounted fees for their services from clients of the Network. The dentists neither pay nor receive compensation for inclusion in the Network. The Network Organizer provides access to the Network to employers and other clients, in exchange for a per employee per month fee.1

The Network Organizer entered into an agreement with [name redacted] (the “Marketing Company”) to market the Network to potential clients. If a potential client identified by the Marketing Company enters into an agreement to acquire access to the Network, the Network Organizer is obligated to pay the Marketing Company a designated percentage of its per employee per month fee from that client. The Requestors have certified that this

1We have not been asked, and express no opinion, about: (i) the arrangement between the Network Organizer and the dentists; (ii) any fees charged by the dentists; or (iii) any agreements between the Network Organizer and any Network client (including the TPA, as defined below).
The Marketing Company introduced [name redacted], a third-party administrator (the “TPA”), to the Network Organizer. The TPA entered into an agreement for access to the Network and made it available to one of its clients, [name redacted], a Federal employee health benefits plan (the “Federal Employee Plan”). As a result, the TPA is required to pay a fee to the Network Organizer, based on the number of employees in the Federal Employee Plan. The Network Organizer, in turn, is required to pay a percentage of its fee to the Marketing Company.\(^3\)

Some of the Federal Employee Plan beneficiaries also may be beneficiaries of Federal health care programs (e.g., because they are seniors or disabled persons who qualify for Medicare or because their income is sufficiently low that they qualify for Medicaid). Thus, a Federal Employee Plan beneficiary could visit a dentist in the Network and have such services paid for, at least in part, by a Federal health care program. According to the Requestors, the amount of Federal health care program dollars at issue in connection with the Arrangement is relatively small. Most beneficiaries in Federal employee health benefits plans do not qualify for any Federal health care program benefits. Some qualify for Medicare, but Medicare does not cover most dental procedures. For any who may be eligible for Medicaid, the Federal Employee Plan would be the primary payer for dental services, and Medicaid would be secondary. It is estimated that less than one percent (1%) of the billings for dental items and services do not vary based on, or otherwise reflect, the actual use by patients of the Network or the payor of the items or services furnished by the Network dentists.\(^2\)

\(^2\)The same parties entered into another written agreement of at least one year’s duration, by which the Marketing Company provides the Network Organizer with utilization management services, credentialing and re-credentialing services, and customer complaint resolution services, for an aggregate annual fee that is set in advance. The Requestors have certified that this agreement is separate from and independent of the Arrangement, and that the compensation owed to the Marketing Company pursuant to this agreement is for the services described in the agreement only. We have not been asked, and express no opinion about, this agreement.

\(^3\)The Network Organizer and the TPA negotiated a lower than usual fee to be paid to the Network Organizer for access to the Network by members of the Federal Employee Plan. While the Marketing Company’s fee is a percentage of the Network Organizer’s fee, it is subject to its own per employee per month floor and ceiling. Commensurate with the lowering of the Network Organizer’s fee for the Federal Employee Plan business, the Marketing Company agreed to a lower floor to its fee for the same business. The Marketing Company has no separate arrangements with the TPA or Federal Employee Plan.
services provided to Federal Employee Plan beneficiaries by Network dentists are paid by Federal health care programs.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the 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 was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Arrangement. Among the conditions of this safe harbor are that (i) the aggregate compensation to be paid under the contract must be fixed in advance; (ii) the compensation must be consistent with fair market value in an arms-length transaction; and (iii) the compensation must not be determined in a manner that takes into account the volume
or value of any referrals or business otherwise generated between the parties for which payment may be made by a Federal health care program. However, the Arrangement does not qualify for the protection under this safe harbor because the aggregate compensation under the Arrangement is not fixed in advance.

B. Analysis

The Requestors have inquired whether payment by the Network Organizer to the Marketing Company of compensation based on the Federal Employee Plan business generated for the Network Organizer (which has the potential to generate business for the Network dentists) would give rise to sanctions under the anti-kickback statute.

Parties that market health care items and services (including, without limitation, the marketing of health plans and provider networks) are in the business of arranging for or recommending the purchase of items and services on behalf of their principals. Where any items or services are reimbursable, in whole or in part, by a Federal health care program, the anti-kickback statute is potentially implicated. Per patient, per unit-of-service, percentage, or similar variable compensation structures are particularly problematic under the statute, because they relate to the volume or value of business generated between parties.

Here, the Marketing Company is owed compensation for marketing services that connect dentists with potential patients, some of whom may be Federal health care program beneficiaries. Notwithstanding the general concerns noted above, for a combination of the following reasons we conclude that we would not subject the Arrangement to administrative sanctions arising under the anti-kickback statute.

In the circumstances presented, the compensation owed to the Marketing Company under the Arrangement appears only tangentially related to the generation of any Federal health care program business. First, relatively few Federal health care program dollars would be paid to the Network dentists as a result of the Arrangement. The Federal Employee Plan is not itself a Federal health care program for purposes of the anti-kickback statute (see section 1128B(f) of the Act), and few of its beneficiaries are likely to be Federal health care program beneficiaries. Medicare and Medicaid eligibility, payment and coverage rules substantially constrain the amount of Federal dollars that are potentially payable for dental services in this arrangement. It is estimated that less than one percent (1%) of the billings for dental items and services provided to Federal Employee Plan beneficiaries by Network dentists are paid by Federal health care programs. Indeed, the fact that some Federal health care program beneficiaries may gain access to the Network dentists as a result of the Arrangement appears entirely incidental to the Arrangement.
Second, based on the facts presented by the Requestors, the compensation owed to the Marketing Company under the Arrangement creates no discernable incentive for the Marketing Company to generate Federal health care program business for the Network or the Network dentists. The Marketing Company’s compensation under the Arrangement does not depend in any respect on whether the members of the Federal Employee Plan are Federal health care program beneficiaries or whether they actually obtain any dental items or services from the Network dentists.4

For these reasons in combination, we conclude that the Marketing Company’s compensation under the Arrangement poses a minimal risk under the anti-kickback statute. We might have reached a different conclusion, however, if the proportion of items and services payable by Federal health care programs had been greater, or if there were other indicia suggesting a nexus between the compensation paid to the Marketing Company and the generation of Federal health care program business.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG will not impose administrative sanctions on [name redacted] or [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted] and [name redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

4For the same reasons, we discern no nexus between the negotiated reduction in the fee for the Federal Employee Plan business and the generation of Federal health care program business.
This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion.

This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied 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.

This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

No opinion is expressed herein regarding the liability of any party 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 the Requestors 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 the Requestors with respect to any action 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General