

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 9, 2024

Posted: December 12, 2024

[Address block redacted]

Re: OIG Advisory Opinion No. 24-10 (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 a proposed expansion of its existing customer loyalty program. Currently, Requestor's customers earn points on purchases of dental-related items and services and redeem them to reduce the dollar amounts those customers pay for other dental-related items and services. The expansion would update certain terms and add certain subsidiary entities of Requestor to participate in the customer loyalty program, which would continue to allow Requestor's customers to earn points on purchases of dental-related items and services and redeem them to reduce the dollar amounts those customers pay for other dental-related items and services (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—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.

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 a medical and dental supplies distributor with global operations. Requestor owns [redacted] (the "Dental Division"), which services office-based dental practitioners by offering dental and laboratory supplies, equipment and technology, repair services, and business support services. The Dental Division offers items and services reimbursable by Federal health care programs.

A. Existing Loyalty Program²

Requestor operates an existing loyalty program under which member customers ("Members") can earn points on Dental Division purchases and redeem them to reduce the dollar amount a Member pays for purchases of other items and services within the Dental Division. Members include general dental practitioners; dental and orthodontic specialists; dental laboratories; and local dental service organizations ("DSOs").³ In addition to earning redeemable points, Members generally are assigned a tiered membership level based on annual spending on Dental Division purchases. Each tier provides defined benefits; such benefits increase in value as a Member progresses through the different membership tiers. Benefits include, for example: priority scheduling for in-office services; guaranteed repair and customer service response times; extended labor warranties; labor discounts; rental equipment discounts; and a dedicated account representative. Requestor awards points to Members based upon their membership tier, and Members can use those points to receive discounts on future Dental Division purchases. All Members within the same tier earn the same points on purchases. Lastly, Requestor operates a paid premium membership program with assorted rebates, benefits, and spend requirements, where the additional value of these features is incorporated into the amount charged for annual dues.

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 is not seeking an opinion on its existing customer loyalty program. Accordingly, this opinion is focused on the Proposed Arrangement involving the expanded loyalty program, and we express no opinion on Requestor's existing loyalty program other than the components of the existing loyalty program that the Proposed Arrangement would encompass.

³ Requestor defines "local DSOs" as multi-site practices with 3 to 20 practice locations.

B. The Proposed Arrangement

Under the Proposed Arrangement, Requestor would expand its existing customer loyalty program beyond the Dental Division to allow Members to earn points on purchases from the Dental Division and certain of its other subsidiaries, including those that are at least 50 percent owned by Requestor (collectively, the "Participating Entities"). The Participating Entities operate business lines that offer items and services related to dental practice; offer specialty dental services, such as restorative dentistry, dental implants, and orthodontics; or provide general business software and financial services that support these lines of business. Requestor certified that the Participating Entities ultimately report to the same upper management, often use the same brand names, utilize common resources, and share common aims to meet the needs of similar customer types.

Under the Proposed Arrangement, Members would continue to include general dental practitioners; dental and orthodontic specialists; dental laboratories; and local DSOs.⁴ Any customer that falls into these categories could become a Member; the points system described further below would be offered on equal terms to all Members. Requestor certified that the Proposed Arrangement would be intended for smaller customers whose spend is relatively small but who generally purchase a high percentage of their needed products and services from Participating Entities. Membership would not be offered to certain categories of larger customers (for whom other purchasing programs outside of the Proposed Arrangement are available), including dental and medical schools; academic dental and medical centers; community health centers and rural health centers; Federal and State customers; national DSOs; cost-reporting entities; or certain other institutional customers.⁵

1. Earning Points

Under the Proposed Arrangement, Members would earn points on purchases of items and services from Participating Entities to be used in dentistry practices. Requestor and Participating Entities would offer points on purchases of approximately 200,000 dental-related products manufactured by thousands of entities ("Qualifying Purchases").⁶ A Member would earn points based upon the Member's membership tier. All Members within the same tier earn the same points on Qualifying Purchases.

⁴ Requestor may consider expanding membership to regional DSOs (which Requestor defines as having 21 to 99 practice locations). Requestor would be able to use the same technology to track qualifying purchases and point redemptions for regional DSOs that it uses for local DSOs.

⁵ We have not been asked to opine, and express no opinion, on Requestor's other purchasing programs.

⁶ Qualifying Purchases would exclude charges incidental to purchases, including taxes and shipping and handling fees; such charges would not be eligible for points. In addition, Qualifying Purchases would exclude certain very limited categories of items and services (<u>e.g.</u>, vaccines).

Members could earn points on items and services that are both reimbursable and non-reimbursable by Federal health care programs. For purposes of earning points, purchases of items and services that could be reimbursable by a Federal health care program would be treated the same as any other purchases. In other words, dollars spent on Qualifying Purchases that could be reimbursable by a Federal health care program would not result in higher or different points than dollars spent on Qualifying Purchases that would not be reimbursable by a Federal health care program. There would be no cap on the number of points that could be earned. Points would be awarded after a Member's order is shipped and invoiced. A Member would see the points in Requestor's Loyalty Program Dashboard (the "Points Dashboard"), managed by a third-party vendor, roughly 48 hours after the time the order is placed. Returned items would result in forfeiting the associated earned points. Depending on the membership tier, points would expire either 12 or 24 months after the month in which the points were earned. The Points Dashboard would allow Members to view the total points accumulated through their purchases across all Participating Entities.

2. Redeeming Points

Members would need to progress above the lowest level tier (as detailed in the next section) before any points could be redeemed. Under the Proposed Arrangement, points could be redeemed on approximately 200,000 distinct dental-related products manufactured and supplied by thousands of entities ("Redeemable Dental Items and Services"). Members would be limited to redeeming points up to 50 percent of the purchase price of any Redeemable Dental Items and Services offered by Participating Entities. Other products or services offered by Requestor and Participating Entities, i.e., non-dental items and services, would not be eligible for points redemption. Redeemable Dental Items and Services would include items and services that are both reimbursable and non-reimbursable by Federal health care programs, representing a broad selection of items and services from Participating Entities. Requestor certified that it would not direct Members to redeem points for any specific item or service.⁸

⁷ If the point deduction results in a negative point balance, no redemptions would be allowed. The Member then would have 90 days to make sufficient purchases to bring their point balance above zero. If the Member does not do so within 90 days after the start of the negative balance, then the Member would be billed for the remaining negative point balance at the equivalent monetary rate.

⁸ Requestor certified that, from time to time, it would provide Members with opportunities to earn multiple points on purchases, but such promotions would not be linked to specific items or services. Rather, multiple-point promotions would be made available to customer segments that spend a minimum dollar amount on products within a selected category of products. Requestor would not direct Members to purchase any specific item or service included in a category of products for which multiple points are offered. Any multiple-point promotion would be available only for a maximum of 3 months, and there would be no more than one such offer per calendar quarter per product category. The multiple-point promotion would be capped at eight times the regular points offered. At present, and by way of example, given that one point is

At present, each point would be worth \$0.005⁹ towards the purchase of Redeemable Dental Items and Services. Requestor certified that no Redeemable Dental Items and Services would be offered to Members at or below cost to Requestor. Points would not be redeemable for cash, and points would have no value if not redeemed. Points would not be transferable, including by gift, donation, or sale of a practice, to other Members or non-Member customers. In addition to tracking when points are earned, the Points Dashboard would display points available for redemption, used points, and expired points. Lastly, Requestor would notify Members of their monthly points balances through regular email communication and would issue summary documents with point balance notifications annually.

Requestor would provide notice to Members of the points program described above (the "Points Program") in a number of ways, including, but not limited to: (i) marketing materials describing the Proposed Arrangement; (ii) the terms Members agree to in membership agreements required to participate in the Proposed Arrangement ("Membership Agreements"); (iii) monthly email communications to Members with point balance notifications; (iv) invoices; and (v) annual summary documents to Members with point balance notifications.

3. Membership Tiers

Membership tiers would be based generally on a Member's spending history on all Qualifying Purchases based on a rolling 12-month lookback period, and benefits would increase in value as a Member progresses through the different membership tiers. These benefits would generally include a variety of discounts and offerings on Requestor's support services and warranties ("Tiered Benefits"). Tiered Benefits would be set in advance with notifications to Members when changes or amendments have been made. In both the Membership Agreement and corresponding marketing materials, Requestor would inform Members of the terms under which Tiered Benefits could be earned, including the volume of Qualifying Purchases required to reach each tier and the types of benefits available at each tier.

Spending requirements¹⁰ for each tier would be as follows (each based on a rolling 12-month lookback period):

• Bronze: \$1 to \$14,999 in Qualifying Purchases

• Silver: \$15,000 to \$34,999 in Qualifying Purchases

• Gold: \$35,000 to \$74,999 in Qualifying Purchases

• Platinum: \$75,000 and above in Qualifying Purchases

regularly worth \$0.005 for redemption, the maximum redemption under the multiple-points promotion would be \$0.04 per point.

⁹ Requestor certified that this amount may be adjusted to reflect inflation and other reasonable financial adjustments in the future.

¹⁰ Requestor certified that spending requirements may be adjusted to reflect inflation and other reasonable financial adjustments in the future.

Tiered Benefits would begin at the Silver level. Examples of Tiered Benefits would include: (i) priority service and scheduling for in-office equipment service calls; (ii) extended labor warranties on equipment purchases; (iii) a discount on in-office hourly service labor rates; and (iv) one discount annually off the price of any one of Requestor's educational events related to training on Requestor's products. Each of these benefits would be offered and supplied by Requestor or one of its Participating Entities directly (or through an agent), as opposed to an independent external entity, and none of the items or services would be reimbursable by a Federal health care program. Beginning at the Silver level, Tiered Benefits would increase in time and value with the additional benefits of dedicated concierge customer services and sameday emergency service for, and repair responses to, critical equipment failures that prevent the practice from treating patients. Requestor would award Tiered Benefits to a Member immediately upon the Member passing the relevant spending threshold, and Requestor would reassess the Member's Tiered Benefits level at the end of the annual membership anniversary date based on a rolling 12-month lookback period.

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. 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. 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, OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also may

¹¹ Section 1128B(b) of the Act.

¹² Id.

E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey,
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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.¹⁴ 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.¹⁵ However, 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 safe harbor for discounts potentially would apply to the Proposed Arrangement. This safe harbor interprets a statutory exception that protects "a discount or other reduction in price obtained by a provider of services or other entity under [Medicare or a State health care program] if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under [Medicare or a State health care program]." The discount exception—interpreted by the OIG through the discount safe harbor ¹⁷—reflects Congress' intent to encourage price competition that benefits Federal health care programs. The discount safe harbor specifies different requirements for sellers, buyers, and offerors of discounted items and services.

B. Analysis

The Proposed Arrangement would result in two remuneration streams that would implicate the Federal anti-kickback statute. First, Requestor and Participating Entities would give remuneration to Members in the form of points earned on Qualifying Purchases that could be redeemed to reduce the dollar amount a Member pays for Redeemable Dental Items and Services. Second, Requestor and Participating Entities would provide Tiered Benefits to Members based on the amount of their Qualifying Purchases. Both Qualifying Purchases and Redeemable Dental Items and Services include items and services reimbursable by Federal health care programs.

We next determine whether any safe harbors to the Federal anti-kickback statute would apply to the Proposed Arrangement. For the Proposed Arrangement to have safe harbor protection, each stream of remuneration must fit squarely in one or more safe harbors. Because the discount safe harbor is potentially applicable, we must determine whether it would protect each form of remuneration offered to Members under the Proposed Arrangement.

¹⁴ Section 1128B(b)(3) of the Act.

¹⁵ 42 C.F.R. § 1001.952.

¹⁶ Section 1128B(b)(3)(A) of the Act.

¹⁷ 42 C.F.R. § 1001.952(h).

Under the safe harbor, the term "discount" is defined as "a reduction in the amount a buyer . . . is charged for an item or service based on an arms-length transaction." This definition includes certain caveats. Most relevant to the Proposed Arrangement, a discount does not include "[o]ther remuneration, in cash or in kind, not explicitly described in this paragraph (h)(5)." Neither remuneration stream under the Proposed Arrangement would be protected by the discount safe harbor. The Points Program does not meet the definition of a "discount" under the discount safe harbor because the points are "other remuneration"—a benefit conferred on Members with each point valued at \$0.005 towards the purchase of Redeemable Dental Items and Services. Points carrying such value would not operate as reductions in the purchase price of Redeemable Dental Items and Services but rather would serve as "other remuneration" that may be used to pay part of the purchase price (in combination with dollar amounts paid by Members) for the Redeemable Dental Items and Services. Similarly, the Tiered Benefits do not fit the definition of a "discount" because they also include "other remuneration," such as priority services and extended warranties, in addition to discounted support items and services.

We caution that purported "discount" programs that do not meet the discount safe harbor are typically high risk and suspect under the Federal anti-kickback statute. That said, arrangements that implicate the Federal anti-kickback statute and do not have safe harbor protection are evaluated on a case-by-case basis, accounting for the totality of the facts and circumstances. Based on this assessment, and for the combination of the following reasons, we conclude that the Proposed Arrangement would pose a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

1. The Points Program

First, the low dollar value of each point (worth \$0.005²⁰ towards the purchase of Redeemable Dental Items and Services) would somewhat mitigate the risk of steering to Requestor in the overall context of the Proposed Arrangement. In addition, the Points Program has features that reduce the risk of steering Members to purchase particular items or services. The Points Program would not incentivize Members to purchase any particular product from among the approximately 200,000 items on offer because all Qualifying Purchases earn points in the same way. Likewise, points earned under the Points Program could be used on equal terms toward the purchase of any of those 200,000 items—the Redeemable Dental Items and Services. This distinguishes the Points Program from problematic purported "discount" programs designed to steer buyers towards purchasing particular items. Furthermore, the Points Program would not steer Members towards buying from Requestor's non-dental service lines. The Qualifying

¹⁸ 42 C.F.R. § 1001.952(h)(5).

¹⁹ <u>Id.</u> § 1001.952(h)(5)(vii).

²⁰ Requestor certified that this amount may be adjusted to reflect inflation and other reasonable financial adjustments in the future.

²¹ This holds true for Requestor's occasional multiple point promotions, which would not be linked to specific items or services.

Purchases and Redeemable Dental Items and Services would be limited to dental-related items and services such that Requestor's other service lines (e.g., medical supplies) would not be part of the Proposed Arrangement. A customer loyalty program for a different type of entity in a different health care sector, as opposed to a dental industry distributor, may present different risks to Federal health care programs.

<u>Second</u>, the Points Program would not allow for the provision of free items or services in exchange for purchases of federally reimbursable items and services, a practice that creates substantial risk under the Federal anti-kickback statute.²² By limiting the redemption of points to cover at most 50 percent of the purchase price of any Redeemable Dental Item or Service, Requestor has designed the Points Program so that it would not result in no-cost items and services to Members in exchange for their purchases.²³

Third, the specific terms under which points could be redeemed reduce the risk that Members would be incentivized to engage in practices that the Federal anti-kickback statute is designed to prevent, such as steering and overutilization. The Proposed Arrangement is distinguishable from rewards programs that bestow concert and sports tickets, consumer electronics, vacation travel, or other items of personal value. In contrast, the Proposed Arrangement contains limits to ensure points—each with a \$0.005 redemption value—would be used only towards the purchase of Redeemable Dental Items and Services. The points would have no value outside Requestor's Points Program: points could not be redeemed for cash; points would have no value if they were not redeemed; points would not be transferable to other Members or non-Member customers; and returned items would result in forfeiting the associated earned points. Requestor and Members would be able to account for points earned and redeemed on an item-by-item and service-by-service basis via the Points Dashboard, managed by a third-party vendor, which adds transparency to the Proposed Arrangement.

2. Tiered Benefits

<u>First</u>, the types of benefits offered under the Tiered Benefits would reduce the risk of unfair competition and improper steering of customers to Requestor. The Tiered Benefits would consist of a variety of benefits related to Requestor's customer service offerings (<u>e.g.</u>, priority service and scheduling for in-office equipment service calls; extended labor warranties on equipment purchases; discounts on in-office hourly service rates; and one discount annually off the price of any one of Requestor's educational events related to training on Requestor's products). As such, the Tiered Benefits resemble support services for Requestor's dental-related items and services. This distinguishes the Tiered Benefits from more problematic rewards, such

²² See, e.g., OIG, Industry Segment-Specific Compliance Program Guidance for Skilled Nursing Facilities and Nursing Facilities (November 20, 2024), Sect. II.C.1., https://oig.hhs.gov/compliance/nursing-facility-icpg.

²³ With respect to the amount of the purchase price for which points may be redeemed, we offer no opinion on what threshold percentage presents low risk under the Federal anti-kickback statute, which depends on an assessment of the totality of the facts and circumstances if a safe harbor is not met.

as concert and sports tickets, personal electronics, or vacation travel, which encourage improper steering or foment unfair competition based on which distributor can offer the more lavish rewards.

<u>Second</u>, the structure of the Tiered Benefits would be unlikely to drive overutilization or corrupt medical decision-making. A Member's increasing volume of Qualifying Purchases would earn the Member an increase in Tiered Benefits—generally comprised of customer support services relating to those purchases—but would not earn the Member any additional, independently valuable rewards, let alone the types of problematic rewards discussed above that would be more likely to drive overutilization or corrupt medical decision-making. We find it unlikely that there would be an incentive for a Member to stockpile Qualifying Purchases only to earn Tiered Benefits that relate to support for those purchases.

<u>Third</u>, the design of the Tiered Benefits would reduce the risk that they could be abused to selectively reward particular Members or particular types of purchases. Tiered Benefits would be based on objective criteria set in advance with notifications to Members when changes or amendments have been made. In both the Membership Agreement and corresponding marketing materials, Requestor would inform Members of the terms under which Tiered Benefits could be earned, including the volume of Qualifying Purchases required to reach each tier and the types of benefits available at each tier. Accordingly, the terms under which Tiered Benefits would be earned and received are consistent for all Members and based on objective criteria that are set in advance and are related to their respective tiers.

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—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.

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.

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 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,

/Susan A. Edwards/

Susan A. Edwards Assistant Inspector General for Legal Affairs