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: September 10, 2024

Posted: September 13, 2024

[Address block redacted]

Re: OIG Advisory Opinion No. 24-08 (Unfavorable)

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 share a percentage of its savings with certain groups to which it provides coverage, in the circumstances specified below (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 the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act.

This opinion may not be relied on by any person[1] 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. Background

Requestor is a [redacted] corporation which, on behalf of itself and its affiliates, contracts with the Centers for Medicare & Medicaid Services ("CMS") to offer Medicare Advantage ("MA") plans, MA-Prescription Drug ("MA-PD") plans, and MA/MA-PD Employer Group Waiver Plans ("EGWPs"). Requestor provides health insurance coverage and administrative services to group health plans consistent with 42 C.F.R. § 422.106(d)(6), such as employers, trusts, and union groups (each, a "Group," and collectively, "Groups").

Both MA organizations that offer plans in the individual market[2] and MA organizations that offer EGWPs contract with CMS to provide their enrollees the basic benefits available to enrollees under Medicare Parts A and B and may also provide supplemental benefits that go beyond what enrollees would have received under Parts A and B. Both MA organizations that offer plans in the individual market and MA organizations that offer EGWPs may also offer enrollees prescription drug benefits under Medicare Part D. In addition, both MA organizations offering plans in the individual market and MA organizations offering EGWPs receive a capitated, per-member, per-month payment from CMS. However, there are certain differences between MA organizations offering plans in the individual market and MA organizations offering EGWPs that are relevant to this advisory opinion, detailed directly below.

First, unlike MA organizations offering plans in the individual market, MA organizations offering EGWPs do not submit bids to CMS.[3] Instead, CMS granted a waiver from MA bidding requirements for EGWPs beginning with contract year 2017, and an EGWP's capitated amount

[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] An MA plan offered in the "individual market" means a plan offered and marketed by MA organizations to eligible Medicare enrollees.

[3] An MA organization offering plans in the individual market submits a bid that should represent the MA organization's anticipated cost of providing basic benefits to a Medicare enrollee in that payment area with an average risk profile. See generally section 1854(a)(6) of the Act. CMS then compares that bid to an annually calculated benchmark amount. See section 1853 of the Act.

is based on the average bids and benchmarks in the individual MA market, across all plans at the county level.[4]

Second, while MA organizations offering MA plans in the individual market are subject to uniform premium requirements for members enrolled in the same plan, Requestor certified that MA organizations offering EGWPs, such as Requestor, may negotiate with Groups with respect to, among other details, the scope of benefits and any additional premium amounts to be paid by the Group or its enrollees. MA organizations offering EGWPs may—but are not required to—charge a Group an additional premium for each enrollee enrolled in the EGWP, which the Group may collect, in whole or in part, from its enrollees.

Finally, as described in 42 C.F.R. § 422.266, MA organizations offering MA plans in the individual market must use a "rebate" (equal to a percentage of the amount by which an MA organization's bid is lower than the benchmark), if any, in the form of: (i) payment for supplemental benefits (which can include reductions in cost sharing compared to Medicare fee-for-service cost sharing); (ii) a reduction in the enrollee's Medicare Part B premium; or (iii) a reduction in the enrollee's premium that is attributable to prescription drug coverage.[5] Responding to a statement that CMS made in the 2022 Advance Notice that "the limits in [42 C.F.R.] § 422.266 on how the MA rebate may be used have not been waived and therefore continue to apply for EGWPs," Requestor certified that it asked CMS to clarify whether MA organizations offering EGWPs may use any funds that qualify as a rebate under CMS's definition to make "gainshare" payments to Groups.[6] In response, CMS explained that MA organizations offering EGWPs receive a monthly payment for each enrollee that consists of two components, a base county payment rate and a rebate (as described above), which are added together and multiplied by the enrollee's risk score to produce a single payment amount; these two components are not subsequently broken out. CMS further explained that, because these components are combined and not broken out, MA organizations offering EGWPs are unable to identify the amount of their total payment that is a rebate payment. Therefore, CMS has, since

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[4] CMS has continued the waiver each year since it was initially issued for 2017. See, e.g., CMS, Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Apr. 4, 2016), at 27-44, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf; Announcement of Calendar Year (CY) 2025 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Apr. 1, 2024), at 69-72, https://www.cms.gov/files/document/2025-announcement.pdf. CMS's Advance Notice of Methodological Changes and Rate Announcements for Medicare Advantage Capitation Rates and Part C and Part D Payment Policies ("Advance Notice") for each year is available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.

[5] 42 C.F.R. § 422.266(b).

[6] See CMS, Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Jan. 15, 2021), at 52–53, https://www.cms.gov/files/document/2022-announcement.pdf.

2017, waived the requirement for MA organizations to inform CMS how the EGWPs will distribute amounts paid as rebates among the options at 42 C.F.R. § 422.266(b). CMS also has waived the requirement that MA organizations offering EGWPs rebate to their enrollees a specific percentage of the overall payment from CMS. Accordingly, under CMS guidance, an MA organization offering an EGWP could choose not to rebate any portion of its overall payment from CMS to its enrollees. CMS also explained, however, that if an MA organization offering an EGWP chose to rebate a portion of its payment, then "any amounts that an MA EGWP rebates to enrollees must be provided in a form and manner that is consistent with [42 C.F.R.] § 422.266(b)."[7] In other words, an MA organization offering an EGWP is not required to issue any rebate, but if it does issue a rebate, then the EGWP must provide those rebates in a form consistent with the options at 42 C.F.R. § 422.266(b). In addition, Requestor cites to CMS's statement that: "[CMS does] not regard the regulation at [42 C.F.R.] § 422.266, which governs the use of beneficiary rebates, as restricting how the EGWP can use the entire payment it receives from CMS, particularly its own gain/loss margin."[8]

B. The Proposed Arrangement

Under the Proposed Arrangement, Requestor would give Groups the opportunity to share in a percentage of Requestor's savings ("Gainshare Payment"). First, Requestor would enter into agreements with Groups to provide coverage to the Group's enrollees for the basic benefits under Medicare Parts A and B and, if applicable, prescription drug coverage under Medicare Part D through an MA-PD plan, plus any supplemental benefits that Requestor and each Group may negotiate. Requestor and each Group also would negotiate whether Requestor would charge any additional amount as a premium.[9]

Then, as part of the Proposed Arrangement, Requestor and a Group would include conditions in their contract that would govern when a Group would be eligible to share a percentage of Requestor's savings as a Gainshare Payment. The Gainshare Payment would be based on a negotiated "medical loss ratio" ("Negotiated MLR").[10] Requestor certified that the Negotiated MLR would be calculated by dividing certain expenses incurred by Requestor by certain revenues Requestor received. Requestor and a Group also would negotiate a particular target

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[7] Id.

[8] Id.

[9] Requestor certified that any additional premium charged would encompass all benefits (i.e., there would be a single additional premium that applies to the basic MA benefit, the basic Part D benefit, and any additional benefits offered as part of the plan).

[10] The regulations governing calculation of the medical loss ratio for purposes of the MA program are set forth at 42 C.F.R. Part 422, subpart X. The calculation of the Negotiated MLR for purposes of the Proposed Arrangement would be defined and negotiated by the parties and would not be the same as the medical loss ratio calculated pursuant to 42 C.F.R. § 422.2420. Similarly, the Negotiated MLR would not be used to calculate any remittance owed to CMS pursuant to section 1847(e)(4) of the Act and 42 C.F.R. § 422.2470.

Negotiated MLR percentage for the Group. If the final calculated Negotiated MLR for the Group is below the negotiated target, Requestor would pay the Group an amount representing a separately negotiated percentage of the savings below the target (i.e., the Gainshare Payment). The amount of the Gainshare Payment could exceed any additional premium amount paid by the Group and could be paid to Groups that do not pay an additional premium to Requestor.

Requestor would make the final Negotiated MLR calculations and conduct final reconciliation of these payments following a one- or two-year settlement period after the plan year concludes. Requestor also certified that a contract between Requestor and a Group could include conditions upon which Requestor could terminate or modify the Proposed Arrangement (e.g., termination could be triggered by the number of enrollees in a Group falling below a negotiated threshold). Requestor would not restrict how a Group may utilize the Gainshare Payment. However, Requestor noted that Groups with which it would enter into the Proposed Arrangement may be subject to the Employee Retirement Income Security Act[11] ("ERISA") or State laws that impose fiduciary requirements. Any Group subject to ERISA, State law, or both could be subject to legal requirements that could impact how the Group uses the Gainshare Payment (e.g., a Group may be required to use plan assets for the benefit of plan participants).

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.[12] 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.[13] 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.[14] 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

[11] See 29 U.S.C. § 1001 et seq.

[12] Section 1128B(b) of the Act.

[13] Id.

[14] 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).

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.

B. Analysis

The Proposed Arrangement would implicate the Federal anti-kickback statute because Requestor, an organization that offers EGWPs,[15] would offer remuneration to a Group in the form of sharing a percentage of its savings that could induce the Group to refer its enrollees to Requestor so that Requestor, via its EGWP, would arrange for the furnishing of items or services that are reimbursable by a Federal health care program. No safe harbor would apply. For the following reasons, we believe the risk of fraud and abuse presented by the Proposed Arrangement is not sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

First, the Proposed Arrangement presents a risk of steering, which also could impact competition. Specifically, under the Proposed Arrangement, Groups would be given the opportunity to receive an incentive—the Gainshare Payment—to choose a particular plan that would arrange for federally reimbursable items and services for the enrollees. Unlike a rebate governed by the requirements of 42 C.F.R. § 422.266, the Gainshare Payment would not necessarily be used to benefit enrollees. The ability of the Group to use the Gainshare Payment for purposes other than benefitting enrollees could steer the Group to choose Requestor's plan for the Group's enrollees over other plans that are unable or unwilling to provide such incentives. Moreover, Requestor certified that one possible trigger for Requestor to terminate an arrangement involving a Gainshare Payment with a Group would be if the number of enrollees in a Group were to fall below a negotiated threshold. This trigger further enhances the risk of a Group steering its enrollees to Requestor's EGWP plan in order to avoid having its arrangement terminated by Requestor.

Second, the steering concern would not be offset by any guaranteed benefits to enrollees. We recognize that MA organizations that contract with CMS to offer EGWPs are permitted certain flexibilities that can impact a Group's decision regarding whether to contract with that MA organization, such as what supplemental benefits might be offered and the total cost of the plan for the Group and its enrollees. However, Groups are under no obligation to negotiate for enhanced benefits or lower costs for their enrollees. If a Group does not contract for enhanced benefits, then the Group's enrollees may generate fewer costs, and thus increase the Group's chance of receiving the Gainshare Payment. Moreover, Requestor certified that the amount of the Gainshare Payment could exceed any additional premium amount paid by the Group and could be paid to a Group that does not pay an additional premium to Requestor. Therefore, the

[15] We recognize that Requestor contracts with CMS to offer various types of plans, including EGWPs that offer Part D coverage and EGWPs that do not. The differences do not impact the analysis, and therefore we do not refer separately to the different types of EGWPs.

Proposed Arrangement could result in financial gain for Groups while resulting in fewer benefits for enrollees.

Finally, we note that CMS's statement that it does not regard "the regulation at [42 C.F.R.] § 422.266, which governs the use of beneficiary rebates, as restricting how the EGWP can use the entire payment it receives from CMS, particularly its own gain/loss margin"[16] does not expressly permit Gainshare Payments as part of the program; it simply states that 42 C.F.R. § 422.266 does not apply to the portion of a payment not issued as a rebate. Moreover, the statement does not insulate such payments from implicating the Federal anti-kickback statute.

We want to emphasize that, while we have concluded that the risk of fraud and abuse presented by the Proposed Arrangement is not sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion, this does not mean that any possible payment arrangement that could be made under the Proposed Arrangement necessarily would violate the Federal anti-kickback statute. We recognize that MA organizations offering EGWPs are afforded a number of flexibilities as part of the program design and that it is possible that a particular arrangement between an MA organization offering an EGWP and a Group could be sufficiently low risk under the Federal anti-kickback statute despite having as one element of the negotiated arrangement the offer and receipt of a potential payment in the form of sharing a percentage of the MA organization's savings. However, we cannot conclude that the framework set forth by Requestor is sufficiently low risk to issue a favorable advisory opinion.

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 generate prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act.

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.

[16] CMS, Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Jan. 15, 2021), at 53, https://www.cms.gov/files/document/2022-announcement.pdf.

- 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 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.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs