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 30, 2021

Posted: October 5, 2021

[Name and address redacted]

Re: OIG Advisory Opinion No. 21-14

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 a proposal to extend an existing discount program for chiropractic patients to include Federal health care program beneficiaries (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: (i) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the 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, the 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 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

Requestor operates chiropractic clinics in [state redacted]. The chiropractors who furnish services in Requestor's clinics do not participate as in-network providers with any third-party payors, including the Medicare program.[2] Patients, including Federal health care program beneficiaries, pay Requestor directly for the services they receive at Requestor's clinics, and Requestor provides them with an itemized receipt to, as applicable, submit to their insurance plan for any reimbursement they may be owed under their plans' out-of-network coverage. Requestor certified that, patients who have Medicare as their primary insurance pay Requestor directly at the time of service, and per Medicare program requirements, Requestor submits the claims to Medicare on the patients' behalf.[3] When Requestor submits that claim, it directs that Medicare's reimbursement decision be sent directly to the patient. Thus, while a Medicare patient may pay Requestor up-front at the time services are provided, if the services furnished are covered by Medicare, that patient may be reimbursed by Medicare, in whole or in part, for the amount the patient initially paid Requestor.

Requestor currently offers various discounts to the general public but prohibits Federal health care program beneficiaries from utilizing these discounts. Under the Proposed Arrangement, Requestor would permit all patients, including Federal health care program beneficiaries, to utilize any offered discounts on the same terms. Any such discounts would be offered and advertised to the general public and not targeted to Federal health care program beneficiaries. Consistent with its current practice, under the Proposed Arrangement, Requestor would offer various discount promotions throughout the year, each of which would be limited in supply, expire on a specified date, or both. Requestor does not and would not notify patients of any discount offers while patients are at a clinic; in other words, patients already must be aware of a discount offer and must affirmatively ask for the discount when they present for an appointment. Requestor charges its standard rates to patients who do not request a discount.

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[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 chiropractors are enrolled as non-participating providers with Medicare.

[3] Requestor certified that, when billing Medicare beneficiaries, it adheres to the Medicare Physician Fee Schedule, which sets limiting charges for covered services.

Requestor typically offers discounts on a package of services. Some packages might consist entirely of services that are not reimbursable by Federal health care programs, while other packages might include both reimbursable and non-reimbursable services. Requestor certified that, under the Proposed Arrangement, it would allocate the discount proportionally across each of the services in the package, with the same percentage discount applied to each service. Thus, when an offer includes a discounted package of various services for a set price, the discounted charges for each component service would be reflected on the billing statement or receipt (e.g., if the aggregate, non-discounted cost for Services A, B, and C is $200.00, with Service A's cost being $40.00, Service B's cost being $60.00, and Service C's cost being $100, and a discounted package for the same services is $100.00 (i.e., an overall discount of 50 percent), then the billing statement or receipt would reflect the following line items: Service A: $20.00, Service B: $30.00, and Service C: $50.00). Requestor certified that all claims submitted to Medicare would reflect the discounted amount for the covered service(s), including any discount Requestor might offer on a stand-alone service that is not part of a bundle.

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.[4] 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.[5] 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.[6] 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

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

[5] Id.

[6] 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).

also may 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.[7] 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.[8] However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the applicable 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 and expands upon 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]."[9] The discount exception—interpreted by the OIG through the discount safe harbor[10]—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. As explained in more detail below, for the remuneration offered under the Proposed Arrangement to be protected under the discount safe harbor, Requestor would have to comply with the requirements for sellers.[11]

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" and includes a number of exceptions to the definition,

[7] Section 1128B(b)(3) of the Act.

[8] 42 C.F.R. § 1001.952.

[9] Section 1128B(b)(3)(A) of the Act.

[10] 42 C.F.R. § 1001.952(h).

[11] See id.

including an exception for any permissible practice specified in a statutory exception to the Federal anti-kickback statute or a safe harbor regulation.[12]

B. Analysis

1. Federal Anti-Kickback Statute

The Proposed Arrangement would implicate the Federal anti-kickback statute. Requestor would give remuneration in the form of discounted services to Federal health care program beneficiaries, and while Requestor is a non-participating provider in Medicare and does not receive any reimbursement from Federal health care programs, some services that Requestor provides as a non-participating provider are reimbursable directly to the beneficiary by Medicare. Because the discount safe harbor is potentially applicable, we must determine whether it would protect the remuneration offered to beneficiaries under the Proposed Arrangement. As an initial step, we must determine whether the Proposed Arrangement would involve a "discount" as defined in the safe harbor.

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."[13] This definition includes certain caveats. Most relevant to the Proposed Arrangement, a discount does not include:

> [s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology.[14]

We have expressed concerns about discounts on bundled items and services for multiple reasons, including that these discounts can shift costs among reimbursement systems and distort the true cost of items and services.[15] For example, a company might offer a discount to a hospital on items reimbursable under Medicare Part A to induce the purchase of items reimbursable under Medicare Part B. In this scenario, not only would the cost be shifted among reimbursement systems, but it would be difficult to determine the net price of any item for reporting purposes. We noted in the preamble to the 1999 Final Rule, however, that "discounts offered on one good or service to induce the purchase of a different good or service where the net value can be properly reported do not pose a risk of program abuse and may benefit the programs through

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[12] Section 1128A(i)(6)(B) of the Act.

[13] 42 C.F.R. § 1001.952(h)(5).

[14] Id. § 1001.952(h)(5)(ii).

[15] See Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,530 (Nov. 19, 1999) (the "1999 Final Rule").

lower costs or charges achieved through volume purchasing and other economies of scale."[16] That particular statement was made to support the concept of allowing bundled discounts when the goods and services are reimbursed by the same payment methodology.

Under the Proposed Arrangement, Requestor would offer various discounted services to all patients, including Federal health care program beneficiaries. Some of those discounts might be on a package of services, which could include a mix of non-reimbursable services and reimbursable services. Because access to the discounted price would be available only if the patient received all services in the bundle, and all services would not be reimbursed by the same methodology, the discounted price would not meet the definition of a "discount" for purposes of the safe harbor, and thus, the Proposed Arrangement would not be protected.[17] However, the concerns we expressed when excluding bundled discounts from protection would not be present here. The reimbursable services furnished to Medicare beneficiaries would all be services reimbursed under the same payment methodology, Medicare Part B, pursuant to the Physician Fee Schedule. Requestor certified it would allocate the discount proportionally across each of the services in the package and would reflect such allocation on any receipt, billing statement, or claim, such that payors, including Medicare, would know the amount charged for each service, i.e., the discount would be readily attributable to each service purchased. Requestor would not, for example, be offering a deep discount on a non-reimbursable service to induce a patient to get additional reimbursable services. For these reasons, the Proposed Arrangement presents a low risk under the Federal anti-kickback statute.

2. Beneficiary Inducements CMP

The Proposed Arrangement also would implicate the Beneficiary Inducements CMP because Requestor would give something of value (a discount) that is likely to influence a beneficiary to receive federally reimbursable services from Requestor. Because we conclude that the Proposed Arrangement would not meet the requirements of the discount safe harbor, the Proposed Arrangement also would not meet the exception to the Beneficiary Inducements CMP for any permissible practice specified in a statutory exception to the Federal anti-kickback statute or a safe harbor regulation. However, in an exercise of our discretion and for the reasons stated above, we would not impose administrative 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 prohibited remuneration under the Federal anti-kickback statute if the requisite intent

[16] Id.

[17] We note that any discounts that Requestor might offer on a single service could be protected by the safe harbor for discounts. However, because the Proposed Arrangement would include both stand-alone and bundled discounts, the Proposed Arrangement as a whole would not be protected.

were present, the 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, the 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 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