



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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**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:** February 7, 2025

**Posted:** February 12, 2025

[Address block redacted]

**Re: Notice of Modification of OIG Advisory Opinion No. 21-13 (Favorable)**

Dear [redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request on behalf of [redacted] (collectively “Requestors”) to modify Advisory Opinion No. 21-13 (“AO 21-13”), which we issued to Requestors on September 29, 2021. In AO 21-13, we opined favorably on Requestors’ proposal to subsidize certain Medicare cost-sharing obligations in the context of a clinical study; Requestors subsequently implemented the proposal under the same terms and pursuant to the same procedures described in AO 21-13 (the “Arrangement”). Requestors now request a modified opinion to reflect changes in the Arrangement resulting from changes in Medicare coverage policy that impact payment for certain services provided during the clinical study (the “Modified Arrangement”).

Requestors have inquired whether the Modified Arrangement, in light of certain changes in Medicare coverage policy, constitutes 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.

Requestors have certified that all of the information provided in their request for a modification of AO 21-13, 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 Modified Arrangement, and we have relied solely on the facts and information Requestors provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestors. This opinion is limited to the relevant facts presented

to us by Requestors in connection with the Modified 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 modification and supplemental submissions, we conclude that: (i) although the Modified Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestors in connection with the Modified 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 Modified Arrangement generates prohibited remuneration under the Beneficiary Inducements CMP, OIG will not impose administrative sanctions on Requestors in connection with the Modified 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<sup>1</sup> other than Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

## **I. FACTUAL BACKGROUND**

### **A. Summary of the Arrangement as Set Forth in AO 21-13**

[Redacted] (the “Professional Association”) is a professional medical society representing radiologists, and [redacted] (the “Charity”) is a non-profit organization that provides support and facilitates research relating to Alzheimer’s disease (“AD”). The Professional Association is the sponsor of a clinical study (the “Study”) designed to evaluate the association between a brain imaging procedure and patient-centered outcomes in an ethnoracially and clinically diverse group of Medicare participants experiencing cognitive impairment. The Charity is the Study director, which involves providing scientific and operational guidance and support to the Study.

The Study involves an investigation into the use of a positron emission tomography (“PET”) scan of the brain that detects beta amyloid (“A $\beta$ ”) plaques, a core feature of AD, in patients with mild cognitive impairment or dementia of uncertain cause. Since 2013, the Centers for Medicare and Medicaid Services (“CMS”) has provided limited coverage through Coverage with Evidence Development (“CED”) for the use of one PET A $\beta$  scan per patient in approved clinical studies. The CED paradigm allows CMS to offer Medicare coverage for otherwise non-covered items and services on the condition that they are provided to Medicare beneficiaries enrolled in an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary. As described in AO 21-13, under the Arrangement, Requestors pay the cost-sharing amounts that Medicare beneficiaries participating in the Study otherwise would owe for Medicare-reimbursable PET A $\beta$  scans provided during the Study. Requestors explained that these subsidies promote enrollment

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<sup>1</sup> 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.

from minority communities by removing a financial barrier. In AO 21-13, we concluded that the Arrangement presented a minimal risk of fraud and abuse under the Federal anti-kickback statute and that, in an exercise of our discretion, we would not impose sanctions under the Beneficiary Inducements CMP.

## **B. Relevant Changes to Medicare Coverage Policy**

After OIG issued AO 21-13, Requestors implemented the Arrangement. In October 2023, CMS issued a decision memorandum ending coverage for PET A $\beta$  imaging under the CED paradigm, which shifted coverage decisions for these scans to the Medicare Administrative Contractors (“MACs”).<sup>2</sup> In its decision memorandum, CMS emphasized that the focus of the Study—to include ethnoracially and clinically diverse Medicare participants—remains important.

After termination of Medicare coverage of PET A $\beta$  scans under the CED paradigm, scans provided as part of the Study have received Medicare coverage via the MACs. As with the prior Medicare coverage regime, payment for each scan results in a cost-sharing obligation for the Study participant. Although the Study is scheduled to conclude in 2025, Requestors wish to continue offering cost-sharing subsidies through the Study’s conclusion in order to meet the Study’s recruitment goals. Accordingly, Requestors have continued providing cost-sharing subsidies to study participants under the same terms and pursuant to the same procedures described in AO 21-13. Requestors have certified that the Modified Arrangement presents only one change from the material facts certified in connection with AO 21-13: the changes in Medicare coverage policy for PET A $\beta$  scans described above.

## **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.<sup>3</sup> 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.<sup>4</sup> For purposes of the Federal anti-kickback

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<sup>2</sup> CMS, Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease, CAG-00431R (Oct. 13, 2023), <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=308>.

<sup>3</sup> Section 1128B(b) of the Act.

<sup>4</sup> Id.

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.<sup>5</sup> Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

## 2. Beneficiary Inducements CMP

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines “remuneration” for purposes of the Beneficiary Inducements CMP as including “transfers of items or services for free or for other than fair market value.”

### **B. Analysis**

As detailed in AO 21-13, we concluded that, although the Arrangement would implicate the Federal anti-kickback statute and the Beneficiary Inducements CMP, the Arrangement presented a sufficiently low risk of fraud and abuse for OIG to issue a favorable advisory opinion. We conclude that the combination of reasons detailed in AO 21-13 is neither diminished nor altered as a result of the changes in Medicare coverage policy with respect to scans provided as part of the Study. Accordingly, consistent with the conclusion in AO 21-13, the Modified Arrangement—even after the relevant change in Medicare coverage policy—presents a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute for OIG to issue a favorable modification of AO 21-13 and, in an exercise of our discretion, we will not impose sanctions under the Beneficiary Inducements CMP.

### **III. CONCLUSION**

Based on the relevant facts certified in your request for an advisory opinion modification and supplemental submissions, we conclude that: (i) although the Modified Arrangement would

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<sup>5</sup> 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).

generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestors in connection with the Modified 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 Modified Arrangement generates prohibited remuneration under the Beneficiary Inducements CMP, OIG will not impose administrative sanctions on Requestors in connection with the Modified 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 Modified 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 Requestors. 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 Requestors 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 Modified 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 Requestors with respect to any action that is part of the Modified 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 Modified 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 Requestors with respect to any action that is part of the Modified 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