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 29, 2021
Posted: October 4, 2021

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 21-13

Dear [Names redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of the [names redacted] (collectively, "Requestors") regarding the proposed subsidization of certain Medicare cost-sharing obligations in the context of a clinical study (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.

Requestors have 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 Requestors. This opinion is limited to the relevant facts presented to us by Requestors 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 Requestors in connection with the Proposed Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate 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 Requestors 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 Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] (the "Professional Association") is a professional medical society representing radiologists, and [name 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 the [study name redacted] (the "Study"), a clinical study designed to evaluate the association between a certain brain imaging procedure and patient-centered outcomes in an ethno-racially 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.

A. Overview of the Study

The Study involves an investigation into the use of a positron emission tomography ("PET") scan of the brain that detects beta amyloid ("Aβ") plaques, a core feature of AD, in patients with mild cognitive impairment or dementia of uncertain cause. The Study will explore whether PET Aβ imaging affects patient health outcomes in a diverse sample of patients with mild cognitive impairment by assessing: (i) the extent to which PET Aβ imaging results are associated with changes in clinical management of patients with mild cognitive impairment or dementia; (ii) whether any such changes in clinical management result in improved health outcomes for patients; and (iii) how these effects manifest in patients of different ethno-racial backgrounds, clinical presentations, and disease stages. The Study is limited to Medicare beneficiaries. To be eligible to participate in the Study, beneficiaries must meet certain enrollment criteria and must execute an informed consent document.

The research team will be led by Requestors, in collaboration with a principal investigator and researchers from various academic research institutions (collectively, the "Study Team"). The Study will be conducted by investigators, who are responsible for recruiting and enrolling eligible subjects as well as completing three Study-related clinical visits per subject.

The Professional Association aims to enroll approximately 350 sites, each of which must be a hospital outpatient department or an independent diagnostic testing facility at which the PET Aβ scans will be performed. Sites will be rated via a feasibility questionnaire based on objective factors to gauge the site's fitness to participate in the Study, including, for example, accreditation

[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.

and adequate experience conducting PET scans of the brain.

To be eligible to participate as an investigator, a physician must: (i) be trained and board-certified in neurology, psychiatry, or geriatric medicine; (ii) devote a substantial proportion of patient contact time to the evaluation and care of adults with acquired cognitive impairment or dementia; (iii) be located in a geographic region of the United States with access to the technology necessary for the Study; and (iv) be enrolled in the Medicare program. Prospective investigators will be identified through relevant professional societies and will be vetted through a feasibility questionnaire that rates physicians on objective factors relevant to the Study.

The Professional Association will enter into a written contract with each investigator setting forth the investigator's duties and the compensation the Professional Association will pay for services the investigators provide as part of the Study, including recruitment and enrollment of Study subjects, obtaining informed consent, compiling a medical history, and completing pre- and post-PET clinical assessments. The Professional Association certified that the compensation to be paid for Study-related services provided by investigators is fair market value.[2]

Requestors have certified that the Study will be performed in compliance with all Federal regulations concerning the protection of human subjects found in 45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56, and all other applicable laws and regulations and will include, among other things, oversight and monitoring by an Institutional Review Board ("IRB").

B. Medicare Coverage for the Study

In 2013, the Centers for Medicare & Medicaid Services ("CMS") issued a National Coverage Determination ("NCD") and accompanying Decision Memorandum ("Decision Memo") announcing that Medicare would provide limited coverage through Coverage with Evidence Development ("CED") for the use of one PET Aβ scan per patient in clinical studies that meet certain criteria established by CMS and set forth in the Decision Memo.[3] 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

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[2] We have not been asked to opine on, and express no opinion regarding, the proposed compensation arrangements between Requestor and the investigators. We are precluded by statute from opining on whether fair market value shall be, or was, paid for goods, services, or property. Section 1128D(b)(3)(A) of the Act. For purposes of this advisory opinion, we rely on Requestor's certification regarding fair market value. If the compensation is not fair market value, this opinion is without force and effect.

[3] Medicare National Coverage Determination Manual ch. 1, § 220.6.20 - Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_part4.pdf; Decision Memo for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-00431N) (Sept. 27, 2013), available at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=265.

with a particular beneficiary.[4] Coverage in the context of ongoing clinical research protocols or with additional data collection can expedite earlier beneficiary access to innovative technology while ensuring that systematic patient safeguards are in place to reduce the risks inherent to new technologies or to new applications of older technologies.[5]

The NCD authorizes Medicare coverage for PET Aβ scans in a CMS-approved, comparative, longitudinal study that meets certain criteria. CMS noted in the Decision Memo that the use of PET Aβ imaging is promising "to enrich clinical trials seeking better treatments or prevention strategies for AD, by allowing for selection of patients on the basis of biological as well as clinical and epidemiological factors."

In April 2020, CMS approved the Study as a clinical study for which Medicare would cover one PET Aβ scan per patient under CED pursuant to the NCD.[6] According to Requestors, the Study is consistent with one of the objectives identified by CMS for clinical studies related to PET Aβ imaging. Specifically, in the Decision Memo, CMS emphasized the need for more diverse clinical studies:

> Subjects in key clinical trials on PET Aβ imaging . . . are generally > 90% white, despite data that older African-Americans are twice as likely, and older Hispanics 1.5 times as likely, to have AD (and other dementias) as older whites . . . . This lack of evidence about racial and ethnic factors represents in our view an evidence gap that we encourage trial designers to consider when proposing clinical trial designs under this NCD. While recognizing that this consideration may complicate the design of appropriate clinical studies, we will nevertheless prefer clinical study proposals in which data on racial and ethnic factors are specifically collected and analyzed.

Requestors certified that the Study is specifically designed to collect clinical information about treatment of dementia in minority populations. Of an anticipated 7,000 subjects, the Study aims to enroll at least 2,000 African Americans and at least 2,000 Latinos.

C. The Proposed Arrangement

Under the Proposed Arrangement, Requestors would pay the coinsurance amounts that Medicare beneficiaries participating in the Study otherwise would owe for Medicare-reimbursable PET Aβ scans provided during the Study. The Professional Association would pay a site directly for the coinsurance that a Medicare beneficiary participating in the Study otherwise would owe for the

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[4] Section 1862(a)(1)(E) of the Act permits Medicare coverage for items and services furnished in certain clinical research studies; in general, CED has been used when the available evidence is not sufficient for coverage under section 1862(a)(1)(A) of the Act.

[5] See generally CMS, Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development (Nov. 20, 2014), available at https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27.

[6] [Citation redacted].

PET Aβ scan used in the Study.

According to Requestors, enrollment in the Study from minority communities could be jeopardized because these beneficiaries may, in many cases, lack the financial resources to meet their coinsurance obligations for the scan. In order to remove a potential obstacle to general enrollment, and in particular, minority enrollment, Requestors propose to subsidize coinsurance obligations for the scan for virtually all subjects participating in the Study, regardless of financial need.[7]

To finance the subsidies of the coinsurance obligations, Requestors would use funds donated to the Charity by individuals and foundations with the express purpose of supporting the Charity's research programs, including the Study. Requestors have certified that none of these donations would be from entities with a financial interest in the Study, such as manufacturers of the imaging agents used in the PET Aβ scans. The funding and administration of the coinsurance subsidies would not further the commercial interests of Requestors because the Study is not intended to develop, study, or benefit any specific commercial product sold or marketed by Requestors. The Professional Association further certified that it would keep funding to be used for coinsurance subsidies segregated from funding used to support other aspects of the Study.

Requestors certified that neither they nor the Study Team nor the investigators would offer the coinsurance subsidies as part of any advertisement or solicitation relating to the Study. Information about the coinsurance subsidy would be included in the informed consent documents provided to each subject.

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.[8] 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.[9] 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.

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[7] The Professional Association would not provide financial assistance to beneficiaries who have supplemental insurance, such as Medigap, that covers their coinsurance obligations. The Proposed Arrangement also would not include subsidization of any unmet beneficiary deductibles.

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

[9] Id.

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.[10] 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 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. 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." Section 1128A(i)(6)(A) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term "remuneration" does not apply to the waiver of coinsurance and deductible amounts by a person if: (i) the waiver is not offered as part of any advertisement or solicitation; (ii) the person does not routinely waive coinsurance or deductible amounts; and (iii) the person waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need or fails to collect coinsurance or deductible amounts after making reasonable collection efforts.

B. Analysis

Under the Proposed Arrangement, Requestors would offer and pay coinsurance amounts for Medicare-billable PET Aβ scans provided to beneficiaries participating as subjects in the Study. The Proposed Arrangement would implicate the Federal anti-kickback statute because these coinsurance subsidies could induce Medicare beneficiaries to participate in the Study, during which they would receive federally reimbursable health care items and services. Although Requestors would not advertise the availability of coinsurance subsidies, investigators nevertheless would inform subjects of the subsidies as part of the informed consent process. The Proposed Arrangement would implicate the Beneficiary Inducements CMP because the remuneration is likely to influence a beneficiary to receive Medicare-billable items and services from a particular practitioner, provider, or supplier.

The Proposed Arrangement also would provide remuneration to the investigators and sites participating in the Study in two forms: (i) the opportunity to bill Federal health care programs for items and services related to the Study; and (ii) a guaranteed payment of beneficiary coinsurance,

[10] 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).

which, in some circumstances, an investigator or site may not otherwise be able to collect in full. Both forms of remuneration to investigators and sites would implicate the Federal anti-kickback statute.

The Proposed Arrangement would not fall squarely within any safe harbor to the Federal anti-kickback statute or exception to the definition of "remuneration" for purposes of the Beneficiary Inducements CMP. For example, the Proposed Arrangement would not meet the exception to the Beneficiary Inducements CMP at section 1128A(i)(6)(A) of the Act for waivers of beneficiary coinsurance obligations because, among other reasons, the exception only applies to a "waiver" of coinsurance obligations. Insofar as Requestors would pay investigators and sites the coinsurance amount they otherwise would have collected from beneficiaries, the remuneration is a subsidy paid on behalf of the beneficiary by a third party, not a waiver of coinsurance by the provider obligated under Medicare programmatic requirements to collect cost sharing from the beneficiary. Nevertheless, for the combination of reasons set forth below, we conclude that the Proposed Arrangement would present a minimal risk of fraud and abuse under the Federal anti-kickback statute and, in an exercise of our discretion, we would not impose sanctions under the Beneficiary Inducements CMP.

First, the Proposed Arrangement is part of a clinical study that has been developed in consultation with, and approved by, CMS. Further, the coinsurance subsidy appears to be designed to meet the policy objective of advancing treatment and prevention of AD, particularly for minorities. Most notably for purposes of our analysis, the Study is specifically designed to collect and analyze data on underrepresented minorities by enrolling a substantial but fixed number of subjects: of an anticipated 7,000 subjects, the Study aims to enroll at least 4,000 minorities. As a result, the Study potentially could address a real or perceived evidence gap on racial and ethnic factors in AD research. More broadly, the Study is designed to gather data on the effect of PET Aβ imaging in treating patients suffering from dementia. The coinsurance subsidies offered under the Proposed Arrangement appear to be a reasonable means to facilitate enrollment of a diverse set of subjects by removing a potential financial barrier to participation in the Study.

Second, the Proposed Arrangement would pose a low risk of overutilization or inappropriate utilization of Federal health care program items and services. Because the coinsurance subsidy is specifically designed to facilitate participation in the Study by a diverse group of subjects, it is possible that overall utilization of items and services may increase, but there is nothing to suggest that such an increase would be inappropriate. Indeed, the Proposed Arrangement would include various guardrails that mitigate the risk of inappropriate utilization or an improper increase in costs to Federal health care programs. In particular, Requestors certified that neither they nor the Study Team nor the investigators would advertise the availability of coinsurance subsidies. In addition, beneficiaries must satisfy the enrollment criteria set forth in the Study protocol and execute an informed consent document to be eligible to participate in the Study. Further, investigators must comply with the Study protocol and are subject to oversight and monitoring by an IRB.

Finally, the Proposed Arrangement is distinguishable from problematic seeding arrangements, such as those in which manufacturers offer subsidies initially to lock in future reimbursable utilization of an item or service. Beneficiaries would receive only one Medicare-billable PET Aβ scan and three Medicare-billable office visits as part of the Study, and there is no expectation that participation in the Study would trigger subsequent utilization of items or services billable to Federal health care programs. Accordingly, the Proposed Arrangement would not present the risk of problematic

seeding arrangements that could be used to steer beneficiaries to other Medicare-reimbursable treatments in the future. Moreover, Requestors are a charity and a professional association that are not in a position to benefit financially from the services provided as part of the Study, and Requestors have certified that the coinsurance subsidies would be funded by donations to the Charity from individuals and foundations without a financial interest in the Study.

For the combination of reasons described above, we conclude that the Proposed Arrangement would present a minimal risk of fraud and abuse under the Federal anti-kickback statute. For the same reasons, in an exercise of our discretion, we would not impose 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 were present, the OIG would not impose administrative sanctions on Requestors in connection with the Proposed Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate 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 Requestors 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 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 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 Requestors 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 Requestors 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