DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001 and 1003

RIN 0936-AA16

Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: This request for information seeks input from the public on whether any additions or modifications are needed to the safe harbor regulations under the Federal anti-kickback statute or the exceptions to the civil monetary penalty provision prohibiting inducements to beneficiaries (the "Beneficiary Inducements CMP") for remuneration provided to individuals in connection with their participation in clinical trials.

DATES: To ensure consideration, comments must be received no later than 5 p.m. on [60 DAYS FROM *FEDERAL REGISTER* PUBLICATION DATE].

ADDRESSES: Please submit comments electronically at http://www.regulations.gov. Follow the "Submit a comment" instructions and refer to file code OIG-2602-N. For information on viewing public comments, please see the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Chris Hinkle, (202) 465-6245 or christina.hinkle@oig.hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period as soon as possible after they have been received on the following website: https://www.regulations.gov. Follow the search instructions on that website to view public comments.

I. Introduction

The reliability and validity of clinical trial results depends on recruiting enough eligible individuals with a wide range of baseline characteristics that reflect the intended use population, as well as the continued cooperation of enrolled participants with the clinical trial protocol and follow-up data collection efforts. For some people, extra costs or burdens associated with trial participation may create a disincentive to enroll or stay enrolled in a clinical trial. Historically, clinical trial participants have been offered and provided various forms of remuneration in connection with their participation in a clinical trial. Examples include subsidizing cost-sharing amounts owed to insurers, including Medicare, transportation expenses, childcare expenses, and stipends. For the last several years, OIG has received submissions in response to our annual *Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts*[1]

[1] See, e.g., OIG, Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts, 90 Fed. Reg. 57016 (Dec. 9, 2025), https://www.federalregister.gov/documents/2025/12/09/2025-22327/solicitation-of-proposals-for-new-and-modified-safe-harbors-and-special-fraud-alerts.

requesting that OIG consider establishing a safe harbor that would protect certain remuneration to clinical trial participants.[2]

We have published 10 favorable advisory opinions over the last 2 decades permitting the waiver or subsidization of certain Federal health care program cost-sharing obligations for clinical trial participants in the context of specified clinical trials by different entities, including the manufacturer of the product being studied, the clinical trial site, and other organizations, such as non-profit organizations.[3] We have not issued any advisory opinions or guidance relating to other remuneration provided to clinical trial participants, such as transportation costs, childcare costs, or stipends.

We are seeking visibility into: (i) whether, and if so how, clinical trial participation is meaningfully enhanced by providing appropriate remuneration to Federal health care program enrollees; (ii) whether clinical trial sponsors, clinical trial sites, or other organizations view the Federal anti-kickback statute as a barrier to providing appropriate remuneration to clinical trial participants and if so, why; (iii) the types and amounts, if applicable, of remuneration stakeholders may seek to provide to clinical trial participants to facilitate participation; (iv) the fraud and abuse risks that may be associated with the offer and provision of such remuneration; (v) the types of arrangements necessary to provide such remuneration; and (vi) safeguards

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[2] See, e.g., OIG, Fall 2025 Semiannual Report to Congress, OIG-SAR-FALL-2025 (2025), https://oig.hhs.gov/documents/sar/11445/Fall_2025_SAR--508.pdf; OIG, Fall 2024 Semiannual Report to Congress, OIG-SAR-FALL-2024 (2024), https://oig.hhs.gov/documents/sar/10084/Fall_2024_SAR_508.pdf; OIG, Fall 2023 Semiannual Report to Congress, OIG-SAR-FALL-2023 (2023), https://oig.hhs.gov/documents/sar/1275/OIG-SAR-FALL-2023-Complete%20Report.pdf.

[3] For more information, please see https://oig.hhs.gov/compliance/advisory-opinions/.

necessary or prudent to prevent fraud and abuse when clinical trial participants receive remuneration.

OIG is issuing this Request for Information ("RFI") to identify ways in which it might: (i) modify or add new safe harbors to the Federal anti-kickback statute as provided at 42 CFR 1001.952 or exceptions to the Beneficiary Inducements CMP's definition of "remuneration" at 42 CFR 1003.110; or (ii) publish or amend other guidance to foster arrangements that facilitate clinical trial participation, while also protecting against harms caused by fraud and abuse. To inform our efforts, we welcome public comment on new or modified safe harbors to the Federal anti-kickback statute and new or modified exceptions to the Beneficiary Inducements CMP definition of "remuneration," as well as public comment on other guidance we could amend or publish. In particular, we welcome comments in response to the questions presented in this RFI.

II. Background

A. Federal Anti-Kickback Statute

Section 1128B(b) of the Social Security Act (Act), (42 U.S.C. 1320a-7b(b), the "Federal anti-kickback statute"), provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward the referral of business reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act (42 U.S.C. 1320a-7b(f)). The offense is classified as a felony and is punishable by fines of up to $100,000 and imprisonment for up to 10 years. Violations of the Federal anti-kickback statute also may result in the imposition of civil monetary penalties ("CMPs") under section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)), and liability under the False Claims Act (31 U.S.C. 3729-3733).

The types of remuneration covered by the Federal anti-kickback statute include, without limitation, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. In addition, prohibited conduct includes not only the payment of remuneration intended to induce or reward referrals of patients but also the payment of remuneration intended to induce or reward 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 any Federal health care program.

Because of the broad reach of the statute and concerns that some relatively innocuous business arrangements were covered by the statute and therefore potentially subject to criminal prosecution, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93 (note to section 1128B of the Act; 42 U.S.C. 1320a-7b); S. Rep. 100-109 (1987), as *reprinted in* 1987 U.S.C.C.A.N. 682, 683. This provision specifically requires the development and promulgation of regulations, the so-called safe harbor provisions, that would specify various payment and business practices that would not be subject to sanctions under the Federal anti-kickback statute, even though they potentially may be capable of inducing referrals of business for which payment may be made under a Federal health care program.

Section 205 of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, established section 1128D of the Act (42 U.S.C. 1320a-7d), which includes criteria for modifying and establishing safe harbors. Specifically, section 1128D(a)(2) of the Act (42 U.S.C. 1320a-7d(a)(2)) provides that, in modifying and establishing safe harbors, the Secretary may consider whether a specified payment practice may result in:

- an increase or decrease in access to health care services;

- an increase or decrease in the quality of health care services;
- an increase or decrease in patient freedom of choice among health care providers;
- an increase or decrease in competition among health care providers;
- an increase or decrease in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations;
- an increase or decrease in costs to Federal health care programs;
- an increase or decrease in the potential overutilization of health care services;
- the existence or nonexistence of any potential financial benefit to a health care professional or provider, which benefit may vary depending on whether the health care professional or provider decides to order a health care item or service or arranges for a referral of health care items or services to a particular practitioner or provider; or
- any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs.

In giving HHS the authority to protect certain arrangements and payment practices under the Federal anti-kickback statute, Congress intended the safe harbor regulations to be updated periodically to reflect changing business practices and technologies in the health care industry.[4] Since July 29, 1991, there have been a series of final regulations published in the *Federal*

[4] H.R. Rep. No. 100-85, Pt. 2, at 27 (1987).

Register establishing safe harbors in various areas.[5] These safe harbor provisions have been developed to limit the reach of the statute somewhat by permitting certain non-abusive arrangements while encouraging beneficial or innocuous arrangements.[6]

Health care providers and others may voluntarily seek to comply with final safe harbors so that they have the assurance that their business practices will be insulated from liability under the Federal anti-kickback statute and the Beneficiary Inducements CMP only; individuals and entities remain responsible for complying with all other laws, regulations, and guidance that apply to their businesses.

B. Overview of OIG CMP Authorities

In 1981, Congress enacted the CMP law, section 1128A of the Act (42 U.S.C. 1320a-7a) as one of several administrative remedies to combat fraud and abuse in Medicare and Medicaid. The law authorized the Secretary to impose penalties and assessments on persons who defrauded Medicare or Medicaid or engaged in certain other wrongful conduct. The CMP law also

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[5] Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952 (July 29, 1991); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Protecting Health Plans, 61 FR 2122 (Jan. 25, 1996); Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 FR 63504 (Nov. 19, 1999); 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 FR 63518 (Nov. 19, 1999); 64 FR 63504 (Nov. 19, 1999); Medicare and State Health Care Programs: Fraud and Abuse; Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute, 66 FR 62979 (Dec. 4, 2001); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 FR 45109 (Aug. 8, 2006); Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 72 FR 56632 (Oct. 4, 2007); Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 FR 79202 (Dec. 27, 2013); Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 FR 88368 (Dec. 7, 2016); and Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 FR 77684 (Dec. 2, 2020).

[6] Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR at 35958 (July 21, 1991).

authorized the Secretary to exclude persons from Federal health care programs (as defined in section 1128B(f) of the Act, 42 U.S.C. 1320a-7b(f)) and to direct the appropriate State agency to exclude the person from participating in any State health care programs (as defined in section 1128(h) of the Act, 42 U.S.C. 1320a–7(h)). Congress later expanded the CMP law and the scope of exclusion to apply to all Federal health care programs, but the CMP applicable to beneficiary inducements remains limited to Medicare and State health care program beneficiaries.

Section 1128A(a)(5) of the Act (42 U.S.C. 1320a-7a(a)(5)) the Beneficiary Inducements CMP, provides for the imposition of CMPs against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). Section 1128A(i)(6) of the Act (42 U.S.C. 1320a-7a(i)(6)) 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) of the Act also includes a number of exceptions to the definition of "remuneration."

Pursuant to section 1128A(i)(6)(B) of the Act (42 U.S.C. 1320a-7a(i)(6)(B)), any practice permissible under the Federal anti-kickback statute, whether through statutory exception or safe harbor regulations issued by the Secretary, is also excepted from the definition of "remuneration" for purposes of the Beneficiary Inducements CMP. However, no parallel exception exists in the Federal anti-kickback statute for practices permissible under the CMP law. Thus, the exceptions in section 1128A(i)(6) of the Act apply only to the definition of "remuneration" applicable to section 1128A and do not offer protection under the Federal anti-kickback statute.

III. Request for Information

We welcome public input on any or all of the topics identified below. We ask that commenters support claims with relevant data, studies, analyses, and other citations that the commenter believes supports their response.

1. Please explain whether offering Federal health care program enrollees remuneration facilitates clinical trial participation and the specific factors that make such remuneration either effective or ineffective at facilitating participation.

2. Please explain whether you view the Federal anti-kickback statute or the Beneficiary Inducements CMP as barriers to offering and providing appropriate remuneration to clinical trial participants and if so, why. In your answer, please describe any other identified barriers to offering and providing appropriate compensation/remuneration to clinical trial participants and how those barriers relate to any barriers created by the Federal anti-kickback statute and Beneficiary Inducements CMP.

3. Please explain what categories of remuneration (including, for example, reimbursement for actual incurred expenses such as travel, lodging, parking, childcare, and meals; stipends; compensation for a participant's time; incentives to encourage enrolling in and completing the trial) and at what levels those categories of remuneration are useful to facilitate participation in clinical trials and why. Similarly, please explain what categories of remuneration are not useful to facilitate clinical trial participation. Please explain the extent to which such categories of remuneration already are offered to clinical trial participants. Please explain whether there are categories of remuneration that may be subject to heightened risks of fraud and abuse.

To the extent that there is more uncertainty regarding how the Federal anti-kickback statute and Beneficiary Inducements CMP would apply to certain categories of remuneration, please explain.

4. Please explain whether clinical trials currently impose value caps or other limits, like demonstrated financial need, or reimbursement only for actual documented costs incurred, for any remuneration given to clinical trial participants. Please explain whether any such value caps or limits permit remuneration adequate to facilitate participation in clinical trials. Describe what limitations, such as value caps, would guard against the harms resulting from fraud and abuse.

5. Please explain whether clinical trials currently limit or prohibit who is eligible to provide remuneration to clinical trial participants (e.g., the clinical trial sponsor, investigators, other providers or suppliers). Describe what limitations or prohibitions would guard against the harms resulting from fraud and abuse.

6. Please explain the role of an Institutional Review Board ("IRB") in reviewing the provision of remuneration to clinical trial participants and whether an IRB's review of the type, amount, and frequency of remuneration provided to clinical trial participants and the advertising of that remuneration is a meaningful safeguard against the harms resulting from fraud and abuse. If so, please specify the rationale and the standards the IRB should use.

7. Please enumerate any safeguards that should be in place to ensure clinical trial participants who receive remuneration to participate in a clinical trial are not

inappropriately steered to items or services offered by the individual or entity offering the remuneration outside the clinical trial.

8. Please explain whether remuneration to clinical trial participants is provided during all stages of product development (e.g., phase 1-4 clinical trials) and whether different amounts or types of remuneration are necessary to promote participation in early-stage versus late-stage development. To the extent that there is more uncertainty regarding how the Federal anti-kickback statute and Beneficiary Inducements CMP would apply to certain stages of development, please explain. Describe what, if any, limitations would guard against the harms resulting from fraud and abuse in connection with different phases of clinical trials.

9. Please identify and explain if there are specific types or categories of clinical trials that should or should not pay remuneration to clinical trial participants due to that type's or category's relative risk of the harms resulting from fraud and abuse under the Federal anti-kickback statute and Beneficiary Inducements CMP. For example, please explain whether remuneration to clinical trial participants should only be protected under the Federal anti-kickback statute and Beneficiary Inducements CMP when provided to participants of government-sponsored clinical trials.

10. Please explain whether there should be advertising limitations relating to remuneration to clinical trial participants to protect the integrity of the clinical trial and guard against the harms resulting from fraud and abuse.

11. Please identify what, if any, additional or modified safe harbors to the Federal anti-kickback statute or exceptions to the definition of "remuneration" under the

Beneficiary Inducements CMP may be necessary to protect remuneration to clinical trial participants and any arrangements necessary to offer and provide such remuneration. Please explain any key provisions that should be included in any additional or modified safe harbor or exception. Specifically, and to the extent that you did not do so in response to the questions above, please describe what conditions would be appropriate to include in a safe harbor or exception to protect against the harms resulting from fraud and abuse in the context of such arrangements, including what, if any, disclosures should be required by such safe harbors or exceptions. Additionally, please identify which criteria for modifying and establishing safe harbors under section 1128D(a)(2) of the Act (42 U.S.C. 1320a-7d(a)(2)), listed in section II.A above, would be impacted and how.

12. Please explain, with specificity, why any existing safe harbors to the Federal anti-kickback statute or exceptions to the definition of "remuneration" under the Beneficiary Inducements CMP do not adequately protect the arrangements necessary to effectuate the provision of remuneration to clinical trial participants.

13. Please discuss any potential broader impacts or implications—and in particular, as they relate to the criteria set forth in section 1128D(a)(2) of the Act (e.g., an increase or decrease in access to health care services, an increase or decrease in costs to Federal health care programs)—that may result from the provision of remuneration to clinical trial participants, additional or modified safe harbors to the Federal anti-kickback statute, or exceptions to the definition of "remuneration" under the Beneficiary Inducements CMP. For instance, if remuneration would result in higher

participation rates of federal health care program enrollees in clinical trials, could that lead to improved health care for individuals in those programs?

14. Are there opportunities where OIG could clarify its position through guidance as opposed to regulation? For example, would a Special Advisory Bulletin, an FAQ response, or other guidance offer sufficient protection in some instances? If so, please elaborate.

Respondents are encouraged to provide complete but concise and organized responses, including any relevant data and specific examples. Respondents are not required to address every issue or respond to every question discussed in this RFI to have their responses considered. All responses will be considered, and we request that responses contain information OIG can use to identify the commenter.

Please note: This is a request for information only. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal ("RFP"), application, proposal abstract, or quotation. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, OIG is not seeking proposals through this RFI and will not accept unsolicited proposals. Respondents are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that

OIG will not respond to questions about the policy issues raised in this RFI. Contractor support personnel may be used to review RFI responses.

Responses to this RFI are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a nonattribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur costs for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. OIG may publicly post the comments received or a summary thereof.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. However, section III of this document does contain a general solicitation of comments in the form of a request for information. In accordance with the implementing regulations of the Paperwork Reduction Act ("PRA"), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the *Federal Register* or other publications, regardless of the form or format thereof (provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration) are not generally considered information subject to the PRA. Consequently, there is no need for review by the Office of Management and Budget under the authority of the PRA (44 U.S.C. 3501 et seq.).

V. Response to Comments

Because of the large number of public comments we normally receive on *Federal Register* documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, if we proceed with a subsequent document, we may respond to the comments in the preamble to that document.

T. March Bell

Inspector General,

Office of Inspector General

Robert F. Kennedy, Jr.

Secretary,

Department of Health and Human Services.