DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Parts 1001 and 1003

RIN 0936–AA15

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 emerging direct-to-consumer (''DTC'') sales programs established by pharmaceutical manufacturers, including those that will be available through TrumpRx.

DATES: To ensure consideration, comments must be received no later than 5 p.m. on March 30, 2026.

ADDRESSES: Please submit comments electronically at *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions and refer to file code OIG–2601–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

Consistent with the Executive Order 14297 ''Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients,'' the Department of Health and Human Services (''HHS'') is establishing TrumpRx, a platform through which American patients can buy their drugs directly from pharmaceutical manufacturers at a ''Most-Favored-Nation'' price, bypassing middlemen.[1] TrumpRx and DTC sales prices that will be offered to Americans by pharmaceutical manufacturers through TrumpRx put America first by furthering efforts to get American patients and taxpayers a fair deal for prescription drugs. Removing unnecessary Government obstacles to ensure appropriate access to affordable prescription drugs offered by manufacturers through DTC programs is a key priority for HHS.

To help accelerate the availability of affordable prescription drugs offered through TrumpRx and other DTC programs established by manufacturers outside of TrumpRx, HHS has launched this Request for Information (''RFI''). The HHS Office of Inspector General (OIG) is issuing this RFI to identify ways in which it might: (i) modify or add new safe harbors to the Federal anti-kickback statute at 42 CFR 1001.952 and 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 promote the affordability of and patient access to prescription drugs offered through DTC programs, 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, as each of these relate to the goals of the Executive Order ''Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients.'' 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. 3729–33).

The types of remuneration covered by the 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 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;

[1] The White House, Executive Order 14297, ''Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients'' (May 12, 2025), *available at https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/.*

- 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.[2] Since July 29, 1991, there have been a series of final regulations published in the **Federal Register** establishing safe harbors in various areas.[3] 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.[4]

Health care providers and others may voluntarily seek to comply with final safe harbors so that they have the assurance that their business practices would not be subject to any Federal anti-kickback statute enforcement action. Compliance with an applicable safe harbor insulates an individual or entity 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 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. Since 1981, Congress has created various other CMP authorities covering numerous types of fraud and abuse.

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, 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. Thus, the exceptions in section 1128A(i)(6) of the Act apply only to the definition of ''remuneration'' applicable to section 1128A.

Through a ''Special Advisory Bulletin: Application of the Federal Anti-Kickback Statute to Direct-to-Consumer Prescription Drug Sales by Manufacturers to Patients with Federal Health Care Program Coverage,'' published on OIG's website, OIG provided information on the application of the Federal anti-kickback statute to DTC sales of prescription drugs by manufacturers to patients with coverage under a Federal health care program. This guidance addresses only the arrangement between the manufacturer and consumer for the sale of the manufacturer's prescription drug(s) and does not address the application of the statute to any other arrangements or remuneration relating to the provision of drugs offered and provided through a DTC program that a manufacturer (or others) may have with other individuals or entities (*e.g.,* pharmacy or telemedicine arrangements). To inform our understanding of other arrangements or remuneration related to DTC programs and any perceived need for additional safe harbor or exception rulemakings, we are seeking additional information through this RFI. Any new rulemaking would balance additional flexibility for industry stakeholders to promote the affordability of medically necessary prescription drugs with protections against fraud and abuse.

III. Request for Information

We welcome public input on any or all of the topics identified below.

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

[3] 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).

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

1. Please tell us about potential arrangements that the industry is interested in pursuing in connection with prescription drug DTC programs that may implicate the Federal anti-kickback statute or Beneficiary Inducements CMP. For example, we are interested in better understanding the structure and terms of the arrangements (*e.g.,* categories or types of parties; financial relationships involving potential referral sources and seekers created by the arrangements; and types of items and services provided by the arrangements). We also are interested in understanding how the arrangements promote access to and affordability of prescription drugs and prevent potential harms, such as increased costs, inappropriate steering, unfair competition, inappropriate utilization, poor quality of care, and distorted decision making.

2. 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 such arrangements and any key provisions that should be included in any additional or modified safe harbor or exception. Existing safe harbors and exceptions of particular relevance to DTC programs may include, for example, the safe harbor for personal services and management contracts (42 CFR 1001.952(d)). Specifically, please describe what conditions would be appropriate to include in a safe harbor or exception to protect against 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 would be impacted and how.

3. 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 beneficial DTC programs.

4. 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 proliferation of DTC programs, additional or modified safe harbors to the Federal anti-kickback statute, or exceptions to the definition of ''remuneration'' under the Beneficiary Inducements CMP.

5. As noted above, OIG published a Bulletin on its website, ''Special Advisory Bulletin: Application of the Federal Anti-Kickback Statute to Direct-to-Consumer Prescription Drug Sales by Manufacturers to Patients with Federal Health Care Program Coverage.'' Please explain whether this Special Advisory Bulletin adequately addresses the concerns of industry stakeholders in connection with DTC sales to people covered by Federal health care programs or if additional guidance, safe harbors, exceptions, or some combination of the three are necessary to promote beneficial DTC arrangements.

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

7. The Special Advisory Bulletin includes several guardrails intended to mitigate risk under the Federal anti-kickback statute. Please identify any operational difficulties in implementing those guardrails and potential solutions to ensure appropriate guardrails are in place to protect Federal health care program enrollees. In addition, please explain whether additional guardrails may be necessary to sufficiently address fraud and abuse risks under the Federal anti-kickback statute.

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.

Thomas Bell,

Inspector General, Office of Inspector General.

Robert F. Kennedy, Jr.

Secretary, Department of Health and Human Services.

[FR Doc. 2026–01817 Filed 1–27–26; 4:15 pm]

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 106, 107, 171, 172, 173, 174, 175, 176, 177, 178, 179, and 180

[Docket No. PHMSA–2024–0065 (HM–267)]

RIN 2137–AF69

Hazardous Materials: Modernizing Regulations To Facilitate Transportation of Hazardous Materials Integral to Spacecraft Components and Payloads

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: PHMSA is publishing this ANPRM to solicit feedback on streamlining and modernizing the Agency's regulations as they relate to the transportation of hazardous materials integral to spacecraft payloads or components.

DATES: Comments must be received by April 29, 2026. However, PHMSA will consider late-filed comments to the extent possible.

ADDRESSES: You may submit comments identified by the docket number PHMSA–2024–0065 (HM–267) by any of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Management System, U.S. Department of Transportation, Dockets Operations, M–30, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, Ground Floor, Room W12–140 in the West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and docket number (PHMSA–2024–0065) or RIN 2137–AF69 for this ANPRM at the beginning of the comment. Note that all comments received will be posted without change to *http://www.regulations.gov* including any personal information provided. If sent by mail, comments must be submitted in duplicate. Persons wishing to receive confirmation of receipt of their comments must include a self-addressed stamped postcard.

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is treated both customarily and actually as private by its owner. Under the Freedom of Information Act (FOIA, 5 U.S.C. 552), CBI is exempt from public disclosure. It is important you clearly designate the comments submitted as CBI if your comments responsive to this document contain commercial or financial information that customarily is treated as private; you actually treat as private; and is relevant or responsive to this notice. Pursuant to 49 CFR 105.30, you may ask PHMSA to provide confidential treatment to information you give to the Agency by taking the following steps: (1) mark each page of the original document submission containing CBI as ''Confidential:'' (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Submissions containing CBI should be sent to Noah Jacobson by mail at Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration, 2nd Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, or by email at *noah.jacobson@dot.gov.* Any information PHMSA receives that is not designated specifically as CBI will be placed in the public docket.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov*. Follow the online instructions for accessing the docket. You also may review the documents in person at the address listed above.

FOR FURTHER INFORMATION CONTACT: Noah Jacobson by email at *noah.jacobson@dot.gov* or Steven Andrews by email at *steven.andrews@dot.gov,* or by mail at Standards and Rulemaking Division, Office of Hazardous Materials Safety, PHMSA, East Building, PHH–10, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

Abbreviations and Terms

ANPRM Advance Notice of Proposed Rulemaking
CBI Confidential Business Information
CFR Code of Federal Regulations
DHS Department of Homeland Security
DOT Department of Transportation
DOW Department of War (*i.e.,* the Department of Defense)
FAA Federal Aviation Administration
FMCSA Federal Motor Carrier Safety Administration
FRA Federal Railroad Administration
HMR Hazardous Materials Regulations
NASA National Aeronautics and Space Administration
PHMSA Pipeline and Hazardous Materials Safety Administration
PRD Pressure Relief Device
USCG United States Coast Guard

Table of Contents

I. Executive Summary

PHMSA is publishing this ANPRM to solicit stakeholder input on opportunities to amend requirements in the Hazardous Materials Regulations (HMR) for spacecraft (*e.g.,* launch vehicles, reentry vehicles) and space operations that require the transportation of hazardous materials integral to spacecraft payloads or components (*i.e.,* transporting satellites, capsules, and related equipment to and from launch and recovery sites by all transportation modes, but most often by highway or vessel).[1] The President identified enabling competition and innovation in the commercial space industry as a priority in Executive Order (E.O.) 14335 (''Enabling Competition in the Commercial Space Industry'').[2] Consistent with the President's directive, PHMSA is seeking stakeholder feedback regarding opportunities to streamline and modernize the requirements in the HMR that apply to commercial space operations.

The commercial space sector is growing rapidly. Hazardous materials are often incorporated into spacecraft payloads and components. However, the goods shipped for these space operations are often limited-use shipments of unique packagings or articles containing various hazardous materials with unique containment

[1] *See* 49 CFR parts 171–180.

[2] 90 FR 40219 (Aug. 19, 2025).