



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### 42 CFR Parts 1001 and 1003

### RIN 0936-AA10

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

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Request for information.

**SUMMARY:** This request for information seeks input from the public on how to address any regulatory provisions that may act as barriers to coordinated care or value-based care.

**DATES:** Comment Date: To ensure consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [INSERT DATE 60 DAYS FROM DATE OF FEDERAL REGISTER PUBLICATION DATE].

**ADDRESSES:** In commenting, refer to file code OIG-0803-N. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission. However, you may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.
2. *By regular, express, or overnight mail.* You may send written comments to the following address: Susan Edwards, Office of Inspector General, Department of Health and Human Services, Attention: OIG-0803-N, Room 5513, Cohen Building, 330 Independence Avenue, SW Washington, DC 20201

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver your written comments by hand or courier before the close of the comment period to: Susan Edwards, Office of Inspector General, Department of Health and Human Services, Attention: OIG-0803-N, Room 5513, Cohen Building, 330 Independence Avenue, SW, Washington, DC 20201

Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619-0335.

For information on viewing public comments, please see the SUPPLEMENTARY INFORMATION section.

**FOR FURTHER INFORMATION CONTACT:** Susan Edwards, (202) 708-9845.

**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 on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. Comments received in a timely manner will also be available for public inspection as they are received at the Office of Inspector General, Department of Health and Human Services, Cohen Building, 330

Independence Avenue, SW, Washington, DC 20201, Monday through Friday, from 10 a.m. to 5 p.m. To schedule an appointment to view public comments, phone (202) 619-0335.

## **I. Introduction**

The Department of Health and Human Services (HHS) is working to transform the health care system into one that better pays for value. Care coordination is a key aspect of systems that deliver value. Removing unnecessary government obstacles to care coordination is a key priority for HHS. To help accelerate the transformation to a value-based system that includes care coordination, HHS has launched a Regulatory Sprint to Coordinated Care, led by the Deputy Secretary. This “Regulatory Sprint” is focused on identifying regulatory provisions that may act as barriers to coordinated care, assessing whether those regulatory provisions are unnecessary obstacles to coordinated care, and issuing guidance or revising regulations to address such obstacles and, as appropriate, to encourage and incentivize coordinated care while protecting against harms caused by fraud and abuse.

The Office of Inspector General (OIG) seeks to identify ways in which it might modify or add new safe harbors to the anti-kickback statute and exceptions to the beneficiary inducements civil monetary penalty (CMP) definition of “remuneration” in order to foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse. Through internal discussion and with the benefit of facts and information received from external stakeholders, OIG has identified the broad reach of the anti-kickback statute and beneficiary inducements CMP as a potential impediment to beneficial arrangements that would advance coordinated care. To inform our efforts, we welcome public comment on the safe harbors to the anti-kickback statute and the

exceptions to the beneficiary inducements CMP definition of “remuneration” as they relate to the goals of the Regulatory Sprint outlined above. In particular, we welcome comments in response to the questions presented in this Request for Information (RFI).

## **II. Background**

Section 1128B(b) of the Social Security Act (the Act), the Federal anti-kickback statute, provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under Federal health care programs, as defined in section 1128B(f) of the Act. The law endeavors to protect patients and the Federal health care programs from fraud and abuse by curtailing the corrupting influence of remuneration on health care decisions; however, because the statute is broadly written, when it was enacted there was concern that some relatively innocuous and potentially beneficial arrangements were technically covered by the statute and therefore were subject to criminal prosecution.

In response to this concern, Congress passed section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, which required HHS to set forth “safe harbors” to the anti-kickback statute. Specifically, section 1128B(b)(3)(E) of the Act protects from the anti-kickback statute “any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987.” In giving HHS the authority to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended the safe harbors to be evolving rules that would be

updated periodically to reflect changing business practices and technologies in the health care industry.<sup>1</sup>

Health care providers and others may voluntarily comply with safe harbors in an effort to ensure that their business practices will not be subject to criminal prosecution under the anti-kickback statute, the imposition of civil monetary penalties (CMPs) under section 1128A(a)(7) of the Act, program exclusion under section 1128(b)(7) of the Act, and liability under the False Claims Act (31 U.S.C. 3729-33). Since finalizing the first safe harbors in 1991, OIG has continued to engage the industry on the application of the Federal anti-kickback statute and development of safe harbors.

Section 1128A(a)(5) of the Act, 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 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. In the same administrative proceedings in which it may seek to impose CMPs against a person, OIG may seek to exclude such person from the Federal health care programs. For purposes of section 1128A(a)(5) of the Act, the statute defines "remuneration" to include, without limitation, waivers of co-payments and deductible amounts (or any part thereof) and

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<sup>1</sup> H.R. Rep. No. 100-85, Pt. 2, at 27 (1987).

transfers of items or services for free or for other than fair market value.<sup>2</sup> The statute and associated regulations contain a limited number of exceptions.<sup>3</sup>

OIG is mindful of the impact of delivery system and payment reform on Federal health care programs and the changing relationships between providers, suppliers, and other entities in delivering higher quality, better coordinated care; enhancing value; and improving the overall health of patients. We have received several suggestions for new safe harbors and proposed modifications to existing safe harbors that may promote care coordination and reduce regulatory impediments to value-based arrangements, including in response to our annual “Solicitation of New Safe Harbors and Special Fraud Alerts.”<sup>4</sup>

We continue to consider how to balance additional flexibility for industry stakeholders to provide efficient, well-coordinated, patient-centered care with protections against the harms caused by fraud and abuse. We are requesting additional information in this RFI to help inform our efforts. We are particularly interested in thoughts on topics that include, but are not limited to: (i) the structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements designed to promote care coordination and value; (ii) the need for new or revised safe harbors and exceptions to the definition of “remuneration” under the beneficiary inducements CMP to promote beneficial care coordination, patient engagement, and value-based arrangements; and (iii) terminology related to alternative payment models, value-based arrangements, and care coordination. We are interested in any special

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<sup>2</sup> See section 1128A(i)(6) of the Act.

<sup>3</sup> See *id.*; 42 CFR § 1003.110.

<sup>4</sup> See, e.g., Solicitation of New Safe Harbors and Special Fraud Alerts, 82 FR 61,229 (Dec. 27, 2017), available at <https://www.gpo.gov/fdsys/pkg/FR-2017-12-27/pdf/2017-27117.pdf>; OIG, *Semiannual Report to Congress*, April 1, 2017-September 30, 2017, available at <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2017/sar-fall-2017.pdf>.

considerations for rural providers and others serving underserved populations, including American Indian and Alaska Native communities.

Where relevant, we intend to review comments submitted in response to the Medicare Program; Request for Information Regarding the Physician Self-Referral Law, RIN 0938-AT64, issued by the Centers for Medicare & Medicaid Services (CMS).<sup>5</sup> However, given the volume of questions included in that RFI and OIG's separate, and different, authorities, we urge individuals and entities to resubmit any relevant comments to this RFI to ensure they are considered by OIG. We look forward to receiving input in response to this RFI.

### **III. Request for Information**

We welcome public input on any or all of the topics identified below. Respondents are not required to address every issue or respond to every question discussed in this RFI to have their responses considered.

#### **1. Promoting Care Coordination and Value-Based Care**

A. Please tell us about potential arrangements that the industry is interested in pursuing, such as care coordination, value-based arrangements, alternative payment models, arrangements involving innovative technology, and other novel financial arrangements that may implicate the anti-kickback statute or beneficiary inducements CMP. For example, we are interested in better understanding the structure and terms of the arrangement (*e.g.*, categories/types of parties; how risk is allocated among

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<sup>5</sup> Medicare Program; Request for Information Regarding the Physician Self-Referral Law, 83 FR 29,524 (June 25, 2018), available at <https://www.gpo.gov/fdsys/pkg/FR-2018-06-25/pdf/2018-13529.pdf>.

parties; financial relationships involving potential referral sources and seekers created by the arrangement; and types of items and services provided by the arrangement).

We are also interested in understanding how the arrangement promotes care coordination or value-based care and how the arrangement prevents potential harms, such as increased costs, inappropriate utilization, poor quality of care, and distorted decision making.

- B. Please identify what, if any, additional or modified safe harbors to the 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 the additional or modified safe harbor or exception. Existing safe harbors and exceptions of particular relevance to coordinated care include, for example, those related to personal services and management contracts, electronic health record arrangements, warranties, transportation, and promoting access to care. Suggested new safe harbors or exceptions might address care coordination services arrangements or arrangements promoting the use of innovative technology. In particular, 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.
- C. Please explain how “value” could be defined and used in a safe harbor or exception such that OIG could evaluate “value” within an arrangement to determine compliance with the safe harbor or exception.

D. In the context of health care delivery reform, payment reform, and the anti-kickback statute, please share thoughts on definitions for critical terminology such as:

- i. Alternative payment model
- ii. Care coordination services
- iii. Care coordinator
- iv. Clinical integration
- v. Coordinated care
- vi. Financial integration
- vii. Gainsharing
- viii. Health system
- ix. Integrated care model
- x. Integrated delivery system
- xi. Incentive payments
- xii. Outcomes-based care
- xiii. Risk
- xiv. Risk-sharing
- xv. Value-based care
- xvi. Value-based arrangement

E. Are there opportunities where OIG could clarify its position through guidance as opposed to regulation? For example, would a law enforcement policy statement offer sufficient protection in some instances? If so, please elaborate.

## 2. Beneficiary Engagement

### A. Beneficiary Incentives

i. Please provide feedback regarding the types of incentives providers, suppliers, and others are interested in providing to beneficiaries, how providing such incentives would contribute to or improve quality of care, care coordination, and patient engagement, including adherence to care plans, and whether the types of providers, suppliers, or other entities that furnish the incentives matter from an effectiveness and program integrity perspective. Please be as specific as possible.

Additional areas of interest include:

- a. What, if any, restrictions should OIG place on the sources, types, or frequency of beneficiary incentives that could be provided to reduce the risk of fraud and abuse?
- b. Examples of beneficiary incentive arrangements that are appropriate and effective.
- c. Should beneficiary incentives connected to medication adherence and medication management be treated differently than other types of beneficiary incentives? If so, how and why?
- d. What, if any, disclosures should OIG require the offeror to make to beneficiaries regarding an incentive (*e.g.*, the source of the incentive)?

- ii. Please identify (and provide citations to) any recent studies assessing the positive or negative effects of beneficiary incentives on patient care or patient engagement.
- iii. In the context of beneficiary incentives, please identify any risks or benefits from the following types of potential remuneration, as well as any safeguards to mitigate risks, and describe how these terms should be defined for purposes of any rulemaking related to coordinated care or value-based arrangements:
  - a. Cash equivalent
  - b. Gift card
  - c. In-kind items and services
  - d. Nonmonetary remuneration
- iv. To promote care coordination and value-based care, should OIG amend its “Office of Inspector General Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries”<sup>6</sup> to increase “nominal value” from no more than \$15 per item or \$75 in the aggregate per patient on an annual basis? If so, why? Please provide data or other support for any suggested changes in the dollar amounts. Also, please provide

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<sup>6</sup> OIG, Office of Inspector General Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries (Dec. 7, 2016), *available at* <https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf>.

input on whether OIG should have a similar policy under the anti-kickback statute and, if so, how such policy would contribute to care coordination or value-based care.

#### B. *Cost-Sharing Obligations*

- i. We are interested in input about how relieving or eliminating beneficiary cost-sharing obligations might improve care delivery, enhance value-based arrangements, and promote quality of care. Please describe any patient care scenarios in which cost-sharing obligations are particularly problematic.
- ii. Please describe the financial impact on providers, suppliers, and other entities, as well as the fraud and abuse risks, if cost-sharing amounts could be waived (*i.e.*, the amount owed is not paid) by participants in a care coordination or value-based arrangement. What, if any, concerns arise if cost-sharing obligations could be subsidized by providers, suppliers, or other entities in a care delivery arrangement?
- iii. Please describe any risks to beneficiaries and Federal health care programs from the reduction or elimination of cost-sharing obligations.
- iv. Please describe any suggested protections or safeguards that OIG should incorporate if we were to create a safe harbor for certain beneficiary cost-sharing waiver or subsidy arrangements.

### 3. Other Related Topics of Interest

#### A. Current Fraud and Abuse Waivers

i. Please provide feedback on the current waivers developed for the purposes of testing models by the Center for Medicare and Medicaid Innovation (Innovation Center) and carrying out the Medicare Shared Savings Program (MSSP).<sup>7</sup> Feedback from parties who are using or who are eligible to use those waivers would be helpful as we consider the issues raised in this RFI. For example, we are interested in the following:

- a. How, if at all, have stakeholders found compliance with the waiver conditions challenging? Please be as specific as possible.
- b. Are any waiver requirements particularly burdensome, such that they impede the goals of the models, initiatives, or programs? If so, please specify which waiver requirements and why they impede the goals of the model, initiative, or program.
- c. What waiver structures or conditions, if any, work well?  
Should OIG consider any waiver structures or conditions for

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<sup>7</sup> CMS, Fraud and Abuse Waivers for Select CMS Models and Programs, *available at* <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>.

any future safe harbors or exceptions related to care coordination and value-based care (including beneficiary incentives to promote patient engagement)? Please be as specific as possible and provide reasons.

- d. One of the key safeguards to mitigate the risk of fraud or abuse from arrangements protected by the pre-participation and participation waivers developed pursuant to the MSSP, the Next Generation ACO Model's participation waiver, and the Pioneer ACO Model's participation waiver<sup>8</sup> is the involvement of the accountable care organization's (ACO's) governing body in the authorization of each arrangement. We are interested in feedback on how the ACO governing body concept is working, and whether and if so how, it could be applied to safe harbors or exceptions for alternative payment models and coordinated care arrangements.
- e. We invite specific feedback regarding the pros and cons of fraud and abuse protections (*e.g.*, waivers or safe harbors) that are uniform across different types of CMS-sponsored models, initiatives, and programs.

## B. *Cybersecurity-Related Items and Services*

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<sup>8</sup> The Pioneer ACO model began in 2012, and the final performance year concluded on December 31, 2016.

- i. We are aware of interest in donating or subsidizing cybersecurity-related items and services to providers and others with whom they share information. We are interested in information about the types of cybersecurity-related items or services that entities wish to donate or subsidize, and how existing fraud and abuse laws may pose barriers to such arrangements. For example, we are interested in (i) the types of persons that would be parties to, or benefit from, such arrangements; (ii) whether any persons should be excluded from such arrangements; (iii) the particular types of items that would be involved in such arrangements (*e.g.*, hardware, software, and other items); and (iv) the types of services that would be involved in such arrangements (*e.g.*, testing services, training services, monitoring services, or repair or maintenance services). Other areas of interest include:
  - a. How might such items or services reduce cybersecurity risks to the following: the donor, the recipient, patients, and other nonparties to the arrangement?
  - b. Are there technical or legal barriers (besides the physician self-referral law and the anti-kickback statute) that could prevent or limit the arrangements?
  - c. Are there any potential risks or unintended consequences to such arrangements (*e.g.*, potential for fraud or abuse,

information blocking, or anti-competitive practices) and, if so, how might these risks be mitigated?

d. Are there any particular risks if HHS takes no action?

*C. ACO Beneficiary Incentive Program (Section 50341(b) of the Bipartisan Budget Act of 2018)*<sup>9</sup>

Section 50341(b) of the Bipartisan Budget Act of 2018, which added section 1128B(b)(3)(K) of the Act, states that “illegal remuneration” under the anti-kickback statute does not include “. . . an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program established under subsection (m) of section 1899, if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish.”

i. For the purposes of implementing this new statutory exception through a safe harbor, what, if any, “other conditions” should this safe harbor include as protections or safeguards? Please provide supporting reasons.

*D. Telehealth (Section 50302(c) of the Bipartisan Budget Act of 2018)*<sup>10</sup>

Section 50302(c) of the Bipartisan Budget Act of 2018 creates a new exception to the definition of “remuneration” in the beneficiary inducements CMP. This exception applies to “telehealth technologies” provided on or after January 1, 2019, by a provider of services or a renal dialysis facility to an individual with end-stage renal disease (ESRD) who is receiving

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<sup>9</sup> Bipartisan Budget Act of 2018, Pub. L. 115-123, 115th Cong. (2018) (enacted).

<sup>10</sup> *Id.*

home dialysis for which payment is being made under Medicare Part B. Under the statute, “telehealth technologies” is a term to be defined by the Secretary. The exception requires that (i) the telehealth technologies not be offered as part of any advertisement or solicitation; (ii) the telehealth technologies must be provided for the purpose of furnishing telehealth services related to the patient’s ESRD; and (iii) the provision of the telehealth technologies must “meet[] any other requirements set forth in regulations promulgated by the Secretary.”

i. For the purposes of this exception, please provide input on how “telehealth technologies” should be defined. Please provide examples of telehealth technologies that may be used to furnish telehealth services related to a beneficiary’s ESRD (*e.g.*, technologies that address services on the Medicare telehealth list). Also, please indicate whether telehealth technologies should include services. If so, please explain, in detail, what services should be considered “telehealth technologies.”

ii. For the purposes of this exception, should OIG include protections or safeguards as “any other requirements set forth in regulations promulgated by the Secretary?” If so, please explain what protections or safeguards and why.

#### **4. Intersection of Physician Self-Referral Law and Anti-Kickback Statute**

Please share any feedback regarding specific circumstances in which (i) exceptions to the physician self-referral law and safe harbors to the anti-kickback statute should align for purposes of the goals of this RFI; and (ii) exceptions to the physician self-referral law in furtherance of

care coordination or value-based care should not have a corresponding safe harbor to the 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, provided they 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.

Dated: August 20, 2018

**Daniel R. Levinson**  
Inspector General

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