WASHINGTON STRATEGIC CONSULTING

September 14, 2018

WSC REGULATORY ALERT

HHS Seeking Information on Anti-Kickback Statute

On August 27, 2018, the Department of Health and Human Services (HHS), Office of Inspector General (OIG) issued a request for information (RFI), seeking to identify ways in which the agency might modify or add new safe harbors to the anti-kickback statute.

OIG is particularly interested in thought on topics that include, but are not limited to: (1) The structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements designed to promote care coordination and value; (2) 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 (3) terminology related to alternative payment models, value-based arrangements, and care coordination.

To ensure consideration, comments must be received no later than 5 p.m. on October 26, 2018.

Background

Section 1128B(b) of the Social Security 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. 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, giving HHS the authority to protect certain arrangement and payment practices.

The statute defines "remuneration" as to include, without limitation, waivers of co-payments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. The statute and associated regulations contain a limited number of exceptions.

Request for Information

OIG welcomes 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.

Promoting Care Coordination and Value-Based Care [link to full question/examples]

1) 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.

2) 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.

3) 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.

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

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5) Are there opportunities where OIG could clarify its position through guidance as opposed to regulation?

Beneficiary Incentives [link to full question/examples]

1) 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.

2) Please identify any recent studies assessing the positive or negative effects of beneficiary incentives on patient care or patient engagement.

3) 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.

Should OIG amend its "Office of Inspector General Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries" to increase "nominal value" from no more than $15 per item or $75 in the aggregate per patient on an annual basis?

Cost-Sharing Obligations [link to full question/examples]

1) Please describe any patient care scenarios in which cost-sharing obligations are particularly problematic.

2) 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.

3) Please describe any risks to beneficiaries and Federal health care programs from the reduction or elimination of cost-sharing obligations.

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4) 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.

Other Related Topics of Interest [link to full question/examples]

1) Please provide feedback on the current fraud and abuse 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). [full question]

2) 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. [full question]

3) Federal law 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 if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish." 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? [full question]

4) 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 home dialysis for which payment is being made under Medicare Part B. [full question]

    a. For the purposes of this exception, please provide input on how "telehealth technologies" should be defined.

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b. 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.

Physician Self-Referral Law and Anti-Kickback Statute [link to full question/examples]

1) Please share any feedback regarding specific circumstances in which:

   a. 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

   b. 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.

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