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HHS watchdog eyes anti-kickback safe harbors for care coordination, beneficiary incentives, and cost-sharing

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On Monday, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) published a wide-ranging request for information (RFI) seeking ideas on how it might add or modify safe harbors to the Anti-Kickback Statute (AKS) and exceptions to the beneficiary inducement provisions of the Civil Monetary Penalty (CMP) statute that would promote care coordination and value-based payment systems, while also safeguarding against the risks posed by fraud and abuse. The RFI offers an opportunity for health care providers, manufacturers, payers, and others to seek greater clarity on how federal fraud and abuse laws may apply to arrangements they have considered or may consider in the future. The RFI also presents the opportunity to advocate to the OIG for more expansive safe harbors and exceptions protecting value-based arrangements, beneficiary incentives, or other arrangements that may advance important public health or policy goals but are not clearly protected under the AKS or CMP statute.

Comments on the RFI are due by **October 26, 2018**.

The RFI requests comments concerning the following subjects. For each type of arrangement, the RFI indicates that the OIG is interested in comments addressing both (1) what kinds of arrangements health care providers and companies would like to pursue and (2) what changes are needed for providers and companies to pursue those arrangements legally.

Value-based arrangements and care coordination

- Potential arrangements that the industry is interested in pursuing, including care coordination, value-based arrangements, alternative payment models, arrangements involving innovative technology, and other novel financial arrangements. Specifically, the OIG wants to understand
    - the structure and terms of such arrangements (types of parties, how risk is allocated among parties, financial relationships involving potential referral sources created by the arrangement, types of items and services provided by the arrangement); and
    - how such arrangements promote care coordination or value-based care and prevents potential harms, such as increased costs, inappropriate utilization, or distorted decision making.

- How safe harbors to the AKS or CMP statute exceptions could be added or modified to protect such novel financial arrangements
- Potential definitions for "value" in a safe harbor or exception, and potential definitions for other key terms like "clinical integration," "gainsharing," "risk-sharing," and "value-based care"
- Whether the OIG could clarify its position through guidance as opposed to regulations

Beneficiary incentives and cost-sharing obligations

- What beneficiary incentives providers, suppliers, and others are interested in providing to beneficiaries, and how such beneficiary incentives contribute to or improve quality of care, care coordination, and patient engagement, including information on
    - examples of beneficiary incentives that are appropriate and effective;
    - whether beneficiary incentives connected to medication adherence and medication management should be treated differently than other types of beneficiary incentives;
    - what, if any, disclosures the OIG should require the offeror to make to beneficiaries regarding an incentive;
    - what restrictions, if any, the OIG should place on the sources, types, or frequency of beneficiary incentives to reduce the risk of fraud and abuse;
    - whether the OIG should increase the "nominal value" that Medicare and Medicaid beneficiaries may receive; and
    - input on risks, benefits, potential safeguards, and definitions related to the following specific categories of incentives: (1) cash equivalents, (2) gift cards, (3) in-kind items and services, and (4) non-monetary remuneration.
- How relieving or eliminating beneficiary cost-sharing obligations could improve care delivery, enhance value-based arrangements, and promote quality of care, including:
    - Patient care scenarios where cost-sharing obligations are particularly problematic;
    - If cost-sharing obligations could be waived or subsidized in a value-based or care coordination arrangement, the likely impact on providers, suppliers, and others, and potential fraud and abuse risks;
    - Potential risks to beneficiaries or federal health care programs from reduction or elimination of cost-sharing obligations; and
    - Suggested protections or safeguards that the OIG should incorporate into a safe harbor for certain beneficiary cost-sharing waivers or subsidies.

Fraud and abuse waivers under Innovation Center models and Medicare shared savings program

- Information related to current fraud and abuse waivers available for models created under the Center for Medicare and Medicaid Innovation (CMMI) and for the Medicare Shared Savings Program, including:

- whether stakeholders have found compliance with the waiver conditions challenging or particularly burdensome, such that the requirements impede the goal of the models, initiatives, or programs;
- whether any waiver structures or conditions work well;
- feedback on the requirement of an accountable care organization (ACO) governing body and whether a similar requirement could be applied to safe harbors or exceptions for alternative payment models and coordinated care arrangements; and
- pros and cons of safe harbors or waivers that are uniform across different types of CMS-sponsored models, initiatives, and programs.

Telehealth technologies exception to beneficiary inducements CMP

- How the OIG should define the "telehealth technologies" exception to the beneficiary inducements CMP

Alignment with Stark Law exceptions

- Whether and how the exceptions to the physician self-referral law (Stark Law) should align with AKS safe harbors in furtherance of care coordination and value-based care and the other goals of the RFI

This RFI was released on the same day comments were due on the Centers for Medicare & Medicaid Services' (CMS) June 25 RFI that asked how to address any undue impact and burden of the Stark Law. HHS Deputy Secretary Eric D. Hargan has described these RFIs as part of a concerted effort dubbed the "Regulatory Sprint to Coordinated Care," to reduce regulatory burden. Deputy Secretary Hargan said on June 20, "[r]emoving unnecessary government obstacles to care coordination is a key priority for this Administration. We need to change the healthcare system so that it puts value and results at the forefront of care, and coordinated care plays a vital role in this transformation."

Under its "Regulatory Sprint," HHS also plans to issue RFIs from the Office for Civil Rights (OCR), which will likely ask for information on potential changes to the Health Insurance Portability and Accountability Act (HIPAA), and from the Substance Abuse and Mental Health Services Administration (SAMHSA), which will likely seek ideas for potential changes to the Confidentiality of Substance Use Disorder Patient Records regulations.

Through this and other requests for information, HHS has made clear its prioritization of promoting care coordination and value-based payment, and this RFI may present a good opportunity for health care companies and health care providers involved in or considering such arrangements to weigh in on appropriate protection under federal fraud and abuse laws. If you are interested in commenting or have questions about the RFI, please reach out to the Hogan Lovells lawyer with whom you regularly work or any Hogan Lovells lawyer listed in this alert.

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