

OIG Seeks Public Input on Anti-Kickback Statute and Beneficiary Inducements CMP as part of the “Regulatory Sprint to Coordinated Care”

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The Department of Health and Human Services’ (HHS) Office of Inspector General (OIG) has identified the anti-kickback statute (AKS) and beneficiary inducements civil monetary penalty (CMP) as potential barriers to arrangements that could promote better patient care coordination and value-based arrangements. On August 27, 2018, the OIG published a [Request for Information \(RFI\)](#) seeking input from industry stakeholders on how the agency could modify existing or add new safe harbors to the AKS and exceptions to the beneficiary inducements 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.”

The RFI describes how transforming the healthcare system into one that better pays for value is a key priority for HHS, and that HHS has launched what it calls a “Regulatory Sprint to Coordinated Care” to accelerate this

transformation, with a focus of removing “unnecessary obstacles” to coordinated care. This OIG RFI is part of HHS’s Regulatory Sprint. As we described in our blog post [here](#), the Centers for Medicare & Medicaid Services (CMS) also recently published an RFI related to reforms to the federal physician self-referral law (or “Stark Law”) as part of HHS’s Regulatory Sprint.



Related People

- Alissa Smith

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Comments are due from stakeholders to the OIG RFI by 5 PM on October 26, 2018.

Specifically, OIG is seeking input on the following topics:

1. Promoting Care Coordination and Value-Based CareThe OIG would like information about potential arrangements that the healthcare industry is interested in pursuing,

which may implicate the AKS and CMP, such as care coordination arrangements, value-based arrangements, alternative payment models, arrangements involving innovative technology and other novel financial arrangements. The OIG requests a detailed explanation of the proposed structure and terms of the arrangements, and a description of how the arrangement promotes care coordination or value-based care. The description should also include an explanation of how the proposed arrangement prevents potential harms such as increased costs, inappropriate utilization, poor quality of care and distorted decision-making. For each detailed description, the OIG requests that stakeholders describe the new or modified AKS safe harbors or exceptions to the beneficiary inducements CMP definition of “remuneration” that may be necessary in order to protect the described arrangement. The OIG is also seeking input on several key definitions that are used in the regulatory provisions related to health care delivery reform, payment reform and the AKS, such as the definition of coordinated care, care coordinator and care coordination services.

2. Beneficiary Engagement, including Beneficiary Incentives and Beneficiary Cost-



Sharing Obligations The OIG is seeking feedback on the types of incentives that providers, suppliers and others want to provide to beneficiaries. For each incentive, the OIG wants to know how providing the incentive would contribute to or improve quality of care, care coordination and patient engagement (including adherence programs). The OIG published several specific

questions in the RFI such as whether beneficiary incentives connected to medication adherence and medication management should be treated differently than other types of beneficiary incentives, and if so, how and why. Further, the OIG is seeking input regarding what disclosures the offer or should be required to make to beneficiaries regarding an incentive, such as the source of the incentive, as well as input regarding the risks and benefits related to certain types of incentives such as cash equivalents, gift cards, in-kind items and services, and non-monetary remuneration. Additionally, the OIG is also seeking input on whether the “nominal value” threshold under the CMP should be increased from \$15 per item and \$75 in the aggregate per patient on an annual basis, whether a similar nominal value “policy” should be applied to the AKS, and if so, how such policy would contribute to care coordination or value-based care. The OIG is also requesting information about how reducing or eliminating patient cost-sharing obligations might improve care delivery and promote quality of care.

3. Other Related Topics of Interest The OIG is seeking feedback on a number of related topics of interest. These include: (a) current fraud and abuse waivers developed for purposes of carrying out the Medicare Shared Savings Program; (b) donated or subsidized cybersecurity-related items and services; and (c) new exceptions under the Bipartisan Budget Act of 2018 related to (i) incentive payments under the ACO Beneficiary Incentive Program and (ii) telehealth technologies.

4. The Intersection of the Stark Law and the AKS Finally, the
OIG would like feedback regarding circumstances in which Stark Law exceptions and AKS safe harbors should align for purposes of the goals of the RFI and circumstances in which Stark Law exceptions related to care coordination/value-based care should not have a corresponding AKS safe harbor. The
OIG noted that, where relevant, it intends to review comments submitted in



response to the CMS RFI related to the Stark Law (described above), but that it urges commenters to resubmit any relevant comments to the OIG RFI to ensure that they are considered by the OIG, given the volume of questions included in the CMS RFI and the separate authorities of the OIG and CMS.

Please contact the authors or your regular attorney at Dorsey & Whitney if you want more information about the RFI process or desire to submit comments to the RFI by the October 26, 2018 deadline.