HHS-OIG Seeks Comments on Value-Based Care, AKS and CMP

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On August 27, 2018 the Office of Inspector General of the United States Department of Health and Human Services (the OIG) issued a request for information on the interplay among value-based payment models, the federal anti-kickback statute (the AKS), and the beneficiary inducements civil monetary penalties law (the Beneficiary Inducements CMP) (the RFI).

The goal of an RFI is to provide the issuing entity – here the OIG – with information that may or may not result in a formal rulemaking. This RFI is part of HHS' recently-launched "Regulatory Sprint to Coordinated Care," which is focused on identifying regulations that may "act as barriers to coordinated care," and issuing guidance or revising such regulations "to encourage and incentivize coordinated care while protecting against harms caused by fraud and abuse."

Throughout the RFI, the OIG requests industry input focusing on the structure of alternative payment arrangements that promote care coordination and value, and asks whether new or revised safe harbors and exceptions are needed to "promote beneficial care coordination, patient engagement and value-based arrangements." The OIG also asks how to define terms related to alternative payment models, value-based arrangements and care coordination. Below is a short summary of the primary issues on which the OIG is seeking input from industry. Providers, ACOs and others interested in submitting comments must do so by October 26, 2018.

1. PROMOTING CARE COORDINATION AND VALUE-BASED CARE

The OIG is seeking information on how value-based payment arrangements that members of industry are interested in pursuing may implicate the AKS or the Beneficiary Inducements CMP. OIG has also asked what new or modified safe harbors might be needed to protect such arrangements. Last, OIG has requested comments regarding how "value" should be defined and used in a safe harbor or exception addressing value-based care. Value-based payment arrangements often target the "triple aim" of health care: increased access and increased quality while decreasing cost. It will be important for any safe harbor in the value-based arena to accurately encompass such concepts.

2. BENEFICIARY ENGAGEMENT

The second area in which the OIG is seeking input through the RFI is beneficiary engagement, involving beneficiary incentives and cost-sharing obligations. OIG has requested feedback regarding the sorts of incentives that providers, suppliers and other stakeholders want to provide to beneficiaries, and how such incentives would "contribute to or improve quality of care, care coordination, and patient engagement, including adherence to treatment plans." OIG is also interested in

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whether the particular party that furnishes the incentive to the patient – *e.g.*, a provider, a supplier, or an ACO – will impact outcomes "from an effectiveness and program integrity perspective."

OIG is exploring whether restrictions should be imposed upon the approved sources of such incentives, or the types or frequency of incentives that can be provided, or whether beneficiary incentives connected to medication adherence and management should be treated differently than other incentives, and whether OIG should require entities offering incentives to disclose those activities to OIG. Finally, OIG has requested comments on how the terms "cash equivalent," "gift card," "in-kind items and services," and "nonmonetary remuneration" should be defined in the context of beneficiary incentives related to value-based care.

OIG is seeking input about how reducing or removing beneficiary cost-sharing obligations could "improve care delivery, enhance value-based arrangements, and promote quality of care." The RFI seeks input on the financial impact of modifying cost-sharing obligations for providers and other stakeholders, as well as the fraud and abuse risks that such actions might create. The OIG also asks about the concerns that would arise if cost-sharing obligations were *subsidized* by providers, suppliers or other health care entities participating in a value based care delivery arrangement.

3. OTHER TOPICS: FRAUD AND ABUSE WAIVERS, CYBERSECURITY, ACO INCENTIVE PROGRAM, TELEHEALTH

ACO Fraud and Abuse Waivers. The RFI seeks feedback on waivers developed by the Center for Medicare and Medicaid Innovation (CMMI or the Innovation Center) and to carry out the Medicare Shared Savings Program (MSSP). The RFI asks stakeholders whether complying with the waivers has been challenging, what waiver requirements have been particularly burdensome, and whether any waivers have made achieving the goals of the relevant models, initiatives or programs more difficult. ACOs and ACO-participating providers and facilities should note that the OIG specifically highlighted the "governing body" concept among ACOs, and noted the governing body's role in the authorization of each arrangement as central to mitigating the fraud and abuse risks that ACOs receiving protection through MSSP pre-participation and participation waivers introduce.

Cybersecurity Donations. The RFI addresses recent interest from stakeholders in "donating or subsidizing cybersecurity-related items and services to providers and others with whom they share information." OIG is interested in information from stakeholders about the types of cybersecurity items or services that entities are interested in donating or subsidizing, and how existing fraud and abuse laws could present barriers to such arrangements.

ACO Beneficiary Incentive Program. OIG is seeking comments regarding a provision of the Bipartisan Budget Act related to the AKS and ACOs. Specifically, the Bipartisan Budget Act added section 1128B(b)(3)(K) of the Social Security Act, an exception to permit incentive payments made to Medicare fee-for-service beneficiaries by an ACO under an ACO Beneficiary Incentive Program, provided that such payment "is made in accordance with the requirements of [Section 1899(m)] and meets such other conditions as the Secretary may establish." The RFI specifically requests information as to what "other conditions" a safe harbor implementing this statutory exception should include.

Defining Telehealth Technologies for ESRD. The RFI seeks comments related to Section 50302(c) of the Bipartisan Budget Act, which creates a new exception in the beneficiary inducement CMP for "telehealth technologies" provided by a provider or a renal dialysis facility to an individual with end-stage renal disease (ESRD) who is receiving home dialysis for which payment is made under Medicare Part B. The term "telehealth technologies" is not yet defined, though the exception requires that such telehealth technologies not be provided as part of an advertisement or solicitation, be provided to furnish telehealth services related to the patient's ESRD, and the services must meet other regulatory requirements promulgated by the Secretary.

OIG specifically seeks input through the RFI about how "telehealth technologies" should be defined. Note that these "telehealth technologies" are separate from the communication technology-based and remote evaluation services that CMS proposed to cover, but excluded from "Medicare telehealth services," in the 2019 Physician Fee Schedule Proposed Rule.

4. INTERSECTION OF STARK AND AKS

The RFI also requests feedback outlining the circumstances where exceptions to the physician self-referral (or Stark) law and AKS safe harbors should align for purposes of the goals of the RFI. The OIG also seeks input regarding exceptions to the Stark law that promote care coordination and/or value-based care that should *not* have a corresponding AKS safe-harbor.

Hooper, Lundy & Bookman's attorneys will continue to monitor developments at the intersection of health care fraud and abuse and value-based care. For more information, please contact Jeremy Sherer in Boston, Charles Oppenheim in Los Angeles, Mark Johnson in San Diego, Katrina Pagonis in San Francisco, or Bob Roth in Washington, D.C.

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