

OIG REQUESTS INFORMATION FROM STAKEHOLDERS TO EXPAND ANTI-KICKBACK STATUTE AND CIVIL MONETARY PENALTY SAFE HARBORS

On August 27, 2018, the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") published a Request for Information ("RFI") regarding the Anti-Kickback Statute ("AKS") and Civil Monetary Penalties Law ("CMP"). The RFI, published as a result of HHS's desire to transition the current health care system to one that pays for the value of services provided not volume, seeks input and recommendations from industry stakeholders regarding modifications and possible expansion of permissible activities and arrangements under the AKS and CMP. This RFI is a byproduct of the "Regulatory Sprint to Coordinated Care" recently launched by HHS in an attempt to identify regulations that may inhibit coordinated care, assessing whether those regulations are unnecessary obstacles to coordinated care and issuing guidance and/or revising regulations to address any obstacles.

OIG has identified the broad nature of the AKS and CMP's restrictions on beneficiary inducements as potential obstructions to care coordination. OIG is seeking input on ways it might modify existing or add new safe harbors to the AKS and exceptions to the beneficiary inducements CMP definition of "remuneration." The goal of the modified or new AKS safe harbors and CMP exceptions would be to advance the delivery of value-based care and promote care coordination while protecting against health care fraud and abuse.

Health care providers, suppliers and other industry stakeholders should consider submitting comments to OIG in order to advocate for the necessary tools to promote care coordination within their organization.

BACKGROUND

The AKS imposes criminal sanctions for individuals and entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce or reward referrals or generation of federal health care program business. However, HHS has the authority to create new and/or modify existing AKS safe harbors from time to time.

The CMP imposes monetary penalties against any person who offers or transfers remuneration to a Medicare or state health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of an item or service from a particular provider, practitioner or supplier when that item or service is reimbursable by Medicare or a state health care program.

By satisfying the elements of a particular safe harbor, individuals and entities can ensure that their business arrangements will not be subject to criminal prosecution under the AKS, penalties under the CMP or liability under the False Claims Act.

SPECIFIC REQUESTS FROM OIG

OIG is specifically interested in the thoughts of industry stakeholders related to:

- The structure of arrangements between parties that participate in alternative payment models designed to promote care coordination and value;
- The need for new or revised AKS safe harbors and exceptions to the beneficiary inducements CMP's definition of remuneration to promote care coordination, patient engagement and value-based arrangements; and
- Terminology related to alternative payment models, value-based arrangements and care coordination.

OIG has also stated a specific interest in any special considerations regarding rural providers and providers that serve other underserved populations, including American Indian and Alaska Native communities.

FOCUS AREAS

OIG's RFI has several key focus areas, which are discussed in further detail below. Note that each focus area is tailored to solicit information in response to specific questions posed by OIG for each topic. When considering comment submission to OIG, commenters should refer back to the RFI and the specific information sought by OIG for each topic.

Promoting Care Coordination and Value-Based Care

OIG is interested in gaining a better understanding of the structures and terms commonly used in arrangements intended to promote care coordination, value-based arrangements, alternative payment models, arrangements involving innovative technology and other novel financial arrangements that may implicate the AKS or CMP. Specifically, OIG has asked stakeholders to identify what additional or modified AKS safe harbors or CMP exceptions may be necessary to protect these types of arrangements. OIG has identified the following types of arrangements as existing safe harbors and exceptions that may be particularly relevant to care coordination: personal services and management contracts; electronic health record arrangements; warranties; transportation; and promoting access to care.

OIG is also seeking feedback on 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. For example, vendors are not only providing products and services that assist in patient care, but they can also be pivotal in the coordination of care by sharing their clinical and economic expertise, supply chain management capability and data analytics proficiency. Using that data and other knowledge coupled with clinical feedback would allow for meaningful modifications to care that would likely lower cost and provide an enhanced patient experience.

Defining critical terminology, such as care coordination services, clinical integration, gainsharing, incentive payments, risk-sharing and value-based arrangements, is also important as OIG looks to modify or supplement current regulations. That said, under the current regulations, suppliers and providers are cautious about moving forward with any risk-sharing or value-based models based upon the regulatory hurdles. Thus, OIG is soliciting feedback on these types of concepts to assist in their current examination of the regulatory environment in light of the current health care landscape.

Beneficiary Engagement

OIG is specifically seeking input regarding: i) the types of incentives that providers, suppliers and other stakeholders are interested in providing to beneficiaries; ii) how providing these incentives would contribute to or improve the quality of care, care coordination and patient engagement; and iii) whether the types of entities that furnish the incentives matter from both an effectiveness standpoint as well as a program integrity perspective.

OIG seems particularly interested comments related to any differences in possible incentives that promote adherence to medication protocols, as well as assessments of the risks and benefits of various types of remuneration (e.g., cash equivalents, gift cards, in-kind items and services and non-monetary remuneration).

OIG has also requested input regarding its position on gifts of nominal value (currently defined as \$15 per occurrence and \$75 annual aggregate) permitted by the CMP and whether these thresholds should be increased on an annual basis. OIG is also interested in comments regarding whether it should have a similar policy under the AKS and, if so, how this policy would contribute to care coordination and/or value-based care.

Information has been requested regarding beneficiary cost-sharing obligations and whether relieving or eliminating these obligations for Medicare and state health care program beneficiaries may improve the care delivery system and promote the quality of care received by the beneficiaries.

Providers, suppliers and other industry stakeholders should consider aspects of their particular care coordination strategies and determine if an expanded ability to provide items and services to Medicare and state health care program beneficiaries would further the goals of the organization and its ability to provide appropriate health care items and services to the communities they serve. For example, fewer limitations on incentives that can be provided to beneficiaries may allow organizations to better focus on assisting their communities and bettering the health of the population as a whole.

Current Fraud and Abuse Waivers

OIG is interested in feedback on current fraud and abuse waivers utilized to carry out the Medicare Shared Savings Program ("MSSP") from parties that are using or who are eligible to use such waivers. Specifically, OIG has asked commenters to describe if and how the utilization of the waivers has been challenging, what elements of the waivers have been burdensome, what aspects of the waivers have worked well and general feedback regarding the pros and cons of the waiver utilization.

Cybersecurity-Related Items and Services

OIG is aware of interest in donating and/or subsidizing cybersecurity-related items and services to other providers with whom the donor may share information. OIG is particularly interested in the types of items and services that would be involved in such arrangements (e.g., software, hardware, training, monitoring, etc.) and what entities should be included/excluded from the receipt of such donations and subsidizations. Although the AKS currently contains a safe harbor for electronic medical record donation, it is not broad enough to protect arrangements regarding cybersecurity items and services. However, as regulators continue to increase the emphasis on machine-to-machine information sharing, the cybersecurity status of other providers becomes a critical factor in protecting your own computing environment. Thus, to achieve the goal of interoperability, the ability to support the security of other entities in a manner that meets regulatory requirements becomes more important. An expanded safe harbor has the potential to improve the cybersecurity of all health care organizations.

ACO Beneficiary Incentive Program

The Bipartisan Budget Act of 2018 added language stating that remuneration under the AKS does not include incentive payments made to Medicare fee-for-service beneficiaries by an ACO under an ACO Beneficiary Incentive Program if the payment is made in accordance with the applicable requirements and meets such "other conditions" as may be established. OIG has sought guidance regarding what, if any, "other conditions" should be established by OIG to provide protections or safeguards.

Telehealth

The Bipartisan Budget Act of 2018 created a new exception to the definition of "remuneration" in the beneficiary inducements CMP. This exception permits remuneration of telehealth technologies provided after January 1, 2019 by providers of services or a renal dialysis facility to an individual with end-stage renal disease who is receiving home dialysis for which payment is made under Medicare Part B.

The telehealth technologies: cannot be offered as a part of an advertisement; must be provided for a purpose related to the patient's end-stage renal disease; and must meet "any other requirements" set forth in regulations. As such, OIG has sought information regarding how "telehealth technologies" should be defined and whether this definition should include services. There seems to be no clear line between telehealth technology and services (i.e., support and connectivity may be an inherent part of the telehealth technology). Furthermore, the health care services provided via telehealth technology have been developed to accommodate the applicable technology and medical instruments utilized in the delivery platform. On the patient side, the technology investment is typically minor. In fact, many telehealth capabilities use technology that is commonly already owned or leased by patients; for example, a mobile or smart phone. The costs associated with telehealth on the patient side are largely related to the services; they are attributable to the cost of the caregiver, the telecommunication services or maintenance/support services required to maintain connectivity. Of course, as remote monitoring and treatment-related technologies continue to evolve, the cost attributable to such technology may become a more significant percentage of total patient cost. Recent developments in consumer-directed medical devices that integrate with telemedicine applications, such as electronic stethoscopes, EKG machines and laboratory analytics devices, hold great promise, and the ability to provide patients with these tools for use in telemedicine-based care will likely result in better care and lower cost.

Intersection of Stark Law and AKS

Lastly, the RFI has requested feedback pertaining to circumstances where Stark Law exceptions and AKS safe harbors should align for purposes of the goals described in the RFI.

PRACTICAL TAKEAWAYS

This is an opportunity for organizations to provide industry knowledge and insight into specific proposed arrangements and programs to further push health care into the value-based world. This could be in the form of a vendor-proposed arrangement that an organization previously identified as off-limits due to certain AKS or other regulatory requirements or by identifying gaps in service that may have developed as a result of strict regulatory oversight. In seeking suggestions for everything from program design to relevant terminology, OIG is looking to the health care industry for its expertise and direction on these important issues. By providing comment, industry stakeholders can help shape the future framework for the statutory and regulatory guidelines by which it must abide.

Commenters should also consider providing feedback on the importance of including in the definition consumer-based wearables, as

consumer-focused, non-traditional companies continue to increasingly engage in health care.

Although OIG is not bound to take any action based upon the recommendations received as a result of the RFI, organizations are encouraged to submit comments to OIG in order to ensure that any future regulations are set forth in a manner that best benefits federal health care program beneficiaries. Industry stakeholders are privy to the information and evidence that reflects how to best transition the health care reimbursement system from volume to value. In addition, these organizations know the most efficient ways resources could be utilized in order to best help the patient populations serviced by the organizations.

All comment submissions are due no later than 5:00 PM on October 26, 2018. Comments may be submitted electronically, by mail or by hand/courier. If you would like assistance submitting a comment or would like additional information on these topics, please contact:

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