Proposed Coordinated Care Safe Harbors – Fulfilling the Promise

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Fulfilling its promise to help facilitate the health care system's transition from "volume" to "value," the Office of the Inspector General ("OIG") has proposed three new safe harbors to the Anti-Kickback Statute that would shield certain arrangements that are designed to enhance coordinated care.[1] While these types of arrangements are already becoming more common in the health care industry, providers have been cautious about employing them because of persistent concerns over recent aggressive enforcement by the OIG and the Department of Justice of the Anti-Kickback Statute ("AKS"). With these proposals, OIG seeks to assuage those concerns as part of its "Regulatory Sprint to Coordinated Care."

At present, providers desiring to venture into care coordination arrangements that do not fall within an established CMS program need to seek an advisory opinion from OIG to eliminate the risk of violating the AKS – an expensive and time-consuming process. There have been a number of recent opinion requests at least peripherally related to coordinated care. For example, earlier this year a medical center sought an opinion on an arrangement that provided free, in-home follow-up care to patients who are at high risk for admission or re-admission to a hospital.[2] While OIG advisory opinions afford some guidance to providers that are considering similar arrangements, OIG explicitly limits the applicability of any opinion to the specific requestor of that opinion.

To address that concern, OIG's proposed new safe harbors would enhance providers' ability to enter into coordinated care and value-based arrangements. Specifically, the three safe harbors cover: (1) care coordination arrangements to improve quality, health outcomes, and efficiency,[3] (2) value-based arrangements with substantial downside financial risk,[4] and (3) value-based arrangements with full financial risk.[5] The proposed safe harbors are designed to provide increasing flexibility to the participants in structuring their relationships as the parties assume greater financial risk.[6] By way of example, the care coordination safe harbor is limited to providing "in kind remuneration," whereas the safe harbors for arrangements with substantial and full downside risk permit monetary remuneration.

While each of these proposed safe harbors contains several required elements,[7] the heart of each is that the participants are parties to a "value-based arrangement" and are engaged in "value-based activities" that have a "value-based purpose." Not surprisingly, these terms have detailed and interlaced definitions that will likely require detailed analysis to ensure compliance.

As a starting place, it is helpful to consider what is meant by a *value-based purpose*, which includes the following four activities: (1) coordinating and managing the care of a target patient population (discussed in more detail later below); (2) improving the quality of care for a target patient population; (3) appropriately reducing costs to payors or reducing expenditure growth without reducing the quality of care for the target population; and (4) transitioning from healthcare delivery and payment mechanisms that are based on the value of the items and services provided to mechanisms that are based on the quality of care and control of costs of care for a target patient population.

Moreover, a "*value-based activity*" is broadly defined as "any of the following activities, provided that the activity is reasonably designed to achieve at least one *value-based purpose* of the value-based enterprise: (A) the provision of an item or service; (B) the taking of an action; or (C) the refraining of taking an action" and specifically does not include the making of a referral.[8] To further explain this definition, the OIG states:

With this definition, we acknowledge that a "value-based activity" may encompass not only affirmative actions taken by VBE participants (e.g., providing care coordinators to help patients with complex needs navigate the transition from a hospital to their homes) but also instances of inaction (e.g., refraining from ordering certain items or services in accordance with a medically appropriate care protocol that reduces the number of required steps in a given procedure).[9]

Finally, a *value-based arrangement* is defined as "an arrangement for the provision of at least one *valued-based activity*" between: (1) a valued-based enterprise and one or more participants in that enterprise, or (2) participants in the same value-based enterprise.[10]

Each of the three proposed coordinated care safe harbors requires that the arrangement include activities that, at a minimum, further the first of the four value-based purposes involving the coordination and management of care for a target patient population. The coordination and management of care for a targeted population is further defined as:

[T]he deliberate organization of patient care activities and sharing of information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population.[11]

These coordination and management activities could include using case managers, providing care or medication management, creating a patient-centered medical home, holding with transitions of care, and sharing, using health data to improve outcomes, or sharing accountability for the care of a patient.[11] Note that OIG's approach is narrower than the protections proposed by CMS under the Stark Law, which would only require that value-based activities be connected to or reasonably designed to achieve any of the value-based purposes. OIG has solicited comments on whether it should follow the CMS approach.

OIG's preamble to the proposed rule provides an example of a compliant value-based arrangement under the coordinated care safe harbor. In that example, an acute care hospital and skilled nursing facility receive shared savings payments from a payer for improved quality and reduced emergency room visits. The hospital provides a behavioral health nurse to the skilled nursing facility; the nurse follows for one year certain patients who have recently been discharged from the hospital and who have mental disorders. While such an arrangement could violate the Anti-Kickback Statute, OIG indicates that this arrangement would be a protected if it meets the requirements of the coordinated care safe harbor.

While OIG has proposed pathways to protect certain innovative arrangements that would advance the transition from "volume" to "value," the proposed safe harbors contain complex and layered definitions that remain subject to change during the rulemaking process.[12] Once issued, the final rules will require careful analysis to ensure arrangements are compliant with the intended safe harbor. OIG has also cautioned that any final safe harbors would only provide prospective protection. Until that time, providers should continue to exercise caution and restraint to ensure compliance with existing AKS and CMP regulations and guidance.

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[1] Note that OIG has also proposed additional new safe harbors that are beyond the scope of this article, including safe harbors for arrangements promoting patient engagement and support that improve quality and health outcomes; arrangements under CMS-sponsored models and initiatives; and donations of certain cybersecurity technology and related services.

[2] Advisory Opinion 19-03. In this opinion, OIG decided not to impose sanctions under either the Civil Monetary Penalties law ("CMP") or the AKS. The opinion is nevertheless disconcerting insofar as OIG concluded that the arrangement would not qualify for the "promotes access to care" exception under the CMP.

[3] 84 FR 55708.

[4] 84 FR 55716.

[5] 84 FR 55719.

[6] By way of example, "substantial downside risk" is defined to include "shared savings with a repayment obligation to the payor or at least 40% of any shared loss when the arrangement is compared to historical expenditures, while "full downside risk" is defined to include a capitated payment for all services for a targeted population. 84 FR at 55717, 55719.

[7] Many of these requirements are commonly incorporated into other AKS safe harbors, such as the requirements that arrangements be in writing and that they be for a term of at least a year. It is noteworthy that none of the proposed rules for value-based arrangements has a fair market value requirement, however.

[8] 84 FR 55703.

[9] *Id*.

[10] A value-based enterprise is a "network of individual and entities that collaborate together to achieve one or more valued-based purposes." 84 FR 55701. It is important to note that the OIG specifically excludes pharmaceutical manufacturers, manufacturers, distributors, or suppliers of DMEPOS, and laboratories from the definition of "value-based entity participant." 84 FR 55703-4.

[11] *Id*. at 55707.

[12] OIG has solicited comments on these proposed safe harbors, which OIG will then review before finalizing its regulations. The comment period ends on December 31, 2019.
