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Value-based arrangements between hospitals and physicians: New pathways for innovation

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At the time this article went to print, it was unclear whether the Biden administration would revisit certain regulations that were published shortly before the transition, including the Stark and Anti-Kickback regulations discussed here. While changes are not anticipated, readers are advised to confirm the current status of these regulations prior to relying on them.

In late 2020, the Centers for Medicare & Medicaid Services (CMS) and Department of Health & Human Services Office of Inspector General (OIG) respectively released the long-awaited new federal Physician Self-Referral Law (referred to as the Stark Law)[1] and federal Anti-Kickback Statute (AKS) regulations.[2] These new regulations were issued as part of the Department of Health & Human Services' Regulatory Sprint to Coordinated Care, with the goal of removing potential barriers to care coordination and value-based care. A key feature is the introduction of new protections for certain "value-based arrangements," which aim to provide flexibility to encourage innovation between various healthcare providers and other individuals and entities.

The Stark Law, in particular, has historically presented potential barriers to innovative financial relationships between hospitals and physicians, given its nature as a strict liability statute and the fact that any financial relationship must fit every element of an applicable exception to be in compliance. In addition, under the AKS, hospitals and physicians may be hesitant to enter into an innovative arrangement unless it meets a safe harbor (although, unlike the Stark Law exceptions, the AKS safe harbors are voluntary). For example, although gainsharing arrangements between hospitals and physicians can help achieve cost efficiencies and enhance patient quality of care, without a clear AKS safe harbor and corresponding Stark Law exception, some parties have been hesitant to enter into such arrangements due to potential fraud and abuse risk exposure.

The new value-based regulations present significant opportunities for hospitals and physicians to enter into innovative arrangements. At the same time, the new regulations are nuanced, and arrangements must be structured thoughtfully to ensure compliance. While a comprehensive review of all the requirements of the new rules is beyond the scope of this article, the following provides an overview, along with some examples of value-based arrangements between hospitals and physicians and key compliance considerations.

What is a 'value-based arrangement' under the new regulations?

The new Stark Law exceptions and AKS safe harbors apply to a "value-based arrangement" entered into by a "value-based enterprise" made up of value-based enterprise participants, in which the parties engage in "value-based activities" with respect to a "target patient population." An understanding of the meaning of these terms is critical for compliance with the new exceptions and safe harbors (see Table 1).

Key value-based terms	Summary (full definitions located at Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,492, 77,657–663 (December 2, 2020) and Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684, 77,889–894 (December 2, 2020))
Value-based arrangement	An arrangement in which a value-based enterprise and/or its participants engage in value-based activities.
Value-based enterprise (VBE)	Two or more value-based participants collaborating to achieve a value-based purpose pursuant to a value-based arrangement, which has (a) an accountable body or person responsible for oversight, and (b) a governing document. Formation of a VBE can be accomplished in many ways, ranging from formation of a new joint venture legal entity to simply amending an existing professional services agreement.
VBE participants	Individuals or entities engaged in a value-based activity as part of a VBE (e.g., hospitals, physicians, digital health companies, skilled nursing facilities); protection under AKS unavailable for some provider types.
Value-based activities	An activity that is reasonably designed to achieve a value-based purpose. May include providing an item or service, taking an action, or refraining from taking an action, but does not include making a referral.
Value-based purposes	Coordinating and managing care, improving quality, appropriately controlling costs of payers, or transitioning from volume to value. Internal cost savings is not a sufficient purpose.
Target patient population	Identified patient population selected using "legitimate and verifiable" criteria set out in writing, in advance, which further a value-based purpose (e.g., based on diagnosis, zip code, or payer type).

Table 1: The OIG final rule terms and definitions