

Value-Based Arrangement Exceptions and Safe Harbors Have Narrow Utility for Medical Device and Pharmaceutical Companies



On December 2, 2020, the Department of Health & Human Services (HHS) published its long-awaited two final rules – one by the [Office of Inspector General](#) (OIG) and one by the [Center for Medicare & Medicaid Services](#) (CMS) – finalizing changes to regulations implementing the federal anti-kickback statute (AKS), the beneficiary inducement provisions of the civil monetary penalty law (CMPL), and the physician anti-self-referral law (Stark Law) and their safe harbors and exceptions. Among the most anticipated aspects of the final rules are the new value-based arrangement AKS safe harbors and Stark Law exceptions.

The two final rules, while complicated, are aligned in their definitions of value-based arrangements.

A **value-based enterprise (VBE)** is two or more participants that: (1) are collaborating to achieve at least one value-based purpose; (2) are each a party to a value-based arrangement with the other (or at least one other participant in the same VBE); (3) have an accountable body or person responsible for financial and operational oversight of the VBE; and (4) have a governing document describing the VBE and how its participants intend to achieve the VBE’s value-based purpose(s).

A **value-based arrangement** is an arrangement entered into between (1) a VBE and one or more of its participants, or (2) among participants in the same VBE, for the provision of one or more value-based activities for a target patient population.

A **value-based purpose** is (1) coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

While the new AKS safe harbors exclude pharmaceutical and medical device manufacturers, distributors, and wholesalers; DMEPOS suppliers; laboratories; compounding pharmacies; and pharmacy benefit managers, there is a narrow exception intended to facilitate the deployment of health technologies for care coordination. These entities are eligible for protection under the care coordination safe harbor as “**limited technology participants**” that exchange “**digital health technology**” (defined broadly) with a VBE or VBE participant. The OIG Final Rule provided as an [example](#) “a medical technology company could partner with physician practices, to better coordinate and manage care for patients discharged from a hospital with digitally-equipped devices that collect and transmit data to the physicians to help monitor the patients’ recovery and flag the need to intervene in real time (e.g., a device that monitors range of motion that could inform what

an appropriate physical therapy intervention may be). The technology company could provide the physician group with necessary digital health technology that improves the physician group's ability to observe recovery and intervene, as necessary." However, the OIG final rule requires that the exchange of digital health technology by a limited technology participant is *not* conditioned on any recipient's exclusive use of, or minimum purchase of, any item or service manufactured, distributed, or sold by the limited technology participant.

The Stark Law final rule does not exclude such entities from qualifying as VBE participants under any exception for value-based arrangements. However, because the Stark Law is focused on prohibiting self-referrals by physicians, the new Stark Law exceptions for value-based arrangements will be of limited value to medical device and pharmaceutical companies.