

**Summary of Major Provisions in Stark Law and Anti-Kickback Statute Final Rules**

**Background:** The physician self-referral (i.e. “Stark) law was enacted in 1989 and can be found in section 1877 of the Social Security Act. It aims to (1) prohibit a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibit the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (HHS) authority to create additional regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Congress also granted the Secretary authority to waive certain provisions for the Medicare Shared Savings Program and other models being tested under the CMS Innovation Center.

HHS has since identified the broad reach of the Stark Law, AKS, and civil monies penalty (CMP) law as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and the coordination of care among clinicians in both the federal and commercial sectors. Because the consequences of noncompliance are so dire, physicians may be discouraged from entering into innovative arrangements that would improve quality outcomes, produce health system efficiencies, and lower costs. To address these concerns, on Nov. 20, 2020, HHS and OIG finalized two rules with several reforms to modernize and remove potential regulatory barriers to care coordination and value-based care and clarify certain provisions to reduce the burden of compliance. **The major provisions of both rules are summarized in the pages that follow.**

***Disclaimer: This document is not intended to be an exhaustive list of all provisions in the final rules and does not constitute legal advice.***

**Stark Law**

**I. Terminology definitions**

* ***Value-based activity:*** 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: (1) the provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action. We also proposed that the making of a referral is not a value-based activity.
  + Remuneration paid in furtherance of the objectives of a value-based health care system does not always involve one-to-one payments for items or services provided by a party to an arrangement. For example, a shared savings payment would qualify. The act of referring patients for designated health services is itself *not* a value-based activity.
  + HHS declined to provide a list of items or services, actions, and ways to refrain from taking an action that qualify as value-based activities to maximize flexibility and encourage innovation.
  + HHS does not dictate how parties should demonstrate that an activity is “reasonably designed” to achieve a value based purpose but encourages “contemporaneous documentation” and notes that new exceptions in this rule “do not impose an additional or different burden of proof” than those that already exist for Stark Law, which can be found at §411.353.
* ***Value-based arrangement:*** An arrangement for the provision of at least one value-based activity for a target patient population between or among: (1) the value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.
  + All parties to the value-based arrangement must be VBE participants in the same value-based enterprise.
  + The value-based arrangement must be a compensation arrangement and not another type of financial relationship to which the physician self-referral law applies.
  + HHS declined to expand the definition to specifically include Advanced APMs, all-payer/other-payer APMs, MIPS APMs, and state-based Medicaid initiatives on the basis that the definition of “value-based arrangement” relates to a compensation arrangement between a physician and an entity that participate in the same value-based enterprise and does *not* cover compensation arrangements between a payer and a physician.
* ***Value-based enterprise:*** Two or more VBE participants: (1) collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).
  + HHS did not believe it would be beneficial to dictate particular legal or other structural requirements so as to encompass a wide-range of structures in this definition. It may be a distinct legal entity—such as an ACO—or an informal affiliation between two or more with written documentation recording a value-based arrangement. Essentially, it is a network of participants (clinicians, suppliers, etc.) that have agreed to collaborate to coordinate care, increase efficiencies, and improve patient outcomes.
  + Each of the financial relationships that results from the contract must be analyzed separately under Stark Law. Therefore, adding a new physician to an existing value-based arrangement will not be viewed as an “addition” to an existing value-based arrangement but, rather, a separate and distinct compensation arrangement that must be analyzed for compliance with an applicable exception.
  + HHS does not dictate the format or content of the governing document or the structure or composition of the accountable body, reasoning that staffing infrastructures and documentation depend on the size and structure of the value-based enterprise. The accountable body may be the governing board, a committee of the governing board, a corporate officer of the legal entity that is the value-based enterprise, or the party designated as responsible for financial and operational oversight of the VBA.
* ***Value-based purpose:*** (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, payers 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.
  + “Value-based purpose” would apply during the period of a value-based enterprise’s start-up or preparatory activities and would include such activities as: integrating new VBE participants, establishing a necessary infrastructure to provide coordinated care, preparing to accept increased levels of financial risk, formalizing a legal/operational structure for a new value-based enterprise, hiring of new staff to support enhanced care coordination activities, contracting with legal and financial consultants, securing capital investments, and installing new clinical management systems, performance measurement and improvement mechanisms, or integrated EHR or other Health IT. In many cases, these may overlap with arrangements that qualify for the pre-participation waiver under the Medicare Shared Savings Program.
* ***VBE participant:*** An individual or entity that engages in at least one value-based activity as part of a value-based enterprise.
  + Does not exclude any specific persons, entities, or organizations (including laboratories and DMEPOS suppliers) from qualifying.
* ***Target patient population:*** An identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise’s value-based purpose(s).
  + May include medical or health characteristics, geographic characteristics, payer status, or other defining characteristics. However, selecting a target patient population consisting of only lucrative or adherent patients (i.e. “cherry-picking”) or avoiding costly or noncompliant patients (i.e. “lemon-dropping”) would not be permissible.
  + Selection criteria for the target patient population could be described as “the target patient population to be identified by the payor in accordance with criteria established by the payor for retrospective attribution.” The value-based enterprise or the VBE participants that are parties to the specific value-based arrangement under which value-based activities are undertaken for the target patient population must ensure that the payor’s methodology for attribution of the target patient population are legitimate and verifiable and that they will further the value-based enterprise’s value-based purpose(s). In addition, the selection criteria must be documented in advance of the commencement of the value-based arrangement. It is not sufficient for the value-based enterprise or its VBE participants to merely state that the selection criteria will be determined by another party (in this case, the payor).

**II. Permanent exceptions for value-based arrangements**

* The compensation arrangements must satisfy specified requirements based on the characteristics of the arrangement and the level of financial risk undertaken.
* The exceptions apply regardless of whether the arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both.
* Many value-based arrangements, such as pay-for-performance arrangements or certain risk-sharing arrangements, do not qualify.
* The final exceptions at §411.357(aa) are applicable to the compensation arrangements between parties in a CMS-sponsored model, program, or other initiative