

Compliance Today – February 2020 CMS issues long-awaited Stark proposed rulemaking

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On October 17, 2019, the Centers for Medicare & Medicaid Services (CMS) published a notice of proposed rulemaking (the proposed rule) to update and amend the Stark Law regulations.^[1] Stakeholders have long awaited this proposed rule after CMS issued a Request for Information (RFI) on June 25, 2018, for public input on how to address the regulatory burdens of the Stark Law. Considering those comments, CMS issued this proposed rule to introduce new exceptions addressing value-based care arrangements, and to clarify and introduce new exceptions addressing non-abusive compensation arrangements. More than 330 pages long, the proposed rule is the first stand-alone Stark rulemaking in over a decade. This article explores a selection of aspects of the proposed rule.

Simultaneously with the proposed rule, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued a companion notice of proposed rulemaking introducing new exceptions, amendments, and clarifications to the Anti-Kickback Statute (AKS) and Civil Monetary Penalties (CMP) regulations. A companion article summarizing and discussing the OIG proposed rule (“OIG proposed rule revises federal Anti-Kickback Statute and CMP Law”) can be found in this issue of *Compliance Today*.

The Stark Law background

The Stark Law prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare and prohibits the entity from billing for those referred services, if the physician or a family member has a financial relationship with the entity performing or billing for the DHS.^[2] If an arrangement implicates the Stark Law, it *must* fit within an exception in order to be protected from liability. This restrictive and unforgiving prohibition has been a large burden on entities and providers over time, especially as healthcare reimbursement transitions from pay-for-performance to value-based, coordinated care arrangements. Recognizing that the Stark Law is, in fact, a law that can only be amended by Congressional action, CMS has proposed new exceptions and clarifying language to these regulations in an attempt to ease the regulatory burden on stakeholders.

Coordinated care arrangements

CMS received numerous comments in response to the RFI regarding the transformation of healthcare compensation methodologies, specifically the transition from fee-for-service (FFS) to new value-based, coordinated care arrangements. These new arrangements complement payment models focused on efficiencies and outcomes, versus rendered services. Stakeholders requested regulatory updates to protect arrangements compensating efficiencies and outcomes. In response, the proposed rule issued new definitions for these arrangements and introduced three exceptions to protect compensation arrangements that satisfy certain requirements based on the type of arrangement or value-based enterprise (VBE) and level of the parties’ financial risk. If finalized, these definitions and exceptions are meant to eliminate the need for new CMS-sponsored waivers for value-based arrangements.

Value-based care definitions

CMS introduced definitions for limited terms critical to three exceptions proposed to protect certain coordinated care arrangements.^[3]

- A “value-based activity” would mean any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the VBE: (1) the provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action. The making of a referral is not a value-based activity.
- A “value-based arrangement” would mean an arrangement for the provision of at least one value-based activity for a target patient population between or among: (1) the VBE and one or more of its VBE participants; or (2) VBE participants in the same VBE.
- A “value-based enterprise” would mean 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 VBE; (3) that have an accountable body or person responsible for financial and operational oversight of the VBE; and (4) that have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s).
- A “value-based purpose” would mean: (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 healthcare 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.
- A “VBE participant” would mean an individual or entity that engages in at least one value-based activity as part of a VBE.
- “Target patient population” would mean an identified patient population selected by a VBE 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 furthers the VBE’s value-based purpose(s).

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