

Compliance Today – February 2020 OIG proposed rule revises federal Anti-Kickback Statute and CMP Law

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In 2018, the United States Department of Health and Human Services (HHS) launched the Regulatory Sprint to Coordinated Care initiative (the initiative) to align existing regulations with and remove regulatory impediments to the healthcare industry's shift toward value-based and coordinated care payment models. The initiative covered the regulations implementing the Stark Law,^[1] federal Anti-Kickback Statute (AKS),^[2] and Civil Monetary Penalty Law (CMPL).^[3] In furtherance of the initiative, on August 27, 2018, HHS's Office of Inspector General (OIG) issued a Request for Information seeking recommendations from the public regarding modifying or adding safe harbors to the AKS and exceptions to the CMPL's definition of "remuneration."^[4] After receiving 359 responses from various stakeholders, on October 9, 2019, OIG issued a Notice of Proposed Rulemaking, "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements" (the proposed rule).^[5] A high-level summary of this proposed rule follows.

On the same day, the Centers for Medicare & Medicaid Services (CMS) issued its proposed rule addressing the regulations implementing the Stark Law, which is summarized in "CMS issues long-awaited Stark proposed rulemaking" (also in this issue of *Compliance Today*).

Proposed revisions to the AKS, generally

The AKS prohibits anyone (which includes an individual or a corporation) from knowingly and willfully soliciting or receiving, or offering or paying, any remuneration to a person in return for referring, or to induce such person to refer, an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal healthcare program, or for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal healthcare program.^[6]

However, the AKS regulations carve out certain types of payment arrangements from the definition of the "remuneration" that would otherwise potentially be prohibited (the safe harbors).^[7]

In the proposed rule, OIG proposed five new safe harbors, as well as revisions to four existing safe harbors, intended to "foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse,"^[8] as well as to protect certain incentives offered to beneficiaries to encourage patient engagement, which would otherwise be prohibited.

Definitions

Value-based arrangement: An "arrangement for the provision of at least one value-based activity for a target

patient population between or among: (A) the value-based enterprise (VBE) and one or more of its VBE participants;^[9] or (B) VBE participants in the same VBE.^[10] A VBE is defined as a “network of individuals and entities that collaborate together to achieve one or more value-based purposes.”^[11] VBE participants would not include pharmaceutical manufacturers; manufacturers, distributors or suppliers of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS); or laboratories.

Value-based purposes: Coordinating, managing, and improving the quality of care of a target patient population, reducing the costs to payers without reducing the quality of care for a target patient population, and “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.”^[12]

Target patient population: The “identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that: (A) are set out in writing in advance of the commencement of the value-based arrangement; and (B) further the VBE’s purpose(s).”^[13]

Value-based activity: “Any of the following activities, provided the activity is reasonably designed to achieve at least one value-based purpose of the VBE: (A) the provision of an item or service; (B) the taking of an action; or (C) the refraining from taking an action.” Value-based activities do not include the making of a referral.^[14]

Substantial downside financial risk: Only specific methodologies qualify as substantial downside financial risk. For example, OIG proposes that a VBE is at a substantial downside risk if it is subject to shared savings with a repayment obligation to the payer of at least 40% of any shared losses.

Full financial risk: Similar to the definition of substantial downside financial risk, only certain methodologies qualify as full financial risk. For example, OIG would consider a VBE at full financial risk if it received a “prospective, capitated payment for all items and services covered by Medicare Parts A and B for a target patient population.”^[15]

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