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HHS Issues New Value-Based Care Exceptions and Safe Harbors to Stark Law and Anti-Kickback Statute

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On November 20, 2020, the Department of Health and Human Services (HHS), Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) issued final rules modifying regulations for the Physician Self-Referral Law, commonly known as the Stark Law, and the Anti-Kickback Statute (AKS). HHS issued these new regulatory exceptions and safe harbors to encourage the development of value-based arrangements that might otherwise be prohibited under the existing parameters of the Stark Law or AKS. This article provides an overview of these comprehensive new exceptions and safe harbors; however, it is not exhaustive with respect to the numerous details and requirements included in the new regulations.

The new Stark exceptions and AKS safe harbors for value-based care rely heavily on a set of terms that are substantially the same for the Stark Law and AKS. *These new terms are capitalized in the summaries below and defined in further detail at the end of this article.*

New AKS Safe Harbors

The OIG's new safe harbors addressing value-based care include three safe harbors tied to the level of downside financial risk involved for the parties. These safe harbors include the following:

1. *Care Coordination Arrangements* – Under this safe harbor, Value-Based Enterprise (VBE) Participants in a compliant Value-Based Arrangement may exchange in-kind (nonmonetary) remuneration to promote evidence-based care coordination subject to the safe harbor requirements. While the safe harbor requires no assumption of downside risk by the parties, the arrangement must be commercially reasonable and the recipients of the in-kind remuneration must pay 15% of the offeror's cost or 15% of the fair market value of the remuneration. Additionally, the VBE is required to review the arrangement at least

annually to determine whether the arrangement is achieving its stated outcomes.

1. *Value-Based Arrangements with Substantial Downside Financial Risk* – This safe harbor protects remuneration within a VBE where the VBE has assumed substantial downside financial risk from a payor and where the VBE Participants assume a meaningful share of the VBE's downside financial risk. The safe harbor defines "substantial downside financial risk" to include three options—shared savings with at least 30% loss repayment, episodic or bundled payments with at least 20% loss repayment, or under a partial capitation model as defined in the safe harbor. A VBE Participant assumes a "meaningful share" of the VBE's downside risk for providing or arranging for the provision of items and services for the Target Patient Population if the VBE Participant: (1) assumes two-sided risk for at least 5% of the losses and savings, as applicable, or (2) receives from the VBE a prospective, per-patient payments for a predefined set of items and services under the partial capitation methodology. Additionally, the safe harbor requires that the terms of the Value-Based Arrangement must be put into writing and signed by both parties prior to, or simultaneously with the commencement of the arrangement.
1. *Value-Based Arrangements with Full Financial Risk* – This safe harbor protects remuneration within a VBE where VBE Participants assume full financial risk from a payor. A VBE will be considered to be at "full financial risk" if it is financially responsible on a prospective basis (i.e., prior to the provision of the relevant items and services) for the cost of all patient care items and services covered by a payor for patients in the Target Patient Population over a specified period of time. Full financial risk may take the form of capitation payments, a global budget payment from a payor, or other approaches that involve full financial risk.

Each of these three safe harbors include several additional requirements for covered arrangements regarding, among other things, their permissible purposes, remuneration, and administrative components. These requirements are provided for in full at 42 C.F.R. § 1001.952 (e)(e), (f)(f), and (g)(g).

New Stark Law Exceptions

CMS finalized the three following new Stark Law compensation arrangement exceptions for remuneration to VBE Participants provided pursuant to Value-Based Arrangements:

1. *Value-Based Arrangements that Satisfy Certain Requirements* – Protects remuneration paid under a Value-Based Arrangement with no downside financial risk so long as the arrangement satisfies certain enumerated administrative and operational requirements. The arrangements must be set forth in a writing signed by the parties that includes required details regarding the arrangement, including details specific to how the arrangement qualifies as a Value-Based Arrangement; the methodology for remuneration under the arrangement; and the objective, measureable, and clinical-based outcome measures against which the recipient of the remuneration will be assessed, to the extent the arrangement includes such outcome measures, which are not mandatory. Additionally, the VBE Participants must regularly monitor whether they have furnished the Value-Based Activities required under the arrangement and whether and how continuation of the Value-Based Activities is expected to further the Value-Based Purpose of the VBE. Pursuant to specific requirements set forth in the exception, the VBE must terminate or make modifications to the Value-Based Arrangement if its monitoring activities indicate that any of its Value-Based Activities are not furthering the VBE's stated Value-Based Purposes.

1. *Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician* – Protects remuneration paid under a Value-Based Arrangement if the physician is at meaningful downside financial risk for failure to achieve the Value-Based Purpose(s) of the VBE during the entire duration of the Value-Based Arrangement. "Meaningful downside financial risk" means that the physician is responsible to repay or forego no less than 10% of the total value of the remuneration the physician receives under the Value-Based Arrangement. The nature and extent of the physician's downside financial risk must set forth in writing.
1. *Value-Based Arrangements with Full Financial Risk* – Protects remuneration under a Value-Based Arrangement if the VBE is at full financial risk during the entire duration of the Value-Based Arrangement. "Full financial risk" means that the VBE is financially responsible on a prospective basis (i.e., prior to the provision of the relevant items and services) for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

In addition to the requirements above, which vary among the exceptions, the new Stark Law exceptions for Value-Based Arrangements each also require compliance with certain standard safeguards for such arrangements, including administrative requirements and substantive requirements intended to mitigate the risk of fraud and abuse while promoting value-based care arrangements. These requirements are provided for in full at 42 C.F.R. § 411.357(a)(a).

New Value-Based Care Terms

With the new Stark exceptions and AKS safe harbors for value-based care, CMS and OIG introduced several new defined terms that provide a shared regulatory framework for value-based care under the Stark Law and AKS. These new terms include the following, all as used in the summaries above:

→ *Value-Based Enterprise (VBE)* – Two or more people or entities (referred to as "VBE Participants") who: (1) collaborate to achieve a Value-Based Purpose; (2) are party to a Value-Based Arrangement with at least one other VBE Participant; (3) have an accountable body or person responsible for the financial and operational oversight of the VBE; and (4) have a governing document that describes the VBE and how the VBE Participants intend to achieve the VBE's Value-Based Purposes. The VBE may be separate legal entity (e.g., an ACO) or simply a network of VBE Participants linked through a VBE governing document. Any given Value-Based Arrangement may not include any participants other than the VBE and its VBE Participants.

→ *Value-Based Arrangement* – An arrangement involving only a VBE and/or its VBE Participants for the provision of at least one Value-Based Activity for a Target Patient Population.

→ *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 VBE: (1) the provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action.

→ *Value-Based Purpose* – Any of the following purposes with respect to a Target Patient Population: (1) coordinating and managing care; (2) improving the quality of care; (3) reducing costs or growth in expenditures; or (4) transitioning healthcare delivery and payment from volume-based to value-based (i.e., based on the quality of care and control of costs of care).

→ *Target Patient Population* – An identified patient population selected by the VBE using "legitimate and verifiable criteria" that further the VBE's Value-Based Purpose and that are set out in writing at the commencement of the Value-Based Arrangement. Such criteria could include ZIP code, diagnosis or payor.

If you have any questions or would like more information regarding these safe harbors and exceptions, or the Stark Law and/or AKS generally, please contact Chandler Martin or a member of the Health Care team.