New Opportunities for Provider Collaboration

Stark and Anti-Kickback Statute Standards for Value-Based Care

Part 2

Creating a Value-Based Enterprise

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Creating a Value-Based Enterprise

The Foundation for the Stark Exceptions and Anti-Kickback Statute Safe Harbors for Value-Based Programs

The first step in qualifying to meet the requirements of a value-based Stark exception or a value-based Anti-Kickback Statute safe harbor is that the parties establish a "value-based enterprise." The concept of a value-based enterprise is very definitionally driven, so before attempting to create a value-based enterprise it is imperative to fully understand the regulatory requirements.

A value-based enterprise is essentially a network of participants (such as clinicians, providers, and suppliers) that have agreed to collaborate regarding a target patient population, focusing on increasing efficiencies in the delivery of care and improving outcomes for that patient population.

A value-based enterprise can be as simple as two parties in a value-based arrangement, with a written agreement that specifies the rights, responsibilities and obligations of the parties. A value-based enterprise can also be more complex, such as a separate legal entity with many parties and a formal governing body and organizational documents. A value-based enterprise must be working to achieve at least one value-based purpose while implementing a value-based activity for a defined target patient population.

This overview of a value-based enterprise will first review the Stark Law definitions necessary to create a value-based enterprise and will then highlight where the definitions are different for Anti-Kickback Statute safe harbor purposes.

The Value-Based Enterprise for Stark Law Exceptions

The new Stark Law (or "Stark") exceptions for value-based undertakings introduce several new concepts, including value-based arrangement, value-based activity, value-based enterprise, value-based purpose, value-based enterprise participant and target patient population. In order to be able to utilize the new exceptions it is necessary to understand all these concepts. It is important to remember that the only time the parties to a value-based undertaking need to adhere to one of these exceptions is when the arrangement includes an entity subject to Stark and a physician referring to the entity. Otherwise the Stark Law prohibition is not implicated.

A value-based enterprise can add new participants after it is formed but, to ensure compliance with one of the Stark Law value-based exceptions, each new participant must be analyzed separately as a new compensation relationship.

i. Stark Value-Based Enterprise

A "value-based enterprise" is defined as two or more value-based participants: (i) collaborating to achieve at least one value-based purpose; (ii) each of which is a party to a value-based arrangement; (iii) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (iv) that have a governing document that describes the value-based enterprise and how the value-based enterprise participants intend to achieve its value-based purpose(s).

ii. Stark Value-Based Arrangement

A "value-based arrangement" is an arrangement for the provision of at least one value-based activity for a target patient population between or among:

(i) a value-based enterprise and one or more of its value-based participants; or
(ii) the value-based participants in the same value-based enterprise.

This is key because the Stark exceptions only apply to an arrangement that qualifies as a value-based arrangement. A value-based arrangement only includes the value-based participants in the same value-based enterprise. Additionally, a value-based arrangement does not include parties that are not participants in the value-based arrangement. For example, a value-based arrangement does not cover a compensation arrangement between a payor and a physician (because a payor cannot be a participant in a Stark value-based enterprise). A value-based arrangement also must be a compensation arrangement and not an ownership relationship or other type of financial relationship to which the Stark Law applies.

iii. Stark Value-Based Activity

A "value-based activity" includes:

(i) the provision of an item or service;
(ii) the taking of an action; or
(iii) the refraining from taking an action, provided that the activity is reasonably designed to accomplish a value-based purpose of a value-based enterprise.

A physician "referral" is not, in (i) above, protected as the "provision of an item or service." Importantly, a physician referral to another provider as part of care planning will constitute the "taking of an action" and, per (ii) above, the referral can be a protected value-based activity.

In a show of flexibility, CMS commented that it was declining to provide even a non-exhaustive list of permissible value-based activities in (i), (ii) and (iii) above. It had concerns that a list could unintentionally limit innovation and prohibit robust participation in value-based care delivery and payment systems. The determination of whether the provision of an item or service, the taking of an action, or the refraining from taking an action is a value-based activity, is intended to be a fact-specific analysis and turns on whether the activity is reasonably designed to achieve at least one value-based purpose of a value-based enterprise.

For a value-based activity to be reasonably designed to achieve a value-based purpose of the value-based enterprise, the parties must have a good faith belief that the value-based activity will achieve or lead to the achievement of at least one value-based purpose. The exception does not require that the value-based purpose be achieved. However, if the parties to the arrangement are aware that the value-based activity (i.e., provision of an item or service, the taking of an action, or the refraining from taking an action) will not further a value-based purpose then the activity will not qualify as a value-based activity. In such event the parties may need to amend or terminate the arrangement if the activity would otherwise violate the Stark Law.

In order to memorialize that a value-based activity furthers a value-based purpose, the parties need to monitor whether and how the value-based activity does so. CMS encourages the parties, as a best practice, to contemporaneously document how the value-based activity furthers a value-based purpose. It is the responsibility of the entity submitting a claim for payment of a designated health service (a "Stark service") to ensure compliance with the Stark Law exception if the service is furnished pursuant to a referral from a physician and the entity billing the Stark service has a financial relationship with the referring physician. In other words, the parties to the value-based undertaking must ensure that the value-based activities satisfy a value-based purpose at the time a physician makes a referral for a Stark service.

iv. Stark Value-Based Purpose

A "value-based purpose" is any of the following four core goals:

(i) coordinating and managing the care of a target patient population;
(ii) improving the quality of care for a target patient population;
(iii) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population;
(iv) 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.

One or more of these goals must anchor the activities underlying every compensation relationship that qualifies as a value-based arrangement to which the value-based Stark exception applies.

The value-based purpose of transitioning from volume-based delivery and payment mechanisms to mechanisms based on quality and cost control (goal (iv) above) is intended to cover the clinical integration and infrastructure activities necessary to develop and implement a value-based enterprise and to meet future operational and capital requirements. Accordingly, this purpose applies during the transition period of a value-based enterprise's start-up or preparatory activities. CMS indicated that this transition purpose would cover the integration of value-based participants in team-based coordinated care models. During the transition the parties will establish the infrastructure to provide patient-centered coordinated care and accept (or prepare to accept) increased levels of financial risk from payors or other value-based participants in the value-based undertakings. CMS also indicated that this purpose will cover activities taken by an unincorporated value-based enterprise that is formalizing its legal and operational structure, as well as steps by the enterprise to accept financial risk and to prepare its value-based participants to furnish services in a manner focused on the value, rather than the volume, of those services.

CMS stated that the value-based purpose of transitioning care from volume-based to value-based care is similar to the pre-participation waiver allowed under the Medicare Shared Savings Program for ACOs ("SSP Waivers"), and that the start-up arrangements permitted in the SSP

Waivers are illustrative of the type of transition activities that could be permissible compensation under this value-based purpose. [1]

v. Stark Value-Based Participant

A "value-based participant" is defined as an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.

vi. Stark Target Patient Population

A "target patient population" is defined as an identified patient population selected by the value-based enterprise or its value-based participants, based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement, and which further the value-based enterprise's value-based purposes. CMS interprets this definition to mean that when the target patient population is ascribed to the value-based enterprise by a payor, the value-based enterprise or its participants must ensure that the requirements of this definition are satisfied. [2]

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[1] These start-up arrangements include:

- Infrastructure creation and provision.
- Network development and management, including the configuration of a correct ambulatory network and the restructuring of existing providers and suppliers to provide efficient care.
- Care coordination mechanisms, including care coordination processes across multiple organizations.
- Clinical management systems.
- Quality improvement mechanisms including a mechanism to improve patient experience of care.
- Creation of governance and management structure.
- Care utilization management, including chronic disease management, limiting hospital readmissions, creation of care protocols, and patient education.
- Creation of incentives for performance-based payment systems and the transition from fee-for-service payment system to one of shared risk of losses.
- Hiring of new staff, including care coordinators (including nurses, technicians, physicians, and/or non-physician practitioners), umbrella organization management, quality leadership, analytical team, liaison team, IT support, financial management, contracting, and risk management.
- IT, including EHR systems, electronic health information exchanges that allow for electronic data exchange across multiple platforms, data reporting systems (including all payor claims data reporting systems), and data analytics (including staff and systems, such as software tools, to perform such analytic functions).
- Consultant and other professional support, including market analysis for antitrust review, legal services, and financial and accounting services.
- Organization and staff training costs.
- Incentives to attract primary care physicians.
- Capital investments, including loans, capital contributions, grants, and withholds.

[2] In this circumstance, the 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." However, it is not sufficient for the parties to state that the selection criteria for the target patient population will be determined by the payor. The value-based enterprise or the value-based participants must ensure that the payor's methodology for the attribution of the target

The Value-Based Enterprise for the Anti-Kickback Statute Safe Harbors

The OIG's definition of a value-based enterprise for Anti-Kickback Statute ("AKS") safe harbor purposes and its component definitions are similiar to CMS's definition, other than the differences noted below:

i. AKS Value-Based Enterprise

This definition is the same as for the Stark Law.

ii. AKS Value-Based Arrangement

This definition is the same as for the Stark Law. Just like the Stark law, the value-based arrangement definition is key because the Anti-kickback Statute safe harbors only apply to an arrangement that qualifies as a value-based arrangement. Unlike the Stark exception, the safe harbor is not limited to just physicians and entities providing designated health services (i.e., Stark services).[3]

iii. AKS Value-Based Activity

This definition is the same as the Stark Law definition except that the making of a "referral" is not considered a "value-based activity."

iv. AKS Value-Based Purpose

This definition is the same as the Stark Law definition.

v. AKS Value-Based Participant

This definition is the same as the Stark Law definition except that that the patient, when acting in his or her capacity as a patient, is not a value-based participant.

Another distinction from the Stark Law is that for the Anti-kickback Statute safe harbors not all value-based participants can be protected by a safe harbor. Each Anti-kickback Statute value-based safe harbor lists specific entities that are not eligible to rely upon the safe harbor. This

patient population are legitimate and verifiable, and that it will further the value-based enterprise's value-based purposes. In addition, the selection criteria must be documented in advance of the value-based arrangement. In short, the value-based enterprise or value-based participants may need to collaborate with the payor to ensure that the selection criteria meets the definition of a target patient population.

[3] For example, a Stark Law value-based arrangement does not cover a compensation arrangement between a payor and a physician (because a payor cannot be a participant in a value-based enterprise because it does not perform a value-based activity).

means that remuneration exchanged by these entities with the value-based enterprise or other value-based participants cannot be protected by the safe harbor.

The entities which are precluded from safe harbor protection include: (i) pharmaceutical manufacturers, distributors, and wholesalers, (ii) pharmacy benefit managers, (iii) laboratory companies, (iv) compounding pharmacies, (v) manufacturers of devices or medical supplies, (vi) entities or individuals that sell or rent durable medical equipment, prosthetics, orthotics and supplies, and (vii) medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical suppliers.

vi. AKS Target Patient Population

This definition is the same as the Stark Law definition of the term.