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New Value-Based Enterprise Opportunities in Healthcare

As medical payment evolves to favor care innovation and clinical integration opportunities, value-based enterprises are becoming increasingly prevalent within the healthcare industry. With recent legislative updates allowing for increased collaboration, providers can better address patient needs while reducing costs and improving care quality.

Background information

In late 2020, the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) announced key changes to the Physician Self-Referral, or Stark, Law and the Anti-Kickback Statute. Created to prevent healthcare providers from making patient referrals based on their own financial motivations, the regulations have historically impeded clinical integration advancements.

[The Stark Law and Anti-Kickback Statute updates](#), which went into effect in January 2021, created new exceptions and safe harbors that ease regulatory barriers for integration activities, thus, encouraging health care systems to explore non-volume-based payment options.

The developments also created new safeguards for carefully designed value-based arrangements, which are clinical arrangements to improve health care quality, efficiency, and outcomes.

When considering entering value-based arrangements, participants need to remain aware of two different sets of regulations: those under the Anti-Kickback Statute addressing “care coordination arrangements” and those under the Stark Law addressing “arrangements that facilitate value-based health care delivery and payment” (i.e., each “VBE” activity, as indicated below). As the Stark Law is a strict liability statute, it is imperative that certain financial arrangements with physicians fit explicitly within a Stark exception.

However, such arrangements must also take into consideration the Anti-Kickback Statute to ensure they do not run afoul of criminal prohibitions.

What is a value-based enterprise?

Under the Stark Law, a value-based arrangement involves a value-based enterprise (VBE), or a designated health service entity and a physician, that provides at least one value-based activity (VBA) reasonably designed to achieve at least one value-based purpose (VBP) for a target patient population. Target patient populations are those identified patient populations selected by a VBE based on legitimate and verifiable criteria set out in advance that further the enterprise's purpose.

A value-based activity can consist of providing an item or service, taking an action, or refraining from taking an action. A value-based purpose must be one or more of the following: coordinating and managing care, improving quality of care, reducing costs to payors without reducing quality, or transitioning from volume to value.

In addition to meeting the VBA and VBP requirements, VBEs must satisfy other requirements depending upon the extent of financial risk assumed by the VBE.

Stark Law value-based care exceptions

While the Stark Law included numerous exceptions for financial relationships, it is important to recognize that value-based exceptions are exceptions for compensation arrangements under Stark, not ownership or investment arrangements.

The first such Stark Law exception, at 42 C.F.R. 411.357(aa)(1), requires the VBE to assume full financial risk for all patient care items and services covered by a payor for each patient in the target patient population. This includes capitation payments, or predetermined payments per patient per a period of time, and global budget payments from the payor that compensate for all care items and services for all patients in the target patient population.

The second exception, at 42 C.F.R. 411.357(aa)(2), requires the physician receiving remuneration to have “meaningful downside risk” with respect to such remuneration. This mandates that the physician assume the responsibility to repay or forgo 10% or more of the remuneration the physician receives under the VBE for failing to achieve the related purpose or activity. For example, this applies when a VBE’s total remuneration potentially due to a physician is \$100,000, but at least \$10,000 is withheld and payable and only upon successful completion of the activities called for under the arrangement.

The last exception, at 42 C.F.R. 411.357(aa)(3), does not require the VBE or the physician to hold any financial risk. Due to that, the exception necessitates that arrangements must be in writing and describe the value-based activities to be undertaken, along with how such activities will further the purposes of the enterprise. Additionally, the writing must identify the target patient population, the type or nature of the remuneration, the methodology used to determine the remuneration, and the outcome measures against which the recipient of the remuneration is assessed, if any. This can entail, for example, a hospital paying physicians \$10 each time they order a particular test pursuant to a clinical protocol as part of a value-based agreement. Such an example was provided by the Department in the preamble to the [Final Rule](#).

Incentives to create value-based enterprises

Several VBE advantages benefitting both patients and providers are increasingly drawing in healthcare entities, including:

- VBEs, like other forms of clinical integration, consolidate resources and centralize management.
- VBEs do not require that the arrangement be based on fair market value; however, they must be commercially reasonable (i.e., serve a legitimate business purpose).
- The federal government has created fairly bright-line rules regarding the structure and use of VBEs.
- VBEs present the opportunity to move from fee-for-service to value-based payment in very limited and focused areas.

- VBEs allow for meaningful opportunities for health care providers across the spectrum to collaborate and incentivize proper delivery of quality, lower-cost care.

Though these benefits are alluring, VBEs do require significant time and commitment from those involved, especially considering the complexities of related Medicare payment rules.

If you have questions or would like to learn more, please contact Frost Brown Todd's [Health Care Innovation](#) team.

Read part two of this series, ["The Three Stark Law Exceptions for Value-Based Care Offer Advantages for Providers,"](#) which dives into the three applicable exceptions for financial relationships under the Stark Law.

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