



# The Three Stark Law Exceptions for Value-Based Care Offer Advantages for Providers

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The 2020 Center for Medicare and Medicaid's (CMS) adaptations to the Physician Self-Referral law, or the Stark Law, as well as the recent modifications to the Federal Anti-Kickback Statute bring providers new, and advantageous, options for structuring value-based care arrangements. In our first article, ["New Value-Based Enterprise Opportunities in Healthcare,"](#) we looked at the legislative updates allowing for increased collaboration and how providers can better address patient needs while reducing costs and improving care quality.

This article dives into the three applicable exceptions for financial relationships under the Stark Law. This includes describing what each entails for value-based agreements while also providing insight on how a higher level of risk, according to these exceptions, corresponds to a decreased regulatory constraint and a potentially higher financial outcome for the participants in the value-based enterprise.

## **Exception One: Physician Takes Full Risk – 42 C.F.R. 411.357(aa)(1)**

The first Stark Law exception requires the value-based enterprise (VBE) that a physician has joined to assume full financial risk for patient care and services in a value-based agreement. As the financial risk absorbed by the VBE is substantial, this exception does not require a written description of the value-based methodology used to achieve the value-based purpose or even a written agreement, unless a requirement to make referrals is part of the arrangement.

When dealing with risk-based agreements — this exception and the next — providers do not necessarily need to be compensated at fair market value, nor does the VBE need to show commercial reasonableness, as other Stark Law exceptions mandate. While the

risk physicians take under this exception can directly affect their monetary earnings, this route also gives physicians fewer constraints in developing creative solutions to achieving a value-based purpose.

Some examples of a full risk VBE might involve capitation payments — pre-determined payments per patient per month or other period of time — or a global budget payment from a payor that compensates for all care items and service for patients in the target patient population. Accountable Care Organizations would be good examples of VBEs that have assumed full financial risk, but applicable ACO waivers make this unnecessary. However, clinically integrated networks that do not benefit from the ACO waivers are good examples of VBEs that have assumed full financial risk.

#### **Exception Two: Physician Takes Partial Risk – (42 C.F.R. 411.357(aa)(2))**

The second exception applies to when the physician takes on “meaningful downside risk” for patient care in an agreement by consenting to repay or forgo 10% or more of the financial remuneration the physician receives if the VBE fails to achieve its purpose. As this exception requires a certain amount of financial risk, but not full financial risk, it requires a detailed written description of the physician’s downside risk and the methodology used to determine the amount of remuneration to be paid.

Similar to the first exception described, providers do not need to be compensated at fair market value if they take on partial risk in the agreement, and showing commercial reasonableness is not required. The flexibility of these arrangements allows for providers to take on some risk in a payor arrangement without putting all compensation at stake, creating two-sided financial risk in terms of both positive and negative outcomes.

An example of a partial risk VBE may involve, for example, withholding \$10,000 in payment to a physician — out of an eventual overall \$100,000 payment — to be paid upon successful completion of a value-based purpose. Clinical co-management arrangements and Service Line Agreements that include payments

for quality outcomes are good examples of partial risk VBEs, assuming those payment structures place at least 10% of the total payment at risk.

**Exception Three: Physician Takes No Risk – 42 C.F.R. 411.357(aa)(3)**

In the third Stark Law exception, the physician involved does not need to take on any financial risk in the VBE agreement. As such, these arrangements require a more detailed written description of the value-based activities, how these further the value-based purposes of the VBE, the target patient population, the methodology for determining the remuneration and the outcome measures, all to ensure all value-based activities and their purposes are well-documented. This exception also requires extensive ongoing monitoring of any outcome measures that result from the value-based activity as well as an obligation to terminate any ineffective value-based activity. Physicians' compensation must be set in advance.

These agreements must remain commercially reasonable and monitor progress throughout. Because arrangements modeled after this exception hold no risk for physicians, they may be viewed as a reasonable introduction and possible transition to the VBE world. As providers become more comfortable with value-based care, they may likely look toward increasing the amount of risk they take on for a higher potential payoff and shared savings, thereby allowing the more relaxed coverage of one of the other two exceptions.

An example of a no-risk VBE might involve a hospital paying a physician for providing certain post-discharge follow-up services to patients in the target patient population.

**Selecting an Exception to Model a Value-Based Agreement**

With a focus on quality over quantity in medical care, VBEs offer a range of potential benefits for both patients and providers. Alongside those benefits, providers need to ensure they are following all necessary regulations under the Stark Law and the exceptions permitted.

When basing care on value-based patient outcomes, there are fewer guarantees in terms of compensation for providers, but there is potential for payouts less restricted as to fair market value and commercial reasonableness and possible increased efficiencies for those physicians willing to rethink patient care. Additionally, under these Stark Law exceptions, the level of regulatory constraints and documented activity is inversely related to the amount of financial risk physicians are willing to bear.

While these new regulations open new doors for providers, it is important to weigh the pros and cons of each of the exception models under Stark. We anticipate many providers will enter into this new VBE world slowly, by initially favoring the low-financial-risk option — which aligns well with new AKS safe harbors — and developing a real-world understanding of the regulations before moving into the higher-risk models, where there is more flexibility under the regulations and a potentially higher financial reward.

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

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