New Opportunities for Provider Collaboration

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

Introduction

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Introduction

In November of 2020 the Centers for Medicare & Medicaid Services ("CMS") finalized value-based exceptions under the Stark Law and the Office of Inspector General ("OIG") finalized value-based safe harbors under the Anti-Kickback Statute, in an effort to accommodate and facilitate the evolution of value-based care arrangements among health care providers. "Value-based care" is the phrase often used to describe health care provided by collaborating health care providers that produces higher quality services while lowering or controlling costs, and at the same time improves the patient experience. Methods of compensating those collaborating providers for producing value-based care is usually called "value-based compensation." Providers and payors have been experimenting with variations of value-based payment arrangements for several decades, with limited success largely due to regulatory restraints.

Initially efforts toward value-based care were ad hoc arrangements among health care providers or payors to implement value-based care payment arrangements to the extent possible within the existing regulatory framework. Most of the regulatory restraints were applicable to the Medicare Program and other federal payment programs. In 2010, during the Obama Administration, Congress passed the Affordable Care Act ("ACA"). The ACA was the first major federal legislation designed to encourage providers in the Medicare Program to move towards value-based payment arrangements. The ACA provided some limited relief from the regulatory restraints that impacted the Medicare Program, including regulatory waivers for participation in an accountable care organization ("ACO") or a bundled payment program. However, these waivers were limited in application and did not provide sufficient regulatory modifications to facilitate the healthcare industry, as a whole, to move towards value-based payment arrangements.

Historically, the main regulatory limitations on value-based care arrangements have been three bodies of federal law known as: (i) the Stark Law, (ii) the Anti-Kickback Statute, and (iii) the Civil Monetary Penalty Statute ("CMP"). The Stark Law prohibits certain relationships that compensate physicians, directly or indirectly, for referrals of certain services called "designated health services." The Anti-Kickback Statute generally prohibits any type of payment to reward a party (including, but not limited to, a physician) for referring or steering a Medicare Program patient ("Medicare Beneficiary") to a healthcare provider for healthcare services. The CMP initially prohibited a payment by a hospital to a physician as an inducement to reduce or limit

services to a Medicare Beneficiary in the hospital setting. The CMP language was modified in 2015 to clarify that only "medically necessary services" in the hospital setting cannot be reduced or limited. This distinction softened the impact of the CMP's interference with value-based payments but still left the Stark Law and the Anti-Kickback Statute as major impediments to transitioning health care services to value-based arrangements.

The problem that the Stark Law and the Anti-Kickback Statute have presented for value-based programs is that most health care payment models that incentivize providers to collaborate to lower costs and improve the quality of care have features which can be construed as: (i) based on the volume or value of referrals (prohibited by Stark), or (ii) compensation for referring or steering a Medicare Program patient to a healthcare provider for services (prohibited by the Anti-Kickback Statute). The Stark Law and the Anti-Kickback Statute contain, respectively, exceptions and safe harbors but, up until now, they were generally not helpful in facilitating value-based arrangements.

With the passage of the new value-based Stark Law exceptions and the new value-based Anti-Kickback Statue safe harbors, it appears that pathways to eliminate the Stark Law and the Anti-Kickback Statute barriers to value-based care may have finally arrived. Essentially, these new rules now permit financial relationships between physicians and other healthcare providers that previously were problematic, provided the relationships are created to achieve value-based goals. These new rules create important protections that will allow parties to create value-based payment systems that did not previously exist.

To qualify for these new protections, two or more providers need to partner their efforts through a "value-based enterprise," which is a vehicle established to accomplish value-based purposes. The central theme behind a value-based enterprise is that the providers are either transitioning towards bearing financial risk, or are bearing financial risk, in the value-based arrangement. CMS and the OIG coordinated their efforts in writing these new rules. Both agencies created three parallel models utilizing a value-based enterprise. This was done to allow providers to have a clear pathway to accomplish value-based goals.

While CMS's and the OIG's terminology is slightly different in each agencies' respective rules, conceptually the three models can be characterized as follows:

(i) A Care Coordination Model;

(ii) A Partial Financial Risk Model; and

(ii) A Full Financial Risk Model.

While aimed at the Medicare Program, the impact of these new rules may also result in more provider collaboration models emerging with commercial payor programs.

It is noteworthy that CMS and the OIG each coordinated with the other while creating their respective rules. This has created a significant amount of consistency in the definitions used in the new rules and similarity in the application of the Stark law exceptions and the Anti-Kickback Statue safe harbors.

The Stark Law exceptions for value-based arrangements

The new Stark Law exceptions are as follows:

1. Value-Based Arrangement;
2. Value-Based Arrangement with Meaningful Downside Risk; and
3. Full Financial Risk Arrangement.

CMS believes that full financial risk is a key defining characteristic of a mature value-based payment system. CMS stated that the natural payment limitations in a full financial risk model provides stronger and more effective safeguards against increases in the volume and costs of services than the Stark Law could ever have placed on the fee-for-service payment system. When a value-based enterprise is at full financial risk for the cost of all patient care services the incentives to order unnecessary services or to steer patients to higher-cost sites of service are diminished. CMS also believes that even when participants are only at partial risk the value-based enterprise is still incentivized to monitor for appropriate utilization, referral patterns and quality performance.

The new exceptions for value-based undertakings do not include the traditional Stark Law requirements that compensation must be set at fair market value, and must not take into account the volume or value of a physician's referrals or the other business generated by the physician for the entity. CMS recognized that those requirements are inconsistent with the desire to innovate healthcare to better coordinate care and achieve higher quality outcomes at more efficient costs.[1] However, as an important program safeguard CMS does include the requirement that the compensation arrangement must be commercially reasonable. "Commercially reasonable" means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty.

[1] CMS explicitly acknowledged that innovative arrangements for the distribution of shared savings or repayment of shared losses, gainsharing arrangements, and pay-for-performance arrangements that provide payments to refrain from ordering unnecessary care, among others, may not be able to meet the existing exceptions to the Stark Law.

CMS recognizes that many providers may not be well-positioned at this time to transition to a full financial risk model. However, CMS hopes that by loosening the burdens of the Stark Law it has provided a pathway for participants in a value-based system to evolve into, and more meaningfully participate in, the value-based system. To start this evolution, the Stark Law Value-Based Arrangements exception allows the parties to participate in a value-based undertaking where no financial risk is assumed. The Meaningful Downside Risk exception allows the parties to migrate to a model where risk, but less than full financial risk, is assumed. Finally, the Full Financial Risk Arrangement exception is designed for parties who are prepared to operate under a two-sided risk model.

The new Anti-Kickback Statute safe harbors for value-based arrangements

Similar to CMS's three exceptions for value-based arrangements, the OIG finalized three Anti-kickback Statute safe harbors for value-based arrangements. In crafting these safe harbors, the OIG sought to align the safe harbor value-based terminology and safe harbor conditions with those in the new Stark Law exceptions. However, the OIG noted that, due to the differences in the Stark Law and the Anti-Kickback Statute, complete alignment is not feasible. The value-based Stark Law exceptions adopted by CMS do not need to contemplate the broad range of conduct that implicates the Anti-Kickback Statute. The Anti-Kickback Statute is an intent-based, criminal statute that prohibits payments, whether monetary or in-kind, in exchange for referrals of any Federal health care program business. In contrast to the Anti-Kickback Statute, the Stark Law is a civil, strict-liability law. If the elements of a Stark Law violation are present, then the only way to avoid liability is to meet an exception from the prohibition; the result is that the exceptions define permissible transactions. Even minor or erroneous deviations from the specific terms of a Stark Law exception can result in non-compliance and, because of the law's strict liability, overpayment liability. On the other hand, compliance with the Anti-Kickback Statute safe harbors is voluntary, and there are many arrangements that do not fit within a safe harbor that are lawful under the Anti-Kickback Statute.

The Anti-Kickback Statute safe harbor regulations describe various payment and business practices that are not treated as offenses under the statute.[2] The three new safe harbors cover compensation (or other remuneration) exchanged between or among participants in a value-based arrangement that fosters better coordinated and managed patient care. These safe harbors are similar to, and parallel with, the Stark Law exceptions, and include the following:

[2] Safe harbors are helpful if a transaction fits within a safe harbor but failure to comply with the standards for a safe harbor does not mean the arrangement is illegal.

1. Care Coordination Arrangement;
2. Value-Based Arrangement with Substantial Downside Financial Risk; and
3. Value-Based Arrangement with Full Financial Risk.

The Anti-Kickback Statute safe harbor for a Care Coordination Arrangement is designed to replicate the Value-Based Arrangement under Stark as a transition towards risk-bearing arrangements. The latter two safe harbors for Substantial Downside Financial Risk and Full Financial Risk track the Stark Law exceptions with the same name. While the safe harbors generally mirror the Stark Law exceptions, the safe harbors are not identical to the Stark Law exceptions.