New Opportunities for Provider Collaboration

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

Part 5

How to Create a Full Financial Risk Value-Based Enterprise

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How to Create A Full Financial Risk Value-Based Enterprise

The Stark Model: Full Financial Risk Arrangement

The Stark Full Financial Risk Arrangement exception protects participants in a value-based arrangement in a value-based enterprise that has assumed "full financial risk" on a prospective basis 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. For full financial risk to be prospective, the arrangement cannot allow any additional payments to compensate for costs incurred by the value-based enterprise in providing specific patient care items and services to the target patient population, nor may any participant make a claim to the payor for such items and services. For Medicare Beneficiaries, being responsible for all items and services means the value-based enterprise is responsible for all items and services covered under Parts A and B.

A transitional step allows the parties to be contractually obligated to become financially responsible for all items and services covered by the applicable payor for each patient in the target patient population within 12 months after the commencement date of the value-based arrangement. CMS believes this "pre-risk period" may be necessary to allow the parties to work together in preparation for taking on full financial risk to allow parties to transition to the new model without violating Stark.

Full financial risk can include capitation payments (a predetermined payment per patient per month or other period of time) or globally budgeted payments from a payor that compensate the value-based enterprise for providing all patient care items and services for a target patient population for a pre-determined period of time. Payments for shared savings or other incentives for achieving quality performance, or other benchmarks, are also permitted. CMS noted that a full financial risk model can provide for additional types of payments; the new exception also does not prescribe a specific manner to structure the compensation to the parties for the assumption of full financial risk.

A full financial risk model does not prohibit a value-based enterprise from entering into an arrangement with risk mitigation terms to limit exposure to significant losses. Accordingly, a payor arrangement may include stop-loss protection, reinsurance, global risk adjustments, or risk corridors, to limit exposure to significant or catastrophic losses related to high-cost items or services or overall expenses. The exception does not impose any specific limit on the amount of loss coverage a value-based enterprise may entertain, but CMS stated that it expects stop-loss or other risk adjustment provisions to act as a protection for the value-based enterprise against catastrophic losses and not a

means by which to shift material financial risk back to the payor. CMS further stated that the definition of full financial risk would not permit the full offset of a value-based enterprise's losses.

Notwithstanding the natural influences of a full financial risk payment system to reduce the risk of program or patient abuse, the new exception includes the following safeguards:

1. The value-based arrangement must be at full financial risk during the entire duration of the value-based arrangement.
2. The compensation and other remuneration under the value-based arrangement is for, or results from, the value-based activities undertaken by the provider participant for patients in the target patient population. The exception will not protect payments for referrals or any other actions or business unrelated to the target patient population.
3. The compensation or other remuneration under the value-based arrangement cannot be provided as an inducement to reduce or limit medically necessary services to any patient, whether in the target population or not.
4. If the compensation or other remuneration is conditioned on a physician's referrals to a particular provider the requirement must be set out in writing and does not apply if: (i) the patient expresses a different choice, (ii) the payor determines the provider, or (iii) the physician makes a determination that the referral is not in the patient's best medical interests.

The exception will not protect arrangements where the compensation or other remuneration is conditioned on referrals of patients who are not part of the target patient population.

Importantly, the new exception does 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.

The Anti-Kickback Statute Safe Harbor Model: Full Financial Risk Arrangement

This safe harbor is similar to the Stark Law exception for Full Financial Risk Arrangements. For a value-based arrangement to be protected under the safe harbor, the value-based enterprise must assume "full financial risk" from a payor. For this purpose, full financial risk means that the value-based enterprise is at risk on a prospective basis for the cost of all items and services covered by a payor for each patient in the target patient population for a term of at least one year. While a value-

based enterprise must be at risk for all items and services furnished to the target patient population, the value-based enterprise can limit the number of patients for whom it assumes full financial risk through the selection of the target patient population, as long as the value-based enterprise selects the target patient population using legitimate and verifiable criteria. For example, a value-based enterprise could assume full financial risk for patients with a particular disease condition (e.g., patients with diabetes) by selecting a target patient population comprised only of patients with diabetes, but the value-based enterprise must cover all items and services for those patients.

This safe harbor protects both monetary and in-kind remuneration exchanged pursuant to the value-based arrangements between the value-based enterprise and its participants. The parties to a value-based arrangement that meet the requirements of the Full Financial Risk Safe Harbor may exchange remuneration during a 12 month phase-in period, where the value-based enterprise is contractually obligated to assume full financial risk in the subsequent 12 month period but has not yet assumed such risk. Importantly, during this phase-in period the parties may have, as a value-based purpose, the purpose of transitioning from health care delivery and payment mechanisms based on the volume of items and services to mechanisms based on the quality of care for a target patient population. During that period, the parties may exchange, among other things, remuneration necessary to enable the value-based enterprise to transition to the assumption of full financial risk.

The Full Financial Risk safe harbor requires that remuneration exchanged:

(i) be directly connected to at least one of the four value-based purposes[1];
(ii) cannot be the offer or receipt of an ownership or investment interest in an entity or distributions from ownership or investment interest;
(iii) cannot be connected to marketing items or services furnished by the value-based enterprise or one of its participants to patients or be used for patient recruitment activities: and
(iv) cannot take into account referrals of business or patients outside of the value-based arrangement.

Additional requirements for this safe harbor include conditions related to ineligible entities; writing and record retention requirements; a prohibition against inducing the parties to reduce or limit medically necessary services; and inclusion of a quality

[1] Neither the Substantial Downside Financial Risk nor the Full Financial Risk safe harbors require a direct connection to the coordination and management of care for the target patient populations.

assurance program that protects against underutilization and assesses the quality of care furnished to the target patient population.

As with the Substantial Downside Financial Risk safe harbor, this safe harbor does not protect arrangements downstream of a value-based participant, such as arrangements between two value-based participants or a downstream contractor or an arrangement between two downstream contractors.

Carved out from the Full Financial Risk safe harbor are the following entities: (i) a pharmaceutical manufacturer, distributor or wholesaler; (ii) a pharmacy benefit manager; (iii) a laboratory company; (iv) a pharmacy that primarily compounds drugs or primarily dispenses compounded drugs; (v) a manufacturer of a device or medical supply; (vi) an entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy, provider or other entity that primarily provides services); or (vii) a medical device distributor or wholesaler.

As with the Stark Law Full Financial Risk exception, this safe harbor allows the value-based enterprise to enter into reinsurance or other risk-adjustment arrangements and to address losses incurred by value-based enterprise participants by using reinsurance payments to reimburse value-based participants for such losses. The safe harbor does not impose any specific limit on the amount of loss coverage a value-based enterprise may have, but the OIG stated that it expects the stop-loss or other risk adjustment provisions to act as a protection for the value-based enterprise against catastrophic losses and not a means by which to shift material financial risk back to the payor.