New Opportunities for Provider Collaboration

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

Part 4

How to Create a Partial Risk Value-Based Enterprise

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How to Create A Partial Risk Value-Based Enterprise

The Stark Model: Meaningful Downside Financial Risk Arrangement

The Stark Meaningful Downside Financial Risk Arrangement exception is designed to accommodate alternative payment models that provide for potential financial gain in exchange for undertaking some level of downside financial risk. CMS stated that financial risk assumed directly by a physician will likely affect his or her practice and referral patterns in a way that curbs the influence of traditional fee-for-service, volume-based payments. Further, financial risk which is tied to the achievement, or failure to achieve, value-based purposes is seen as incentivizing the type of behavior-shaping necessary to transform our health care delivery system into one that improves outcomes and reduces the costs to or growth in expenditures of payors. CMS concludes that an arrangement under which a physician is at meaningful downside risk for failure to achieve predetermined cost, quality or other performance benchmarks contains inherent protections against program or patient abuse.

Under the Stark Meaningful Downside Financial Risk exception, a participating physician must have meaningful downside financial risk for the duration of the value-based arrangement. This requirement is meant to curtail any gaming that might occur if parties only add meaningful downside risk for a short portion of the arrangement. Meaningful downside risk means the physician must be at risk to forgo no less than 10% of the value of the compensation (or other remuneration) that might otherwise be provided to the physician under the arrangement. This can be monetary compensation, or in-kind remuneration such as infrastructure or care coordinated services. Withholds, repayment requirements or incentive pay tied to meeting goals or outcome measures are all permissible options for structuring the financial risk terms of a value-based arrangement, provided that the downside risk is tied to the achievement of value-based purposes. This exception requires that the nature and extent of the physician's financial risk be set forth in writing.

The methodology used to determine the compensation (or other remuneration) must be set in advance, before the furnishing of the items or services for which the remuneration is provided. This concept appears frequently in Stark exceptions and is

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designed to keep parties from manipulating compensation to reward a party for referrals.[1]

Any compensation (or other remuneration) between the parties in an allowable value-based arrangement cannot be provided as an inducement to limit medically necessary items or services to a patient, and cannot be conditioned on the referral of patients who are not part of the target patient population or business not covered under the value-based arrangement.[2]

Importantly, the new exception does not include the traditional Stark Law requirements that compensation must be set at fair market value, or 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: Substantial Downside Financial Risk Arrangement

The Anti-Kickback Statute Substantial Downside Financial Risk Arrangement safe harbor requires that a value-based enterprise assume substantial downside financial risk from a payor under one of three methodologies, and a value-based participant must assume a "meaningful share" of the value-based enterprise's substantial downside risk. For this purpose, meaningful share means the value-based participant:

(i) assumes two-sided risk for at least 5% of the losses and savings, as applicable, realized by the value-based enterprise pursuant to its assumption of substantial downside financial risk; or

(ii) receives from the value-based enterprise a prospective, per patient payment on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services, and does not claim payment in any form from the payor for the predefined items and services.

This safe harbor is significantly different from the Stark Law Meaningful Downside Risk exception, which only requires that the physician be responsible to repay or forgo no

[1]The special rule on compensation set forth in Section 411.354(d)(1) deems compensation to be set in advance when certain conditions are met would apply.

[2] This exception is not parallel with the Substantial downside financial risk safe harbor under the Anti-Kickback Statute.

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less than 10% of the total value of the remuneration the physician receives under the value-based arrangement.

The 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 OIG noted that this safe harbor can be used by participants in CMS-sponsored models, if safe harbor conditions are met, but it is primarily for other kinds of value-based undertakings, including arrangements in the commercial market.

The parties to a value-based arrangement who meet the requirements of the Substantial Downside Financial Risk safe harbor may exchange remuneration during a 6 month phase-in period, where the value-based enterprise is contractually obligated to assume substantial downside 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, and the parties may exchange, among other things, remuneration necessary to enable the value-based enterprise to transition to the assumption of substantial downside financial risk.

The safe harbor only applies if eight specified factors are met. These include conditions related to ineligible entities; requirements that remuneration be used to engage in value-based activities directly connected to at least one of the first three of the value-based purposes[3]; writing and record retention requirements; protections for patient choice and clinical decision making; protections against medically unnecessary services; limits on marketing or patient recruitment; and limits on remuneration that takes into account business or patients outside the value-based arrangement. The OIG did not finalize a requirement in the originally proposed safe harbor that would have required that the in-kind remuneration could not be funded by, and not otherwise result from the contributions of, any individual or entity outside of the value-based enterprise. Importantly, the safe harbor does not protect arrangements downstream of a value-based participant, such as arrangements between two value-based participants.

Carved out from the Substantial Downside Financial Risk Arrangements safe harbor are the following entities: (i) a pharmaceutical manufacturer, distributor or wholesaler; (ii)

[3]Coordinating and managing the care of the target population, improving the quality of care for the target population, and reducing the costs to or growth in expenditures or payors without reducing the quality of care for the target patient population. 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.

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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.

The three methodologies for the value-based enterprise to assume substantial downside financial risk from a payor under this safe harbor include:

1. Shared Savings and Losses Methodology - where the value based enterprise assumes financial risk equal to at least 30% of any loss, and losses and savings are calculated by comparing current expenditures for all items and services furnished to the target patient population to a bona fide benchmark designed to approximate the expected total cost of such care;

2. Episodic Payment Methodology - where the value based enterprise assumes financial risk equal to at least 20% of any loss, where (i) losses and savings are calculated comparing current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that are covered by the applicable payor, to a bona fide benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care; and (ii) the parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting; and

3. Partial Capitation Model - where the value-based enterprise receives from the payor a prospective per-patient payment that is (i) designed to produce material savings; and (ii) paid on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services.

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