New Opportunities in Value-Based Care

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

Part 3

How to Create a Care Coordination Value-Based Enterprise

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How to Create A Care Coordination Value-Based Enterprise

The Stark Model: Value-Based Arrangement

The Stark Value-Based Arrangement exception protects a compensation relationship between participants to a value-based arrangement, so long as they are pursuing a value-based purpose. This exception allows the parties to create a value-based arrangement where no risk is assumed by the participants. This is the simplest model to implement. It allows the parties to begin the process of learning how to execute value-based arrangements and to migrate towards partial risk and full risk models. However, since in this model participants, especially the referring physician, do not assume the downside risk which helps to mitigate against overutilization, CMS included additional safeguards within the exception. An arrangement meeting this exception must be set forth in writing and explain:

1. The value-based activities to be undertaken;
2. How the value-based activities are expected to further the value-based purposes of the value-based enterprise;
3. The target patient population;
4. The type or nature of compensation (or other remuneration) under the arrangement;
5. The methodology used to determine the compensation (or other remuneration); and,
6. The outcome measures, if any, against which the recipient of the compensation (or other remuneration) is assessed.

An outcome measure against which the recipient is assessed (item (6) above) means a benchmark that quantifies: (i) improvements in, or the maintenance of the quality of, patient care; or (ii) reductions in the costs to, or reductions in the growth in, expenditures of payors, while maintaining or improving the quality of care. While outcome measures are not required to be included in the value-based arrangement, if used the outcome measures must be objective, measurable, and selected based on clinical evidence or credible medical support. Any changes made to the outcome measures must be prospective. The "methodology to set the compensation" (or other remuneration) must be set in advance of the undertaking for which the compensation (or other remuneration) is paid, and must be in return for activities under the arrangement for patients in the target patient population.

Moreover, the compensation (or other remuneration) cannot be 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. Specifically, CMS stated that the exception cannot be used to protect a side arrangement between participants in the value-based enterprise that is unrelated to the value-based purposes of the value-based enterprise.

A safeguard required for the Value-Based Arrangement exception is that the parties (or the value-based enterprise in which they participate) must monitor the arrangement to ensure it is operating as intended and is serving the intended value-based purposes. The monitoring must occur not less frequently than annually (or, at least once during the term of the arrangement if the arrangement is for a duration of less than one year). The purpose of the monitoring is to determine whether the parties did, in fact, furnish the value-based activities required under the arrangement, and whether and how the continuation of the value-based activities is expected to further the value-based purposes of the value-based enterprise.

If the monitoring indicates that the value-based activity is not expected to further the value-based purposes of the value-based enterprise, the parties must terminate the ineffective value-based activity. An ineffective value-based activity may be terminated by terminating the entire value-based arrangement or by modifying the arrangement to terminate the ineffective value-based activity after the completion of the monitoring.

In addition, during the same time period the value-based enterprise (or one or more of its participants) must monitor the progress toward the attainment of outcome measures (if any) against which the recipient of the monetary compensation (or other remuneration) is assessed. If the monitoring indicates that an outcome measure is unattainable during the term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring.

If the parties fail to monitor the value-based activity or outcome measure within the prescribed time frames or fail to terminate or replace unattainable outcome measures with the prescribed timeframe, the arrangement will no longer satisfy the requirements of the Value-Based Arrangement exception.

An amendment to a value-based arrangement, to address identified deficiencies, may be made at any time, provided the amendment is prospective only, including any amendment to the compensation terms of the arrangement.

In an encouraging show of CMS flexibility, this exception allows the parties grace periods to address the findings of their value-based activity monitoring without the fear

of violating the Stark Law. The parties will be deemed to be compliant with the exception, even with the deficient value-based activity, if the parties (i) terminate the arrangement within 30 consecutive calendar days after the completion of the required monitoring, or (ii) modify the arrangement to terminate the ineffective value-based activity within 90 consecutive days after the monitoring.[1] Similarly, the parties will have 90 consecutive calendar days to terminate or replace an outcome measure that their monitoring indicates is unattainable.

These grace periods give the parties time to terminate or modify an ineffective value-based activity or outcome measure without immediately triggering a Stark violation. In other words, if an ineffective value-based activity or outcome measure is properly terminated upon a determination that it is ineffective, that fact will not cause the arrangement to be non-compliant with the Stark exception during the time it was in existence. This ability to exit an ineffective value-based activity without creating a Stark violation allows the parties, through trial and error, a pathway to experiment with new value-based activities without the fear that a failed strategy will create a Stark Law violation.

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: Care Coordination Arrangement

The Anti-Kickback Statute safe harbor for Care Coordination Arrangements[2] is designed to protect arrangements directed at the coordination and management of care. The "coordination and management of care" means the deliberate organization of patient care activities and sharing of information between two or more value-based participants, one or more value-based participants and the value-based enterprise, or one or more value-based participants and patients, where the parties' efforts are designed to achieve safer, more effective or more efficient care to improve the health outcomes of the target patient population. Similar to the Stark Value-Based

[1] To this end, a value-based activity will be deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise (so as to be compliant with the exception) during the entire period during which it was undertaken by the parties if the parties (i) terminate the arrangement within 30 consecutive calendar days after the completion of the required monitoring, or (ii) modify the arrangement to terminate the ineffective value-based activity within 90 consecutive days after the monitoring.

[2] Technically referred to in the safe harbor as care coordination arrangements to improve quality, health outcomes, and efficiency.

Arrangement exception, the parties do not actually have to achieve the value-based goals, but the efforts of the parties must be designed to achieve such goals. The Care Coordination Arrangements safe harbor only protects in-kind remuneration. The OIG stated that the monetary compensation associated with care coordination activities may be protected under other safe harbors (such as the safe harbors for personal services and management contracts and outcomes-based payments).

The safe harbor only applies if thirteen specified factors are met. These include conditions related to commercial reasonableness, outcomes measures, written documentation, record retention, monitoring termination, marketing and patient recruitment, and diversion and reselling of remuneration. The safe harbor requires that the protected remuneration be used "predominantly" to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. Under this safe harbor, all recipients of the in-kind remuneration must pay at least 15% of the offeror's cost or 15% of the fair market value of such in-kind remuneration. Additional safeguards include that the arrangement cannot induce value-based participants to furnish medically unnecessary care or limit medically necessary care; cannot limit medical decision-making or patient freedom of choice; and cannot take into account the volume or value of business outside of the value-based arrangement. Notably, the OIG did not finalize a provision 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.

Carved out from the Care Coordination Arrangements 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.

Notwithstanding the entities excluded from the safe harbor certain (1) manufacturers of medical devices, and (2) entities or individuals that sell or rent durable medical equipment, prosthetics, orthotics, or supplies, can be a "limited technology participant" participating in care coordination arrangements which only provide digital health

technology.[3] For this purpose, digital health technology includes hardware, software or services that electronically capture, transmit, aggregate, or analyze data that are used for the purpose of coordinating and managing care. The limited technology participant cannot condition the exchange of the in-kind technology on the recipient's exclusive use, or minimum purchase, of any item or service manufactured, distributed, or sold by the limited technology participant.

Similar to the Stark Law Value-Based Arrangement exception, the Care Coordination Arrangements safe harbor requires that the care coordination arrangement be monitored, periodically assessed, and prospectively revised, as necessary to ensure that each measure and its benchmark continue to advance the coordination and management of the target patient population. This monitoring requires that at least annually (or once during the arrangement if the arrangement has a term of less than one year) there be an assessment and report to the accountable body or responsible person for the value based enterprise of the following: (i) the coordination and management of care for the target patient population in the care coordination arrangement; (ii) any deficiencies in the delivery of quality care under the care coordination arrangement; and (iii) progress toward achieving the intended outcome or process measures in the care coordination arrangement. If the accountable body or responsible person for the value based enterprise determines that the care coordination arrangement has produced material deficiencies in the quality of care or is unlikely to further the coordination and management of care for the target patient population, then the parties have 60 days to either (a) terminate the arrangement; or (b) develop and implement a corrective action plan to remedy the deficiencies within 120 days, and if the deficiencies are not remedied within 120 days, terminate the arrangement.

[3] The pathway for limited technology participants does not apply to the Substantial Downside Financial Risk or the Full Financial Risk safe harbors.