Stark Law Reform: A Shift from a Volume to a Value-Based World

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Notes:

Overview

- Key Changes to the Stark Law: Value-Based Arrangements
- Being Practical: How do these new exceptions work in the real world?
- Compliance Guidance: Ensuring you fit within a Stark exception

Notes:

Need for Stark Law Reform

Role of Exceptions & Safe Harbors

- Concern is that the AKS and Stark Law effectively "locks in" providers to fragmented models of care because of fear that cooperative arrangements with other providers will be viewed as remuneration for referrals.
- Requests for safe harbors and exceptions to protect value based arrangements and beneficiary incentives increased significantly as CMS has rolled out programs and models that try to implement value or outcome based models.

Notes:

History of Stark Law Reform

Impediments to Value Based Arrangements

- Clearly, AKS, CMPs, and the Stark Law are not the only impediments to "value based" arrangements among providers that involve or could result in the referral of patients between the participants, or incentivizing beneficiaries.
- However, these laws introduce complexities and risks that can tip the balance against such arrangements.
- It might be hard to reduce risks – and reducing risks might make the arrangement not worth doing.

Notes:

New Value-Based Exceptions

Notes:

New Stark Law Regulations

- Put on display November 20, 2020 and finalized January 19, 2021.
- Significant Similarities between Value-Based Safe-Harbors & Exceptions.
- Other significant revisions to the Stark Law Regulations beyond Value-Based Arrangements.

Notes:

Final Revisions to Stark Law Exceptions

New Exceptions

- Value-Based Exceptions
  - Full Financial Risk
  - Meaningful Downside Risk to the Physician
  - Value-Based Arrangements
  - All three exceptions apply to indirect arrangements

Notes:

New Stark Law Regulations

What is a Value-Base Arrangement?

- "When I use a word, it means just what a choose it to mean – neither more nor less." Humpty Dumpty
- Value-Based Arrangements are what CMS say they are ("The question is which is to be the master – that's all.")

Notes:

Value Based Exceptions

Some Common Definitions

- Value-based activity means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:
  - (1) The provision of an item or service;
  - (2) The taking of an action; or
  - (3) The refraining from taking an action

Notes:

Value Based Exceptions

Some Common Definitions

- Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are:
  - (A) The value-based enterprise and one or more of its VBE participants; or
  - (B) VBE participants in the same value-based enterprise.

Notes:

Value Based Exceptions

Some Common Definitions

- Value-based enterprise or VBE means two or more VBE participants:
  - (A) Collaborating to achieve at least one value-based purpose;
  - (B) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;
  - (C) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and
  - (D) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Notes:

Value Based Exceptions

Some Common Definitions

- Value-based enterprise participant or VBE participant means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise, other than a patient acting in their capacity as a patient.

Notes:

Value Based Exceptions

Some Common Definitions

- Value-based purpose means:
  - (A) Coordinating and managing the care of a target patient population;
  - (B) Improving the quality of care for a target patient population;
  - (C) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or
  - (D) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Notes:

Value Based Exceptions

Definition Differences between Stark Law & AKS

- Under Stark Law, value based activity can be the making of a referral.
- No exclusion of entities
  - CMS proposed limiting application of exception to certain entities including laboratories, but ultimately did not exclude any parties
  - Will find that certain arrangements have Stark Law protection, but no AKS safe harbor protection.
  - Must conduct facts and circumstances analysis to determine level of acceptable risk.

Notes:

Value Based Exceptions

Full Financial Risk ((aa) (1))

- Full financial risk**:** VBE is financially responsible 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.
- Method of Financial Risk and Coverage for Loss
  - No prescribed method of payment, but can include capitation or global budget payment.
  - Risk can be covered by any number of methods including risk corridors, global risk adjustments, reinsurance, or stop-loss provisions.

Notes:

Value Based Exceptions

Full Financial Risk ((aa)(1))

- Additional Requirements
  - The VBE must be at full financial risk during the entire duration of the value-based arrangement
  - The remuneration under the value-based arrangement must be for, or result from, value-based activities undertaken by the recipient of the remuneration for patients in the target patient population
  - Cannot be an inducement to reduce or limit medically necessary items or services

Notes:

Value Based Exceptions

Full Financial Risk ((aa)(1))

- Additional Requirements
  - If referrals are required under the arrangement, then the arrangement must be in writing, signed by the parties, and allow for patient, provider, and payor choice
  - Must keep records of payment methodology and amount of payment for 6 years and available upon request.

Notes:

Example of Full Risk Value Based Arrangement

Full Financial Risk ((aa)(1))

- Hospital and affiliated physicians have entered into an arrangement with a payer where the payer will provide a predetermined amount of payment per insured patient for all healthcare items and services that may be furnished by that hospital and affiliated physicians.
  - What is the Value-Based Enterprise?
  - Who are the Value-Based Participants?
  - What is the Value-Based Purpose?
  - What is Value-Based Activity?
  - What is the Target Population?

Notes:

Value Based Exceptions

Value-Based Arrangements with Meaningful Downside Risk to Physicians((aa)(2))

Meaningful downside financial risk**:**

- "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 FFS, volume-based payment." 85 Fed. Reg. at 77515.
- "There is great potential for behavior-shaping when a physician's failure to achieve value-based purposes is tied to his or her remuneration." 85 Fed. Reg. at 77516

Notes:

Value Based Exceptions

Value-Based Arrangements with Meaningful Downside Risk to Physicians((aa)(2))

Meaningful downside financial risk**:**

- Physician is at meaningful downside financial risk when he or she has at least the prescribed level of risk under the value-based arrangement for the failure to achieve the value-based purpose of the value-based enterprise.
- The physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement.

Notes:

Value Based Exceptions

Value-Based Arrangements with Meaningful Downside Risk to Physicians((aa)(2))

- Methods of financial risk:
  - Incentives tied to achieving quality or performance metrics;
  - Claw back arrangements;
  - Withholds; or
  - Reductions in compensation.

Notes:

Value Based Exceptions

Value-Based Arrangements with Meaningful Downside Risk to Physicians((aa)(2))

- Additional Requirements
  - Nature and extent of physician downside risk needs to be in writing
  - Methodology is set in advance
  - Remuneration is for or results from value-based activities undertaken by recipient of remuneration for patients in target patient population
  - Payment not conditioned on referrals of patients or business not covered under the value-based arrangement

Notes:

Value Based Exceptions

Value-Based Arrangements with Meaningful Downside Risk to Physicians((aa)(2))

- Additional Requirements
  - If referrals are required under the arrangement, then the arrangement must be in writing, signed by the parties, and allow for patient, provider, and payor choice
  - Must keep records of payment methodology and amount of payment for 6 years and available upon request.

Notes:

Example of a Value Based Arrangement with Meaningful Downside Risk

- Physician receives base compensation of $50,000 from a hospital , but is entitled to receive an additional $10,000 for performing value-based activities.
  - What is the Value-Based Enterprise?
  - Who are the Value-Based Participants?
  - What is the Value-Based Purpose?
  - What is Value-Based Activity?
  - What is the Target Population?

Notes:

Value Based Exceptions

Purpose of the Value Based Arrangements ((aa)(3))

- Designed to permit physician/physician practices that cannot absorb downside financial risk to participate in care coordination activities.
- "[B]old reforms to the physician self-referral regulations are necessary to foster the delivery of coordinated patient care and …[transition] to a truly value-based health care delivery and payment system…." 85 Fed. Reg. at 77518.

Notes:

Value Based Exceptions

Requirements for Value Based Arrangements ((aa)(3))

- Arrangement is set forth in writing and signed by the parties and includes the following:
  - Description of the value based activities;
  - How the value-based activities are expected to further the value based purpose of the VBE;

Notes:

Value Based Exceptions

Requirements for Value Based Arrangements ((aa)(3))

- Arrangement is set forth in writing and signed by the parties and includes the following:
  - The target patient population;
  - Type or nature of the remuneration;
  - The methodology used to determine the remuneration; and
  - The outcome measure(s) against which the recipient is assessed, if any.

Notes:

Value Based Exceptions

Requirements for value based arrangements ((aa)(3))

- Additional Requirements
  - Outcome measures, if any, are objective, measurable, and selected based on clinical evidence or credible medical support
  - Any changes to outcome measures must be prospective
  - Methodology to determine remuneration is set in advance
  - Remuneration is for or results from value-based activity undertaken by recipient of remuneration for target patient population

Notes:

Value Based Exceptions

Requirements for value based arrangements ((aa)(3))

- Monitoring Requirement
  - Evaluate whether value-based activities have been furnished
  - How value-based activity is expected to further value-based purpose
  - Progress towards attainment of outcome measure
  - Required termination if value-based activity is not expected to further value-based purpose

Notes:

Value Based Exceptions

Requirements for value based arrangements ((aa)(3))

- Additional Requirements
  - Not an inducement to reduce or limit medically necessary care
  - Not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement

Notes:

Value Based Exceptions

Requirements for value based arrangements ((aa)(3))

- Additional Requirements
  - If referrals are required under the arrangement, then the arrangement must be in writing, signed by the parties, and allow for patient, provider, and payor choice
  - Must keep records of payment methodology and amount of payment for 6 years and available upon request.

Notes:

Example of Value Based Arrangements

- Hospital pays community physicians $25 for each instance in which they follow a hospital-approved protocol for detecting certain cancers.
  - What is the Value-Based Enterprise?
  - Who are the Value-Based Participants?
  - What is the Value-Based Purpose?
  - What is Value-Based Activity?
  - What is the Target Population?
- Hospital learns that the protocol is not achieving the goal of improving the quality of care for patients by detecting more cancers. What now?

Notes:

Value Based Exceptions

Differences between Stark Law Exception and AKS Safe Harbor for Value Based or Care Coordination Arrangements

- Stark Law exception applies to both in-kind and monetary remuneration while AKS only applies to in-kind remuneration
- But see revised AKS safe-harbors for personal services and management contracts (including outcomes-based payments) and warranties at paragraphs 1001.952(d) and (g) for more flexibility for monetary value-based arrangements with no downside financial risk requirement
- Stark law exception does not require 15% contribution from recipient of in-kind benefit in contrast to AKS safe harbor

Notes:

Examples and Practical Advice

Notes:

Examples for Discussion

- Hospital wants to coordinate care with community physicians and will give them specific digital care coordination tools for population health management.
- Hospital also wants to provide care coordinators that visit physician practices and work directly with patients to facilitate patient hand-offs and ensure medication adherence.
- How should you evaluate?

Notes:

Examples for Discussion

- Is this only an arrangement between the physician and the hospital?
- Are there any upstream payor arrangements where the enterprise is at full financial risk for this patient population?
- Does it matter if the physician is willing to be at meaningful downside risk under this example?
- Shouldn't you also be concerned about the Anti-Kickback Statute?

Notes:

New Opportunities / Observations

- New safe harbors and exceptions provide new pathways for value-based arrangements outside of CMS programs and CMMI models
- These new regulations are considerably more strict and contain many more requirements compared to existing fraud and abuse waivers
- While CMS and OIG will not take away existing fraud and abuse waivers, if parties wish to engage in new value-based models they will need to fit within the new exceptions and safe harbors or accept some level of AKS risk

Notes:

New Opportunities / Observations

- Many healthcare entities that were excluded from safe harbor protection will continue to lobby Congress and HHS to expand coverage
- These regulations are a positive start, but more will need to be done in the years ahead
- As value based arrangements evolve so will the need for the regulations to be updated and/or for Congress to make statutory changes

Notes:

Questions

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