Arnold & Porter

Anti-Kickback Statute (AKS) and Stark Law Proposed Rules

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AKS and Stark Proposed Rules

- As part of it's "Regulatory Sprint to Coordinate Care", HHS Office of Inspector General (OIG) and the Centers for Medicare and Medicaid Services published Notices of Proposed Rule Making on October 9, 2019 for the AKS and Stark Law.
- A significant focus of the Proposed Rules are to institute value-based payment reforms and incentivizing a shift away from reimbursement for healthcare items and services based on volume to payment systems where HCPs and other healthcare provider and suppliers have greater financial accountability for cost-effective, high-quality, coordinated care.
- Under the AKS Proposed Rule, OIG has proposed the addition of new safe harbors and has proposed modification of existing safe harbors.
- Under the Stark Proposed Rule, CMS proposed the addition of new exceptions and proposed several modifications to existing exceptions and definitions.

Value-Based Definitions

- Value Based Enterprise (VBE)
  - Two or more VBE participants: (i) Collaborating to achieve at least one value-based purpose; (ii) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the VBE; (iii) That have an accountable body or person responsible for financial and operational oversight of the VBE; and (D) That have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s).
- Value Based Arrangement
  - An arrangement for the provision of at least one value-based activity for a target patient population between or among: (i) The value-based enterprise and one or more of its VBE participants; or (i) VBE participants in the same value-based enterprise.
- Target Patient Population (TPP)
  - An identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that: (i) are set out in writing in advance of the commencement of the value-based arrangement; and (ii) further the value-based enterprise's value-based purpose(s)

Value-Based Definitions (cont'd)

- Value-Based Activity
  - 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: (i) the provision of an item or service; (ii) the taking of an action; or (iii) the refraining from taking an action."
  - "Value-based activity" does not include the making of a referral.
- Value-Based Participant
  - An individual or entity that engages in at least one value-based activity as part of a VBE.
    - "Engaging in" a value-based activity may be, for example, (i) performing an action to achieve certain quality or outcome metrics and the providing or receiving of payment for such achievement, or (ii) coordinating care to achieve better outcomes or efficiencies
  - OIG expressly excludes pharmaceutical manufacturers; DMEPOS manufacturers, distributors, and suppliers; and laboratories from participating in VBEs, and is considering whether other entities (like medical device manufacturers, PBMs, or pharmacies) should be excluded.
- Value-Based Purpose
  - (i) coordinating and managing the care of a TPP; (ii) improving the quality of care for a TPP; (iii) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a TPP; or (iv) transitioning from healthcare 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 TPP.

AKS Proposed Rule

AKS Proposed Rule New Safe Harbors: Value-Based Arrangements

- Care Coordination Arrangements
  - This Safe Harbor would protect in-kind remuneration exchanged between VBE participants in order to further care coordination.
  - Remuneration: (1) must be in-kind, not a cash payment; (2) must be used to engage in value-based activities directly connected to the coordination and management of care for the TPP; and (3) cannot be funded by or result from contributions of parties outside the VBE.
  - The recipient of the care coordination must pay at least 15% of the offeror's cost for the in-kind remuneration.
- Value Based Arrangements with Substantial Downside Financial Risk
  - This Safe Harbor protects monetary and in-kind remuneration exchanged between a VBE that assumes substantial downside financial risk from a payor and a VBE participant that meaningfully shares in such risk pursuant to a VBA.
  - "Substantial downside financial risk" means (1) shared savings plus a repayment obligation to the payer of at least 40% of shared losses; (2) a repayment obligation to the payer under an episodic or bundled payment arrangement of at least 20% of total loss; (3) prospectively paid population-based payment; or (4) a partial capitated payment from the payer for items and services for the target patient population, reflecting a discount of at least 60% of the total expected fee-for-service payments.

AKS Proposed Rule New Safe Harbors: Value-Based Arrangements (cont'd)

- Value-Based Arrangements with Full Financial Risk
  - This Safe Harbor would protect monetary and in-kind remuneration exchanged between a VBE that assumes full financial risk from a payor and a VBE participant.
  - Full financial risk means the VBE is financially responsible for the cost of all items and services covered by the applicable payor for each patient in the TPP and is prospectively paid by the applicable payor.
- Arrangements for Patient Engagement and Support
  - This Safe Harbor would protect certain arrangements for the provision of patient engagement tools and supports furnished by VBE participants to patients in a TPP.
  - These tools must be (1) in-kind preventive items/services (e.g., health related technology, patient health related monitoring) and cannot be gift cards, cash, or cash equivalents and (2) furnished directly by the VBE participant to the patient.
- CMS-Sponsored Models
  - This Safe Harbor would protect remuneration among parties to arrangements under models or other initiatives being tested or expanded by CMMI or under the MSSP.
  - The Safe Harbor would also permit remuneration in the form of incentives and supports to patients provided by CMS-Sponsored model participants.

AKS Proposed Rule New Safe Harbors: Cybersecurity Technology and Services

1. The technology and services must be necessary and used predominantly to implement and maintain effective cybersecurity.
2. The donor cannot: (i) directly take into account the volume or value of referrals or other business generated between the parties when making an eligibility determination; or (ii) condition the donation on future referrals.
3. Neither the recipient nor the recipient's practice (or any affiliated individual or entity) may make the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.
4. The arrangement must be set forth in a signed writing.
5. The donor cannot shift the costs of the technology or services to any Federal health care program.

AKS Proposed Rule Modified Safe Harbors (cont'd)

- Electronic Health Record (EHR) Items and Services
  - OIG proposed to modify the existing safe harbor protection for donations of EHR software to:
    - (1) amend the requirements relating to interoperability;
    - (2) clarify that certain cybersecurity software and services have always been protected;
    - (3) eliminate the sunset provision;
    - (4) modify certain definitions; and
    - (5) delete the condition that prohibits the donation of equivalent items or services to allow donations of replacement EHR technology.
- Personal Services and Management Contracts
  - OIG proposed to modify the existing Personal Services and Management Contracts Safe Harbor to:
    - Eliminate the requirement that aggregate compensation be set in advance. Instead, only compensation methodology, which must reflect FMV and not take into account the volume or value of referrals, must be set in advance.
    - Eliminate the requirements that, if an agreement provides for services on a periodic or part time basis, the contract must specify the schedule, length, and exact charge for the intervals.
    - Create new protections for certain outcomes-based payments.

AKS Proposed Rule Modified Safe Harbors (cont'd)

- Warranties Safe Harbor
  - OIG proposed:
    - to expand the existing safe harbor to include bundled items and related services. This could include both product support and education support.
    - potential safeguards against the risk of patient harm and inappropriate utilization.
    - to exclude beneficiaries from the report requirements applicable to buyers of products with warranties.
- Transportation Safe Harbor
  - OIG proposed to expand mileage limits for patients residing in rural areas from 50 to 75 miles and to eliminate the distance limit on transportation of discharged patients.

Stark Proposed Rule

Stark Proposed Rule

- CMS proposed new exceptions reflecting OIG's proposed safe harbors for:
  1. in-kind and monetary arrangements where the VBE assumes full downside financial risk from a payor;
  2. in-kind and monetary arrangements where the VBE assumes substantial (or meaningful) downside risk from a payor; and
  3. in-kind remuneration exchanged between qualifying VBE participants for value-based activities that are directly connected to care coordination and care management.
  4. cybersecurity technology
- CMS proposed a new exception for indirect value-based arrangements so that, when the value-based arrangement is the link in the chain closest to the physician the indirect compensation arrangement would qualify as a "value-based arrangement" for purposes of applying the proposed VBA exception.
- CMS also proposed that lack of an AKS violation would no longer be an element of any Stark Law exception (e.g. exceptions for Physician Recruitment, Fair Market Value, Timeshare Arrangements, etc).

Stark Proposed Rule Exceptions: Limited Remuneration to a Physician

- CMS proposed an exception for limited remuneration to a physician if the following are met:
  - the arrangement is for items or services actually provided by the physician;
  - the amount of the remuneration to the physician is limited (does not exceed an aggregate of $3,500 per calendar year);
  - the arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements, regardless of whether it results in profit for either or both of the parties;
  - the remuneration is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; and
  - the remuneration does not exceed the fair market value for the items or services.

Stark Proposed Rule: New Definitions

- Commercial Reasonableness
  - CMS proposed 2 alternatives to the definition of Commercial Reasonableness:
    - 1) the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements
    - (2) the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.
- Fair Market Value and General Market Value
  - CMS proposed to eliminate the connection to the volume or value standard from the definition of Fair Market Value and to create a "general market value" definition which would be consistent with recognized principles of market valuation.
- Volume/Value Standard
  - CMS proposed an objective test to determine whether compensation takes into account the volume or value of referrals or other business generated.
  - The new test would be: whether the formula used to calculate the physician's compensation includes physicians' referrals to the entity or other business as a variable *or* there is a predetermined, direct correlation between the physician's previous referrals or other business generated and the prospective rate of compensation.
- Group Practice
  - CMS proposed to change the group practice rule in order to be consistent with the proposed value-based rules. Under the new group practice rule, profits from DHS that are attributable to participation in a VBE would not be considered to directly take into account the volume or value of the physician's referrals.
  - Group practices would not be allowed to allocate all DHS profits generate by a group of at least 5 physicians back to the applicable group and would not be able to distribute DHS profits on a service-by-service basis.