2022 SUMMER CPE SYMPOSIUM: WHAT'S HOT IN HEALTHCARE

# Understanding the Business Case for Using Value-Based Exceptions

Session 3 | July 28, 2022

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# Introductions

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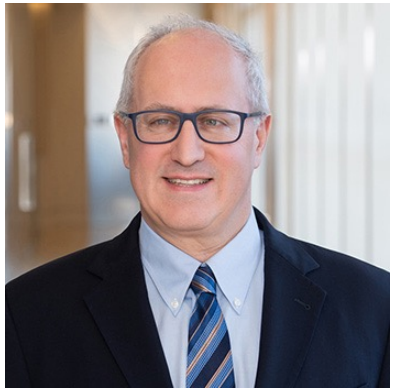

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# Agenda

1. Overview of Value-Based Stark Law Exceptions and Anti-Kickback Statute (AKS) Safe Harbors
2. Practical Examples of Value-Based Stark Law Exceptions and AKS Safe Harbors
3. Brief Overview of Medicare Shared Savings Program ACO Waivers

# Overview of Value-Based Stark Law Exceptions and AKS Safe Harbors

# AKS and Stark Law

| | AKS | Stark Law |
|---|---|---|
| **Prohibition** | Solicitation, receipt, offer, or payment of any remuneration in return for referrals of items/services payable under Medicare or Medicaid | Making referrals for designated health services (DHS) payable by Medicare to an entity with which physician (or family member) has a financial relationship |
| **Knowledge Requirement** | Intent-based ("knowingly and willingly") | Strict liability |
| **Exceptions** | Regulatory "safe harbors" | Regulatory "exceptions" |
| **Penalties** | Criminal and civil penalties (*$25,000 per offense and/or imprisonment up to 5 years; exclusion from Medicare/Medicaid*) | Civil penalties (*$15,000 per improper claim; repayment of claims; exclusion from Medicare/Medicaid*) |

# Value-Based Stark Law Exceptions and AKS Safe Harbors

| | |
|---|---|
| **§ 411.357 (aa)(1)** | Value-based arrangements with full financial risk |
| **§ 1001.952(gg)** | **Arrangements that facilitate value-based health care delivery and payment: Full financial risk** |
| **§ 411.357 (aa)(2)** | Value-based arrangements with meaningful downside financial risk to the physician |
| **§ 1001.952(ff)** | **Arrangements that facilitate value-based health care delivery and payment: substantial downside financial risk** |
| **§ 411.357 (aa)(3)** | (Other) Value-based arrangements |
| **§ 1001.952(ee)** | **Care coordination arrangements to improve quality, health outcomes, and efficiency** |

# Key Value-Based Definitions/Concepts

**Value-Based Purpose**

Coordinating and managing target patient population's care

Improving quality of care for target patient population

Appropriately reducing costs/growth of expenditures of payors (without reducing quality of care for target patient population)

Transitioning from system based on volume of items and services to system based on the quality of care/cost control for target population

**Value-Based Activity**

Activity designed to achieve value-based purpose (not referral itself)

**Value-Based Arrangement**

Activity for provision of a value-based activity between value-based entity and one or more participants, or between two participants in same VBE

**Value-Based Entity (VBE)**

No one structure but includes ACOs and CINs

# Full Financial Risk:
# Stark Exception Compared with AKS Safe Harbor

| Stark Law Risk Exception | AKS Safe Harbor |
|---|---|
| VBE is at full financial risk | VBE has assumed full financial risk from payor |
| Relates to value-based activities | Remuneration directly connected to value-based purposes and not the ownership or investment interests or marketing |
| No inducement to reduce or limit medically necessary items or services | No inducement to reduce or limit medically necessary items or services |
| Not conditioned on outside referrals | Does not take into account the volume or value of referrals |
| Mandated referrals are in writing and provide exceptions | Set forth in a signed written agreement |
| Maintain records of methodology for determining remuneration for 6 years | Maintain records for determining compliance for 6 years |
| | No claim for payment in addition to payments under the value-based arrangement |
| | Includes a quality assurance program |
| | No ineligible entities (e.g., pharma manufacturer, PBM, lab, medical device/supply manufacturer) |

# Partial Financial Risk:
# Stark Exception Compared with AKS Safe Harbor

| Stark Law Risk Exception | AKS Safe Harbor |
|---|---|
| Similar but not identical to full risk exception | Similar but not identical to full risk exception |
| Physician* is at **meaningful downside financial risk** (“MDFR”) for the duration of the VBA | The VBE (directly or through a VBE participant, other than a payor, acting on the VBE's behalf) assumes **substantial downside financial risk** (“SDR”) from a payor |
| MDFR means repaying or forgoing at least 10% of the total value of the remuneration the physician receives under the VBA | SDR means financial risk equal to at least 20%-30% loss (depending on how losses are calculated) or that the VBE receives from the payor a prospective, per-patient payment, subject to conditions. |
| Methodology to determine the risk must be set in advance | VBE participant (unless VBE participant is payor sharing risk) is at risk for a **meaningful share** of VBE's SDR (i.e., at least 5% of the losses and savings or a prospective payment methodology) |

* Note – Contrast with the full financial risk exception, which refers to “VBE” instead of “physician.”

# No Financial Risk:
# Stark Exception Compared with AKS Safe Harbor

| Stark Law VBA Exception | AKS Care Coordination Safe Harbor |
|---|---|
| No specific contribution requirement | 15% contribution requirement for recipient |
| Monetary or in-kind remuneration | In-kind remuneration |
| Outcome measures | Outcome/process measures |
| Commercially reasonable | Commercially reasonable |
| Written agreement meeting content requirements | Written agreement meeting content requirements |
| Referral limitations and prohibition | Referral limitations and prohibition |
| Patient best interests; Marketing prohibition | No parallel requirement |
| Monitoring; termination; record keeping | Monitoring; termination; record keeping |

# POLLING QUESTION #1

# Practical Examples of Value-Based Stark Law Exceptions and AKS Safe Harbors

# Factual Scenario 1

- **EHR transition mandated by health system affiliation**
  - Following affiliation with larger health system using different EHR, necessary for community health system to consolidate onto a new system.
  - Community health system had implemented an EHR using the EHR donation exception and safe harbor approximately 18 months before, and participating physicians and groups had contributed 20% of EHR costs at that time and contribute 20% for ongoing EHR costs.
  - Physicians who have been granted the exception all participate in the community health system's CIN. Many are also in the community health system's ACO.
  - Recognize that the cost of the upgrade has nothing to do with the physicians or the value-based network, and rather the health system affiliation. Concern that physicians might move away from the value-based arrangement of the CIN because of the expense (i.e., less physician alignment).

# Factual Scenario 1 (continued)

- The community health system and physicians recognize that the EHR donation exception and safe harbor 15% contribution is onerous because the physicians would have to contribute for upfront costs twice in a two-year period.
    - Some physicians had only joined the CIN 12 months prior.
- Important to the community health system to remove the 15% upfront contribution requirement of the EHR donation exception and safe harbor.
- Physicians and physician groups would still contribute for ongoing costs of the new system.
- CIN only participates in shared savings arrangements at this time, no downside risk.

# Sticking Point: AKS § 1001.952(ee)

- **Regulatory Options**

  1) Traditional EHR donation exception and safe harbor. Stark Law requires 15% cost sharing, and strict liability. Corresponding AKS safe harbor also contains 15% requirement; or

  2) Value-based non-risk exception. Stark Law does not have 15% requirement. AKS provides:

     - … The recipient pays at least 15 percent of the offeror's cost for the remuneration, using any reasonable accounting methodology, or the fair market value of the in-kind remuneration. If it is a one-time cost, the recipient makes such contribution in advance of receiving the in-kind remuneration. If it is an ongoing cost, the recipient makes such contribution at reasonable, regular intervals.

Note: There are many other prongs to the regulatory analysis. In this scenario, this prong was the sticking point that required further analysis.
42 C.F.R. § 411.357(aa)(3)

# Safeguards

**The relevant physicians and physician groups contracted recently for a new EHR and paid 20% of the EHR cost less than 2 years ago – 5% more than the 15% required under the EHR safe harbor.**

The extra 5% could be viewed as contributing to the 15% at issue here, covering one third of the safe harbor contribution amount.

**The reason for transitioning to the new EHR relates to the recent affiliation, and not referrals or steerage.**

As an additional safeguard, the value-based agreement includes language to prohibit patient steerage, and language confirming that the contribution of the EHR is not conditioned upon or tied to referrals.

# Safeguards (continued)

- Independent physicians operate in small practices, without significant material resources, and located in mostly rural areas.
- Physicians will still pay for ongoing EHR costs at the historical 20% level.
- Physicians are required to continue to participate in the CIN and/or ACO.
- CIN/ACO has existing scorecard/outcome measures used as part of the value-based performance arrangements; CIN/ACO will include metrics related to EHR compliance and use.
- The value-based arrangement's goal is aligned with the purpose of the VBA Exception: *efficient value-based coordination of care through an integrated EHR system, ultimately reducing the burden on Medicare and Medicaid.*

# Safeguards (continued)

- Although the 15% cost-share requirement was ultimately retained, the Office of Inspector General (OIG) considered eliminating the 15% cost-share requirement for the EHR safe harbor.
- The OIG acknowledged in the preamble to the final rule in discussing this 15% safe harbor requirement that not meeting any given prong does not necessarily mean there is a violation: "Arrangements are not necessarily unlawful because they do not fit in a safe harbor. Arrangements that do not fit in a safe harbor are analyzed for compliance with the [AKS] based on the totality of their facts and circumstances, including the intent of the parties."

85 Fed. Reg. 77684, 77685. See also Dept. of Health & Human Services, Office of Inspector Gen., Advisory Opinion No. 12-22 (Dec. 31, 2012), at 12–13 (providing "the absence of safe harbor protection is not fatal. Instead, [the OIG] evaluate[s] the facts and circumstances specific to the [a]rrangement."); *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 47 (D. Mass. 2011) ("To receive protection, a business arrangement must fit squarely within a safe harbor; substantial compliance is not enough, although compliance is voluntary and failure to comply is not a per se violation of the statute."); *Feldstein v. Nash Community Health Services, Inc.*, 51 F. Supp. 2d 673, 682 (E.D.N.C. 1999); *United States v. Shaw*, 106 F. Supp. 2d 103, 112 (D. Mass. 2000); Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, Proposed Rule, Health and Human Services Department, October 17, 2019, 84 FR 55694, 55743.

# Safeguards (continued)

- CMS considered including a 15% cost-share requirement in the VBA Exception, but abandoned it, expressing concern that "requiring a 15 percent contribution from the recipient of nonmonetary compensation under a value-based arrangement could inhibit the goal of transitioning to a value-based health care delivery and payment system."
- The value-based arrangement comports with the Stark Law.
- The value-based arrangement comports with each remaining prong of the AKS.

85 Fed. Reg. 77492, 77522.

# POLLING QUESTION #2

# Factual Scenario 2

- **Statewide system looking to use one EHR platform for its value-based care programming**
  - Statewide health system in multiple geographies.
  - Consolidating existing value-based organization into one CIN.
  - Historically offered EHR to physicians and physician groups in the geographic regions that the health system serves, with 15% contribution requirement for initial and ongoing costs and in compliance with Stark and AKS EHR donation exception and safe harbor.
  - Want to lower 15% contribution requirement for physicians in the health system's value-based arrangements (i.e., CIN, ACOs, and similar) to 5% cost share for the initial donation of the EHR and for ongoing costs.
  - Contributions will not occur in advance of receiving the EHR and will be amortized over the term of the agreement.

# Factual Scenario 2 (continued)

- Goal to grow clinical integration, enhance coordination of care, and improve pro-triple aim metrics in the communities served.
- The statewide health system also desires to put additional incentives into the arrangement to promote long term commitment to value-based care.

# Safeguards

- The written agreements between the parties ensure that the value-based arrangement is tied to the value-based program.
  - Requires physicians and physician groups that exit the arrangement, through a liquidated damages provision, to contribute the full 15% for the initial cost of the EHR and ongoing fees, for the term of the written agreement.

# Safeguards (continued)

**The reason for offering the EHR is to integrate physicians and physician groups in the CIN into the value-based care arrangement for the system; to further clinically integrate the health system's CIN; and to enhance care coordination, transition of care, and continuity of care; not to drive or steer referrals.**

Only the physicians and physician groups in the CIN will be offered the EHR.

The value-based agreement will include language to prohibit patient steering, and language confirming that the contribution of the EHR is not conditioned upon or tied to referrals.

**Independent physicians (including safety net providers) are sometimes small and without significant resources. Physicians are located throughout the health system's service area, which includes rural communities and otherwise medically underserved areas.**

# Safeguards (continued)

- The value-based arrangement's goal is aligned with the purpose of the VBA Exception: efficient value-based coordination of care through an integrated EHR system, ultimately reducing the burden on Medicare and Medicaid.
- Although the 15% cost-share requirement was ultimately retained, the OIG considered eliminating the 15% cost-share requirement for the EHR safe harbor.
- The OIG acknowledged in the preamble to the final rule in discussing this 15% safe harbor requirement that not meeting any given prong does not necessarily mean there is a violation: "Arrangements are not necessarily unlawful because they do not fit in a safe harbor. Arrangements that do not fit in a safe harbor are analyzed for compliance with the [AKS] based on the totality of their facts and circumstances, including the intent of the parties."

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# Safeguards (continued)

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- The value-based arrangement comports with the Stark Law.
- The value-based arrangement comports with each remaining prong of the AKS.

85 Fed. Reg. 77492, 77522.

# Other Potential Uses of Value-Based Exceptions and Safe Harbors

- Hospital Quality and Efficiency Programs
- Care coordination arrangements for embedded care coordinators.
- Advance payments in connection with full financial risk arrangements.
- Transitional care management and remote patient monitoring services.
- Digital intake and scheduling through IT platform.
- AI-enabled technology to reduce A/R delays and claim denials.

# POLLING QUESTION #3

# Medicare Shared Savings Program – ACO Waivers

# Overview of MSSP ACO Fraud and Abuse Waivers

- To encourage participation in CMS initiatives like the MSSP Pathways to Success, CMS makes available waivers of fraud and abuse laws (i.e., Stark Law, AKS, and Civil Monetary Penalties (CMP) Law).
- Waivers help enable MSSP ACOs to align clinical delivery performance with financial model to change the way care is delivered.
- Waivers allow for many creative and innovative arrangements that may otherwise be stifled because of fraud and abuse laws (e.g., joint ventures, leases and licenses, management services, donations of EHR, and more).
- One benefit for hospitals/health systems to sponsor their own MSSP ACO is easier access to waivers, as most waivers require approval of the MSSP ACO's governing body; often times easier to get arrangements "closer to home" on the agenda.

# Most Important Waivers

***Pre-Participation Waiver:*** Applies to ACO-related start-up arrangements in anticipation of participating in the MSSP Pathways to Success.

***Participation Waiver:*** Applies broadly to ACO-related arrangements during the term of an ACO's participation agreement under the MSSP Pathways to Success.

***Patient Incentives Waiver:*** Allows the MSSP ACO to provide beneficiaries free or in-kind care that furthers treatment of care plan and/or improves preventive care.

Other waivers are available under the MSSP Pathways to Success.

# Role of MSSP ACO Waivers

- Given the choice, fitting a valued-based exception and safe harbor may be preferable to obtaining a waiver.
- Waivers may be revoked in the future, while fitting into a Stark exception and AKS safe harbor is more stable.
- Stark Exceptions and AKS safe harbors may allow for more flexibility. For example, a Medicare Advantage arrangement rather than MSSP ACO.
- Some physicians do not or cannot participate in an MSSP ACO (e.g., pediatricians since they would not serve Medicare populations).
- MSSP ACO fraud and abuse waivers are not available for REACH ACOs.

Source: 85 Fed. Reg. 77492, 77508

# How Can We HELP?

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# Thank you!

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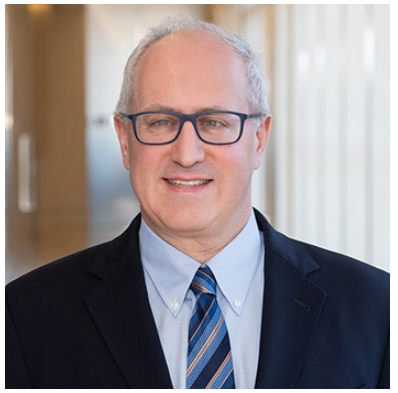

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