HLB

Final Anti-Kickback and Stark Rules: Value Based Arrangements and Beyond

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Presentation Overview

- Snapshot of the Rules
- What are Rules Trying to Accomplish?
- Value-Based Arrangements and Coordination of Care
- Electronic Health Records Items and Services and Cybersecurity
- Group Practice Compensation
- “Fundamental” Stark Law Requirements
- In Other News…

Snapshot of the Rules

- Effective January 19, 2021
  - January 1, 2022 for certain Stark law revisions applicable to group practices
- Sweeping Changes

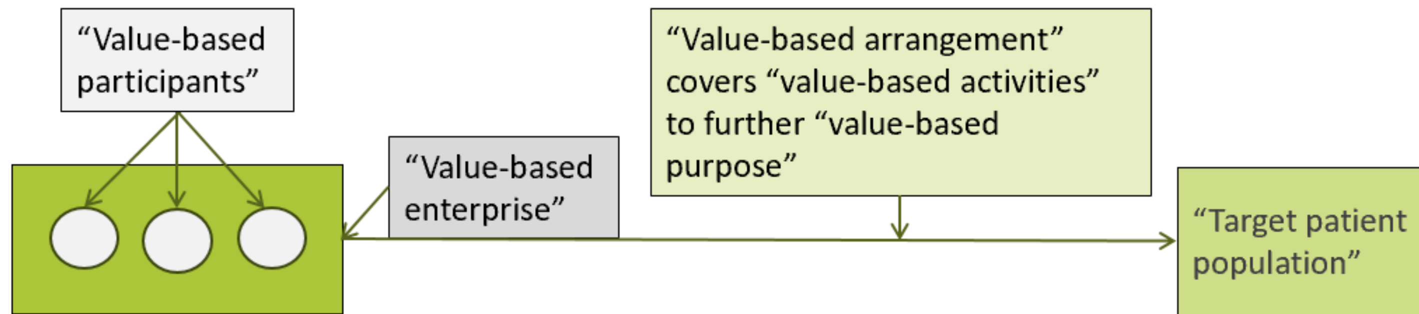
Anti-Kickback Regulations	Stark Law Regulations	CMP Law Regulations
- 7 new safe harbors - 4 safe harbors significantly revised	- 5 new exceptions - Almost every single exception revised to some extent - Significant revisions and new additions to definitions and special rules on compensation	- New exception to remuneration (telehealth technology for home dialysis)

Goals of the Rules

- Remove Regulatory Barriers to Innovation
- Encourage Participation in Value-Based Arrangements
- Clarification/Simplification of Existing Stark/AKS Rules

Value-Based Arrangements and Coordination of Care

Value-Based Arrangements (Stark and AKS)



- **"Value-based participants"** = individuals or entities engaged in value-based activity as part of a value-based enterprise - e.g. hospitals, physicians, digital health companies, SNFs, home health, etc. (OIG excludes some from protection under the safe harbor)
- **"Value-based enterprise" (VBE)** = two or more value-based participants collaborating to achieve value-based purpose, using a value-based arrangement and has an accountable body or person and governing document
- **"Value-based purpose"** = coordinating and managing care; improving quality; appropriately controlling costs; transitioning from volume to value
- **"Value-based activity"** = providing an item or service, taking action, or refraining from an action, all in furtherance of a value-based purpose (does not include making a referral)
- **"Value-based arrangement"** = an arrangement for "value-based activity" by the value-based enterprise and/or its value-based participants
- **"Target patient population"** = an identified patient population selected by value-based enterprise or its value-based participants using "legitimate and verifiable criteria" set out in writing, in advance

Value-Based Arrangements (Stark and AKS)

Stark	AKS
Full financial risk	Full financial risk
Meaningful downside risk to physician	Substantial downside financial risk (to value-based enterprise)
Value –based arrangements	Care coordination arrangements
	Patient engagement and support
Indirect value-based arrangements	
	Personal services arrangements*
Group practice (allocation of value-based reserve)*	

Value-Based Arrangements - Stark Law Exceptions

(additional requirements apply under the AKS safe harbors)

Full Risk	Partial Risk	No Risk
Remuneration for/from value-based activities	Same	Same
Does not induce reduction of medically necessary care	Same	Same
Not conditioned on referrals of unrelated business	Same	Same
Required referrals must satisfy standard requirements	Same	Same
Records kept 6 years	Same	Same
	Arrangement in writing	In writing, signed by parties
	Compensation set in advance	Same
		Outcome measures: objective/credible; changes are prospective & in writing
		Commercially reasonable
		Annual monitoring must satisfy detailed requirements

Full Financial Risk

- VBE - Financially responsible on a prospective basis for all patient items or services covered by a payor
- Example:
  - Health system and physician organization have respective contractual arrangements with a payor to receive capitated payments for items and services provided to Medicare Advantage patients in a geographic area
  - The payor agreements, together, account for all items or services provide to the target patient population
  - Participants engage in various activities to better coordinate and manage care across care settings
  - Physician organization receives a shared savings payment from any collective savings across the VBE

Meaningful Downside Risk; Substantial Downside Risk

- Meaningful downside risk (Stark Law)
  - At least 10% of a physician's compensation is at risk for failure to achieve a value-based purpose
  - Example: Pursuant to a PSA and call coverage agreement with a hospital, orthopedist receives $50,000 annual base payment. Ability to earn an additional $25,000 for abiding by hospital's redesigned care protocols.
- Substantial downside risk (Ant-Kickback Statute)
  - VBE takes on "substantial downside risk" - for example, 20% risk for a clinical episode of care that spans multiple care settings
  - VBE participant (such as a physician) "meaningfully shares" in the risk – for example, two-sided risk for at least 5% of losses and savings

No Risk Required

- Stark Law protects in-kind and cash remuneration. Does not require a contribution from the physician.
  - Example: Physician/hospital VBE. Physician can earn cash incentives for participation in post-discharge meetings after a joint replacement procedure, with a goal of facilitating care transitions and reduction of hospital readmissions. Cash incentives are contingent on the hospital reducing its readmission rate below a set percentage for patients treated by the physician.
- AKS protects in-kind remuneration. Requires a 15% contribution.
  - Example: Physician/hospital VBE. Hospital provides RPM software technology and support to assist physician, with a goal of facilitating care transitions when a patient is discharged home.
  - Example: Physician/hospital VBE. Hospital provides in-office tablets with educational training/resources for use by patients with particular conditions or in advance of particular procedures.

Patient Engagement and Supports Safe Harbor

42 CFR §1001.952(hh)

- New safe harbor available to value-based enterprise
- Protects in-kind remuneration to patients in a target patient population
  - Must be connected to coordination and management of care and meet other requirements
  - Must be recommended by licensed health care professional

Patient Engagement and Supports Safe Harbor

42 CFR §1001.952(hh)

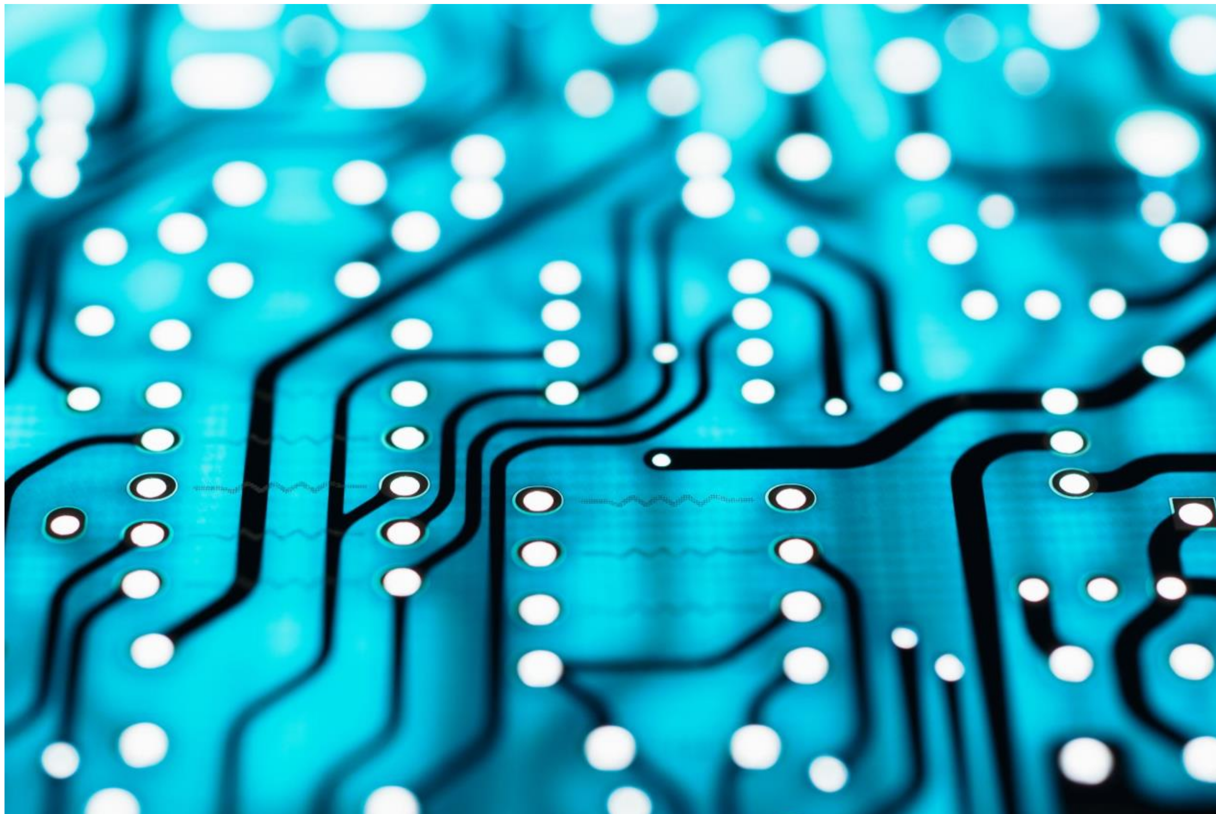
- Protects up to $500 in value annually. Examples:
  - Digital health technology tools
  - Broadband access to enable remote patient monitoring or virtual care
  - Grocery delivery service
- Examples of items or services that would not be protected:
  - $100 debit card
  - Smart pill dispenser provided by a pharmaceutical manufacturer
  - Concert tickets

Patient Engagement and Supports Safe Harbor

42 CFR §1001.952(hh)

- Benefit of forming a value-based enterprise
  - "we perceive the administrative steps required to establish a VBE as relatively minimal, and they should not pose a significant burden on providers and others that desire to furnish protected tools and supports"
- Recognition of the importance of:
  - Addressing social determinants of health
  - Digital health tools
  - Both are recurring themes throughout the rule

Electronic Health Records Items and Services; Cybersecurity



EHR Items and Services Safe Harbor/Exception Modifications

The Highlights:

- No more sunset date!
- Elimination of requirement regarding lack of equivalent items or services
- Payment contribution for updates need not be paid in advance
- Corresponding changes in both the Anti-Kickback Statute safe harbor and Stark law exception

Cybersecurity Technology and Related Services – New!

The Highlights:

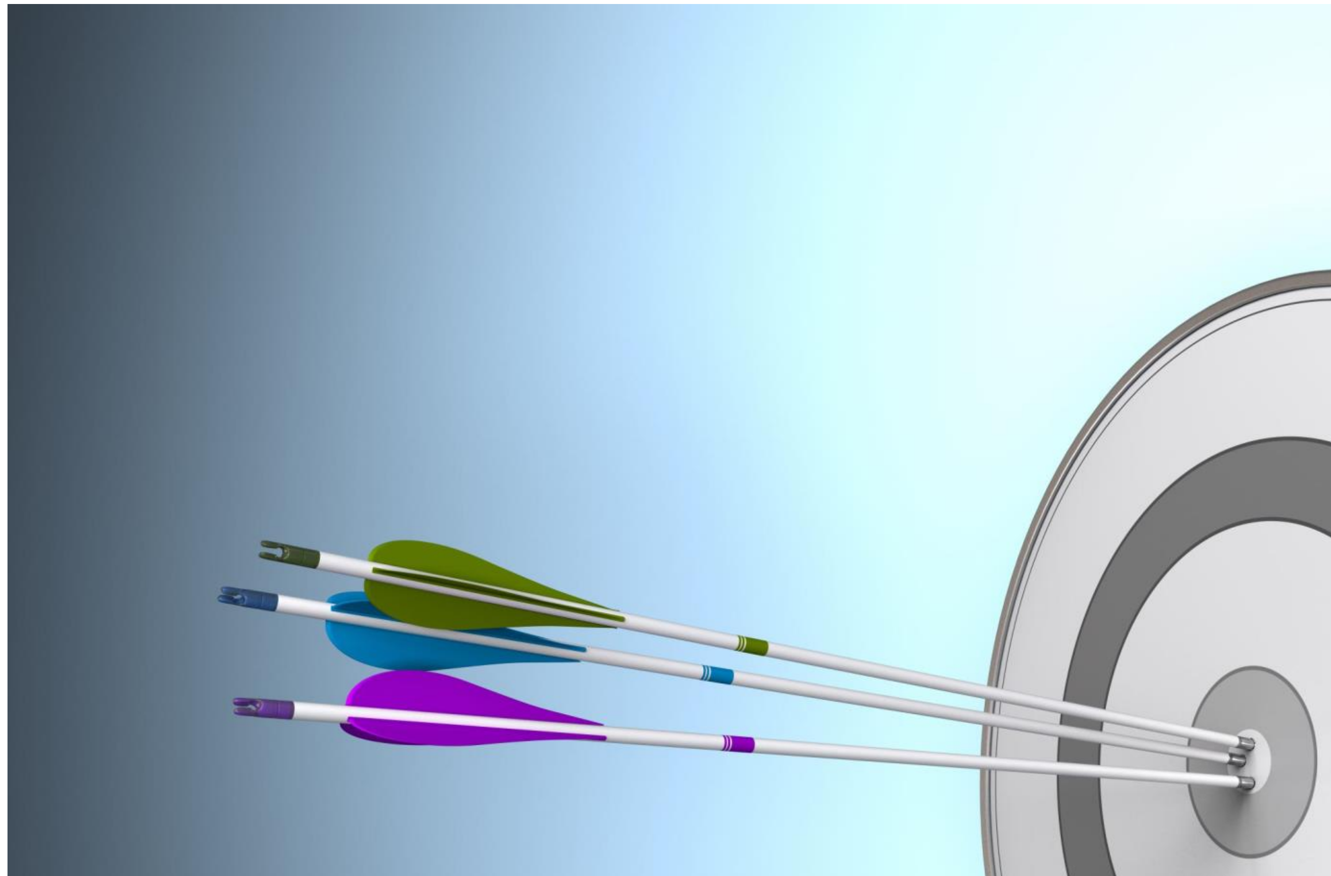
- Protects nonmonetary remuneration consisting of cybersecurity technology and services
  - Necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity
- No contribution by recipient required
- "An organization's cybersecurity posture is only as strong as its weakest link, including weaknesses of downstream providers, suppliers, and practitioners"
- Corresponding Anti-Kickback Statute safe harbor and Stark law exception

Group Practice Compensation

Group Practice Compensation (Effective Jan. 1, 2022)

- Prior Regulatory Language:
  - Physician in a group practice may be "paid a share of overall profits of the group" if not directly related to volume or value of referrals
  - Historically, defined as the "group's entire profits derived from DHS payable by Medicare or Medicaid"
  - Many stakeholders interpreted to protect distribution of overall profits for a particular service line
- New Regulatory Language "clarification":
  - "Overall profits" means "profits derived from all the designated health services"
  - Prohibits distribution of service-line specific profits
  - Delayed effective date to allow for time to adjust compensation methodologies

“Fundamental” Stark Law Requirements



Fundamental Stark Law Requirements in Many Stark Law Exceptions

In the words of CMS: the "big three"

- Commercial reasonableness
- "Volume or value" standard
- Fair market value

Goal is "to establish bright-line, objective regulations for each of these fundamental requirements . . . We believe that clear, bright-line rules would enhance both stakeholder compliance efforts and our enforcement capability"

Commercially Reasonable

42 CFR §411.351

- "Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."

Volume or Value of Referrals or Other Business Generated

42 CFR §411.354(d)(5)(compensation to a physician); 42 CFR §411.354(d)(6)(compensation from a physician)

- Compensation to a physician: takes into account the volume or value of referrals *only if the formula used to calculate compensation includes referrals* (or other business generated) as a *variable*, resulting in an increase or decrease in compensation that positively correlates with the number or value of the referrals (or other business generated)
  - Objective test based on mathematical formula
  - CMS reaffirms – again – productivity bonuses do not take into account the volume or value solely because corresponding hospital services are billed

Volume or Value of Referrals or Other Business Generated

Mathematical Formula Examples

Compensation to physician:

Entity pays a physician 1/5 of a bonus pool that includes all collections from a set of services furnished by an entity, including those from designated health services referred by a physician to the entity

Mathematical Formula:
Compensation =
(.20 x the value of the physician's referrals of designated health services) +
(.20 x the value of the other business generated by the physician for the entity) +
(.20 x the value of services furnished by the entity that were not referred or generated by the physician)

Fair Market Value and General Market Value

42 CFR §411.351

- Re-organization and slight modifications for clarity
- Cautions against over-reliance on salary surveys

In Other News…

Fixing Imperfect Performance

- Relevant Highlights from the Final Rule:
  - Changes to Isolated Transaction Exception (generally not available to correct ***ongoing services arrangement***)
  - ***New*** flexibility for temporary noncompliance with writing and signature requirements (compensation still needs to be ***set in advance***)
  - ***New*** Limited Remuneration to Physician Exception
  - Changes to Payments by Physicians Exception
  - Additional clarification around amendments during first year

Questions?

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