



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
- Fixing Imperfect Performance under the Stark Law
- “Fundamental” Stark Law Requirements and Impact on FCA Cases
- In Other Good News...

# Snapshot of the Rules

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

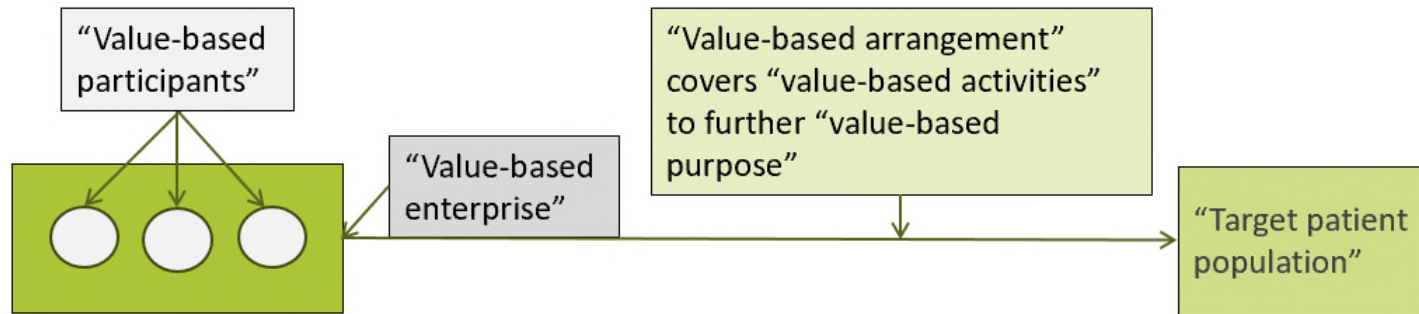
Anti-Kickback Regulations	Stark Law Regulations	CMP Law Regulations
<ul style="list-style-type: none"> <li>- 7 new safe harbors</li> <li>- 4 safe harbors significantly revised</li> </ul>	<ul style="list-style-type: none"> <li>- 5 new exceptions</li> <li>- Almost every single exception revised to some extent</li> <li>- Significant revisions and new additions to definitions and special rules on compensation</li> </ul>	<ul style="list-style-type: none"> <li>- New exception to remuneration (telehealth technology for home dialysis)</li> </ul>

# 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)

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



# Value-Based Arrangements – (AKS Care Coordination Example)

Hospital provides behavioral health nurse to SNF to follow selected patients at the SNF post-discharge from hospital:

1. Hospital and SNF establish outcome measures for SNF
2. They ensure provision of behavioral health nurse is commercially reasonable
3. Hospital and SNF sign written documentation setting forth terms, activities, target patient population, hospital's cost, SNFs contribution to cost, outcome measures
4. Remuneration is in-kind, primarily for value-based activity, etc.
5. Hospital's provision of nurse is unrelated to SNF's referral of patients who are not part of the target population and not covered by value-based arrangement
6. SNF pays at least 15% of hospital's cost of nurse
7. Value-based arrangement must be directly connected to coordination of care and management of target patient population
8. Arrangement does not include marketing to patients or recruiting patients
9. The value-based enterprise's accountable body or person monitors annually
10. The hospital does not and should not know the nurse's services are likely to be "diverted" to unrelated tasks

\*The hospital and/or SNF could potentially also provide patient engagement or support tools to patients

\* The hospital could potentially also pay cash remuneration to the SNF for achieving outcome measures (e.g., for reduction in readmissions)

# Value-Based Arrangements – (Other AKS Care Coordination Examples)

- Specialty physician practice provides data analytics software and services to primary care practice, to assist in predicting need for follow up care
- Hospital provides physician practice with care managers for high-risk patients post-discharge, along with remote patient monitoring capability, to assist in preventing hospital readmissions
- Medical technology company provides physician practice with digital health technology to better manage care for patients discharged from hospital with digitally-equipped devices that transmit data, to improve ability to observe recovery and intervene if necessary
- Hospital provides tablets to physician practices for use in-office for patient asthma education, to help manage asthma

## Value-Based Arrangements – Key Takeaways

- The proposed AKS safe harbors and Stark law exceptions are not interchangeable
- The proposed AKS safe harbors and Stark law exceptions are broad and flexible – intended to foster innovation
- Emphasis on use of digital health technology throughout
  - E.g., RPM, telehealth, AI as tools for coordination and management of care

# **Fixing Imperfect Performance under the Stark Law**

## Fixing Imperfect Performance

- CMS encouraging parties to detect and correct administrative or operational errors or payment discrepancies *during the course of the arrangement*
- 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

# Bad News First? Isolated Transactions Exception

42 CFR §411.357(F)

- Currently Isolated Transaction Exception Protects:
  - ***Payments made in the form of an “isolated financial transactions”*** so long as:
    1. Remuneration is consistent with FMV and doesn't take into account the volume or value of referrals/other business
    2. Remuneration is commercially reasonable (even without referrals)
    3. No additional transactions between parties for 6 months

# Bad News First? Isolated Transactions Exception

42 CFR §411.357(F)

- **CMS Commentary and Revised Definition:**
  - An “isolated financial transaction” cannot include “a single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated).”
  - Uses example of call coverage or other service agreement
- **Current and Future Use of the Exception?**

# Temporary Noncompliance with Writing Requirement

42 CFR §411.353(G)

- Existing special rule for temporary noncompliance signature requirements – evolution over last 5 years
  - Up to 90-days to obtain signatures – arrangement must comply with *all other requirements* of the applicable exception
- Expansion to include temporary noncompliance with “writing” requirements – previously clarified “writing” can consist of a collection of documents
- **Note:** must still have an agreement between the parties prior to commencing services/paying compensation



# **NEW: Limited Remuneration to a Physician Exception**

42 CFR §411.357(Z)

- Proposed **new** exception to Stark Law – flexibility for non-abusive business practices
- Key features:
  - Remuneration for items/services provided that does not exceed \$5,000 annually (adjusted for inflation) – contrast with nonmonetary compensation exception
  - Does **not** require a writing
  - Does require that remuneration is FMV, commercially reasonable and not determined in a manner that takes into account the volume or value of referrals/other business generated

# Payments by Physicians

42 CFR §411.357(I)

- Removed reference to existing regulatory exceptions and the specific reference to fair market value compensation.
- Now generally available to protect fair market value payments by a physician to an entity for items or services furnished even if a regulatory exception may be applicable.

# Commentary Regarding Amendments During First Year

MODIFICATIONS 42 CFR §411.354(D)(1)(II)

- Long-standing discussion around whether physician contracts can be amended during the first year of the term
  - CMS clarified as part of commentary for COVID-19 waivers
  - Additional clarification in Final Rule
    - “[R]eflecting our current policy, ...[d]oes not require that the modified compensation remain in place for at least 1 year from the date of the amendment and there is no prohibition on the number of times that the parties may modify the compensation provided the conditions of 411.354(d)(1)(ii) are met.”
    - “There is no signature requirement under [the revised] 411.354(d)(1)(ii), so the writing that documents the modified compensation need not be signed by the parties.”

# **“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, and fair market value requirements
- Changes seek to provide clarity - counter-blow to FCA cases with expansive readings of the Stark Law (e.g., *Tuomey* case)
- 3 basic questions:
  - Does the arrangement make sense to accomplish the parties’ goals?
  - How did the parties calculate the remuneration?
  - Did the calculation result in compensation that is FMV for the asset, item, service, or rental property?

*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
  - Unit-based compensation “deeming rules” superseded

# Volume or Value of Referrals or Other Business Generated

## Mathematical Formula Examples

### Compensation from physician:

Physician leases medical office space from a hospital for \$5,000/month. Monthly charges are reduced by \$5 for each diagnostic test ordered by the physician and furnished at the hospital

#### Mathematical Formula:

*Compensation = \$5,000 – (\$5 x the number of DHS referrals)*



# Volume or Value of Referrals or Other Business Generated

## Mathematical Formula Examples

### Compensation to physician:

Physician organization (not a group practice) pays a physician 50% of collections attributed to a physician (the physician's "pool"), including personally performed services and services furnished by the organization – which includes DHS that the physician ordered but did not personally perform.

### Mathematical Formula:

*Compensation = (.50 x collections from personally performed services) + (.50 x collections from referred designated health services) + (.50 x collections from non-designated health services referrals)*

# Fair Market Value and General Market Value

42 CFR §411.351

- Re-organization and slight modifications for clarity
  - Fair Market Value - generally: value in an arm's length transaction, consistent with the general market value of the subject transaction
    - Specific definitions for equipment and office space rentals
  - General Market Value: different definitions for assets, services, and equipment or office space rentals
    - Fundamentally, considers whether the amount would be paid by well-informed parties not otherwise in a position to generate business for each other
- Removes reference to “volume or value” standard to “disentangle” concepts
- Cautions against over-reliance on salary surveys

**In Other Good News...**

# In Other Good News...



## Indirect Compensation Arrangements (Stark)

- Narrows scope of what constitutes such an arrangement
- Varies with volume/value AND (1) individual unit of compensation is not FMV, or includes physician's referrals or other business generated



## Personal Services Safe Harbor (AKS)

- *Aggregate* compensation no longer needs to be set in advance (methodology, as opposed to exact dollar amount, suffices)
- Eliminates requirement for part-time arrangements to specify exact schedule, precise length, and exact charge per interval



## EHR Items and Services AKS Safe Harbor/Stark Exception

- No more sunset date – permanent
- After initial implementation, generally allows collection of cost-sharing at a “reasonable interval” (not required in advance)

# Speakers



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