Morgan Lewis

FAST BREAK: REGULATORY SPRINT PART 1

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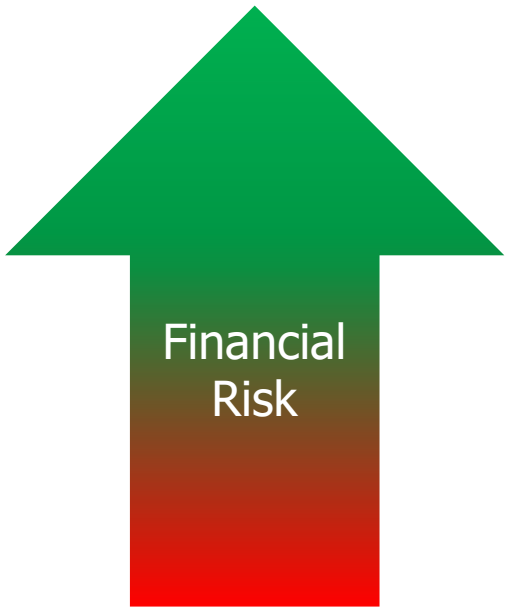
Agenda

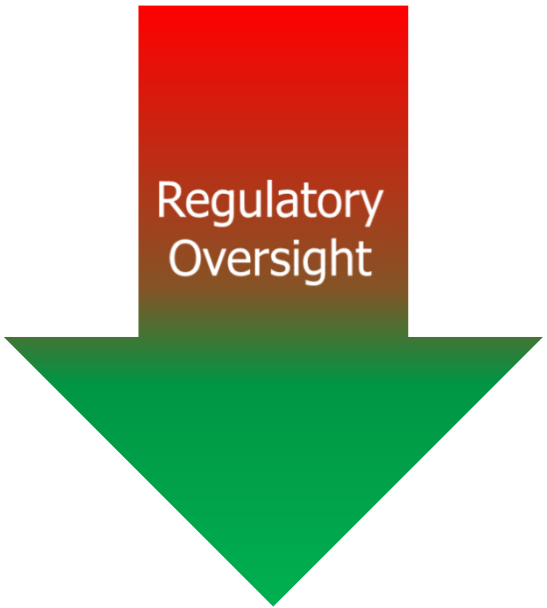
- The role of financial risk in the proposed value-based Stark Law exceptions and AKS safe harbors
- How providers will make use of the proposed value-based exceptions
- Other important Stark Law exceptions
- Changes designed to reduce regulatory burdens imposed by the Stark Law

THE ROLE OF FINANCIAL RISK IN THE PROPOSED VALUE-BASED STARK LAW EXCEPTIONS AND AKS SAFE HARBORS

VBE Theory

- Both CMS and OIG approach value-based regulations the same way:





Levels of Risk

- Both proposed rules use 3-tiered classification system
  - Increasing requirements to meet exception/safe harbor as financial risk decreases

- Stark Law (CMS Rule)
  - Full financial risk
  - "Meaningful" downside risk (25% of value of remuneration is at risk)
  - Value-based arrangement (no downside risk)

- AKS (OIG Rule)
  - Full financial risk
  - Substantial downside risk
  - Care coordination agreements (no downside risk)

Similar, But Different

- Although the proposed rules were released in concert and are meant to be considered together, there are several important differences

- OIG acknowledges that, because of the different statutory structures and penalties associated with the Stark Law and the AKS, the AKS safe harbors are intentionally more restrictive, including with respect to:
  - Commercial reasonableness
  - Only in-kind remuneration
  - Recipient must contribute 15% of the cost of the in-kind remuneration

- Practical effect of meeting Stark Law exception but not AKS safe harbor?

Fair Market Value

- Perhaps the most notable feature of the new exception/safe harbors is the absence of any fair market value (FMV) requirement
  - FMV typically forms the main "goal posts" – for courts and counsel alike- in assessing whether an arrangement is permissible
  - VBE arrangements, however, do not need to be FMV
    - CMS rule also does not require commercially reasonable compensation and permits compensation based on volume or value of referrals
  - Remains to be seen how providers will react to this aspect of the proposed rule, given there may be no AKS safe harbor protection in many situations

Important Definitions

- *VB Activity* - the provision of items and services; taking an action; or not taking an action. Making a referral is not a VB activity.

- *VB Arrangement* - an arrangement between VB participants where at least one VB Activity is provided to a target population

- *VB Purpose* - coordinating/managing care for a target population; improving quality of care for a target population; appropriately reducing costs to or growth in expenditures of payors without reducing quality; and transitioning care delivery from volume-based (*i.e.*, FFS) to value-based

- *VB Participant* - a person or entity that is engaged in at least one VB Activity

HOW PROVIDERS WILL MAKE USE OF THE PROPOSED VALUE-BASED EXCEPTIONS

Who Stands to Use These Exceptions

- CMS and OIG want all providers and suppliers to enter into value-based arrangements in some form
- However, as the ACO experience shows, most except for large health systems and physician groups are hesitant to take on the downside financial risk these rules promote
- In addition, many other healthcare stakeholders are directly excluded from VBE arrangements
  - Pharma
  - Manufacturers
  - PBMs
  - Wholesalers and distributors

OTHER IMPORTANT STARK LAW CHANGES

New Definitions / Fundamental Terminology

- **Commercially Reasonable**
  - The particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements.
  - Commercial reasonableness does not require that the arrangement result in a profit for one or more of the parties.

New Definitions / Fundamental Terminology

- **Fair Market Value (FMV)**
  - Generally, the value in an arm's-length transaction, with like parties and under like circumstances, of like assets or services, consistent with the general market value of the subject transaction – the value to hypothetical parties in a hypothetical transaction.
  - General market value is the price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement – the value to actual parties to a transaction.
  - Revised definitions of FMV for equipment and space rental also proposed.

New Definitions / Fundamental Terminology

- **Volume or Value / Other Business Generated Standard**
  - Compensation from an entity to a physician takes into account the volume or value of referrals or other business generated by the physician only when:
    - the formula used to calculate the compensation includes as a variable the physician's referrals or other business generated, resulting in an increase or decrease in compensation that positively correlates with the number or value of referrals or other business generated for the entity; or
    - there is a pre-determined, direct correlation between the physician's prior referrals to or other business generated for the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement.
  - Also addresses compensation from physician to entity.
  - Recent 3rd Circuit opinion?

New Definitions / Fundamental Terminology

- **Clarifications**
  - FMV requirement is separate and distinct from volume or value / other business generated standard.
  - For employed physicians, a productivity bonus will not take into account the volume or value of referrals solely because corresponding hospital services are billed each time the physician personally performs a service.
  - Under a personal service arrangement, a unit-based compensation formula for personally performed services that meets the special rule for unit-based compensation will not take into account the volume or value of referrals even when the entity bills for designated health services that correspond to the personally performed services.

REDUCING THE STARK LAW REGULATORY BURDEN

New Exceptions

- **Limited Remuneration to Physician**
  - Applies to items or services provided by physician to entity not exceeding $3,500 per calendar year, adjusted for inflation.
  - Compensation not determined in any manner that takes into account volume or value of referrals or other business generated.
  - Compensation doesn't exceed fair market value.
  - Arrangement is commercially reasonable.

Changes to Reduce Regulatory Burdens

- **Writing and Signature Requirements**
  - The requirement for a written signed agreement is satisfied if:
    - the compensation arrangement meets an exception except with respect to the writing and signature; and
    - the parties obtain the required writing and signature within 90 days.
- **Period of Disallowance**
  - Deleted delineation of period of disallowance.

Changes to Existing Exceptions

- **Isolated Transaction**
  - Isolated financial transaction defined as transaction involving a single payment between two or more persons or a transaction that involves integrating related installment payments if:
    - the total payment is fair market value and does not take into account the volume or value of referrals or other business generated; and
    - payments are immediately negotiable, guaranteed by a third party, or secured by promissory note.
  - Does not include a single payment for multiple or repeated services.
- **EHR Donation**
  - Added cybersecurity technology and services.
- **Compliance with AKS and Billing Requirements**
  - Eliminated from exceptions.
- **Compliance with Requirements when Referrals to a Particular Provider is Required**
  - Added to employment, personal services, group practice arrangements, and fair market value compensation exceptions.

What To Do Next

- **Comment**
  - Although these rules reflect substantive reforms, CMS and OIG appear open to healthcare stakeholders' opinions
  - The agencies consistently request input from the provider community, which suggests that stakeholders have the ability to influence the final rules
  - Evaluate the impact the proposed rules might have on your organization and its future plans and assess how changes to these proposals could be beneficial
- **Collaborate**
  - Value-based arrangements promote collaborative arrangements between physicians, hospitals, and other healthcare providers
  - CMS and OIG have shown no signs of backing off of value-based models so it is likely an eventuality for all providers
  - Developing clinically integrated networks and value-based arrangements now may lead to competitive advantages in the near- and long-term

Thanks!

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Al focuses his practice on counseling healthcare companies of all types on regulatory, fraud and abuse, Stark law, Medicare reimbursement, and transactional matters. Al devotes a substantial portion of his practice to corporate compliance issues, including internal and government investigations, and has experience representing clients before regulatory agencies such as the Centers for Medicare and Medicaid Services (CMS), the US Department of Health and Human Services' Office of Inspector General, and the Provider Reimbursement Review Board.

Thanks!

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Donna advises healthcare providers on issues concerning US federal laws governing the relationships between physicians and other healthcare providers, and the entities to which they refer patients. Donna has practiced healthcare law exclusively for nearly 35 years and is intimately familiar with the potential issues healthcare providers may encounter, as well as the solutions available to them. Donna also advises on structuring joint ventures and contractual relationships in compliance with laws governing referral relationships, including the federal and state Anti-Kickback Statute and Stark Law, and assists in investigations when problems arise.

Join us next month!

Please join us for next month's webinar:

"*Fast Break*: Regulatory Sprint Part 2"

Featuring Matt Hogan and Katie McDermott

➢Wednesday, November 20 3:00 PM (EST)