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Stark Law Overhaul

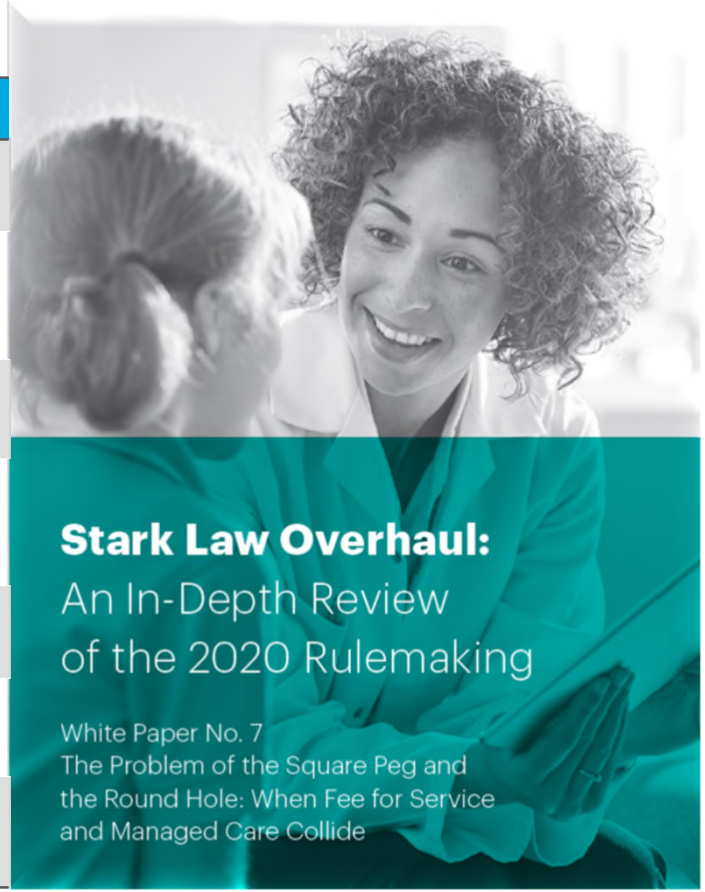
An In-Depth Series on CMS's New Final Rule

Webinar 7

The Problem of the Square Peg and the Round Hole: When FFS and Managed Care Collide

Stark Law Overhaul Series

Date	Topic
March 18	Rolling Up Our Sleeves: A Stark Law Refresher (and Clearing the Brush)
April 1	Separating the Wheat From the Chaff: Technical Requirements, Low-Dollar Violations, and Payment Discrepancies
April 15	Key Standards (Part I): The 'Volume or Value' Standard
April 29	Key Standards (Part II): The 'Fair Market Value' and 'Commercial Reasonableness' Standards, and Indirect Compensation Arrangements
May 13	New Wine in Old Bottles: Providing Greater Flexibility Under Existing Exceptions
May 27	What's Past is Prologue: Technology Subsidies Part Deux
June 10	**The Problem of the Square Peg and the Round Hole: When FFS and Managed Care Collide**



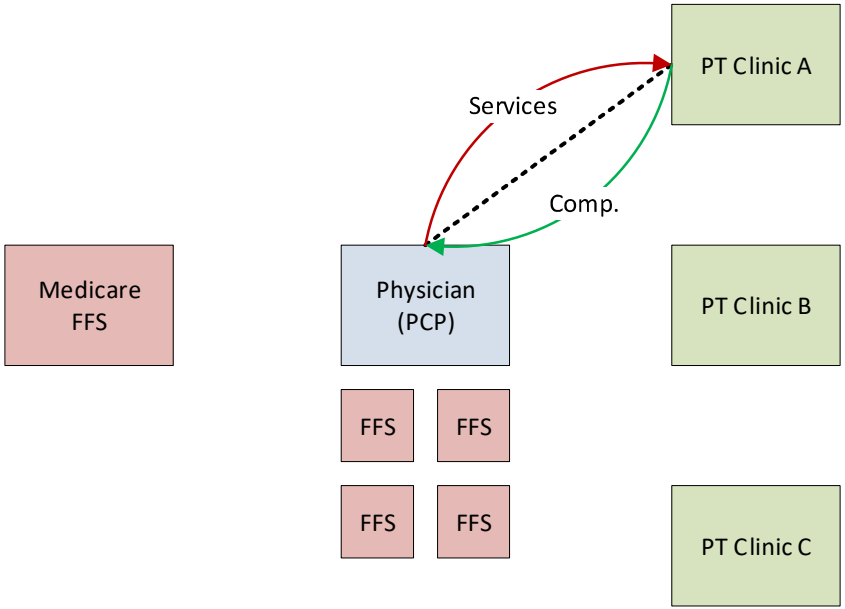
Agenda

- Introduction
- Key Definitions
- Common Requirements
- Full Financial Risk Exception
- Meaningful Downside Financial Risk Exception
- Value-Based Arrangement Exception
- Application to Indirect Compensation Arrangements (ICAs)
- Q&A (Time Permitting)

Introduction

Stark Law Enacted to Address FFS Concerns

- The Stark Law was enacted in the late 1980s to address public policy concerns that are unique to a fee-for-service (FFS) system driven by volume-based reimbursement.
  - Overutilization
  - Increased Costs
  - Patient Steering
  - Unfair Competition
- Principal Tools
  - Volume/Value Standard
  - Fair Market Value Standard

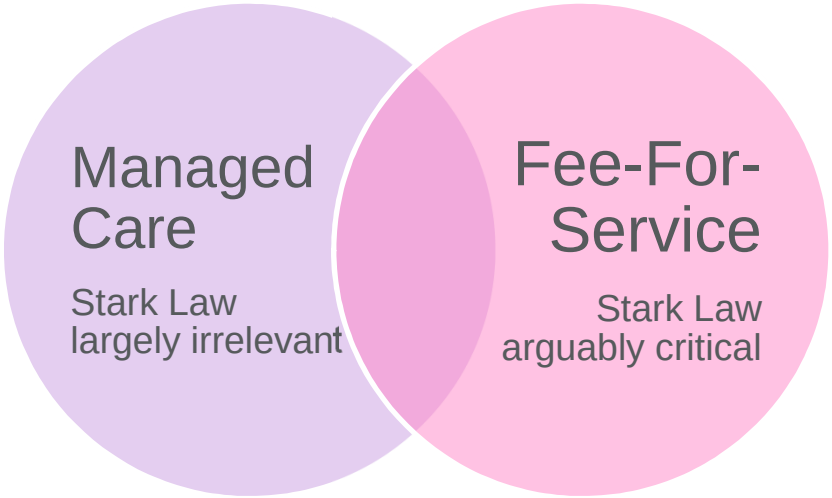


Comparison to Managed Care World

- **Managed Care: FFS public policy concerns don't apply.**
  - Overutilization: Not a concern; the worry is just the opposite: underutilization ("stinting").
  - Increased Costs: Not a concern; Medicare pays $100 whether cost of care is $80, $100, or $120.
  - Patient Steering: Not a concern; that's the "managed" in "managed care."
  - Unfair Competition: Not a concern; insurers and providers negotiate based on price, quality, etc.
- Volume/Value Standard
  - Doesn't work; to manage costs, providers may need to be rewarded for ordering **fewer** items/services.
  - So compensation ***will*** vary based on the volume or value of services.
- FMV Standard
  - Doesn't work; to manage costs, providers may need to be rewarded for **doing nothing**.
  - What's the FMV of doing nothing?

Transition from FFS to Managed Care

- Once upon a time, the managed care and FFS worlds were largely distinct.
  - **Managed Care**: Some beneficiaries chose to enroll in MA plan; CMS paid MAO sponsoring the plan a capitated amount per beneficiary; MAOs negotiated network provider agreements. Program costs easier to manage because **MAO** assuming risk.
  - **FFS**: All other beneficiaries participated in FFS; providers billed CMS directly (not MAOs). Program costs harder to manage because **government** assuming risk.
- Over the past 10-15 years, CMS has been actively exploring arrangements pursuant to which non-MAOs (e.g., ACOs, DCEs, providers) are paid (like MAOs) to **manage** the care of **FFS** beneficiaries.



Role of Value-Based Exceptions

- Physicians, DHS Entities, and other organizations participating in “hybrid” programs—and in similar programs offered by commercial insurers—have complained for years that the Stark Law, principally due to the operation of the Volume/Value and FMV Standards, has made it difficult and/or impossible to safely participate in these programs.
- The Final Rule represents CMS’s first, full-blown effort to address these concerns and, thereby, jump-start interest in these programs.
- As a threshold matter, and critically, **none of the three new “value-based exceptions” includes Volume/Value or FMV Standards**.
- Instead, the exceptions rely on a series of (i) interlocking definitions, (ii) common requirements, and (iii) exception-specific requirements that, collectively, are intended to lower Medicare program costs by permitting at least **some** financial incentives to be provided to at least **some** physicians to engage in at least **some** patient steering, with the government’s ultimate hope (prayer?) being that—when all is said and done—not too much patient autonomy and care quality will have been lost in the shuffle.

Key Definitions

Value-Based Arrangement

- All three Value-Based Exceptions apply to remuneration paid under a **value-based arrangement**.
- A “value-based arrangement” means an arrangement:
  - for the provision of at least one “**value-based activity**”
  - for a “**target patient population**”
  - to which the only parties are
    - the “**value-based enterprise**” (VBE) and one or more of its “**VBE participants**” *or*
    - VBE participants in the same value-based enterprise.

Parties to a Value-Based Arrangement

VBE Participant

- a person or entity that engages in at least one **value-based activity** as part of a **value-based enterprise**

Value-Based Enterprise

- two or more **VBE participants**
  - collaborating to achieve at least one **value-based purpose**,
  - each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise,
  - that have an "**accountable body or person** responsible for the financial and operational oversight of the value-based enterprise," and
  - that have a "**governing document** that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s)"

Value-Based Enterprise

Legal Structures

- No limit on allowable legal structures
- Examples
  - Distinct legal entity (e.g., ACO)
  - Only the two parties to a value-based arrangement with written documentation recording the arrangement

Accountable Body or Person

- Examples
  - Governing board
  - Committee of governing board
  - Corporate officer of legal entity that is the VBE (if VBE is a separate legal entity)
  - The party to a value-based arrangement that is designated as being responsible for the financial and operational oversight of the arrangement between the parties

Value-Based Purpose

- A “value-based purpose” means any of the following:
  - **coordinating and managing care** of a target patient population,
  - **improving quality of care** for a target patient population,
  - appropriately **reducing costs to or growth in expenditures of payors** without reducing the quality of care for a target patient population, or
  - transitioning from health care 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 target patient population.

Value-Based Activity

- A “value-based activity” means:
  - an activity that consists of (1) the provision of an item or service, (2) the taking of an action, or (3) the refraining from taking an action,
  - provided that the activity is “**reasonably designed**” to achieve at least one **value-based purpose** of the value-based enterprise.
- **What does it means for an activity to be “reasonably designed”?**
  - “[N]othing in our final regulations requires that the value-based purpose(s) must be *achieved* in order for a value-based arrangement to be protected” under a Value-Based Exception.
  - But the parties must have a “**good faith belief**” that the activity “will achieve or lead to the achievement of at least one value-based purpose of the value-based enterprise.”
    - If the parties are aware that the activity “will not further the value-based purpose(s) of the value-based enterprise,” the activity “will cease to qualify as a value-based activity and the parties may need to amend or terminate their arrangement.”
  - **Open question:** *Is there an affirmative duty to monitor the effectiveness of a value-based activity?*

Target Patient Population

- A “target patient population” means:
  - an identified patient population
  - selected by a value-based enterprise or its VBE participants based on “**legitimate and verifiable**” **criteria** that
    - are “**set out in writing**” in advance of the commencement of the value-based arrangement and
    - further the value-based enterprise’s value-based purpose(s).

Legitimate and Verifiable Criteria

- Whether criteria are “legitimate and verifiable” will depend on the “facts and circumstances.”
- Example of legitimate and verifiable criteria could include:

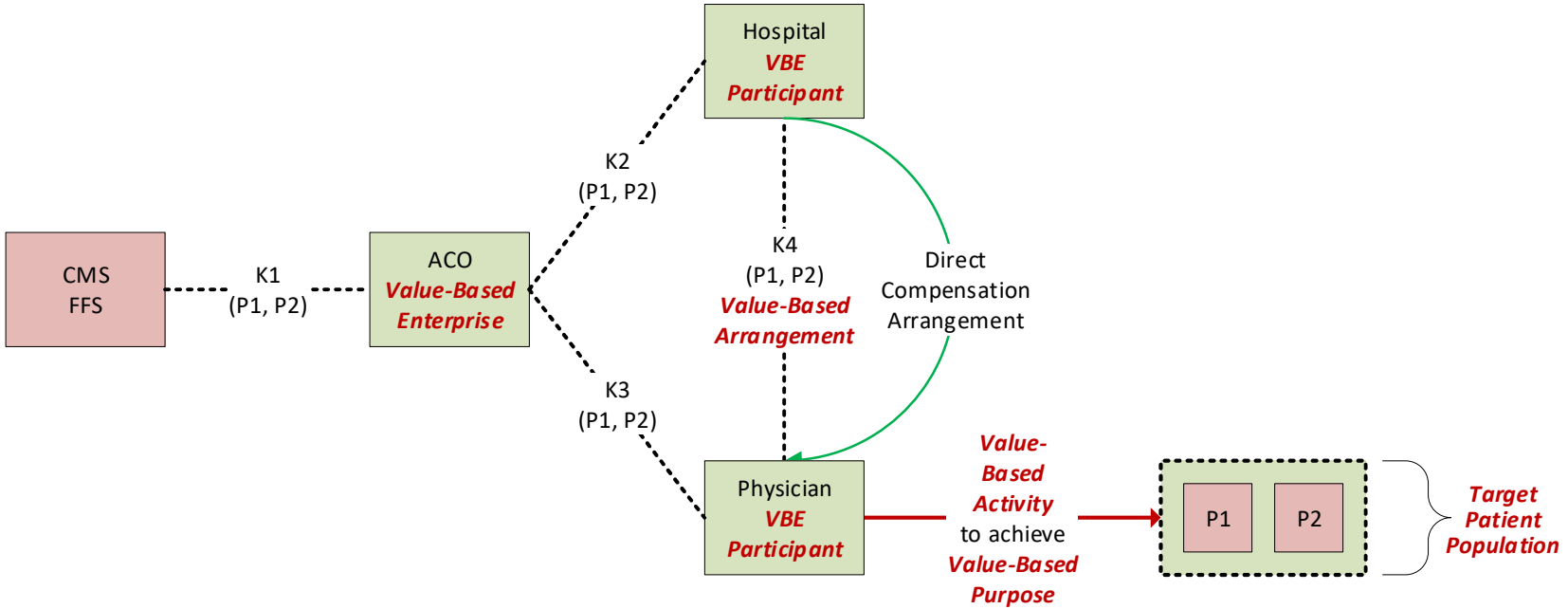
Medical or Health Characteristics	Geographic Characteristics	Payor Status
• Patients undergoing knee replacement surgery • Patients with newly diagnosed type 2 diabetes	• All patients in an identified county or zip code	• All patients with a particular health insurance or payor

- Selecting a target patient population “consisting of only lucrative or adherent patients (**cherry-picking**) and avoiding costly or noncompliant patients (**lemon-dropping**)” would not be permissible “under most circumstances.”

Hypothetical

- ACO has entered into an agreement with CMS (K1), pursuant to which ACO has agreed to manage and coordinate the care for all Medicare FFS beneficiaries within a specific county ("ACO Aligned Beneficiaries"). The ACO Aligned Beneficiaries are P1 and P2.
- ACO's participating providers include Hospital (i.e., a DHS Entity) and Physician. The ACO contracts with these providers pursuant to K2 and K3, respectively.
- Our ACO Aligned Beneficiaries (P1 and P2) are patients of both Physician and Hospital.
- Hospital and Physician, acting in their capacities as ACO participants, enter into an agreement (K4), pursuant to which:
  - Physician agrees to implement a new care protocol (Care Protocol) for the ACO Aligned Members under its care (i.e., P1 and P2); and
  - Hospital agrees to pay Physician in connection with her implementation of the Care Protocol.

Hypothetical



Common Requirements

Common Requirements for All Three Exceptions

- The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
- The remuneration is **not an inducement to reduce or limit medically necessary items or services to any patient**.
- The remuneration is **not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement**.
- If the remuneration is conditioned on referrals of patients who are part of the target patient population, the conditions of the Required Referrals Special Rule must be met.
  - The Required Referrals Special Rule requires, among other things, that the referral requirement must be "set out in writing and signed by the parties."
- Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary of HHS upon request.

Exclusion of Some “Traditional” Safeguards

- No FMV Standard
- No Volume/Value Standard
- CMS Rationale
  - These “traditional” safeguards may be difficult to satisfy under a value-based health care delivery and payment system, and thus might have a “chilling effect” on the transition to value-based care.

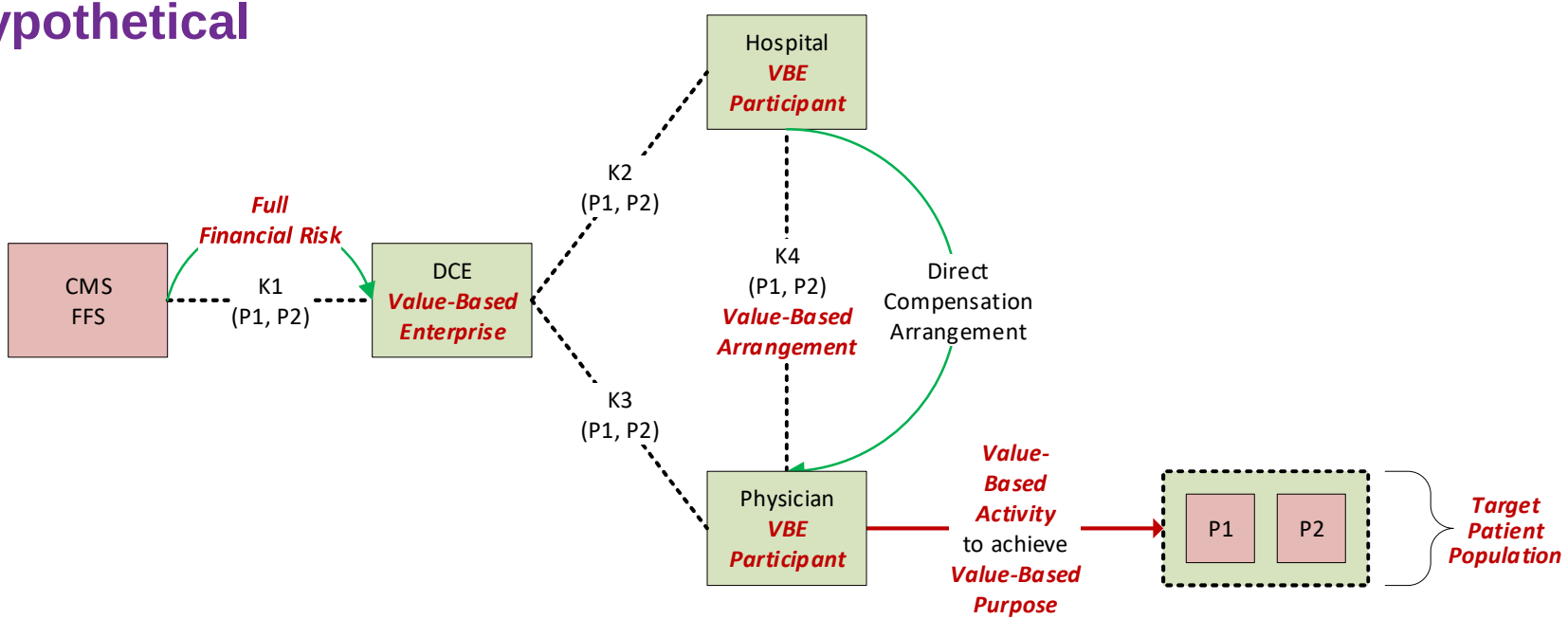
Full Financial Risk Exception

Overview

- **if**:
  - all “value-based arrangement” definitions are met, **and**
  - all Common Requirements are met,
- **then**:
  - Full Financial Risk Exception will apply if **one** condition is satisfied:

The *value-based enterprise* is at *full financial risk* (or is contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) during the *entire duration* of the value-based arrangement.

Hypothetical



- The “full financial risk” test applies to **K1**: The arrangement between the VBE and CMS.
- The arrangement actually being protected is **K4**: The value-based arrangement between the two VBE participants.

“Full Financial Risk” Defined

- Full financial risk means
  - The ***value-based enterprise*** is
    - financially responsible on a ***prospective basis***
    - for the cost of ***all*** patient care covered by the applicable payor
    - for each patient in the target patient population.
- **All patient care items and services covered by the applicable payor for the target patient population**
  - Where the payor is Medicare, this means that the VBE, at a minimum, is responsible for all items and services covered under Parts A and B that are furnished to the target patient population.
  - CMS rejected requests from commenters to (i) permit coverage for smaller, defined sets of patient care items or services (like episode-based bundled payment models) or (ii) carve out certain high-cost or specialty items or services (e.g., organ transplants, pharmacy benefits) from the definition of “full financial risk.”

Assuming Full Financial Risk

No specific financial mechanism prescribed for assuming financial risk.

- Capitation payments (i.e., a predetermined payment per patient per month or other period of time).
- Global budget payment from a payor.

No specific legal mechanism prescribed for assuming financial risk.

- If VBE is separate legal entity, VBE could assume full financial risk through agreement with relevant payor.
- All VBE participants could each sign the contract for the VBE to assume full financial risk from the payor.
- VBE participants could vest a designated person with authority to contract for full financial risk on behalf of all participants (similar to an IPA).
- VBE participants could contract among themselves to assign risk jointly and severally.
- Each VBE participant could assume full financial risk for a subset of care (e.g., hospital could assume full financial risk for hospital services, physicians could assume full financial risk for physician services, etc.), provided that, in the aggregate, the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population is assumed.

Assumption of Risk on a “Prospective” Basis

On a “prospective basis” means . . .

- The VBE has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor *prior to* providing patient care items and services to patients in the target patient population.

Contract terms that are prohibited

- The contract between the VBE and payor may not allow for any *additional payment to compensate for costs incurred by the VBE* in providing specific patient care items and services to the target patient population.

Risk mitigation terms not prohibited

- E.g., risk corridors, global risk adjustments, reinsurance, or stop-loss provisions to protect against significant and catastrophic losses.
- But risk mitigation terms cannot effectively shift material financial risk back to payor.

Pre-Risk Period and “Entire Duration” Requirement

- **Pre-Risk Period**
  - VBE must be contractually obligated to be at full financial risk **within 12 months** following the commencement of the value-based arrangement.
  - **Rationale**: CMS recognized that assuming full financial risk can require extensive preparation.
- **“Entire Duration” Requirement**
  - Full Financial Risk Exception will not protect value-based arrangements “that begin at some point during a period when the value-based enterprise has assumed full financial risk, but that continue into a timeframe when the safeguards intrinsic to full financial risk payment, such as the disincentive to overutilize or stint on medically necessary care, no longer exist.”

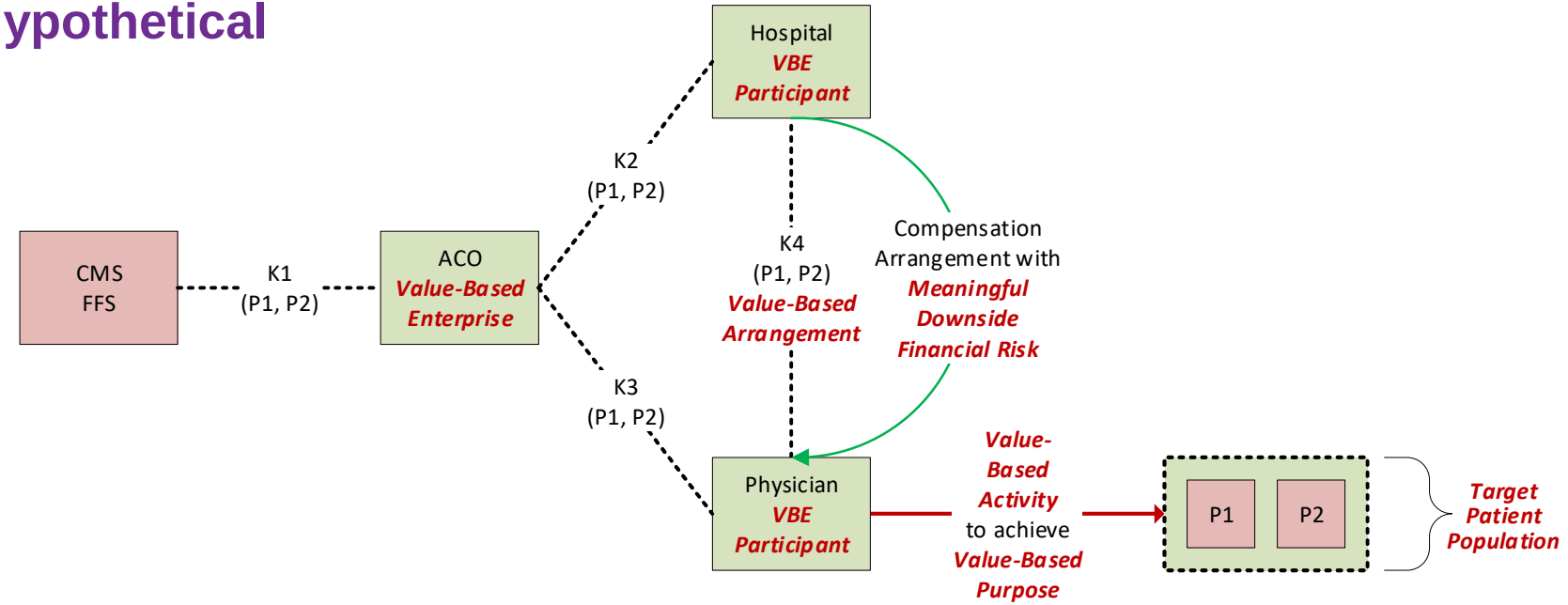
Meaningful Downside Financial Risk Exception

Overview

- **if**:
  - all “value-based arrangement” definitions are met, **and**
  - all Common Requirements are met,
- **then**:
  - Meaningful Downside Financial Risk Exception will apply if **three** conditions are satisfied:

1. The ***physician*** is at ***meaningful downside financial risk*** for failure to achieve the value-based purpose(s) of the VBE during the entire duration of the value-based arrangement.
2. A description of the nature and extent of the physician’s downside financial risk is ***set forth in writing***.
3. The ***methodology*** used to determine the amount of the remuneration is ***set in advance*** of the undertaking of value-based activities for which the remuneration is paid.

Hypothetical



- The “meaningful downside risk” test applies to **K4**: The value-based arrangement pursuant to which Physician is assuming risk.
- The arrangement being protected **also** is **K4**: The value-based arrangement between the two VBE participants.

“Meaningful Downside Financial Risk” Defined

“Meaningful downside financial risk” means . . .

- The **physician**
- is responsible to “**repay or forgo**”
- no less than **10 percent** of the total value of the remuneration the physician receives under the value-based arrangement.

No limit on type of remuneration

- May include in-kind remuneration, e.g. infrastructure or care coordination services.

“Repay or forgo”

- “Permissible options” include withholds, repayment requirements, or incentive pay tied to meeting goals or outcome measures.

Writing Requirement

Meaningful Downside Risk Exception

- The “description of the nature and extent of the physician’s downside financial risk is set forth in writing.”

Value-Based Arrangement Definition

- Selection criteria for target patient population must be set out in writing.
- VBE must have a governing document that describes the VBE and how the VBE participants intend to achieve the VBE’s value-based purpose(s).
- Any referral requirement must be set out in a signed writing (per Required Referrals Special Rule).

Set In Advance Requirement

- The **methodology** used to determine the amount of the remuneration under the value-based arrangement must be set in advance.
- The parties “need not know the **ultimate amount** of remuneration under the value-based arrangement.”

Value-Based Arrangement Exception

Overview

- **if**:
  - all “value-based arrangement” definitions are met, **and**
  - all Common Requirements are met,
- **then**, Value-Based Arrangement Exception will apply if the following conditions are satisfied:
  - The arrangement must be **set forth in writing** and signed by the parties.
  - The **outcome measures** against which the recipient of the remuneration is assessed (if any) must be objective, measurable, and selected based on clinical evidence or credible medical support, and any changes to the measures must be made prospectively and set forth in writing.
  - The methodology used to determine the amount of the remuneration must be **set in advance**.
  - The arrangement must be **commercially reasonable**.
  - The parties must conduct certain **monitoring** activities at least annually.
  - If this monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the VBE, the parties must **terminate the ineffective value-based activity**.

Writing Requirement

- The value-based arrangement must be set forth in writing and signed by the parties.
- The “writing” must include a description of:
  - The **value-based activities** to be undertaken under the arrangement,
  - How the value-based activities are expected to further the **value-based purpose(s)** of the VBE,
  - The **target patient population** for the arrangement,
  - The type or nature of the **remuneration**,
  - The **methodology** used to determine the remuneration, and
  - The **outcome measures** against which the recipient of the remuneration is assessed, if any.
- A single formal contract is not required. The writing requirement can be met through a collection of contemporaneous documents.

Outcome Measures Requirement

An “outcome measure” means . . .

- A “benchmark” that “quantifies” either:
  - improvements in or maintenance of the quality of patient care, or
  - reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.
  - Outcome measures, “if any,” must be objective, measurable, and selected based on clinical evidence or credible medical support, and any changes to the measures must be made prospectively and set forth in writing.

“if any”

- CMS explicitly recognized that “**outcome measures may not be available for or applicable to certain value-based activities**.”
  - E.g., if the value-based activity is adoption of the same EHR system or completion of training on the EHR system.
- **Open question:** Does the failure to include outcome measures where they could be “available for or applicable to” a value-based activity preclude the value-based arrangement from meeting the requirements of the Value-Based Arrangement Exception?

Commercial Reasonableness Requirement

- The arrangement must be “commercially reasonable.”
  - “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.
- **Open question:** Does the Commercial Reasonableness Requirement also apply to the Full Financial Risk Exception and the Meaningful Downside Risk Exception?
  - Based on the regulatory text: No.
  - **But** CMS used broad language in the preamble to the Final Rule.

Monitoring Requirement

- On **at least an annual basis** (or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year), the VBE must monitor:

Whether the parties have furnished the value-based activities required under the arrangement

Whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the VBE

Progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed

- **Open question:** Does the definition of a "value-based activity" create an affirmative duty to monitor under all three Value-Based Exceptions?
  - For the definition of a "value-based activity" to be met, the activity must be "reasonably designed" to achieve at least one value-based purpose of the VBE.

Termination Based on Monitoring Activities

- If monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the VBE, the parties must either:
  - Terminate the **value-based arrangement** within 30 consecutive calendar days after completion of the monitoring, or
  - Terminate the **ineffective value-based activity** within 90 consecutive calendar days after completion of the monitoring.
  - **Grace Period:** As long as either of these termination provisions are satisfied during the 30/90-day period in question, the value-based arrangement will be **deemed to comply with the "reasonably designed" requirement** during that period.
- Similarly, if the monitoring indicates that an **outcome measure** is unattainable during the remaining term of the arrangement, "the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring."

Application to ICAs

ICA Exception Special Rule

- Prior to the Final Rule, only two exceptions in 42 C.F.R. § 411.357 applied to ICAs:
  - ICA Exception, 42 C.F.R. § 411.357(p)
  - Risk-Sharing Arrangements Exception, 42 C.F.R. § 411.357(n)
- CMS recognized that these exceptions might not protect many value-based arrangements.
  - E.g., because the ICA Exception contains FMV and Volume/Value Standards.
- In the Final Rule, CMS adopted a new "special rule" confirming that **the new Value-Based Exceptions apply to certain ICAs**.
  - The Value-Based Exceptions will apply to an ICA if, in the chain of financial relationships between the DHS Entity and the referring physician, the physician (or their physician organization) is a "direct party" to a value-based arrangement.

Q&A

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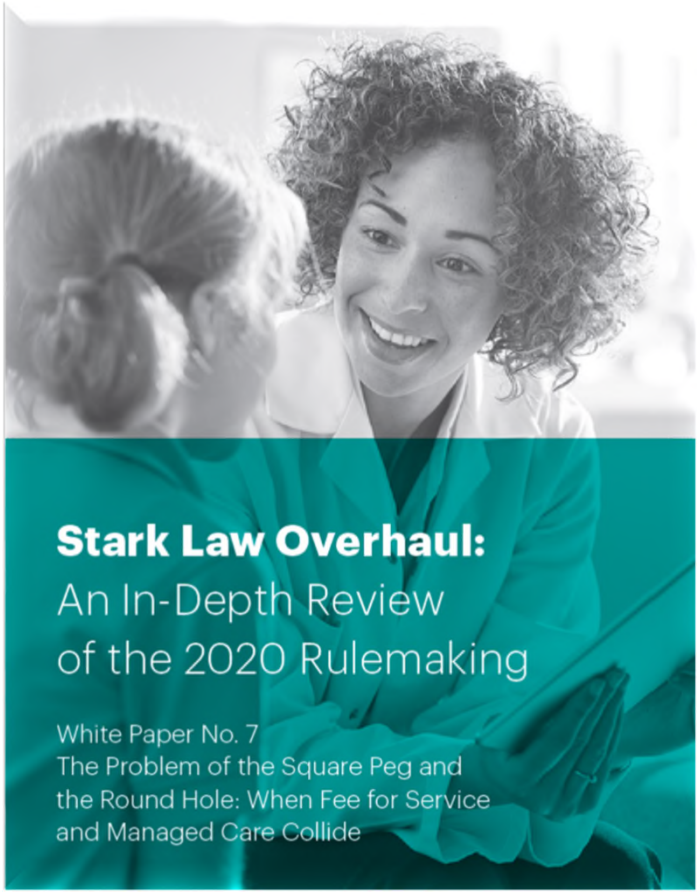

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