Stark and Anti-Kickback Final Rules: The Regulatory Sprint Crosses the Finish Line

Session Two: Value-Based Arrangements

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Agenda

- **Stark Law Regulations: Value-Based Arrangements Exceptions**
  - Definitions
  - Exceptions
    - Full Financial Risk
    - Meaningful Downside Financial Risk
    - Value-Based Arrangements (No Risk)
- **Anti-Kickback Statute Regulations: Value-Based Arrangements Safe Harbors**
  - Major differences between the Stark and Anti-Kickback regulations
  - Safe Harbors
    - Care Coordination Arrangements (No Risk)
    - Substantial Downside Financial Risk
    - Full Financial Risk
  - CMS Sponsored Models
  - Accountable Care Organization Beneficiary Incentive Programs

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Stark Value-Based Arrangement Exceptions

Stark Value-Based Arrangement Exceptions

- **Full Risk**
  - 100% downside risk to value-based enterprise

- **Physician at Meaningful Risk**
  - ≥ 10% downside risk to physician
  - Additional safeguards

- **Value-based Arrangements**
  - No downside risk required
  - Significant safeguards

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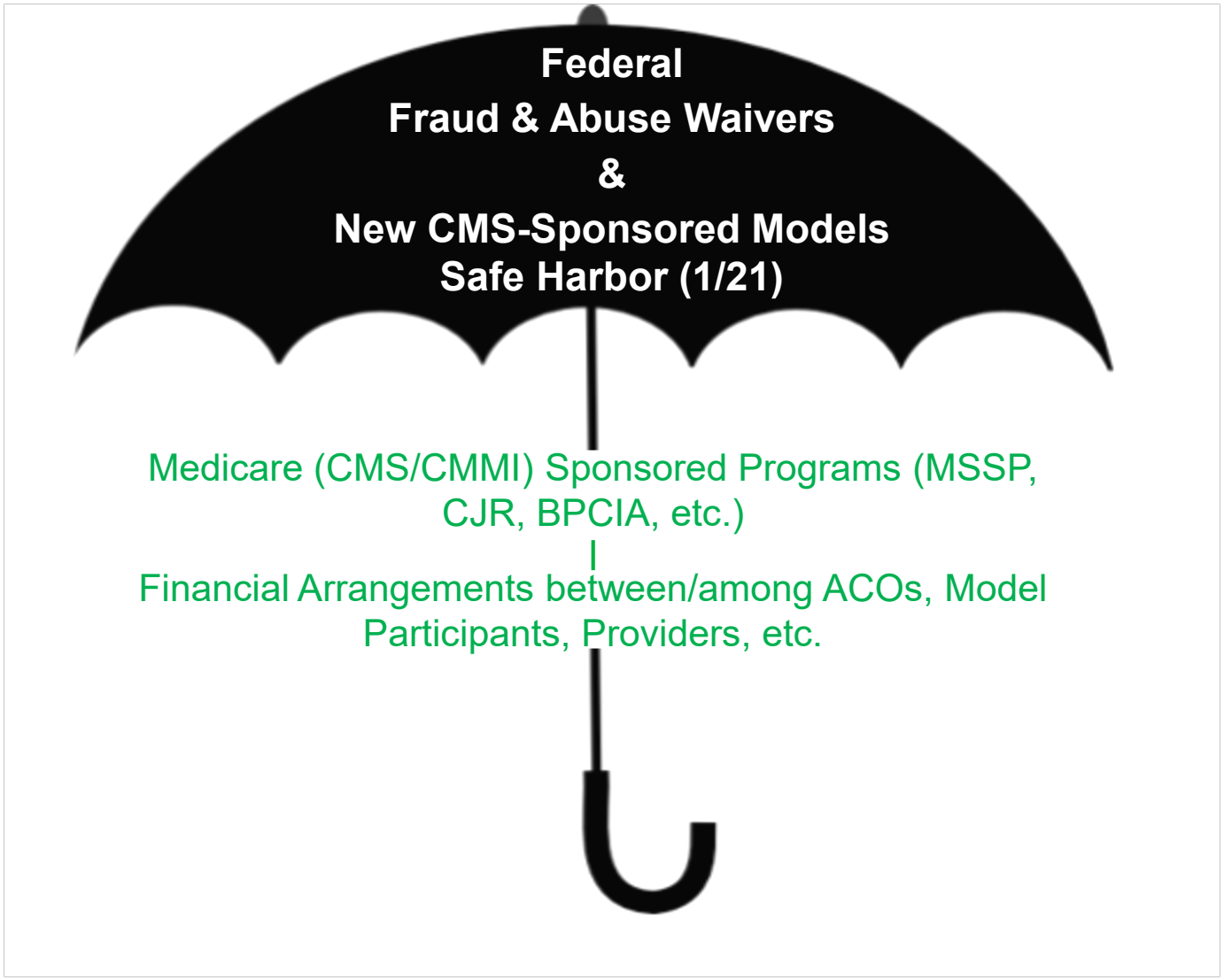
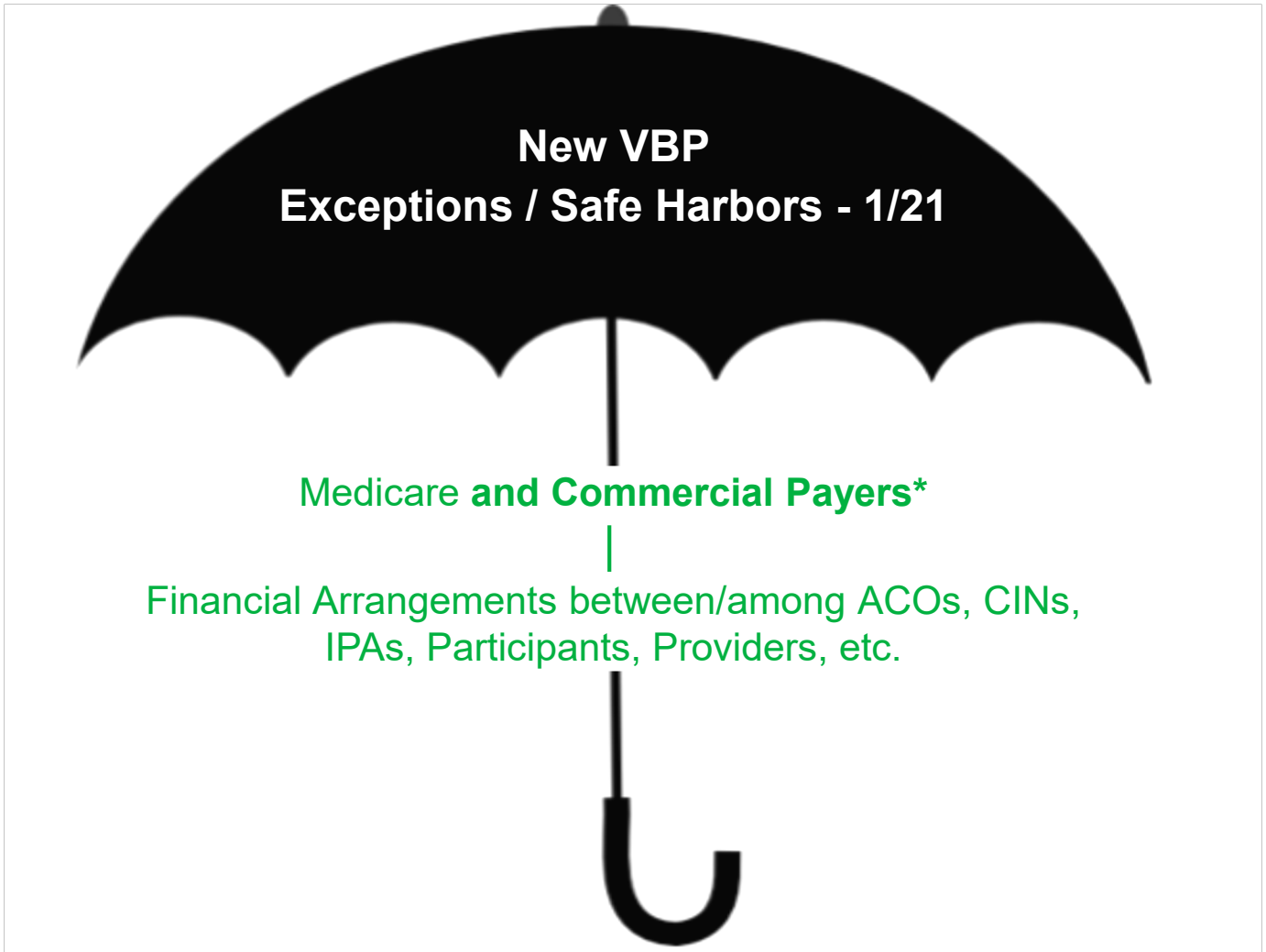
Where They Fit In…

- Financial Arrangements Exceptions
  - Ownership/Investment Interests
  - Compensation arrangements:
    - 42 CFR 411.357 (aa) Arrangements that facilitate value-based health care delivery and payment
      1. “Full financial risk” arrangements
      2. “Meaningful downside risk” to the physician
      3. Value-based arrangements

- Note: If ownership/investment relationship(s) are also present, then must meet ownership exception(s) as well.


Federal
Fraud & Abuse Waivers
&
New CMS-Sponsored Models
Safe Harbor (1/21)
Medicare (CMS/CMMI) Sponsored Programs (MSSP, CJR, BPCIA, etc.)
Financial Arrangements between/among ACOs, Model Participants, Providers, etc.



*VBP Exceptions/Safe Harbors only apply to commercial arrangements that implicate Stark/Anti-Kickback statute

Exceptions Apply To:

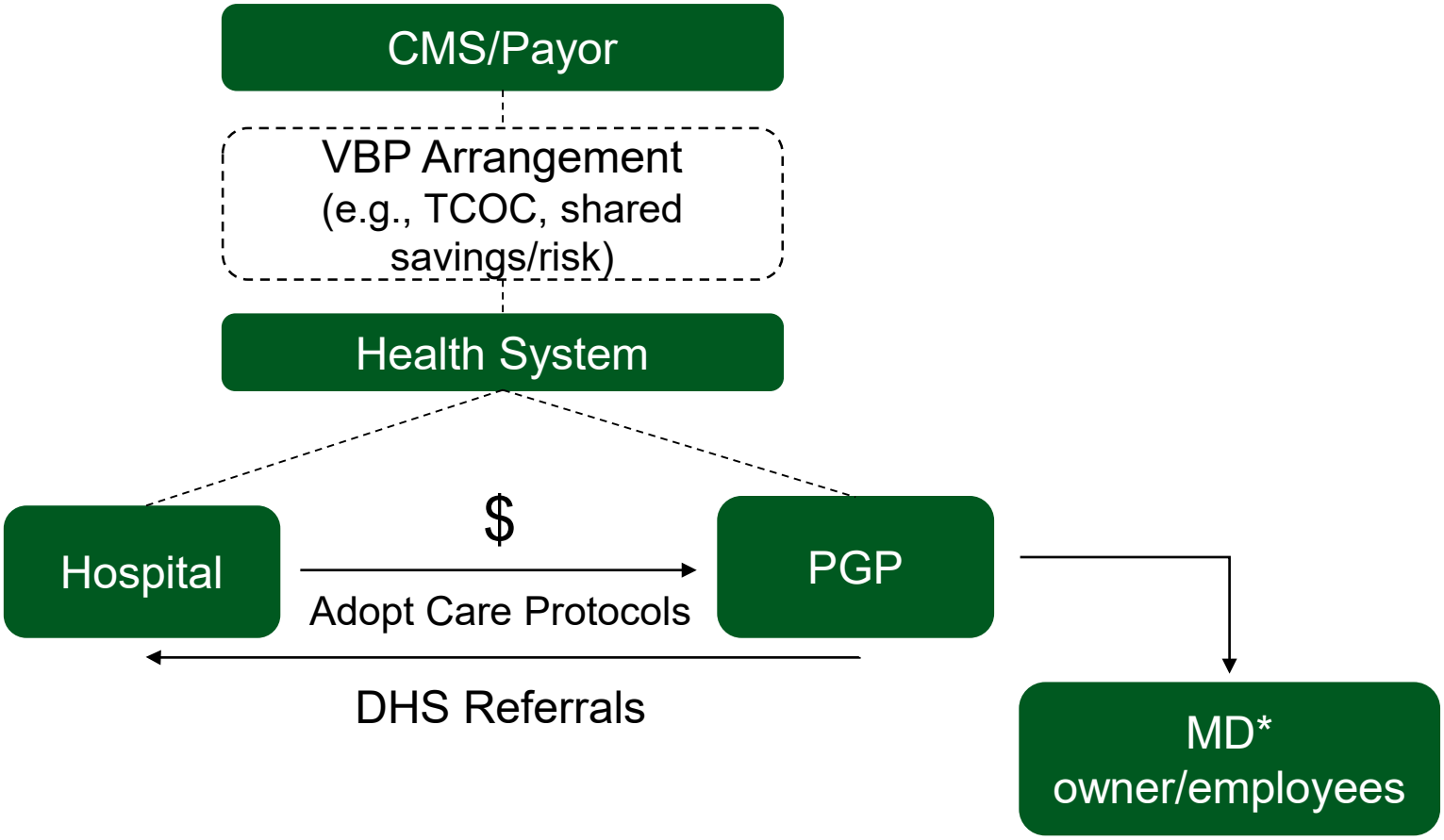
- Compensation arrangements
- Between physician and entity to which DHS are referred
- In the same value-based enterprise

- Note:

  - Do **NOT** apply to arrangements between payors and physicians (No referrals for DHS)

  - "Entity" ≠ "DHS Entity"
    - Everyday meaning

Example:



*Stand-in shoes: Each new MD to PGP creates compensation arrangement that must meet exception requirements

Definitions + Exception = Protection

Definitions (42 CFR 411.351)

- **Value-based activity**
- Value-based arrangement
- Value-based enterprise
- VBE participant
- **Value-based purpose**
- Target patient population

Value-Based Purpose

- Per CMS: One or more of these must anchor every VBP arrangement
  1. **Coordinating and managing** the care of a target population

  2. Appropriately reducing costs to, or growth in expenditures of, **payors**, without reducing the quality of care for a target population

  3. Improving the quality of care for a target population; **or**

  4. **Transitioning** from health care delivery and payment mechanisms based on the volume of term and services provided, to mechanisms based on the quality of care and control of costs of care for a target population

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“Coordinating and Managing…”

- Not formally defined
- More efficient care transitions between care settings and providers
- Fewer duplicative orders for tests, items, services
- Open sharing of EMR

Reducing Costs to Payors

- Intent of the VBP arrangement must be focused on reducing costs to payors; not the parties to the VBP arrangement

  Example: An arrangement in which the parties to a bundled payment arrangement agree to share in each other's internal cost savings, without passing along at least of some the savings to the payor, would not qualify.

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“Transitioning…”

- Undergoing the process of moving from fee-for-service (FFS) delivery/payment to value-based delivery/payment.

- Start-up, preparatory phase

- *Examples*:
  - Setting up infrastructure
    - e.g., EMR platform
  - Moving from informal arrangement to formal legal entity/structure
  - Preparing to accept risk

"Value-Based Activity"

- "Activity"
  1. Providing an item on service
  2. Taking an action; or
  3. Not taking an action

- "Reasonably Designed":
  - Good faith belief that activity will lead to achievement of ≥ one value-based purpose
  - Actual success at achieving the purpose is not required

- "Achieve ≥ one value-based purpose of the enterprise"

- *Examples*:
  - Mandatory post-discharge meeting between operating hospital and physician responsible for patient's post-discharge care in a bundle
  - Implementing disease registry
  - Participating in an HIE

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“Value-Based Arrangement”

- Arrangement (formal or informal)
- Provide ≥ one value-based activity for a target population
- Between or among:
  - A value-based enterprise and ≥ one of its value-based enterprise participants (VBE participant)

    or
  - VBE participants in the same value-based enterprise

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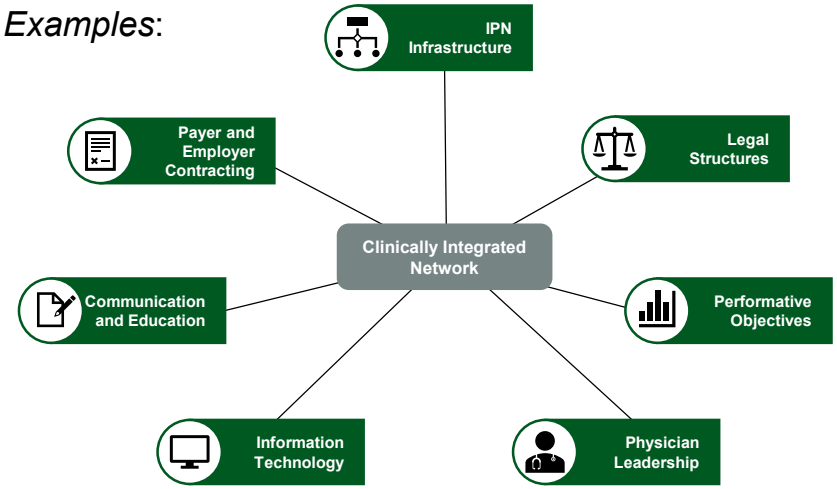
Value-Based Enterprise (VBE)

- ≥ Two VBE participants:
  - Collaborating to achieve ≥ one value-based purpose

    and
  - Each VBE participant is a party to a value-based arrangement with the other, or ≥ one other VBE participant in the same value-based enterprise
- May or may not be a separate legal entity
- Can be informal arrangement between two or more providers
- *Examples*:



Value-Based Enterprise *cont.*

- Must also have:
  - Governing body or person responsible for oversight of the enterprise
  - Governing document(s)
    - Describes the enterprise and how the participants intend to achieve its value-based purpose(s)

- *Examples*:
  - Bylaws
  - Operating Agreement
  - Transaction documents themselves
  - Statement of Purpose

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VBE Participant

- An individual or entity engaged ≥ one value-based activity as part of a value-based enterprise

- No restrictions on individuals/entities that can be VBE participants.

- *Examples*:
  - Physician(s)
  - PGPs
  - ACO, CIN, IPA
  - Hospital
  - Ancillary provider(s)

Target Population

- Identified patient population
- Selected by value-based enterprise or VBE participants
- Based on **legitimate**, **verifiable** criteria which are set **in advance** and in **writing**
- Further the value-based enterprises value-based purposes

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Target Population *cont.*

- "Legitimate and Verifiable":
  - Medical or health characteristics
    - Knee replacement patients
    - Diabetes patients
  - Geographic characteristics
    - Patients residing in certain zip codes or counties
  - Other characteristics
    - Patients attributed to certain participants based on historic claims data
  - No "cherry-picking"/"lemon dropping"
  - If payor determines attribution, VBE participant still required to ensure payor's criteria are legitimate and verifiable

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The Exceptions

Requirements Applicable to All Exceptions

1. Remuneration is "**for or results from**" the recipient's value-based activities for the target population
   - One-to-one correlation not required, but remuneration tied to other activities is not protected, e.g., marketing or sales
2. Remuneration not inducement to limit or reduce medically necessary services/items to any patient
3. Remuneration not conditioned on referrals of patients outside the target population, or on business not covered under the value-based arrangement
4. If remuneration to the physician is conditioned on referral to a particular provider (directed referrals), then:
   - The requirement is in writing and signed
   - No directed referrals if:
     - Patient chooses different provider
     - The payor determines the provider, or
     - Referral is not in the patient's best medical interest
5. Records of method used to determine, and the actual amount paid to the physician retained for ≥ six years, and available to HHS on request.

Full Risk Exception

- **Value-based enterprise** assumes **"full risk"** at the start, or **within 12 months** of start, and remains at risk for **entire duration** of the arrangement, and:
  - Value-based enterprise is prospectively responsible for cost of all patient care items and services covered by payor for each patient in the target population
  - "Prospective": The VBS enterprise has assumed financial responsibility before the services/items are provided.
    - Pre-payment (e.g. capitation at beginning of month) not required
- "All services"
  - Medicare:
    - All Part A + Part B services
  - Commercial:
    - All covered services under the target population's benefit plan(s)

Full Risk Exception *cont.*

- NO:
  - Partial capitation
  - Carve outs
- OK:
  - Catastrophic loss mitigations, e.g., stop-loss, reinsurance
  - Risk corridors
  - Shared savings
  - Quality incentive payments
- No specific payment method required
  - Presumably global capitation, percent of premium or FFS reconciled against a pre-determined budget are OK.
- Risk can be assumed by:
  - Value-based intermediate entity, e.g., ACO, CIN, PHO; or
  - VBE participants directly; risk can be apportioned among VBE participants on joint or several basis, so long as "full risk" is assumed by the VBE participants in the aggregate.

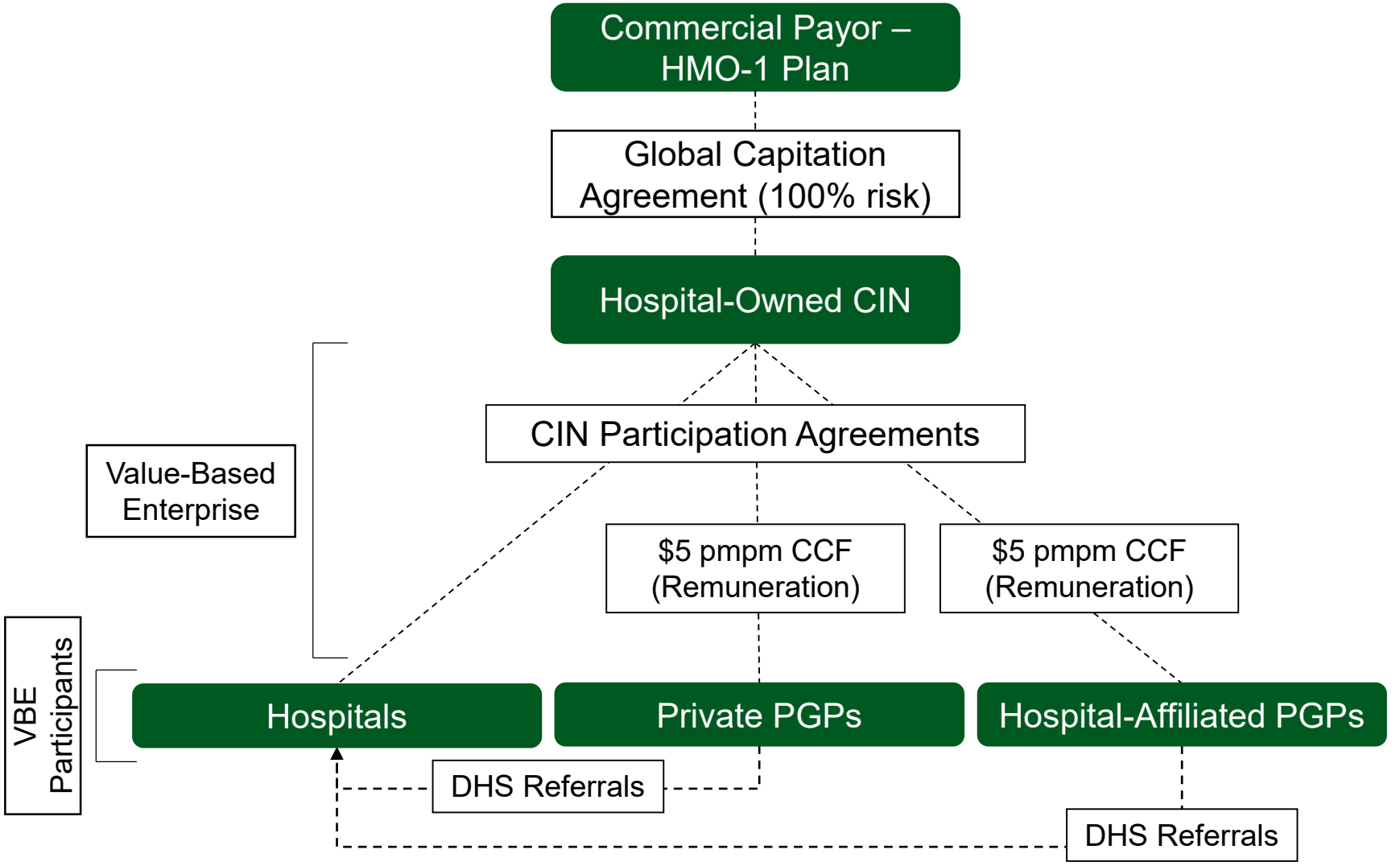
“Entire Duration”

- **“Entire Duration”**
  - ≤ one year “ramp-up” to full risk is OK
  - Arrangement cannot convert to anything other than full risk for entire term of agreement
  - Agreements ≤ one year are OK

Full Risk Exception Example

- Commercial payor
- Global capitation to hospital-sponsored Clinically Integrated Network (CIN)
- CIN “at risk” for all HMO-1 plan members who select a CIN-affiliated PCP
- CIN has hospital-affiliated and private practice physicians
- HMO-1 plan has multiple retiree members for whom Medicare is primary
- CIN pays all physicians fee-for-service (FFS) basis, with quality component (5% bonus for meeting quality metrics)
- CIN pays primary care PGPs $5 pmpm care coordination fee to coordinate/manage patients with multiple chronic conditions
- Multiple chronic condition patients attributed based on plurality of claims over prior three-year benchmark period.
- All CIN physicians admit HMO-1 plan members ≥ one hospital-sponsor of the CIN

Full Risk Exception



Physician at “Meaningful Risk” Exception

Additional Safeguards/Requirements:

- The entity is in the same value-based enterprise with the physician
- The remuneration is tied to achievement (or failure to achieve) value-based purposes of the enterprise
- The physician has assumed “meaningful” downside risk, i.e., ≥ 10% of total compensation
- Writing sets forth nature and extent of risk
  - Transaction documents suffice
- Methodology used to determine remuneration is set in advance

Meaningful Risk *cont.*

- "**At-risk**"
  - Physician is obligated to "repay or forgo" ≥ 10% of total value of remuneration received under the arrangement
    - Withholds, repayment mechanisms, quality incentive payments
- "Entire duration" of arrangement (no mid-contract conversions)
- Monetary and in-kind remuneration – OK

Physician at “Meaningful Risk” Example

- Commercial Payor/Health Plan
- Network Participation Agreement: Health system contracts on behalf of system hospitals and physicians to participate in Health Plan Network, on FFS and MS-DRG basis.
- Health system sponsored–ACO contracts with payor to manage attributed diabetes population, some of whom have Medicare primary (ESRD)
- Payor pays ACO $10 pmpm to manage payor’s diabetes spend
- ACO pays endocrinologists $5 pmpm to coordinate care of diabetes population.

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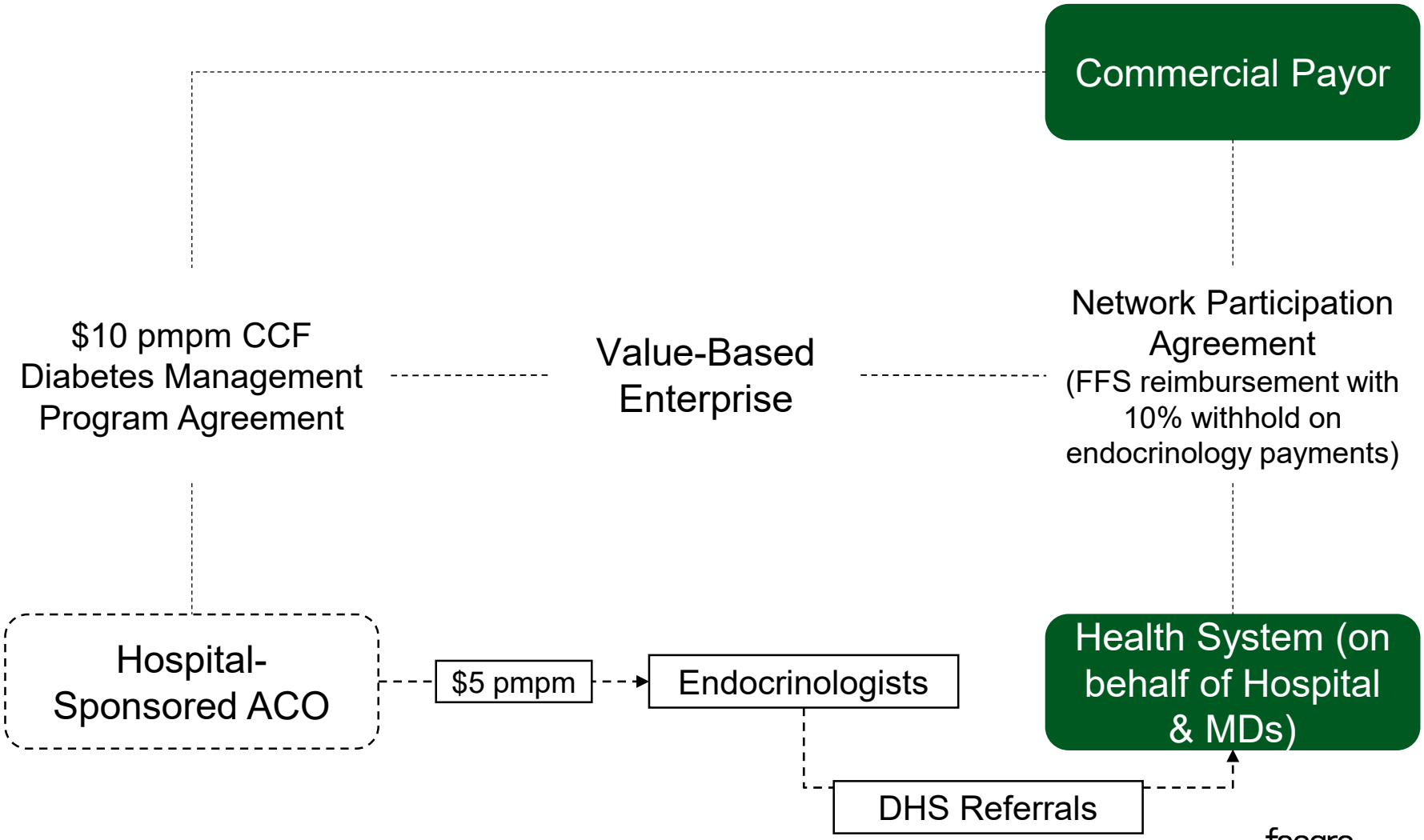
Physician at “Meaningful Risk” Example *cont.*

- ACO guarantees payor 5% savings on cost of care for attributed diabetic population.
- Endocrinologists agree to 10% withhold of FFS payments from Health Plan for attributed diabetics, and to forfeit 10% of CCF ($5 pmpm) payments if fail to achieve savings.
- If savings not achieved, withhold pool and up to 10% of total CCFs paid to physicians used to cover the amount of any shortfall.

Physician Meaningful Risk Example



Value-Based Arrangements Exception (a/k/a-No Risk)

- Arrangement is in writing, and signed, addresses:
  - Value-based activities being initiated
  - How activities are expected to further value-based purposes of enterprise
  - Target population
  - Type and nature of remuneration
  - Method to determine remuneration
  - Any Outcome Measures
- Outcome measures (if any):
  - Improvements in or maintenance of patient care quality; or cost reductions, or reductions in cost growth of payors, and maintaining or improving quality
    - Objective, Measurable and Selected based on clinical evidence or credible medical support
- Any changes to outcome measures are in writing, and prospective
- Method used to determine amount of remuneration determined in advance
- Commercially reasonable (Note: ≠ profitable)

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Value-Based Arrangement Exception Requirements *cont.*

Monitoring

- **At least annually, for:**
  1. Have the parties been performing value-based activities, and whether and how continued activities will further the value-based purpose

     and

  2. Progress toward attainment of any outcome measures that are part of the arrangement

- "Deemed" Protection:
  1. Activities
     - If as a result of monitoring, parties determine that any activity is "ineffective" in furthering the enterprise's value-based purposes, the activity is deemed to meet the "reasonably designed" test, so long as:
       a. The entire value-based arrangement is terminated within 30 days of the end of monitoring period

          or

       b. The "ineffective" activity is eliminated ≤ 90 days

  2. Outcome measures not attainable
     - If the parties determine, as a result of monitoring, that one or more outcomes measure(s) is unattainable during remaining term of the arrangement, they must eliminate or replace the measure within 90 days of end of monitoring period.

     - Failure to meet requirements within specified times renders the arrangement non-compliant

Value-Based Arrangement Example

- Health System implements Patient Centered Medical Home (PCMH) Model, with community based primary care PGPs.
- Health System pays PCPs $20 pmpm:
  - Hire embedded care coordinators
  - Acquire IT and care management software
  - Set up disease registry for co-morbid patients
- Shared savings/QI components
  - PCMH PCPs receive 50% of any savings realized on total cost of care of PCMH patients if QI metrics met; e.g.
    - Fall risk screenings
    - Annual Physical
    - Mental health screenings
    - ER utilization
    - A1C levels
  - Savings distributed in proportion to size of PCMH patient panel and score on metrics

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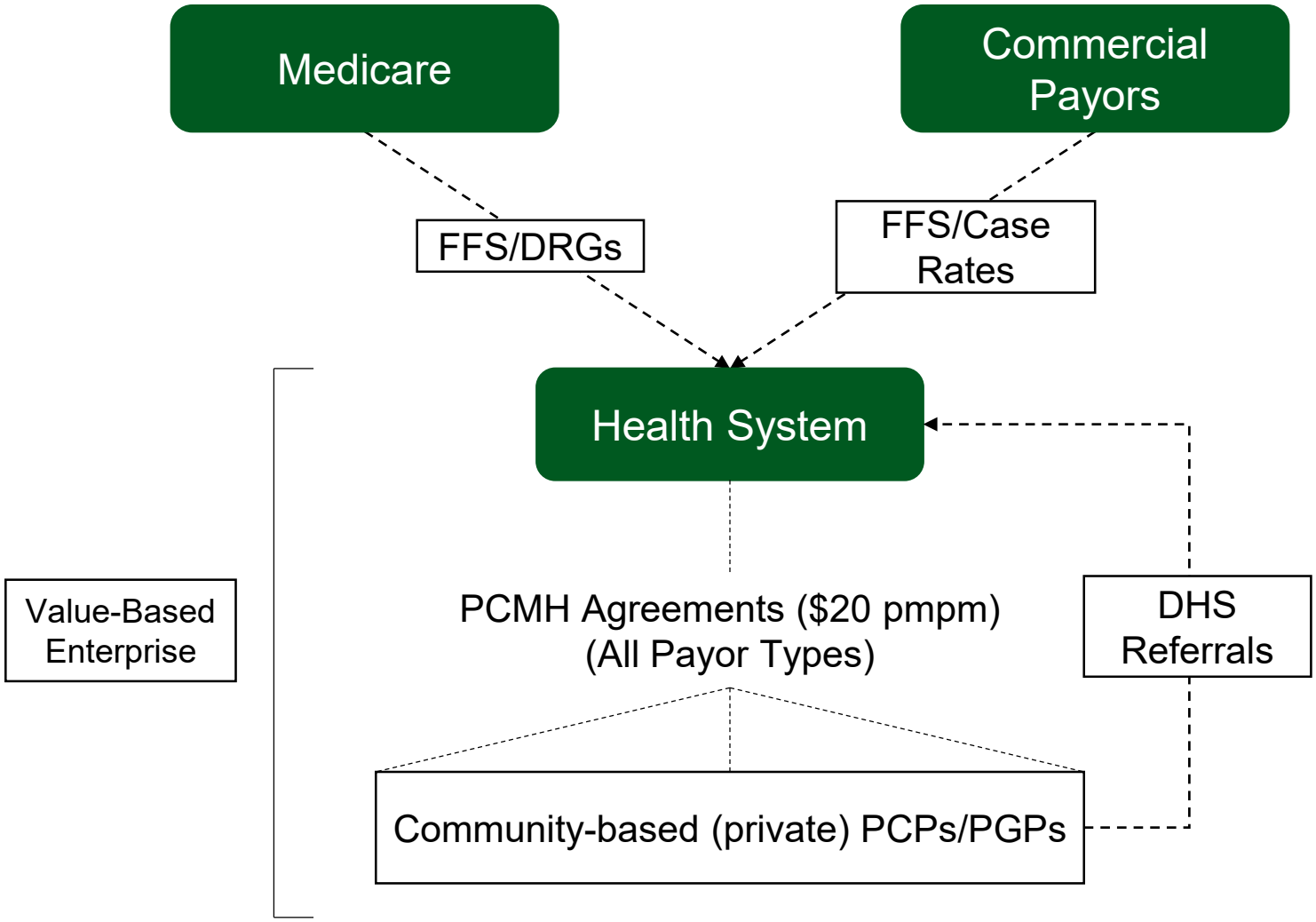
Value-Based Arrangement Exception Example



Anti-Kickback Statute

Value-Based Arrangements
Safe Harbors

Stark Law Exceptions vs. Anti-Kickback Safe Harbors

- **CMS and OIG sought to align value-based terminology and safe harbor conditions with the Stark exceptions**
- **Some differences due to fact that the Stark Law is strict-liability whereas the Anti-Kickback Statute is intent-based**
- **Value-based safe harbors are more narrow than the exceptions**
  - Exceptions = full universe of acceptable arrangements
  - Arrangements may not fit under a safe harbor but are still legal
- **Arrangements may comply with requirements of the Stark Law exceptions or Anti-Kickback safe harbors but not with the other**

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Definition Differences

- **Value-based terminology is aligned under both the Stark exceptions and Anti-Kickback safe harbors except:**

  - Value-Based Activities:
    - (i) Providing an item or service
    - (ii) Taking an action; or
    - (iii) Not taking an action
    - Must achieve at least one value-based purpose
    - *Making of a referral is not a value-based activity*.

  - Value-Based Participant
    - Definitions are aligned except around the use of the term ‘‘individual’’ in AKS rule and ‘‘person’’ in Stark rule
    - Under the Anti-Kickback Statute, patients may not be VBE participants, nor can patient family members or others acting on the patient’s behalf.

Value-Based Arrangements

Safe Harbors

Care Coordination Arrangements (No Risk) Safe Harbor

- **Protects:**
  - Only in-kind remuneration (as opposed to Stark 'no risk' which allows both)
  - Exchanged between a VBE and a VBE participant or
  - Between VBE participants pursuant to a value-based arrangement

- **Requires that remuneration be used:**
  - *Predominantly* to engage in value-based activities
  - That are directly connected to the coordination and management of care for the patient population

Care Coordination Arrangements (No Risk) Safe Harbor

- **Outcomes measures**
  - Parties must establish one or more legitimate outcome or process measures to advance the coordination and management of care
  - Measure must:
    - Include one or more benchmarks
    - Relate to the remuneration exchanged under the value-based arrangement
    - Not be based solely on patient satisfaction or convenience
  - Outcomes and benchmarks must be monitored and revised
  - No set number of outcomes prescribed
  - Parties do **not** need to successfully achieve the outcome or process measure they select in order to qualify for safe harbor protection

Care Coordination Arrangements (No Risk) Safe Harbor

- **Additional Key Requirements**

  - Commercial reasonableness
    - Arrangement must be commercially reasonable as to the arrangement itself and all the value-based arrangements within the VBE (no FMV requirement)
    - Changes in referral pattern alone are not the goal of a value-based arrangement, but may be a consequence

  - Contribution requirement
    - Must pay 15% of offeror's cost of the remuneration or 15% of FMV of the remuneration
    - If a one-time cost, pay in advance; if ongoing, make contributions at regular intervals

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Care Coordination Arrangements (No Risk) Safe Harbor

- **Additional Key Requirements**

  - Monitoring and Assessment
    - Must monitor no less than annually, or once during the term of the value-based arrangement if the term is less than one year, the following:
      - Coordination and management of care
      - Any deficiencies in the delivery of quality care under the value-based arrangement
      - Progress toward achieving the legitimate outcome or process measure

  - Termination of the Agreement
    - If there are material deficiencies in the quality of care or it is unlikely to further the coordination and management of care:
      - 60 days to either terminate the arrangement or develop and implement a corrective action plan to remedy the deficiencies within 120 days
      - If the corrective action plan fails to remedy deficiencies within 120 days, terminate the value-based arrangement

Care Coordination Arrangements (No Risk) Safe Harbor

- **Additional Requirements and Notes:**

  - Must have agreement signed by all parties (can be a collection of writings)
  - VBE participants must maintain records to show compliance for six years

  - No phase-in period
  - No patient notice requirement about participation in VBE

Substantial Downside Financial Risk Safe Harbor

- **VBE must assume "substantial downside financial risk" and a VBE participant must assume a "meaningful share" of the VBE's total risk**
- **Protects both monetary and in-kind remuneration**
- **Risk thresholds differ from those in the Stark substantial financial risk exception:**
  - OIG did not think CMS' methodology was appropriate since it focuses on physician risk arrangements rather than risk assumed at the VBE level

- **No commercial reasonableness requirement**
- **No patient transparency/notice requirement**
- **No termination provisions**
- **No outcome measure requirements**

Substantial Downside Financial Risk Safe Harbor

- **VBE can assume risk from a payor through:**
  - (i) an arrangement that is a "value-based arrangement," or
  - (ii) through a contract that places the VBE at substantial downside financial risk.

- **Provides three methodologies for calculating whether a VBE is assuming "substantial downside financial risk"**
  1. Must repay at least 30% of any shared losses when comparing expenditures to a bona fide benchmark
  2. Must repay at least 20% of any losses under an episodic or bundled payment arrangement when comparing expenditures to a bona fide benchmark
  3. VBE receives a prospective, per-patient capitated payment paid on a monthly, quarterly, or annual basis for a defined set of items and services

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Substantial Downside Financial Risk Safe Harbor

- **Meaningful Share**
  - VBE participant "meaningfully shares" in the VBE's risk if it meets one of the following:
    - VBE participant is at risk for at least 5% of the losses and savings realized by the VBE and any risk assumed by a VBE participant is two-sided risk
    - It is subject to prospective, per-patient payments for a predefined set of items and services furnished to the target patient population

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Substantial Downside Financial Risk Safe Harbor

- **Entities Ineligible for Safe Harbor Protection**

  - Remuneration cannot be exchanged by any of the following entities:
    - Pharmaceutical manufacturers, wholesalers, and distributors
    - PBMs
    - Laboratory companies
    - Pharmacies that primarily compound drugs or primarily dispense compounded drugs
    - Manufacturers of devices or medical supplies
    - Entities or individuals that manufacture, sell or rent DMEPOS (other than a pharmacy or a physician, provider or other entity that primarily furnishes services, all of whom remain eligible)
    - Medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies

Substantial Downside Financial Risk Safe Harbor

- **Additional Requirements:**
  - Six-month phase-in period
  - Remuneration must be used predominantly to engage in value-based activities
  - Remuneration must have a direct connection to at least one of three specified value-based purposes
  - Must be in a signed writing which can be satisfied by a collection of documents
    - Must be established in advance or, or contemporaneous with, the commencement of the value-based arrangement (and any material change)
  - Exchange of remuneration must be between a VBE and VBE participant

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Full Financial Risk Safe Harbor

- **Full Financial Risk**
  - Requires VBE to be at risk:
    - On a "prospective basis"
    - For the cost of all items and services covered by the payor for each patient in the target patient population
    - For a term of at least one year

- **Prospective Basis**
  - VBE has assumed financial responsibility for the cost of all items and services covered by the applicable payor prior to the provision of items and services to patients
  - VBE does not need to be prospectively paid by the payor

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Full Financial Risk Safe Harbor

- **VBE can assume risk from a payor through:**
  - (i) an arrangement that is a "value-based arrangement," or
  - (ii) through a contract that places the VBE at full financial risk.

Full Financial Risk Safe Harbor

- **Entities Ineligible for Safe Harbor Protection**

  - Remuneration cannot be exchanged by any of the following entities:
    - Pharmaceutical manufacturers, wholesalers, and distributors
    - PBMs
    - Laboratory companies
    - Pharmacies that primarily compound drugs or primarily dispense compounded drugs
    - Manufacturers of devices or medical supplies
    - Entities or individuals that manufacture, sell or rent DMEPOS (other than a pharmacy or a physician, provider or other entity that primarily furnishes services, all of whom remain eligible)
    - Medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies

Full Financial Risk Safe Harbor

- **Additional Requirements:**
  - One year phase-in period
  - Remuneration must have a direct connection to at least one of the value-based purposes (VBE has freedom to chose which one)
  - Must be in a signed writing which can be satisfied by a collection of documents
    - Must specify all material terms, including the value-based activities and term
  - Exchange of remuneration must be between a VBE and VBE participant

- **Note that the following do not apply:**
  - Remuneration must be used predominantly to engage in value-based activities
  - No outcomes measures required or public transparency requirements

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CMS-Sponsored Models Safe Harbor (1001.952(ii))

- **In General**
  - Goal: to provide uniformity and predictability
  - Purpose:
    - Allow payments between and among parties to arrangements under MSSP or a model or other initiative being tested or expanded by the Innovation Center
    - Allow payments in the form of incentives by model participants to patients

- **Scope**
  - An individual other than the model participant or its agent may furnish an incentive to a patient under a CMS-sponsored model if that is specified by the participation documentation
  - Very broad; left to CMS to determine for each model

- **Duration**
  - Remuneration may extend beyond termination of the model
  - Patients can retain incentives received prior to termination of the model
    - May be some instances where patient incentives may need to extend beyond model termination

CMS-Sponsored Models Safe Harbor (1001.952(ii))

- **Conditions**
  - Who can furnish? Must be furnished by model participant (or its agent) unless participation states otherwise
  - Patient incentives must have a direct connection to the patient's health care unless the participation documentation expressly identifies a different standard
  - Remuneration cannot induce the furnishing of medically unnecessary services or reduce or limit medically necessary care
  - Participant may not offer or receive remuneration for referrals or other businesses generated outside of the model
  - Participant must document and make records available to CMS upon request
  - CMS must affirmatively state in the participation documentation that the safe harbor applies

CMS-Sponsored Models Safe Harbor (1001.952(ii))

Other Takeaways

- **Declined to expand beyond CMS-Sponsored ACO Models**
  - Regulations rely on CMS oversight, documentation, screening, etc.
- **Deference to CMS**
  - CMS determines the specific types of financial arrangements and incentives to which safe harbor protection will apply
  - Could protect a broad range of incentives
- **Impact on existing fraud and abuse waivers**
- **Impact on future waivers**

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ACO Beneficiary Incentive Program (1001.954(kk))

- For MSSP only
- Merely codifies the statutory exemption to the definition of “remuneration” for the MSSP beneficiary incentive program (under 1899(m))
- This safe harbor protects incentive payments made by a MSSP ACO to an assigned beneficiary (participating in the initiative’s beneficiary incentive program) if the payment is made in accordance with the requirements of 1899(m).
- ACO must mee ALL requirements found in 1899(m)

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Questions?

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