STRATEGIC HEALTH LAW

Value Based Compensation
Legal and Regulatory Environment

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Ninth Conference on Right to Health
Interamericana University of Puerto Rico
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Agenda

- Overview of Health Coverage Types
- Medicare Advantage = Value Based Payment of Health Plans
- Anti-Kickback Statute and Safe Harbors = Designed to Facilitate Value Based Payment Models

Overview of Health Coverage in the U.S.

Publicly Financed

- Medicare
- Medicaid
- Children's Health Insurance Program (CHIP)
- Department of Defense
  - Veterans Administration
  - TRICARE (military)
- State Employee Plans
- Municipal Employee Groups

Privately Financed

- Private sector employer groups
  - Self funded
  - Insured
- Affordable Care Act (ACA) Marketplace plans*
- Individual private insurance
- Medicare Supplement

*Receives federal premium subsidies

Stop-Loss and Reinsurance

Available to payors, providers, and Accountable Care Organizations (ACOs) or other risk-bearing entities

Sample coverage types

- Specific Stop Loss – catastrophic claims
- Per-Member Stop Loss
- Aggregate Stop Loss – overall performance
- Bundled Payment Stop Loss – per procedure

Medicare Advantage Value-Based Payment for Health Plans

Medicare Advantage Bidding

- MA plan sponsors submit bids by the first Monday in June
- CMS has authority to negotiate with plan sponsors before accepting or rejecting a bid
- Plans submit bids with a standard bid amount that will be adjusted for enrollee risk factors or "case mix"
  - Demographic factors
  - Health risk based on claims experience and provider and plan-submitted diagnoses

Medicare Advantage Benchmarks and Quality Bonus Percentage

- CMS sets MA benchmark rates taking into account each county's per capita FFS (Original Medicare) spending
- MA plans are assigned a star rating posted on Medicare.gov based on measures in 5 domains
- Quality Bonus Percentage (QBP)
  - Added to benchmark
  - MA plans with 4 stars or above receive 5% QBP
  - New MA plans receive 3.5% QBP until star rating can be assigned based on performance data

Star Ratings Measures

1. Staying Healthy: Screenings, Tests and Vaccines
   - Ex. Colorectal cancer screening, flu shot
2. Managing Chronic (Long Term) Conditions
   - Ex. Diabetes care – eye exam, kidney disease monitoring, blood sugar controlled
3. Member Experience with Health Plan
   - CAHPS Survey results
4. Member Complaints and Changes in the Health Plan's Performance
   - Ex. Complaints, Disenrollments, Quality Improvement
5. Health Plan Customer Service
   - Ex. Timely appeals decisions based on independent review entity (IRE) data

Relationship of Bid to Benchmark

Rebates or Member Premium

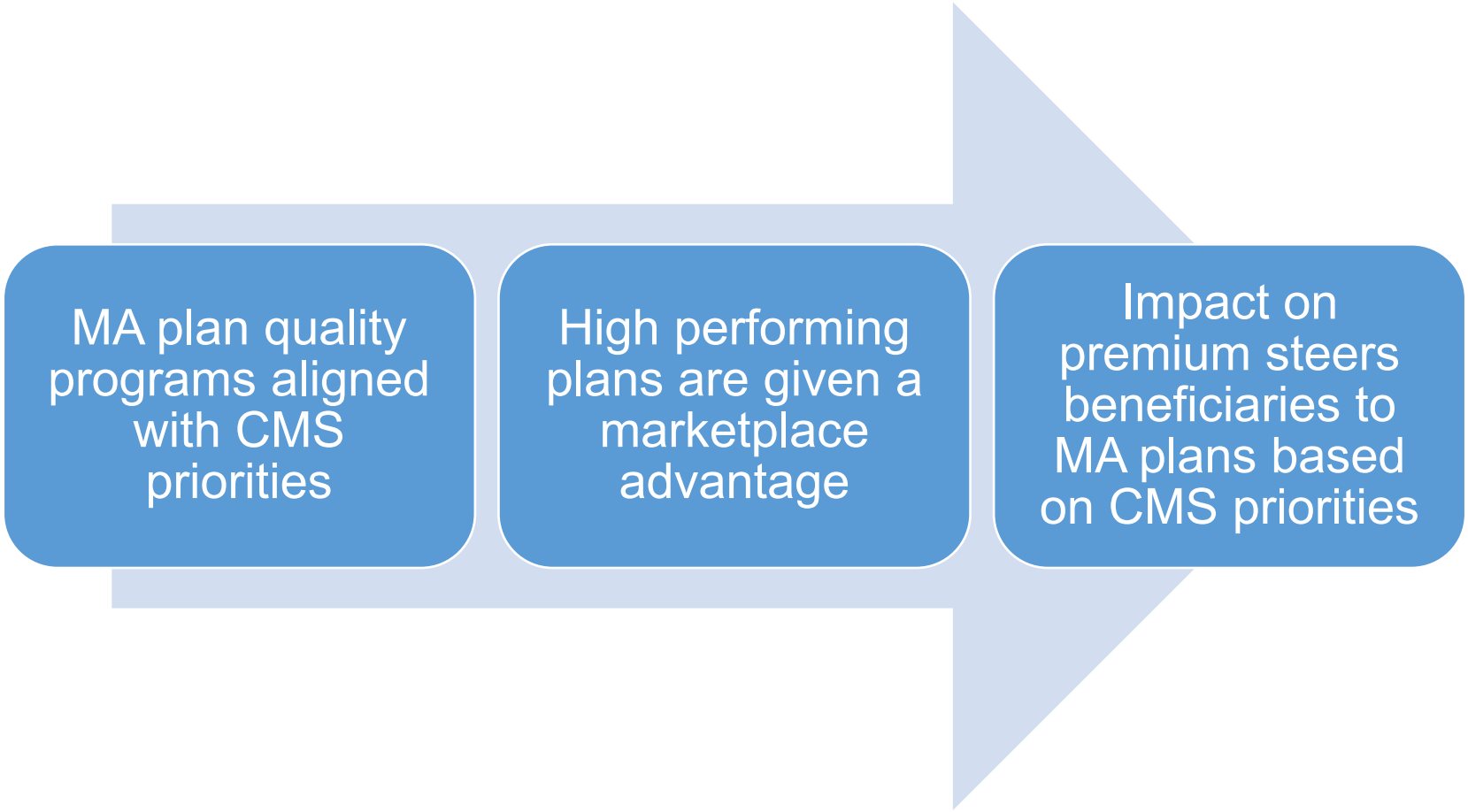
If bid falls below benchmark

- No member premium for medical benefits and percent of the difference is a “rebate” can be used to:
  - Fund supplemental benefits
  - Offset Part D premium in an MA-PD plan
  - Credit to members’ Part B premium
- Percentage of the rebate plan can use to enhance plan depends on its star rating.

If bid higher than benchmark

- Enrollees pay difference as premium
- Member premium for MA plan
- Enrollees also pay Part B premium

Impact of MA Payment Methodology



Anti-Kickback Statute Safe Harbors Updated 2020

Anti-Kickback Statute

Makes it a crime to

- Offer, pay, solicit, or receive
- Any “remuneration,” meaning anything of value
- Directly or indirectly, overtly or covertly
- To induce
  - Referrals of items or services reimbursable by Medicare, Medicaid, or other federal healthcare programs or
  - Purchase, leasing, ordering or arranging for purchasing any good, facility, service or item reimbursable by Medicare, Medicaid, or other healthcare programs.

Stark Law (High Level)

Prohibits

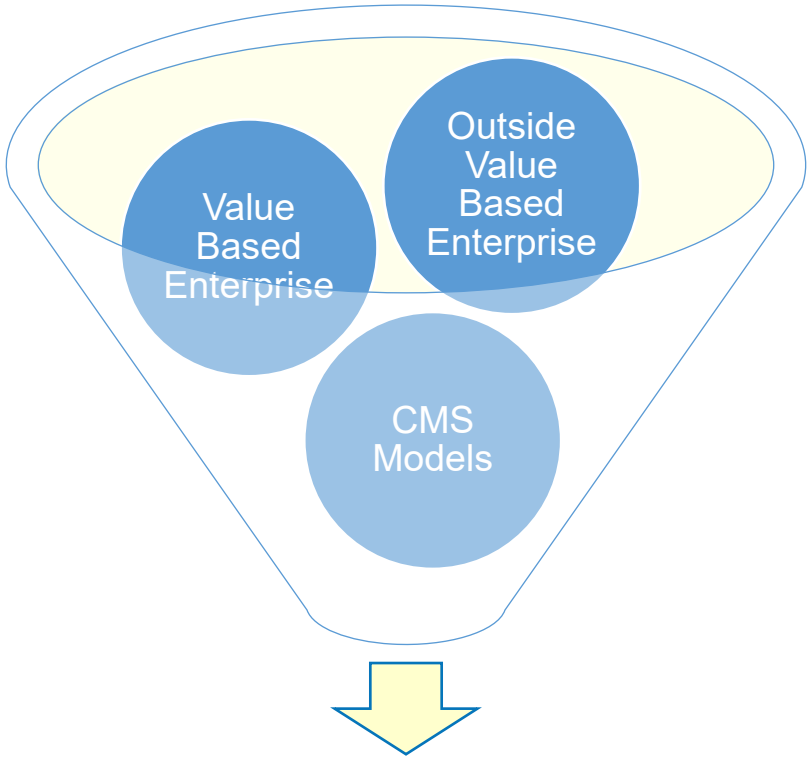
- A **physician** from referring patients for **designated health services** reimbursable by Medicare to an entity with which the physician (or immediate family member) has a **financial relationship**, unless an exception applies

- The **designated health services provider from submitting claims** to Medicare for those services resulting from a prohibited referral

HHS Regulatory Sprint to Coordinated Care
–
A Bigger Box

- 2020 Updates to AKS Safe Harbors and Stark Exceptions facilitate transition to value-based care and payment.
- Plans and provider still need to operate inside the box, but the government built a bigger box.

New and Updated AKS Safe Harbors



Pre-2020 Managed Care Safe Harbors

Price reductions offered to eligible managed care organizations (MCOs)

- Protects payments between eligible MCOs and contractors for providing or arranging for items/services where conditions are met
  - Eligible MCOs include Medicare Advantage organizations, Medicaid MCOs, and risk-based Medicaid plans
- Includes provisions for downstream arrangements
- Unchanged by 2020 final rule

- Safe Harbor Conditions
  - Signed, written agreement
  - Specifies items/services
  - 1+ year
  - Specifies no claims for covered items/services
  - No payment for referrals of business outside arrangement
  - No cost shifting to government programs

42 C.F.R. § 1001.952(t) “managed care discounts”

Price reductions offered by contractors with substantial financial risk to MCOs

- Protects payments between qualified MCOs and contractors for providing or arranging for items/services where conditions are met
- Includes provisions for downstream arrangements
- Unchanged by 2020 final rule
- Safe Harbor Conditions same as managed care safe harbor plus
  - Quality assurance program
  - Payment methodology commercially reasonable and FMV
  - No inappropriate investment interests
  - Contractor has substantial financial risk under approved methodology
  - Claims submitted to the federal program under assignment
  - Identical payments for same items/services for other beneficiaries

42 C.F.R. § 1001.952(u)

2020 New and Revised Safe Harbors

New and Revised Safe Harbors

Outcomes-Based Payments and Part-Time Arrangements (§ 1001.952(d))	**Modified existing safe harbor for personal services and management contracts to add flexibility for outcomes-based payments and part-time arrangements**
Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency (§ 1001.952(ee))*	Three new safe harbors for remuneration exchanged between or among eligible participants in a value-based arrangement that fosters better coordination and management of patient care
Value-Based Arrangements With Substantial Downside Financial Risk (§ 1001.952(ff))*	
Value-Based Arrangements With Full Financial Risk (§ 1001.952(gg))*	
Patient Engagement and Support (§ 1001.952(hh))*	New safe harbor for tools and supports furnished to patients to improve quality, health outcomes, and efficiency
Cybersecurity Technology and Services (§ 1001.952(jj))	New safe harbor for donations of cybersecurity technology and services
Electronic Health Records Items and Services (§ 1001.952(y))	Modified safe harbor to add protections for cybersecurity technology, update interoperability provisions, and remove the sunset date
Warranties (§ 1001.952(g))	Modified safe harbor to provide protection for bundled warranties for one or more items and related services
Local Transportation (§ 1001.952(bb))	Modified safe harbor to expand and mileage limits for rural areas and for transportation for patients discharged from an inpatient facility
CMS-Sponsored Models (§ 1001.952(ii))	New safe harbor for remuneration provided in connection with a CMS-sponsored model
Accountable Care Organization (ACO) Beneficiary Incentive Programs (§ 1001.952(kk))	Codified statutory exception to the definition of "remuneration" under the AKS related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program
Discounts (§ 1001.952(h))+	Modified safe harbor to remove protection for pharmaceutical rebates paid by manufacturers to Part D plan sponsors
Point-of-Sale Reductions in Price (§ 1001.952(cc))+	New safe harbor that protects rebates paid at the point-of-sale and reduce the price of the drug for the member
PBM Service Fees (§ 1001.952(dd))+	New safe harbor that protects certain fees paid by manufacturers to PBMs

Common Themes

- Limited or no protection for ineligible entities
- Expanded protections for digital health technology and cybersecurity
- Rigor around benchmarks and oversight
- Safeguards in definitions
- Flexibility to encourage innovation
- Flexibility increases with level of risk to incentivize transition to value
- Coordinating care across settings

Key Definitions in New Value-Based Enterprise Safe Harbors

Value-Based Enterprise Participant and Arrangement Defined

VBE participant:

- **An individual or entity that engages in at least one value-based activity as part of a value-based enterprise, other than a patient acting in their capacity as a patient.**

Value-based arrangement:

- **An arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are:**
  - (A) The value-based enterprise and one or more of its VBE participants; or
  - (B) VBE participants in the same value-based enterprise.

42 C.F.R. § 1001.952(ee)(14).

Value-Based Activity and Purpose Defined

Value-based activity:

(A) Any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

1. The provision of an item or service;
2. The taking of an action; or
3. The refraining from taking an action; and

(B) Does not include the making of a referral.

Value-based purpose:

(A) Coordinating and managing the care of a target patient population;
(B) Improving the quality of care for a target patient population;
(C) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or
(D) 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.

42 C.F.R. § 1001.952(ee)(14).

Value-Based Enterprise (VBE) Defined

Value-based enterprise (VBE): two or more VBE participants—

A. Collaborating to achieve at least one value-based purpose;

B. 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;

C. That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and

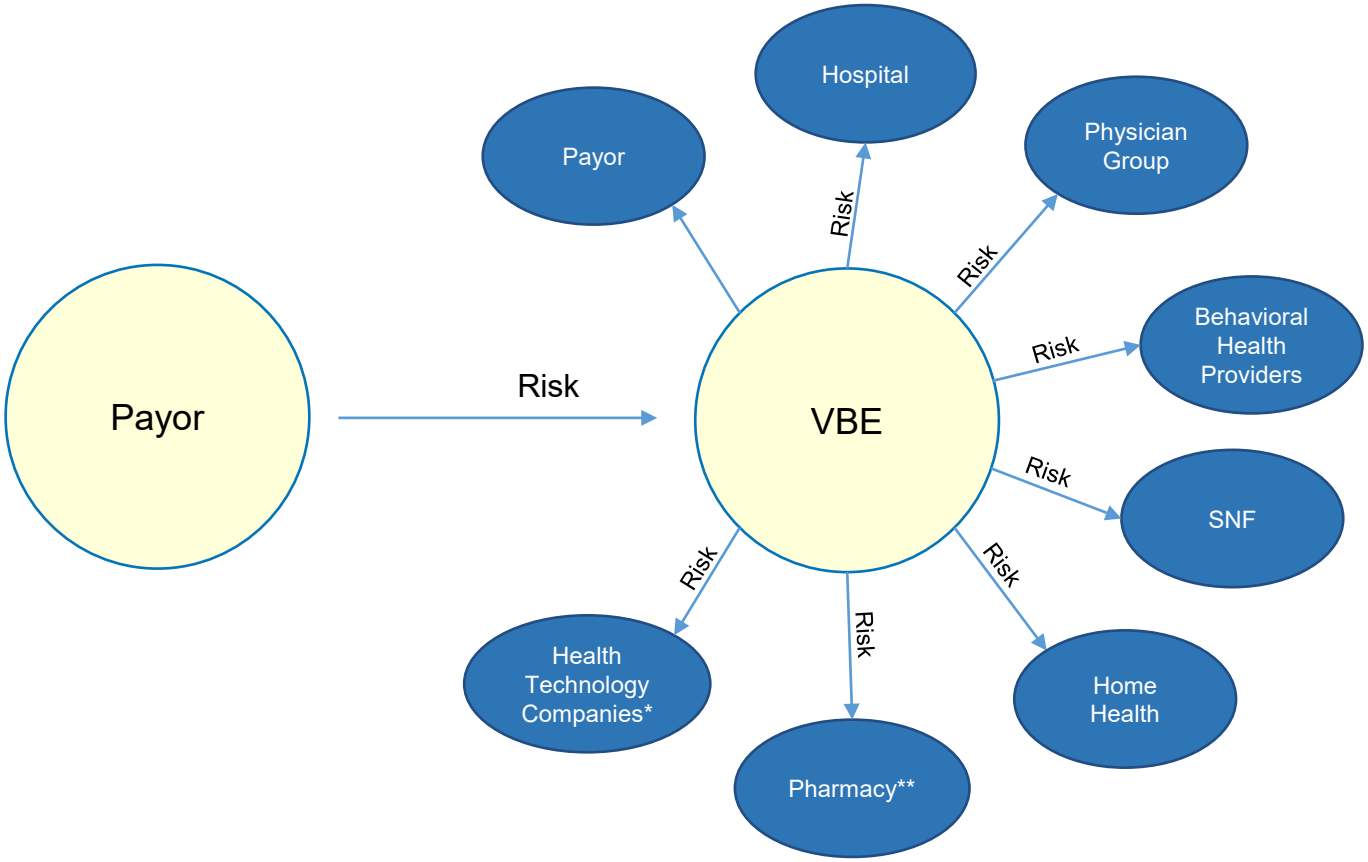
D. That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

42 C.F.R. § 1001.952(ee)(14)

Ineligible Entities

- The following entities are ineligible for protection under value-based safe harbors:
  1. Pharmaceutical manufacturers, distributors, and wholesalers
  2. PBMs;
  3. Laboratory companies;
  4. Compounding Pharmacies
  5. Manufacturers of devices or medical supplies;
  6. Entities or individuals that sell or rent DMEPOS, other than a pharmacy or a physician, provider, or other entity that primarily furnishes services; and
  7. Medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies
- Ineligible entities are not precluded from participating in VBEs
- Payers affiliated with PBMs ARE eligible for protection

Possible VBE Structure



*Not an ineligible entity (i.e. not DMEPOS supplier or device manufacturer)

**Not Compounding Pharmacy

Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency

Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency

Requirements

- **Remuneration (value exchanged) must be**
  - In kind (not monetary but offeror can pay directly for third-party services)
  - Used predominantly to engage in value-based activities directly connected to coordination of care
  - No more than incidental benefit to persons outside target population
  - Not used for
    - Marketing
    - Patient recruitment
- **Commercially reasonable (different from FMV)**
- **No taking into account volume or value of referrals or other business**
- **No ineligible entities**

Agreement

- **Agreement in writing, signed in advance, specifies material terms, including:**
  - Value-based purpose
  - Value-based activities
  - Term
  - Target patient population
  - Remuneration and either
    - Offeror's cost or
    - Reasonable accounting methodology used to determine cost or FMV (for purposes of calculating recipient 15% contribution)
  - Frequency of recipient's contribution payments and amounts
  - Outcome or process measures

42 C.F.R. § 1001.952(ee)(14).

Care Coordination Arrangements Requirements – 15 Percent Recipient Contribution

- Recipient pays back 15% of offeror's cost of in-kind contribution
- Use any reasonable accounting methodology or FMV
- If one-time cost, pay in advance
- If ongoing, recipient makes contribution at regular intervals

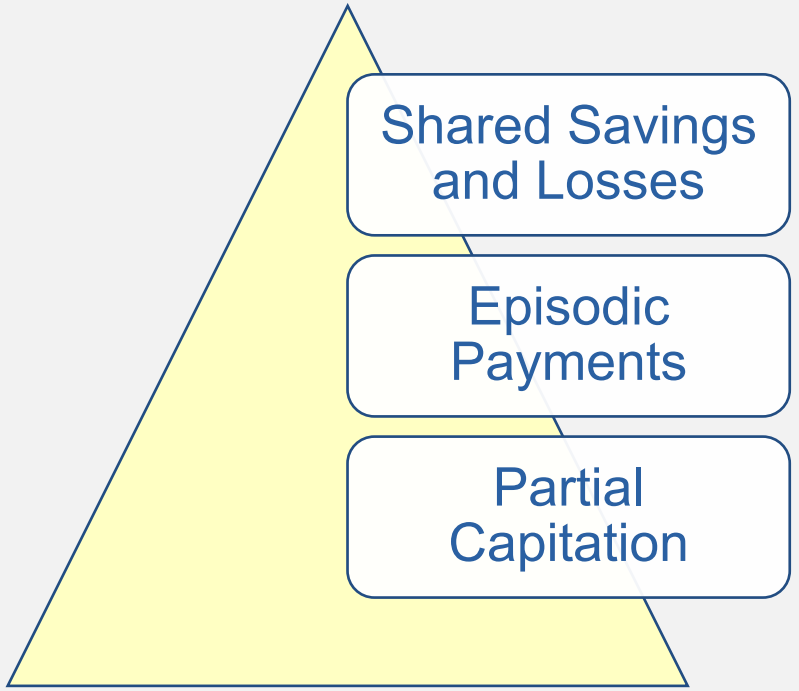
Value-Based Arrangements with Substantial Downside Risk

Value-Based Arrangements with Substantial Downside Risk

Three Pathways for Protection

- Protects payments between VBE and VBE participant where value-based arrangement involves the assumption of substantial downside risk
- Does not protect payments between VBE participants or downstream entities

42 C.F.R. § 100.952(ff)



Substantial Downside Risk Definitions

Shared Savings and Losses Methodology

- Financial risk equal to at least 30% of any loss
- Losses and savings calculated by comparing expenditures for all items/services covered by the payor and furnished to the target patient population to benchmark designed to approximate the expected total cost of such care

Episodic Payment Methodology

- Financial risk equal to at least 20% of any loss
- Losses and savings calculated by comparing expenditures for all items/services furnished to the target patient population pursuant to a defined clinical episode of care covered by the payor to benchmark
- Clinical episode must be designed to include items/services collectively furnished in more than one care setting

Partial Capitation Methodology

- VBE receives prospective, per-patient payment
- Payment must be designed to produce material savings
- Payment must be made on a monthly, quarterly, or annual basis for a predefined set of items/services furnished to the target patient population

Meaningful Share Definitions

Risk Sharing Payment Methodology

- VBE participant assumes two-sided risk
- for at least 5% of the losses and savings realized by the VBE
- pursuant to its assumption of substantial downside financial risk; or

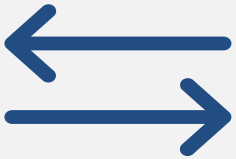
Partial Capitation Methodology

- VBE participant receives from the VBE
- a prospective, per-patient payment
- on a monthly, quarterly, or annual basis
- for a predefined set of items/services furnished to the TPP
- designed to approximate the expected total cost of expenditures for the predefined set of items and services
- and does not claim payment in any form from the payor for the predefined items and services.

Substantial Downside Risk Requirements

Agreement

- VBE assumed substantial downside risk from payor for 1+ year
- VBE participant at risk for meaningful share of downside financial risk
- Value-based arrangement set forth in signed writing
- 6-month phase-in period
- Protections for patients and clinical decision-making
- 6-year record retention



Remuneration

- Not exchanged by ineligible entity
- Not limited to in-kind
- Direct connection to one of three defined value-based purposes
- Used predominantly to engage in value-based activities
- Direct connection to items/services for which VBE assumed risk
- No ownership or investment interest
- Not used to market items/services
- Not based on volume or value of referrals outside arrangement

Value-Based Arrangements with Full Financial Risk

Value-Based Arrangements with Full Financial Risk

- Protects payments between VBE and VBE participant where value-based arrangement involves the assumption of full financial risk
  - Does not protect payments between VBE participants or downstream entities
- Greater flexibility due to increased financial risk
- Intended to remove barrier to providers taking on more risk and having financial incentives to coordinate care

42 C.F.R. § 100.952(gg).

Full Financial Risk Definitions

Full financial risk	VBE is financially responsible 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 1 year.
Prospective basis	VBE has assumed financial responsibility for the cost of all covered items and prior to the provision of items and services to patients in the target patient population.
Items and services	VBE has assumed financial responsibility for the cost of all covered items and prior to the provision of items and services to patients in the target patient population.
Other key terms	Target patient population, value-based activity, value-based arrangement, VBE, value-based purpose, and VBE participant – same as care coordination safe harbor

Full Financial Risk Requirements

Agreement

- VBE assumed full financial risk
- Value-based arrangement set forth in signed writing
- Specifies value-based activities and term
- VBE participant does not claim payment for covered items/services
- 12-month phase-in period
- Patient protections
- Quality assurance program
- 6-year record retention

Remuneration

- Remuneration not exchanged by ineligible entity
- Not limited to in-kind
- No predominance requirement
- Direct connection to any defined value-based purpose
- No ownership or investment interest
- Not used to market items/services
- Not based on volume or value of referrals outside arrangement

Flexibilities in new VBE Safe Harbors

Patient engagement funding	Contemplates multiple providers in VBE	Lawful referral framework (Stark reforms)
VBE could function like a joint venture	Promote collaboration	Care coordination services/cost (no FMV)

Arrangements for Patient Engagement and Support

Arrangements for Patient Engagement and Support

- New safe harbor
- Protects the transfer of items and services for patient engagement and support from VBE participant to patients
- Limited to in-kind items
- Patient must be part of target patient population of value-based arrangement
- Includes limited pathway for digital health technology
- No financial risk requirement

42 CFR § 1001.952(hh).

Patient Engagement and Support Requirements

Remuneration not exchanged by ineligible entity

- Exception for medical device or supply manufacturers if tool or support is digital health technology

Patient engagement tool or support furnished directly to the patient by VBE participant or eligible agent

Patient engagement tool or support:

- Is an in-kind item, good, or service
- Has a direct connection to coordination and management of care of target patient population or TPP
- Does not result in reimbursement of medically unnecessary or inappropriate items/services
- Is recommended by patient's licensed HCP

Patient Engagement and Support Requirements (cont'd)

Tool or support advances one or more of the following goals:

- Adherence to a treatment regimen
- Adherence to a drug regimen
- Adherence to a follow up care plan
- Prevention or management of a disease or condition
- Ensure patient safety

Tool or support:

- Is not funded or contributed by VBE participant outside VBA or ineligible entity
- Is not used for marketing or patient recruitment
- Is not based on insurance coverage

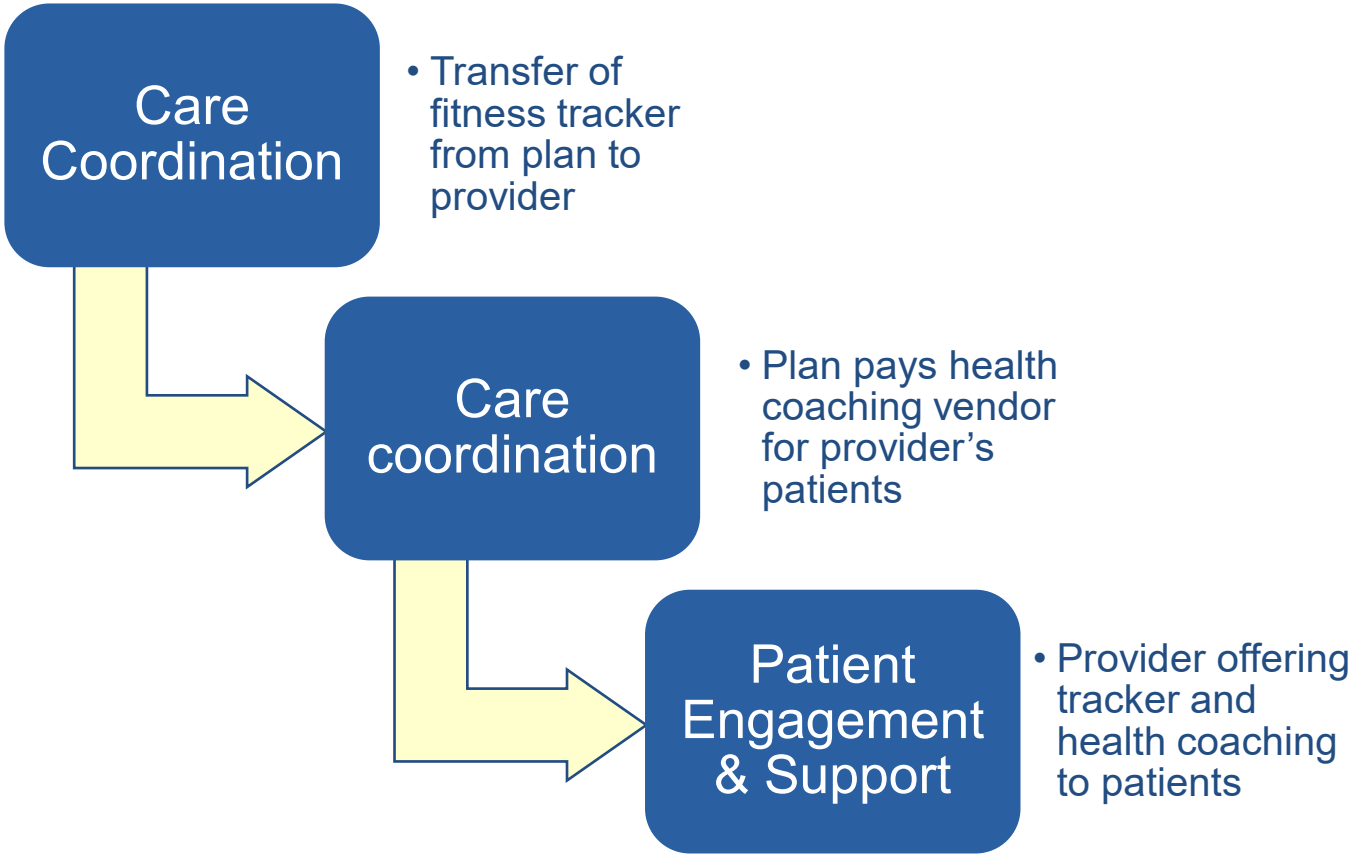
Aggregate annual cap of $500

6 year record retention

New Value-Based Stark Law Exceptions

- Similar to AKS safe harbors but generally easier to meet
  1. Full financial risk
  2. Meaningful downside financial risk (physician responsible for 10 % downside risk)
  3. Value-based arrangements (no risk component)
- Stark Law exception compliance is mandatory (unlike AKS safe harbors, which are voluntary to gain protection)
- If VBE includes payment by a designated health service (DHS) entity to physicians, a Stark Law exception must be met

Using Multiple Safe Harbors in Quality Improvement Arrangements



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