

Where Are They Now: A Check-In on the Development of Value-Based Enterprises

Ohio Hospital Association Annual Meeting

MAY 20, 2025



Today's Presenters



Tim Cahill, Partner
Dinsmore & Shohl LLP
tim.cahill@dinsmore.com



Emily Root, Senior Assistant General Counsel
OhioHealth Corporation
emily.root@ohiohealth.com

Today's Agenda

- Overview of VBEs
- VBE "Pain Points"
- Practical Implementation of VBEs

Value-Based Enterprises



What is a Value-Based Enterprise?

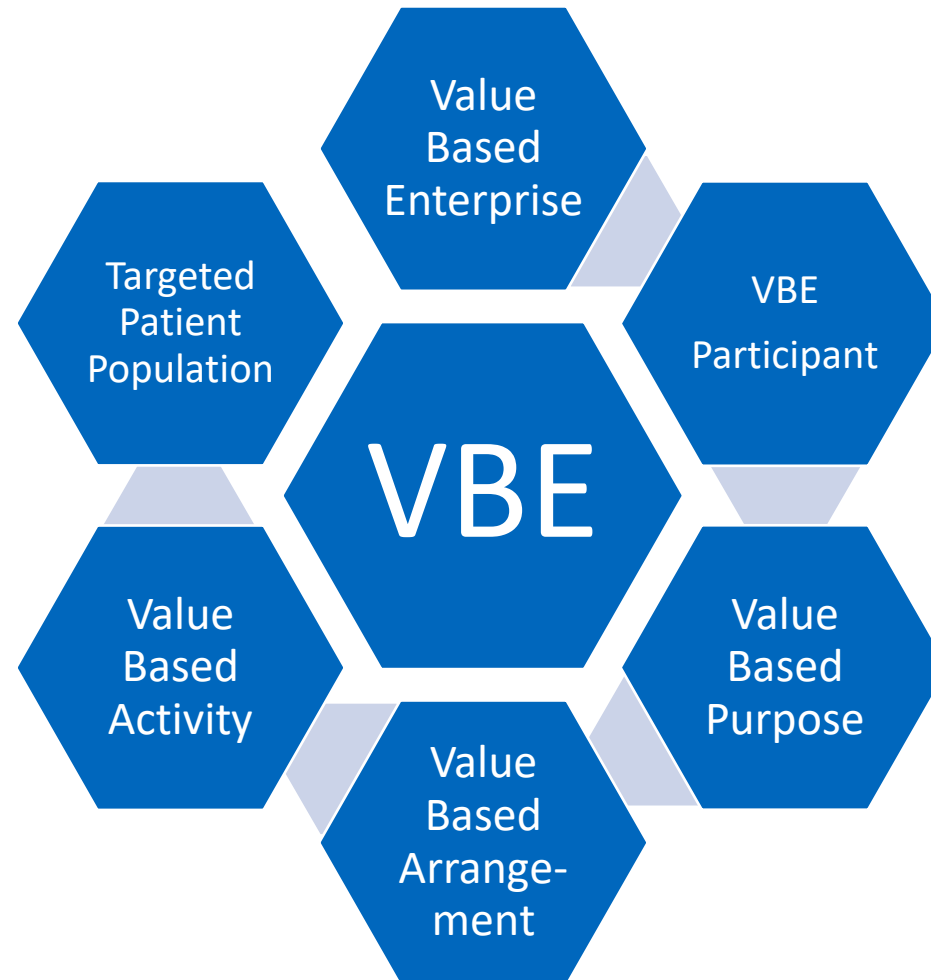
Must Involve:

- Two or more VBE participants
- Collaborate to achieve a value-based purpose
- Engaged in value-based arrangements
- An accountable body or person responsible for the financial and operational oversight of the value-based enterprise
- A governing document that describes the value-based enterprise and how the VBE participants intend to achieve the value-based purposes

May, But Not Required to Be:

- A separate corporate entity
- A clinically integrated network
- An accountable care organization
- A physician-hospital organization
- An independent physician organization

Definitions



What are Value-Based Activities?

Definition:

- The provision of an item or service;
- The taking of an action; or
- The refraining from taking an action.
- Note: For AKS, a value-based activity does not include the making of a referral.

Practically Speaking:

- Provision of care coordinator/equipment
- Payment to complete a patient assessment
- Payment for completion of training
- Payment for “gap closure” and follow-up communication with patients
- \$10 payment for ordering a dual-modality screening instead of single-modality screening

Three Tiers of Risk

FINANCIAL RISK



REQUIREMENTS

Generally, no requirements for FMV or prohibiting payment based on the volume or value of referrals for all three tiers

Stark Exceptions v. AKS Safe Harbors

	STARK	ANTI-KICKBACK
Full Financial Risk	VBE is financially responsible on a prospective basis for the cost of all patient care covered by a payor	VBE is financially responsible on a prospective basis for the cost of all items and services covered by a payor for at least 1 year
Meaningful/ Substantial Downside Risk	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	VBE participants assume substantial downside risk (i.e. 30%/20% of losses based on certain benchmark expenditures) from a payor for 1 year
Value- Based/Care Coordination Arrangements	No VBE or physician risk required	No VBE or physician risk required; remuneration must be for coordination and management of care

More Risk, Fewer Requirements

	STARK	ANTI-KICKBACK
Full Financial Risk	No FMV, V/V, CR, SIA	No FMV, V/V, CR, SIA
Meaningful/ Substantial Downside Risk	No FMV, V/V, CR; must be SIA	No FMV, V/V, CR, SIA
Value- Based/Care Coordination Arrangements	No FMV, V/V; must be CR, SIA, annual monitoring, extensive documentation requirements	No FMV, V/V, SIA; must be CR, annual monitoring, outcome measures, extensive documentation requirements

VBE “Pain Points” in No Risk Arrangements



Will the Arrangement Involve Monetary Compensation?

- Stark allows monetary compensation under a no risk arrangement, but AKS allows in-kind remuneration only
- Under AKS, the recipient of the in-kind remuneration must pay 15% of the offeror's cost
 - One-time v. ongoing costs
- Does the arrangement involve private physician practices exclusively? Or both? Or none?
- OIG concerned about heightened fraud and abuse risks related to monetary remuneration when:
 - Parties not required to assume financial risk
 - Remuneration is not required to be FMV and may take into account the volume or value of referrals
- OIG notes that safe harbors for personal services and outcomes-based payments could be utilized for monetary compensation, but these require FMV
- OIG also notes fundamental differences in statutory structures and sanctions between Stark and AKS, namely that because Stark is strict liability, its exceptions must define the full scope of what is legal
- OIG focused on “backstop” protection against abusive arrangements/disguised kickbacks

Remuneration Requirements

- **Under Stark, remuneration must be for or result from value-based activities, undertaken by the recipient of the remuneration, for patients in the target patient population.**
 - Not limited to compensation arrangements that are specifically for coordination/management of patient care.
- **Under AKS, the remuneration must be used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population**
 - The “coordination and management of care” means the “deliberate organization of patient care activities and sharing of information between two or more VBE participants . . . that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population.”
- **How establish the connection between the remuneration and the coordination and management of the care for the target patient population?**

Outcome Measures

- Stark permits, but does not require outcome measures; AKS requires outcome measures
- Outcome measures must meet the following criteria:
 - The parties reasonably anticipate the outcome measures will advance the coordination and management of care for the target patient population based on clinical evidence or credible medical or health sciences support;
 - Include one or more benchmarks that are related to improving or maintaining improvements in the coordination and management of care for the target patient population;
 - Are monitored, periodically assessed, and prospectively revised as necessary to ensure that the measure and its benchmark continue to advance the coordination and management of care of the target patient population;
 - Relate to the remuneration exchanged under the value-based arrangement; and
 - Are not based solely on patient satisfaction or patient convenience

Target Patient Population

- **Both Stark and AKS require that the target patient population be selected using 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).
- **Nothing precludes the parties from identifying the entire patient population the VBE participant serves.**
- ***In limited circumstances*, broad selection may be appropriate.**
 - All patients in a specific zip code—if that zip code is where the VBE participant draws most or all of its patients
 - Geriatricians may identify all or most of their patients as needing care coordination and management due to comorbidities and complex care needs
- **Remuneration may not result in more than incidental benefits to the persons outside of the target patient population.**

Practical Implementation of VBEs



Establishing the VBE

- **Define the accountable body or person responsible for the financial and operational oversight of the VBE**
 - Will this be a committee? Or a person?
 - The accountable body or person has key responsibility with ensuring VBE compliance. How will they get educated on their role? How will they track compliance?
- **Creating the governing document that describes the VBE and how the VBE participants intend to achieve the value-based purposes**
 - Will this be a charter of the committee? Some other governing document?
- **Create a separate VBE Participation Agreement? Or incorporate the VBE into an existing CIN/ACO/PHO/IPA Participation Agreement?**

Establishing the Value-Based Activities and Remuneration

- **Interplay between legal and the administrators in defining what the VBAs should be**
 - Administrators may want guidance on what they can do; legal will ask them what would be beneficial
 - Legal weighing in before administrators get too far down the path before realizing all the requirements that need to be met
 - Example: Administrators promising a care coordinator to a VBE participant, but not accounting for the 15% contribution
- **Importance of Care Coordination**
 - If the arrangement will involve monetary compensation, how incorporate care coordination activities so as to satisfy as many elements of the AKS safe harbor as possible?
 - How include activities that will show the deliberate organization of patient care activities and sharing of information in a manner that will lead to more efficient care or health outcomes
 - What activities will administrators need to engage in to show that the remuneration is directly connected to the coordination and management of care—again, to satisfy as many elements of the safe harbor as possible
 - Example: Not enough to just provide equipment; need to show that the equipment facilitates care coordination
- **If monetary compensation is involved, is there some amount that may warrant a FMV opinion?**

Establishing the Outcome Measures

- **Even if an arrangement falls squarely under Stark, establishing outcome measures will help to mitigate the AKS risks**

- **The requirements for the outcomes measures, however, are detailed**
 - Advance care coordination, based on clinical evidence or credible medical or health sciences support, includes benchmarks, monitored to ensure the measure and the benchmark advance the care coordination, relate to the remuneration, are not based solely on patient satisfaction
 - How will legal and the administrators collaborate to establish the outcome measures?

HIPAA Considerations

- **Because sharing of information is important, HIPAA should be carefully considered**
 - If the VBE is a CIN, on what grounds can the CIN share PHI with a VBE participant?
 - Has the CIN established an organized health care arrangement?
 - If the CIN has received PHI from a payor as a business associate, does the CIN have a subcontract BAA with the VBE participants?
 - Are VBE participants (i.e. the hospital and a physician group) sharing PHI among themselves?

- **What documents can be set up on the front end to address these concerns?**

- **Still, sharing of PHI must be evaluated for each arrangement**

Monitoring and Oversight

- **VBAAs must be assessed at periodic intervals, but at least annually**
 - Build annual reminders into the contract management software?
- **Monitoring criteria between Stark and AKS are not entirely consistent**
 - How educate accountable body or person on what to monitor?
 - Ensure monitoring is documented, ideally in minutes of the oversight committee
- **If the VBE determines that the VBAAs are not effective, the arrangements must be modified or terminated**
 - Stark and AKS are not consistent; Stark requires a written report be submitted to the accountable body
 - Specific timeframes are required to implement changes to the VBAAs
 - How will the accountable body account for all of these issues and maintain the documentation for 6 years, as required
 - How will the accountable body coordinate with Legal to ensure the requirements are met?



Dinsmôre

Dinsmore & Shohl LLP | Legal Counsel

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