Hospital and Physician Compensation and Value-Based Arrangements

HCCA Healthcare Enforcement Compliance Conference

November 6, 2023, Washington D.C.

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Agenda

- Overview of value-based framework
- Discussion of real-life scenarios with analysis under the VBE regulations
- Takeaways and practical pointers

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Why Value-Based Arrangements?

- American healthcare is moving toward rewarding providers for keeping patients healthy, tying payment to value not volume
- The Stark Law and anti-kickback statute were developed when providers were paid for volume
- New value-based arrangements exceptions reflect the changes happening in healthcare

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Value-Based Arrangements – Definitions

Value-Based Enterprise	• Two or more VBE participants • Collaborating to achieve at least one value-based purpose • Accountable body or person • Governing document
Value-Based Purpose	• Coordinating and managing care • Improving quality of care • Reducing costs without reducing quality • Transitioning from volume to value
Value-Based Activity	• Any of the following, if designed to achieve value-based purpose: (1) providing an item or service; (2) taking an action; (3) refraining from taking an action
Value-Based Arrangement	• Arrangement for at least one value-based activity for a target patient population in which all parties are VBE participants
Target Patient Population	• Specified patient population selected by VBE using “legitimate and verifiable” criteria, set out in advance in writing

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VBE Exceptions

STARK	AKS
Exceptions and Safe Harbors for Value-Based Arrangements Involving Downside Risk	
• Full Financial Risk Exception (42 CFR § 411.357(aa)(1)) • Meaningful Downside Financial Risk Exception (42 CFR § 411.357(aa)(2))	• Full Financial Risk Safe Harbor (42 CFR § 1001.952(gg)) • Substantial Downside Risk Safe Harbor (42 CFR § 1001.952(ff))
Other Value-Based Related Exceptions and Safe Harbors	
• Value-Based Arrangements Exception (42 CFR § 411.357(aa)(3)) • Distribution of Revenue Related to Participation in a Value-Based Enterprise (addition to the Group Practice Exception) (42 CFR § 411.352(1)(3))	• Care Coordination Safe Harbor (42 CFR § 1001.952(ee)) • Patient Engagement and Support Safe Harbor (42 CFR § 1001.952(hh)) • CMS-Sponsored Innovative Payment Models Safe Harbor (42 CFR § 1001.952(ii)) • Outcomes-Based Payment Safe Harbor (42 CFR § 1001.952(d))

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Scenario 1

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Proposed Arrangement

- Hospital has offered cardiologists traditional gainsharing
- Engaging physicians to reduce costs of procedures and surgeries
  - Improve quality of care to patients
  - Consider wasteful procedures during surgery
  - Review products used by surgeons
  - Standardize implants
- Offering physicians a percentage of the cost savings achieved

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Proposed Arrangement (cont'd)

- Complies with OIG advisory opinion guidance
- Hospital wonders if a VBE structure would be better:
  - Share higher percentage of savings with physicians?
  - Reduce compliance concerns with specific Stark exceptions and OIG safe harbors?

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Questions to Ask

What is the nature of the VBE (overall concept)?

- Consider if VBE presents more favorable terms or opportunities to encourage participation
- Expand participants and perhaps impact

Is the formation of a separate VBE desired?

- Two or more VBE participants
- Collaborating to achieve at least one value-based purpose
- Accountable body or person
- Governing document
- Does not need to be formal entity or organization

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Questions to Ask (cont'd)

Who is the proposed target patient population?

- Identified patient population selected by VBE using "legitimate and verifiable" criteria set out in advance in writing and further VBE's value-based purpose

Who are the Value-Based Participants?

- An individual or entity that engages in at least one value-based activity as part of a VBE, other than a patient
- What is each Value-Based Participant's role in the VBE?

Which VBE Participant(s) will participate in the accountable body responsible for the financial, operational and monitoring oversight of the VBE?

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Documentation

- Develop governing document that describes the VBE and how the VBE participants intend to achieve its Value-Based Purpose(s).
- Describe the purpose of the proposed arrangement and how it will achieve one of the following:
  - Coordinate and manage the care of a target population
  - Improve the care of a target population
  - Appropriately reduce the costs to or growth in expenditures of payors without reducing the quality of care for a target population
  - Transition from health care delivery and payment mechanisms based on the quality of care and control of costs of care for a target population
- The following do NOT qualify:
  - Cost Savings to hospital or other provider ALONE is NOT a Value-Based Purpose
    - Consequently, hospital gainsharing arrangements must include a quality or transition purpose
  - Maintaining quality (without cost savings to payor) is NOT a Value-Based Purpose

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Documentation (cont'd)

- Describe in detail the Value-Based Activities that form the basis of the Value-Based Arrangement.
- 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:
  - the provision of an item or service;
  - the taking of an action; or
  - the refraining from taking an action.
- Parties should have a good faith belief that the value-based activity will achieve or lead to the achievement of at least one value-based purpose.

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Care Coordination (OIG) and Value-Based (CMS)

Key Distinctions	
OIG	**CMS**
• Non-Monetary Remuneration **Only**	• Monetary and Non-Monetary Remuneration
• Remuneration is used "predominantly" to engage in value-based activities that are directly related to **care coordination and management of care for target population** • Does not result in more than incidental benefits to persons outside target patient population	• Remuneration is for and results from value-based activities for patients in target population • **Methodology** for determining remuneration must be set in advance
• Recipient must pay at least 15 percent of costs (one-time or reasonable intervals)	• No recipient cost-sharing requirement
• **Must** specify one or more legitimate outcome or process measures	• **Option** to specify outcome measures

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Care Coordination (OIG) and Value-Based (CMS)

Additional Distinctions	
OIG	**CMS**
Writing, signed by the parties, specifying key terms, e.g., donor costs or FMV, recipient contribution and outcome measures	**Writing, signed by the parties**, specifying key terms, e.g., methodology to determine remuneration
Must be commercially reasonable, considering both arrangement itself and all arrangements within the VBE	Arrangement is **commercially reasonable**
Monitoring – Annually or at least once (if less than one year) If material deficiencies in quality of care or unlikely to further coordination and management of care must within 60 days: (1) terminate or (2) implement a corrective action plan to cure deficiencies within 120 days.	**Monitoring** – Annually or at least once (if less than one year) If determined ineffective at furthering value-based purposes, must: (1) terminate in 30 days or (2) modify within 90 days. If outcomes measure determined unattainable, must be terminated or replaced within 90 days.

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Scenario 2

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Case Study – Care Coordination

- Geriatrician practice provides telemedicine visits to patients of assisted living facility (ALF)
- Geriatrician practice provides licensed vocational nurse (LVN) five hours per week to ALF to facilitate telemedicine visits
- Geriatrician practice covers 85% of cost of LVN and ALF covers 15% of cost
- Geriatrician practice form VBE with AFFs using a care coordination agreement

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Case Study – Care Coordination Safe Harbor

- One Common Issue -- where is the line between "education" and "marketing/recruitment"?
  - The recipient of the remuneration is expected to educate patients about the program, but not market to or recruit patients
  - OIG declined to provide a definition for "marketing" or "patient recruitment activities" or "education" because "these terms are commonly understood."
  - OIG "would not consider actions, such as notifying a patient of the criteria used by a VBE participant to determine patient eligibility for care coordination services or informing the target patient population of potential health benefits that may be derived from care coordination for a patient's chronic condition, to be marketing or patient recruitment activities."

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Outcomes-Based Payments

New AKS Safe Harbor at 42 CFR § 1001.952(d)(2)

- Under personal services and management contracts safe harbor

- Specific protection for payments to improve patient or population health through coordination of care or reductions in payor costs while improving (or maintaining) quality of care
- Part of OIG effort to move from volume to value

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Outcomes-Based Payments (cont'd)

Document any outcome or process measures of the proposed VBA

- Outcomes measures = 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 of expenditures, of payors.
- Describe the clinical evidence or credible medical support for these measures.

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Outcomes-Based Payments (cont'd)

- Outcomes-based payment
- Must reward achieving outcome measure or recoup/reduce payment for failing to achieve outcome measure
- Cannot be based solely on
  - Internal cost savings
  - Patient satisfaction or patient convenience

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Additional Considerations

Describe the remuneration for the Value-Based Activities.

Are any items/services proposed to be given to patients in the target patient population?

- Consider patient engagement safe harbor

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Scenario 3

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Stark Law “No Risk” Value-Based Arrangement (Technology Rollout)

- Hospital has proprietary “app” to help pregnant patients manage their prenatal care
- Hospital wants to deploy the app to patients through ob/gyn physicians or its medical staff
- Ob/gyn physicians would make “app” available to their pregnant patients

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Stark Law “No Risk” Value-Based Arrangement (Technology Rollout)

- Could this be the basis for a VBE?
  - Was this a value-based *activity*?
  - Was there a value-based *purpose*?
  - What was the “target patient population”?
  - Was there a value-based *enterprise*, and who were the value-based *participants*?

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Stark Law "No Risk" Value-Based Arrangement (Technology Rollout)

- Does the technology rollout arrangement fit into the value-based arrangement exception?
- What other Stark law exceptions might apply?
- What benefits flow from being a "value-based enterprise"?

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PATIENT ENGAGEMENT AND SUPPORT SAFE HARBOR

- This safe harbor is available only for VBE
- The tool or support is not used to market other reimbursable items or services or for patient recruitment
- The availability of the tool or support is not determined in a manner that takes into account the type insurance coverage of the patient
- Safe harbor limited by a $500 annual monetary cap on the aggregate retail value of the remuneration
  - OIG declined to finalize any exceptions to the cap
  - Cap will be adjusted annually based on the Consumer Price Index
  - Cap applies at the VBE participant level (per patient, per VBE participant)
  - In-kind only remuneration
- Protection from anti-kickback statute and beneficiary inducement CMP

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Takeaways

- Flexibility under AKS and Stark Law re compensation and required referrals
- May come with additional requirements
- State law considerations
- Tax-exempt organization considerations

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VBA Compliance Issues

Potential Non-Compliance:

- Target Patient Population
- Writing requirements
- Organizational failure (VBE)
- Writing/Signature
- Incorrect Value Based Activities
- Goal/Outcome monitoring
- Tracking Activities and outcomes
- Failure to adjust/terminate Activities
- Failure to track and apply downside performance
- Failure to appropriately establish benchmarks
- VBE Participants' misuse of items provided
- Inappropriate mandated/directed referrals
- Failure to retain records for 6 years
- Focus solely on Cost Reduction for Provider (OIG Safe Harbor)

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VBA Compliance Issues

- Non-Compliance with Value Based Arrangement Safe Harbors Exceptions are primarily operational
- If fail to fully comply, other Stark Law Exceptions must be met, all requiring ***fair market value*** for services rendered

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Practical Tips

- Create a checklist for the arrangement being structured
- Consider what requirements are needed based on level of risk
- Document as necessary
- Some arrangements will not benefit from new VBE regulations
- Organizations with existing value-based programs and experience are leading the way for arrangements with higher risk
- Opportunities exist for those entities entering value-based arrangements for first time

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Questions?

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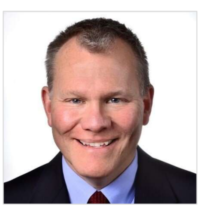
Presenters



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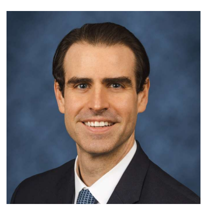
Practice Areas

- Healthcare compliance, including hospital/physician arrangements
- Healthcare transactions



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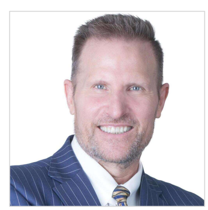

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