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FAST BREAK: REGULATORY SPRINT TO COORDINATED CARE

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February 25, 2021

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TODAY'S PRESENTERS

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Regulatory Sprint to Coordinated Care

Topics to be discussed today include:

Value-based arrangements – terminology

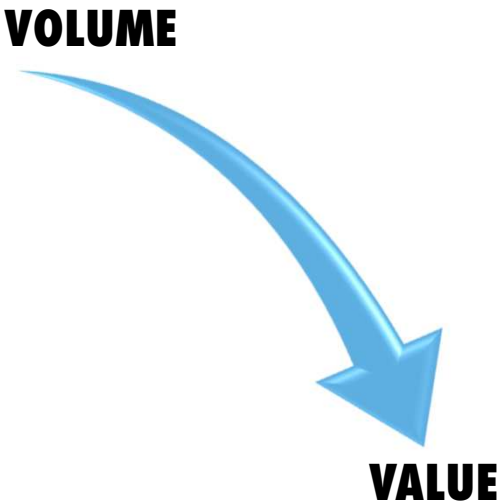
Key elements of VB and other Stark Law exceptions and AKS safe harbors

What do the VB rules anticipate?

Modernizing fraud and abuse laws under the Biden administration

The Regulatory Sprint to Coordinated Care

- Launched in 2018 by HHS to accelerate transformation of healthcare from a fee-for-service to a value-based system.
- One objective of the Regulatory Sprint was to remove "unnecessary obstacles" and reduce regulatory burdens that hinder innovation and limit progress towards coordinated care.
- The Stark Law, the Anti-Kickback Statute and the Beneficiary Inducement Law were identified as creating legal/regulatory obstacles to transitioning to value-based payment models.
- Both CMS (for Stark) and the HHS OIG (for AKS and BIL) finalized in December 2020 significant regulatory changes that establish new value-based exceptions and safe harbors, as well as clarify existing requirements in an effort to promote the transition to value-based care models.



VBE Theory

- Both CMS and OIG approach value-based regulations the same way:

What Does HHS Mean by Value-Based?

HHS implemented several key definitions involving VB Arrangements that critical to understanding the proper scope of the exceptions

VB Enterprise	Means two or more VBE participants (1) collaborating to achieve at least one VB Purpose; (2) each of which is a party to a VB Arrangement with the other or at least one other VBE Participant in the VBE; (3) who have an accountable body or person responsible for the financial and operational oversight of the VBE; and (4) who have a governing document that describes the VBE and how the VBE Participants intend to achieve the VBE's VB Purpose(s).
VB Participant	A person or entity that engages in at least one VB Activity as part of a VB Enterprise.
VB Activity	Means any of the following activities that is reasonably designed to achieve at least one VB Purpose of the VB Enterprise: (1) the provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action.

What Does HHS Mean by Value-Based?

VB Purpose	Is any of the following: (1) coordinating and managing the care of a Target Patient Population; (2) improving the quality of care for a Target Patient Population; (3) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a Target Patient Population; or (4) 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. (Emphasis added.)
VB Arrangement	Defined as an arrangement for the provision of "at least one value-based activity for a target patient population to which the only parties are . . . [t]he [VB Enterprise] and one or more of its VBE participants; or . . . VBE participants in the same [VB Enterprise]."
Target Population	An identified patient population selected by the VB Enterprise or its VB Participants based on legitimate and verifiable criteria that further the VB Enterprise's VB Arrangement.

Risky Business

VB exceptions are categorized into three tiers based on the financial risk a provider is willing to take on:

1.

"Full financial risk" is defined as the assumption of the VB Enterprise of financial responsibility on a "prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target population for a specified time."

2.

"Meaningful downside financial risk" means the provider is responsible to repay or forgo no less than 10% of the total value of the remuneration the provider receives (or may receive) under the VB Arrangement.

3.

No meaningful financial risk exceptions also exist

What Do the VB Rules Anticipate?

- CMS and OIG want all providers and suppliers to enter into value-based arrangements in some form
- However, except for large health systems and physician groups, many providers may be hesitant to take on the downside financial risk these rules promote
- In addition, many other healthcare stakeholders are directly excluded from VBE arrangements
  - Pharma
  - Manufacturers
  - PBMs
  - Wholesalers and distributors

Critical VB Exceptions/Safe Harbors

Full Financial Risk

- To fit within this exception, the following requirements must be met (among others):
  - The VB Enterprise is obligated to assume full financial risk of the cost of care for the entire duration of the VB Arrangement
  - The remuneration exchanged is for or results from the VA Activities undertaken by the recipient for patients in the target population
  - The remuneration cannot be an inducement to reduce or limit medically necessary items/services to any patient, and cannot be conditioned on the physician's referrals of patients who are not members of the target population

Critical VB Exceptions/Safe Harbors

Meaningful Downside Financial Risk

- To fall within this exception, the following requirements must be met (in addition to the requirements imposed by the exception for Full Financial Risk):
  - The physician is at meaningful downside financial risk for failure to achieve the VB Purposes of the VB Enterprise during the entire duration of the VB Arrangement
  - A description of the "nature and extent of the physician's downside financial risk" is set forth in writing
  - The methodology used to determine the amount of the remuneration is set in advance of engaging in VB Activities for which the remuneration is paid
- CMS clarified that the scope of this exception is not limited to VB Arrangements under which a physician is required to repay remuneration already received from the entity.

Critical VB Exceptions/Safe Harbors

Other VB Arrangements

- The third VB exception is more general and applies to arrangements regardless of the level of financial risk involved. CMS believed such an exception was necessary to "foster the delivery of coordinated patient care … and transitioning to a truly value-based health care delivery and payment system …."
- Because no lack of financial risk is required, this exception imposes the most requirements. To fall within this exception, the following requirements must be met:
  - The arrangement must be set forth in writing, signed by the parties, and include
    - (i) a description of the VB Activities to be undertaken,
    - (ii) how the VB Activities are expected to further the VB purpose(s) of the VB Enterprise,
    - (iii) the target patient population for the arrangement,
    - (iv) the type, nature of, and methodology used to determine, the remuneration, and
    - (v) the outcome measures against which the recipient of the remuneration is assessed, if any.

Critical VB Exceptions/Safe Harbors

Other VB Arrangements *Cont'd*

- The outcome measures must be objective, measurable, and selected based on clinical evidence or credible medical support. An "outcome measure" as 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."
- Any changes to the outcome measures must be made prospectively and set forth in writing.
- The methodology used to determine the amount of the remuneration is set in advance of engaging in VB Activities for which the remuneration is paid.
- The remuneration is for, or results from, VB Activities undertaken by the recipient of the remuneration for patients in the target patient population.
- The arrangement must be commercially reasonable.

What Do the VB Rules Anticipate?

Based on a nationally-recognized recommendation, a hospital believes ordering dual modality screening instead of single modality screening for a particular diseases will increase detection of the diseases and improve quality of care to patients in the hospital's service area.

The hospital contracts with community physicians to pay $25 every time they follow the hospital's care protocol by ordering dual modality screening. The hospital believes it will take 2 years to shape physician behavior to always follow the recommend care protocol.

One year into the arrangement, the hospital's data indicate that use of dual modality screening does not result in early detection of the target disease, but instead results in more false positive results, invasive biopsies and unnecessary treatment.

The hospital can terminate the arrangement within 30 days of learning that the VB Activities is ineffective or modify the arrangement within 90 days to replace it with a different VB Activity.

Other Important Rule Changes

Regulatory definition of "commercial reasonableness": "the particular arrangement furthers a legitimate business purpose of the parties and is sensible, considering the characteristic of the parties, including their size, type, scope and specialty."

Important Clarification . . . An arrangement can be commercially reasonable even if it does not result in profit for one or more of the parties.

This was not always the position of enforcement authorities; argued in the context of FCA litigation that it was commercially unreasonable to compensation a physician more than what he/she generated in professional collections

Other Important Rule Changes

Change to "fair market value" definition – reference to "general market value" and, for compensation, "the compensation that would be paid at the time the parties enter into the service arrangement as the result of a bona fide bargain between well-informed parties that are not otherwise in a position to generate business for each other."

"Volume or value" standard - compensation takes into account the volume or value of a physician's referrals "if the formula used to calculate the physician's… compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's… compensation that positively or negatively correlates with the number or value of the physician's referrals to the entity."

Modernizing Fraud and Abuse Laws

What is in store for the new administration?

- Social determinants of health
- Expanded beneficiary inducements for preventive/low-cost care
- Increasing number of MA enrollees
- Medicare-for-all proposals
- Technological advancements

Modernizing Fraud and Abuse Laws

Social Determinants of Health

- A recent Advisory Opinion from OIG highlights the evolution of this issue
  - ➢ AO 20-08 (Dec. 23, 2020) – permitted an FQHC to use gift cards to incentivize patients to compliance with maintaining appointments
    - – OIG insisted on guardrails (i.e., small pool of existing patients, limited financial incentive)
    - – Ultimately, OIG determined that the incentive program, narrowly tailored, furthered the goal of improving attendance rates at primary care visits and the patients' care

Join us next month!

Please join us for next month's webinar:

***Fast Break:* HIPAA Data Breach Enforcement**

Featuring

Scott McBride and Jake Harper

- Late March *(specific details TBD)*

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QUESTIONS?

Thanks and Be Well!

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Thanks and Be Well!

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Al focuses his practice on counseling healthcare companies of all types on regulatory, fraud and abuse, Stark law, Medicare reimbursement, and transactional matters. Al devotes a substantial portion of his practice to corporate compliance issues, including internal and government investigations, and has experience representing clients before regulatory agencies such as the Centers for Medicare and Medicaid Services (CMS), the US Department of Health and Human Services' Office of Inspector General, and the Provider Reimbursement Review Board.

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Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.