Stark and Anti-Kickback final rules provide clarity and flexibility to value-based care

Takeaways

- As a foundation for protection, establish a VBE, either through a separate risk-bearing entity or a collaboration between two persons or entities
- Determine VBE participants and value-based activities (note: referrals and marketing do not qualify)
- Evaluate nature of VBA remuneration to assess protection options
- Monitor arrangement to ensure continued compliance with applicable Stark Law exception and AKS safe harbor

This overview is designed for health care stakeholders currently engaged, or seeking to engage, in value-based arrangements that implicate the federal Stark Law and Anti-Kickback Statute (AKS). In November 2020, the U.S. Department of Health and Human Services (HHS) released coordinated final rules for both laws, which we have previously covered in significant detail (Read about the October 2019 proposed rule; More on the proposed rule and the November 2020 final rule).

These final rules primarily aim to remove obstacles to value-based care, which enables payers and health systems to reward health care providers and suppliers for adopting cost-saving protocols, avoiding waste, and improving quality of care. Both the Stark Law and AKS were developed to address fraud and abuse concerns in a predominantly fee-for-service health care reimbursement environment. As a result of increased interest and investment in value-based care, HHS recognized the need for new exceptions and safe harbors to provide flexibility for value-based arrangements.

The new final rules are complicated. This piece therefore seeks to provide a high-level roadmap to help health care providers and companies that are considering structuring value-based arrangements.

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Who qualifies for protection?

As a threshold matter, value-based participants must be part of a value-based enterprise
Value-based enterprise (VBE): At least two persons or entities that collaborate, and are accountable, to achieve improved care coordination, quality, or efficiency for a defined patient population by taking, or refraining from taking, an action tailored to that improvement. The rules allow flexibility in establishing the accountable body or person overseeing the VBE, as well as a governing document describing the VBE.
VBE participant: An individual or entity that engages in at least one value-based activity as part of a VBE. For purposes of the AKS, this does not include a patient acting as patient.
Ineligible entities under AKS: With a narrow exception available to "limited technology participants" that are under the care coordination safe harbor, the AKS value-based safe harbors deem the following entities ineligible for protection: (i) pharmaceutical companies; (ii) pharmacy benefit managers; (iii) laboratory companies; (iv) compounding pharmacies; (v) device manufacturers or medical supply companies; (vi) durable medical equipment, prosthetics, orthotics, and supplies companies; and (vii) medical device distributors and wholesalers. No similar exclusion applies for the Stark Law exceptions.

What is protected?

Only certain arrangements, activities, and populations are eligible for protection under the Stark and AKS value-based framework
Value-based arrangement (VBA): An arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are: (i) the VBE and at least one of its VBE participants, or (ii) VBE participants in the same VBE.
Value-based purpose: Deliberate organization of patient care activities and sharing of information between VBE/VBE participants or VBE participants/patients designed to achieve safer, more effective, or more efficient care to improve health outcomes for a target patient population.
Value-based activities: If reasonably designed to achieve a value-based purpose, the: (i) provision of an item or service, (ii) taking of an action, and/or (iii) refraining from taking an action.
Target patient population (TPP): An identified patient population selected in advance using legitimate and verifiable criteria that: (i) are set out in writing and (ii) further the value-based purpose of the VBE. No cherry-picking or lemon-dropping.

How do parties protect a VBA?

Increasing financial risk met with increasing flexibility

AKS safe harbors	Stark exceptions
Care coordination arrangements No financial risk required so long as the VBA is directly connected to the coordination and management of care for the TPP (e.g., patient monitoring, patient diagnostic activities, patient treatment, predictive analytics, etc.), but the safe harbor only protects in-kind contributions. Note that there is express requirement to evaluate and modify arrangement at least annually.	**Any value-based arrangements** Unlike the AKS, the Stark Law protects exchange of **monetary** remuneration under a **commercially reasonable** VBA so long as it is documented in a signed writing that demonstrates value-based activities and its relationship to value-based purposes, along with a methodology to calculate remuneration, among other requirements. Note that, with the rule's clarification of "commercial reasonableness," the parties can look to their unique needs in evaluating compliance with that requirement. Note also the express requirement to evaluate and modify at least annually.
Substantial downside financial risk Protects in-kind and monetary remuneration and serves as the middle-ground financial risk model. The VBE can assume "substantial downside financial risk" from a payer via one of the following methodologies: (i) shared savings and losses, (ii) episodic payment, or (iii) VBE partial capitation. Importantly, each VBE participant must "meaningfully share" in the VBE's risk, whether by risk-sharing payments or by partial capitation.	**Substantial downside financial risk** The physician assumes meaningful downside financial risk (i.e., at least 10 percent) under a methodology that is set in advance in a signed document that describes the nature and extent of the downside risk. Risk is defined as risk to the entity with which the physician has a compensation relationship, not a payer.
Full financial risk Protects both in-kind and monetary remuneration and includes more "flexible" conditions and the greatest opportunity to innovate. Under a written agreement, the VBE assumes full financial risk on a prospective basis from a payer for the cost of **all** covered patient care and services for a defined population **for at least one year**. The parties phase in full risk after entering into a VBA, subject to safe harbor requirements.	**Full financial risk** As with the AKS, a Stark Law exception protects both in-kind and monetary remuneration and includes more "flexible" conditions. The VBE must assume full financial risk from a payer for the duration of the VBA. The parties phase in full risk after entering into a VBA, subject to exception requirements.

Deeper dive

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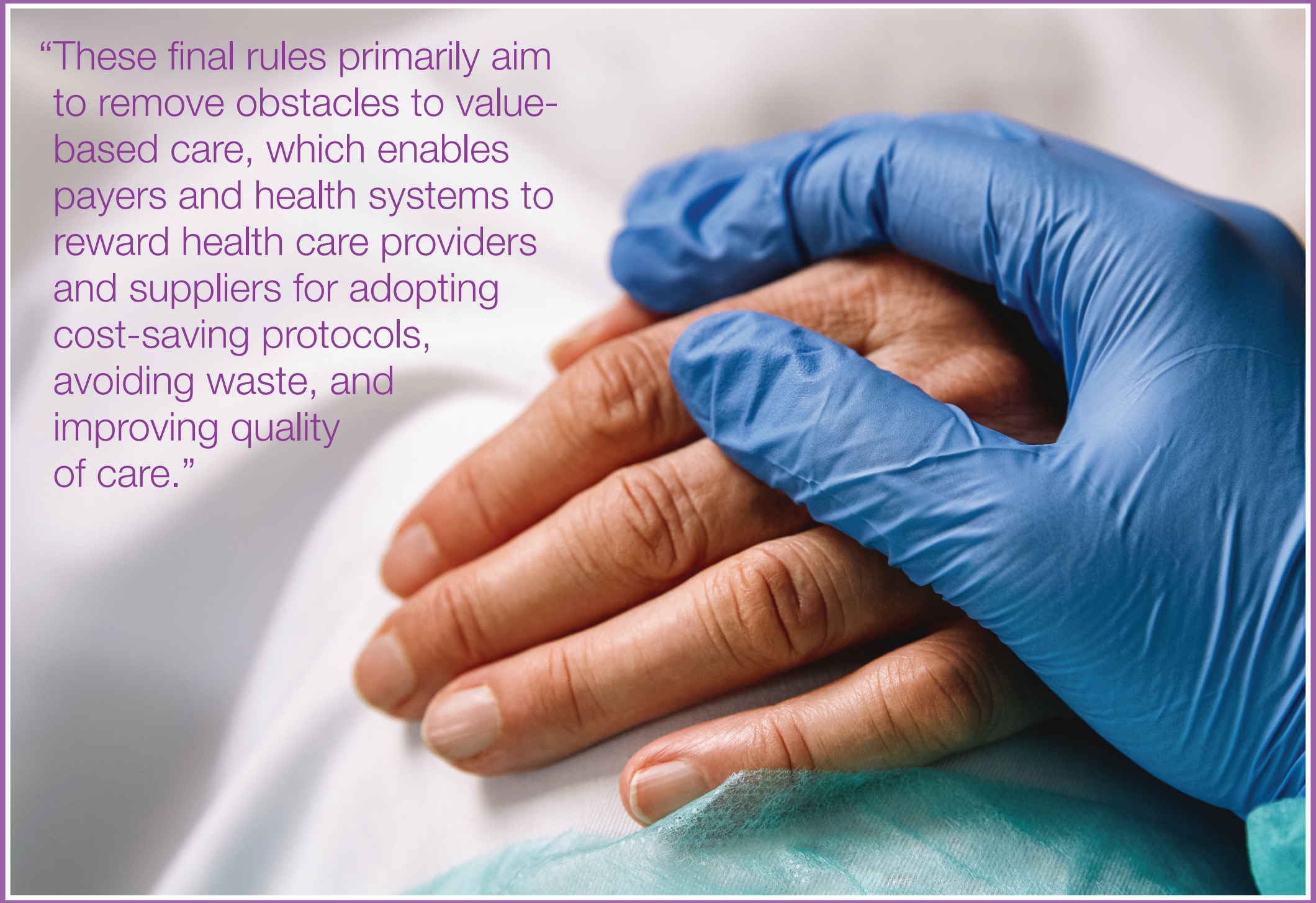
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