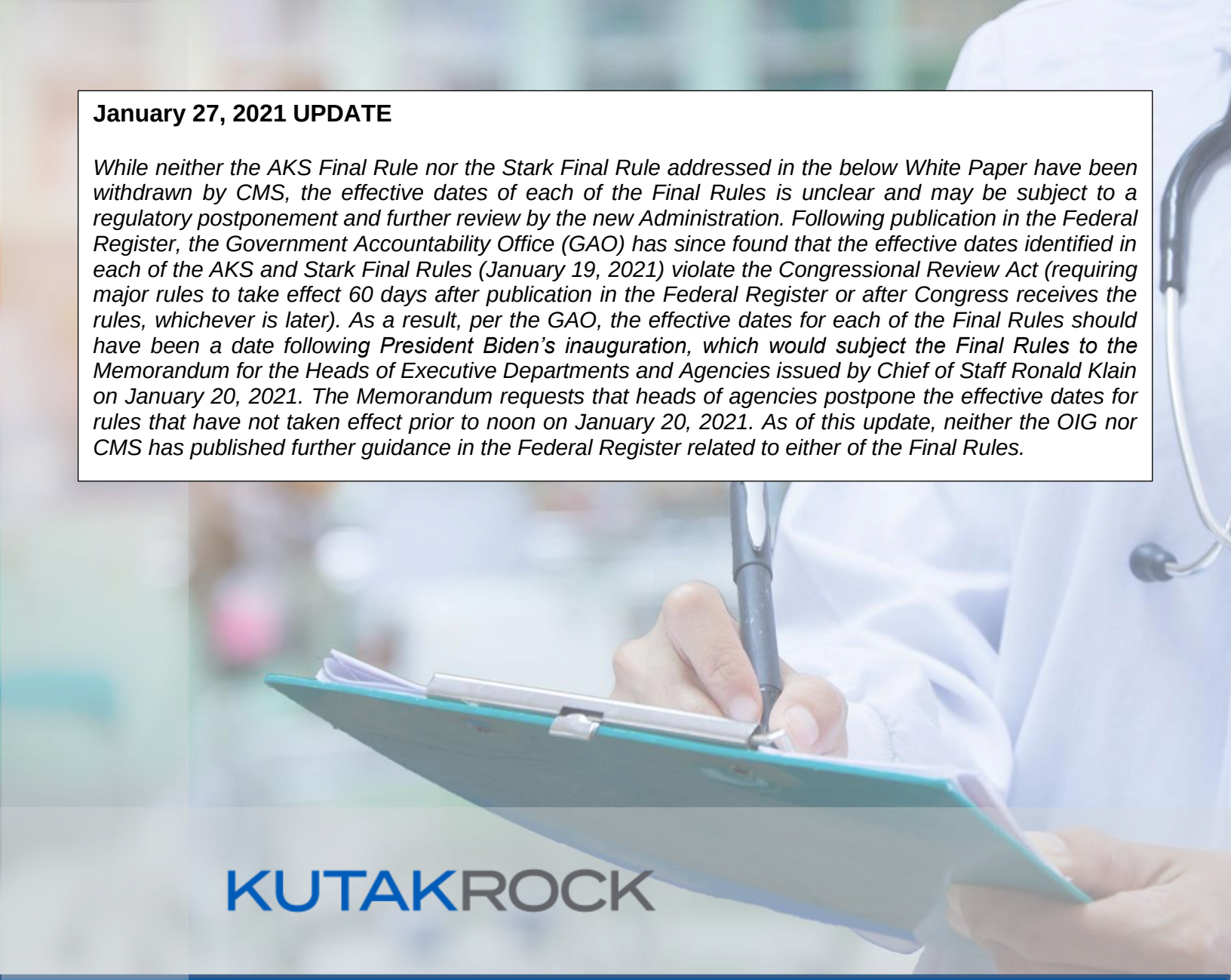

January 27, 2021 UPDATE

While neither the AKS Final Rule nor the Stark Final Rule addressed in the below White Paper have been withdrawn by CMS, the effective dates of each of the Final Rules is unclear and may be subject to a regulatory postponement and further review by the new Administration. Following publication in the Federal Register, the Government Accountability Office (GAO) has since found that the effective dates identified in each of the AKS and Stark Final Rules (January 19, 2021) violate the Congressional Review Act (requiring major rules to take effect 60 days after publication in the Federal Register or after Congress receives the rules, whichever is later). As a result, per the GAO, the effective dates for each of the Final Rules should have been a date following President Biden's inauguration, which would subject the Final Rules to the Memorandum for the Heads of Executive Departments and Agencies issued by Chief of Staff Ronald Klain on January 20, 2021. The Memorandum requests that heads of agencies postpone the effective dates for rules that have not taken effect prior to noon on January 20, 2021. As of this update, neither the OIG nor CMS has published further guidance in the Federal Register related to either of the Final Rules.

KUTAKROCK

White Paper

VBA Exceptions and Safe Harbors Under the Stark Law and AKS Final Rules

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January 8, 2021

INTRODUCTION AND OVERVIEW OF VALUE-BASED CONCEPTS

Introduction

As part of its efforts under the Regulatory Sprint,[1] through the Stark Law Final Rule[2] and the AKS Final Rule[3] (the Stark Law Final Rule and AKS Final Rule are collectively referred to as the "*Final Rules*"), CMS and the OIG, respectively, issued new exceptions and safe harbors and/or finalized revisions to existing regulatory text to assist in removing regulatory barriers to care coordination and value-based care arrangements in order to accelerate the transformation of the health care system from one that pays based on volume of services to one that pays based on the value of care delivered.

The changes made in the Final Rules generally become effective January 19, 2021. However, the changes under the Stark Law Final Rule to the group practice rules relating to profit shares and productivity bonuses, located at 42 CFR 411.352(i), will become effective on January 1, 2022.

The Stark Law Final Rule:

- Creates a new exception for value-based arrangements ("*VBAs*") with full financial risk value-based enterprises ("*VBEs*") (the "*Full-Risk Exception*").

- Creates a new exception for VBAs with meaningful downside financial risk to the physician (the "*Meaningful Downside Risk Exception*").

[1] Acknowledging that the physician self-referral law, located at 42 U.S.C. 1395nn, and implementing regulations at 42 CFR 411.350 et seq. (the "*Stark Law*"), the Federal Anti-Kickback Statute, located at 42 U.S.C. 1320a-7b(b), and accompanying regulations, located at 42 CFR Part 1001.952 (the "*AKS*"), and the Federal beneficiary inducements civil monetary penalty law, located at 42 U.S.C. 1320a-7a(a)(5) (the "*Beneficiary Inducements CMP*"), impede beneficial arrangements that assist in advancing the transition to value-based care and the coordination of care among providers in the Federal and commercial sectors, the U.S. Department of Health and Human Services ("*HHS*"), and agencies within HHS (including the Centers for Medicare and Medicaid Services ("*CMS*") and the Office of Inspector General ("*OIG*")), launched a "Regulatory Sprint to Coordinate Care" (the "*Regulatory Sprint*"). The Regulatory Sprint aims to remove potential barriers to care coordination and value-based care created by four key Federal health care laws and associated regulations: (i) the Stark Law, (ii) the AKS, (iii) the Health Insurance Portability and Accountability Act of 1996 ("*HIPAA*") and (iv) the rules under 42 CFR Part 2 related to opioid and substance abuse disorder treatment. Through the Regulatory Sprint, HHS aims to encourage and improve:

- A patient's ability to understand treatment plans and make empowered decisions,
- Providers' alignment on an end-to-end treatment approach (that is, coordination among providers along the patient's full care journey),
- Incentives for providers to coordinate, collaborate, and provide patients with tools to be more involved, and
- Information sharing among providers, facilities, and other stakeholders in a manner that facilitates efficient care while preserving and protecting patient access to data.

In relation to HIPAA and the data access issues noted above, the Office for Civil Rights within HHS recently released a proposed rule addressing these issues in the context of the Regulatory Sprint.

[2] *See* Medicare Program; Modernizing and Clarifying the Physician Self-Referral Law Regulations, 85 Fed. Reg. 77492 (Dec. 2, 2020).

[3] *See* Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77684 (Dec. 2, 2020).

- Creates a new exception for low-risk or no-risk VBAs involving certain outcome measures (the "*Outcome Measure VBA Exception*" and, together with the Full-Risk Exception and the Meaningful Downside Risk Exception, the "*Stark VBA Exceptions*").

- Creates special rules for indirect compensation arrangements involving VBAs.

- Revises the special rules for profit shares and productivity bonuses in the context of a group practice to address VBE participation.

Similarly, the AKS Final Rule:

- Creates a new safe harbor for VBAs with full financial risk VBEs (the "*Full-Risk Safe Harbor*").

- Creates a new safe harbor for VBAs with substantial downside financial risk (the "*Substantial Downside Risk Safe Harbor*").

- Revises the personal services and management contracts safe harbor to allow for certain outcomes-based payments (the "*Outcomes-Based Payment Safe Harbor*").

- Creates a new safe harbor for VBAs involving CMS-sponsored model arrangements (the "*CMS-Sponsored Model Arrangements Safe Harbor*") and CMS-sponsored model patient incentives (the "*CMS-Sponsored Model Patient Incentives Safe Harbor*").

- Creates a new safe harbor for care coordination VBAs to improve quality, health outcomes, and efficiency (the "*Care Coordination VBA Safe Harbor*").

- Creates a new safe harbor for arrangements for patient engagement and support to improve quality, health outcomes, and efficiency (the "*Patient Engagement Tool / Support Safe Harbor*").

The above enumerated newly created and/or revised safe harbors are collectively referred to herein as the "*AKS VBA Safe Harbors*".[4]

Following is a preview of the discussion topics contained in this White Paper:

- A discussion of the core concepts associated with the Stark VBA Exceptions and AKS VBA Safe Harbors, which begins with the immediately following text and continues to page 6.

- A discussion of the reasons for the differences between the Stark VBA Exceptions and AKS VBA Safe Harbors, which is contained on pages 6 and 7.

- A discussion of the Stark VBA Exceptions and AKS VBA Safe Harbors, which begins on page 7 and continues through page 29, with the following Stark VBA Exceptions and AKS VBA Safe Harbors discussed on the following page numbers:

[4] The AKS Final Rule also makes certain changes to the Federal Beneficiary Inducements CMP. Specifically, the AKS Final Rule codifies a statutory exception for "telehealth technologies" furnished to certain in-home dialysis patients. The AKS Final Rule also notes that, by operation of law, arrangements that fit in the Patient Engagement Tool / Support Safe Harbor, as well as a revised safe harbor for local transportation, are protected from exposure for purposes of the Beneficiary Inducements CMP. Further discussion of these changes can be found here.

- Full-Risk Exception and Full-Risk Safe Harbor, pages 7 – 11
- Meaningful Downside Risk Exception and Substantial Downside Risk Safe Harbor, pages 11 – 16
- Outcome Measure VBA Exception and Outcomes-Based Payment Safe Harbor, pages 16 – 20
- CMS-Sponsored Model Arrangements Safe Harbor, pages 20 – 22
- Care Coordination VBA Safe Harbor, pages 22 – 25
- Patient Incentive Safe Harbors (including the Patient Engagement Tool / Support Safe Harbor, CMS-Sponsored Model Patient Incentives Safe Harbor and ACO Beneficiary Incentive Program Safe Harbor), pages 26 – 28
- Other Stark Law Final Rule changes supporting VBAs (the special rules for indirect compensation arrangements and for profits shares and productivity bonuses in the context of a group practice), pages 29 – 30

- A discussion of the manner in which the Stark VBA Exceptions and the AKS VBA Safe Harbors apply to an example health system hypothetical involving a primary care capitation arrangement, an orthopedic bundled payment arrangement, participation in a CMS-Sponsored Model Program, and other potential VBEs, which is contained on pages 30 – 52.

VBA / VBE Core Concepts

The following core terms must be defined prior to discussing VBAs and VBEs and the new Stark VBA Exceptions and AKS VBA Safe Harbors:

- Value-Based Purpose(s)
- Target Patient Population ("*TPP*")
- VBE Participant
- Value-Based Activity

Each of these core terms is further discussed below.

Value-Based Purpose(s)

Under the Final Rules, any of the following constitute a "*value-based purpose*":

(1) Coordinating and managing the care of a TPP,

(2) Improving the quality of care for a TPP,

(3) Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a TPP, 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 TPP.[5]

Target Patient Population

Under the Final Rules, a TPP means an identified patient population selected by a VBE or VBE Participant based on legitimate and verifiable criteria that (i) are set out in writing in advance of the commencement of the VBA, and (ii) further the VBE's value-based purpose(s).

In the Final Rules, both CMS and the OIG note the following factors could be used, depending on the circumstances, as "legitimate and verifiable criteria" for identifying a TPP:

- Medical or health characteristics (e.g., patients undergoing certain procedures, such as knee replacement surgery; patients with certain diagnoses, such as patients with newly diagnosed type 2 diabetes; or patients with certain MS-DRG assignments).

- Geographic characteristics (e.g., all patients in an identified county or set of zip codes).

- Demographic criteria (e.g., age or socioeconomic status).

- Payor status (e.g., all patients with a particular health insurance plan or payor, like Medicare, Medicaid or commercial payors)[6].

- Other defining characteristics[7].

CMS also states that selecting a TPP primarily for its effect on the parties' profit or other financial concerns, e.g., choosing only lucrative or adherent patients (cherry-picking) or avoiding costly or noncompliant patients (lemon-dropping), would not be permissible under most circumstances, as CMS would not consider the selection criteria to be legitimate even if verifiable.[8]

Finally, the Final Rules note that nothing in the TPP definition would exclude patient populations that are retroactively attributed (e.g., a retrospective claims-based methodology), so long as the methodology for

[5] Under the Stark Law Final Rule, CMS comments on the types of arrangements that may fall within this value-based purpose category, and includes the integration of VBE participants in team-based coordinated care models, establishing the infrastructure necessary to provide patient-centered coordinated care, and accepting increased levels of financial risk from payors, as being among these types of arrangements. CMS also noted that many of the pre-participation waiver start-up arrangement examples contained in its Medicare Shared Savings Program waivers, located at 80 Fed. Reg. 66726 (Oct. 29, 2015), may be illustrative for interpreting the scope of this fourth value-based purpose. *See* 85 Fed. Reg. at 77503-04.

[6] However, the OIG expresses caution in the AKS Final Rule with a TPP based solely on payor status, saying:

> While there may be circumstances, e.g., the assumption of full financial risk (as defined in paragraph 1001.952(gg)), where a VBE identifies all of the patients of a particular payor as the target patient population, we caution that relying on this criterion, without sufficient justification for such a broad approach, could raise questions regarding whether it is legitimate or, instead, is a way to capture referrals of, for example, Medicare business.

See 85 Fed. Reg. at 77703.

[7] *See* 85 Fed. Reg. at 77504-05, 77701-03.

[8] *See* 85 Fed. Reg. at 77499.

determining the TPP was set out in writing in advance of the commencement of the VBA and the other TPP requirements were met.

VBE Participant

Under the Stark Law Final Rule, a "*VBE Participant*" is a person (i.e., an individual) or entity that engages in at least one value-based activity as part of a VBE. The AKS Final Rule clarifies that a VBE Participant may not include a patient acting in his/her capacity as a patient. The intention of this clarification is to ensure that VBE Participants providing remuneration to patients look to the Patient Engagement Tool / Support Safe Harbor for protection, not to the other AKS VBA Safe Harbors.

The AKS Final Rule limits certain persons from being eligible to participate as VBE Participants in a number of the AKS VBA Safe Harbors, including the Full-Risk Safe Harbor, the Substantial Downside Risk Safe Harbor, the Outcomes-Based Payment Safe Harbor, the Care Coordination VBA Safe Harbor, and the Patient Engagement Tool / Support Safe Harbor. This is further discussed below on pages 10 and 11 of this White Paper.

Value-Based Activity

Under the Stark Law Final Rule, a "*value-based activity*" includes any of the following activities, provided the activity is reasonably designed to achieve at least one value-based purpose of the VBE:

(1) The provision of an item or service,

(2) The taking of an action, or

(3) The refraining from taking an action.

The AKS Final Rule contains an identical definition of "*value-based activity*" but adds that a referral is expressly not a value-based activity.

In using the term "*reasonably designed*," CMS and the OIG expect the parties to fully anticipate the value-based activities they develop will further at least one of the value-based purposes, stating that any such determination would be fact-specific. Noting that a referral is expressly not a value-based activity, the OIG states that, although the definition of value-based activity offers parties significant flexibility, it is not intended to facilitate parties' attempts to mask fraudulent referral schemes presented under the guise of a value-based activity.[9]

VBEs / VBAs

VBAs are intertwined with VBEs. As a matter of fact, each VBA arises out of a VBE. Each of these terms is discussed below.

[9] *See* 85 Fed. Reg. at 77704-05.

VBEs

Under the Final Rules, a VBE requires two or more VBE Participants:

(1) Collaborating to achieve at least one value-based purpose,

(2) Each of which is a party to a VBA with the other or at least one other VBE Participant in the VBE,

(3) That have an accountable body or person responsible for the financial and operational oversight of the VBE, and

(4) That have a governing document that describes the VBE and how the VBE Participants intend to achieve the VBE's value-based purpose(s).

Under the Final Rules, a VBE may be a separate and distinct legal entity, with a formal governing body and a separate governing document (e.g., an accountable care organization), or it may consist of two parties to a VBA with the written documentation memorializing the arrangement serving as the governing document that describes the VBE and the manner in which the parties intend to achieve the VBE's value-based purpose.

In summary, a VBE is an organized group or network of participants (such as clinicians, providers and suppliers) that have agreed to collaborate with respect to a TPP to put the patient at the center of care through care coordination, increased efficiencies in the delivery of care and improved outcomes for patients.

VBAs

Under the Final Rules, a VBA is an arrangement for the provision of at least one value-based activity for a TPP to which the only parties are (i) the VBE and one or more of its VBE Participants, or (ii) VBE Participants in the same VBE.

Differences Between the Stark VBA Exceptions and the AKS VBA Safe Harbors

In the Final Rules, both CMS and the OIG note that they received comments requesting that they align the Final Rules to the greatest extent possible, with the commenters noting that a lack of consistency makes it difficult to navigate an already complex regulatory framework. In response, both agencies noted that they attempted to align whenever possible, but that complete alignment was not feasible due to (i) fundamental differences in statutory structures and sanctions across the two laws, as the AKS is an intent-based criminal statute while the Stark Law is a civil, strict-liability statute, (ii) the AKS being broader in scope than the Stark Law (with the AKS covering all referrals of Federal health care program business and the Stark Law covering only referrals for a more limited set of services between physicians who have certain financial relationships with entities who furnish a defined limited set of services) and (iii) the different operation of the Stark Law exceptions and AKS safe harbors. Given these differences, acknowledging that the AKS VBA Safe Harbors are more difficult to meet than the Stark VBA Exceptions, the OIG explains its goal as follows:

> Because the Federal anti-kickback statute is not a strict liability law, the value-based safe harbors we are adopting need not capture the full universe of value-based arrangements that are legal under the Federal anti-kickback statute in order to accomplish the goals of removing barriers to more effective coordination and management of patient care. Thus, in designing our safe harbors, rather than mirror CMS's exceptions, we have included safe harbor conditions designed to ensure that protected arrangements are not disguised

> kickback schemes. We recognize that, for purposes of those arrangements that implicate both the physician self-referral law and the Federal anti-kickback statute, the value-based safe harbors may therefore protect a narrower universe of such arrangements than CMS's exceptions.
>
> To protect Federal health care programs and beneficiaries, we believe that it is important for the Federal anti-kickback statute to serve as "backstop" protection against abusive arrangements that involve the exchange of remuneration intended to induce or reward referrals and that might be protected by the physician self-referral law exceptions. In this way, the OIG and CMS rules, operating together, create pathways for parties entering into value-based arrangements that are subject to both laws to develop and implement value-based arrangements that avoid strict liability for technical compliance, while ensuring that the Federal Government can pursue those parties engaging in arrangements that are intentional kickback schemes.
>
> . . .
>
> In sum, because of statutory distinctions, compliance with a value-based safe harbor may require satisfaction of conditions additional to, or different from, those in a corresponding physician self-referral law exception. This is by design. We have endeavored to ensure that an arrangement that fits in a value-based safe harbor has a viable pathway for protection under a physician self-referral law exception. However, an arrangement that fits under a physician self-referral law exception might not fit in an anti-kickback statute safe harbor or might not fit unless additional features are added to an arrangement. That said, it is the Department's belief that compliance with one regulatory structure should not preclude compliance with the other.[10]

NEW STARK VBA EXCEPTIONS AND AKS VBA SAFE HARBORS

Full-Risk Exception / Full-Risk Safe Harbor

Full Financial Risk

In order to meet the Full-Risk Exception and to fall under the Full-Risk Safe Harbor, the VBE must be at "*full financial risk*". Under the Stark Law Final Rule, "*full financial risk*" requires that the VBE be financially responsible on a "*prospective basis*" for the cost of all patient care items and services covered by the applicable payor for each patient in the TPP. The AKS Final Rule's definition of "*full financial risk*" is virtually identical to the Stark Law's definition, except in the AKS Final Rule the term "*patient care items and services*" is replaced with "*item and service*"[11] and except that the AKS Final Rule requires that the VBE must assume such full financial risk for at least one year. Under both Final Rules, the term "*prospective basis*" means that the VBE has assumed financial responsibility for the cost of all items and services covered by the applicable payor prior to the provision of items and services to patients in the TPP.

Under the Final Rules, CMS and the OIG note that neither the Full-Risk Exception nor the Full-Risk Safe Harbor prevents a VBE from having risk mitigation terms (e.g., risk corridors, global risk adjustments,

[10] *See* 85 Fed. Reg. at 77689-690 (going on to disagree with the premise that compliance with the Stark Law rebuts any implication of intent under the AKS and noting its belief that Stark Law compliance is not evidence that the party does or does not have the intent to induce or reward referrals for purposes of the AKS).

[11] The term "*item and service*" is defined as health care items, devices, supplies and services.

reinsurance or stop-loss protection to protect against significant and catastrophic losses). That said, the financial risk assumed by the VBE must be prospective; thus, the contract between the VBE and the payor may not allow for any additional fee for service or other payments to compensate for costs incurred by the VBE in providing specific patient care items and services to the TPP, nor may any VBE Participant claim payment from the payor for such items or services.[12]

Requirements of the Full-Risk Exception and Full-Risk Safe Harbor

The requirements that must be met in order to meet the Full-Risk Exception and in order to fall under the Full-Risk Safe Harbor are set forth in Table 1 below.

TABLE 1		
Requirement	**Stark Law: Full-Risk Exception**	**AKS: Full-Risk Safe Harbor**
Full Financial Risk	The VBE must be at full financial risk (or contractually obligated to be at full financial risk within the 12 months following the commencement of the VBA) during the entire duration of the VBA.	The VBE (directly or through a VBE Participant, other than a payor, acting on behalf of the VBE) has assumed through a written contract or a VBA (or has entered into a written contract for a VBA to assume in the next one year) full financial risk from a payor. The VBE must assume full financial risk for at least a one-year period.
Scope	<u>Remuneration Scope</u> Covers all remuneration paid under a full-risk VBA. <u>VBE Participant Scope</u> No limitations on VBE Participants.	<u>Remuneration Scope</u> Covers remuneration exchanged between a VBE and a VBE Participant in a full-risk VBA. The safe harbor does *not* apply to downstream arrangements.[13] <u>VBE Participant Scope</u> Any individual or entity other than the Ineligible VBE Participants (see discussion following this table).
Writing	None unless (i) the full-risk VBA commences within the 12-month period prior to the VBE assuming full financial risk and/or (ii) the full financial risk VBA includes a directed referral requirement.	The VBA is set forth in writing, is signed by the parties, and specifies all material terms, including the value-based activities and the term.

[12] *See* 85 Fed. Reg. at 77513, 77759-60. While there is no specific limit on the amount of loss coverage a VBE may have, both CMS and the OIG caution that they would expect any stop-loss or other risk adjustment provisions to act as protection for the VBE against catastrophic losses and not a means by which to shift material financial risk back to the payor. *See* 85 Fed. Reg. at 77513 and 77774.

[13] *See* 85 Fed. Reg. 77696, 77780.

TABLE 1		
Requirement	**Stark Law: Full-Risk Exception**	**AKS: Full-Risk Safe Harbor**
Remuneration Requirements	Remuneration must be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the TPP. Remuneration may not be conditioned on referrals of patients who are not part of the TPP, or business not covered under the VBA.	Remuneration provided by, or shared among, the VBE and VBE Participant: ○ Is directly connected to one or more of the VBE's value-based purposes, ○ Does not include the offer or receipt of an ownership/investment interest in an entity or any distributions related to such ownership/investment interest, ○ Is not exchanged or used for the purpose of marketing items/services furnished by the VBE or VBE Participant to patients or for patient recruitment activities, and ○ The VBE or VBE Participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on, (i) referrals of patients who are not part of the TPP, or (ii) business not covered under the VBA.
Referral Conditioning	If directed referral requirement, the requirement must (i) be in writing and signed by the parties, and (ii) not apply if the patient expresses a preference for a different provider; the patient's insurer determines the provider; or the referral is not in the patient's best medical interests in the physician's judgment.	No analogous requirement.
No Inducement	Remuneration may not be an inducement to reduce or limit medically necessary items or services to any patient.	VBA does not induce parties to reduce or limit medically necessary items or services to any patient.
No Payor Claims	No analogous requirement.	The VBE Participant (unless the VBE Participant is a payor) does not claim payment in any form from the payor for items or services covered under the contract or VBA between the VBE and the payor.
QA Program	No analogous requirement.	The VBA provides or arranges for a quality assurance program for services furnished to the TPP that (i) protects against

TABLE 1		
Requirement	**Stark Law: Full-Risk Exception**	**AKS: Full-Risk Safe Harbor**
		underutilization, and (ii) assesses the quality of care furnished to the TPP.
Records	Records of methodology for determining, and the actual amount of, remuneration must be maintained for six years and made available to the Secretary of HHS (the "*Secretary*") upon request.	Records of methodology for determining, and the actual amount of, remuneration must be maintained for six years and made available to the Secretary upon request.

Ineligible VBE Participants

While, as discussed above, "*VBE Participants*" is defined very broadly under the Final Rules, the OIG (this concept does not appear in the Stark Law Final Rule) has designated certain persons as being ineligible to qualify for certain of the new AKS VBA Safe Harbors (collectively, the "*Ineligible VBE Participants*"). The Ineligible VBE Participant concept is included in the "Scope" row of the above table. The Ineligible VBE Participants are comprised of the following persons:

(1) A pharmaceutical manufacturer, distributor or wholesaler.

(2) A pharmacy benefit manager.

(3) A laboratory company. The OIG notes that it does not intend for the ineligibility of laboratory companies to extend to clinical laboratories that are owned and operated through other types of entities, such as hospitals and physician practices. Such entities operating clinical laboratories that are not the entity's predominant or core line of business may use the AKS VBA Safe Harbors. The OIG further clarifies that a hospital furnishing laboratory services through a laboratory that is a department of the hospital for Medicare purposes (including cost reporting) and that bills for the laboratory services through the hospital's provider number would not be considered a laboratory company, but a hospital-affiliated or hospital-owned laboratory company with its own supplier number that furnishes laboratory services that are billed using a billing number assigned to the company and not the hospital would be considered a laboratory company and would not be eligible for certain of the AKS VBA Safe Harbors.

(4) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs.

(5) A "*manufacturer of a device or medical supply*," meaning an entity that meets the definition of applicable manufacturer in 42 CFR 403.902 because it is engaged in the production, preparation, propagation, compounding, or conversion of a device or medical supply that meets the definition of a covered drug, device, biological or medical supply in 42 CFR 403.902, but not including entities under common ownership with or control of an applicable manufacturer.

(6) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies ("*DMEPOS*") covered by a Federal health care program (other than a pharmacy or a physician, provider or other entity that primarily furnishes services).

(7) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.

Entities with Multiple Business Lines

The OIG offers guidance on classification for purposes of determining whether an entity is an Ineligible VBE Participant when the entity has multiple business lines or regulatory classifications (some of which are eligible and others of which are ineligible). For example:

- A pharmacy that is operated within the same corporate entity as a pharmaceutical manufacturer would be considered an Ineligible VBE Participant, to the extent the corporate entity's core function is the manufacturing of pharmaceuticals and the pharmacy operation merely supports the manufacturing line of business.

- If a corporate entity's predominant function is the manufacturing of devices and it also manufactures a pharmaceutical product that is incorporated into and integral to a medical device, the entity would be treated as a manufacturer of devices or medical supplies because that remains its core business or function.

The OIG goes on to note that large corporations that are organized with multiple business lines within the same corporate entity will need to assess whether they have a predominant or core business. The OIG notes that it is not prescribing a specific standard or test for assessing an entity's predominant or core business function and that it expects entities may use a variety of different methodologies depending on their circumstances. The OIG comments that it would expect entities to use a reasonable methodology (as an example, the OIG states that a share of revenues may be reasonable in certain instances, but where one or more products are still in development, revenues may not be an appropriate metric), which they may wish to document and, in certain instances, may desire to use the OIG advisory opinion process to confirm their methodology and/or conclusion.

According to the OIG, the eligibility of an entity is assessed at the corporate entity level by considering the corporate entity's predominant or core line of business. The OIG notes that corporate affiliation, whether by majority ownership, common ownership or another structure, has no bearing on eligibility. Thus, a pharmacy that is under common ownership with a pharmacy benefit manager would be eligible to rely on the AKS VBA Safe Harbors, notwithstanding the fact that the pharmacy benefit manager is ineligible to rely on the safe harbors. Within a health system comprised of multiple corporate entities, the fact that one or more of those entities might engage in activities that make it a manufacturer of devices or medical supplies would not impact the availability of the safe harbor to other corporate entities in the health system that do not engage in such activities.

Meaningful Downside Risk Exception / Substantial Downside Risk Safe Harbor

Meaningful Downside Financial Risk and Substantial Downside Financial Risk

In order to meet the Meaningful Downside Risk Exception, the physician must be subject to "*meaningful downside financial risk*," meaning that the physician is responsible to repay or forgo no less than 10% of the total value of the remuneration the physician receives under the VBA.

The analogous risk concept under the AKS Final Rule is more complicated. In order to fall within the Substantial Downside Risk Safe Harbor, both (i) the VBE must be at "*substantial downside financial risk*"

and (ii) the VBE Participant must be at risk for a "*meaningful share*" of the VBE's substantial downside financial risk.

For purposes of the Substantial Downside Risk Safe Harbor:

(1) A VBE is at "*substantial downside financial risk*" when any of the following is satisfied:

- 30% of Loss – Single Care Setting: The VBE assumes financial risk equal to at least 30% of any loss, where losses and savings are calculated by comparing current expenditures for all items and services covered by the applicable payor and furnished to the TPP to a bona fide benchmark designed to approximate the expected total cost of such care, or

- 20% of Loss – Multiple Care Settings: The VBE assumes financial risk equal to at least 20% of any loss, where (i) losses and savings are calculated by comparing current expenditures for all items and services furnished to the TPP pursuant to a defined clinical episode of care that are covered by the applicable payor to a bona fide benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care, and (ii) the parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting, or

- Material Savings Per-Patient Payment: The VBE receives from the payor a prospective, per-patient payment that is (i) designed to produce material savings, and (ii) paid on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the TPP, designed to approximate the expected total cost of expenditures for the predefined set of items and services.

    - With respect to clause (i), the OIG declined to define "*material savings*" in the AKS Final Rule, noting it wanted to provide flexibility to parties. The OIG noted that, for example, parties may design a capitation payment with utilization targets that are intended to lower costs versus historical utilization, or the parties may use other methodologies that incentivize the VBE to operate more efficiently and lower costs.

      The OIG further recognizes that, as the VBE and its VBE participants become more efficient, achieving material savings may become more difficult. When a VBE successfully reduces costs in one year, it becomes harder to further reduce costs in subsequent years. The OIG notes that, because it is not defining "material savings," parties have flexibility to design partial capitation payment rates to account for such issues. The OIG further notes that payors will likely have a significant role in designing per-patient methodologies that are designed to achieve material savings, stating:

      > Capitation payments designed consistent with generally accepted actuarial principles can, for example, ensure that a partial capitation payment: (i) captures all reasonable, appropriate, and attainable costs; (ii) is sufficient, based on past and anticipated service utilization by the target patient population; (iii) reflects cost trends; (iv) is risk adjusted as appropriate; and (iv) provides documentation and transparency on how the rate was developed. While not an exhaustive list, these factors would be

relevant in assessing whether a capitation payment is designed to generate material savings.[14]

- With respect to clause (ii), the OIG notes that fee-for-service payments under Medicare (i.e., inpatient prospective payment system payments or other fee-for-service payments under Medicare Parts A or B) would not qualify as per-patient payments, stating that the payment must be for a predefined set of items and services furnished to the TPP that is designed to approximate the expected total cost of expenditures for the predefined set of items and services.[15]

(2) A VBE Participant is at-risk for a "*meaningful share*" if either of the following is satisfied:

- Two-Sided Financial Risk: The VBE Participant assumes two-sided risk for at least 5% of the losses and savings, as applicable, realized by the VBE pursuant to its assumption of substantial downside financial risk, or

- Per-Patient Payment: The VBE Participant receives from the VBE a prospective, per-patient payment on a monthly, quarterly or annual basis for a predefined set of items and 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.

Requirements of the Meaningful Downside Risk Exception and Substantial Downside Risk Safe Harbor

Other attributes and requirements of the Meaningful Downside Risk Exception and Substantial Downside Risk Safe Harbor are set forth in Table 2 below.

TABLE 2

Requirement	Stark Law: Meaningful Downside Risk Exception	AKS: Substantial Downside Risk Safe Harbor
Financial Risk	The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the VBE during the entire duration of the VBA	• The VBE (directly or through a VBE Participant, other than a payor, acting on behalf of the VBE) has assumed through a written contract or a VBA (or has entered into a written contract or a VBA to assume in the next six months) substantial downside financial risk from a payor. As mentioned above, the VBE must assume substantial downside financial risk for at least a one-year period.

[14] *See* 85 Fed. Reg. at 77758.

[15] *See id.*

TABLE 2		
Requirement	**Stark Law: Meaningful Downside Risk Exception**	**AKS: Substantial Downside Risk Safe Harbor**
		• The VBE Participant (unless the VBE Participant is a payor from which the VBE is assuming risk) is at risk for a meaningful share of the VBE's downside financial risk for providing or arrangement for the provision of items and services from the TPP.
Scope	Remuneration Scope Covers all remuneration paid under the VBA. VBE Participant Scope No limitations on VBE Participants.	Remuneration Scope Covers exchange of payments or anything of value between a VBE and a VBE Participant. The safe harbor does not apply to downstream arrangements.[16] VBE Participant Scope Any person other than Ineligible VBE Participants.
Writing	A description of the nature and extent of the physician's downside financial risk is set forth in writing. See also the writing requirement connected with the directed referral requirement below.	The VBA is set forth in writing, is signed by the parties in advance of, or contemporaneously with, the commencement of the VBA and any material change to the VBA, and specifies all material terms, including: o Terms evidencing that the VBE is at substantial downside financial risk or will assume such risk in the next six months for the TPP, o A description of the manner in which the VBE Participant (unless the VBE Participant is the payor from which the VBE is assuming risk) has a meaningful share of the VBE's substantial downside financial risk, and o The value-based activities, the TPP, and the type of remuneration exchanged.

[16] *See* 85 Fed. Reg. 77696, 77769.

TABLE 2		
Requirement	**Stark Law: Meaningful Downside Risk Exception**	**AKS: Substantial Downside Risk Safe Harbor**
Remuneration Requirements	• The methodology used to determine the amount of remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid. • Remuneration must be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the TPP. • Remuneration may not be conditioned on referrals of patients who are not part of the TPP, or business not covered under the VBA.	• Remuneration provided by, or shared among, the VBE and VBE Participant: o Is directly connected to one or more of the VBE's value-based purposes, at least one of which must be: (A) coordination and managing the care of a TPP, (B) improving the quality of care for a TPP, or (C) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a TPP; o Unless exchanged pursuant to the risk methodologies set forth in the definitions of "*substantial downside financial risk*" or "*meaningful share*" definitions, is used predominately to engage in value-based activities that are directly connected to the items and services for which the VBE has assumed (or has entered into a written contract or value-based arrangement to assume in the next six months) substantial downside financial risk; o Does not include the offer or receipt of an ownership/investment interest in an entity or any distributions related to such ownership/ investment interest; and o Is not exchanged or used for the purpose of marketing items/services furnished by the VBE or VBE Participant to patients or for patient recruitment activities. • The VBE or VBE Participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on, (i) referrals of patients who are not part

TABLE 2		
Requirement	**Stark Law: Meaningful Downside Risk Exception**	**AKS: Substantial Downside Risk Safe Harbor**
		of the TPP, or (ii) business not covered under the VBA.
Referral Conditioning	If directed referral requirement, the requirement must (i) be in writing and signed by the parties, and (ii) not apply if the patient expresses a preference for a different provider; the patient's insurer determines the provider; or the referral is not in the patient's best medical interests in the physician's judgment.	The VBA does not (i) limit the VBE Participant's ability to make decisions in the best interests of its patients or (ii) direct or restrict referrals to a particular provider, practitioner, or supplier if (A) a patient expresses a preference for a different provider; (B) the patient's payor determines the provider; or (C) the direction or restriction is contrary to applicable law under Titles XVIII or XIX of the Social Security Act.
No Inducement	Remuneration may not be an inducement to reduce or limit medically necessary items or services to any patient.	The VBA does not induce parties to reduce or limit medically necessary items or services to any patient.
Records	Records of methodology for determining, and the actual amount of, remuneration must be maintained for six years and made available to the Secretary upon request.	Records of methodology for determining, and the actual amount of, remuneration must be maintained for six years and made available to the Secretary upon request.

Outcome Measure VBA Exception / Outcomes-Based Payment Safe Harbor

The Final Rules contain an exception and a safe harbor, respectively, protecting certain payments for achievement of outcome measures. The definition of "outcome measures" under both Final Rules is substantially similar. Under the Stark Law Final Rule, an outcome measure is defined as a benchmark that is objective and measurable and that quantifies (i) improvements in or maintenance of the quality of patient care, or (ii) a reduction in the costs to or growth in expenditures of payors while maintaining or improving the quality of patient care. Under the AKS Final Rule, the outcome measure must be *legitimate* and must be a benchmark that is used to quantify (i) improvements in, or *the maintenance of improvements in*, the quality of patient care, (ii) a *material* reduction in the costs to or growth in expenditures of payors while maintaining or improving quality of care for patients, or (iii) both (i) and (ii).[17] Additionally, both Final Rules require that the outcome measure be selected based on clinical evidence or credible medical support.

[17] The AKS Final Rule amends an existing AKS safe harbor, the personal services and management contracts safe harbor, located at 42 CFR 1001.952(d), to incorporate the Outcomes-Based Payment Safe Harbor. In addition to these amendments, the OIG makes two revisions to the original language of the personal services and management contracts safe harbor. These revisions eliminate the language requiring the agreement to specify the exact schedule of intervals and the precise length and the exact charge for the intervals for part-time arrangements, and change the requirement from the aggregate compensation having to be set in advance to the methodology for determining the compensation

Other attributes and requirements of the Outcome Measure VBA Exception and the Outcomes-Based Payment Safe Harbor are set forth in Table 3 below.

TABLE 3		
Requirement	**Stark Law: Outcome Measure VBA Exception**	**AKS: Outcomes-Based Payment Safe Harbor**
Financial Risk	There is no level of financial risk required to meet this exception.	There is no level of financial risk required to fall within this safe harbor.
Scope	<u>Remuneration Scope</u> Covers remuneration paid under a VBA that meets the conditions of the exception. <u>VBE Participant Scope</u> No limitation on VBE Participants.	The safe harbor covers any outcomes-based payment between or among a principal and an agent that (i) either (A) rewards the agent for successfully achieving an outcome measure or (B) recoups from or reduces payment to an agent for failure to achieve an outcome measure, and (ii) meets the conditions of the safe harbor. The safe harbor does not cover any payments (i) made directly or indirectly by the Ineligible VBE Participants, (ii) related solely to the achievement of internal cost savings for the principal or (iii) based solely on patient satisfaction or patient convenience measures. For purposes of this safe harbor, an agent of a principal is any person other than a bona fide employee of the principal who has an agreement to perform services for or on behalf of the principal.
Writing	The VBA is set forth in writing, is signed by the parties and includes a description of: ○ The value-based activities to be undertaken under the arrangement, ○ How the value-based activities are expected to further the value-based purpose(s) of the VBE, ○ The TPP for the arrangement, ○ The type or nature of the remuneration,	The agreement between the parties is set out in writing and signed by the parties in advance of, or contemporaneous with, the commencement of the terms of the outcomes-based payment arrangement. The writing states at a minimum: ○ A general description of the services to be performed by the parties for the term of the agreement,

having to be set in advance. These amendments should make it easer to structure arrangements to fall within the personal services and management contracts safe harbor. Further discussion of these changes can be found here.

TABLE 3		
Requirement	**Stark Law: Outcome Measure VBA Exception**	**AKS: Outcomes-Based Payment Safe Harbor**
	○ The methodology used to determine the remuneration, and ○ The outcome measures against which the recipient of the remuneration is assessed, if any. Any changes to the outcome measures against which the recipient of the remuneration will be assessed must be made prospectively and must be set forth in writing.	○ The outcome measure(s) the agent must achieve to receive an outcomes-based payment, ○ The clinical evidence or credible medical support relied on by the parties to select the outcome measure(s), and ○ The schedule for the parties to regularly monitor and assess the outcome measure(s).
Remuneration	The methodology used to determine the amount of remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid. Remuneration must be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the TPP. Remuneration may not be conditioned on referrals of patients who are not part of the TPP, or business not covered under the VBA. The arrangement must be commercially reasonable.	The methodology for determining the aggregate compensation (including any outcomes-based payments) paid between or among the parties over the term of the agreement must be: ○ Set in advance, ○ Commercially reasonable, ○ Consistent with fair market value, and ○ Not determined in a manner that directly takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part by a Federal health care program.
Monitoring	<u>Frequency of Monitoring</u> Monitoring must be done by the VBE or one or more of the parties at least annually or, for arrangements with a duration of less than one year, at least once during the term of the arrangement. <u>Monitoring Activity</u> The following items must be monitored: ○ Whether the parties have furnished the value-based activities required under the arrangement,	For each outcome measure under the agreement, the parties: ○ Regularly monitor and assess the agent's performance, including the impact of the outcomes-based payment arrangement on patient quality of care, and ○ Periodically assess, and as necessary revise, benchmarks and remuneration under the arrangement to ensure that the remuneration is consistent with fair

TABLE 3		
Requirement	**Stark Law: Outcome Measure VBA Exception**	**AKS: Outcomes-Based Payment Safe Harbor**
	○ Whether and how continuation of the value-based activities is expected to further the value-based purpose of the VBE, and ○ Progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed. <u>Results of Monitoring</u> • If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the VBE, the parties must terminate the ineffective value-based activity either (i) through terminating the VBA within 30 consecutive calendar days after completion of the monitoring or (ii) through modifying the VBA to terminate the ineffective value-based activity within 90 consecutive calendar days after completion of the monitoring. • If the monitoring indicates that an outcome measure is unattainable during the remaining term of the agreement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring	market value in an arm's-length transaction during the term of the agreement. The principal has policies and procedures to promptly address and correct identified material performance failures or material deficiencies in quality of care resulting from the outcomes-based payment arrangement.
Referral Conditioning	If directed referral requirement, the requirement must (i) be in writing and signed by the parties, and (ii) not apply if the patient expresses a preference for a different provider; the patient's insurer determines the provider; or the referral is not in the patient's best medical interests in the physician's judgment.	No analogous requirement.
No Inducement	Remuneration may not be an inducement to reduce or limit medically necessary items or services to any patient.	The agreement neither limits any party's ability to make decisions in their patients' best interest nor induces any party to reduce

TABLE 3		
Requirement	**Stark Law: Outcome Measure VBA Exception**	**AKS: Outcomes-Based Payment Safe Harbor**
		or limit medically necessary items or services.
Records	Records of methodology for determining, and the actual amount of, remuneration must be maintained for six years and made available to the Secretary upon request.	No analogous requirement.
Other	None.	Term The term of the agreement must be not less than one year. No Violation of State or Federal Law The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

CMS-Sponsored Model Arrangements Safe Harbor

The OIG has finalized a safe harbor for CMS-Sponsored Models (i.e., models administered by the Center for Medicare and Medicaid Innovation and the Medicare Shared Savings Program). The CMS-Sponsored Model Arrangements Safe Harbor protects an exchange of anything of value between or among "*CMS-Sponsored Model Parties*" under a "*CMS-Sponsored Model Arrangement*" for which CMS has determined that this safe harbor is available,[18] provided the requirements set forth in Table 4 below are met.

The term "*CMS-Sponsored Model Parties*" means a CMS-Sponsored Model Participant (i.e., an individual or entity that is subject to and is operating under participation documentation[19] to participate in a CMS-Sponsored Model). The term "*CMS-Sponsored Model Arrangement*" means a financial arrangement between or among CMS-Sponsored Model Parties to engage in activities under the CMS-Sponsored Model that is consistent with, and is not a type of arrangement prohibited by, the participation documentation.

The OIG notes that the goal of the CMS-Sponsored Model Arrangements Safe Harbor is to provide uniformity and predictability for those participating in CMS-Sponsored Models. However, this safe harbor does not supersede the OIG's existing fraud and abuse waivers for CMS-Sponsored Models. Existing model

[18] The OIG notes that the purpose of this CMS determination language is to allow Centers for Medicare and Medicaid Services Innovation Center ("CMMI") to evaluate each model and determine whether waivers are necessary for parties to enter into certain arrangements to effectuate the purposes of the particular model. *See* 85 Fed. Reg. at 77812-13.

[19] The term "*participation documentation*" means the participation agreement, a legal instrument setting forth the terms and conditions of a grant or cooperative agreement, regulations, or model-specific addendum to an existing contract with CMS that specifies the terms of a CMS-Sponsored Model.

waivers will continue in effect in accordance with the waiver terms. Additionally, the safe harbor does not preclude the OIG from issuing model-specific waivers in the future, though the OIG notes that this will likely be infrequent.[20]

The requirements that must be met in order to fall within the CMS-Sponsored Model Arrangements Safe Harbor are set forth in Table 4 below.

TABLE 4	
Requirement	**AKS: CMS-Sponsored Model Arrangements Safe Harbor**
Scope	Covers the exchange of anything of value between or among CMS-Sponsored Model Parties under a CMS-Sponsored Model Arrangement. If the participation documentation is anything other than the legal instrument setting forth the terms and conditions of a grant or a cooperative agreement, the safe harbor protects the exchange of remuneration between CMS-Sponsored Model Parties that occurs on or after the first day on which services under the CMS-Sponsored Model begin and no later than six months after the final payment determination made by CMS under the model. If the participation documentation is the legal instrument setting forth the terms and conditions of a grant or a cooperative agreement, the safe harbor protects the exchange of remuneration between CMS-Sponsored Model Parties that occurs on or after the first day of the period of performance (as defined at 45 CFR 75.2) or such other date specified in the participation documentation and no later than six months after closeout occurs pursuant to 45 CFR 75.381.
Advancement of Goals	The CMS-Sponsored Model Parties must reasonably determine the CMS-Sponsored Model Arrangement will advance one or more goals of the CMS-Sponsored Model.
Writing	The CMS-Sponsored Model Parties, in advance of or contemporaneously with the commencement of the CMS-Sponsored Model Arrangement, set forth the terms of the CMS-Sponsored Model Arrangement in a signed writing. The writing must specify at a minimum the activities to be undertaken by the CMS-Sponsored Model Parties and the nature of the remuneration to be exchanged under the CMS-Sponsored Model Arrangement.
Remuneration	The CMS-Sponsored Model Parties do not offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any Federal health care program referrals or other Federal health care program business generated outside of the CMS-Sponsored Models.
No Inducement	The exchange of value does not induce CMS-Sponsored Model Parties or other providers or suppliers to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient. The VBA does not induce parties to reduce or limit medically necessary items or services to any patient.

[20] *See* 85 Fed. Reg. at 77810.

TABLE 4	
Requirement	**AKS: CMS-Sponsored Model Arrangements Safe Harbor**
Records	The parties to the CMS-Sponsored Model Arrangement make available to the Secretary, upon request, all materials and records sufficient to establish whether the remuneration was exchanged in a manner that meets the conditions of this safe harbor.
Satisfaction of Programmatic Requirements	The CMS-Sponsored Model Parties satisfy such programmatic requirements as may be imposed by CMS in connection with the use of the safe harbor.

Care Coordination VBA Safe Harbor

Introduction

While the safe harbors contained in the AKS Final Rule that have been discussed to this point have protected any type of remuneration (i.e., both cash and in-kind), the Care Coordination VBA Safe Harbor limits its protection to in-kind remuneration between a VBE and a VBE Participant or between VBE Participants pursuant to a care coordination VBA that is designed to improve quality, health outcomes or efficiency.

Furnishing of Digital Health Technology by Limited Technology Participants

While, similar to the other VBA safe harbors, the OIG has excluded Ineligible VBE Participants from eligibility for the Care Coordination VBA Safe Harbor, it has provided a limited exception that allows "*Limited Technology Participants*" to furnish "*Digital Health Technology*" under the Care Coordination VBA Safe Harbor.

The term "*Limited Technology Participant*" means a VBE Participant that exchanges Digital Health Technology (as defined in the immediately following paragraph) with another VBE Participant or a VBE and that is (i) a manufacturer of a device or medical supply that is not obligated to make "sunshine reports,"[21] or (ii) an entity or individual that sells or rents DMEPOS covered by a Federal health care program (other than a pharmacy or a physician, provider or other entity that primarily furnishes services).[22]

The term "*Digital Health Technology*" means hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care. The intention is for the term to encompass a wide range of digital health technologies (even those that are not yet developed or available), including the following as examples:

[21] "*Sunshine reports*" are reports of one or more ownership or investment interests held by a physician or an immediate family member of a physician that are required to be made pursuant to 42 CFR 403.906 during the preceding calendar year, or that the owner reasonably anticipates will need to be made during the current calendar year.

[22] In the AKS Final Rule, the OIG notes that the same classification guidance used to determine whether an entity that has multiple business lines is an Ineligible VBE Participant also applies for purposes of determining whether an entity with multiple business lines is a Limited Technology Participant. This classification guidance is discussed on page 11 of this White Paper.

- Remote monitoring
- Data analytics
- Patient portals
- Software and applications that support patient care and health outcomes (for individuals and populations)
- Software used to enable hospitals to access data from cardiac devices used by EMS providers in the field so that they can coordinate and manage the care of patients undergoing a cardiac emergency
- Predictive analytics
- Care consultations
- Telehealth and other communications
- Diabetes management services that leverage devices and cloud storage services to monitor blood sugar levels and transmit data
- Any internet or other connectivity services (including dial-up and mobile hotspots and plans) that are necessary and used to enable the operation of the item or services for the purpose of coordinating and managing care

Care Coordination VBA Safe Harbor Requirements

The requirements of the Care Coordination VBA Safe Harbor are included in Table 5 below.

TABLE 5	
Requirement	**AKS: Care Coordination VBA Safe Harbor**
Scope	Remuneration Scope Protects in-kind remuneration exchanged between a VBE and VBE Participant or between VBE Participants of a VBA, provided the remuneration: • Is used predominately to engage in value-based activities that are directly connected to the coordination and management of care for the TPP and does not result in more than incidental benefits to persons outside the TPP; and ○ *Coordination and management of care* means the deliberate organization of patient care activities and sharing of information between two or more VBE Participants, one or more VBE Participants and the VBE or one or more VBE Participants and patients that is designed to achieve safer, more effective or more efficient care to improve the health outcomes of the TPP • Is not exchanged or used (i) more than incidentally for the recipient's billing or financial management services, (ii) for the purpose of marketing items or services furnished by the VBE or a VBE Participant to patients or (iii) for patient recruitment activities. VBE Participant Scope Any person other than Ineligible VBE Participants, provided that Limited Technology Participants have the ability to furnish Digital Health Technology to another VBE Participant or a VBE.

TABLE 5	
Requirement	**AKS: Care Coordination VBA Safe Harbor**
Commercially Reasonable	The VBA is commercially reasonable, considering both the VBA itself and all VBAs within the VBE.
Writing	• The terms of the VBA are set forth in writing and signed by the parties in advance of, or contemporaneously with, the commencement of the VBA and any material change to the VBA. • The writing states at a minimum the following: o The value-based purpose(s) of the value-based activities provided for in the VBA, o The value-based activities to be undertaken by the parties to the VBA, o The term of the VBA, o The TPP, o A description of the remuneration, o Either the offeror's cost for the remuneration and the reasonable accounting methodology used by the offeror to determine its cost, or the fair market value of the remuneration, o The percentage and amount contributed by the recipient, o If applicable, the frequency of the recipient's contribution payments for ongoing costs, and o The outcome or process measure(s) against which the recipient will be measured.
Outcome or Process Measures	The parties to the VBA must establish one or more legitimate outcome or process measures that: o The parties reasonably anticipate will advance the coordination and management of care for the TPP based on clinical evidence or credible medical or health sciences support, o Include one or more benchmarks that are related to improving or maintaining improvements in the coordination and management of care for the TPP, o 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 to the TPP, o Relate to the remuneration exchanged under the VBA, and o Are not based solely on patient satisfaction or patient convenience.
Volume or Value and Cost-Sharing Obligations	V/V Prohibition: The offeror of the remuneration does not take into account the volume or value of, or condition the remuneration on, referrals of patients who are not part of the TPP or business not covered under the VBA. Cost-Sharing: The recipient pays at least 15% of the offeror's cost for the remuneration, using any reasonable accounting methodology, or the fair market value of the in-kind

TABLE 5	
Requirement	**AKS: Care Coordination VBA Safe Harbor**
	remuneration. If it is a one-time cost, the recipient makes such contribution in advance of receiving the in-kind remuneration. If it is an ongoing cost, the recipient makes such contribution at reasonable, regular intervals.
Monitoring	Frequency of Monitoring The VBE, a VBE Participant in the VBA acting on the VBE's behalf, or the VBE's accountable body or responsible person reasonably monitors and assesses the following and reports the monitoring and assessment of the following to the VBE's accountable body or responsible person, as applicable, no less frequently than annually or at least once during the term of the VBA for arrangements that are less than one year: o The coordination and management of care for the TPP in the VBA, o Any deficiencies in the delivery of quality care under the VBA, and o Progress toward achieving the legitimate outcome or process measure(s) in the VBA. Results of Monitoring If the VBE's accountable body or responsible person determines, based on monitoring and assessment, that the VBA has resulted in material deficiencies in quality of care or is unlikely to further the coordination and management of care for the TPP, the parties must within 60 days either (i) terminate the arrangement or (ii) develop and implement a corrective action plan designed to remedy the deficiencies within 120 days, and, if the corrective action plan fails to remedy the deficiencies within 120 days, terminate the arrangement.
Directed Referral and No Inducement	The VBA does not: o Limit the VBE Participant's ability to make decisions in the best interest of its patients; o Direct or restrict referrals to a particular provider if (i) the patient expresses a preference for a different provider; (ii) the patient's insurer determines the provider or (iii) such direction or restriction is contrary to applicable law under Medicare and Medicaid; or o Induce parties to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient.
Records	For a period of at least six years, the VBE or VBE Participant makes available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of the Care Coordination VBA Safe Harbor.
Other	If the exchange of remuneration involves a limited technology participant, the exchange by a limited technology participant and another VBE Participant or VBE must not be conditioned on any recipient's exclusive use or minimum purchase of any item or service manufactured, distributed or sold by the limited technology recipient.

Patient Incentive Safe Harbors

The AKS Final Rule includes the following three safe harbors that protect certain remuneration provided directly to patients:

- Patient Engagement Tool / Support Safe Harbor: This safe harbor protects remuneration in the form of a patient engagement tool or support to improve quality, health outcomes and efficiency.

- CMS-Sponsored Model Patient Incentives Safe Harbor: This safe harbor protects patient incentives provided in the context of a CMS-Sponsored Model.

- ACO Beneficiary Incentive Program Safe Harbor: This safe harbor was added as a result of Section 50341 of the Budget Act of 2018 and protects incentive payments made by an ACO to an assigned beneficiary under a beneficiary incentive program that is established in accordance with 42 U.S.C. 1395jjj(m), which allows incentive payments from an ACO to a beneficiary in an amount up to $20 for certain primary care services under certain conditions, provided all of the requirements found in 42 U.S.C. 1395jjj(m) are met. The OIG notes that, due to the nature of the statutory language of the Budget Act of 2018, it is not incorporating a requirement to comply with regulations that CMS has issued with respect to ACO beneficiary incentive programs as a condition to falling within the ACO Beneficiary Incentive Program Safe Harbor, though it advises ACOs to review the regulations to ensure that their beneficiary incentive programs meet all applicable programmatic requirements.

The conditions that are required to be met to fall within the Patient Engagement and Support Safe Harbor and the CMS-Sponsored Model Patients Incentive Safe Harbor are set forth in Table 6 below.

TABLE 6

Requirement	AKS: Patient Engagement Tool / Support AKS Safe Harbor	AKS: CMS-Sponsored Model Patient Incentive Safe Harbor
Scope	Remuneration Scope Covers remuneration in the form of a patient engagement tool or support furnished by a VBE Participant to a patient in the TPP of a VBA to which the VBE Participant is a party. VBE Participant Scope Any person other than Ineligible VBE Participants.	Remuneration Scope Covers CMS-Sponsored Model Patient Incentives with respect to which CMS has determined that the safe harbor is available. VBE Participant Scope No limitations.
Furnishing of the Patient Incentive	The patient engagement tool or support must be furnished directly to the patient (or the patient's caregiver, family member or other individual acting on the patient's behalf) by a VBE Participant that is a party to the VBA or	The CMS-Sponsored Model Patient Incentive must be furnished by a CMS-Sponsored Model Participant (or by an agent of a CMS-Sponsored Model Participant under its direction and control), unless otherwise specified by the participation documentation.

TABLE 6		
Requirement	**AKS: Patient Engagement Tool / Support AKS Safe Harbor**	**AKS: CMS-Sponsored Model Patient Incentive Safe Harbor**
	its eligible agent (i.e., any person other than an Ineligible VBE Participant).	
Goals for the Patient Incentive	The patient engagement tool / support must advance one or more of the following goals: ○ Adherence to a treatment regimen determined by the patient's licensed health care professional, ○ Adherence to a drug regimen determined by the patient's licensed health care professional, ○ Prevention or management of a disease or condition as directed by the patient's licensed health care professional, or ○ Ensure patient safety.	The CMS-Sponsored Model Participant must reasonably determine that the CMS-Sponsored Model Patient Incentive will advance one or more goals of the CMS-Sponsored Model.
Patient Incentive Requirements	• The patient engagement tool/ support must: ○ Be an in-kind item, good or service, ○ Have a direct connection to the coordination and management of care[23] of the TPP, ○ Not include any cash or cash equivalent, ○ Not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program,	• The CMS-Sponsored Model Patient Incentive must have a direct connection to the patient's health care unless the participation documentation expressly specifies a different standard. • The CMS-Sponsored Model Patient Incentive must be furnished consistent with the CMS-Sponsored Model and must satisfy such programmatic requirements as may be imposed by CMS in connection with the safe harbor.

[23] "*Coordination and management of care*" means the deliberate organization of patient care activities and sharing of information between two or more VBE Participants, one or more VBE Participants and the VBE or one or more VBE Participants and patients, that is designed to achieve safer, more effective or more efficient care to improve the health outcomes of the TPP.

TABLE 6		
Requirement	**AKS: Patient Engagement Tool / Support AKS Safe Harbor**	**AKS: CMS-Sponsored Model Patient Incentive Safe Harbor**
	○ Be recommended by the patient's licensed health care professional, and ○ Advance one or more of the patient engagement tool/ support goals referenced above. • The patient engagement tool/ support may not be funded or contributed by a VBE Participant that is not a party to the applicable VBA or an Ineligible VBA Participant.	
Records	For a period of at least six years, the VBE Participant makes available to the Secretary, upon request, all materials and records sufficient to establish that the patient engagement tool or support was distributed in a manner that meets the requirements of the Patient Engagement Tool / Support Safe Harbor.	The CMS-Sponsored Model Participant makes available to the Secretary, upon request, all materials and records necessary to establish whether the CMS-Sponsored Model Patient Incentive was distributed in a manner that meets the conditions of the safe harbor.
Other Conditions	<u>Retail Value Limitation</u> The aggregate retail value of patient engagement tools / supports furnished to a patient by a VBE Participant on an annual basis may not exceed $500, subject to an annual CPI adjustment. <u>No Marketing</u> The VBE Participant or any eligible agent does not exchange or use the patient engagement tool / support to market other reimbursable items or services or for patient recruitment purposes. <u>Insurance Coverage Limitation</u> The availability of a tool / support is not determined in a manner that takes into account the type of insurance coverage for the patient.	None.

Other Stark Law Final Rule Changes Supporting VBAs

Indirect Compensation Arrangement Changes

CMS finalized an amendment specifying the exceptions that are applicable to indirect compensation arrangements, adding the following provision to its definition of an indirect compensation arrangement at 42 CFR 411.354(c): [24]

> (iii) Special rule for indirect compensation arrangements involving value-based arrangements. When an unbroken chain described in paragraph (c)(2)(i) of this section includes a value-based arrangement (as defined at § 411.351) to which the physician (or physician organization in whose shoes the physician stands under this paragraph) is a direct party –
>
> (A) Only the exceptions at §§ 411.355, 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement if the entity furnishing DHS is not an MCO or IPA; and
>
> (B) Only the exceptions at §§ 411.355, 411.357(n), 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement if the entity furnishing DHS is an MCO or IPA.

Accordingly, under this amended rule, CMS specifies that, if an indirect compensation arrangement existed between a DHS entity and a physician and if the compensation arrangement to which the physician is a direct party qualifies as a VBA, then the parties could structure the VBA to fall within the Full-Risk Exception, the Meaningful Downside Risk Exception or the Outcome Measure VBA Exception and, if the parties did so, then the indirect compensation arrangement would fall within a compensation arrangement exception and the DHS entity and the physician would not be subject to the billing and referral limitations set forth in the Stark Law.

Group Practice – Changes to Special Rules for Profit Shares and Productivity Bonuses

CMS revised the special rules for profit shares and productivity bonuses that are applicable to group practices and are located at 42 CFR 411.352(i). The amended language reads:

> (3) Notwithstanding paragraph (g) of this section, profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined at §411.351, may be distributed to the participating physician.

Unlike the other changes discussed herein, which are effective January 19, 2021, this change will become effective on January 1, 2022.

[24] In addition to the special rule for indirect compensation arrangements involving value-based arrangements, CMS also confirms the default rule with respect to exceptions available for indirect compensation arrangements (i.e., only those exceptions located in §§ 411.355 and 411.357(p) are applicable to indirect compensation arrangements), as well as a special rule for indirect compensation arrangements involving a MCO or IPA under which CMS specifies that "[o]nly the exceptions at §§ 411.355, 411.357(n), and 411.357(p) are applicable in the case of an indirect compensation arrangement in which the entity furnishing DHS is a MCO or IPA".

This amended rule allows group practices to distribute DHS profits directly attributable to a physician's participation in a VBE to the participating physician without concern that the distribution would be deemed to directly take into account the volume or value of the physician's referrals.

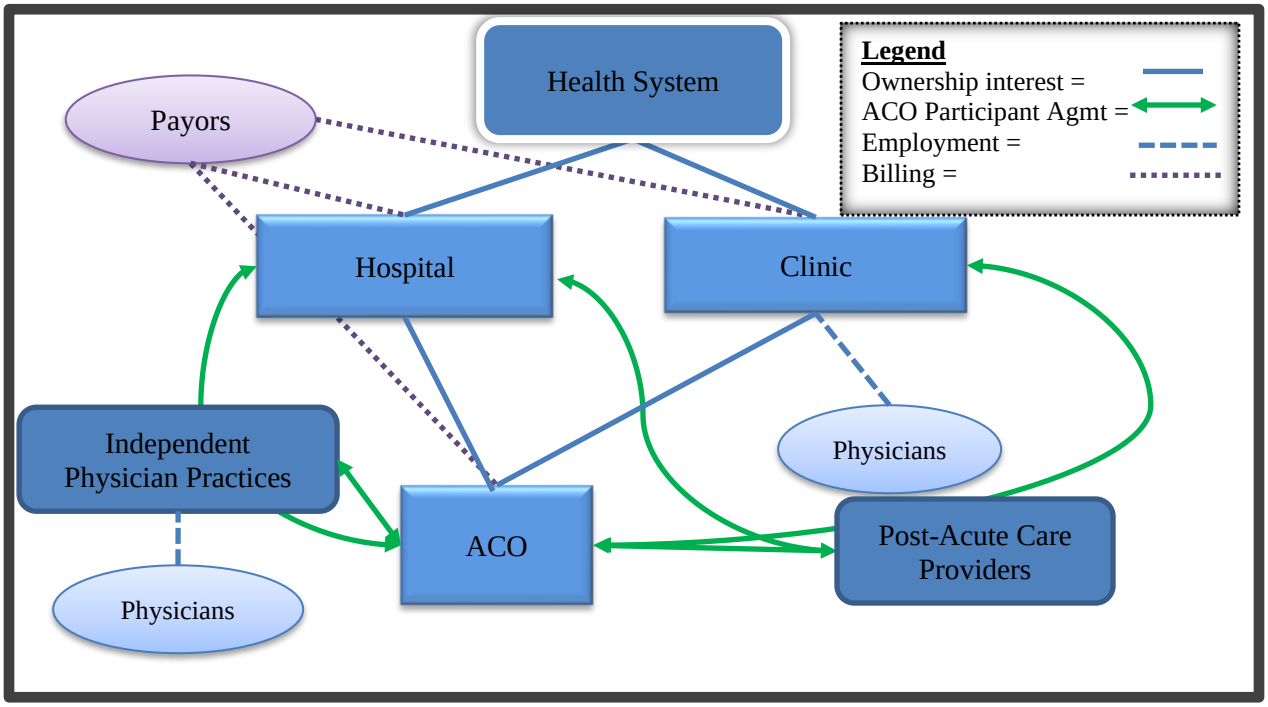
EXAMPLE APPLICATION OF THE STARK VBA EXCEPTIONS AND AKS VBA SAFE HARBORS

Health System Hypothetical

Introduction

To assist with an understanding of the manner in which the Stark VBA Exceptions and AKS VBA Safe Harbors contained in the Final Rules will apply to VBAs, we are using the hypothetical scenario described herein.

In order to better understand the corporate structure of the entities involved in the scenario, a corporate structure diagram of the hypothetical health system is included below.



As seen from the diagram, the Health System has two subsidiaries, one of which operates a Hospital and the other of which operates a Clinic. The Clinic employs physicians in various specialties, including primary care physicians, orthopedic surgeons, and interventional cardiologists. The Clinic compensates its physician employees using various compensation methodologies, though the Clinic withholds an amount equal to 5% of the compensation otherwise due the physician employees, which the physicians may earn if they achieve certain quality metrics, including patient satisfaction metrics.

The Hospital is an acute-care hospital that receives reimbursement from governmental and non-governmental payors under traditional prospective payment systems.

The Clinic participates in the Medicare and Medicaid programs as a physician group practice and has entered into payor contracts with both commercial payors and employer-based health plans. The physician employees of the Clinic reassign their billing rights with respect to all payors to the Clinic, and the Clinic bills for the physicians' services in its name and under its provider/supplier numbers. In addition to the alternative payment models discussed below, the Clinic is reimbursed for the physicians' services under the Medicare physician fee schedule and similar physician fee schedules of other payors.

In addition to traditional payor models discussed above, the Health System participates in the following alternative payment models through its various direct and indirect subsidiaries.

Primary Care Capitation Model

The ACO has entered into a primary care capitation model with a Medicare Advantage organization ("*MAO*") applicable to the MAO's beneficiaries. Under this capitation model, the ACO receives a per-member-per-month ("*PMPM*") payment, subject to a quality pool withhold and to certain risk corridors. The PMPM payment is designed to cover all primary care services for the beneficiaries covered by the MAO. In return for this PMPM payment, the ACO is required to meet the primary care service needs of the patient populations covered by the capitation model.

At six-month intervals, the ACO's progress toward meeting certain quality metrics is measured and scored. Based on the ACO's score, the ACO receives a prorated portion of the quality pool created from the PMPM withholds.

The ACO has entered into a participant agreement with the Clinic.[25] In this agreement, the Clinic agrees, among other things, to render, through its primary care physicians, mid-level providers and other clinical nursing staff, primary care services pursuant to the capitation model and to meet certain quality metrics/targets relating to these services. In return for its provision of the primary care services, the ACO agrees to pay the Clinic a fixed PMPM payment that is a percentage of the ACO's PMPM payment. If the ACO's costs of providing care are less than its PMPM payment, then the Clinic retains the difference, but if the ACO's costs of providing care exceed its PMPM payments, the Clinic sustains such loss.

Additionally, at the end of each year, the Clinic's progress toward meeting the quality metrics/targets set forth in the Clinic participant agreement is scored and, based on this score, the ACO makes a payment to the Clinic equal to a prorated portion of the quality pool created from the PMPM withholds.

The Clinic pays its clinical nursing staff an hourly rate that is market-commensurate. The Clinic pays its mid-level professionals a fixed annual salary, with the potential to earn a quality bonus based on the Clinic's mid-level professionals meeting certain quality targets distributed to the mid-level professionals. The Clinic pays its primary care physicians an annual salary that is designed to constitute 80% of the market rate for physicians, with the remainder of the salary dependent on the primary care physicians reaching certain cost productivity measures as well as certain quality metrics that are tied to efficient management of the patient panel being managed by the physicians. If the primary care physicians meet all of the relevant efficiency and quality metrics, the resulting salary for the physicians would be equal to 120% of the market rate for primary care physicians.

The Clinic provides patients with a patient portal pursuant to which the patient can review lab and other test results and see the status of other services relevant to the care of the patient. Additionally, the Clinic

[25] The ACO has entered into participant agreements with other providers as well in furtherance of rendering care to the primary care patient population. These other arrangements are not addressed herein.

offers primary care video consultations and email consultations with the mid-level professionals and primary care physicians employed by the Clinic for no additional charge to patients.

Employer-Based Health Plan – Orthopedic Surgery Services

The ACO has entered into a bundled payment model with an employer-based health plan, pursuant to which the ACO receives a flat bundled rate (subject to a 10% quality withhold, which forms a quality pool, as well as certain risk corridors) that is based on a percentage of the historic costs the health plan has incurred with respect to items and services associated with certain orthopedic surgery procedures identified by the plan. The items and services cover all items and services covered by the health plan relating to the procedures coming within the scope of the program. To the extent the flat bundled rate received by the ACO exceeds the ACO's costs in rendering care to patients undergoing these procedures, the ACO is able to retain such excess proceeds. To the extent the flat bundled rate received by the ACO does not cover all of the ACO's costs in rendering care to the patients covered by the program, the ACO is required to bear up to 20% of any such loss.

The ACO has in turn entered into agreements with various providers, including, but not limited to, the Hospital, the Clinic (which employs orthopedic surgeons), an independent orthopedic physician group, an independent anesthesia group, and various post-acute care providers, through which the providers are required to render care to health plan members undergoing orthopedic procedures and, in return, receive an established rate from the ACO for these services, subject to a withhold of 10% for meeting certain quality metric targets. In addition to the rates for services, the Hospital also is entitled to receive 10% of any savings achieved by the ACO under the program, but is also required to fund 10% of any losses, while the Clinic and the post-acute care providers (collectively) are entitled to receive 5% of savings achieved by the ACO and must fund 5% of any losses.

In its arrangement with its employed orthopedic surgeons, the Clinic withholds 10% of the surgeons' compensation. The surgeons will be paid this withheld compensation if they meet certain cost and quality metrics relating to the orthopedic surgery health plan program. Currently, the independent practices do not similarly place their physician employees' compensation at risk, but rather distribute funds earned under the program to the physicians who participate in the program as part of an annual profit-sharing plan.

As part of the arrangement with the ACO, the Hospital agrees to provide a care coordinator to the Clinic, the independent orthopedic physician group and the post-acute providers who assists those providers in managing the care of patients undergoing orthopedic procedures that are subject to the ACO arrangement.

The ACO has also entered into an arrangement with a DMEPOS company that, in furtherance of the orthopedic services arrangement with the health plan, agrees to provide needed DMEPOS to patients undergoing orthopedic procedures, receiving compensation from the ACO for its provision of DME items and services, with 5% of its compensation dependent on the DME provider meeting certain timeliness and patient satisfaction standards.

BPCIA

The Hospital participates in Bundled Payment for Care Improvement Advanced, a Medicare alternative payment model ("*BPCIA*"), through an arrangement where the Hospital acts as a "nonconvenor participant." BPCIA is a bundled payment model in which Medicare retrospectively determines the costs spent by providers with respect to Medicare patients experiencing certain clinical episodes in an inpatient or outpatient setting that are selected by BPCIA participants and compares those costs against a target price set by Medicare (the target price covers the total cost of care (both Medicare Part A and Part B spending)

during the clinical episode). The clinical episodes begin on the first day of the triggering inpatient stay or outpatient procedure and continue through the 90-day period from the day of discharge from the inpatient stay and/or outpatient procedure.

Providers continue to receive traditional reimbursement for the services rendered to Medicare beneficiaries undergoing a clinical episode. However, they have the potential to participate in gains and losses experienced by Medicare as a result of the providers' participation in BPCIA. If total spending for care rendered to a patient undergoing a clinical episode is less than the target price, Medicare will pay 50% of the "savings" to the participant. However, if the cost of care rendered to a patient undergoing a clinical episode exceeds the target price, the participant must pay Medicare an amount equal to 50% of the "loss" experienced by the Medicare program, subject to certain stop-loss protection. Payments under BPCIA are also adjusted based on quality performance of the participants.

Here, in its BPCIA application, the Hospital selected a variety of clinical episodes to participate in through BPCIA, including certain cardiac procedures. The Hospital has entered into an agreement known as an "*NPRA Sharing Agreement*" with the Clinic pursuant to which the Clinic agrees, and agrees to cause its interventional cardiologists, to implement the care redesign mechanisms developed by the Hospital that are designed to lower costs and increase quality of care provided to patients undergoing the selected clinical episodes. Under the NPRA Sharing Agreement, the Hospital agrees to share with the Clinic 30% of any payments the Hospital receives from Medicare under BPCIA, provided certain quality metrics are met, though the Clinic does not agree to assist the Hospital with any repayment obligations the Hospital may have with respect to Medicare.

In turn, the Clinic has entered into a distribution agreement with its three (3) interventional cardiologists through which the interventional cardiologists agree to implement the Hospital's care redesign mechanisms, and, in return, each of the three interventional cardiologists is entitled to 25% of any amounts received by the Clinic that are attributable to his or her own selected cardiac procedure clinical episodes, provided certain quality metrics are met.

Analysis

Introduction

In reviewing the Health System's arrangements for purposes of the new Stark VBA Exceptions and AKS VBA Safe Harbors, the first step is to identify potential VBEs, including potential VBAs that exist within the context of a VBE.

The following VBEs potentially exist in the Health System's arrangements:

- A VBE among the ACO, the Clinic and potentially the mid-level professionals primary care physicians with respect to the primary care capitation model (the "*Primary Care VBE*").

- A VBE among the ACO, the Hospital, the Clinic, the independent physician practices, and the post-acute care providers with respect to the arrangement with the employer-based health plan to provide orthopedic surgery services (the "*Orthopedic Surgery VBE*").

- A VBE among the Hospital and the Clinic with respect to the Hospital's participation in BPCIA (the "*BPCIA VBE*").

Each of these potential VBEs, as well as the potential VBAs that exist within the context of each VBE and whether the potential VBAs meet the requirements of the Stark VBA Exceptions and the AKS VBA Safe Harbors, is discussed below.

Primary Care VBE

Does the Primary Care VBE constitute a VBE under the Final Rules?

The Primary Care VBE is a VBE under the Final Rules due to its meeting the following four VBE elements:

- *First Element – Value-Based Purpose*: The ACO, the Clinic and potentially the mid-level professionals and physicians are VBE Participants collaborating to achieve one or more of the following value-based purposes: (i) coordinating and managing the care of a TPP (the Medicare beneficiaries enrolled under the MAO plan who are in need of primary care services); (ii) potentially improving the quality of care for a TPP (the primary care arrangement contains a quality metric component to the arrangement that appears designed to improve the quality of care for the TPP); and (iii) appropriately reducing the costs to the MAO while maintaining the quality of care for the TPP.

- *Second Element – VBE Participants*: The ACO and Clinic are both parties to the Primary Care VBE. Additionally, the arrangement could probably be structured such that the mid-level professionals and the primary care physicians are also parties to the Primary Care VBE.

- *Third Element – Accountable Body/Person*: The accountable body element of the VBE is met, assuming that the governing board of the ACO would be determined to be the entity which has the financial and operational oversight of the Primary Care VBE.

- *Fourth Element – Governing Document*: We assume there would be an agreement among the ACO and the Clinic, as well as potentially the mid-level professionals and physicians, which would describe the Primary Care VBE and which would describe how the VBE Participants (i.e., the ACO, the Clinic and other providers) intend to achieve their value-based purpose.

What are the potential VBAs associated with the Primary Care VBE?

After confirming the existence of the Primary Care VBE, we next move to identifying VBAs within the Primary Care VBE. These include:

- The participant agreement between the ACO and Clinic, under which the Clinic agrees to render primary care services through its primary care physicians, mid-level providers and other clinical nursing staff and primary care services pursuant to the capitation models and to meet certain quality metrics/targets relating to these services in return for a smaller PMPM payment than that received by the ACO as well as a portion of the quality pool created through the PMPM withholds (the "*ACO-Clinic Primary Care VBA*").

- The Clinic's provision of a patient portal and telehealth video and email consultations with mid-level professionals and physicians (the "*Primary Care Additional Support Tools*").

- The Clinic's payment arrangement with its mid-level professionals of a fixed annual salary, with the potential to earn a quality bonus based on the Clinic's mid-level professionals meeting certain quality targets distributed to the mid-level professionals (the "*Clinic-MLP Primary Care VBA*").

- The Clinic's payment arrangement with its primary care physicians, who receive an annual salary constituting 80% of the market rate for physicians, with the remainder of the salary dependent on the primary care physicians reaching certain cost productivity measures as well as certain quality metrics that are tied to efficient management of the patient panel being managed by the physicians, resulting in a maximum potential salary equal to 120% of the market rate for primary care physicians (the "*Clinic-Physician Primary Care VBA*").

The above-identified VBAs are referred to collectively herein as the "*Primary Care VBAs*". In addition, the ACO-Clinic Primary Care VBA, the Clinic-MLP Primary Care VBA, and the Clinic-Physician Primary Care VBA shall be collectively referred to as the "*Primary Care Cash Remuneration VBAs*".

Next, we turn to analyzing whether each of the above Primary Care VBAs meets a Stark VBA Exception and/or an AKS VBA Safe Harbor.

Do the Primary Care Cash Remuneration VBAs meet the Stark VBA Exceptions or the AKS VBA Safe Harbors?

Stark VBA Exception Analysis

For purposes of the Stark Law, we are only concerned with those Primary Care VBAs that involve physicians (either directly or through the creation of an indirect financial arrangement). Accordingly, we are primarily reviewing the Clinic-Physician Primary Care VBA and the financial relationships created as a result of that VBA from a Stark Law perspective.

The Clinic-Physician Primary Care VBA creates two potential compensation arrangements from a Stark Law perspective: (i) a direct compensation arrangement between the Clinic and its primary care physician employees and (ii) a potential indirect compensation arrangement between the Hospital and the Clinic's primary care physician employees given the following relationship chain: primary care physician employee – employment relationship – Clinic – participant agreement – ACO – ownership interest – Hospital.

That said, if the Primary Care VBE meets the requirements to be considered at "full financial risk" under the Full-Risk Exception, then this would protect both the direct compensation arrangement between the physicians and the Clinic and the potential indirect compensation arrangement between the physicians and the Hospital because the Full-Risk Exception covers all remuneration paid under a full-risk VBA. In order to be considered to be at full financial risk, the VBE must be financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the TPP.

Here, it would appear that the Primary Care VBE meets the requirements to be considered at "full financial risk" since, under the arrangement with the MAO, the ACO is financially responsible on a prospective basis for the cost of all patient care items and services covered by the ACO for each patient in the TPP. Additionally, the fact that the primary care arrangement includes risk corridors should not preclude the arrangement as being considered at "full-risk."

As noted above, if the Primary Care VBE is considered to be at "full financial risk," then all remuneration under the VBE would be covered by the Full-Risk Exception, assuming the following conditions are met: (i) the remuneration is for, or must result from, value-based activities undertaken by the recipient of the remuneration for patients in the TPP; (ii) the remuneration is not conditioned on referrals of patients who are not part of the TPP or business not covered under the VBA; (iii) to the extent there is a directed referral requirement, it must be in writing and signed by the parties and must not apply if the patient expresses a

preference for a different provider and the patient's insurer determines the provider or the referral is not in the patient's best medical interests in the physician's judgment; (iv) the remuneration is not an inducement to reduce or limit medically necessary items or services to any patient; and (v) records of the methodology for determining, and the actual amount of, remuneration are maintained for six years and made available to the Secretary upon request.

Accordingly, assuming the Full-Risk Exception is met, it would cover the direct compensation arrangement between the Clinic and its employed primary care physicians (allowing those physicians to receive compensation that potentially is 20% in excess of market value).[26] Assuming that there was an indirect compensation arrangement created between the physicians and the Hospital, meeting the Full-Risk Exception would also protect that arrangement, given the changes made to the special rules for indirect compensation arrangements allowing the Stark VBA Exceptions to apply to indirect compensation arrangements.

AKS VBA Safe Harbor Analysis

Assuming that the term of the Primary Care VBE is at least one year, the Primary Care VBE will also be considered at full financial risk for purposes of the Full-Risk Safe Harbor.

While the Full-Risk Safe Harbor would clearly cover remuneration exchanged between the ACO and the Clinic, since both of those entities would be parties to the Primary Care VBE, the Full-Risk Safe Harbor does not apply to downstream arrangements. Thus, if the mid-level providers and the physicians were not direct parties to the Primary Care VBE (but rather contracted only with the Clinic with respect to the care of patients in the TPP of the Primary Care VBE), then the Full-Risk Safe Harbor would apply to neither the Clinic-MLP Primary Care VBA nor the Clinic-Physician Primary Care VBA. Accordingly, to allow for such safe harbor protection, the employed mid-level professional and physician employees of the Clinic should be VBE Participants, rather than downstream contractors of the VBE.

Assuming the mid-level professional and physician employees are VBE Participants, then all of the Primary Care Cash Remuneration VBAs should fall within the Full-Risk Safe Harbor so long as the following requirements are met:

- Each of the Primary Care Cash Remuneration VBAs is set forth in writing, is signed by the parties and specifies all the material terms of the VBA, including the term of the VBA and the value-based activities of the VBA;

- The remuneration provided by or shared among the VBE and each VBE Participant: (i) is directly connected to one or more of the VBE's value-based purposes; (ii) does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and (iii) is not exchanged or used for the purpose of marketing items or services furnished by the VBE or VBE Participant to patients or for patient recruitment activities;

[26] However, even if the arrangement also met the requirements of the Full-Risk Safe Harbor, which also does not contain a fair market value requirement, the Health System, if tax-exempt, would continue to need to consider any private inurement and private benefit implications of this arrangement.

- The VBE or VBE Participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on, (i) referrals of patients who are not part of the TPP or (ii) business not covered under the VBA;

- The VBA does not induce parties to reduce or limit medically necessary items or services to any patient;

- The VBE Participant (unless the VBE Participant is a payor) does not claim payment in any form from the payor for items or services covered under the contract or VBA between the VBE and the payor;

- The VBA provides or arranges for a quality assurance program for services furnished to the TPP that (i) protects against underutilization, and (ii) assesses the quality of care furnished to the TPP; and

- Records of methodology for determining, and the actual amount of, remuneration are maintained for six years and made available to the Secretary upon request.

Falling within the Full-Risk Safe Harbor would protect the remuneration paid to the VBE Participants under the Primary Care Cash Remuneration VBAs (including the above market compensation that is paid to the primary care physicians, though the Health System, if tax-exempt, would continue to need to consider any private inurement and/or private benefit implications of this arrangement).

Do the Primary Care Additional Support Tools meet the requirements of a Stark VBA Exception or an AKS VBA Safe Harbor?

The Primary Care Additional Support Tools would appear to fall under the Full-Risk Exception and the Full-Risk Safe Harbor for the same reasons and under the same conditions as the Primary Care Cash Remuneration VBAs, given these exceptions and safe harbors cover both cash remuneration and in-kind remuneration.

In addition, the Primary Care Additional Support Tools could be structured to fall within the Care Coordination VBA Safe Harbor and the Patient Engagement Tool / Support Safe Harbor, provided all of the conditions relating to those exceptions are met. To review a list of the conditions applicable to the Care Coordination VBA Safe Harbor, see Table 6 on pages 26 – 28 of this White Paper. To review a list of the conditions applicable to the Patient Engagements Tool / Support Safe Harbor, see Table 5 on pages 23 – 25 of this White Paper.

Orthopedic Surgery VBE

Does the Orthopedic Surgery VBE constitute a VBE under the Final Rules?

The Orthopedic Surgery VBE is a VBE under the Final Rules because it meets the following four elements:

- *First Element – Value-Based Purpose*: The ACO, Hospital, Clinic, independent physician practices and post-acute care providers are all VBE Participants that are collaborating to achieve one or more of the following value-based purposes: (i) coordinating and managing the care of a TPP (the TPP would be defined as members of the employer-based health plan who are undergoing orthopedic surgery procedures); (ii) potentially improving the quality of care for a TPP (this would be true given the quality-related metrics contained in the Orthopedic Surgery VBE); (iii) appropriately reducing the costs to the health plan, while maintaining the quality of care for the TPP; and

(iv) 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 TPP.

- *Second Element – VBE Participants*: Each of the ACO, the Hospital, the Clinic, the independent physician practices and the post-acute care providers are parties to the Orthopedic Surgery VBE.

- *Third Element – Accountable Body/Person*: The participant agreements between the ACO and each of the participants in the Orthopedic Surgery VBE would likely identify the ACO as the entity responsible for the financial and operational oversight of the Orthopedic Surgery VBE, which would meet the accountable body/person element of the VBE definition.

- *Fourth Element – Governing Document*: The participant agreements should, if structured appropriately, serve as the governing document that describes the Orthopedic Surgery VBE and should also describe how the VBE Participants (i.e., the ACO, the Hospital, the Clinic, the independent practices and the post-acute care providers) intend to achieve the value-based purpose of the Orthopedic Surgery VBE.

What are the potential VBAs associated with the Orthopedic Surgery VBE?

After confirming the existence of the Orthopedic Surgery VBE, we next move to identifying VBAs within the Orthopedic Surgery VBE. These include:

- The arrangement between the ACO and the Hospital pursuant to which the ACO pays the Hospital compensation for its provision of services to a health plan member undergoing an orthopedic procedure, with the compensation being at a set rate, subject to a 10% withhold for meeting certain quality metrics. In addition, under the ACO-Hospital arrangement, the Hospital agrees to a two-sided risk arrangement, under which it agrees to share in 10% of the ACO's gains and losses (the "*ACO-Hospital Orthopedic Procedure VBA*");

- The arrangement between the ACO and the Clinic pursuant to which the ACO pays the Clinic compensation for its provision of services to a health plan member undergoing an orthopedic procedure, subject to 10% withhold for meeting certain quality metric targets. In addition, under the ACO-Clinic arrangement, the Clinic agrees to a two-sided risk arrangement, under which the Clinic agrees to share in 5% of the ACO's gains and losses (the "*ACO-Clinic Orthopedic Procedure VBA*");

- The arrangement under which the Clinic compensates its employed orthopedic surgeons, with 10% of the compensation being at risk for meeting certain cost and quality targets relating to health plan members under the Orthopedic Surgery VBE (the "*Clinic-Orthopedic Surgeon VBA*");

- The arrangement between the ACO and the independent physician practices pursuant to which the ACO pays the independent practices compensation for its provision of services to a health plan member undergoing an orthopedic procedure, subject to a 10% withhold for meeting certain quality targets (the "*ACO-Independent Practice Orthopedic Procedure VBA*");

- The arrangement between the independent practices and their employed physicians under which the independent practices distribute funds earned by the practices under the health plan orthopedic surgery program to those physician employees participating in the program as part of its annual

profit-sharing arrangement, without any of the funds being at risk for the physician employees (the "*Independent Practices – Employed Physicians VBA*");

- The arrangement between the ACO and the post-acute care providers pursuant to which the ACO pays the post-acute care providers compensation for their provision of services to a health plan member undergoing an orthopedic procedure, subject to a 10% withhold for meeting certain quality metric targets. In addition, under the ACO-post-acute care provider arrangement, the post-acute providers agree to a two-sided risk arrangement, under which they agree to share collectively in 5% of the ACO's gains and losses (the "*ACO – Post-Acute Providers Orthopedic Procedure VBA*");

- The arrangement between the Hospital and the Clinic, the independent orthopedic physician practices and the post-acute care providers under which the Hospital supplies the Clinic, the independent orthopedic physician practices and the post-acute care providers care coordination and management personnel who will assist in managing the care of health plan members who have undergone orthopedic procedures (the "*Care Coordination Orthopedic Procedure VBA*"); and

- The arrangement between the ACO and the DMEPOS provider under which the DMEPOS provider agrees to supply health plan members who have undergone orthopedic procedures with DMEPOS items (the "*Orthopedic Procedure DME VBA*").

The above VBAs are collectively referred to herein as the "*Orthopedic Surgery VBAs*". Next, we turn to analyzing whether each of the Orthopedic Surgery VBAs within the Orthopedic Surgery VBE falls into a Stark VBA Exception and/or an AKS VBA Safe Harbor.

Do the Orthopedic Surgery VBAs that implicate the Stark Law fall within a Stark VBA Exception?

Of the Orthopedic Surgery VBAs within the Orthopedic Surgery VBE, only those involving physicians implicate the Stark Law; hence, only the Clinic-Orthopedic Surgeon VBA, the Independent Practices – Employed Physicians VBA, and the Care Coordination Orthopedic Procedure VBA need to be analyzed to determine whether they fall within the Stark VBA Exceptions.

Clinic-Orthopedic Surgeon VBA

Turning first to an analysis of the Clinic-Orthopedic Surgeon VBA, that VBA creates two potential compensation arrangements from a Stark Law perspective, one involving a direct compensation arrangement between the Clinic and its orthopedic surgeons and the other involving a potential indirect compensation arrangement between the Hospital and the Clinic's orthopedic surgeon employees given the following relationship chain: orthopedic surgeon employee – employment relationship – Clinic – participant agreement – ACO – ownership interest – Hospital.

The Orthopedic Surgery VBE does not meet the Full-Risk Exception because the VBE is not at full financial risk since the ACO is required to cover only 20% of loss under the program. However, since the orthopedic surgeons are responsible for forgoing at least 10% of the total value of the remuneration the surgeons could potentially receive under the Clinic-Orthopedic Surgeon VBA based on their meeting certain cost and quality targets, the Meaningful Downside Risk Exception could be met, assuming the other conditions of the exception are satisfied. These include: (i) a description of the nature and extent of the physician's downside financial risk being set forth in writing; (ii) the methodology used to determine the amount of remuneration being set in advance of the undertaking of value-based activities for which the remuneration is paid; (iii) the remuneration being for or resulting from value-based activities undertaken by the recipient

of the remuneration for patients in the TPP; (iv) the remuneration not being conditioned on referrals of patients who are not part of the TPP or business not covered under the VBA; (v) if there is a directed referral requirement, the requirement (A) being in writing and signed by the parties, and (B) not applying if the patient expresses a preference for a different provider, the patient's insurer determines the provider or the referral is not in the patient's best medical interests in the physician's judgment; (vi) the remuneration not being an inducement to reduce or limit medically necessary items or services to any patient; and (vii) the records of methodology for determining, and the actual amount of, remuneration being maintained for six years and made available to the Secretary upon request.

Accordingly, assuming the Meaningful Downside Risk Exception is met, it would cover the direct compensation arrangement between the Clinic and its employed orthopedic surgeons (which would allow the Clinic to compensate the surgeons without having to confirm the fair market value of the compensation, at least from a Stark Law perspective).[27]

Additionally, assuming that there was an indirect compensation arrangement created between the surgeons and the Hospital, falling within the Meaningful Downside Risk Exception would also protect that arrangement, given the changes made to the special rules for indirect compensation arrangements, which allow the Stark VBA Exceptions to apply to indirect compensation arrangements.

The Independent Practices – Employed Physicians VBA

The Independent Practices – Employed Physicians VBA also creates two potential compensation arrangements from a Stark Law perspective: (i) a direct compensation arrangement between the independent practice and the employed physician and (ii) a potential indirect compensation arrangement between the Hospital and the employed independent practice physicians given the following relationship chain: independent practice physician – employment relationship – independent practice – participant agreement – ACO – ownership interest – Hospital.

As with the Clinic-employed orthopedic surgeons, the Full-Risk Exception is not met. However, unlike the situation with the Clinic-employed orthopedic surgeons, the Meaningful Downside Risk Exception is not met with respect to the independent practice physicians since their compensation from the health plan arrangement is not at-risk based on meeting quality metrics (rather, these physicians' compensation from the arrangement is through funds distributed to the physicians who participate in the program based on the practices' annual profit-sharing plan).

Beginning in 2022, a failure to meet the Meaningful Downside Risk Exception would not present concerns with respect to the direct compensation arrangement between the independent practices and the employed physicians, assuming the independent practices meet the qualifications of a group practice. This is due to the changes made in the Stark Law Final Rule to the special rules for productivity bonuses and profit shares. These revised special rules, which are effective January 1, 2022, allow for "profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise . . . to be distributed to the participating physician" without the compensation being based on the volume or value of the physician's referrals. Accordingly, compensating the physicians who participate in the program through a distribution under the practices' annual profit-sharing plan should meet the requirements of these new group practice special rules.

[27] The Clinic would continue to need to comply with the AKS, which, depending on the safe harbor, may include a fair market value requirement. Additionally, the Clinic, if tax-exempt, would also have to comply with tax-exempt considerations relating to private benefit and private inurement.

However, the special rules for productivity bonuses and profit shares would not provide protection for the potential indirect compensation arrangement between the Hospital and the independent practice physicians, as the group practice rule changes do not assist with protection for that compensation arrangement (rather, only the exceptions available at 42 CFR 411.355, 411.357(p) and 411.357(aa) are available to protect the potential indirect compensation arrangement between the Hospital and the independent practice physicians).

Accordingly, meeting the Meaningful Downside Risk Exception would be helpful for purposes of the potential indirect compensation arrangement between the Hospital and the independent practice physicians, and the independent physician practices should likely alter their compensation arrangement with their employed physicians to take advantage of that exception.[28] This would require the independent practices to place at least 10% of their compensation under the Independent Practices – Employed Physicians VBA at risk based on the physicians meeting the value-based purpose(s) of the Orthopedic Surgery VBE.

Care Coordination Orthopedic Procedure VBA

Under the Care Coordination Orthopedic Procedure VBA, the Hospital supplies care coordination personnel to various participants, including the Clinic and the independent practices, to assist in the coordination of care of the patients undergoing the orthopedic procedures. Assuming that there is benefit provided to the Clinic and independent practices through the arrangement, the Care Coordination Orthopedic Procedure VBA creates a potential indirect compensation arrangement between the Hospital and the physician employees of the Clinic and the independent practices.

However, if both the Clinic-Orthopedic Surgeon VBA and the Independent Practices – Employed Physicians VBA are structured to meet the Meaningful Downside Risk Exception, that could also provide protection for the care coordination personnel being provided by the Hospital, so long as the parties structure the care coordination personnel to be part of the Clinic-Orthopedic Surgeon VBA and the Independent Practices – Employed Physicians VBA.

Alternatively, the Care Coordination Orthopedic Procedures VBA could also likely be structured to meet the Outcome Measure VBA Exception. This would require the following conditions to be met:

- The Care Coordination Orthopedic Procedures VBA is set forth in a written "care coordination agreement" that includes a description of (i) the care coordination and other value-based activities involved in the arrangement, (ii) how these activities are expected to further the value-based purpose(s) of the Orthopedic Procedures VBE, (iii) the TPP of the VBA (i.e., health plan members who are undergoing orthopedic procedures covered by the arrangement), (iv) the type of the remuneration and the methodology used to determine the remuneration (which must be set in advance prior to the undertaking of the value-based activities for which the remuneration is paid), and (v) the outcome measures against which the Clinic physicians and independent practice physicians will be assessed, if any.

- The outcome measures identified in the care coordination agreement must be "objective and measurable" in a way that quantifies (i) improvements in, or maintenance of, the quality of patient care or (ii) a reduction in the costs to or growth in expenditures of the health plan while maintaining

[28] While the Independent Practices – Employed Physicians VBA could also potentially meet the Outcome Measure VBA Exception, given the more onerous requirements of that exception (as compared to the Meaningful Downside Risk Exception), all other things being equal, we would generally recommend the independent practices to amend their compensation arrangement with their employed physicians to meet the Meaningful Downside Risk Exception.

or improving the quality of patient care. Monitoring of the outcome measures must be done by the Orthopedic Surgery VBE or one of the VBE Participants at least annually, during which the following items must be monitored: (A) whether the parties have furnished the value-based activities required under the arrangement, (B) whether and how continuation of the value-based activities is expected to further the value-based purpose of the Orthopedic Surgery VBE, and (C) progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed. Finally, the care coordination agreement must set forth the requirements of the Outcome Measure VBA Exception with respect to the results of monitoring.

- The remuneration under the care coordination agreement must be for or result from value-based activities undertaken by the physicians for patients in the TPP; the remuneration may not be conditioned on referrals of patients who are not part of the TPP or business not covered under the Care Coordination Orthopedic Procedures VBA; and the remuneration may not be an inducement to reduce or limit medically necessary items or services to any patient.

- The Care Coordination Orthopedic Procedures VBA must be commercially reasonable.

- If there is a directed referral requirement included in the arrangement, the requirement must (i) be in writing and signed by the parties, and (ii) not apply if the patient expresses a preference for a different provider, the patient's insurer determines the provider or the referral is not in the patient's best medical interests in the physician's judgment.

- Records of methodology for determining, and the actual amount of, remuneration must be maintained for six years and made available to the Secretary upon request.

Structuring the Care Coordination Orthopedic Procedure VBA in a manner that meets the Outcome Measures VBA Exception would protect the indirect compensation arrangement that may be created between the Hospital and the Clinic-employed orthopedic surgeons and the physicians affiliated with the independent practices, given the changes CMS made in the Stark Law Final Rule specifying that the Stark VBA Exceptions are available exceptions for indirect compensation arrangements.

Do the Orthopedic VBAs fall within the AKS VBA Safe Harbors?

Full-Risk Safe Harbor, CMS-Sponsored Model Arrangements Safe Harbor and CMS-Sponsored Model Patient Incentives Safe Harbor: Not Applicable to Any of the Orthopedic Procedure VBAs

From an AKS VBA Safe Harbor perspective, the Orthopedic Procedure VBAs do not meet the Full-Risk Safe Harbor (since the Orthopedic Surgery VBE is not assuming full-financial risk) or either the CMS-Sponsored Model Arrangements Safe Harbor or the CMS-Sponsored Model Patient Incentives Safe Harbor (since the Orthopedic Surgery VBE does not involve a CMS-Sponsored Model).

Substantial Downside Risk Safe Harbor: ACO – Hospital Orthopedic Procedure VBA and ACO – Clinic Orthopedic Procedure VBA

In order to meet the Substantial Downside Risk Safe Harbor, both (i) the Orthopedic Surgery VBE would need to assume "*substantial downside financial risk*" from the health plan for at least one year and (ii) the VBE Participant would need to be at risk for a "*meaningful share*" of the Orthopedic Surgery VBE's downside financial risk.

While there are multiple methods for a VBE to assume "*substantial downside financial risk*," the method most applicable to the Orthopedic Surgery VBE is the episode of care method applying to multiple care settings. This method requires the Orthopedic Surgery VBE to assume financial risk equal to at least 20% of any loss, where (i) loss and savings are calculated by comparing current expenditures for all items and services furnished to the TPP pursuant to a clinical episode of care that are covered by the health plan to a bona fide benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care and (ii) the parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting. Here, the Orthopedic Surgery VBE appears to have assumed "*substantial downside financial risk*" given that the ACO is at risk for up to 20% of any loss incurred by the ACO in its provision of care to health plan members undergoing the orthopedic procedures within the health benefit program.

Next, looking at the "*meaningful share*" element, this requires either of the following to be satisfied:

- Two-Sided Financial Risk: The VBE Participant assumes two-sided risk for at least 5% of the losses and savings, as applicable, realized by the VBE pursuant to its assumption of substantial downside financial risk; or

- Per-Patient Payment: The VBE Participant receives from the VBE a prospective, per-patient payment on a monthly, quarterly or annual basis for a predefined set of items and 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.

Here, of the Orthopedic Surgery VBAs, the ACO – Hospital Orthopedic Procedure VBA and the ACO – Clinic Orthopedic Procedure VBA appear to meet the "*meaningful share*" element, since the Hospital agrees to assume 10% two-sided risk and the Clinic agrees to assume 5% two-sided risk.[29]

Accordingly, the ACO – Hospital Orthopedic Procedure VBA and the ACO – Clinic Orthopedic Procedure VBA would be able to meet the Substantial Downside Risk Safe Harbor if all of the following conditions are met:

- Each VBA is set forth in writing, is signed by the parties in advance of, or contemporaneously with, the commencement of the VBA and any material change to the VBA, and specifies all material terms, including (i) terms evidencing that the Orthopedic Surgery VBE is at substantial downside financial risk or will assume such risk in the next six months for the TPP, (ii) a description of the manner in which the Hospital and Clinic has a meaningful share of the VBE's substantial downside financial risk, and (iii) the value-based activities, the TPP, and the type of remuneration exchanged;

- Remuneration provided by, or shared among, the Orthopedic Surgery VBE and the Hospital and Clinic: (i) is directly connected to one or more of the Orthopedic Surgery VBE's value-based purposes, at least one of which must be: (A) coordination and managing the care of a TPP, (B) improving the quality of care for a TPP, or (C) appropriately reducing the costs to or growth in expenditures of the health plan without reducing the quality of care for a TPP; (ii) is used predominately to engage in value-based activities that are directly connected to the items and services for which the Orthopedic Surgery VBE has assumed substantial downside financial risk;

[29] Note that the post-acute providers collectively agree to 5% two-sided risk, but since there are multiple post-acute providers who comprise the 5% meaningful share, it does not appear that the ACO – Post Acute Provider Orthopedic Procedure VBA meets the "*meaningful share*" requirement of the Substantial Downside Risk Safe Harbor.

(iii) does not include the offer or receipt of an ownership/investment interest in an entity or any distributions related to such ownership/investment interest; and (iv) is not exchanged or used for the purpose of marketing items/services furnished by the Orthopedic Surgery VBE or VBE Participant to patients or for patient recruitment activities;

- The Orthopedic Surgery VBE or VBE Participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on, (i) referrals of patients who are not part of the TPP, or (ii) business not covered under the VBA;

- The VBA does not (i) limit the VBE Participant's ability to make decisions in the best interests of its patients or (ii) direct or restrict referrals to a particular provider, practitioner, or supplier if (A) the patient expresses a preference for a different provider; (B) the patient's payor determines the provider or (C) the direction or restriction is contrary to applicable law under Titles XVIII or XIX of the Social Security Act;

- The VBA does not induce parties to reduce or limit medically necessary items or services to any patient; and

- Records of methodology for determining, and the actual amount of, remuneration must be maintained for six years and made available to the Secretary upon request.

ACO – Independent Practice Orthopedic Procedure VBA and ACO – Post-Acute Provider Orthopedic Procedure VBA

While, as discussed above, the Orthopedic Surgery VBE assumes "*substantial downside financial risk*," the independent practices under the ACO – Independent Practice Orthopedic Procedure VBA and the post-acute providers under the ACO – Post-Acute Providers Orthopedic Procedure VBA do not assume a "*meaningful share*" of the VBE's "*substantial downside financial risk*;" accordingly, neither the ACO – Independent Practice Orthopedic Procedure VBA nor the ACO – Post-Acute Providers Orthopedic Procedure VBA fall within the Substantial Downside Risk Safe Harbor.

The ACO – Independent Practice Orthopedic Procedure VBA and the ACO – Post-Acute Providers Orthopedic Procedure VBA may, however, meet the Outcomes-Based Payment Safe Harbor. To fall within this safe harbor, the ACO – Independent Practice Orthopedic Procedure VBA and the ACO – Post-Acute Providers Orthopedic Procedure VBA would need to meet the following requirements:

- Each VBA will need to be set forth in a written agreement that has a term of at least one year and states at a minimum (i) a general description of the services to be performed by the ACO and the independent practice, (ii) the outcome measure(s) that must be achieved to receive the outcomes-based payment, (iii) the clinical evidence or credible medical support relied on by the parties to select the outcome measure(s), and (iv) the schedule for the parties to regularly monitor and assess the outcome measure(s);

- The "outcome measures" identified in the written agreement must be "legitimate" and based on a benchmark that is used to quantify (i) improvements in, or the maintenance of improvements in, the quality of patient care, or (ii) a *material* reduction in the costs to or growth in expenditures of payors while maintaining or improving the quality of patient care, or both (i) and (ii). Additionally, the written agreement should set forth the parties' plans (A) to regularly monitor and assess the independent practices' performance with respect to the outcome measure(s), including the impact of the VBA on patient quality of care, as well as (B) to periodically assess, and as necessary revise,

benchmarks and remuneration to ensure the remuneration is consistent with fair market value in an arm's-length transaction. The ACO should also have established policies and procedures, and the written agreement should allow the ACO to use the policies and procedures, to correct identified material performance failures or deficiencies in quality of care resulting from the VBA;

- The methodology for determining the outcomes-based payments payable by the ACO to the independent practices over the term of the arrangement is (i) "set in advance," (ii) commercially reasonable, (iii) consistent with fair market value and (iv) not determinized in a manner that *directly* takes into account the volume or value of referrals or business otherwise generated between the parties; and

- The written agreement does not limit any party's ability to make decisions in a patient's best interest or induce any party to reduce or limit medically necessary items and services.

Finally, in the event the ACO – Independent Practice Orthopedic Procedure VBA and/ or the ACO – Post-Acute Providers Orthopedic Procedure VBA does not meet the Outcomes-Based Payment Safe Harbor, the arrangement would be subject to traditional fraud and abuse analysis.

With respect to the ACO – Independent Practice Orthopedic Procedure VBA, given that under that VBA, the ACO pays the independent practices primarily for professional services, along with a 10% withhold for meeting certain quality metric targets, the arrangement may be able to meet a traditional safe harbor (e.g., the personal services and management contracts safe harbor) and/or may be determined to pose a low amount of risk under the AKS.

The facts and circumstances of the ACO – Post-Acute Providers Orthopedic Procedure VBA would also need to be reviewed to determine whether the arrangement falls into a traditional AKS safe harbor and/or to determine the level of risk posed by the arrangement under the AKS, though we note that the ACO – Post-Acute Providers Orthopedic Procedure VBA may involve somewhat greater risk, depending on the facts, than the ACO – Independent Practice Orthopedic Procedure VBA, given that the post-acute providers are eligible to participate in the upside of the ACO's arrangement with the health plan.

Clinic – Orthopedic Surgeon VBA and Independent Practices – Employed Physicians VBA

Unless the Clinic-affiliated orthopedic surgeons and the physicians employed by the independent practices are parties directly to the Orthopedic Procedures VBE, they would not be eligible for any of the AKS VBA Safe Harbors, since those safe harbors do not protect downstream arrangements. In that event, the arrangements would be subject to a traditional AKS analysis.

Although these VBAs meet the Meaningful Downside Risk Exception for purposes of the Stark Law, they would not meet the analogous AKS VBA Safe Harbor, because the physicians are not assuming a "*meaningful share*" of the "*substantial downside financial risk*" that the Orthopedic Procedures VBE is assuming from the benefit plan.[30]

Accordingly, since these VBAs involve cash remuneration, the only exception available for the VBAs is the Outcome-Based Payments Safe Harbor. That safe harbor would be available to the VBAs assuming they are structured to meet the conditions of the safe harbor. Accordingly, the parties would need to undergo the same analysis and meet the same conditions as set forth immediately above in the discussion of the

[30] This is true even though the physicians' compensation is at risk under the VBAs, because the physicians are not obligated to share in at least 5% of the Orthopedic Surgery VBE's obligation to pay losses back to the health plan.

ACO – Independent Practice Orthopedic Procedure VBA and the ACO – Post-Acute Provider Orthopedic Procedure VBA.

Care Coordination Orthopedic Procedure VBA

The Care Coordination Orthopedic Procedure VBA should be capable of being structured to fall within the Care Coordination VBA Safe Harbor. That safe harbor protects in-kind remuneration exchanged between a VBE and VBE Participant or between VBE Participants of a VBA, provided the remuneration (i) is used predominately to engage in value-based activities that are directly connected to the coordination and management of care for the TPP and does not result in more than incidental benefits to persons outside the TPP, and (ii) is not exchanged or used (A) more than incidentally for the recipient's billing or financial management services, (B) for the purpose of marketing items or services furnished by the VBE or a VBE Participant to patients or (C) for patient recruitment activities. The term "coordination and management of care" means the deliberate organization of patient care activities and sharing of information between two or more VBE Participants, one or more VBE Participants and the VBE or one or more VBE Participants and patients, that is designed to achieve safer, more effective or more efficient care to improve the health outcomes of the TPP.

Given that, under the Care Coordination Orthopedic Procedure VBA, the Hospital is furnishing a care coordinator registered nurse to the Clinic, the independent orthopedic physician group and the post-acute care provider to assist those providers in managing the care of health plan beneficiaries who have undergone orthopedic procedures that are subject to the health plan's program, it would appear the Care Coordination Orthopedic Procedure VBA is the type of arrangement that qualifies for protection under the Care Coordination VBA Safe Harbor, though the arrangement between the Hospital and the Clinic and the orthopedic physician group would need to be amended to meet the cost contribution requirements set forth below. To ensure safe harbor protection, the following conditions would need to be met:

- The Care Coordination Orthopedic Procedure VBA must be commercially reasonable, considering both the VBA itself and all Orthopedic Procedure VBAs within the Orthopedic Surgery VBE;

- The terms of the Care Coordination Orthopedic Procedure VBA must be set forth in writing and signed by the parties in advance of, or contemporaneously with, the commencement of the VBA and any material change to the VBA. The writing must state at a minimum the following: (i) the value-based purpose(s) of the value-based activities provided for in the VBA, (ii) the value-based activities to be undertaken by the parties to the VBA, (iii) the term of the VBA, (iv) the TPP, (v) a description of the remuneration, (vi) either the Hospital's cost of providing the care coordination nurse and the reasonable accounting methodology used by the Hospital to determine its cost, or the fair market value of the care coordination nurse, (vii) the percentage and amount contributed by the Clinic and the orthopedic physician group, (viii) if applicable, the frequency of the Clinic's and orthopedic physician group's contribution payments for ongoing costs, and (ix) the outcome or process measure(s) against which the Clinic and the orthopedic physician group will be measured;

- The parties to the VBA must establish one or more legitimate outcome or process measures that (i) the parties reasonably anticipate will advance the coordination and management of care for the TPP based on clinical evidence or credible medical or health sciences support, (ii) include one or more benchmarks that are related to improving or maintaining improvements in the coordination and management of care for the TPP, (iii) 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 to the TPP, (iv) relate to the remuneration exchanged under the VBA, and (v) are not based solely on patient satisfaction or patient convenience;

- The Hospital does not take into account the volume or value of, or condition the remuneration on, referrals of patients who are not part of the TPP or business not covered under the Care Coordination Orthopedic Procedure VBA;

- The Clinic and orthopedic physician group must pay at least 15% of the Hospital's cost for the care coordination nurse, using any reasonable accounting methodology, or the fair market value of the care coordination nurse. Since it would be an ongoing cost, the Clinic and the orthopedic physician group would need to make their contributions at reasonable, regular intervals;

- The Orthopedic Surgery VBE, a VBE Participant in the VBA acting on the VBE's behalf, or the VBE's accountable body or responsible person reasonably monitors and assesses the following and provides reports of the monitoring and assessment of the following to the VBE's accountable body or responsible person, as applicable, no less frequently than annually or at least once during the term of the VBA for arrangements that are less than one year: (i) the coordination and management of care for the TPP in the VBA, (ii) any deficiencies in the delivery of quality care under the VBA, and (iii) progress toward achieving the legitimate outcome or process measure(s) in the VBA;

- If the Orthopedic Surgery VBE's accountable body or responsible person determines, based on monitoring and assessment, that the VBA has resulted in material deficiencies in quality of care or is unlikely to further the coordination and management of care for the TPP, the parties must within 60 days either (i) terminate the arrangement or (ii) develop and implement a corrective action plan designed to remedy the deficiencies within 120 days, and, if the corrective action plan fails to remedy the deficiencies within 120 days, terminate the arrangement;

- The Care Coordination Orthopedic Procedure VBA does not: (i) limit the VBE Participant's ability to make decisions in the best interest of its patients; (ii) direct or restrict referrals to a particular provider if (A) the patient expresses a preference for a different provider; (B) the patient's insurer determines the provider or (C) such direction or restriction is contrary to applicable law under Medicare and Medicaid; or (iii) induce parties to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient; and

- For a period of at least six years, the VBE or VBE Participant makes available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of the Care Coordination VBA Safe Harbor.

In the event the parties decided not to structure the Care Coordination Orthopedic Procedure VBA in a manner that meets the Care Coordination VBA Safe Harbor (e.g., the parties elected not to meet the contribution requirements set forth in the safe harbor), the arrangement would be subject to traditional AKS analysis.

Orthopedic Procedure DME VBA

The Orthopedic Procedure DME VBA is not capable of meeting any of the AKS VBA Safe Harbors that protect cash remuneration because DMEPOS companies are listed among the Ineligible VBE Participants

for purposes of the Full-Risk Safe Harbor, the Substantial Downside Risk Safe Harbor and the Outcomes-Based Payment Safe Harbor.[31]

Accordingly, the Orthopedic Procedure DME VBA would need to be analyzed under a traditional AKS analysis. Under that analysis, the Orthopedic Procedure DME VBA may be able to meet the personal services and management contract safe harbor. Even if it does not meet the personal services and management contracts safe harbor, the Orthopedic Procedure DME VBA may present a low amount of risk under the AKS, assuming the rate that is being paid the DME company is a fair market value rate for the items and services being provided by the DMEPOS company under the Orthopedic Surgery VBE and assuming the absence of facts that would increase the AKS risk.

BPCIA VBE

Does the BPCIA VBE constitute a VBE under the Final Rules?

The Hospital appears to have created a VBE in relation to the Hospital's participation in BPCIA as a "nonconvenor participant." The BPCIA VBE appears to meet the following four VBE elements:

- *First Element – Value-Based Purpose*: The Hospital and Clinic, as well as potentially the interventional cardiologists, are VBE Participants that are collaborating to achieve one or more of the following value-based purposes: (i) coordinating and managing the care of a TPP (the TPP could be defined by the parties as the Medicare beneficiaries who are undergoing the selected cardiovascular procedures); (ii) potentially improving the quality of care for a TPP (whether this would be one of the value-based purposes of the Hospital-Clinic BPCIA VBE would depend on whether the Hospital and Clinic set quality metrics within the NPRA Sharing Agreement that improves the quality of care for the TPP); and (iii) appropriately reducing the costs to Medicare, while maintaining the quality of care for the TPP.

- *Second Element – VBE Participants*: Each of the Hospital and Clinic are parties to the BPCIA VBE. In addition, if structured appropriately, the interventional cardiologists could also be considered participants in the BPCIA VBE.

- *Third Element – Accountable Body/Person*: Assuming the NPRA Sharing Agreement identifies the Hospital as the entity responsible for the financial and operational oversight of the BPCIA VBE, the accountable body/person element of the VBE would be met.

- *Fourth Element – Governing Document*: The NPRA Sharing Agreement should, if structured appropriately, serve as the governing document that describes the BPCIA VBE and should also describe how the VBE Participants (i.e., the Hospital, the Clinic and potentially the interventional cardiologists) intend to achieve its value-based purpose.

What are the potential VBAs associated with the BPCIA VBE?

After confirming the existence of the BPCIA VBE, we next move to identifying VBAs within the BPCIA VBE. These include:

[31] If the DME company was providing Digital Health Technology under the Orthopedic Surgery VBE, the provision of the Digital Health Technology by the DME Company could potentially be structured to meet the Care Coordination VBA Safe Harbor.

- The arrangement between the Hospital and Clinic evidenced through the NPRA Sharing Agreement under which the Hospital agrees to share with the Clinic 30% of any payments the Hospital receives from Medicare under BPCIA provided certain quality metrics are met, though the Clinic does not agree to assist the Hospital with any repayment obligations the Hospital may have with respect to Medicare (the "*Hospital-Clinic BPCIA VBA*"); and

- The Clinic's distribution agreements with its interventional cardiologists, under which each interventional cardiologist is entitled to 25% of any amounts received by the Clinic but is not obligated to fund any portion of the losses suffered by the Hospital under BPCIA (the "*Clinic-Physician BPCIA VBA*").

The Hospital – Clinic BPCIA VBA and the Clinic – Physician BPCIA VBA are collectively referred to herein as the "*BPCIA VBAs*". Next, we turn to analyzing whether the BPCIA VBAs meet a Stark VBA Exception and/or an AKS VBA Safe Harbor.

Do the BPCIA VBAs meet the Stark VBA Exceptions?

Only the VBAs involving physicians implicate the Stark Law; hence, only the Clinic-Physician BPCIA VBA needs to be analyzed to determine whether it falls within the Stark VBA Exceptions.

The Clinic-Physician BPCIA VBA creates two potential compensation arrangements from a Stark Law perspective, one involving a direct compensation arrangement between the Clinic and its interventional cardiologists and the other involving a potential indirect compensation arrangement between the Hospital and the Clinic's interventional cardiologists given the following relationship chain: interventional cardiologist employee – distribution agreement – Clinic – NPRA Sharing Agreement – Hospital.

Unlike the AKS VBA Safe Harbors (which include safe harbors applicable to CMS-sponsored models), the Stark VBA Exceptions do not contain analogous exceptions applicable to CMS-sponsored models. Therefore, the Stark Law exceptions that would be potentially applicable to the Clinic-Physician BPCIA VBA would be limited to the Stark VBA Exceptions (i.e., the Full-Risk Exception, the Meaningful Downside Risk Exception and the Outcome Measure VBA Exception), the traditional Stark Law compensation arrangement exceptions and any fraud and abuse waivers issued with respect to the CMS-sponsored model.

While the Clinic-Physician BPCIA VBA does not meet the Full-Risk Exception because the BPCIA VBE does not involve a "full-risk" arrangement, and while the Clinic-Physician BPCIA VBA also does not meet the Meaningful Downside Risk Exception since the interventional cardiologists are not required to repay or forgo at least 10% of the remuneration they receive under the Clinic-Physician BPCIA VBA, the Clinic-Physician BPCIA VBA may meet the Outcome Measure VBA Exception, assuming the following requirements are met:

- The Clinic-Physician BPCIA VBA will be set forth in a distribution agreement which should meet the writing requirement of the Outcome Measure VBA Exception so long as it includes a description of (i) the value-based activities to be undertaken, (ii) how the value-based activities are expected to further the value-based purpose(s) of the VBE, (iii) the TPP of the VBA, (iv) the type of the remuneration and the methodology used to determine the remuneration (which must be set in advance prior to the undertaking of the value-based activities for which the remuneration is paid), and (v) the outcome measures against which the interventional cardiologists is assessed, if any;

- The outcome measures identified in the distribution agreement must be a benchmark that is "objective and measurable" and that quantifies (i) improvements in, or maintenance of, the quality of patient care, or (ii) a reduction in the costs to or growth in expenditures of payors while maintaining or improving the quality of patient care. Monitoring of the outcome measures must be done by the BPCIA VBE or one of the VBE Participants at least annually, during which the following items must be monitored: (A) whether the parties have furnished the value-based activities required under the arrangement, (B) whether and how continuation of the value-based activities is expected to further the value-based purpose of the VBE, and (C) progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed. Finally, the distribution agreement should set forth the requirements of the Outcome Measure VBA Exception with respect to the results of monitoring.

- The remuneration under the distribution agreement must be for or result from value-based activities undertaken by the intervention cardiologists for patients in the TPP; the remuneration may not be conditioned on referrals of patients who are not part of the TPP or business not covered under the Clinic-Physician BPCIA VBA; and the remuneration may not be an inducement to reduce or limit medically necessary items or services to any patient.

- The Clinic-Physician BPCIA VBA must be commercially reasonable.

- If there is a directed referral requirement included in the arrangement, the requirement must (i) be in writing and signed by the parties, and (ii) not apply if the patient expresses a preference for a different provider and the patient's insurer determines the provider or the referral is not in the patient's best medical interests in the physician's judgment.

- Records of methodology for determining, and the actual amount of, remuneration must be maintained for six years and made available to the Secretary upon request.

Meeting the Outcome Measures VBA Exception would protect not only the arrangement between the Clinic and the Physician, but also the potential indirect compensation arrangement that may be created between the Hospital and the interventional cardiologists as a result of the Clinic-Physician BPCIA VBA, given that CMS has specified that the Stark VBA Exceptions are an available exception for indirect compensation arrangements.

Finally, in addition to the Stark VBA Exceptions, the Clinic-Physician BPCIA VBA could be reviewed to determine if it meets a traditional Stark Law exception. Alternatively, the fraud and abuse waivers issued by CMS and the OIG with respect to BPCIA may also be available to protect the Clinic-Physician BPCIA VBA.

Do the BPCIA VBAs meet the AKS VBA Safe Harbors?

Hospital – Clinic BPCIA VBA

From an AKS VBA Safe Harbor perspective, for the following reasons, the Hospital-Clinic BPCIA VBA would not be able to meet the Full-Risk Safe Harbor or the Substantial Downside Risk Safe Harbor, but may be able to meet the Outcomes-Based Payment Safe Harbor and CMS-Sponsored Model Arrangements Safe Harbor (though the CMS-Sponsored Model Safe Harbor appear to be easiest to meet):

- *Full-Risk Safe Harbor*: The Hospital-Clinic BPCIA VBA would not be able to meet the Full-Risk Safe Harbor because the Hospital-Clinic BPCIA VBE is not at full financial risk for the TPP

covered by the BPCIA program since the Hospital and Clinic are not financially responsible for the cost of all Medicare-covered patient items and services of the TPP. Rather, under the BPCIA program, the Hospital and Clinic continue to receive reimbursement from Medicare in accordance with their traditional payment systems and, in addition to that reimbursement, are potentially eligible for a share of the savings, or subject to repayment of a share of the losses, from the selected clinical episodes. Accordingly, the Hospital-Clinic BPCIA VBE is not a full-risk VBE and would not be eligible for the Full-Risk Safe Harbor.

- *Substantial Downside Risk Safe Harbor*: In order to fall within the Substantial Downside Risk Safe Harbor, both (i) the VBE must be at "*substantial downside financial risk*" and (ii) the VBE Participant must be at risk for a "*meaningful share*" of the VBE's substantial downside financial risk. Here, since the VBE involves a clinical episode of care that covers services in multiple care settings and since the Hospital under the Hospital-Clinic BPCIA VBE is at risk for greater than 20% of the losses, the VBE appears to meet the "*substantial downside financial risk*" requirement; however, while the Clinic is eligible to share in the "upside" of the arrangement, it is not obligated to pay any portion of the losses and, therefore, it is not at risk for a "*meaningful share*" of the VBE's substantial downside financial risk. Accordingly, the Hospital-Clinic BPCIA VBE would not be eligible for the Substantial Downside Risk Safe Harbor.

- *Outcomes-Based Payments Safe Harbor*: The Hospital-Clinic BPCIA VBA could potentially meet the Outcomes-Based Payment Safe Harbor assuming all of the following conditions are met:

    - The Hospital-Clinic BPCIA VBA will be set forth in a NPRA Sharing Agreement that should meet the writing requirement of the Outcomes-Based Payment Safe Harbor so long as it has a term of at least one year and states at a minimum (i) a general description of the services to be performed by the Hospital and Clinic, (ii) the outcome measure(s) that must be achieved to receive the outcomes-based payment, (iii) the clinical evidence or credible medical support relied on by the parties to select the outcome measure(s), and (iv) the schedule for the parties to regularly monitor and assess the outcome measure(s).

    - The "outcome measures" identified in the NPRA Sharing Agreement are "legitimate" and are based on a benchmark that is used to quantify (i) improvements in, or the maintenance of improvements in, the quality of patient care, or (ii) a *material* reduction in the costs to or growth in expenditures of payors while maintain or improving the quality of patient care, or both (i) and (ii). Additionally, the NPRA Sharing Agreement should set forth the parties' plans (A) to regularly monitor and assess the Clinic's performance with respect to the outcome measure(s), including the impact of the Hospital-Clinic BPCIA VBA on patient quality of care, as well as (B) to periodically assess, and as necessary revise, benchmarks and remuneration to ensure the remuneration is consistent with fair market value in an arm's-length transaction. The Hospital should also have established policies and procedures, and the NPRA Sharing Agreement should allow the Hospital to use the policies and procedures to correct identified material performance failures or deficiencies in quality of care resulting from the Hospital-Clinic BPCIA VBA.

    - The methodology for determining the outcomes-based payments payable by the Hospital to the Clinic over the term of the arrangement is "set in advance," commercially reasonable, consistent with fair market value and not determinized in a manner that *directly* takes into account the volume or value of referrals or business otherwise generated between the parties.

- The NPRA Sharing Agreement should not limit any party's ability to make decisions in a patient's best interest or induce any party to reduce or limit medically necessary items and services.

- *CMS-Sponsored Model Arrangements Safe Harbor*: The Hospital-Clinic BPCIA VBA should be able to meet the CMS-Sponsored Model Arrangement Safe Harbor, since (i) it will advance one or more goals of BPCIA, a CMS-Sponsored Model; (ii) it will be memorialized in a NPRA Sharing Agreement, assuming it is entered in advance of, or contemporaneously with, the NPRA Sharing Agreement and specifies the activities to be undertaken by the Clinic and Hospital and the remuneration to be exchanged between the parties; (iii) we assume it will not induce either the Hospital or Clinic to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient; (iv) we assume it will require the Hospital and the Clinic to make available to the Secretary, upon request, all materials and records sufficient to establish whether the remuneration was exchanged in a manner that meets the conditions of this safe harbor; and (v) it will satisfy such programmatic requirements as may be imposed by CMS in connection with the use of the safe harbor.

In addition to the above safe harbors, the Hospital and Clinic could also structure the NPRA Sharing Agreement between the parties to take advantage of the BPCIA fraud and abuse waivers, available here.

Clinic – Physician BPCIA VBA

Assuming that the interventional cardiologists are direct parties to the BPCIA VBE, the Clinic – Physician BPCIA VBA should first be analyzed under the AKS VBA Safe Harbors to determine whether any of those safe harbors apply to the arrangement. For reasons similar to those set forth above with respect to the Hospital-Clinic BPCIA VBA, the Clinic – Physician BPCIA VBA would not be able to meet the Full-Risk Safe Harbor or the Substantial Downside Risk Safe Harbor. That said, again, based on this similar reasoning, the Clinic – Physician BPCIA VBA likely could be structured to meet the Outcomes-Based Payment Safe Harbor, as well as the CMS-Sponsored Model Arrangements Safe Harbor.

If the interventional cardiologists were not direct parties to the BPCIA VBE, then, the Clinic – Physician BPCIA VBA would be subject to traditional AKS analysis. Under a traditional AKS analysis, the Clinic – Physician BPCIA VBA may be able to fall within the AKS employment safe harbor.

Finally, in addition to the AKS VBA Safe Harbors and the traditional AKS safe harbors, the Clinic and interventional cardiologists could also structure the distribution agreement to take advantage of the BPCIA fraud and abuse waivers, available here. Structuring the distribution agreement to take advantage of these waivers would not require the interventional cardiologists to be direct parties to the BPCIA VBE.

Conclusion

There may be other potential VBEs and VBAs under the hypothetical health system arrangement that may qualify for Stark VBA Exceptions and AKS VBA Safe Harbors.

For example, consider the Clinic's employment relationship with its employed physicians. If structured appropriately, this relationship may be able to qualify as a VBE, with the TPP being those individuals who are patients of the Clinic. If structured to constitute a VBE, then the compensation arrangement between the Clinic and its physician employees could potentially qualify for the Meaningful Downside Risk Exception from a Stark Law perspective if the Clinic changed the amount of the physician's compensation at risk with respect to quality and patient satisfaction metrics from 5% to 10% and ensured that the metrics

used to qualify for the at-risk compensation were quality-related metrics (meaning that the Clinic may need either to remove the patient satisfaction-related metrics or to ensure that the 10% at-risk compensation is tied to quality metrics and any compensation tied to patient satisfaction metrics is in addition to the quality metric compensation). That said, this structure would not qualify for the analogous Substantial Downside Risk Safe Harbor (because the Clinic would not be assuming substantial downside financial risk with respect to the Clinic – employed physician VBE), though the arrangement may qualify for other AKS safe harbors, or even non-AKS VBA Safe Harbors (e.g., the employment safe harbor).

However, our goal with this White Paper was not to identify all VBEs and VBAs set forth in the Health System hypothetical, but to provide an example of the types of VBEs and VBAs that may be entered by providers and the manner in which the new Stark VBA Exceptions and the AKS VBA Safe Harbors apply to these VBEs and VBAs.

If you have any questions about the new Stark VBA Exceptions and AKS VBA Safe Harbors and/or any aspect of this White Paper, please contact one of the authors of this White Paper, listed below, or any member of Kutak Rock's National Healthcare Practice Group.

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