A GIANT LEAP FORWARD IN VALUE-BASED INNOVATION OR AN AVALANCHE OF NEW ADMINISTRATIVE REQUIREMENTS? AN ANALYSIS OF THE VALUE-BASED ASPECTS OF HHS'S AKS AND STARK PROPOSED RULES

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U.S. Health Care Alert

By: Limo T. Cherian, Zachary W. Ernst, Steven G. Pine

As part of the Department of Health and Human Services' ("HHS") "Regulatory Sprint to Coordinated Care," the following two proposed rules were issued on October 17, 2019, that, if finalized, will markedly change the regulatory fraud and abuse landscape for value-based activities:

> i. The HHS Office of the Inspector General ("OIG") published a Proposed Rule that would introduce new safe harbor protections under the federal Anti-Kickback Statute ("AKS") [1] for certain coordinated care and risk-sharing value-based arrangements between or among clinicians, providers, suppliers, and others that squarely meet all safe harbor conditions ("AKS Proposed Rule"). [2] ii. The HHS Centers for Medicare & Medicaid Services ("CMS") published a Proposed Rule that proposed similar exceptions to the Physician Self-Referral Law ("Stark Law") [3] for certain value-based compensation arrangements between or among physicians, providers, and suppliers ("Stark Proposed Rule" and together with the AKS Proposed Rule, the "Proposed Rules"). [4]

The Proposed Rules each contain a variety of wide-reaching changes that go well beyond only value-based arrangements. The Stark Proposed Rule is discussed in our previous K&L Gates Alert titled "A Starkly Different Landscape – A Deep Dive Into CMS' Recently Proposed Amendments to the Stark Law." [5]

The AKS safe harbors and Stark Law exceptions relating to value-based arrangements are explained in detail below. Both CMS and the OIG propose a sliding scale of safe harbors/exceptions, with greater protection offered and fewer operational requirements for arrangements that require a greater level of downside risk-sharing among value-based enterprise (as defined below) participants.

Agency	Limited Risk Share	Significant Risk Share	Full Risk Share
OIG/AKS Safe	"Care Coordination Arrangements to Improve Quality, Health	"Value-Based Arrangements with Substantial Downside	"Value-Based Arrangements

Harbor	Outcomes, and Efficiency Safe Harbor"	Financial Risk"	With Full Financial Risk"
CMS/Stark Exception	"Value-Based Arrangements"	"Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician"	"Full Financial Risk"

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i. Proposed Limited Risk Share Arrangements

> a. The **AKS Care Coordination Arrangements** safe harbor would protect in-kind (not monetary) remuneration within compliant value-based arrangements that further patient care coordination purposes. One example CMS uses is a skilled nursing facility providing a hospital with staff to assist in coordinating patient care through the inpatient discharge process. [6] b. The **Stark Value-Based Arrangements** exception would protect physician compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken though he arrangement.

ii. Proposed Significant Risk Share Arrangements

> a. The **AKS Value-Based Arrangements with Substantial Downside Financial Risk** safe harbor would protect both monetary and in-kind remuneration and would offer greater flexibility than the AKS Care Coordination Arrangements safe harbor in recognition of the assumption of an intermediate level of downside risk in a payor arrangement. b. The **Stark Meaningful Downside Risk** exception is meant to protect remuneration paid under a value-based arrangement where both the physician and value-based enterprise take on downside financial risk under a payor arrangement.

iii. Proposed Full Financial Risk Share Arrangements

> a. The **AKS Value-Based Arrangements with Full Financial Risk** safe harbor is intended to protect arrangements (including in-kind and monetary remuneration) involving value-based enterprises that have assumed “full financial risk” for a target patient population. b. The **Stark Full Financial Risk Exception** would only apply for arrangements that involve a value-based enterprise taking on full downside risk in a value-based arrangement with an applicable payor. However, unlike the meaningful downside risk exception, it would not require a physician participating in the arrangement to also assume financial risk.

While CMS and the OIG have tried to harmonize the Proposed Rules where possible, their respective proposals are different, which leaves stakeholders to navigate the varying approaches. For example, CMS and the OIG each state that they feel it is appropriate for the AKS, which is an intent-based criminal law, to serve as "backstop" protection for arrangements that might be protected by an exception to the strict liability of the Stark Law.

There are a large number of areas on which CMS and the OIG are specifically seeking comment. Given the scale of what is being requested, it is likely that there will be significant changes when and if the Proposed Rules are finalized. Some key areas where CMS and the OIG are seeking comments are discussed at the end of this Alert. Comments for both Proposed Rules are due December 31, 2019.

BACKGROUND

Since the passage of the Affordable Care Act ("ACA"), CMS has explored a number of innovative value-based payment arrangements. One of the first payment arrangements, the Medicare Shared Savings Program ("MSSP"), was authorized under Section 3022 of the ACA and implemented in 2013. [7] In 2018, the MSSP generated $739.4 million in total net savings across 548 Accountable Care Organizations ("ACOs"). [8] Other value-based programs introduced in recent years include the Comprehensive Care for Joint Replacement Model, Oncology Care Model, Comprehensive Primary Care Plus Model, Bundled Payments for Care Improvement Models, and Bundled Payments for Care Improvement Advanced Model, among others. One common thread for these arrangements is a focus on tying reimbursement to value — that is, providing financial incentives to providers who provide high-quality care, finding ways to reduce unnecessary costs, and facilitating the coordination of care among providers. To foster a transition to value-based, coordinated care models, HHS promulgated various waivers of the AKS, Stark Law, and civil monetary penalty ("CMP") laws in connection with these CMS-driven innovation model.

At the same time, nongovernmental payors have likewise sought to transition from fee-for-service reimbursement to payment for value. However, federal fraud and abuse laws have historically served to limit innovation in this space because reimbursement for value may be inherently tied to the value of services. Nonetheless, CMS and the OIG have been unwilling to extend innovation waivers to comparable models related to nongovernmental payors. CMS and the OIG recognized that lack of waivers was limiting innovation and issued a request for information ("RFI") during the summer of 2018 to stakeholders seeking comment on how the Stark Law and AKS laws could be modified to alleviate unnecessary barriers. [9] Based on the feedback received from the RFIs, CMS and the OIG have now offered the Proposed Rules to create new pathways for providers and payors to come together in innovative ways without fear of violating fraud and abuse regulations, including in the context of nongovernmental value-based arrangements.

Moving forward, CMS and the OIG intend to move away from the individualized waivers offered for specific programs and instead rely on the safe harbors offered in the Proposed Rule. [10] While the Proposed Rules do not suggest the individualized waivers will be eliminated for existing CMS-sponsored models, stakeholders will need to verify when renewing participation in a CMS innovative payment model whether they can continue to rely on a previously issued waiver if their arrangements do not fall within the AKS safe harbors and Stark exceptions in the Proposed Rules.

KEY LIMITATIONS TO PROPOSED WAIVERS

While the Proposed Rules offer exciting new opportunities for providers, payors, and clinically integrated networks to innovate, it is important at the onset to note several key limitations.

> i. The safe harbors and exceptions are tied to specific types of value-based arrangements. The fact that an arrangement is associated with a legitimate value-based arrangement alone will not guarantee that the arrangement will fit within one of the safe harbors or exceptions. ii. Much like existing AKS and Stark Law regulations, these safe harbors and exceptions are highly prescriptive, often with specific requirements for written agreements, complex qualifying definitions, and other types of oversight, which are discussed in greater detail below. Thus, existing value-based arrangements will likely not satisfy all of the requirements for an AKS safe harbor protection or compliance with a Stark exception set forth in the Proposed Rules. iii. As shown in the chart below, certain types of organizations are carved out of these proposed safe harbors and exceptions based on what CMS and the OIG see as heightened fraud and abuse concerns.

> | **Agency** | **Excluded Entities**[11] | **Potential Additional Excluded Entities**[12] |
> |---|---|---|
> | **OIG/AKS Safe Harbor** | Pharmaceutical manufacturers;
Manufacturers, distributors, or suppliers of durable medical equipment, prosthetics, orthotics and supplies (“DMEPOS”); and
Laboratories. | Pharmacies (including compounding pharmacies);
Pharmacy benefits managers;
Wholesalers; and
Distributors. |
> | **CMS/Stark Exception** | None proposed. Among potential excluded entities, CMS is particularly concerned with:
Laboratories; and
DMEPOS suppliers. | Laboratories;
DMEPOS manufacturers, distributors, and suppliers;
Pharmaceutical manufacturers;
Pharmacy benefit |

		managers; Wholesalers; and Distributors.

iv. In furtherance of CMS's stated goal of price transparency for all patients, CMS is considering whether to include a requirement related to price transparency in every exception for value-based arrangements. [13] For example, CMS is considering whether to require that a physician provide a notice or have a policy regarding the provision of a public notice that alerts patients that their out-of-pocket costs for items and services for which they are referred by the physician may vary based on the site where the services are furnished and based on the type of insurance that they have. CMS is seeking comments on other options for price transparency requirements in the Stark Proposed Rule's value-based exceptions to the Stark Law, as well as the existing Stark regulations. [14]

KEY DEFINITIONS IN PROPOSED RULES

Both Proposed Rules are designed to only protect remuneration occurring under a "value-based arrangement" as part of a "value-based enterprise." These defined terms are very important but are, as drafted, somewhat circular, and we anticipate that commenters will suggest more detail be provided in the final rule.

A **"value-based enterprise"** ("VBE") is a network of participants that agree to collaborate for a **"value-based purpose."** A "value based purpose" defined as: (i) coordinating/managing care, (ii) improving quality of care, (iii) reducing cost growth, or (iv) transitioning health care delivery for a "target patient population." [15] VBE's are made up of two or more "VBE participants." Existing Clinically Integrated Networks ("CINs") and ACOs are examples of organizations that might qualify as a VBE. [16]

A **value-based arrangement** is an arrangement for the provision of at least one "value-based activity" for a "target patient population" between or among: (i) the VBE and one or more of its VBE participants, or (ii) VBE participants in the same VBE. [17]

The protections of the safe harbors and exceptions are available to a **"VBE participant,"** i.e., an individual or entity that engages in at least one **"value-based activity"** through a VBE value-based arrangement. [18] A "value-based activity" is one of the following activities reasonably designed to achieve a value-based purpose: (i) the provision of an item or service, (ii) the taking of an action, or (iii) the refraining from taking an action. [19] As noted above, an arrangement must identify a **"target patient population"** using legitimate and verifiable criteria that is: (i) set out in writing in advance of the value-based arrangement, and (ii) furthers the VBE's value-based purpose(s). [20]

Some key eligibility requirements to become a VBE include the following:

> i. **Accountable Body**: The VBE must have an accountable body or person responsible for financial and operational oversight of the VBE. The OIG intends for the VBE to implement the criterion regarding the accountable body or responsible person in a manner that is tailored to the complexity and sophistication of the VBE. [21] ii. **Governing Document**: The VBE must have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s). There is no similar requirement for the governing document to be formal bylaws or in any other specific format. [22]

DEEP DIVE INTO EXCEPTION AND SAFE HARBOR REQUIREMENTS – LIMITED RISK SHARE ARRANGEMENTS

As part of the effort to provide protections to a continuum of arrangements, the limited risk share arrangements present the lowest level of protection. While the relevant Stark Law exception and AKS safe harbor provide some protections, it is noteworthy that a significant number of current risk sharing arrangements in the market fall into the limited risk share category.

AKS Safe Harbor – Care Coordination Arrangements [23]

The AKS proposed safe harbor for Care Coordination Arrangements would protect in-kind remuneration exchanged between qualifying VBE participants in a value-based arrangement connected to the coordination and management of care of the target patient population. [24] Under this proposed safe harbor, each offer of in-kind remuneration among VBE participants must be analyzed separately for compliance with the safe harbor.

This proposed safe harbor does not require parties to bear or assume downside financial risk. The OIG is concerned that the offer or provision of remuneration under value-based arrangements could present opportunities for the types of fraud and abuse traditionally seen in the fee-for-service system, particularly where the parties offering or receiving the remuneration have not assumed downside financial risk for the care of the target patient population. For this reason and to ensure that the safe harbored arrangements operate to achieve their value-based purposes, the OIG has proposed numerous conditions and safeguards, set forth in detail in the chart below. [25]

Stark Exception – Value-Based Arrangements [26]

This proposed Stark Law exception applies to physician compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken by the VBE or any of its VBE participants. [27] As proposed, the exception would permit both monetary and nonmonetary remuneration between the parties. However, CMS is considering whether to limit the scope of the proposed exception to only nonmonetary remuneration and is seeking comment regarding the impact such a limitation may have on the transition to a value-based health care delivery and payment system. CMS intends for the value-based purpose of the arrangement to relate to the VBE as a whole. The exception would not protect a "side" arrangement between two

VBE participants that is unrelated to the goals and objectives (that is, the value-based purposes) of the VBE of which they are participants, even if the arrangement itself serves a value-based purpose. [28]

Takeaway – Many Major Differences Between AKS and Stark Law for Arrangements Without Downside Risk

CMS and the OIG took significantly different approaches as to nonrisk sharing arrangements. As a result, there is limited overlap between the requirements of the proposed AKS safe harbor and the Stark exception, and if a CIN or ACO wants a nonrisk sharing arrangement to be compliance with both the AKS safe harbor and the Stark exception, it will need to ensure that the arrangement meets a long list of largely nonoverlapping requirements. The following chart shows the key requirements under each:

	AKS – Care Coordination Arrangements[29]	**Stark – Value-based Arrangements**[30]
Scope of Remuneration Protected	In-kind remuneration under arrangements directly connected to the coordination and management of care of the target patient population.	Any remuneration paid under a value-based arrangement.
Quality/Performance Measures	VBE participants must establish one or more evidence-based, valid outcome measures reasonably anticipated to advance coordination and management of a Target Patient Population.	Any performance or quality standards that a recipient will be measured against (if any) must be objective and measureable. Any changes to performance/quality measures must be made prospectively and set forth in writing.
Commercially Reasonable	Arrangement must be commercially reasonable.	No similar requirement.
Reduce to Writing	Agreement must be set forth in contemporaneous writing signed by parties.	Agreement must be set forth in contemporaneous writing signed by parties.
Contents of Agreement	Written agreement must include: ▪ A description of value-based activities undertaken under the arrangement; ▪ Term of value-based agreement; ▪ The target patient population for the	Written agreement must include: ▪ A description of value-based activities undertaken under the arrangement; ▪ How the value-based activities are expected to

	arrangement; ▪ A description of remuneration; ▪ The offeror's cost for the remuneration; ▪ A percentage of the offeror's cost contributed by recipient; ▪ Frequency of recipient's contribution payments for ongoing costs; ▪ The specific evidence-based, value outcomes measures against which the recipient will be measured.	further the value-based purpose(s) of a VBE; ▪ The target patient population for the arrangement; ▪ The type or nature of remuneration; ▪ The methodology used to determine the remuneration; and ▪ The performance or quality measures against which the recipient will be measured.
Limitations on Remuneration	▪ Only covers in-kind remuneration. ▪ Must be used primarily to engage in value-based activities directly connected to coordination and management of care for the target patient population. ▪ Cannot be an inducement to reduce or limit medically necessary services. ▪ Cannot be funded by or directly result from contributions of an individual or entity outside of the VBE. ▪ The offeror must not and should not know that remuneration is likely to be diverted, resold, or used for an unlawful purpose.	▪ Must be for or result from activities undertaken by the recipient for patients in the target patient population. ▪ Cannot be an inducement to reduce or limit medically necessary services. ▪ Methodology used to determine amount of remuneration must be set in advance.
Referrals	Offeror of remuneration does not take into account the volume or value of, nor condition remuneration on, referrals of patients who are not part of target patient population or for business not covered by	Remuneration cannot be conditioned on referrals of patients who are not part of target patient population or for business not covered by the value-based arrangement.

	the value-based arrangement.	
Cost-Sharing Requirement	Recipient pays at least 15 percent of the offeror's cost for the in-kind remuneration (either in advance for one-time costs, or at regular intervals for ongoing costs).	No similar requirement.
Patient Best Interest	Arrangement does not place any limitations on participants' ability to make decisions in the best interest of their patients.	No similar requirement.
Referrals to a Particular Provider	Remuneration can be tied to a requirement to direct referrals to a particular provider, practitioner, or supplier unless: ▪ A patient expresses a different preference; ▪ The patient's payor determines the referral; or ▪ The referral or restriction is contrary to law.	Remuneration paid to physicians that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier must meet the requirements of 42 C.F.R. § 411.354(d)(4)(iv).
Marketing	The agreement cannot include marketing to patients of items or services or engaging in patient recruitment activities.	No similar requirement.
Monitoring	At least annually, a responsible person must assess and report on the arrangement's coordination and management of care for the target patient population, deficiencies in delivery of quality care, and progress toward achieving evidence-based outcomes measures.	No similar requirement.
Termination	Parties must terminate the agreement within 60 days if the responsible person determines the agreement has material deficiencies described in the safe harbor.	No similar requirement.
Record Keeping	VBE must make available all records to secretary upon request as necessary to	Maintained for six years and

	establish compliance.	available to secretary upon request.

DEEP DIVE INTO EXCEPTION AND SAFE HARBOR REQUIREMENTS – SIGNIFICANT RISK SHARE ARRANGEMENTS

As more providers move to downside risk arrangements in the market, the protections of the Significant Risk Share Arrangements are likely to have the most impact on providers. Because this segment of the market is a significant step on the glide path to risk, the differences between the Stark Law exception and the AKS safe harbor are likely to create concern as to whether arrangements can be adequately protected.

AKS – Value-Based Arrangements with Substantial Downside Financial Risk [31]

The proposed AKS safe harbor for Value-Based Arrangements with Substantial Financial Risk, which would protect both monetary and in-kind remuneration, is proposed to offer greater flexibility than the safe harbor for care coordination arrangements in recognition of the VBE's assumption of an intermediate level or downside risk, i.e., substantial downside financial risk. [32] As proposed, this safe harbor would apply only to the exchange of remuneration between VBEs that have assumed substantial downside financial risk and VBE participants that meaningfully share in the VBE's downside financial risk. This proposed safe harbor would protect remuneration exchanged between such VBEs and VBE participants if several standards are met, which are outlined in the chart below.

In addition, this safe harbor also contains several limitations and protections found within the Care Coordination safe harbor, notably that the remuneration must at a minimum further the coordination and management of care for the target patient population. Other requirements include a signed agreement, limitations on directed referrals for business outside of the target patient population, record-keeping requirements, and marketing restrictions, among other requirements.

Stark – Meaningful Downside Risk Exception [33]

The proposed Stark Law exception for Meaningful Downside Risk is similarly meant to protect remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the VBE. Otherwise, the Stark Law's prohibitions would not be implicated. [34]

Although the physician must be at meaningful downside financial risk for the entire term of the value-based arrangement, the remuneration could be paid to or from the physician. Some of the notable conditions required to meet this exception are outlined in the chart below.

	AKS – Substantial Downside Risk[35]	**Stark – Meaningful Downside Risk**
VBE Risk Share	The VBE must assume "substantial downside financial risk" from payor for target patient	No similar requirement.

Requirement	population. "Substantial downside financial risk" is defined as risk, for the entire term, in the form of (each tied to historical expenditures): Shared savings with at least 40 percent loss repayment; Episodic or bundled payments with at least 20 percent loss repayment; Prospectively paid population-based payment; or Partial capitation, where capitated payment reflect a discount of at least 60 percent of expected fee-for-service payments.	
VBE Participant Risk Share Requirement	The VBE participant must meaningfully share in risk based on one of the following three methodologies: Participant at risk for eight percent of amount for which the VBE is at risk under its agreement with the payor; Partial or full capitation payment or similar payment methodology; or For VBE participants that are physicians, if it meets the requirements of the Stark Proposed Rule's Meaningful Downside Risk Exception (42. C.F.R. § 411.357(aa)(2)).	A physician is required to maintain "meaningful downside financial risk" for failure to achieve the value-based purpose(s) of the VBE during the entire duration of the value-based arrangement. "Meaningful downside financial risk" means that the physician: Is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement; or Is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.
Limitations on and Requirements of	The remuneration provided by, or shared among, the VBE and VBE participant must meet the following requirements: Primarily used to engage in value-based	The remuneration to or from the physician involved must meet the following requirements: The methodology used to determine

Remuneration	activities tied to risk; Directly connected to value-based purposes, at least one of which must be the care coordination for target patient population; Does not induce VBE participants to limit medically necessary services; Does not include distributions related to ownership or investment interest; and Is not funded by or resulting from individuals or entities outside of VBE. The VBE or VBE participant offering the remuneration must not take into account the volume or value of, or condition the remuneration on: Referrals of patients who are not part of the target patient population; or Business not covered under the value-based arrangement.	the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid. The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient. The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement. If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of 42 C.F.R. § 411.354(d)(4)(iv).
Writings and Records	In advance of, or contemporaneous with, the commencement of the value-based arrangement or any material change to the value-based arrangement, the VBE and VBE participant must set forth the terms of the value-based arrangement in a signed writing that contains the requirements listed in the Proposed Rule. The VBE or VBE participant must make available to the secretary, upon request, all materials and records sufficient to establish compliance.	A description of the nature and extent of the physician's downside financial risk must be set forth in writing. Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least six years and made available to the secretary upon request.
Other Requirements	The value-based arrangement must not: Place any limitation on VBE participants' ability	No similar requirements.

	to make decisions in the best interest of their patients; Include marketing to patients of items or services or engaging in patient recruitment activities; or Direct or restrict referrals to a particular provider, practitioner, or supplier if: (A) a patient expresses a preference for a different practitioner, provider, or supplier; (B) the patient's payor determines the provider, practitioner, or supplier; or (C) such direction or restriction is contrary to applicable law or regulations.	

DEEP DIVE INTO EXCEPTION AND SAFE HARBOR REQUIREMENTS – FULL FINANCIAL RISK SHARE ARRANGEMENTS

CMS and the OIG have provided the most extensive protection and flexibility to the Full Financial Risk Share Arrangements. However, full risk arrangements are less common in the market. While the protections offered are significant, few providers are financially able to bear full risk for a target population.

AKS – Value-Based Arrangements with Full Financial Risk [36]

The proposed AKS safe harbor Value Based Arrangements with Full Financial Risk is intended to protect certain arrangements (including in-kind and monetary remuneration) involving VBEs that have assumed "full financial risk" for a target patient population. This proposed safe harbor would include more flexible conditions than the proposed care coordination arrangements and substantial downside financial risk safe harbors, which the OIG believes would reduce burden for the VBE and its VBE participants. [37] However, this safe harbor would only protect arrangements between VBEs and VBE participants and not agreements among VBE participants or with downstream entities. [38] Some of the notable requirements to meet this safe harbor are outlined in the chart below.

Stark – Full Financial Risk Exception [39]

The proposed Stark Law exception for Full Financial Risk applies to value-based arrangements between VBE participants in a VBE that has assumed "full financial risk" for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

CMS explains that this exception requires that the VBE is financially responsible (or is contractually obligated to be financially responsible within the six months following the commencement date of the value-based arrangement) on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

Notably, the OIG is proposing to protect only those value-based arrangements under which remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement. [40] Some of the notable conditions required to meet this exception are outlined in the chart below.

	AKS – Full Financial Risk[41]	**Stark — Full Financial Risk**[42]
VBE Risk Share Requirement	The VBE must assume full financial risk (or is contractually obligated to be at full financial risk within the six months following the commencement of the value-based arrangement) from payor with signed writing evidencing full risk for minimum of one year.	The VBE must assume full financial risk (or is contractually obligated to be at full financial risk within the six months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.
Definition of Full Financial Risk	"Full financial risk" means the VBE is financially responsible for cost of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively paid.	"Full financial risk" means that the VBE is 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 target patient population for a specified period of time.
Limitations on Remuneration	The remuneration exchanged between the VBE and a VBE participant must meet the following requirements: The remuneration is primarily used to engage in value-based activities tied to risk; It is directly connected to value-based purposes, at least one of which must be the care coordination for target patient population; It does not induce VBE participants to limit medically necessary services; It does not include distributions related to ownership or investment interest; and It is not funded by, and does not otherwise result from the contributions of, any individual or entity outside of the VBE. The VBE or VBE participant must not take into account the volume or value of, or	The remuneration exchanged must meet the following requirements: The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population; It is not an inducement to reduce or limit medically necessary items or services to any patient; It is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement; and If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of 42 C.F.R. § 411.354(d)(4)(iv).

	condition the remuneration on: Referrals of patients who are not part of the target patient population; or Business not covered under the value-based arrangement.	
Writing and Record Requirements	The value-based arrangement must be set out in a writing signed by the parties that specifies the material terms of the value-based arrangement, including the value-based activities to be undertaken by the parties, and is for a period of at least one year. The VBE or VBE participant makes available to the secretary, upon request, all materials and records sufficient to establish compliance.	Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least six years and made available to the secretary upon request.
Other Requirements	The VBE participant must not claim payment in any form directly or indirectly from a payor for items or services covered under the value-based arrangement. The VBE must provide or arrange for: an operational utilization review program; and a quality assurance program that protects against underutilization and specifies patient goals, including measurable outcomes, where appropriate. The value-based arrangement must not include marketing to patients of items or services or engaging in patient recruitment activities.	No similar requirements.

ADDITIONAL VALUE-BASED SAFE HARBORS AND EXCEPTIONS

AKS – Safe Harbor for Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency [43]

A common component of value-based arrangements is the desire to provide in-kind assistance to patients to help ensure adherence to a treatment plan, with a goal of improving health outcomes and reducing overall costs. In addition to potential AKS barriers, such assistance can also be problematic under the beneficiary inducements CMP law, [44] which penalizes remuneration to a beneficiary when the offeror knows or should know the remuneration is likely to influence the selection of a provider.

Accordingly, this proposed AKS safe harbor [45] would allow VBE participants to offer patients in the VBE's target patient population with beneficial tools and supports to improve quality, health outcomes, and efficiency by promoting patient engagement with their care and adherence to care protocols. [46] Some of the notable requirements to meet this safe harbor include the following:

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i. The patient engagement tool or support is furnished directly to the patient by a VBE participant. [47]
ii. No individual or entity outside of the applicable VBE funds or otherwise contributes to the provision of the patient engagement tool or support. [48]
iii. The patient engagement tool or support meets the following requirements:

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a. It is in-kind and is (i) preventative, (ii) health-related technology/monitoring, or (iii) designed to identify/address social determinants of health.
b. It has direct connection to coordination and management of care for the population.
c. It is not used for patient recruitment or marketing.
d. It advances one or more of the following goals:

> 1. adherence to treatment regimen;
> 2. adherence to drug regimen;
> 3. adherence to follow-up care plan;
> 4. management of disease or condition;
> 5. improvement in measurable evidence-based health outcomes; and/or
> 6. ensuring patient safety. [49]

iv. The aggregate retail value of patient engagement tools and supports furnished to a patient by a VBE participant on an annual basis cannot exceed $500 unless such patient engagement tools and supports are furnished to patients based on a good-faith, individualized determination of the patient's financial need. [50]

Stark Law – Exceptions Applicable to Indirect Compensation Arrangements [51]

Under the current Stark Law regulations, if an indirect compensation arrangement exists, the exception for indirect compensation arrangements at 42 C.F.R. § 411.357(p) is available to protect the compensation arrangement. As currently drafted, this exception includes requirements not found in the proposed exceptions for value-based arrangement. Thus, this creates the possibility that when a value-based arrangement exists in the chain of

financial relationships, the indirect compensation exception may technically not be available to protect the relationship.

Accordingly, CMS proposes to amend the current indirect compensation exception to address this issue. Under this proposal from CMS, parties would determine whether the indirect compensation arrangement to which the physician is a direct party qualifies as a value-based arrangement eligible for a Stark Law exception. If so, the exceptions proposed for value-based arrangements would be applicable under the indirect compensation exception. [52]

KEY AREAS WHERE COMMENTS ARE REQUESTED

As mentioned above, CMS and the OIG are seeking comment on various important aspects of the Proposed Rules. A few notable areas where HHS specifically requests comments include the following:

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i. AKS Proposed Rule:

> a. What role (i) pharmaceutical companies; (ii) DMEPOS manufacturers, distributors, or suppliers; and (iii) laboratories can play in the coordination of care, whether safe harbor protections should be extended to these entities, and, if so, what additional protection may be necessary to prevent abusing marketing practices, protect clinical decision-making, and reduce inappropriate cost shifting. [53]
> b. Whether other types of entities should be excluded from the definition of VBE participant, such as pharmacies (in particular, compounding pharmacies), pharmacy benefit managers, or medical device manufacturers. [54]
> c. Whether to define a “commercially reasonable arrangement” as an arrangement that would make commercial sense if entered into by reasonable entities of a similar type and size, even without the potential for referrals. [55] The OIG also seeks comment on whether to include a fair market value requirement as part of care coordination the safe harbor or whether to include some limited prohibition on tying remuneration to the value or volume or referrals. [56]
> d. What level of contribution amount is appropriate for the care coordination safe harbor. The OIG is, in particular, considering contribution amounts ranging from 5 percent to 35 percent. [57]
> e. The OIG is considering an entirely different regulatory structure to protect care coordination agreements. Under the alternative structure, it would not offer a specific care coordination safe harbor but would instead expand the current personal services and management contract safe harbor, with a tiered approach that would remove certain conditions of that safe harbor to align with a value-based care coordination approach. The OIG seeks comments on this alternative approach. [58]
> f. For the substantial and full downside risk safe harbors, the OIG seeks comment on whether and how any safe harbor protection might be extended to remuneration that involves entities that are have not assumed financial risk, such as downstream contractor arrangements. [59]

ii. Stark Proposed Rule:

> a. CMS has not proposed to limit the universe of compensation arrangements that would qualify as value-based arrangements to only those arrangements specifically for the coordination and management of patient care. CMS seeks comment regarding whether this approach — designed to provide needed flexibility for parties participating in alternative payment models (including those sponsored by CMS) to succeed in the transition to value-based payment — poses a risk of program or patient abuse that should be addressed through a revised definition of "value-based arrangement" that requires care coordination and management in order to qualify as a value-based arrangement. [60]
> b. CMS seeks comment regarding permissible ways to determine whether quality of care has improved, a methodology for determining whether costs are reduced or expenditure growth has been stopped, or what parties must do to show they are 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. [61]
> c. CMS seeks comment on the role laboratories and DMEPOS suppliers play in care coordination for patients and value-based delivery and payment models. [62]
> d. CMS seeks comment on: (i) which persons and entities should qualify as VBE participants; (ii) CMS's alternative proposals regarding protection for arrangements involving physicians (or their immediate family members) and the specified persons or organizations, and, in particular; (iii) whether other providers or suppliers, such as health technology companies, should be excluded from the definition of VBE participant or the application of the proposed exceptions due to program integrity concerns. [63]
> e. CMS seeks comments regarding: (i) the structure and scope of the proposed exceptions; (ii) specific compensation arrangements that are permissible under a CMS-sponsored model, program, or other initiative but might not be able to satisfy the requirements of one of the proposed value-based exceptions; and (iii) suggested modifications to CMS's proposals that would bridge any perceived or actual gaps in the protection of the exceptions. [64]

Stakeholders should consider submitting comments to help CMS and the OIG identify the impact of the proposed AKS and Stark Law rules on value-based arrangements.

CONCLUSIONS

Notwithstanding the complexity and number of requirements that CMS and the OIG have set forth, these proposed value-based safe harbors and exceptions ultimately represent a major regulatory shift that will offer providers, payors, and other stakeholders the opportunity to unlock a wide range of new innovative arrangements without fear of conflicting with fraud and abuse laws. In the short term, hospitals, physicians, and post-acute providers will have new opportunities to coordinate and provide in-kind assistance to further care coordination purposes. Longer term, greater opportunities may be present for CINs and ACOs when downstream participants and physicians in a CIN are ready and willing to share in downside risk within payor arrangements, which will unlock a much broader scope of possible protection.

Providers and CINs will need to comprehensively assess the practical compliance elements of the Proposed Rules. In particular, given the scope of proscriptive requirements, it is unlikely existing arrangements qualify under any of the new proposal without at least some level of amendment. K&L Gates' health care practice can assist health care providers in conducting this analysis and will continue to closely monitor the development of the Proposed Rules, any legislative developments, and industry reaction and comment, and we will provide updates as HHS moves to finalizing these proposed changes.

K&L Gates' multidisciplinary team of lawyers is uniquely positioned to advise stakeholders on a broad spectrum of health care, life sciences, and technology matters, including Medicare program integrity initiatives, and to facilitate stakeholder engagement with CMS through the development and submission of public comments.

NOTES:

[1] 42 U.S.C. § 1320a-7b.
[2] OIG, Revisions to Safe Harbors under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, Proposed Rule, 84 Fed. Reg. 55,694 (Oct. 17, 2019), https://www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the.
[3] 42 U.S.C. § 1395nn.
[4] CMS, Modernizing and Clarifying the Physician Self-Referral Regulations, Proposed Rule, 84 Fed. Reg. 55,766 (Oct. 17, 2019), https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations.
[5] Carolyn Fixel Merritt, Macy L. Flinchum, Kelsey U. Jernigan & Hannah C. Maroney, *A Starkly Different Landscape – A Deep Dive Into CMS' Recently Proposed Amendments to the Stark Law*, K&L GATES (Nov. 7, 2019), http://www.klgates.com/a-starkly-different-landscape--a-deep-dive-into-cms-recently-proposed-amendments-to-the-stark-law-11-07-2019/.
[6] 84 Fed. Reg. at 55,708.
[7] CMS, MSSP Program Statutes & Regulations, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-statutes-and-regulations.html.
[8] Seema Verma, Interest in *"Pathways to Success" Grows: 2018 ACO Results Show Trends Supporting Program Redesign Continue*, HEALTHAFFAIRS (Sept. 30, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190930.702342/full/; CMS, Shared Savings Program Accountable Care Organizations (ACO) Public-Use Files, https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/index.html.
[9] OIG, Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, Request for Information, 83 Fed. Reg. 43607 (Aug. 27, 2018), https://www.federalregister.gov/documents/2018/08/27/2018-18519/medicare-and-state-health-care-programs-fraud-and-abuse-request-for-information-regarding-the; CMS, Request for Information Regarding the Physician Self-Referral Law, Request for Information, 83 Fed. Reg. 29524 (June 25, 2018), https://www.govinfo.gov/content/pkg/FR-2018-06-25/pdf/2018-13529.pdf.
[10] 84 Fed. Reg. 55,694 at 55,700.
[11] 84 Fed. Reg. 55,694 at 55,703–04; 84 Fed. Reg. 55,766 at 55,775–76.

[12] 84 Fed. Reg. 55,694 at 55,704; 84 Fed. Reg. 55,766 at 55,775.
[13] 84 Fed. Reg. 55,766 at 55,788–89.
[14] *Id.* at 55,789.
[15] 84 Fed. Reg. 55,694 at 55,706–07; 84. Fed. Reg. 55,766 at 55,773.
[16] 84 Fed. Reg. 55,694 at 55,700–01; 84. Fed. Reg. 55,766 at 55,773.
[17] 84 Fed. Reg. 55,694 at 55,702; 84. Fed. Reg. 55,766 at 55,773.
[18] 84 Fed. Reg. 55,694 at 55,703; 84. Fed. Reg. 55,766 at 55,773. Note that VBE participants are not required to be health care providers or suppliers.
[19] 84 Fed. Reg. 55,694 at 55,703; 84. Fed. Reg. 55,766 at 55,773.
[20] 84 Fed. Reg. 55,694 at 77,702; 84. Fed. Reg. 55,766 at 55,773. The proposed definition is not limited to federal health care program beneficiaries.
[21] 84 Fed. Reg. 55,694 at 55,701; 84. Fed. Reg. 55,766 at 55,773.
[22] 84 Fed. Reg. 55,694 at 55,701; 84. Fed. Reg. 55,766 at 55,773.
[23] 84 Fed. Reg. 55,694 at 55,708–17.
[24] *Id.* at 55,708.
[25] *Id.*
[26] 84. Fed. Reg. 55,766 at 55,783–86.
[27] *Id.* at 55,783.
[28] *Id.* at 55,783–84.
[29] 84 Fed. Reg. 55, 694 at 55,761–62.
[30] 84 Fed. Reg. 55, 766 at 55,847.
[31] 84 Fed. Reg. 55,694 at 55,716–19.
[32] *Id.* at 55,716.
[33] 84 Fed. Reg. 55,766 at 55,781–83.
[34] *Id.* at 55,781.
[35] 84 Fed. Reg. 55,694 at 55,716–19.
[36] 84 Fed. Reg. 55,694 at 55,719–21.
[37] *Id.* at 55,719.
[38] *Id.* at 55,721.
[39] 84 Fed. Reg. 55,766 at 55,779–81.
[40] *Id.* at 55,779–80.
[41] 84 Fed. Reg. 55,694 at 55,719–21.
[42] 84 Fed. Reg. 55,766 at 55,779–81.
[43] 84 Fed. Reg. 55,694 at 55,721–30.
[44] 42 U.S.C. 1320a-7a(a)(5).
[45] Which accordingly would also provide protection against beneficiary inducement CMP as an activity permissible under AKS. 42 U.S.C. 1320a-7a(i)(1)(6)(b).
[46] 84 Fed. Reg. 55,694 at 55,721-–22.
[47] *Id.* at 55,764.
[48] *Id.*
[49] *Id.*
[50] *Id.*

[51] 84 Fed. Reg. 55,766 at 55,786–88.
[52] *Id.* at 55,787.
[53] 84 Fed. Reg. 55,594 at 55,704.
[54] *Id.* at 55,704–06.
[55] *Id.* at 55,710.
[56] *Id.* at 55,714.
[57] *Id.* at 55,711.
[58] *Id.* at 55,715–16.
[59] *Id.* at 55,717, 55,721.
[60] 84 Fed. Reg. 55,766 at 55,774.
[61] *Id.*
[62] *Id.*
[63] *Id.* at 55,776.
[64] *Id.* at 55,779.

KEY CONTACTS

LIMO T. CHERIAN
PARTNER

CHICAGO
+1.312.807.4262
LIMO.CHERIAN@KLGATES.COM

