Contracts Management and Processes for the Transition to Value-Based Arrangements

Managing existing **AKS** and **Stark** Arrangements that do not meet the exceptions and safe harbor protections while, at the same time, revising and originating new value-based arrangements can be more easily accomplished with sound processes and practices to keep contracting risk at a minimum.

The U.S. Department of Health and Human Services' (HHS) issued two Final Rules at the end of 2020 in conjunction with its "Regulatory Sprint to Coordinated Care" which markedly changed the regulatory fraud and abuse landscape for "value-based" arrangements effecting how healthcare organizations manage these relationships and the contracts detailing the terms and conditions therein:

- The HHS Office of the Inspector General (**OIG**) published a Final Rule that introduces new safe harbor protections under the federal Anti-Kickback Statute (AKS) 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 Final Rule).

- The HHS Centers for Medicare & Medicaid Services (**CMS**) published a Final Rule that finalizes similar exceptions to the Physician Self-Referral Law (Stark Law) for certain value-based compensation **arrangements** between or among physicians, providers, and suppliers (Stark Final Rule, and together with the AKS Final Rule, the Final Rules).

These Final Rules introduced a new framework for **structuring permissible arrangements and relationships** between and among health care providers and payors.

This white paper reiterates the definitions, exceptions and safe harbor protections that will need to be managed and accounted for and provides contract management processes and practices to mitigate risk.

I. Key Elements to Consider

Since the passage of the Affordable Care Act (ACA), the Department for Health and Human Services (HHS) has communicated that transitioning away from traditional fee-for-service payment systems is a high priority. This has resulted in a concerted move toward value-based models that link provider reimbursement and remuneration to increased quality, reduced costs, enhanced care coordination, and improved patient outcomes.

With the introduction of "Triple-aim" or "Quadruple-aim" of health care, emphasized with the adoption of the Medicare Shared Savings Program, which was authorized under Section 3022 of the ACA and implemented in 2013, CMS has tested alternative value-based innovations. Centers for Medicare and Medicaid Innovation have, over time, refined these models with a focus on a **variety of provider types** and clinical conditions. The value-based payment model shift has not been limited to Medicare or other governmental programs. Commercial insurers have likewise taken up the mantle to shift reimbursement away from volume and toward value.

HHS enacted various waivers of the AKS, the Stark Law, and civil monetary penalty (CMP) laws in connection with these CMS-driven innovation models to help with the transition. This reflected a recognition that many traditional fraud and abuse concerns, such as provider overutilization, are mitigated when payments are tied to value instead of volume.

Historically CMS waivers have been tied to specific CMS models. Value-based arrangements in the commercial setting (i.e. Outside of the scope of specifically waived Medicare and Medicaid models; subject to the Stark Law and Anti-Kickback Statute (AKS) under a traditional regulatory analysis based on long-standing safe harbors and exceptions.) These safe harbors and exceptions, however, have been a challenge for health care to address innovative value-based arrangements and relationships.

HHS launched the "Regulatory Sprint to Coordinated Care" in 2018 to accelerate a transformation of the health care system, with an emphasis on eliminating "unnecessary obstacles" to coordinated care. In providing a framework for supporting value-based arrangements and relationships, the Final Rules align with the goals of the "Regulatory Sprint to Coordinated Care," as HHS seeks to drive increased provider engagement with value-based care. Through the Final Rules, CMS and the OIG offer fresh roadways for providers and payors to come together in innovative ways, without fear of violating fraud and abuse regulations, for both governmental and nongovernmental value-based arrangements and relationships.

The safe harbors and exceptions are intended to cover **a broad array of arrangements**. The Final Rules reflect an opportunity for payors and providers to co-create considering one or many elements, for example, the patient populations, value-based purposes and activities, quality measures, payment methodologies, referral requirements, and other components of an arrangement without these parameters being prescribed or narrowly defined. At the same time, however, CMS and OIG have included **a robust set of requirements and safeguards** within each of the new exceptions and safe harbor protections, which help ensure that the arrangements are structured to drive providers toward **clear value-based goals and objectives**.

For arrangements that are designed and implemented to fit within the parameters set forth in the Final Rules, care providers will be able to adopt practices of operating outside the purview of many traditional fraud and abuse safeguards. **The provisions for these arrangements must be managed and reviewed periodically.**

Some of the new safe harbors and exceptions are:

- **Does not** contain a requirement that an arrangement be set at fair market value (FMV).
- **Does not** require that compensation or other remuneration under an arrangement be set in advance.
- **Does** allow for directed referrals of patients to specific providers (so long as a series of conditions and exceptions are accounted for).
- **Does not** contain a broad prohibition on remuneration under an arrangement while considering the volume or value of referrals.

While these flexibilities provide exciting new opportunities for payors and care providers, especially when care providers are prepared to take on risk, they can only be taken advantage of through careful structured arrangements that satisfy a series of requirements set forth in the Final Rules for each relationship.

Careful review of these requirements become heightened with value-based arrangements which **may specifically include provisions** that would be in violation of regulatory requirements outside of a structured arrangement reflecting these value-based safe harbors and exceptions.

II. 6 Primary Safe Harbor and Exceptions to Begin Risk Categorization

Our primary focus is on three AKS safe harbors and three Stark Law exceptions for value-based arrangements and relationships. Utilizing a simple HML risk categorization in figure 1 to categorize the **level of risk sharing that is incorporated into the agreement**. The greater the amount of risk sharing incorporated into the arrangement, the more flexibility provided under the safe harbor or exception is realized. As these elements are incorporated into the instruments, visibility and oversight become more profoundly necessary in order to maintain consistent controls and accountability of these arrangements. **Categorize draft and executed arrangements with one of the six elements and risk levels as follows:**

Enforcement Agency	Limited or No Risk Share	Significant Risk Share	Full Risk Share
OIG/AKS Safe Harbor	LOW "Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency"	MEDIUM "Value-Based Arrangements with Substantial Downside Financial Risk"	HIGH "Value-Based Arrangements With Full Financial Risk"
CMS/Stark Law Exception	LOW "Value-Based Arrangements"	MEDIUM "Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician"	HIGH "Full Financial Risk"

Fig. 1 HML Risk Definitions and Categories

A. Definitions with Risk Categorization

i. Limited or No Risk Share Arrangements

- **Low Risk** - The AKS Care Coordination Arrangements safe harbor protects in-kind (nonmonetary) remuneration within compliant value-based arrangements that further patient care coordination purposes. This safe harbor requires no assumption of downside risk by parties to a value-based arrangement. 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.
- **Low Risk** - The Stark Value-Based Arrangements exception protects physician compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken though the arrangement.

ii. Significant Risk Share Arrangements

- **Medium Risk** - The AKS Value-Based Arrangements with Substantial Downside Financial Risk safe harbor protects both monetary and in-kind remuneration and offers 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. As detailed below, this safe harbor requires the value-based enterprise (VBE) to take on defined percentages of downside risk.
- **Medium Risk** - The Stark Meaningful Downside Risk exception is meant to protect remuneration paid under a value-based arrangement where both the physician and VBE take on downside financial risk under a payor arrangement.

iii. Full Financial Risk Share Arrangements

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

B. Revised Value-Based Definitions. Every affected arrangement must have at its core, one or more value-based purpose defined as: **(i)** Coordinating and managing the care of a target patient population; **(ii)** Improving the quality of care for a target patient population; **(iii)** Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; **OR (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 target patient population. While there may be other goals to an arrangement or relationship, at least one of these enumerated value-based purposes is necessary. For example, while cost savings to a provider or maintenance of a current level of quality may very well be legitimate and valuable goals of an arrangement, such goals will not qualify as value-based purposes and will not be sufficient to obtain Stark Law and AKS protection.

With value-based purposes in mind, the Final Rules define a **"value-based activity"** as one or more activities reasonably designed to achieve a value-based purpose, which can be the provision of an item or service, the taking of an action, or the refraining from taking an action. OIG specified that a value-based activity does not include the making of a referral. CMS did not make a similar exclusion because the definition of referral in the Stark Law already reflects a policy that referrals are not items or services for which a physician may be compensated. In other words, if the value-based purpose is the goal of an arrangement, the value-based activity is the action intended to accomplish that goal.

Value-based activities must then be set forth in a "value-based arrangement," which is an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are **(i)** the VBE and one or more of its participants, **or (ii)** two or more participants in the same VBE.

A VBE can be thought of as the network of participants engaging in value-based activities. A VBE might be an accountable care organization **(ACO)** or clinically integrated network **(CIN)**, although a series of structures for VBEs are permissible. Specifically, a VBE means **two or more participants** collaborating to achieve at least **one value-based** purpose, where each participant is a party to a value-based arrangement with the other or at least one other participant in the VBE. While a VBE does not need to be a separate legal entity, a VBE must **(i)** have an accountable body or person responsible for financial and operational oversight of the VBE; **AND (ii)** have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s).

As referenced above, each value-based purpose (and thus, each value-based arrangement) must identify and be tied to a specific "target patient population." (TPP). This TPP must be set in advance, selected using documentable legitimate and verifiable criteria, and must further the value-based purpose of the VBE.

C. Waiver Limitations

3 key limitations include **(i)** The safe harbors and exceptions require compliance with the technical requirements for each specific type of value-based arrangements. The fact that an arrangement is associated with a legitimate value-based purpose alone will not guarantee that the arrangement will fit within one of the safe harbors or exceptions**. (ii)** Similar to the existing AKS and Stark Law regulations, these safe harbors and exceptions are highly prescriptive, with specific requirements that are set herein. Thus, existing value-based arrangements will likely not satisfy all AKS or Stark Law value-based requirements without review and amendment. **(iii)** OIG has not limited the types of individuals and entities that may participate in a VBE. However, the AKS Final Rule prohibits certain types of organizations from relying on value-based safe harbors.

These provider types are those that the OIG believe pose heightened fraud and abuse concerns. OIG revised the exclusion of these entities as VBE participants to recognize the role they may have, while denying protections for most arrangements involving these entities. While they are generally excluded from protections under the safe harbors, certain durable medical equipment, prosthetics, orthotics, and supplies (**DMEPOS**) providers and suppliers that qualify as limited technology participants may utilize the care coordination arrangements safe harbor for arrangements involving digital health technology. Categorizing these arrangements, providers and suppliers provides for improved visibility and can help to mitigate risk.

III. Exceptions and Safe Harbor – Limited Risk Share Arrangements

As part of the effort to provide protections to a continuum of arrangements and relationships, limited risk share arrangements present the least amount of flexibility. While the relevant Stark Law exception and AKS safe harbor provide some protections, it is important to mention that a significant number of current risk-sharing arrangements in the market fall into the limited risk share category and therefore the Stark Final Rule includes additional and significant non-value-based changes.

A. AKS Safe Harbor – Care Coordination Arrangements

The AKS safe harbor for care coordination arrangements protects 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. Under this safe harbor, each offer of in-kind remuneration among VBE participants must be analyzed separately for compliance with the safe harbor. One key component of this safe harbor is the requirement that the recipient pay 15 percent of either: **(i)** the offeror's cost, **OR (ii)** the fair market value of the in-kind remuneration[1] .

OIG provided certain examples of arrangements that could be structured to satisfy the care coordination safe harbor. OIG suggested that the care coordination safe harbor could be used to coordinate care between hospitals and post-acute care providers, specialists and primary care providers, or hospitals and physician practices and patients. Such coordination could involve the use of care managers, providing care or medication management, creating a patient-centered medical home, helping with effective transitions of care, sharing and using health data to improve outcomes, or sharing accountability for the care of a patient across the continuum of care. These arrangements often naturally involve referrals across provider settings, but they include beneficial activities beyond the mere referral of a patient or ordering of an item or service. The OIG stressed that it "sees a clear distinction between coordinating and managing patient care transitions for the purpose of improving the quality of care or improving efficiencies, which would fit in the definition, and churning patients through care settings to capitalize on a reimbursement scheme or otherwise generate revenue, which would not fit in the definition." Likewise, the OIG noted that **arrangements involving the provision of data analytics software, care managers, or remote patient monitoring could likely fit within the safe harbor**. OIG specifically responded to commenters that income guarantees are not in-kind remuneration and therefore would not qualify for protection under the care coordination arrangements safe harbor.

This 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 harbor arrangements operate to achieve their value-based purposes, the OIG has finalized numerous conditions and safeguards.

B. Stark Law Exception – Value-Based Arrangements

This 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. The exception permits both monetary and non-monetary remuneration between the parties.

CMS intends for the value-based purpose of the arrangement to relate to the VBE as a whole. The exception does 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.

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

CMS and the OIG took significantly different approaches as to no- or low-risk sharing arrangements. As a result, there is limited overlap between the requirements of the finalized AKS safe harbor and the Stark Law exception, and if a CIN or ACO wants a no- or low-risk sharing arrangement to be compliant with both the AKS safe harbor and the Stark Law exception, it will need to ensure that the arrangement meets a long list of largely non-overlapping requirements. These requirements must be reviewed during the production of the arrangement to ensure conditions are met.

The key similarity between the finalized AKS safe harbor and the Stark Law exception is the referral requirement. Specifically, both the OIG and CMS finalized requirements that the remuneration within a value-based arrangement not be conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement. This means that the value-based safe harbors and exceptions do not protect arrangements where one or both parties have made referrals—or other business—not covered by the value-based arrangement a condition of the remuneration. One example provided by CMS is that a VBE could not receive protection under a value-based Stark Law exception for a value-based arrangement between an entity and a physician that are VBE participants in the VBE if, as part of the arrangement, the entity requires the physician to refer Medicare patients who are not part of the target patient population for designated health services furnished by the entity. Similarly, the value-based AKS safe harbors do not provide protection for value-based arrangements that condition an offer of remuneration on: **(i)** referrals of patients that are not part of the value-based arrangement's target patient population, **OR (ii)** business not covered under the value-based arrangement.

IV. Exceptions and Save Harbor – Significant Risk Share Arrangements

As more providers move to downside risk arrangements in the market, the protections of the significant risk share arrangement exceptions and safe harbors are likely to have the most impact on providers. Because this segment of the market has taken 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. **Assessing and potentially risk scoring these arrangements can reduce the likelihood of inadequate protections.**

A. AKS – Value-Based Arrangements with Substantial Downside Financial Risk

The AKS safe harbor for value-based arrangements with substantial financial risk, which protects both monetary and in-kind remuneration, offers 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). As finalized, this safe harbor applies 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. OIG reduced the risk sharing percentages from the proposed rule. Under the Final Rule, substantial downside risk includes shared savings with at least 30 percent loss repayment, episodic or bundled payments with at least 20 percent loss repayment, or under a partial capitation model as defined in the rule[2] . This safe harbor protects remuneration exchanged between such VBEs and VBE participants if several standards are met.

One key clarification in the commentary to the Final Rule is that the downside financial risk must consider all items and services covered by the applicable payor and furnished to the target patient population, not just the items furnished by a VBE participant. As an example, OIG indicated that a VBE could not limit its risk for outpatient services by entering into value-based arrangements with a narrow set of providers that provide care in outpatient settings. OIG also clarified that the risk can be prospective or retrospective, including calculations compared to a benchmark. OIG also **removed the specific 60 percent discount** that was included in the proposed rule for partial capitation.

An additional key distinction between this safe harbor and the care coordination safe harbor is that the VBE participant must meaningfully share in the financial risk. In the Final Rule, this requirement was set at a two-sided risk of 5 percent of the shared savings or losses of the VBE or prospective, per-patient payments[3] for a predefined set of items and services furnished to the target patient population under the partial capitation methodology. OIG declined to finalize an exception under the corresponding CMS exception methodology under the Stark Law rules for meaningful downside risk arrangements. Once available, we will publish a supplemental to this white paper for your consideration.

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.

B. Meaningful Downside Risk Exception for Stark

The 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.

Although the physician must be at meaningful downside financial risk for **the entire term of the value-based arrangement,** the remuneration may be paid to or from the physician. Meaningful downside risk means the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement. This represents a significant reduction in the 25 percent risk share required in the proposed rule. Managing these risk share percentages to meet the exception must be accomplished in order to demonstrate compliance.

V. Exceptions and Safe Harbor – Full Financial Risk Share Arrangements

CMS and the OIG have provided the most extensive protection and flexibility to the arrangement that take on full risk. 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. While these arrangements are rare, keeping them highly visible and accessible by the affected stakeholders is paramount to their success.

A. Value-Based Arrangements with Full Financial Risk for AKS

The AKS safe harbor for 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 safe harbor includes more flexible conditions than the care coordination arrangements and substantial downside financial risk safe harbors, which the OIG believes reduces burden for the VBE and its participants. However, this safe harbor only protects arrangements between VBEs and VBE participants and not agreements among VBE participants or with downstream entities. Some of the notable requirements to meet this safe harbor are outlined in the chart below. **OIG extended the phase-in period for this safe harbor from six months to one year**.

Commenters asked OIG to clarify what level of stop-loss coverage a VBE could have under a full financial risk arrangement. OIG declined to do so, but it specified that it would expect stop-loss or other risk adjustment arrangements to be limited to protection for the VBE against catastrophic losses and not as a means to shift material financial risk back to the payor or another third party–i.e., the VBE must maintain material financial risk. OIG recognized that this safe harbor would apply to a limited number of providers, but it promulgated the safe harbor to remove a potential barrier to providers taking on additional risk. OIG did note that some state laws limit the ability of providers to take full financial risk without forming licensed health plans or meeting other licensure requirements, and OIG indicated providers must still comply with state law.

B. Full Financial Risk Exception for Stark

The 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. Like OIG, CMS increased the time period before the VBE must be a full financial risk to **one year from six months** as originally set forth in the proposed rule.

Like OIG, CMS addressed questions regarding stop-loss by not limiting an amount of loss mitigation but indicating that such mitigation should not shift material financial risk to the payor.

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.

VI. Additional Safe Harbors and Exceptions to Consider

A. AKS – Safe Harbor for Arrangements, Patient Engagement, Support to Improve Quality, Outcomes, and Efficiency

A typical 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, 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 AKS safe harbor will 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.

Notable requirements to meet this safe harbor to consider in crafting the arrangements include **(i)** Goods, items, and services given to target patient populations as patient engagement tools or supports are provided directly to patients by VBE participants (or their agents); **(ii)** The patient engagement tool or support must not be funded or contributed by a VBE participant that is not a party to the applicable value-based arrangement, or by the list of enumerated entities that cannot rely on the value-based AKS safe harbors as set forth in Section II.C (e.g., pharmaceutical companies); **(iii)** For a period of at least **6 years**, the VBE participant makes available to the Secretary, upon request, **all materials and records** sufficient to establish compliance; **(iv)** The availability of a tool or support is not determined in a manner that accounts for the type of insurance coverage of the patient. **(v)** The aggregate retail value of patient engagement tools and supports furnished to a patient by a VBE participant on an annual basis cannot exceed USD $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; **AND (vi)** the patient engagement tool or support meets the following requirements:

- It is in-kind **AND IS (i)** preventative, **(ii)** health-related technology/monitoring, **OR (iii)** designed to identify/address social determinants of health.
- It has direct connection to coordination and management of care for the population.
- It does not include any cash or cash equivalent.
- It is not used for patient recruitment or marketing.
- Does not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program.
- It is recommended by the patient's licensed health care professional and advances one or more of the following goals: Adherence to treatment regimen; adherence to drug regimen; adherence to follow-up care plan; prevention or management of a disease or condition; or ensuring patient safety.

B. Stark Law – Exceptions Applicable to Indirect Compensation Arrangements

Under the longstanding 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 therein. The indirect compensation exception includes requirements not otherwise found in the exceptions for value-based arrangements. 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 finalized in the Stark Final Rule an amendment to the indirect compensation exception to address this issue. Under the revised exception, parties will 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 for value-based arrangements will be applicable under the indirect compensation exception and need to be managed accordingly.

C. AKS – Other Safe Harbors

The Final AKS Rule also includes other new safe harbors and changes to existing safe harbors that are not specifically related to value-based care. These changes include: a new safe harbor for CMS-sponsored model arrangements, a new safe harbor for donations of cybersecurity technology, a new safe harbor to codify statutory changes made to the definition of remuneration for Medicare Shared Savings Program ACOs operating a CMS-approved beneficiary incentive program, and revisions to existing safe harbors for **personal services arrangements**, **warranties**, **local transportation**, and **electronic health records**.

VII. SUMMARY

Managing existing contracts and originating new value-based arrangements must be considered as two separate but related functions when considering exceptions and safe harbors for transitioning some or all. Notwithstanding the complexity and number of requirements created by the Final Rules, these value-based safe harbors and exceptions ultimately represent a major regulatory shift that recognizes the reduced need for aspects of these laws that were designed in part to prevent overutilization. CMS's and OIG's rule each recognize the reduced need for some of the regulations when providers are bearing financial risk and therefore are not incentivized for increasing utilization. The new rules will offer providers, payors, and other stakeholders the opportunity to unlock a wide range of new innovative arrangements with greater flexibility under the 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 when downstream participants and physicians are ready and willing to share in downside risk within payor arrangements, which will unlock a much broader scope of possible protection.

The need to comprehensively assess and potentially risk score the practical compliance elements of the Final Rules are paramount. In particular, given the scope of proscriptive requirements, it is unlikely existing arrangements can qualify under any of the new exceptions and safe harbors without at least some level of amendment. The Healthy Contracts CLM can assist health care providers in conducting this analysis and managing the entire lifecycle of the arrangement.

Figure 2 provides risk scoring and categorization to support processes and practices for managing potential transitions of current arrangements and the creation of new value-based relationships while mitigating risk:

Risk Category	Pre Value-Based Risk	Limited/No Risk Share	Significant Risk Share	Full Risk Share
AKS	NONE	LOW	MEDIUM	HIGH
Stark Law	NONE	LOW	MEDIUM	HIGH

Fig. 2 HML Risk Scoring and Categories

Existing Pre Value-Based Arrangements:

- Categorize existing AKS and Stark arrangements for potential value-based transition by "Risk Share Level"
- Gap assess the arrangements for potential remediation and transition
- Remediate select arrangements towards value-based requirements
- Monitor/review periodically for key performance indicators

New Value-Based Arrangements:

- Categorize all new value-based arrangements drafts and requests by "Risk Share Level"
- Gap assess proposed provisions to ensure requirements of the value-based category are met
- Record structural decisions and monitor regulatory for possible gap
- Monitor/review periodically for key performance indicators

Disclaimer: While the processes and practices mentioned herein are meant to assist you in managing potential transitions to and development of new value-based arrangements, it is not intended to opine upon the decisions utilized in structuring and determining acceptable risk levels for value-based arrangements. The Healthy Contracts CLM is intended to be utilized as a resource for managing and assisting with processes and practices.