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Sprint Regulations: Value-Based Stark Exception and AKS Safe Harbors

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The Value-Based Proposals: Turning Tides or Shifting Sands?

Industry stakeholders have waited with bated breath to see whether CMS and OIG would offer meaningful changes to the Stark and AKS landscape in support of the transition to value-based care and emphasis on patient-centered care coordination. The proposed Sprint Regulations are here, but it's too early to tell whether the changes will achieve the agencies' lofty goals to remove barriers to value-based care or just add a new layer to the unruly regulatory framework.

CMS's contribution to the value-based Sprint Regulations comes in the form of new exception AA with three subparts that address arrangements with varying levels of financial risk. OIG proposed three new safe harbors with similar themes, and also proposed changes to the personal and management services safe harbor to protect remuneration paid in connection with value-based arrangements. In general, CMS' proposed value based Stark exceptions are

broader than the OIG's proposed value based AKS safe harbors. Should the proposals be finalized, participants in value based arrangements may well need to determine if they are comfortable satisfying a Stark exception but operating outside of an AKS safe harbor. The proposed definitions, exception, and safe harbors are discussed in detail below.

The Good, the Bad, and the Ugly

The Sprint Regulations are good in a few big-picture ways.

First, both the Stark and AKS proposals would apply to arrangements for care furnished to patients across all payor sources. This improves upon the limited applicability of existing fraud and abuse waivers and reflects the reality of the practice of medicine: the quality and efficiency of appropriate care for a given patient should be divorced from payor status.

The proposed Sprint Regulations are also indicative of CMS's and OIG's recognition of the modern healthcare landscape, the emphasis on aligned incentives and coordination of care, and the need to remove unnecessary regulatory barriers. This is also the first time CMS has meaningfully weighed in on how gainsharing arrangements, which are the subject of many advisory opinions on the AKS side, may be structured under Stark.

On the other hand, CMS's and OIG's proposed exception and safe harbors are a far cry from a bright-line rule. Many of the critical definitions that must be met to even apply the requirements of the exception and safe harbors incorporate vague concepts that introduce subjective judgment into a strict liability regulatory scheme and a statute with criminal repercussions.

CMS also indicated that appropriately conceived value-based arrangements may fall out of compliance with one of the new exceptions, opening up the parties to potential liability.

The unwieldy construction of the Stark exception's reliance on six circular defined terms is most certainly the ugly side of the Sprint Regulations. If the concept of reducing regulatory burden was meant to lessen the need for lawyers to apply Stark to value-based arrangements, CMS missed the mark.

On the AKS side, the exceptions contain so many safeguards that they could be deemed impractical by providers. Some safeguards are also very unconventional when compared to common arrangements in the current market.

If the exception and safe harbors are viewed as setting an unreachable standard, providers could be discouraged from pursing innovative alignment and integration models. In other words, the new exception and safe harbors could have the opposite effect from the intended purpose of removing barriers and facilitating coordination.

The key requirements and limitations of the exceptions and safe harbors are discussed below.

The Devil Is in the (Definition) Details – Value-Based Arrangement

The stated purpose of the proposed Stark exception and AKS safe harbors is to remove potential barriers to more effective coordination and management of patient care and delivery of value-based care that improves quality of care, health outcomes, and efficiency. The proposals to accomplish this purpose are similar under both laws.

True to their nature, CMS and the OIG have proposed a veritable dictionary of defined terms that must be met before applying the value-based exception or safe harbors. These definitions are generally consistent between the proposed Stark and AKS regulations. Notable interpretive guidance on these definitions appears in italics:

Value-based arrangement is an arrangement for the provision of at least one value-based activity for a target patient population between or among:

- The value-based enterprise and one or more of its VBE participants, or
- VBE participants in the same value-based enterprise.

Preamble: Only compensation arrangements may qualify as value-based

arrangements. The definition of value-based arrangement is also broad enough to cover commercial and private insurer arrangements.

Value-based enterprise (VBE) is two or more VBE participants:

- Collaborating to achieve at least one value-based purpose;
- Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;
- That has an accountable body or person responsible for financial, operational and compliance oversight of the value-based enterprise; and
- That has a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s).

Preamble: Organized networks of health care providers, suppliers, and other components of the health care system have flexibility to adopt any legal structure that meets these requirements, including a distinct legal entity such as an ACO. However, a VBE could be a contractual arrangement as well, if all definitional elements are met. The accountable body/person may be a party to a value-based arrangement or if the VBE is a legal entity, it may be the governing board, a committee, or an officer of the legal entity.

VBE participant is an individual or entity that engages in at least one value-based activity as part of a VBE.

Preamble: A VBE participant could include physician practices, hospitals, payors, post-acute providers, pharmacies, chronic care and disease management companies, social service organizations, etc. Entity means any non-natural person, not just DHS entities subject to Stark. For purposes of the AKS safe harbors, the definition of VBE participant expressly excludes pharmaceutical manufacturers, DMEPOS manufacturers, distributors or suppliers, and laboratories. CMS and the OIG are also considering whether to exclude "health technology companies" from the scope of the exception, though they did not define the term.

Value-based activity means providing an item or service, taking an action, or refraining from an action that is reasonably designed to achieve a value-based purpose of the value-based enterprise.

Preamble: Making a referral is not a value-based activity.

Value-based purpose means the following with respect to a target patient population:

- Coordinating and managing care;

  Preamble: This phrase is not defined for the Stark exceptions, but CMS is considering whether to adopt a definition requiring deliberate organization of patient care activities and sharing of information between VBE participants to improve health outcomes and to achieve safer and more effective care, similar to the corresponding AKS safe harbor. For the proposed AKS safe harbors, the OIG has proposed defining "coordinating and managing care" to mean "The deliberate organization of patient care activities and sharing of information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population."

- Improving quality of care;

- Appropriately reducing costs or growth in expenditures of payors without reducing quality of care; or

  Preamble: CMS is considering whether to require the purpose to improve quality or maintain improved quality rather than simply not reduce quality in addition to reducing costs/growth in expenditures. This approach would limit the purpose to situations where the VBE has already achieved improvement in the quality of care.

- 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.

Preamble: CMS acknowledges this purpose is subjective. One example is establishing infrastructure to facilitate patient-centered coordinated care.

Target patient population must be selected based on legitimate and verifiable criteria that:

- Are set out in writing in advance of the commencement of the arrangement; and
- Further the value-based purpose.

Preamble: Medical, health, geographic, and payor status characteristics are all examples of acceptable criteria, while criteria that effectively "cherry-pick" or "lemon-drop" patients would not be acceptable. The proposed definition is not limited to federal healthcare program patients. CMS and the OIG are also considering limiting the definition of "target patient population" to patients with a chronic disease or a shared disease state that would benefit from care coordination.

Much like the in-office ancillary services exception is dependent on meeting the definition of "group practice," Exception AA is only available for value-based arrangements. A critical difference in CMS's proposal in the Sprint Regulations is that the definitions incorporate big-picture concepts that leave room for interpretation.

While CMS may have intended to allow parties more flexibility than its historic rulemaking approach, finite definitions have the benefit of certainty in a strict liability regulatory scheme like Stark. To guide VBE participants to safe ground, more specific examples of what constitutes a "value based purpose" or what does or does not qualify as a "value based activity" would certainly be helpful.

The proposal to exclude "health technology companies" from the protections without defining the term is also cause for concern. The healthcare industry is adopting tech solutions at a rapid pace to deliver care more efficiently, and uncertainty about which DHS entities might be excluded in this category could be a barrier to accessing Exception AA.

The Main Event: Value-Based Exception and Safe Harbors

The Sprint Regulations have separate requirements for value-based arrangements involving full financial risk, downside financial risk, and qualifying arrangements without strict financial risk requirements. Both CMS and the OIG designed the exceptions and safe harbors to include more rigorous requirements as the level of financial risk in the arrangement decreases.

The Stark exception and the safe harbors do not reqpreuire the remuneration under a value-based arrangement to be consistent with fair market value, not determined in a manner that takes into account the volume or value of a physician's referrals or other business generated for the entity, or commercially reasonable, which greatly improves the utility of the exception.

All of the Stark proposals share five common requirements, which also appear in substantially similar forms in the three value-based AKS safe harbors:

1. The remuneration must be for or result from value-based activities undertaken by the recipient for patients in the target population.

   Note: While the term value-based activity is defined as a particular item, service, or action, the preamble guidance confirms that gainsharing payments, shared savings distributions, and other payment methodologies that do not have a one-to-one relationship with a particular item, service, or action would meet this requirement of the exception.

   However, without more guidance from the agencies about the causation standard that will be applied when assessing whether remuneration "resulted from" a particular activity, this requirement could pose a challenge.

   In-kind remuneration that is duplicative of an item or service, such as technology or infrastructure, that the recipient already possesses would not meet the requirement, but in-kind remuneration may be used to benefit all patients, not only those in the target population.

2. The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

3. 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.

4. If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement must meet the requirements of 42 CFR 411.354(d)(4)(iv) (requiring the arrangement to be set out in writing and signed by the parties and not prohibit referrals elsewhere based on patient preference, insurance requirements, or physician judgment).

5. Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for at least six years and made available to the Secretary upon request.

Full Financial Risk

Exception AA's subpart addressing value-based arrangements with full financial risk is only available if the VBE is at full financial risk 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.

The exception could apply during the six month period before the VBE is at full financial risk to protect remuneration provided in the start-up phase of an arrangement. The full financial risk exception appears sufficiently broad to replace the fraud and abuse waivers CMS (with OIG) has issued for CMS-sponsored models.

We are particularly interested to see whether the final rule will require the VBE to be at full financial risk for a particular time period or addresses more targeted arrangements by permitting the full financial risk to be narrowed to particular types of services. For example, if a VBE with a targeted patient population of total hip replacement patients is required to have full financial risk for covered services for six months post-surgery, and a patient in the

population has COPD, Exception AA would arguably require the VBE to be at financial risk for the patient's COPD care that is totally unrelated to the VBE's value-based purpose.

The proposed AKS safe harbor for "Value-Based Arrangements with Full Financial Risk" would protect in-kind and monetary arrangements between a VBE and VBE participants where the value-based entity assumes full financial risk from a payor. The OIG, like CMS, recognizes that arrangements involving full financial risk present fewer fraud and abuse risks, therefore this safe harbor is intended to offer VBEs the greatest ability to innovate with respect to coordinated care arrangements.

For purposes of this safe harbor, "full financial risk" means the VBE is financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively paid by the applicable payor.

Additional safeguards applicable to this safe harbor are:

- The VBE must provide for a utilization review program and quality assurance program that protects against underutilization and specifies patient goals;
- The value-based arrangement does not include marketing to patients of items or services or engaging in patient recruitment activities.

Downside Financial Risk Arrangements

Stark Exception AA would also 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 of the VBE during the duration of the arrangement. CMS proposed to define meaningful downside financial risk as requiring the physician to be responsible for at least 25 percent of the value of the remuneration (including in-kind remuneration) that the physician receives under the arrangement, or financially responsible on a prospective basis for the cost of all or a defined set of patient-care items and services covered by the payor for each patient in the target patient population for a specified period.

The nature and extent of the downside financial risk must be set forth in a writing, and the methodology for determining the amount of the remuneration must be set in advance of undertaking the value-based activities. Like the full financial risk arrangements discussed above, the remuneration must be for or result from the recipient's value-based activities for patients in the target patient population.

The proposed safe harbor for "Value-Based Arrangements with Substantial Downside Financial Risk" would protect in-kind and monetary arrangements between a VBE and VBE participant where the VBE is at substantial downside financial risk from a payor. To qualify, the VBE must assume substantial downside financial risk from a payor in one of the following forms for services related to a target patient population:

- Downside risk of at least 40 percent in a shared savings arrangement;
- Downside risk of at least 20 percent under an episodic or bundled payment arrangement;
- A prospectively paid population-based payment for a defined subset of the total cost of care; or
- A partial capitated payment from the payor that reflects a discount equal to at least 60 percent.

Next, the VBE participant must "meaningfully share" in this risk arrangement with the VBE, in one of the following ways:

- The VBE participant assumes risk for 8 percent of the amount for which the VBE is at risk under its agreement with the applicable payor;
- The VBE participant receives a partial or full capitated payment from the VBE; or
- In the case of a VBE participant that is a physician, a payment that meets the requirements of the Stark Law's Exception AA for meaningful downside financial risk, as discussed above.

To balance the need to protect start-up arrangements while also limiting potential program integrity risks, this safe harbor would protect arrangements

between the VBE and the VBE participant during the six months prior to commencement of the arrangement.

Other Value-Based Arrangements

The last iteration of Stark Exception AA is a catch-all, many-strings-attached option for other value-based arrangements regardless of the level of risk undertaken by the VBE and its participants. These arrangements must be set forth in a writing signed by the parties that describes the value-based activities of the arrangement and how they further the VBE's value-based purpose(s), the target patient population, the type or nature of remuneration, the methodology used to determine the remuneration, and the performance or quality standards against which the recipient will be measured (if any).

CMS is considering excluding monetary remuneration from this part of Exception AA which would eliminate gainsharing arrangements from the scope. If adopted, this would be particularly impactful to value-based arrangements since the revised volume or value standard in the Sprint Regulations would still likely prohibit many common gainsharing metrics such as reducing cut-to-close time and using standardized surgical implants.

Also troubling is that CMS is considering whether to require that performance or quality standards "be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery." Again, this is a nebulous standard not suited for a strict liability regulatory scheme.

The preamble discussion for this part of Exception AA has some similarities to the CMS 60-Day Overpayment Rule in that CMS believes VBE participants have an affirmative obligation to monitor progress toward the value-based purpose of the VBE. CMS gives a few examples of situations where an arrangement would fall out of compliance with Exception AA even if the arrangement was "reasonably designed to achieve the value-based purpose" because data and experience through the course of the arrangement reveal that the activities do not have the intended outcomes.

CMS may adopt a required monitoring framework or require physicians to cease referring for DHS within a certain timeframe of the determination that the value-based purpose will not be achieved through the value-based activities. This begs the question, however, of when the arrangement will be

deemed to no longer comply with the exception and whether VBE participants may be deemed to have retroactively unprotected compensation arrangements because the value-based purpose was later determined to be unachievable.

CMS is also toying with the idea of requiring recipients of nonmonetary remuneration to contribute some threshold—perhaps 15 percent of the donor's cost—for the donated items or services similar to the EHR exception.

The corollary AKS safe harbor is titled, the "Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor." Similar to its counterpart under Stark, the Care Coordination safe harbor would protect certain value-based arrangements even when no financial risk is assumed, provided that the following safe guards are met:

- **Adopt Outcome Measures:** The parties to the value-based arrangement must establish one or more specific evidence-based, valid outcome measures against which the recipient of remuneration will be measured, and which the parties reasonably anticipate will advance the coordination and management of care of the target patient population;

  Preamble: The OIG will not consider measures related to patient satisfaction or convenience to be valid outcome measures. The OIG is also considering how to define "evidence-based," and whether outcome measures must be periodically rebased (i.e., reset the benchmark used to determine whether the outcome measure was achieved).

- **Commercial Reasonableness:** The value-based arrangement must be commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE.

- **Limitations on Remuneration:** The remuneration must be in-kind, non-monetary remuneration (gift cards are prohibited);

  Preamble: The OIG is considering for the final rule whether in-kind remuneration can have a "spillover" effect and benefit patients outside the target patient population, or whether it may only benefit the target patients. If the latter standard is adopted, safe harbor protection would be unavailable

for common arrangements that involve donation of health tech used across all facets of a provider's business.

- **Contribution Requirement:** Safe harbor protection is conditioned upon the recipient's payment of at least 15 percent of the offeror's cost for the in-kind remuneration.

  Preamble: This requirement is intended to mirror a requirement in the EHR safe harbor. The OIG is considering for the final rule how to determine value for purposes of calculating the 15 percent payment. The OIG is also considering whether to adjust the contribution amount within a range of five to 35 percent, or perhaps waive this requirement for parties in rural or low-access areas.

- **Monitoring and Assessment.** At least annually, an accountable body or responsible person within the VBE must monitor, assess and report regarding:

  - The coordination and management of care for the target population;

  - Any deficiencies in the delivery of quality care under the value-based arrangement; and

    Preamble: The OIG is not proposing a definition for a material deficiency in the quality of care.

  - Progress toward achieving outcome measure(s).

- **No Diversion, Resell, or Use for Unlawful Purpose.** Safe harbor protection is not available if the offeror knows or should know that the remuneration is likely to be diverted, resold or used by the recipient for an unlawful purpose.

And the OIG may not be done yet. In addition to the ten safeguards described above, the OIG is considering adding several other safeguards for the Care Coordination safe harbor. These potential additional safeguards that may be adopted in the final rule are:

- **Bona Fide Determinations:** In advance of or contemporaneous with the commencement of a value-based arrangement, the VBE's accountable body or responsible person must make a bona fide determination that the value-based arrangement is directly connected to the coordination and management of care for the target patient population and that the value-based arrangement is commercially reasonable.

- **Cost-Shifting Prohibition:** VBEs or VBE participants may not bill other payors for remuneration paid under a value-based arrangement, or claim it as bad debt, or otherwise shift the cost of the remuneration to other payors.

- **Fair Market Value Requirement and Restriction on Remuneration Tied to the Volume or Value of Referrals:** The OIG may decide to include a fair market value requirement on any remuneration exchanged pursuant to a value-based arrangement, and may prohibit VBE participants from determining the amount remuneration in a manner that takes into account the volume or value of referrals or other business generated.

- **Additional Requirements for Dialysis Providers:** Due to the OIG's concern with a consolidated market of dialysis providers in the United States, the OIG is considering whether to include provisions specific to dialysis providers to further ensure that their care coordination arrangements operate to improve the management and care of patients and are not pay-for-referral schemes.

Personal Services and Management Contracts and Outcomes-Based Payment Arrangements

In the Sprint Regulations, the OIG also proposes to protect certain outcomes-based compensation (regardless of whether it meets the criteria for substantial downside financial risk) through proposed modifications to the personal services and management contracts safe harbor. Making the following modifications to the safe harbor for Personal Services and Management Contracts at 1001.952(d) creates a different avenue for protecting value-based arrangements than the new proposed safe harbors.

Modify the "set in advance" requirement

The existing safe harbor for personal services and management contracts requires that such agreements be for a term of at least one year and that the aggregate compensation be set in advance. To provide enhanced flexibility, the OIG is proposing to remove the requirement that the "aggregate" amount of compensation paid over the term of the agreement be "set in advance." The proposed modification would require the parties to determine the arrangement's *compensation methodology* in advance.

Eliminate the requirement to specify the schedule, length and charges for service intervals

The OIG has proposed eliminating the requirements set forth at 42 CFR 1001.952(d)(3) relating to agreements for services provided on a periodic, sporadic, or part-time basis. This paragraph of the safe harbor requires contracts that provide for services on such a basis to specify "exactly the schedule of such intervals, their precise length, and the exact charge for such intervals." Removing this requirement would afford parties additional flexibility in designing business arrangements, including care coordination and quality-based arrangements.

Add new language to protect outcomes-based payments

The last change to the personal and management services safe harbor would add new language to expressly protect payments defined as "outcome-based" payments from models such as shared savings, shared losses, episodic payments, gainsharing and pay-for-performance.

An "outcome-based payment" is defined as a payment that rewards a party for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that coordinate care across care settings, or achieve outcome measures that reduce payor costs while improving quality. Also, outcome-based payments cannot relate to internal cost savings.

The OIG's proposal for outcomes-based payment arrangements includes the following conditions:

- **Goal of the Outcomes-Based Payment Arrangement:** The OIG will limit safe harbor protection to outcome-based payment arrangements that foster the goals to measurably improve quality of patient care (or maintain improvement); appropriately and materially reduce costs to or growth in expenditures of payors while improving or maintaining the improved quality of care; or both. Notably outcomes-based payments specifically exclude any payments that relate solely to the achievement of internal cost savings for the principal. That means that most hospital gainsharing programs are not likely to qualify for protection.

- **Outcome Measures:** The parties must establish one or more specific evidence-based, valid outcome measures that the agent must satisfy to receive the outcomes -based monetary remuneration. Outcome measures must be measurable and valid and must promote improved quality or efficiencies in the delivery of care or appropriate cost reduction. Parties must also rebase the benchmark or outcome measure periodically.

- **Fair Market Value:** The methodology for determining compensation (including any outcomes-based payments) must be fair market value, despite the lack of industry standards developed to determine fair market value for some outcome-based payment arrangements in the value-based care arena. However, the OIG anticipates that the industry will evolve and adapt to assess fair market value for value-driven outcomes-based payment arrangements.

- **Volume or Value of Referrals:** The compensation methodology for determining the outcome-based payment may not be determined in a manner that *directly* takes into account the volume or value of referrals or other business generated between the parties. Outcome-based payments that *indirectly* take volume or value or other business generated into account are permissible. Unfortunately, the OIG does not define or provide examples regarding indirect payments.

- **Writing and Monitoring:** A written agreement that includes payments for outcome-based measures must include: the outcome measures;

the evidence-based data or information upon which the parties relied to select the outcome measures; and the schedule for the parties to regularly monitor and assess the outcome measures. The OIG suggests that the parties should also consider retaining documentation showing the agent's achievement of the outcome measures.

- **Stinting:** The agreement may not limit any party's ability to make medically appropriate decisions for patients, nor induce the reduction of medically necessary services.

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The Other Half of the Stark Sprint Regulations - Valuable (but Not Value-Based) Proposals