
# Assessing the Stark and Anti-Kickback Proposals for Value-Based Arrangements

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**Through two separate notices of proposed rule-making (NPRMs), the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) Office of Inspector General (OIG), seek to remove regulatory barriers and promote value-based innovation and care.**

In publishing NPRMs related to implementation of the Federal Physician Self-Referral or "Stark Law" and the Federal Anti-Kickback Statute (AKS), the agencies also convey the Administration's intent to move the health care payment and incentive systems away from fee-for-service to those focused on quality, cost control and financial risk.

Discussed below are certain key requirements, potential implications and open questions related to the Stark, AKS and related proposals designed to facilitate "value-based" health care payment and delivery. Comments on both proposals are due by December 31, 2019. Given the breadth of the proposed rule changes and their likely impact on the nation's evolving health care system, stakeholders will be well served to weigh-in on the proposals, which are likely to impact their business operations in a fundamental way.

## I. Policy Context

The proposed rules follow CMS and OIG requests for industry input directed at promoting value-based health care that involves greater integration and coordination among physicians and other health care providers as part of the Administration's "Regulatory Sprint to Coordinated Care." HHS leadership has identified health information technology, improved transparency, new payment and delivery models, and the removal of regulatory burden as central to these goals.

The proposed rule changes build on the foregoing themes and experiences, while also taking into account agency experience garnered through the Stark self-disclosure reporting protocol, CMS and OIG advisory opinion processes, and other means. If finalized in their current form, the proposed rule changes would likely provide an improved regulatory framework for existing and innovative value-based initiatives in the health care industry.

## II. Common Themes and Concepts

The proposals use consistent terms in the context of value-based care that are defined in a largely similar manner in the two NPRMs, but with slight variations in a few instances. In practical terms, the value-based Stark exceptions and AKS safe harbors are designed to provide flexibility to permit:


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- Two or more "value-based participants" such as hospitals, physician groups, and other provider entities (but with certain exclusions under the proposed AKS definition);
- To establish a "value-based enterprise" (VBE) that is focused on achieving certain "value-based purposes," where that enterprise has a governing document and an accountable body or person responsible for financial and operational oversight and meets other requirements;
- In connection with a "value-based arrangement" in which the enterprise and/or its participants undertake at least one "value-based activity" (such as providing items/services, taking actions or refraining from taking certain actions);
- Where such activities are directed at the defined "target patient population," which is selected by the VBE using "legitimate and verifiable" criteria set out in writing in advance of the commencement of the value-based arrangement and have at least one "value-based purpose."

These conditions represent prerequisites that must be present for an arrangement to be considered under the new Stark Law value-based exceptions or AKS safe harbors.

The definition of "value-based purposes" is important because it defines the universe of objectives and/or permitted activities that can underlie a value-based arrangement for the proposed exceptions and safe harbors. The agencies propose to define "value-based purposes" to include, with respect to a target patient population:

1. Coordinating or managing the population's care;
2. Improving the quality of the population's care;
3. Reducing costs to, or growth in expenditures of payors for the population, without reducing care quality; or
4. Transitioning health care delivery and payment systems from volume, to mechanisms based on quality and cost control for a target patient population.

A value-based arrangement must meet at least one of these permitted purposes to qualify for a new exception or safe-harbor. Importantly, these permitted purposes may not permit certain relatively common arrangements in use today, such as internal "gainshare" programs operated by hospitals which focus on reducing and sharing savings from reduced medical device costs, while ensuring no reduction in care quality. Such programs (similar to those described in OIG Advisory Opinion 17-09) might not fit within one of the "value-based purposes" because they involve internal hospital savings rather than savings to a payor, and they merely maintain (rather than improve) care quality. Therefore, under the current NPRM proposals, these types of internal gainshare programs would likely need to be modified to include quality improvement (rather than maintenance) for defined populations.

In general, the proposals would implement changes to the Stark and AKS rules to provide new regulatory protections for certain arrangements, including those involving "full" or partial financial risk, as well as "value-based" or "care coordination" arrangements involving in-kind remuneration without financial risk.

The AKS NPRM also includes two additional new safe-harbors, with one addressing "patient engagement to support and improve quality, health outcomes and efficiency," and the second addressing "CMS-sponsored model arrangements."

Both NPRMs propose conforming changes to existing regulatory provisions, including proposed changes to the Stark indirect compensation arrangements exception related to value-based compensation, and changes to the AKS personal services and management contracts safe harbor to facilitate outcomes-based compensation arrangements. The key themes, proposed requirements, and potential implications of some of the proposals are discussed below.

## III. New Stark Law Proposals Directed at Value-Based Care

The proposed Stark Law rule changes would establish a new exception for arrangements that facilitate value-based care delivery and payment where the arrangement involves: (1) remuneration paid under a "value-based arrangement," (2) "meaningful" financial risk, or (3) "full" financial risk. Common to each of these options are requirements that the remuneration:

- Is or results from value-based activities for patients in the target patient population;
- Is not an inducement to reduce or limit medically necessary items or services;
- 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 conditioned on the physicians' referrals to a particular provider or supplier, the arrangement satisfies other requirements of the Stark rule governing "required referrals."

Each also requires records of the methodology for determining the actual amount of remuneration to be maintained for at least six years and made available upon request. The particular option available for use would depend on the underlying nature of the arrangement.

**Value-Based Arrangements Exception**. The proposed Stark "value-based arrangements" exception doesn't require financial risk, but the arrangement must be for, or result from, value-based activities undertaken for patients in the target population, and meet other terms and conditions. Those include a signed writing between the parties that describes the value-based activities to be undertaken, their relation to the value based purposes of the VBE, the target patient population, type or nature of remuneration, and the compensation methodology applicable to the arrangement and remuneration must be set in advance of the undertaking of the value-based arrangement. In addition, the exception requires that any performance and quality standards must be "objective and measureable."

The value-based arrangements exception is likely to be the most useful in today's current environment *because* neither would require any type of financial risk, and therefore, would have the potentially greatest application as the payment and delivery system transitions to arrangements involving financial risk.

Where quality and performance standards are used in the arrangement, the value based arrangements exception requires them to be objective, measureable, prospectively determined, and set in advance of the arrangement. This option would likely be considered by hospitals, physicians, and other providers to address arrangements directed at quality and/or cost variables (e.g., co-management and similar arrangements).

**Risk-Based Value-Based Exceptions Under Stark**. The two Stark Law "risk-based" proposals vary with respect to the parties bearing financial risk and the amount of that risk.

**Full Financial Risk**. This option requires the value-based enterprise to be at "full financial risk" – defined as being financially responsible on a prospective basis for the cost of all patient care items an services covered by the applicable payor for each patient in the target population for a specified period of time. Under this "full risk" option, the VBE as a whole must bear the financial risk, so an individual physician is not required to bear direct out of pocket financial risk under the arrangement.

**Meaningful Financial Risk**. Although this option does not require the VBE to be at risk, it does require a physician to be at "meaningful" downside financial risk for failure to achieve the value-based purposes of the value-based enterprise. It offers two alternative means for a physician to have the requisite "meaningful" risk.

Under the first alternative, the individual physician recipient must bear direct responsibility for at least 25% of the value of the remuneration he/she receives under the arrangement. This alternative potentially would permit individual physicians to first receive payments (e.g., fee-for-service (FFS) payments from a payor), but be obligated to pay a portion of that compensation back to the "entity" involved in the arrangement.

Under the second alternative to achieve "meaningful risk," the physician must be "financially responsible" prospectively for the cost of all or a defined set of patient care items or services for each patient covered under the arrangement. The use of "financially responsible" introduces some uncertainty regarding whether "performance risk" (i.e., a physician's contractual obligation to furnish care to a patient such as in the context of a pre-defined episode of care arrangement) qualifies as "financial risk" within the meaning of this alternative.

**Conforming Refinements to Existing Stark Exceptions**. In the Stark NPRM, CMS proposes a number of changes to the existing regulatory requirements. These include proposing a new "special rule" governing indirect compensation arrangements involving value-based arrangements.

## IV. Anti-Kickback Value-Based Safe Harbor Proposals

OIG and CMS collaborated in an attempt, where appropriate, to provide consistency across the NPRMs. But OIG noted that its proposed rules for value-based arrangements under the AKS may be more restrictive than CMS's proposals in recognition of the differences in the laws' structures and penalties and to have the AKS act as a "backstop" for arrangements that might be protected under a less-restrictive Stark law exception.

OIG proposed three new value-based safe harbors, somewhat similar in structure to the Stark law exceptions, that would be available in connection with "care coordination arrangements" and "at-risk" arrangements involving either "full" or "substantial" downside financial risk.

**Care Coordination Arrangements Proposed Safe Harbor**. This proposed safe harbor would protect certain care coordination arrangements involving in-kind/non-monetary remuneration only. Given the absence of downside financial risk, OIG considers the arrangements that could meet this safe harbor to be at higher risk for the types of fraud and abuse opportunities traditionally seen in the FFS model. Consequently, additional specific safe-guards are proposed, including:

- The need to establish one or more specific evidence-based, valid outcome measures – grounded in legitimate, verifiable data, either internal to one or more of the VBE participants or from a credible external source like a medical journal – which are reasonably anticipated to advance the coordination and management of care for the target patient population against which the recipient of remuneration will be measured;
- The value-based arrangement(s) in the VBE must be commercially reasonable;
- The recipient of the in-kind remuneration would have a cost-share obligation of at least 15% of the offeror's cost for the in-kind remuneration;
- The must be monitored, assessed and reported to the VBE's accountable body or person at least annually relative to the arrangement's achievement of care coordination and management, any deficiencies in care quality and progress in achieving the evidence-based, valid outcome measures, and the arrangement must be terminated within 60 days if the accountable body or person determines that the arrangement is unlikely to achieve the these performance goals or has resulted in material care deficiencies.

In total, the care coordination safe harbor proposal would impose at least ten specific additional safe-guards to an arrangement. Given the status of value-based care in most health care markets and the relatively limited number of at-risk arrangements in most settings, the proposed care coordination safe harbor is likely to be the favored choice for many health care organizations in connection with their value-based activities in the near term.

**Risk-Based AKS Safe Harbors Proposals.** OIG proposes two value-based safe harbors based on the level and type of downside financial risk involved.

**Full Financial Risk Value-Based Arrangements**. Arrangements involving "full" downside financial risk provide organizations with the greatest flexibility and ability to innovate with respect to coordinated care arrangements due that assumption of risk. "Full financial risk" would be defined as a VBE being financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population, and prospectively paid (meaning that the anticipated cost is determined and paid in advance) by the applicable payor. This proposed definition for full risk would not include partial capitated payments that cover a limited set of items or services or a combination of reduced FFS and capitation payments for a defined set of items or services.

The proposed full-risk value-based safe harbor also would prohibit the VBE or VBE participant from claiming additional or separate payment in any form, directly or indirectly, from a payor for items or services covered under the arrangement. Additionally, the remuneration must not be funded by or otherwise result from contributions from an individual or entity that is outside of the VBE. VBEs could, however, still enter into arrangements such as global risk adjustments, risk corridors, reinsurance, or stop loss agreements to protect against catastrophic losses. They would also be permitted to conduct "back end" reconciliation with resulting payment adjustments due to performance on quality or financial metrics, so long as these arrangements are not used as a mechanism to shift material financial risk back to the contracting payor.

OIG is also considering other methodologies for defining full financial risk, such as an actuarial equivalence standard like the one used in Medicare Part D, as well as other situations that should qualify a VBE for assuming "full financial risk." Under the full risk proposal, a VBE would also need to operate programs to protect against underutilization and promote quality assurance.

**Substantial Downside Financial Risk Safe Harbor**. The second proposed value-based safe harbor involving financial risk protects both monetary and in-kind remuneration involving substantial downside financial risk. This safe harbor would only apply to VBEs that have contractually assumed substantial downside financial risk, and only where the VBE participants also "meaningfully share" in the VBE's downside financial risk.

The proposed definition of "substantial downside risk" applicable to VBEs includes:

- Shared savings repayment obligations to the payor of at least 40% of shared losses, measured by costs in relation to historical expenditures;
- A repayment obligation to a payor under an episodic or bundled payment arrangement of at least 20% of any total loss, with losses based on a comparison of costs to historical expenditures;
- A prospectively-paid population-based payment for a defined subset of the total cost of care of a target patient population based on historical expenditures; and
- A partial capitated payment from the payor for a set of items and services for the target patient population, where the capitated payment reflects a discount equal to at least 60% of the total expected FFS payments.

In the alternative, to the extent that historical cost and other data described above is not available, evidence-based, comparable expenditures could be used.

Under this proposed safe harbor, the VBE participants also must meaningfully share in the VBE's substantial downside financial risk, where "meaningfully share" is proposed to mean:

- A risk-sharing payment pursuant to which the VBE participant is at risk for 8% of the amount for which the VBE is at risk under its agreement with the applicable payor;

- A partial or full capitated payment or similar payment methodology; or
- Where the VBE participant is a physician, a payment arrangement that meets the requirements of the Stark law's "meaningful downside financial risk" exception described above.

All three proposed AKS value-based safe harbors would impose additional safeguards and requirements including that remuneration must be used primarily to engage in value-based services, it must not induce limitations on or reductions of medically necessary items or services, not take into account the volume or value of, or condition remuneration on business or patients not covered by the value-based arrangement, and the arrangement may not include marketing items or services to patients or patient recruitment activities. The proposals also include requirements for written agreements, record keeping and other compliance safeguards.

## V. Other Proposed New and/or Refined AKS Safe-Harbors Related to Value-Based Care

OIG also proposed additional revisions or new safe harbors directed at value-based care.

Expansion of Personal Services Safe Harbor to Protect "Outcome-Based Payments." Notably, OIG proposes to add a new provision to the existing AKS personal services and management contracts safe harbor to protect "outcome-based payments"— defined as "payments from a principal to an agent that:

- Reward the agent for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or
- Achieve one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved, quality of care for patients.

OIG proposes to exclude payments made directly or indirectly by pharmaceutical manufacturers; DMEPOS suppliers, manufacturers, or distributors; and laboratories from this safe harbor, based on OIG's concern that these types of entities might use outcomes-base payments to market their products to providers and patients. These types of providers should consider commenting on the NPRM to help OIG understand how they can further value-based purposes while simultaneously safeguarding the program.

The proposed outcomes-based payments safe harbor would require the parties to an "outcome-based" arrangement to establish one or more specific evidence-based, valid outcome measures that the agent must satisfy to receive the monetary remuneration. The outcome measures would also need to be regularly monitored and assessed on a schedule set forth in the governing agreement.

OIG also proposes to make changes to the existing personal services and management contracts safe harbor to replace the requirement that aggregate compensation be set in advance, with the requirement that the parties to determine the arrangement's compensation *methodology* in advance of the initial payment. OIG also proposes to eliminate the requirement that the schedule of part-time arrangements must be specified in advance in order to allow for more flexibility in creating *bona fide* business arrangements.

**New AKS Safe Harbor for CMS-Sponsored Model Arrangements**. OIG has historically issued waivers for certain "CMS-sponsored model" payment arrangements established through the Center for Medicare & Medicaid Innovation and under the Medicare Shared Savings Program. The proposed CMS-sponsored model safe harbor would simplify AKS compliance for CMS-sponsored model participants, by effectively permitting CMS to grant AKS safe harbor protection in connection with defining the particular CMS-sponsored model. The safe harbor would also permit incentives and support provided by model participants and their agents to patients covered under the CMS-sponsored model, for as long as the entity participates in the CMS-sponsored model.

## VI. Other Proposed Exceptions, Safe Harbors and CMP Exceptions

EHR and Cybersecurity Technology, Training, and Services. In recognition of the significant benefits that EHRs can bring to care delivery, OIG and CMS also propose changes to the current safe harbor and exception for certain donations of electronic health records (EHR) in order to facilitate its use. The changes would modify the existing EHR safe harbor to remove the current sunset date in 2021 and update provisions related to interoperability and prohibit information blocking in order to align with rules proposed by the Office of the National Coordinator for Health Information Technology in connection with the 21st Century Cures Act. OIG and CMS are requesting comments to help determine whether the sunset provision should be removed *entirely*, or whether it should be limited in some other manner.

Both agencies also propose new provisions to add protections and permit donations of "cybersecurity technology and related services" that are used predominantly to implement and maintain effective cybersecurity between referral sources in order to strengthen "weak links" in the health care system (i.e. those without adequate cybersecurity) so as to improve overall resistance to cyberattacks. The NPRMs also clarify that cybersecurity software and services can be included in EHR donation programs. OIG and CMS have requested comments in connection with numerous aspects of EHR and cybersecurity technology, training and services, acknowledging the importance these programs and the need to protect patient information.

**Beneficiary Incentives Protections**. OIG also proposed additional protections for certain beneficiary incentives in a variety of forms. These include:

- A proposed AKS safe harbor related to in-kind tools and supports with a retail value of less than $500 to increase patient engagement with their care and adherence to care protocols;
- Modifying the local transportation safe harbor to expand the distance that residents of rural areas may be transported from 50 miles to 75 miles, and removing any mileage limit on transportation for patients discharged from an inpatient setting to a residence; and
- Adding an exception to the provision of certain telehealth technologies related to in-home dialysis services to the definition of "remuneration" applicable to the beneficiary inducements Civil Monetary Penalties law.

These proposals would modify requirements under the beneficiary inducements provisions of the Civil Monetary Penalties law which prohibits offering inducements to beneficiaries of government payors that the offeror knows or should know are likely to influence the selection of particular providers, practitioners or suppliers.

## VII. Comment Needs and Opportunities

Both CMS and OIG requested comments on numerous issues discussed in the NPRMs. For example, the OIG solicited comments on whether the NPRM finds the right balance between flexibility for beneficial innovation and safeguards to protect patients such that participants in an arrangement should be protected from criminal liability. Additionally, the agency requested information on fact patterns that illustrate how other types of risk would operate to change ordering or referring behaviors of suppliers that might still be paid on an FFS basis, or otherwise help ensure that safe-harbored arrangements would serve appropriate value-based purposes.

Numerous comments might also be appropriate regarding a host of concepts involved in one or both proposals, such as whether internal cost savings to health care providers should be included as an acceptable "value-based purpose," or whether such savings should be limited to those incurred by payors. Likewise, comments were specifically sought regarding the scope of target patient populations, including, for example, whether they should be limited to persons with chronic conditions or involve broader populations. OIG also requested input regarding whether payor-driven or home-grown quality and performance measures should be required or used.

The agencies will likely benefit from industry comments on the specific details of their proposals, such as what constitutes different levels of "financial risk" under the Stark and AKS proposals and cost-sharing obligations (along with potential exceptions to those obligations), among others. And finally, members of the health care industry might consider providing comments on whether the proposals, if implemented in their current form would reduce or potentially increase regulatory burden, as well as whether the rules could establish "bright lines" to inform compliance or whether they will contribute to compliance uncertainty and risk.

## VI. Conclusion

The proposed Stark exceptions, AKS safe harbors, and related provisions in the NPRMs represent serious proposals put forth by HHS that are intended to facilitate the growth of value-based care. Unlike past proposals directed at similar goals which were never finalized, today, CMS, OIG and the nation's health care payment and delivery environment may be more receptive to the movement to value-based care. As such, while far from perfect, the proposals may represent a reasonable step to update the existing regulatory environment to facilitate a movement from traditional fee-for-service arrangements to those involving greater attention to quality, cost, care-coordination, and financial risk. Stakeholders would be well-served to take advantage of this opportunity to provide comments to the NPRMs' proposed provisions, which have the potential to impact their day-to-day operations in a meaningful way.

Comments on the two NPRMs will be accepted through December 31, 2019.