CMS and the OIG Issue Far-Reaching Proposed Rules to the Federal Stark and Anti-Kickback Laws

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BASS BERRY SIMS

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In a coordinated effort, the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) published proposed rules to modernize regulations implementing the federal physician-self referral law, commonly referred to as the "Stark Law" (Stark), the federal Anti-Kickback Statute (AKS) and the beneficiary inducement provisions of the Civil Monetary Penalties Law (CMP Law). The proposed rules take steps to create a framework to support value-based payment models and promote improvements in technology infrastructure. Perhaps most notable, however, are the strides taken by CMS toward adding flexibility and attempting to clarify the Stark regulations. Those who were hoping for less complexity may be disappointed, but simplicity was likely an unrealistic expectation given the complexity of our healthcare system and the underlying statutory mandates. Nonetheless, the healthcare industry should be pleased with clarifications and changes that may allow them to avoid Stark self-disclosures in seemingly innocuous circumstances and defend against frivolous whistleblower lawsuits.

THE CHANGES IN THE PROPOSED RULES INCLUDE:

1. New Value-Based Exceptions and Safe Harbors
2. Enabling Technology Infrastructure Improvements
3. Other Notable Proposals, Clarifications and Commentary

Redline documents showing the proposed textual changes to the current Stark regulations are available here and to the AKS regulations are available here. The proposed rules published in the Federal Register are available here and here.

Comments to the proposed rules are due to the respective agencies by 5:00 p.m. On December 31, 2019. Given the number of industry stakeholders these proposals impact, the agencies are likely to receive hundreds of comments; meaning it may be some time before CMS and the OIG issue a final rule.

1. NEW VALUE-BASED EXCEPTIONS AND SAFE HARBORS

OVERVIEW

The proposed rules issued by CMS and the OIG focus extensively on the transition to value-based care delivery and payment models. To support that transition, CMS and the OIG propose new exceptions, safe harbors, and additional changes to existing regulations, relating to value-based care. The below table lists the value-based related topics covered by the proposed rule.

STARK	AKS
Exceptions and Safe Harbors for Value-Based Arrangements Involving Downside Risk	
Full Financial Risk Exception (42 CFR § 411.357(aa)(1))	Full Financial Risk Safe Harbor (42 CFR § 1001.952(gg))
Meaningful Downside Financial Risk Exception (42 CFR § 411.357(aa)(2))	Substantial Downside Risk Safe Harbor (42 CFR § 1001.952(ff))
Other Value-Based Related Exceptions and Safe Harbors	
Value-Based Arrangements Exception (42 CFR § 411.357(aa)(3))	Care Coordination Safe Harbor (42 CFR § 1001.952(ee))
Distribution of Revenue Related to Participation in a VBE (addition to the Group Practice Exception) (42 CFR § 411.352(i)(3))	Patient Engagement and Support Safe Harbor (42 CFR § 1001.952(hh))
	CMS-Sponsored Innovative Payment Models Safe Harbor (42 CFR § 1001.952(ii))

CMS and the OIG recognized the Stark and AKS prohibitions were deterring parties who would otherwise participate in innovative arrangements to facilitate care coordination. Under both proposed rules, CMS and the OIG aim to implement changes promoting beneficial innovations and to remove regulatory barriers – real or perceived – to more effectively coordinate and deliver value-based care that will improve quality of care, health outcomes, and efficiency. CMS and the OIG attempt to strike a balance between the flexibility necessary for innovation and the safeguards necessary to protect patients and federal healthcare programs against fraud and abuse. For example, CMS and the OIG express similar concerns regarding potential risks associated with value-based payment models, such as limiting medically necessary care, "cherry picking" lucrative patients while "lemon dropping" costly patients, and inappropriately manipulating data used to verify performance and outcomes for reimbursement. Both agencies recognize there may be risks and challenges not yet identified, and both are soliciting comments to confirm whether the proposed rules achieve the appropriate balance or leave any gaps.

Both CMS and the OIG note that the OIG's requirements for value-based arrangements are more restrictive than CMS's comparable proposals because the AKS is a criminal intent-based statute, whereas the Stark Law is a civil, strict-liability statute. The newly proposed AKS safe harbors are designed to serve as a "backstop" protection against abusive arrangements that might otherwise qualify for protection under the less restrictive Stark exceptions. For example, the Stark value-based arrangement exception protects both monetary and in-kind remuneration if the exception criteria are met, while the comparable AKS care coordination safe harbor protects in-kind remuneration only.

Overall, the proposed rules represent a comprehensive effort to support a shift to reimbursement models driven by quality and efficiency rather than volume. However, some aspects of the proposed value-based exceptions and safe harbors may be difficult to interpret and apply in practice. Only time will tell whether these changes, if finalized, will be sufficient to stimulate innovation and wide-spread adoption of value-based models.

TERMINOLOGY

CMS and the OIG generally use consistent terminology to describe the universe of value-based arrangements potentially eligible for protection under both proposed rules. The proposed definitions are intended to be broad and flexible. As described below, there is only one term defined by both agencies that differs in a significant way, and there is only one term defined by the OIG that was *not* included as a defined term by CMS. We have created a table with the full definitions applicable to the value-based Stark proposed exceptions and the AKS proposed safe harbors, which is available here. Below we discuss relevant commentary provided by CMS and the OIG regarding each term.

Value-Based Participant

The most significant difference in terminology between the Stark defined terms and the AKS defined terms is the definition of value-based participant. Specifically, the OIG proposes to exclude certain entities furnishing designated health services (DHS) from the definition of value-based participant due to its concern about protecting against potentially abusive arrangements.

The entities excluded from the OIG definition are as follows:

1. Pharmaceutical manufacturers.

2. Manufacturers, distributors, or suppliers of durable medical equipment, prosthetics, orthotics, or supplies.

3. Laboratories.

While not excluding these entities from its definition of value-based participant, CMS seeks comment about whether it also should exclude these entities due to concerns about potentially abusive compensation arrangements, especially since it is unclear whether these entities have direct patient contacts justifying their inclusion in any value-based arrangements. Both agencies are considering whether to exclude pharmacy benefit managers (PBMs), wholesalers, and distributors from the definition of value-based participant. The OIG (but not CMS) is also considering excluding certain types of pharmacies from the definition, such as compounding pharmacies, while not excluding other types of pharmacies, such as retail and community pharmacies, due to the OIG's belief that compounding pharmacies may pose a higher risk of fraud and abuse based upon its enforcement experience.

Value-Based Enterprise (VBE)

CMS and the OIG note that they intend for VBE to include many forms, ranging from the collaboration of two individual physician practices to a network of sophisticated providers (e.g., accountable care organizations (ACO), hospital systems, post-acute care (PAC) providers, and large physician practices). The definition of VBE includes certain conditions, such as requirements for a governing document and an accountable body or person responsible for oversight of the enterprise. Examples of a governing body could be a governing board, a committee of the governing board, a corporate officer of the VBE's legal entity, or a party to the value-based arrangement designated as responsible for the financial and operational oversight of the arrangement. The OIG is considering adding specific oversight responsibilities and reporting requirements for which the VBE accountable body would be responsible.

Value-Based Arrangement

The definition of value-based arrangement is key to CMS's and the OIG's proposals facilitating the transition to value-based care, as the exceptions and safe harbors apply *only* to arrangements qualifying as value-based arrangements. The proposed value-based exceptions and safe harbors protect certain remuneration provided or exchanged under a value-based arrangement among a VBE and its value-based participants that will provide at least one value-based activity for a target patient population to achieve a value-based purpose. CMS notes that it expects most value-based arrangements would involve activities that coordinate and manage the care of a target patient population but does not limit the definition to apply only to compensation arrangements that coordinate and manage care. The OIG notes that the term value-based arrangement is broadly defined to cover commercial and private insurer arrangements. CMS similarly states that the Stark value-based exceptions can apply to arrangements regardless of whether the arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients, or a mixture of both.

Value-Based Activities

Value-based activities are activities reasonably designed to achieve at least one value-based purpose of a VBE. Value-based activities can be providing an item or service, taking an action, or refraining from taking an action. CMS and the OIG emphasize in their commentary that the making of a referral is *not* a value-based activity. An example of taking an action to achieve a value-based purpose would be a physician joining other providers and suppliers to achieve savings. An example of refraining from taking an action for a value-based purpose would be a physician agreeing to a redesigned care protocol, which implicitly requires the physician to refrain from following previously used patient care protocols.

Value-Based Purpose

The definition of value-based purpose includes the following four core goals:

1. Coordinating and managing care of the target patient population.

2. Improving the quality of care for the target patient population.

3. Appropriately reducing the costs to, or stopping the growth in expenditures of, payors without reducing the quality of care for the target patient population.

4. Transitioning from healthcare 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 the target patient population.

CMS is debating whether to revise the definition of value-based purpose to adjust the provision addressing cost reduction to "appropriately reducing the costs to, or the growth in expenditures of,

payors *while improving or maintaining the improved quality of care for the target patient population*." If CMS uses this alternative language in its final rule, this purpose could not be used by a VBE to qualify its compensation arrangement as a value-based arrangement meeting one of the value-based exceptions unless the VBE has already achieved some improvement in the quality of care to its target patient population.

Target Patient Population

Both CMS and the OIG define target patient population broadly, to mean an identified patient population selected by the VBE (or its VBE participants) using legitimate and verifiable criteria set out in writing in advance that further the VBE's value-based purposes. Legitimate and verifiable criteria could include patients with common medical or health characteristics, geographic characteristics, or payor status, among others. Neither CMS nor the OIG view "cherry picking" lucrative patients or "lemon dropping" costly patients as legitimate selection methods (even if verifiable). Additionally, the OIG is considering, and soliciting comment on, narrowing this definition to include only patients with chronic conditions or shared disease states.

Coordinating and Managing Care

The AKS proposed rule defines coordinating and managing care for purposes of value-based arrangements. This term could include using care managers, providing care or medication management, creating a patient-centered medical home, helping with transitions of care, sharing and using health data to improve outcomes, or sharing accountability for the care of a patient across a continuum of care. The OIG notes that this coordination might occur between hospitals and post-acute care providers, between specialists and primary care physicians, or between hospitals or physician practices and patients. Nevertheless, the OIG is careful to distinguish between (1) suspect referral arrangements designed to "churn" patients through care settings to capitalize on a reimbursement scheme and (2) legitimate care coordination arrangements involving multiple settings of care that include beneficial activities beyond the mere referral of patients or ordering an item or service. The OIG is soliciting comments regarding additional elements that could be incorporated into the definition to prevent fraud and abuse, including excluding some or all protection under the proposed safe harbors for arrangements between entities that have common ownership. Unlike the OIG, CMS's proposed rule does not include a definition for "coordinating and managing care," but CMS notes that it is seeking comment on whether such a definition is desirable or necessary.

STARK PROPOSED VALUE-BASED ARRANGEMENT EXCEPTIONS

CMS is proposing three new Stark value-based exceptions to remove regulatory barriers and allow for innovation in payment models, increased efficiency and coordination in the delivery of care, and an overall improvement in the quality of care. CMS's proposed Stark value-based exceptions, if finalized, will be codified at 42 CFR § 411.357(aa)(1)-(3). These exceptions are as follows:

1. The full financial risk exception.
2. The meaningful downside financial risk exception.
3. The value-based arrangements exception.

The first two exceptions require parties to take downside risk to qualify for the exception, while the third exception does not. These exceptions only address compensation arrangements (as defined at 42 CFR § 411.354(c)) that qualify as value-based arrangements. An indirect compensation arrangement can qualify as a value-based arrangement for purposes of applying one of the value-based exceptions if there is an unbroken chain of financial relationships between an entity and a physician, and if the

compensation arrangement to which the physician is a party qualifies as a value-based arrangement. Alternatively, CMS is considering adding a new defined term for "indirect value-based arrangement" and specifying in regulations that the new proposed value-based exceptions would be available to protect the arrangement. The value-based exceptions should eliminate the need for any future waivers of Section 1877 of the Social Security Act (the Act) for parties in CMS-sponsored models, programs, or initiatives, as long as the compensation arrangement meets the definition of a value-based arrangement. However, CMS specifically states that participants in CMS-sponsored models, programs, or initiatives may elect to use such waivers that apply to their particular model, program, or initiative.

The proposed value-based exceptions do not require remuneration to be consistent with fair market value and do not prohibit taking into account the volume or value of referrals (volume or value standard). CMS is seeking comment as to whether such requirements should be inserted into the value-based exceptions and whether it should require that the value-based arrangement is commercially reasonable.

Requirements Applicable to All Three of the Value-Based Exceptions

Five requirements are common among all three value-based exceptions; if a value-based arrangement cannot meet these requirements, it cannot qualify for protection under the new exceptions.

1. **The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.** CMS recognizes certain incentive payments are difficult to tie to specific items or services and clarifies that this requirement does not mandate a one-to-one payment for an item or service. Gainsharing payments, shared saving distributions, and similar payments resulting from value-based activities could qualify assuming other elements are met. The exception will not protect remuneration for referrals or any other actions or business unrelated to the target patient population.

2. **The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.** Note this requirement applies to *all patients* and not just patients in the target patient population. Remuneration leading to a reduction in medically necessary services would be inherently suspect and could implicate sections 1128A(b)(1) and (2) of the Act.

3. **The remuneration is not conditioned on referrals of patients not part of the target patient population or business not covered under the value-based arrangement.** As an example, the value-based exceptions will not protect a value-based arrangement if the VBE requires the physician to refer Medicare patients not part of the target patient population for DHS furnished by the VBE.

4. **If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of 42 CFR § 411.354(d)(4)(iv)[1].** Because the value-based exceptions do not contain the volume or value standard, the special rule at the current 42 CFR § 411.354(d)(4)(iv) would not apply to value-based arrangements in which remuneration under the value-based arrangement is conditioned on the physician's referrals. Thus, CMS has included in all of the proposed value-based exceptions a requirement that if remuneration provided to the physician under the value-based arrangement is conditioned

[1] This provision is a requirement of the Stark exceptions for employment arrangements, personal services arrangements, or managed care contracts that allows the restriction or direction of physician referrals, provided that additional requirements protecting a patient's choice of healthcare provider, the physician's medical judgment, and the insurer's freedom from interference in operations are met.

on the physician's referrals, the value-based arrangement must satisfy the requirements of 42 CFR § 411.354(d)(4)(iv).

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

In addition to these requirements, CMS is seeking comment to determine whether it should include a requirement related to price transparency in every exception for value-based arrangements at proposed 42 CFR § 411.357(aa).

Full Financial Risk Exception

This proposed exception requires the VBE to be fully financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified time period. Additionally, CMS is seeking comment regarding whether it should allow a VBE to be fully financially responsible for the cost of only specific items or services, as opposed to the cost of *all* patient care items or services and whether it should specify a time period for which the VBE must be fully responsible, such as, for example, one year. The exception requires the VBE to be at full financial risk within six months of commencing the value-based arrangement (allowing six months for implementation of the arrangement).

The financial risk under the full financial risk exception must be set out in advance and does not permit additional payments for costs incurred by the VBE for providing specific patient care items or services. However, the full financial risk exception does not prohibit a payor from paying a VBE to offset losses above and beyond the losses prospectively agreed to between the parties. The payment of shared savings or other incentive payments for achieving quality, performance, or other benchmarks are also not prohibited.

Examples of payment models falling under the full financial risk exception would be capitation payments or global budget payments, but CMS is seeking comment on other types of full financial risk payment models. Additionally, CMS notes that the VBE and the VBE participants have freedom of contracting regarding the allocation of risk among themselves. CMS explicitly notes that there are no documentation requirements for the full financial risk exception, although it considers documenting any relationship between referral parties as a good business practice that can assist the parties in their ongoing monitoring of the operation of the arrangement.

Meaningful Downside Financial Risk Exception

CMS has proposed another exception under which providers who are not prepared to be responsible for the total cost of care for a target patient population may undertake financial risk in exchange for potential financial gain. The meaningful downside financial risk exception protects compensation arrangements under which a physician is at a meaningful downside financial risk for the entire term of the value-based arrangement if the value-based purpose(s) of the VBE is not achieved. The nature and extent of the meaningful downside risk is required to be in writing before undertaking any value-based activities.

CMS defines "meaningful downside financial risk" in the following two ways:

1. The physician must pay the VBE a minimum of 25% of the remuneration (or of the *value* of the remuneration for in-kind remuneration) that the physician receives from the value-based arrangement.

2. The physician is prospectively financially responsible for all of, *or a defined set of*, patient care items or services covered by the applicable payor for each patient in the target population for a specified period of time.

CMS is seeking comment as to whether the 25% minimum is appropriate, and whether, under the second definition of "meaningful downside financial risk," there is a potential for gaming if the parties can limit the set of patient care items or services for which a physician is at risk.

The meaningful downside financial risk exception already includes three safeguards to protect against gaming. First, as mentioned above, the nature and extent of the downside risk must be in writing. Second, the physician must remain at meaningful downside risk for failure to achieve the value-based purpose(s) of the VBE for the duration of the value-based arrangement. Third, while the *amount* of remuneration for value-based activities is not required to be set in advance, the *methodology* for determining the amount of remuneration must be set in advance. CMS has included these requirements as a defense against the manipulation of a value-based arrangement to reward referrals.

Value-Based Arrangements Exception

The last of the new proposed value-based exceptions is the value-based arrangements exception. This exception protects compensation arrangements that qualify as value-based arrangements, regardless of whether the VBE or any of its VBE participants undertake any downside risk. The goal of this exception is to encourage parties to start participating in coordinated care activities and will build toward participation in arrangements involving two-sided risk sharing. As currently written, the proposed exception applies to both monetary and non-monetary remuneration, but CMS is seeking comment about whether it should limit this exception to non-monetary remuneration. For arrangements involving non-monetary remuneration, CMS is considering adding a requirement that the party receiving the remuneration must contribute at least 15% of the donor's cost of the non-monetary remuneration. If the donation of the non-monetary remuneration is a one-time cost, CMS would require the 15% contribution within 90 days of the donation, and if the donation of the nonmonetary remuneration is an ongoing cost to the donor, CMS would require the contribution at reasonable, regular intervals. CMS is also seeking comment as to whether 15% is an appropriate amount for the contribution, and whether certain recipients (like small or rural providers) should be exempt from the requirement.

Because the value-based arrangements exception involves arrangements with no downside risk for participants, CMS believes additional safeguards are required to protect program integrity. One familiar requirement under Stark is that the arrangement must be in writing and signed by the parties. The writing must include a description of the following:

1. The value-based activities under the arrangement.

2. How the value-based activities are expected to further the value-based purpose(s) of the VBE.

3. The target patient population.

4. The type or nature of remuneration.

5. The methodology used to determine the remuneration.

6. The performance or quality standards against which the recipient of remuneration will be measured, if any.

Additionally, the performance or quality standards referenced above, if any, must be set in advance and must be objective and measurable. If the parties want to make changes to these standards, the changes must be made in advance and in writing. CMS notes that not all value-based arrangements will have applicable performance or quality standards, such as an arrangement where a VBE provides infrastructure to a physician in the VBE, since such an arrangement may not require the physician to achieve specific performance or quality goals to receive or keep the infrastructure items or services. However, in arrangements having specific performance or quality standards against which the recipient of remuneration will be measured, the performance or quality standards should not simply reflect the status quo. CMS is considering requiring that such standards be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery. CMS is seeking comment on the burdens or costs of including such a requirement.

Finally, as with the meaningful financial downside risk exception, while the *amount* of remuneration for the value-based activities is not required to be set in advance, the value-based arrangements exception does require that the *methodology* for determining the amount of remuneration is set in advance.

VBEs have an implicit ongoing obligation to monitor the financial relationships that they have with a physician to ensure compliance with the applicable exceptions. CMS is considering adding additional safeguards in the value-based arrangements exception to protect program integrity, including the following:

1. The VBE or VBE participant providing the remuneration must monitor to determine whether the value-based activities are furthering the value-based purpose(s) of the VBE.

2. If the value-based activities are determined to be unable to achieve the value-based purpose(s), the physician must cease referring DHS to the VBE, either immediately or within 60 days of such determination.

CMS is seeking comment on how parties would monitor performance if such requirements were added to the value-based arrangements exception (specifically, should CMS require monitoring to occur in specified intervals, and if so, what those intervals should be), and the burden or cost of including such a requirement. CMS is also seeking comment on whether to impose time limits by which a VBE or VBE participant should decide that the value-based purpose will not be achieved through the value-based activities.

AKS PROPOSED VALUE-BASED SAFE HARBORS

The following three primary AKS value-based arrangements safe harbors are designed to address a wide range of arrangements involving participants and providers that comprise a VBE.

1. Full financial risk safe harbor.

2. Substantial downside risk safe harbor

3. Care coordination safe harbor.

Common Requirements in Proposed Value-Based Safe Harbors

Eight requirements generally apply to the proposed value-based safe harbors, which are required for an arrangement to be eligible for protection.

1. **The remuneration is used primarily to engage in value-based activities directly connected to the coordination and management of care of the target patient**

population. Analyzing the care coordination safe harbor, the OIG notes in-kind remuneration exchanged for value-based activities may result in "spillover" benefits (e.g., provision of staff or other providers), but the parties must primarily use the remuneration for its intended purposes. Although it is unclear how this requirement would apply to monetary remuneration, this provision could limit the practicality and utility of the safe harbor. For example, parties to gainsharing arrangements may be unwilling to limit the use of shared savings to value-based activities.

2. **The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.** The OIG notes any remuneration that induces a provider to furnish unnecessary care is inherently suspect, and a reduction in medically necessary services contrary to the goals of the proposed rule could violate the CMP Law.

3. **Remuneration is not funded or otherwise results in contributions by any individual or entity outside of the applicable VBE.** The OIG notes this safeguard ensures protected arrangements are closely related to the VBE and ensures coordination and management of care of the target patient population. This requirement also prevents non-VBE participants (e.g., an excluded pharmaceutical manufacturer or DMEPOS supplier) from indirectly using the safe harbor to protect arrangements designed to influence the referrals or decision making of VBE participants.

4. **The remuneration does not take into account the volume or value of, or condition the remuneration on, referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.** The OIG safeguard addresses concerns with "swapping arrangements," including remuneration offered under the guise of a value-based arrangement when that remuneration actually is intended to induce referrals of patients or businesses not covered under the value-based arrangement.

5. **The proposed care coordination safe harbor and substantial downside risk safe harbor prohibit including a prohibition on mandatory referrals or restrictions of referrals to a particular provider or supplier if a patient expresses a preference for a different provider or supplier or if the payor determines the provider or supplier.** The AKS full financial risk safe harbor does not include a corresponding requirement. OIG includes this requirement to ensure VBEs and their participants will maintain their independent medical judgment and preserve patients' freedom of choice.

6. **Requirement that the arrangement does not include marketing to patients of items or services or engaging in patient recruitment activities.**

7. **Although the requirements vary depending on the safe harbor, each of the value-based safe harbors requires some form of writing.**

8. **Records and materials sufficient to establish compliance with the safe harbor must be made available to the Secretary upon request.**

Full Financial Risk Safe Harbor

The full financial risk safe harbor protects certain in-kind and monetary arrangements involving VBEs that have assumed "full financial risk" for a target patient population. The OIG recognizes VBEs that have assumed full financial risk present fewer traditional fee-for-service (FFS) fraud and abuse risks. It notes this safe harbor would include more flexible conditions than the care coordination safe harbor. The AKS proposed rule contemplates a VBE would be at full financial risk for the cost of care of a target patient population if 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. This would not protect an entity receiving a partial capitated payment covering a limited set of items or services or a payment arrangement where an entity receives a combination of reduced FFS and capitation payments for a defined set of items of services. For example, a bundled payment program for patients receiving knee replacements receiving an episodic payment for all costs associated with the procedure and 90 days of follow-up care would not be eligible for the full financial risk safe harbor because it covers a limited set of services instead of the patient's total cost of care.

To ensure accountability and transparency, the full financial risk safe harbor requires the following:

1. A signed agreement between the VBE and payor detailing the target patient population and confirming the VBE is at full financial risk for at least one year.

2. A signed agreement between the parties to the value-based arrangement setting forth the material terms, including the value-based activities to be undertaken, for a term of at least one year.

This safe harbor would only apply to remuneration exchanged between a VBE and a VBE participant according to a value-based arrangement. Although the OIG is soliciting comments regarding this point, the safe harbor as currently written will not protect remuneration exchanged among VBE participants that are part of the same VBE or remuneration between a VBE participant and a downstream contractor. In addition to the shared safeguards described above, the full financial risk safe harbor also prohibits VBE participants from seeking any additional payment for the items or services furnished to the target patient population, requires the VBE to have both an operational utilization review program and a quality assurance program to protect against underutilization, and to specify patient goals.

Substantial Downside Risk Safe Harbor

The substantial downside risk safe harbor addresses monetary and in-kind remuneration involving value-based arrangements where a VBE assumes substantial downside financial risk from a payor. First, the VBE (directly or through an agreement between the payor and a VBE participant) must assume substantial downside risk from a payor for providing items and services for a target patient population. This proposed safe harbor would also protect arrangements between the VBE and VBE participants during the six months prior to the date that the VBE assumes downside risk. The safe harbor includes specific definitions detailing what constitutes substantial downside financial risk, including the following:

1. Shared savings with a repayment obligation to the payor of at least 40% of any shared losses.

2. A repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20% of any total loss.

3. A prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population.

4. A partial capitated payment from the payor for a set of items and services for the target patient population, where such capitated payment reflects a discount equal to at least 60% of the total expected FFS payments.

The AKS proposed rule clarifies that prospective payment systems, including those applicable to acute inpatient hospitals, home health agencies, hospices, inpatient rehabilitation facilities, and skilled nursing facilities, and other similar payment methodologies, would not fall within the definition of substantial downside financial risk. However, the OIG is soliciting comments regarding whether advanced payment models (APM) (as defined at 42 CFR §414.1305) should be included in the definition of substantial

downside financial risk. The OIG notes it is unclear whether APM participants would rely on this safe harbor versus the CMS-sponsored innovative payment models safe harbor.

The substantial downside risk safe harbor would protect remuneration from a VBE to a VBE participant pursuant to a value-based arrangement that requires the VBE participant to "meaningfully share" in the substantial downside risk, which means the value-based arrangement must contain any of the following:

1. 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.

2. A partial or full capitated payment or similar methodology (excluding prospective payment systems as described above).

3. In the case of a VBE participant who is a physician, a payment that meets the requirements of the Stark proposed meaningful downside risk exception at 411.357(aa)(2).

Additionally, the AKS proposed rule does not currently allow for downstream arrangements where remuneration passes from one VBE participant to another unless the risk-bearing VBE is a party to the arrangement. The OIG indicates concern for such arrangements where the downstream provider bills on a traditional FFS basis without assuming risk. Further, the OIG also notes this safe harbor would not protect an ownership or investment interest in the VBE or any related distribution. The substantial downside risk safe harbor also includes several requirements and safeguards similar to the care coordination safe harbor, described below, such as a requirement for a written document describing the arrangement.

Care Coordination Safe Harbor

The care coordination safe harbor is intended to protect in-kind remuneration related to evidence-based outcome measures, which will advance the coordination and management of care of the target patient population. The OIG intends for the measures to serve as benchmarks for assessing performance by the entity receiving remuneration against valid outcomes-based measures that do not simply reflect the status quo. Any arrangement relying on the care coordination safe harbor must be commercially reasonable and set forth in a signed writing executed in advance of or contemporaneously with the commencement of the arrangement (or any material change), which includes the following six elements:

1. The value-based activities to be undertaken by the parties.

2. The term of the arrangement.

3. The target patient population.

4. A description of the remuneration, including the offeror's cost.

5. The percentage of such cost contributed by the recipient and (as applicable) the frequency of such contributions for ongoing costs.

6. The evidence-based, valid outcome measure(s) against which the recipient will be measured.

The care coordination safe harbor only protects in-kind remuneration primarily used to engage in value-based activities directly connected to the coordination and management of care for the target patient population (e.g., the provision of personnel in a VBE to improve the transition process from

acute care to skilled nursing care). As monetary remuneration is excluded, this proposed safe harbor would not protect an ownership or investment interest in the VBE or any related distributions. To ensure the parties are mutually vested in achieving the goal of the value-based arrangement, the entity receiving remuneration must also pay at least 15% of the offeror's cost of the in-kind remuneration, including contributions at regular intervals for ongoing costs. OIG is soliciting comments to determine whether to adjust the 15% contribution percentage or to eliminate such a requirement for rural and small providers. In addition to the safeguards described above, the safe harbor also includes a requirement that the parties ensure the remuneration is not likely to be diverted, resold, or used by the recipient for an unlawful purpose.

The care coordination safe harbor also requires certain monitoring and assessment activities, including submission of annual reviews to the VBE's accountable body addressing the following:

1. The coordination and management of care for the target population in the value-based arrangement.

2. Any deficiencies in the delivery of quality care under the value-based arrangement.

3. Progress toward achieving the measures in the valid outcome arrangement.

Depending on the outcome of the monitoring and assessment activities, the safe harbor could require termination of the arrangement within 60 days of an adverse determination by the VBE's accountable body.

Other Value-Based Related Safe Harbors

The AKS proposed rule also has two additional value-based related safe harbors beyond those directly applicable to VBEs, including the following:

1. **Patient Engagement and Support Safe Harbor.** This proposed safe harbor is intended to reduce barriers created by the AKS and CMP Law for providers to offer patients beneficial tools and supports to improve quality, health outcomes, and efficiency through patient engagement. Specifically, the patient engagement and support safe harbor would apply to in-kind patient engagement tools or supports furnished directly by a VBE participant to a patient in a target population directly connected to the coordination and management of care, including adherence to a treatment or drug regimen or follow-up plan of care. This safe harbor permits only VBE participants to provide such tools and supports, and the AKS proposed rule explicitly notes that pharmaceutical manufacturers, DMEPOS suppliers, and laboratories may not offer protected remuneration, in part, because of their ability to improperly influence patients' or clinical decision-making.

   The patient engagement and support safe harbor is also limited to in-kind remuneration in the form of a "tool or support," regardless of whether covered by Medicare or another federal healthcare program. The "tool or support" may include items and services related to preventive care, health-related technology, patient health-related monitoring, and identification of social determinants of health. However, this safe harbor places a $500 annual monetary cap on the aggregate resale value of the remuneration and excludes the provision of gift cards, cash, and any cash equivalent. The safe harbor would also not apply to a waiver or reduction of cost-sharing obligations, including coupons leading to such waivers or reductions. Lastly, this safe harbor includes many of the standard safeguards incorporated into the VBE safe harbors.

2. **CMS-Sponsored Innovative Payment Models Safe Harbor.** Unlike the Stark proposed rule, the OIG proposed a new safe harbor to permit remuneration (1) between parties to arrangements under a model being tested or expanded by the CMS Innovation Center and (2) incentives and supports provided by CMS-sponsored model participants to patients covered by the CMS-sponsored model. The goal of this safe harbor is to simplify the application of the AKS and CMP Law for CMS-sponsored model participants, which currently rely on individual fraud and abuse waivers jointly issued by the OIG and CMS on a model-by-model basis. This safe harbor was intended to be more flexible since CMS oversees and monitors its models and initiatives, which often have pre-embedded program integrity safeguards. For example, pharmaceutical manufacturers, DMEPOS suppliers, and laboratories are not categorically excluded from relying on the safe harbor, which allows CMS flexibility to test new models. However, this safe harbor does not extend to commercial and private insurance arrangements that may operate alongside, but outside of, a CMS-sponsored model, because CMS would not have the same level of oversight.

   The OIG notes CMS can determine whether the safe harbor will be available for arrangements or patient incentives under a given CMS-sponsored model. The safe harbor could also be limited by the applicable model participation documentation, which often includes numerous and separate requirements and restrictions. For example, the safe harbor only applies to "CMS-sponsored model arrangements" between "CMS-sponsored model parties," which are signed in advance or contemporaneously with the arrangement, advance the goal of the CMS-sponsored model, and do not involve remuneration prohibited by the applicable participation document. This safe harbor also includes many of the standard safeguards incorporated into other aspects of the AKS proposed rule.

2. ENABLING TECHNOLOGY INFRASTRUCTURE IMPROVEMENTS

OVERVIEW

In response to comments urging additional protections for transfers of information technology, data, and cybersecurity tools, CMS and the OIG propose new protections and modify previous guidance related to donations of cybersecurity technology and related services for electronic health records (EHR) arrangements. Both agencies recognize the value of technology in improving the quality of patient care and the significant burdens faced by providers in cost-effectively implementing such technologies.

CYBERSECURITY TECHNOLOGY AND RELATED SERVICES
(42 CFR § 411.357(bb) and 42 CFR § 1001.952(jj))

The healthcare industry must increasingly rely on electronic data systems for storing, processing, and transmitting health information. Recognizing the importance of ensuring these important data systems remain secure, both agencies acknowledge providers' increasing need for cyber-protection and the significant financial and legal impact of a data breach.

CMS proposes a new compensation exception for donations of cybersecurity technology and related services. This new exception would exist alongside the EHR exception; however, parties only need to meet the requirements of one of the available exceptions to avoid noncompliance. Similarly, the OIG proposes a parallel cybersecurity safe harbor by excluding donations of certain types of cybersecurity technology and services from the AKS's definition of remuneration.

The proposed Stark cybersecurity technology and related services exception allows the donation of nonmonetary compensation consisting of certain technology and services if the following four conditions are met:

1. The technology and services are necessary and used predominantly to implement and maintain effective cybersecurity.

2. Neither the eligibility nor the amount or nature of donated technology or services is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.

3. Neither the physician nor the physician's practice conditions the receipt of technology or services, or the amount or nature of such technology or services, on doing business with the donor.

4. The arrangement is documented in writing, which requires the parties to maintain documentation of the arrangement identifying the donation recipient, describing the technology and services provided, setting forth the timeframe of the donation, and providing a reasonable estimate of the value of the donation and any financial responsibility shared by the recipient.

The OIG's safe harbor mirrors the CMS cybersecurity technology and related services exception's requirements with few modifications and additional requirements. First, both donors and recipients may not condition the donation or receipt of technology or services, or the amount or nature of technology or services donated or received, on future referrals or doing business with the other party to the arrangement. Second, rather than maintaining documentation evidencing the arrangement, the OIG

cybersecurity technology and related services safe harbor requires a written agreement signed by the parties generally describing the technology and services provided and the amount of the recipient's contribution, if any. Third, the donor cannot shift the costs of the donated technology or services to any federal healthcare program.

The Stark exception and AKS safe harbor would both apply to information technology, other than hardware, "used predominantly to implement, maintain, and reestablish cybersecurity." Assuming this standard is met, the proposals could protect software used for malware prevention, network access control, business continuity, encryption, or email traffic filtering. In addition, the protection could cover services associated with developing, installing, and updating cybersecurity software, or services associated with responding to cyber-threats or attacks. Hardware and donations related to installation or repair of infrastructure related to physical safeguards, such as upgrading wiring or installing high-security doors, however, are excluded.

Currently, neither rule limits the types of individuals and entities that may donate or receive cybersecurity donations. Thus, patients are permissible recipients of donations. In contrast to the respective Stark exception and AKS safe harbor related to EHR, cost-sharing between the donor and recipient is optional under the cybersecurity safe harbor.

Both agencies request comments on their respective proposed rules and additional concepts ancillary to those proposals. Although its proposals would relate largely to software, CMS is also considering whether the cybersecurity exception should permit the donation of cybersecurity hardware under certain circumstances.

CMS is considering a narrow exception that would apply to hardware "necessary" for cybersecurity, not integrated within multifunctional equipment, and serving "only cybersecurity purposes." Alternatively, CMS is considering an exception that would protect a broader range of hardware, provided certain requirements are satisfied. For example, under the broader proposal, CMS may take the following action:

1. Require the donor and the recipient to have a cybersecurity risk assessment identifying a risk to the recipient's cybersecurity.

2. Limit the types of cybersecurity hardware permitted.

3. Impose a 15% financial contribution from the recipient.

4. Establish a cap on the value of the donated hardware.

Similarly, the OIG seeks comment on the inclusion of an alternate condition to the AKS safe harbor, allowing donations of cybersecurity hardware if the parties satisfy the other conditions and a risk assessment of the donor and the recipient determines the hardware is reasonably necessary.

Finally, both agencies seek comment regarding the inclusion of a "deeming provision," permitting donors or recipients to demonstrate compliance with the first element described above if the parties show the donation furthers compliance with a recipient's written cybersecurity program that reasonably conforms to a widely-recognized cybersecurity framework or standards.

ELECTRONIC HEALTH RECORDS ITEMS AND SERVICES
(42 CFR § 411.357(w) and (42 CFR § 1001.952(y))

The proposed rules also respectively propose revisions to the existing EHR Stark exception and AKS safe harbor, which protect the donation of interoperable EHR software or information technology and

training services. The agencies' proposed changes are largely aimed at reducing provider burden and facilitating the ability of small and rural providers to more widely adopt EHR. For example, CMS is considering whether to eliminate or reduce the exception's 15% contribution provision, which requires a recipient to pay 15% of the donor's cost of the technology. CMS is specifically considering whether it should eliminate the percentage contribution for small or rural physician organizations, recognizing the contribution requirement may be especially burdensome on those providers. The OIG has requested comments on similar proposed changes to the AKS safe harbor.

Both agencies propose to allow donations of replacement EHR technology. The current prohibition on donations of replacement technology can force a practice to choose between paying the full amount for a new EHR system and continuing to pay 15% of the cost of a substandard system. Practically speaking, this may lock a physician practice into an EHR vendor, even if the practice is dissatisfied with that vendor's service. The proposals by CMS and OIG, if finalized, would address these concerns by allowing a provider currently using an EHR technology to later adopt another, more satisfactory technology.

In addition, both agencies propose to eliminate the sunset provision for the EHR exception and safe harbor, or, in the alternative, to extend the sunset date, which is currently set for December 31, 2021. The OIG is also considering expanding the scope of protected donors under the EHR safe harbor.

Finally, CMS and the OIG propose certain technical and clarifying edits to their respective existing EHR exception and safe harbor. For example, CMS's proposal clarifies the EHR exception is and has been available to protect certain cybersecurity software and services, provided that such donations are "closely related" to EHR. CMS also proposes to clarify that the EHR exception prohibits using donated items or services as an instrument of information blocking, *i.e.*, to limit or restrict the use, compatibility, or interoperability with other EHR systems. The OIG has made similar proposals to clarify the EHR safe harbor.

BENEFICIARY INDUCEMENTS CMP EXCEPTION FOR TELEHEALTH TECHNOLOGIES FOR IN-HOME DIALYSIS PATIENTS

(42 CFR § 1003.110)

To effectuate statutory changes codified by § 50302(c) of the Bipartisan Budget Act of 2018,[2] the OIG proposes to update its regulations implementing the beneficiary inducement prohibitions of the CMP Law. The OIG excludes from the definition of remuneration certain "telehealth technologies" provided to end-stage renal disease (ESRD) patients receiving in-home dialysis covered under Medicare Part B. Permissible "telehealth technologies" are defined as "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and the distant site physician . . . Used in the [patient's] diagnosis, intervention, or ongoing care management . . . ." Although smartphones capable of providing two-way, real time interactive communications would be permitted, telephones, fax machines, and electronic mail systems are not considered telehealth technologies.

For the exception to apply, four conditions must be met:

1. The provider or renal dialysis facility currently providing the in-home dialysis, telehealth visits, or other ESRD care to the patient furnishes the telehealth technologies.

2. The telehealth technologies are not offered as part of any advertisement or solicitation.

[2] Bipartisan Budget Act of 2018, Pub. L. No. 115-123, § 50302(c), 132 Stat. 64, 191-92 (2018).

3. The telehealth technologies contribute substantially to the provision of telehealth services related to the patient's ESRD, are not of excessive value, and are not duplicative of technology the beneficiary already owns if adequate for telehealth purposes.

4. The provider or the renal dialysis facility does not bill federal healthcare programs, other payors, or individuals for the telehealth technologies, claim the value of telehealth technologies as bad debt for payment purposes, or otherwise shift the burden of the value of telehealth technologies to federal healthcare programs, other payors, or individuals.

In addition to requesting comments on these conditions, the OIG seeks input on whether to impose supplemental conditions on providers and facilities, such as requiring providers and facilities to consistently offer telehealth technologies to patients meeting certain criteria and to take reasonable steps to ensure a patient does not already possess the necessary technology.

3. OTHER NOTABLE PROPOSALS, CLARIFICATIONS AND COMMENTARY

OVERVIEW

As expected, a significant portion of the Stark proposed rule is dedicated to clarifying key regulatory terminology and adding increased flexibility for compliance with Stark's highly technical requirements. CMS proposes several new or revised definitions, changes to the scope and interpretation of existing exceptions, and an exception for limited remuneration to a physician. Although this is a *proposed* rule, the guidance and clarifications CMS provides regarding existing Stark terms will likely have an immediate impact on the analysis of arrangements under Stark. In addition, the OIG made other changes impacting both the AKS regulations and the beneficiary inducement provisions of the CMP Law.

STARK PROPOSALS, CLARIFICATIONS AND COMMENTARY

Clarifying Commercially Reasonable, Volume or Value, and Fair Market Value
(42 CFR § 411.351 and 42 CFR § 411.354(d)(5)&(6))

CMS endeavors to create "clear, bright-line rules" that would "enhance both stakeholder compliance efforts and [CMS's] enforcement capability," by proposing clarifications on three fundamental requirements appearing in many of the existing Stark exceptions:

1. **Commercially Reasonable.** There is currently no codified definition for the term "commercially reasonable" under the Stark Law, and it has been more than 20 years since CMS provided guidance on what it means to be "commercially reasonable."[3] In this proposed rule, CMS fills this void by proposing one of two alternative definitions of the term "commercially reasonable." Under the first definition, "commercially reasonable" would mean "the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements." In the alternative, CMS proposes to define the term to mean "the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and reasonable physician of similar scope and specialty." CMS requests comment on both alternatives. Regardless of the ultimate disposition on the definition, the proposed rule clarifies CMS's belief that the determination of commercial reasonableness turns on "whether the arrangement makes sense as a means to accomplish the parties' goals."

   CMS also makes clear that commercial reasonableness is not a question of valuation and does not hinge on whether the arrangement is profitable for either party. To reflect that viewpoint, CMS proposes to include the following statement as part of the definition: "An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties." This one statement, if finalized, will alleviate regulatory angst among healthcare providers, but providers should still be sure to contemporaneously document the rationale for entering into an arrangement absent any potential financial gain.

2. **Volume or Value.** As part of the special rules on compensation found at 42 CFR § 411.354(d), the proposed rule would establish a set of four multi-pronged "objective tests" for determining "exactly when" compensation takes into account the volume or value of

[3] 63 Fed. Reg. 1,659, 1,700 (Jan. 9, 1998).

referrals or other business generated between the parties. Under the proposed approach, the "volume or value" requirement would be violated "only when the mathematical formula used to calculate the amount of the compensation includes as a variable referrals or other business generated, and the amount of the compensation [positively or negatively] correlates with the number or value of the physician's referrals to or the physician's generation of other business for the entity." By way of illustration, CMS states under one of the proposed tests, if a physician (or immediate family member) receives additional compensation from an entity as the number or value of the physician's referrals to the entity increase, the physician's (or immediate family member's) compensation would be deemed to positively correlate with the number or value of the physician's referrals.

In response to concerns about the controversial "volume or value" logic adopted by the U.S. Court of Appeals for the Fourth Circuit in *U.S. ex rel. Drakeford v. Tuomey*, CMS "reaffirm[s]" its position that a productivity bonus paid to an employed physician based on personally performed services does not take into account the volume or value of the physician's referrals "solely because corresponding hospital services . . . Are billed each time" the physician performs a service. While CMS clarifies this guidance may extend to personal services arrangements under which physicians are paid using a unit-based formula for personally performed services, CMS stops short of proposing to codify its position on productivity-based compensation.

3. **Fair Market Value and General Market Value.** The Stark proposed rule would effectively replace the definition of "fair market value" at 42 CFR § 411.351 by eliminating the connection to the "volume or value" standard, which CMS reiterates to be an independent requirement. While some commenters encouraged CMS to create "safe harbors" or prescriptive standards for what constitutes fair market value, the new proposed definition includes a general definition and two separate definitions for equipment rentals and space rentals, each of which is relatively broad with substantial room for interpretation. In general, CMS proposes to define "fair market value" as "[t]he value in an arm's-length transaction, with like parties and under like circumstances, of like assets or services, consistent with the general market value of the subject transaction." To more closely align the concept of fair market value with principles of market valuation, CMS proposes to redefine "general market value" regarding the price that assets or services would bring as the result of *bona fide* bargaining between the particular parties to that specific transaction at the relevant time.

Changes to Certain Ownership & Investment Interests
(42 CFR § 411.354(b))

CMS's proposed rule also seeks to exclude from all ownership and investment interests "titular" ownership and investment interests not including the right to the financial benefits of ownership, such as the distribution of profits, dividends, proceeds of a sale, or similar returns on investment. CMS believes this proposal will afford providers greater flexibility and certainty under existing regulations, especially in states where the corporate practice of medicine is prohibited. Specifically, CMS explains a physician with titular ownership in an entity does not have a right to the distribution of profits or the proceeds of a sale, and therefore, does not have a financial incentive to make referrals to the entity in which the titular ownership or investment interest exists. CMS also proposes excluding from all ownership and investment interests any interest in an entity arising through participation in an employee stock ownership program (ESOP) qualified under Section 401(a) of the Internal Revenue Code.

Narrowing of DHS
(42 CFR § 411.351)

CMS's proposed rule incorporates several other notable changes designed to ease Stark's burden on regulated parties, including a revision to the definition of DHS. The proposed revision clarifies that a service provided by a hospital to an inpatient does not constitute a DHS "if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS)." To illustrate this approach, CMS provides the following example:

> *After an inpatient has been admitted to the hospital under an established DRG, the patient's attending physician requests a consultation with a specialist who was not responsible for the patient's admission and the specialist orders an X-ray. By the time the specialist orders the X-ray, the rate of reimbursement has already been established by the DRG. Insofar as the X-ray does not affect the rate of payment, the physician has no financial incentive to over-prescribe the service. As described in this example, CMS does not believe that the X-ray is a designated health service that is payable, in whole or part, by Medicare.*

Thus, under the proposed rule, the specialist's referral to the hospital for the X-ray services would not be tainted by any financial relationship between the hospital and the specialist that fails to satisfy the requirements of a Stark exception, and the hospital would not be prohibited from billing Medicare for the admission. However, this proposed carve-out is narrowly limited to inpatients. A Stark exception is still required to shield a financial relationship with a physician who orders, or may order, an inpatient admission, any other item or service impacting the DRG payment, or any outpatient service. In not extending the carve-out to outpatient services, CMS explained there is typically only one ordering physician and generally each additional referred service is separately compensated under the Outpatient Prospective Payment System.

If finalized, the proposed revision to the definition of DHS could significantly reduce the number of Stark violations and associated penalties. However, hospitals should not categorically stop their efforts to ensure all financial relationships with specialists meet a Stark exception based on this proposed change given the difficulty in predicting what referrals may impact the DRG and the likelihood most specialists probably also refer patients for outpatient services. Practically, if finalized, this change may be better relied upon defensively when other systems break down, such as in cases of technical noncompliance arising from a failure in the contracting process. Services ordered by a specialist during an inpatient stay remain referrals for purposes of the AKS.

Clarifying Isolated Transactions
(42 CFR § 411.351 and 42 CFR § 411.357(f))

CMS explains that, through its administration of the Voluntary Self-Referral Disclosure Protocol (SRDP), CMS has become aware that healthcare providers may be incorrectly interpreting the scope of the isolated transactions exception to protect service arrangements where a party makes a *single* payment for *multiple* services provided over an extended period of time. CMS provides the following example:

> *Assume that a hospital makes a single payment to a physician for working multiple call coverage shifts over the course of a month (or several months) and seeks to utilize the [isolated transactions exception] to avoid qualification of the payment as a financial relationship subject to [Stark]. That is, the parties wish to consider the single payment for multiple services an "isolated financial transaction."*

CMS notes it sees parties turn to this argument when they discover, typically after services have been provided by the physician, that they failed to document the service arrangement in writing, and thus cannot rely on the exceptions for personal services arrangements or fair market value compensation. In the proposed rule, CMS explicitly states that "it is our policy that the exception for isolated transactions is not available to except payments for multiple services provided over an extended period of time, even if there is only a single payment for all the services."

CMS is therefore proposing to establish an independent definition of "isolated financial transaction" and to clarify that "isolated financial transaction" does not include payment for multiple services provided over an extended period, even if there is only one payment for such services. Under the proposal, the term "transaction" would mean "an instance or process of two or more persons doing business." CMS also proposes revisions to the exception for isolated transactions to reference isolated financial transactions to remedy a statutory and regulatory text incongruity.

Eliminating "Overly Prescriptive and Impractical" Period of Disallowance Rules (42 CFR § 411.353(c)(1))

CMS also proposes to eliminate the existing Stark rules on the period of disallowance found at 42 CFR § 411.353(c)(1). Providers often rely on the "period of disallowance" rules to help determine the time period during which a physician may not make referrals for DHS to an entity and the entity may not bill Medicare for the referred DHS when a financial relationship between the parties failed to meet an applicable Stark exception. Through its administration of the SRDP, CMS has concluded the existing rules are, in application, "overly prescriptive and impractical." Recognizing the disallowance analysis will always be a case-by-case analysis, CMS clarifies its belief that the period of disallowance under Stark should begin on the date a financial relationship fails to satisfy all requirements of an applicable exception and end on the date the financial relationship ends or is brought into compliance with an applicable exception.

Leeway to Remedy Stark Violations and a New "Limited Remuneration" Exception (42 CFR § 411.354(e) and 42 CFR § 411.357(z))

In the Stark proposed rule, CMS advises parties may, while an arrangement is "live," remedy compensation problems arising from operational or administrative errors by recovering or repaying problematic compensation. CMS acknowledges "it is a normal business practice, and a key element of an effective compliance program, to actively monitor active ongoing, live financial relationships, and to correct problems that such monitoring uncovers." By contrast, CMS also clarifies that, once a financial relationship has ended, the parties cannot retroactively cure previous noncompliance to avoid a disallowance.

CMS's experience administering the SRDP, particularly its review of numerous compensation arrangements presenting instances of only minor technical noncompliance, prompted this proposal to codify a 90-day grace period for parties to satisfy both the writing and signature requirements of an applicable exception. This proposal would not amend or affect the "set in advance" requirement under numerous compensation arrangement exceptions. However, CMS clarifies compensation terms need not be reduced to writing before the furnishing of items and services to satisfy the "set in advance" standard; rather, "records of a consistent rate of payment over the course of an arrangement, from the first payment to the last, typically support the inference that the rate of compensation was set in advance."

Finally, CMS proposes a new exception to protect certain non-abusive arrangements under which a limited amount of remuneration (*i.e.*, up to an aggregate of $3,500 per calendar year, adjusted for inflation) is paid to a physician in exchange for items or services rendered by the physician. This new exception would apply even absent supporting documentation or evidence the rate was set in advance, so long as the following is true:

1. The arrangement is commercially reasonable.

2. The remuneration is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

3. The remuneration does not exceed fair market value.

The new proposed exception also incorporates the prohibitions present in other Stark exceptions on percentage-based and per-unit of service compensation for the use or lease of office space or equipment.

While CMS takes this opportunity to clarify its policy that the exception for isolated transactions cannot be used to protect single payments to a physician for multiple services provided over an extended time period, it suggests this new exception for limited remuneration to a physician might be invoked to cover such financial relationships.

Stark: CMS Breathes Life into the "Remuneration Unrelated to the Provision of DHS" Exception (42 CFR § 411.357(g))

CMS proposes to revise the exception to protect remuneration provided by a hospital to a physician if the remuneration does not relate to the provision of DHS. Historically, this "certain arrangements with hospitals" exception had been so narrowly construed by CMS that it had little, if any, practical utility. CMS now proposes to restructure the exception to apply when the remuneration is not related to the provision of patient care services. As proposed, items that relate to the provision of patient care services include, but are not limited to, any item, supply, device, equipment or space that is used in the diagnosis or treatment of patients and any technology that is used to communicate with patients regarding patient care services. A service, however, will be deemed not to relate to the provision of patient care services if it could be provided by someone without a medical professional license (e.g., medical, nursing) and the service is of the type that is typically provided by unlicensed persons. CMS signals that it still views call-coverage, medical directorship, and even utilization review to relate to patient care services. Comparatively, however, CMS explained that administrative services of a physician for the business operations of a hospital do not relate to patient care services (e.g., serving as a member of a governing board along with unlicensed individuals on identical terms and conditions as the unlicensed individuals). To qualify for the exception, the remuneration cannot be determined in a manner that takes into account the volume or value of referrals.

The Decoupling of Stark, AKS and Federal and State Laws or Regulations Governing Billing or Claims Submission

Many Stark regulatory exceptions currently require the arrangement not violate the AKS or any federal or state law or regulation governing billing or claims submission. In response to commenters' opposition to this continued coupling of the strict-liability Stark with the intent-based AKS and other billing and claims submission laws, CMS proposes to eliminate compliance with these requirements as a condition of satisfying a Stark exception. CMS acknowledges, in part based on its experience working with the Department of Justice, the OIG, and other law enforcement partners, it is no longer "necessary or appropriate" to bootstrap these requirements into the Stark Law's exceptions. However, CMS states it intends to monitor excepted financial relationships going forward and may revisit this decision if needed "to protect against program or patient abuse."

VBE Profit Distributions in Stark Group Practice
(42 CFR § 411.352(i))

While not part of the new value-based exceptions proposed at 42 CFR § 411.357(aa), CMS proposes to add a subsection to the profit distribution rules for Stark group practices at proposed 42 CFR

§411.352(i)(3) protecting payments made directly to physicians in a group practice of profits earned as a result of the physicians' participation in value-based activities. Many value-based models include shared savings or productivity bonuses paid to physicians for their participation in the model and their achievement of the model's benchmarks, goals, and/or purposes. However, under the current regulations, the distribution of profits rule strictly prohibits any payments to physicians in a group practice that directly take into account the volume or value of the physicians' referrals of DHS to the group practice. As mentioned in the above section regarding the proposed Stark value-based exceptions, the proposed value-based exceptions do not contain the volume or value standard, and CMS views the proposed changes to 42 CFR §411.352(i) as an extension of that policy. Stakeholders and CMS agree that allowing physicians to participate in payment arrangements such as shared savings, gainsharing, production bonuses, and others, encourages their participation in value-based healthcare delivery models. To protect a group practice's ability to meet the Stark group practice profit distribution rules, proposed 42 CFR §411.352(i)(3) would deem the volume or value standard met for group practices with physicians who receive payments as a result of their participation in a value-based payment model. In other words, this addition would deem profits distributed to a physician in a group practice as not directly taking into account the volume or value of the physician's referrals to the group practice if the profits are for DHS furnished by the group practice derived from the physician's participation in a VBE, including profits from DHS referred by the physician.

AKS PROPOSALS, CLARIFICATIONS AND COMMENTARY

AKS Personal Services and Management Contracts and AKS Outcomes-Based Payment Safe Harbor (42 CFR § 1001.952(d))

The OIG proposes changes seeking to modernize the personal services and management contracts safe harbor and alleviate barriers to developing care coordination and value-based arrangements by essentially creating a new safe harbor for certain outcomes-based payments.

Personal Services and Management Contracts

To add flexibility in creating bona fide business arrangements where parties provide legitimate services on an as-needed basis, the OIG proposes to remove the existing safe harbor's requirements for documenting an exact schedule of services and charges for each interval, if the services will be provided on a periodic, sporadic, or part-time basis. The OIG's proposal also removes the requirement that the *aggregate compensation* paid over the term of the agreement be set out in advance. Instead, the safe harbor would require only the *compensation methodology* to be set out in advance. This revision would more closely resemble the Stark personal service arrangements exception, while guarding against compensation arrangements that can be adjusted throughout the term of the agreement to reward referrals or encourage overutilization.

Outcomes-Based Payment Arrangements

The OIG proposes to add an exclusion from the definition of remuneration for outcomes-based payments, which are payments between a principal and agent collaborating to do the following:

1. Measurably improve, or maintain improvement in, the quality of patient care.

2. Appropriately and materially reduce payor costs, or growth in payor costs, while improving, or maintaining the improved, quality of patient care.

To qualify for the outcomes-based payments, the parties must satisfy numerous conditions, including several that mirror the safe harbor's existing program integrity safeguards. Among these conditions, the agent must satisfy one or more evidenced-based, valid outcomes measures related to one or both

of the aforementioned goals based on clinical evidence or credible medical support. The parties must regularly monitor and assess the agent's performance, and periodically rebase, or reset the benchmark to take into account improvements already received. The OIG anticipates these arrangements will be conceptually similar to those used in CMS Innovation Center models and the Medicare Shared Savings Program, and may include payment arrangements such as shared savings, shared losses, gainsharing, pay-for-performance, and episodic or bundled payments. The OIG is considering restricting this safe harbor to protect only VBE participants, which are discussed in more detail above.

There are two major exclusions from the proposed protection for outcomes-based payments:

1. Payments made by a pharmaceutical manufacturer; manufacturer, distributor, or supplier of DMEPOS; or a laboratory. This exclusion reflects concerns that these entities, which rely heavily on provider prescriptions and referrals, may use the safe harbor to market their products to providers and patients. The OIG is soliciting comments as to whether it should add pharmacies, PBMs, wholesalers, and distributors to this exclusion.

2. Payments relating solely to achieving internal cost savings for the principal. So for instance, hospital gainsharing arrangements under prospective payment systems will not be covered if they create savings for the providers, but not for the payor.

AKS Warranties Safe Harbor
(42 CFR § 1001.952(g))

The OIG has previously stated the AKS warranties safe harbor applies only to warranties for a single item. The OIG proposes to extend the safe harbor to cover bundled warranties for one or more items and related services as long as, among other conditions, the bundled items and services are reimbursable by the same federal healthcare program and in the same payment (e.g., by the same MS-DRG payment or the same Medicaid managed care payment). It includes protections against certain steering practices by prohibiting the conditioning of warranties on the exclusive use or minimum purchase of any items or services. Federal program beneficiaries are also exempt from reporting requirements applicable to other buyers. This proposal does not protect warranties covering only services, but the OIG is considering whether to extend the protection to service-only warranties if sufficient safeguards are present to minimize fraud and abuse risks.

AKS Local Transportation Safe Harbor
(42 CFR § 1001.952(bb))

Recognizing the impact of transportation on access to care, quality of care, healthcare outcomes, and effective coordination of care, the AKS proposed rule extends the mileage limit under this safe harbor for patients residing in rural areas from 50 miles to 75 miles. It also eliminates the mileage limit for patients being discharged from inpatient facilities and transported to their residences, regardless of whether they reside in an urban or rural area. The OIG is soliciting comments on whether to protect transportation to other locations of the person's choice, including another healthcare facility, and whether to protect transportation in cases where the patient is not admitted as an inpatient, such as after the patient has been seen in the emergency room, or has had a procedure performed at an ambulatory surgery center. The OIG is also considering extending protection to transportation for non-medical purposes that are part of a care coordination arrangement, or are related to improving and maintaining health (e.g., transportation to grocery stores, gyms, or social services facilities). In commentary to the proposed rule, the OIG also clarifies the transportation safe harbor includes ride-sharing services.

AKS ACO Beneficiary Incentive Program Safe Harbor
(42 CFR § 1001.952(kk))

In the AKS proposed rule, the OIG proposes to adopt regulatory language nearly identical to the statutory exception for ACOs.[4] The new safe harbor would protect an incentive payment made by an ACO to an assigned beneficiary under a beneficiary incentive program established under 42 U.S.C. § 1395jjj(m), if the incentive payment is made in accordance with the requirements found in that subsection. The safe harbor would clarify the ACO may furnish incentive payments only to *assigned* beneficiaries. The OIG also clarifies that, for an incentive payment to satisfy this safe harbor, all of the requirements included at section 1395jjj(m)—which governs providing incentive payments to beneficiaries for qualifying primary care services under the Medicare Shared Savings Program—must be satisfied. This includes requirements related to ACO beneficiary incentive programs and incentive payments made under such programs. As an AKS safe harbor, incentive payments satisfying the requirements of the proposed safe harbor would qualify as an exception under the beneficiary inducements CMP.

The proposed rules are comprehensive and represent an attempt by CMS and the OIG to address the shifting healthcare landscape. The 75-day public comment period began when the proposed rules were published in the Federal Register on October 17, 2019. Comments can be submitted by mail or hand delivery, as well as electronically via this link: https://www.regulations.gov/. Bass, Berry & Sims is here to assist with submitting comments or to discuss the impact of the proposed rules to your respective organization.

[4] 42 U.S.C. § 1320a-7b(b)(3)(K).

AUTHORS

BRIAN D. BEWLEY
Member

ANNA M. GRIZZLE
Member

CYNTHIA Y. REISZ
Member

DANIELLE M. SLOANE
Member

KAITLYN L. DUNN
Associate

RICHARD EILER
Associate

LAUREN M. GAFFNEY
Associate

DAWN PEREZ-SLAVINKSKI
Associate

BRIANNA R. POWELL
Associate

PAGE MINTON SMITH
Associate

JAMIE GORDON STEAKLEY
Associate