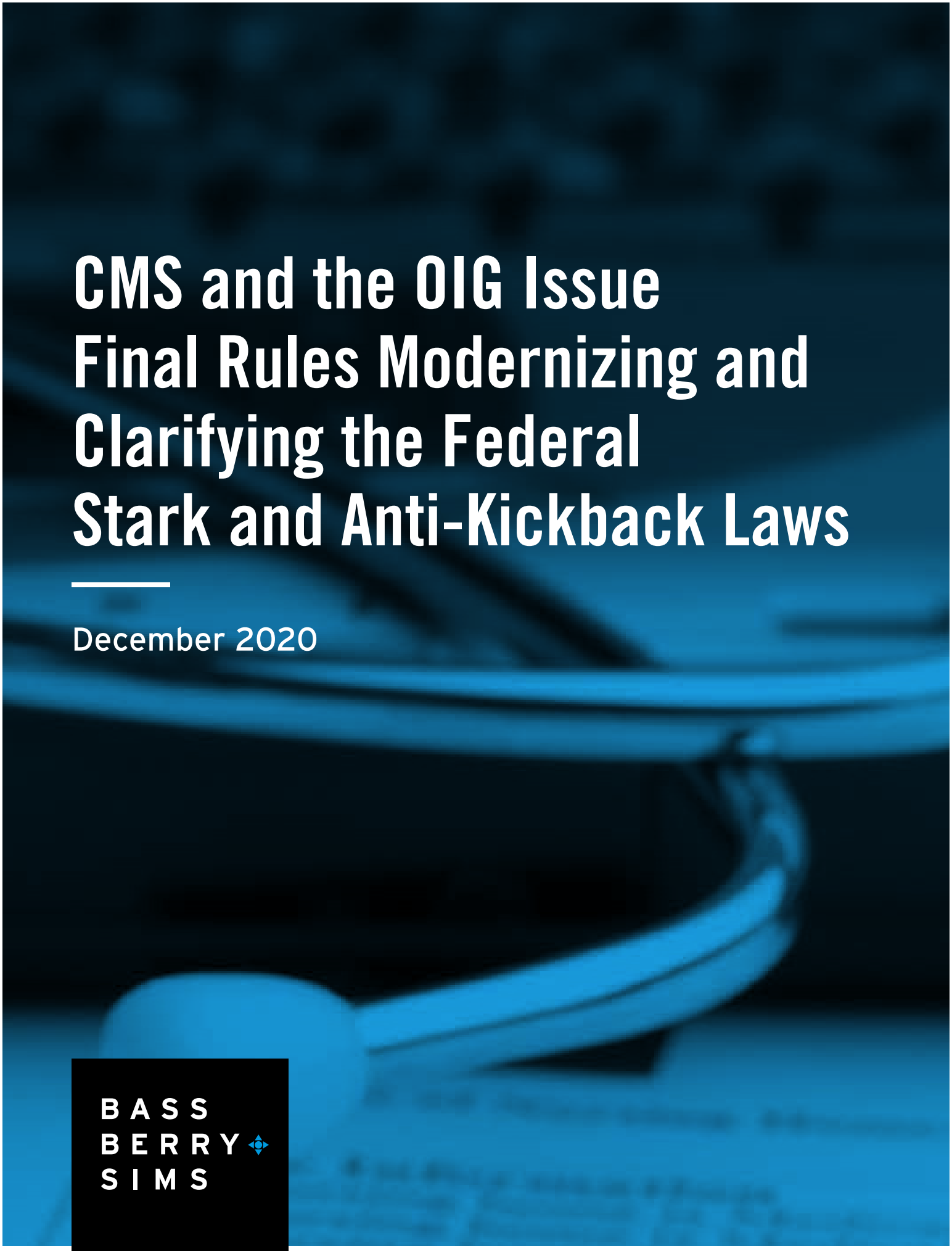

CMS and the OIG Issue Final Rules Modernizing and Clarifying the Federal Stark and Anti-Kickback Laws

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In a coordinated effort, on November 20, 2020, the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) published final 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). Together, the final rules implement a framework to support transitions to value-based payment models and promote improvements in technology infrastructure. Perhaps most notable, however, are the strides CMS has taken toward adding flexibility and attempting to clarify the Stark regulations.

On the same day, in an effort to increase transparency in drug pricing and lower those prices, the OIG separately released a final rule to alter the way prescription drug discounts are handled and to protect certain drug-manufacturer payments to pharmacy benefit managers (PBMs).

Although the regulations remain complex, the healthcare industry should be pleased with the new flexibilities to support innovation, the avenues to protect financial relationships with referral sources, and the clarifications to help fend off frivolous whistleblower lawsuits.

THE CHANGES IN THE FINAL RULES INCLUDE:

- New Value-Based Exceptions and Safe Harbors
- Enabling Technology Infrastructure Improvements
- Modernizing Stark and AKS: New Rules, Definitions, and Clarifications
- AKS: Pharmaceutical Rebates and PBM Service Fees

Redline documents showing the final textual changes to the current Stark regulations are available here and to the AKS regulations are available here. The final rules published in the Federal Register are available here (final Stark rule), here (AKS) and here (AKS Pharma) (collectively, final AKS rules).

The Stark and AKS final rules aimed at modernization, clarification, and establishment of value-based arrangements are effective **January 19, 2021**, with one exception. The changes to the Stark group practice regulations at 42 CFR § 411.352(i) regarding the distribution of profits related to participation in a value-based enterprise will be effective **January 1, 2022**. The changes promulgated in the second final AKS rule, related to eliminating pharmaceutical rebates from the AKS discount safe harbor are also expected to become effective **January 1, 2022**, but the effective date of those changes related to creating new AKS safe harbors for pharmaceutical point-of-sale price reductions and PBM service fees, which was originally January 29, 2021, was later delayed to March 22, 2021 to provide time for the new administration to review the rule.[1] Further, the delayed effective dates are in recognition that the industry may need additional time to comply with these new rules.

[1] OIG Final Rule (scheduled to be published in the federal register on Feb 2, 2021) available at https://public-inspection.federalregister.gov/2021-02132.pdf.

New Value-Based Exceptions and Safe Harbors

OVERVIEW

The final rules issued by CMS and the OIG focus extensively on the transition to value-based care delivery and payment models. To support that transition and related innovation, CMS and the OIG finalized new definitions, exceptions, safe harbors, and additional changes to existing regulations relating to value-based care, which were originally proposed in October 2019.[2] The table below lists the value-based exceptions and safe harbors created in the final rules.

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

Under both final rules, CMS and the OIG intended 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 attempted 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 expressed 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.

While the OIG and CMS attempted to align the requirements of the value-based safe harbors and exceptions, including through the use of related terminology, the OIG's safe harbors for value-based arrangements are more restrictive than CMS's comparable exceptions because the AKS is a criminal intent-based statute, whereas the Stark Law is a civil, strict-liability statute. The newly finalized 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 arrangements 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.

[2] See 84 Fed. Reg. 55694 (Oct. 17, 2019) and 84 Fed. Reg. 55766 (Oct. 17, 2020) for details regarding the 2019 proposed rules.

Overall, the final rules represent a comprehensive effort to support a shift to reimbursement models driven by quality and efficiency rather than volume. Despite efforts by CMS and the OIG to simplify some of the conditions to the value-based safe harbors and exceptions in the final rules, some aspects of these exceptions and safe harbors may be difficult to interpret and apply in practice, particularly for small and rural providers. Only time will tell whether these changes will be sufficient to stimulate innovation and widespread adoption of value-based arrangements. The final value-based exceptions and safe harbors generally take effect on **January 19, 2021**.

TERMINOLOGY

CMS and the OIG generally use consistent terminology to describe the universe of value-based arrangements potentially eligible for protection under their respective final rules. The final definitions are intended to be broad and flexible. As described below, a few terms defined by both agencies differ in either terminology or application, and one term was defined by the OIG that was not included as a defined term by CMS. Below we discuss the definitions and relevant commentary regarding each term.

Value-Based Enterprise Participant

CMS (42 CFR § 411.351)	OIG (42 CFR § 1001.952(ee)(14)(ix))
VBE participant means a person or entity that engages in at least one value-based activity as part of a value-based enterprise.	Value-based enterprise participant or VBE participant means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise, other than a patient acting in their capacity as a patient.

Although the definitions of value-based enterprise (VBE) participant (VBE participant) finalized by CMS and the OIG are substantially similar, the manner in which the agencies apply the term appears to differ. In their proposed rules, both CMS and the OIG contemplated excluding certain entities (*e.g.*, durable medical equipment (DME) suppliers, laboratories, manufacturers, and distributors) from the definition of VBE participant due to concerns for potential abuse of the new value-based exceptions and safe harbors. While neither agency ultimately chose to exclude any entities from their respective definitions of VBE participant, the OIG effectively excluded some types of entities by instead restricting the types of VBE participants that may utilize the value-based safe harbors (as detailed below). The Stark value-based exceptions do not have similar limitations, but CMS noted that it plans to monitor its broad inclusion of all entities for program-integrity risk.

The OIG effectively divided the universe of VBE participants into three categories: (1) those that may rely on all value-based safe harbors for all types of arrangements, (2) limited technology participants, and (3) VBE participants ineligible to rely on any of the value-based safe harbors for any arrangement. The OIG elected to make the following entities largely ineligible for value-based safe harbor protection (collectively, Ineligible Entities):

- Pharmaceutical manufacturers, distributors, or wholesalers;
- PBMs;
- Laboratory companies;
- Compounding pharmacies;
- Manufacturers, distributors, and wholesalers of a device or medical supply; and
- DME prosthetics/orthotics and supplies (DMEPOS) providers (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services).

The final AKS rules also created a new "limited technology participants" category, which includes certain medical-device manufacturers and suppliers and DMEPOS companies. Limited technology participants may only rely on the care coordination arrangements safe harbor for arrangements involving digital health technology that is used for coordinating and managing care, including hardware and software that capture, transmit, or analyze data.

Recognizing that providers often engage in multiple lines of business, the OIG noted that whether a particular entity fits into one of these categories is assessed at the corporate-entity level, and if a single corporate entity operates multiple lines of business, the issue turns on the entity's predominant or core business. For example, a hospital that furnishes laboratory services billed through the hospital's provider number is not considered an ineligible laboratory company. Conversely, in a situation involving a distinct hospital with a hospital-affiliated or hospital-owned laboratory company that has its own supplier number, the laboratory with its own supplier number (but not the hospital) would be ineligible for safe harbor protection.

Value-Based Enterprise

CMS (42 CFR § 411.351)	OIG (42 CFR § 1001.952(ee)(14)(viii))
Value-based enterprise (VBE) means two or more VBE participants–	Value-based enterprise or VBE means two or more VBE participants:
(1) Collaborating to achieve at least one value-based purpose;	(A) Collaborating to achieve at least one value-based purpose;
(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;	(B) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;
(3) That have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and	(C) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and
(4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).	(D) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

CMS and the OIG both noted in the final rules their intent for the definition of VBE to be broad and flexible, including providers, suppliers, and other entities of varying size, complexity, and financial means. CMS explains "whatever its size and structure, a [VBE] is essentially a network of participants (such as clinicians, providers and suppliers) that have agreed to collaborate with regard to a target patient population to put the patient at the center of care through care coordination, increase efficiencies in the delivery of care, and improve outcomes for patients."[3]

VBE participants may join and leave a VBE throughout the existence of a VBE, but the definition of VBE requires at least two VBE participants. CMS noted that nothing in its definition of VBE precludes adding new VBE participants, but the arrangement between the new VBE participant and the VBE would be considered a new financial relationship that must separately satisfy an applicable exception to the physician self-referral law.

Qualifying as a VBE necessitates meeting other conditions, such as requirements for a governing document and an accountable body or person responsible for oversight of the enterprise. The accountable body must be appropriate for the size and resources of the VBE. While there is no specific format for a governing document, the OIG requires that it be a *single* document that generally describes the VBE and how VBE participants intend

[3] 85 Fed. Reg. 77498 (Dec. 2, 2020).

to achieve the value-based purpose(s). Though CMS did not expressly state that a single document is necessary, that is likely best practice. CMS did indicate, however, that written agreements entered into between parties in the normal course of business may be sufficient. Implicit in the governing-document requirement (although, not explicitly stated in the VBE definition) is that the VBE must have at least one value-based purpose. Notably, the OIG had solicited comments and proposed incorporation of additional responsibilities and reporting requirements but elected not to do so.

Value-Based Arrangement

CMS (42 CFR § 411.351)	OIG (42 CFR § 1001.952(ee)(14)(vii))
Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are— (1) The value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.	Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are: (A) The value-based enterprise and one or more of its VBE participants; or (B) VBE participants in the same value-based enterprise.

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 final value-based exceptions and safe harbors protect certain remuneration provided or exchanged under a value-based arrangement to which the only parties are a VBE and one or more of its VBE participants, or between VBE participants in the same VBE, that will provide at least one value-based activity for a target patient population.

In response to commentary, in the final AKS rules, the OIG did not preclude protection for arrangements between entities that have common ownership in the definition of value-based arrangement or in the individual safe harbors. The OIG also reiterated that its definition of value-based arrangement broadly covers commercial and private insurer arrangements.

CMS explained that it expects most value-based arrangements to involve activities that coordinate and manage the care of a target patient population, but CMS did not limit the definition only to compensation arrangements that coordinate and manage care. CMS also stated that the Stark value-based exceptions can apply regardless of whether the arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients, or a mixture of both.

Value-Based Activities

CMS (42 CFR § 411.351)	OIG (42 CFR § 1001.952(ee)(14)(vi))
Value-based activity means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) The provision of an item or service; (2) The taking of an action; or (3) The refraining from taking an action.	Value-based activity. (A) Means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) The provision of an item or service; (2) The taking of an action; or (3) The refraining from taking an action; and (B) Does not include the making of a referral.

CMS and the OIG define value-based activities using substantially the same terminology. An example of taking an action to achieve a value-based purpose might include a physician joining other providers and suppliers in an arrangement to achieve savings. An example of refraining from taking an action for a value-based purpose might include a physician agreeing to a redesigned care protocol, which implicitly requires the physician to refrain from following previously used patient care protocols.

Notably, only the definition in the OIG's final AKS rule excludes a referral from being a value-based activity. CMS elected not to include a similar restriction because the Stark Law's separate definition of "referral" includes the establishment of a plan of care (that includes the provision of designated health services (DHS)), and it did not want to exclude care planning as a value-based activity. As a result, care-planning activities that meet the definition of referral at 42 CFR § 411.351 will qualify as "the taking of an action" for purposes of applying the definition of value-based activity. Both agencies noted that the final rules do not require an activity to achieve a value-based purpose, only that it be "reasonably designed" to do so (*i.e.*, the parties to the arrangement fully expect the developed activities to further one or more value-based purposes). CMS noted that the parties must have a good faith belief that the value-based activity will achieve, or lead to the achievement of, at least one value-based purpose of the VBE and recognized that parties may undertake activities that do not ultimately achieve the value-based purpose(s) of the VBE. CMS advised that contemporaneous documentation is a best practice for parties concerned about showing that a value-based activity is reasonably designed to achieve a value-based purpose.

Value-Based Purpose

CMS (42 CFR § 411.351)	OIG (42 CFR § 1001.952(ee)(14)(x))
Value-based purpose means any of the following:	Value-based purpose means:
(1) Coordinating and managing the care of a target patient population;	(A) Coordinating and managing the care of a target patient population;
(2) Improving the quality of care for a target patient population;	(B) Improving the quality of care for a target patient population;
(3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or	(C) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or
(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.	(D) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Both agencies define value-based purpose in the exact same manner. Several commenters to the proposed rule thought that CMS should include the reduction in costs to, or growth in expenditures of, *healthcare providers and suppliers* as a value-based purpose. CMS declined because it did not think letting parties focus on that goal alone would adequately protect the Medicare program or its beneficiaries from abuse. CMS stated that allowing parties to share in the reduction of costs without also improving or maintaining the quality of care for patients or otherwise benefitting payors does not advance the transition to a value-based healthcare delivery and payment system.

This definition of value-based purpose is intended to provide flexibility; there are no set criteria for how to measure quality or achievement of the VBE's value-based purpose(s). The parties do not necessarily have to achieve the value-based purpose(s) but must have a good faith belief that the value-based activities will achieve, or lead to achieving, at least one value-based purpose of the VBE. CMS did include a requirement in the final value-based arrangements exception (further discussed below) for monitoring the value-based activities and how continuation is expected to further the value-based purpose(s) of the VBE.

Target Patient Population

CMS (42 CFR § 411.351)	OIG (42 CFR § 1001.952(ee)(14)(v))
Target patient population means an identified patient population selected by a VBE or its VBE participants based on legitimate and verifiable criteria that: (1) Are set out in writing in advance of the commencement of the value-based arrangement; and (2) Further the value-based enterprise's value-based purpose(s).	Target patient population means an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that: (A) Are set out in writing in advance of the commencement of the value-based arrangement; and (B) Further the value-based enterprise's value-based purpose(s).

Both CMS and the OIG define "target patient population" broadly and in substantially the same manner. The OIG confirmed that only the selection criteria (not the individual patients) must be identified in advance and any modifications to those criteria could only be prospective.

CMS addressed concerns raised by commenters about the "set in advance" requirement in the context of a payor selecting the target patient population based on retrospective claims-based methodology. Where a payor is ascribing the target patient population to a VBE based on payor-established criteria, CMS provided that the VBE or its VBE participants are still obligated to ensure that the requirements of the target patient population definition are satisfied. In the payor-selection situation, CMS stated that the selection criteria required to be set in advance in writing could be described as "the target patient population to be identified by the payor in accordance with criteria established by the payor for retrospective attribution."[4] However, the VBE or VBE participants must ensure that the payor's methodology for retrospective attribution is legitimate, verifiable, and will further the VBE's value-based purpose(s). Importantly, CMS clarified that it is not sufficient for the VBE or its VBE participants to merely state that the selection criteria will be determined by another party (in this case, the payor). The VBE or its VBE participants may need to collaborate with the payor to ensure that the patient population attributed meets the definition of target patient population.

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 notes that VBEs that select a target patient population comprised of the parties' entire patient population could result in additional scrutiny for compliance depending on the circumstance. Along those same lines, CMS stated that choosing a target patient population solely because it appears likely to reduce the costs to one of the parties involved in a value-based arrangement would be suspect.

Coordinating and Managing Care

The final AKS rules define coordinating and managing care for purposes of value-based arrangements, whereas CMS opted not to finalize a definition of this term in its final rule.

AKS (42 CFR § 1001.952(ee)(14)(i))
Coordination and management of care (or coordinating and managing care) means the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population.

[4] 85 Fed. Reg. 77505 (Dec. 2, 2020).

This term might 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 suspect referral arrangements designed to "churn" patients through care settings to capitalize on a reimbursement scheme and 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. As noted above, the OIG did not move forward with excluding entities under common ownership from the safe harbor protections.

Commenters urged CMS not to define "coordinating and managing care," suggesting that it was self-explanatory and any definition could inadvertently limit innovation. CMS agreed and opted not to define this term.

STARK FINAL VALUE-BASED ARRANGEMENT EXCEPTIONS

CMS added 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. These exceptions are as follows:

1. The full financial risk exception,
2. The meaningful downside financial risk exception, and
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. In general, CMS takes the position that as financial risk to the participants increases, the incentives to order unnecessary services or steer patients to high-cost sites of services diminish. As a result, CMS imposes more requirements on value-based arrangements that entail less risk.

All of these exceptions are only available to protect 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.

CMS, unlike the OIG, did not create a separate value-based exception to protect value-based arrangements in CMS-sponsored models, programs, or initiatives (CMS Models). Additionally, CMS stated that the final value-based exceptions should eliminate the need for any future waivers of Section 1877 of the Social Security Act (SSA) as long as the compensation arrangement meets the definition of a value-based arrangement. However, participants in the CMS Models may elect to continue using waivers that currently apply to their model, program, or initiative; and, the Secretary of the Department of Health and Human Services (Secretary) has the authority to address future financial arrangements that may not fit within the final Stark value-based exception framework.

CMS also did not include the coordination and management of care as an explicit requirement for value-based arrangements as the OIG did in its final AKS rules. CMS stated that "well-coordinated and managed patient care is the cornerstone of a value-based health care system,"[5] and explained that it is implicit that most value-based arrangements will have the coordination and management of care of patients at heart. Furthermore, CMS felt that adding such a requirement could act to prevent potential beneficial value-based arrangements from meeting a value-based exception because they did not directly coordinate or manage the care of the target patient population.

[5] 85 Fed. Reg. 77509 (December 2, 2020).

As in the proposed rules, the final value-based exceptions do not require remuneration to be consistent with fair market value or prohibit taking into account the volume or value of referrals (volume or value standard). CMS did, however, decide to include commercial reasonableness as a requirement to qualify for the value-based arrangements exception (which is the only value-based exception that does not require any financial risk on the part of the VBE or any of the VBE participants).

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 any of 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 recognized that certain incentive payments are difficult to tie to specific items or services and clarified 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 SSA.

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 who are 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 must satisfy conditions for the protection of patient choice.** Although achieved in a slightly different manner from the proposed rules, the final value-based exceptions all include a requirement aimed at preserving patient choice if remuneration provided to the physician under the value-based arrangement is conditioned on the physician's referrals.

   In that instance, the requirement to make referrals to a particular provider, practitioner, or supplier must:

   - Be set out in writing and signed by the parties; and
   - May not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

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

In the proposed Stark rule, CMS sought comments regarding whether to include a requirement related to price transparency in each of the value-based exceptions. In the final Stark rule, CMS explained that, although price transparency is an important step in breaking down barriers to cost-of-care discussions, given the strict liability nature of the Stark Law, CMS did not believe that requiring price-transparency disclosures in Stark exceptions was an appropriate mechanism for the promotion of price transparency.

Full Financial Risk Exception
(42 CFR § 411.357(aa)(1))

The Stark full financial risk exception requires the VBE to take "full financial risk," which means being "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."[6] There are no additional requirements for this exception other than the five common requirements applicable to all three new Stark exceptions listed above. The exception requires the VBE to be at full financial risk within 12 months of commencing the value-based arrangement, allowing 12 months for implementation of the arrangement instead of six months as originally proposed. In its commentary, CMS explicitly stated that there are no documentation requirements for the full financial risk exception, but reminded readers that documenting any relationship between referral parties is a good business practice.

Examples of payment models eligible to use the full financial risk exception include capitation payments or global budget payments. CMS noted that the VBE and the VBE participants have the freedom to allocate the risk among themselves as opposed to a single organization (*e.g.*, the VBE) assuming the full financial risk. This could be helpful in states like California, where state law requires providers or suppliers that assume full financial risk for healthcare items and services to become licensed as health plans.

To meet the definition of full financial risk, CMS explained that the financial risk must be determined in advance and may not include additional fee-for-service or other payments to compensate for costs incurred by the VBE in providing specific patient-care items or services. Under this exception, the payment of shared savings or other incentive payments for achieving quality, performance, or other benchmarks is permitted. Finally, CMS stated that this exception does not prohibit contracting with a payor for stop-loss protection or applying risk corridors to limit exposure to significant losses related to high-cost items or services or overall expenses. However, any such stop-loss or other risk-adjustment provisions are to act as protection for the VBE against catastrophic losses and should not be a means to shift material financial risk back to the payor.

Meaningful Downside Financial Risk Exception
(42 CFR § 411.357(aa)(2))

CMS finalized another exception aimed at physicians who are not prepared to be responsible for the total cost of care for a target patient population but are willing to undertake some financial risk in exchange for potential financial gain. The meaningful downside financial risk exception protects compensation arrangements under which a physician has 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. CMS defines "meaningful downside financial risk" as the physician being responsible to repay or forgo a minimum of 10% of the total remuneration (or 10% of the total value of the remuneration for in-kind remuneration) that the physician receives under the value-based arrangement. Notably, the 10% downside risk threshold is a change from the proposed rule, which required a 25% downside risk on the part of the physician.

In addition to the five common requirements mentioned above, the meaningful downside financial risk exception includes three safeguards to protect against misuse of the exception.

1. The nature and extent of the meaningful downside risk must be in writing before undertaking any value-based activities.
2. 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.
3. The methodology for determining the amount of remuneration must be set in advance.

[6] 42 CFR § 411.357(aa)(1)(vii) (as set forth in the final rule at 85 Fed. Reg. 77681 (Dec. 2, 2020)) (emphasis supplied).

CMS indicated that these requirements work as defenses against the manipulation of a value-based arrangement to reward referrals.

CMS clarified that parties could use withholds, repayment requirements, and/or incentive payments tied to meeting goals or outcomes measures under the meaningful downside financial risk as long as the physician's downside financial risk is tied to the achievement of the value-based purpose(s) of the VBE and not the goals of the parties or the arrangement. Some commenters to the proposed rule requested CMS adopt the same "pre-risk" period that is available in the full financial risk exception (*i.e.*, the 12-month implementation period). Unlike the OIG in the AKS substantial downside risk safe harbor, CMS declined to adopt any pre-risk application period in the meaningful downside financial risk exception primarily because CMS saw its inclusion as a program-integrity risk. CMS expressed concern that parties would "front load" the remuneration by providing high-value remuneration to the physician during the pre-risk period before the physician was required to take on the assumption of downside risk.

CMS made a point to emphasize the fact that this exception is focused on the risk assumed by an *individual physician*, as opposed to the substantial downside risk safe harbor issued by the OIG, which places the downside risk at the VBE level. CMS stated that it intends this exception to encourage physicians to begin taking on some downside risk in a shift toward value-based care. CMS believes that taking on such risk has great potential for physician behavior-shaping when failure to achieve the value-based purpose(s) is tied to his or her remuneration.

Value-Based Arrangements Exception
(42 CFR § § 411.357(aa)(3))

CMS also finalized, with several changes from the proposed rule, 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 participation in coordinated-care activities as a stepping stone toward participation in two-sided risk-sharing arrangements. The exception applies to both monetary and non-monetary remuneration. Although CMS sought comments regarding limiting this exception to non-monetary remuneration and requiring some contribution from the VBE participants, CMS ultimately opted for simplicity in not implementing those concepts.

Because the value-based arrangements exception does not involve downside risk for participants, CMS included additional program-integrity safeguards beyond the five common requirements discussed above. One such safeguard is the requirement that the arrangement be commercially reasonable. CMS acknowledged that most value-based arrangements that satisfy all of the requirements of an applicable value-based exception and are aimed at reducing costs and improving quality are likely commercially reasonable. CMS suggested, however, that adding this commercial reasonableness requirement to the value-based arrangements exception will ensure that the parties structure the arrangement in a manner intended to further their legitimate business purposes (which must include achievement of value-based purpose(s) of the VBE in which they are participants).

The value-based arrangements exception also requires the arrangement to be in writing and signed by the parties. CMS specifically noted that while it expects the parties to plan to satisfy the writing requirement in advance of the commencement of the value-based arrangement, the special rule for writing and signature requirements (*i.e.*, 90-day grace period as finalized, discussed further below) applies. Unlike the other value-based exceptions, the final value-based arrangements exception requires more detail in the written documentation, including a description of the following:

- The value-based activities under the arrangement;
- How the value-based activities are expected to further the value-based purpose(s) of the VBE;
- The target patient population;
- The type or nature of remuneration;

- The methodology used to determine the remuneration; and
- The outcome measures against which the recipient of remuneration is assessed, if any.

For purposes of the value-based arrangements exception, "outcome measure" is defined to mean a benchmark that quantifies either of the following:

- Improvements in or maintenance of the quality of patient care; or
- Reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.

CMS explained that this definition is intended to align with the OIG's final regulations. Outcome measures (if any) must be set in advance and must be objective, measurable, and selected based on clinical evidence or credible medical support. If the parties want to make changes to the outcome measures, the changes must be made prospectively and in writing. CMS noted that not all value-based arrangements will have applicable outcome measures. In the proposed Stark rule, CMS considered whether to require that the outcome measures be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery (as opposed to maintaining the status quo), but declined to include such a requirement in the final Stark rule.

VBEs have an implicit ongoing obligation to monitor the financial relationships they have with a physician to ensure compliance with the applicable exceptions. In the final Stark rule, CMS added an explicit monitoring requirement to the value-based arrangements exception as an additional program-integrity safeguard. The monitoring must take place at least once a year, or, at least once during the term if the arrangement has a duration of less than one year. This monitoring timeframe coincides with the final AKS safe harbors for value-based arrangements.

The monitoring requirements of the value-based arrangements exception (and the steps the parties to the value-based arrangement are required to take if some aspect of the value-based arrangement is found to be deficient) are different for value-based activities and outcome-based measures.

Monitoring of Value-based Activities:

Monitoring: The VBE or a VBE participant must determine the following:

- Whether the parties have furnished the value-based activities required under the arrangement; and
- Whether and how the continuation of the value-based activities is expected to further the value-based purpose(s) of the VBE.

Action Steps: If a value-based activity is not expected to further the value-based purpose(s) of the VBE, the parties may do either of the following:

- Terminate the value-based arrangement within 30 calendar days following the completion of the monitoring; or
- Modify the arrangement within 90 calendar days to terminate the ineffective value-based activity.

Monitoring Outcome Measures (if any):

In addition to the monitoring and action steps described above, the following actions must also be taken for a value-based arrangement that includes outcome measures:

Monitoring: The VBE or a VBE participant must assess the progress toward attainment of the outcome measure(s) against which the recipient of the remuneration is assessed.

Action Steps: If the monitoring determines that an outcome measure is unattainable during the remaining term of the value-based arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring.

CMS indicated that it is providing for the noted "grace periods" because it recognizes that the parties to the value-based arrangement may need time to address an ineffective value-based activity identified through their monitoring, and the grace periods would allow them to do that without fear of violating the physician self-referral law.

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

Although not part of the new Stark value-based exceptions, in an effort to eliminate potential barriers for participation by physicians in the delivery of value-based care, CMS also finalized its proposal regarding the distribution of profits generated from a physician's participation in a VBE. Specifically, profits from DHS that are directly attributable to a physician's participation in a VBE may be distributed to such physician and will not be considered to directly relate to (or take into account) the volume or value of the physician's referrals for purposes of the group practice definition. Although the rest of the regulatory changes in the final Stark rule will be effective **January 1, 2021**, the changes related to group practice profit shares and productivity bonuses at 42 CFR § 411.352(i) will come into effect on **January 1, 2022**.

CMS made other adjustments to the group practice definition, which are discussed further below.

AKS 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; and
3. Care coordination safe harbor.

Common Requirements in Value-Based Safe Harbors

Although technically not excluded from the definition of VBE participant, none of the AKS value-based safe harbors protect remuneration exchanged by Ineligible Entities (as defined in the VBE participant section above). However, certain DMEPOS providers and suppliers that qualify as limited technology participants may utilize the care coordination arrangements safe harbor for arrangements involving digital health technology used to coordinate and manage care.

Five common requirements apply to all of the value-based safe harbors:

1. **The value-based arrangement must not induce the parties to reduce or limit medically necessary items or services to any patient.** The OIG noted a reduction in medically necessary services could violate the CMP Law.

2. **The remuneration must not take into account the volume or value of, or condition the remuneration on, referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.** This safeguard addressed the OIG's concern with "swapping arrangements," including remuneration offered under the guise of a value-based arrangement when that remuneration is intended to induce referrals of patients or businesses not covered under the value-based arrangement.

3. **The remuneration must not be exchanged for the purpose of marketing items or services furnished by the VBE to patients or engaging in patient recruitment activities.**

4. **Some form of writing must be maintained (varies by safe harbor).** With limited exceptions (*e.g.*, the VBE's governing document), the final AKS rules permit the writing requirement to be satisfied by a collection of documents.

5. **At least six years of records and materials sufficient to establish compliance with the safe harbor must be made available to the Secretary upon request.**

In addition, both the care coordination safe harbor and substantial downside risk safe harbor prohibit limiting the VBE participant's ability to (1) make decisions in the best interest of its patients or (2) direct or restrict 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. Like CMS, the OIG included this requirement to ensure VBEs and their participants will maintain their independent medical judgment and preserve patients' freedom of choice.

The OIG elected not to finalize one proposed common requirement for the value-based safe harbors that would have prohibited remuneration funded by any individual or entity outside of the applicable VBE. Although the OIG noted that remuneration exchanged outside of a value-based arrangement would still not be protected by the safe harbors, the OIG did not seem to think that requirement would add to the program-integrity protections offered by the other requirements included in the final AKS rule. One notable exception is the patient engagement and support safe harbor, which still includes a variation of this requirement with carve-outs for certain "eligible agents."

Full Financial Risk Safe Harbor
(42 CFR § 1001.952(gg))

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. Like CMS, the OIG recognized VBEs that have assumed full financial risk present fewer traditional fee-for-service (FFS) fraud and abuse risks. As a result, this safe harbor includes more flexible conditions than the care coordination safe harbor, due in part to state laws that may limit providers and other healthcare entities from assuming full risk without licensure. The final AKS rules contemplate a VBE being at full financial risk for the cost of care of a target patient population if the VBE, either directly or through a VBE participant (other than a payor) acting on behalf of the VBE, is financially responsible on a prospective basis for the cost of all healthcare items and services covered by the applicable payor for each patient in the target patient population for at least one year. Unless the VBE participant is a payor, the VBE participant cannot claim payment in any form from the payor for items or services covered under the contract or value-based arrangement between the VBE and the payor.

To ensure accountability and transparency, the full financial risk safe harbor requires a signed agreement between the parties to the value-based arrangement setting forth the material terms, including the value-based activities and the term. Payors that do not wish to be part of the VBE can choose to enter into a contract with the VBE that is not a value-based arrangement for purpose of the VBE's assumption of full financial risk. Under this option, a payor would not be a VBE participant, and the written contract between the payor and the VBE would not be a value-based arrangement (*i.e.*, the payor would not be subject to the other conditions of this safe harbor). However, remuneration exchanged under this type of contract that is not a value-based arrangement would not be protected by the safe harbor. The parties would have to analyze the arrangement under the AKS without the benefit of the full financial risk safe harbor.

This safe harbor also protects arrangements between the VBE and VBE participants during the 12 months before the date that the VBE assumes full downside risk, provided the VBE has a contract or value-based arrangement with the payor during this phase-in period. 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 or services.

The remuneration must be directly connected to one or more of the VBE's value-based purposes and cannot include an ownership interest or any related ownership distributions. This standard is simpler and less onerous than the proposed version.

This safe harbor only applies to remuneration exchanged between a VBE and a VBE participant (excluding Ineligible Entities) according to a value-based arrangement. The OIG elected not to extend safe harbor protection to 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 requires the VBE to have a quality assurance program to protect against under-utilization and to assess the quality of care furnished to the target patient population.

Substantial Downside Risk Safe Harbor
(42 CFR § 1001.952(ff))

The substantial downside risk safe harbor addresses monetary and in-kind remuneration in the context of 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 another VBE participant acting on the VBE's behalf) must assume substantial downside risk from a payor for providing items and services for a target patient population.

Given the requirement the VBE assume risk from a payor, the OIG noted this safe harbor is unlikely to be available for an arrangement with a patient population comprised of Medicare FFS beneficiaries (outside of certain CMS Models and the Medicare Shared Savings Program). Similar to the full financial risk safe harbor, this safe harbor also protects arrangements between the VBE and VBE participants during a six-month phase-in period, which is notably different from the Stark exception for meaningful downside financial risk. The safe harbor includes specific definitions detailing what constitutes substantial downside financial risk, including any of the following:

- Shared savings with a repayment obligation to the payor of at least 30% of any shared losses;
- A repayment obligation to the payor under a defined clinical episode of care of at least 20% of any total loss covering more than one care setting; or
- A partially capitated methodology involving a prospective per-patient payment designed to produce material savings that is paid on a monthly, quarterly, or annual basis for a predefined subset of items and services furnished to a target patient population.

The final AKS rules reduce the originally proposed risk threshold required for shared savings and losses methodology from 40% to 30%. The AKS final rules also eliminate any risk threshold in the VBE partial capitation methodology given the capitated payments reflect the risk assumed by the VBE. The OIG noted this decision was in response to comments and based on further consideration of risk-assumption requirements used by CMS Models.

The substantial downside risk safe harbor protects remuneration from a VBE to a VBE participant (excluding Ineligible Entities) 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 either of the following:

- A two-sided risk pursuant to which the VBE participant is at risk for 5% of the losses and savings for which the VBE is at risk under its agreement with the applicable payor; or
- A partially capitated methodology involving a prospective per-patient payment on a monthly, quarterly, or annual basis for a predefined set of times and services furnished to the target patient population.

The proposed definition of substantial downside risk was modified in the final AKS rules to lower the two-sided risk thresholds from 8% to 5% and delete the proposed methodology applicable to physician payments that meet the requirements of the Stark Law's regulatory exception for value-based arrangements. The OIG also noted that participants in advanced payment models will not automatically qualify as having a meaningful share of a VBE's substantial downside risk and must meet the risk thresholds in the safe harbor.

Except for remuneration exchanged pursuant to assumption of risk, the remuneration must be directly connected to one or more of the VBE's value-based purposes, used predominantly to engage in value-based activities, and cannot include an ownership interest or any related ownership distributions. Additionally, the OIG reaffirmed the AKS substantial downside risk safe harbor does not protect downstream arrangements where remuneration passes from one VBE participant to another unless the risk-bearing VBE is a party to the arrangement. The OIG expressed concern for arrangements where the downstream provider bills on a traditional FFS basis without assuming risk.

Care Coordination Safe Harbor
(42 CFR § 1001.952(ee))

The care coordination safe harbor is intended to protect in-kind remuneration related to legitimate outcome or process measures, which the parties reasonably anticipate will advance the coordination and management of care of the target patient population. The outcome or process measures must relate to the remuneration exchanged and must be monitored and periodically assessed. The measures cannot be based solely on patient satisfaction or patient convenience, which the OIG was concerned are too subjective and uninformative. The OIG noted these safeguards ensure the measures 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—or collection of documents—executed in advance of or contemporaneously with the commencement of the arrangement (or any material change), which includes each of the following elements:

- The value-based activities to be undertaken by the parties and the value-based purposes of such activities provided for in the arrangement;
- The term of the arrangement;
- The target patient population;
- A description of the remuneration, including the offeror's cost or the fair market value of the remuneration;
- The percentage of such cost contributed by the recipient and (as applicable) the frequency of such contributions for ongoing costs; and
- The outcome or process measure(s) against which the recipient will be measured.

The care coordination safe harbor only protects in-kind remuneration predominantly 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 from acute care to skilled nursing care). Monetary remuneration is excluded; additionally, this safe harbor does not protect any 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 in-kind remuneration must pay at least either (1) 15% of the offeror's cost, or (2) the fair market value of the in-kind remuneration, including contributions at regular intervals for ongoing costs. Note that the proposed rule did not include the option to base remuneration on fair market value; the OIG added this in the final AKS rules to provide additional flexibility.

In addition to the common safeguards described above, the care coordination safe harbor 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 final AKS rules also add an additional requirement: remuneration exchanged may not be used more than incidentally by the recipient for billing or financial management services. Although typically considered an Ineligible Entity, certain DMEPOS or device manufacturers or suppliers that constitute limited technology participants may utilize this safe harbor. However, for arrangements with a limited technology participant, the remuneration must not be conditioned on exclusive or minimum purchases of any item or service manufactured or sold by the limited technology participant.

Like the value-based arrangements exception, the care coordination safe harbor also requires certain monitoring and assessment activities, including submission of annual reviews (or, at least once for arrangements with terms of less than one year) 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; and
3. Progress toward achieving the legitimate outcome or process measures in the valid outcome arrangement.

Depending on the outcome of the monitoring-and-assessment activities, the safe harbor requires one of the following within 60 days of an adverse determination by the VBE's accountable body: implementation of a corrective action plan designed to remedy the deficiencies within 120 days or termination of the arrangement if a corrective action plan fails to remedy the deficiencies within 120 days. The OIG revised these monitoring-and-assessment standards with updated timelines and procedures in response to concerns expressed by commenters and to provide more flexibility.

Other Value-Based Related Safe Harbors

The final AKS rules also include the following three additional value-based related safe harbors beyond those directly applicable to VBEs:

1. **Patient Engagement and Support Safe Harbor (42 CFR § 1001.952(hh)).** This 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 applies to in-kind patient engagement "tools or supports" furnished by a VBE participant to a patient in a target population of a value-based arrangement to which the VBE participant is a party. The patient engagement tool or support must also be recommended by the patient's licensed healthcare professional and advance at least one goal required by the safe harbor, which includes ensuring patient safety, adherence to a treatment or drug regimen or follow-up plan of care, or prevention or management of a disease or condition. The availability of a tool or support must also not be determined in a way that takes into account the patient's type of insurance coverage.

   The final AKS rules expand the safe harbor to apply to a VBE participant that provides patient engagement tools or supports directly or through a third party that qualifies as an "eligible agent." The OIG noted that examples of eligible agents could include employees and contractors of the VBE participant or other third parties such as technology vendors or retailers. Otherwise, the patient engagement tool or support cannot be funded or contributed by a VBE participant that is not a party to the applicable value-based arrangement; pharmaceutical manufacturers, DMEPOS suppliers, and laboratories are ineligible to furnish protected remuneration. However, the final AKS rules carve out from the list of Ineligible Entities manufacturers of devices and medical supplies that furnish patient engagement tools or supports in the form of digital heath technologies, recognizing the increasing role of digital health technology in improving care coordination.

   While the safe harbor places a $500 annual monetary cap on the aggregate resale value of the remuneration and continues to exclude cash or cash equivalents, the final AKS rules do not explicitly exclude all gift cards from protection under the safe harbor. The OIG noted that some gift cards could be considered

in-kind remuneration, including, for instance, a voucher for a particular tool or support, such as a meal or taxi voucher. Debit cards and rebate checks would not be included, as they would be considered cash equivalents. The OIG also modified the $500 annual monetary cap by clarifying the cap would be adjusted each year based on the Consumer Price Index.

The OIG did not finalize an illustrative list of in-kind items, tools, and services that qualify for safe harbor protection as proposed, fearing the list would inadvertently preclude types or categories of tools or supports that could qualify for safe harbor protection. So long as all other safe harbor requirements are met, the final AKS rules allow VBE participants greater flexibility to provide patients with a broad range of tools and supports, including, but certainly not limited to, items and services related to preventive care, health-related technology, patient health-related monitoring, or the identification of social determinants of health.

2. **CMS-Sponsored Innovative Payment Models Safe Harbor (42 CFR § 1001.952(ii)).** Unlike the final Stark rule, the OIG finalized a new AKS safe harbor to permit (1) remuneration between parties to arrangements under a model being tested or expanded by the CMS Innovation Center, and (2) incentives and supports provided by CMS Model participants to patients covered by the CMS Models. The OIG noted that safe harbor protection will not apply to every possible financial arrangement or incentive that CMS Model parties may wish to implement as they participate in the Medicare Shared Savings Program or another CMS Model, and CMS will determine the specific types of financial arrangements and incentives to which the safe harbor will apply.

   The goal of this safe harbor is to simplify the application of the AKS and CMP Law for CMS 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 is intended to be more flexible since CMS oversees and monitors its models and initiatives, which often have pre-embedded program integrity safeguards. For example, Ineligible Entities are not categorically excluded from relying on the safe harbor. However, this safe harbor does not extend to commercial and private insurance arrangements that may operate alongside, but outside of, a CMS Model, because CMS would not have the same level of oversight.

   The OIG noted CMS can determine whether the safe harbor will be available for arrangements or patient incentives under a given CMS Model. The safe harbor in the final AKS rules provides even greater deference than the proposed rule to the applicable model participation documentation, which often includes numerous requirements and restrictions. For example, while the finalized safe harbor requires that any patient incentive be directly connected to the patient's healthcare, the participation document may specify a different standard. Similarly, the final rules allow the participation document to identify an individual other than the CMS Model participant or its agent to furnish an incentive to a patient. This safe harbor also includes many of the standard safeguards incorporated into other aspects of the final AKS rules.

3. **Outcomes-Based Payment Safe Harbor (42 CFR § 1001.952(d)(2)-(3)).** The final AKS rules add an exclusion from the definition of remuneration for outcomes-based payments that meet the requirements of the safe harbor. Outcomes-based payments are payments between or among a principal and agent that reward the agent for successfully achieving an outcome measure, or allow the principal to recoup from or reduce the payment to an agent unable to achieve an outcome measure.

   To qualify for the outcomes-based payments safe harbor, the parties must satisfy numerous conditions, including several that mirror the personal services safe harbor's existing program integrity safeguards (*e.g.*, aggregate compensation methodology is set in advance, commercially reasonable, and consistent with fair market value, etc.). Uniquely, the agent must also satisfy one or more legitimate outcomes measures that (1) are selected based on clinical evidence or credible medical support, and (2) have benchmarks that quantify improvements in (or maintenance of improvements in) the quality of patient care and/or material reductions in costs to (or growth in expenditures of) *payors* while improving or maintaining quality care.

Notably, the OIG considered using the terms "evidence-based" and "valid" to describe the outcomes measures, but instead chose the terms "clinical evidence" and "legitimate" to create additional flexibility. It clarified that protections are not limited to a specific subset of value-based arrangements, and thus "parties have broad latitude under this safe harbor to identify opportunities for improving or maintaining the improvement of patient care and reducing costs to payors in ways that are scientifically valid, measurable, and transparent."

The final safe harbor does not require the parties to track outcome measures through claims data; instead, the parties must regularly monitor and assess the agent's performance, and periodically rebase—or assess and, as necessary, revise—benchmarks and remuneration to ensure consistency with fair market value. Moreover, the arrangement cannot limit any party's ability to act in the patients' best interest or induce any reduction of medically necessary items or services.

There are three categories of exclusions from the protection for outcomes-based payments:

1. **Payments made by Ineligible Entities (as defined in the VBE participant section above), such as pharmaceutical and medical device manufacturers, distributors or wholesalers, PBMs; laboratories, compounding pharmacies, and most DMEPOS suppliers.** These exclusions reflect concerns that Ineligible Entities, which rely heavily on provider prescriptions and referrals, potentially could use the safe harbor to market their products to providers and patients or divert patients from a more clinically appropriate option without regard to the medical appropriateness of the selection.

2. **Payments that relate solely to achieving internal cost savings for the principal.** The OIG expressed concerns that such payments may negatively affect the quality or safety of patient care; however, if structured properly, arrangements that compensate a provider for achieving cost savings could satisfy subsection (d)(1) of this safe harbor.

3. **Payments that are based solely on patient satisfaction or convenience scores.** While the OIG recognized these measures are relevant to assessing patient care, it concluded that, alone, these measures do not adequately shield against abusive or sham compensation arrangements.

Enabling Technology Infrastructure Improvements

OVERVIEW

In response to comments urging additional protections for transfers of information technology (IT), data, and cybersecurity tools, CMS and the OIG finalized new protections and modified previous guidance related to donations of cybersecurity technology and related services for electronic health records (EHR) arrangements. Both agencies recognized 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 increasingly relies on electronic data systems for storing, processing, and transmitting health information. Recognizing the importance of ensuring these critical data systems remain secure, both agencies acknowledged providers' increasing need for cyber-protection and the significant financial and legal impact of a data breach.

The CMS and OIG final rules establish a new Stark compensation exception and a new AKS safe harbor, respectively, protecting donations of cybersecurity technology and related services. The new exception and safe harbor exist alongside their corresponding EHR exception and safe harbor, though parties need only meet the requirements of one of the available exceptions or safe harbors, as applicable, to avoid noncompliance. Under both the exception and the safe harbor, cybersecurity-related donations may qualify as value-based arrangements to which the new value-based exceptions and safe harbors discussed above may apply.

Both the exception and safe harbor allow for the donation of *non-monetary* compensation, consisting of certain technology and services "necessary and used predominantly to implement, maintain, or reestablish cybersecurity." In the final rules, CMS and the OIG both prohibited any exchange of monetary remuneration or reimbursement for cybersecurity technology and services. In addition, while donated technology and services may include functions other than cybersecurity, CMS and the OIG emphasized that the core functionality of the technology and services must be implementing, maintaining, or reestablishing cybersecurity, and the cybersecurity use must predominate. Notably, neither CMS nor the OIG finalized a proposed "deeming provision," which would have allowed parties to demonstrate compliance with the "necessary and used predominantly" standard by showing the donation furthered compliance with a recipient's written cybersecurity program that reasonably conformed to a widely recognized cybersecurity framework or standards.

If the threshold necessary and used predominantly standard is satisfied, the new Stark exception applies if the following three conditions are met:

1. 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;
2. 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; and
3. The arrangement is documented in writing, which requires the parties to maintain documentation of the arrangement identifying the donation recipient, generally 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 original written documentation evidencing the donation of cybersecurity technology or services may incorporate the future provision of patches and updates, relieving the parties from developing additional documentation each time a patch or update is issued. Notably, there is no signature requirement, meaning the parties may use a compilation of documents to support the arrangement rather than a formal, executed contract.

The OIG's safe harbor largely mirrors CMS's cybersecurity technology and related services exception, with certain modifications. For example, the OIG requires a *signed writing* describing the technology provided and the recipient's contribution, if any. In contrast to the proposed safe harbor, the OIG's final rule permits this signed writing requirement to be satisfied through a "collection of documents" as opposed to a single, signed written agreement. The OIG's safe harbor also prohibits the donor from shifting the costs of the donated technology or services to any federal healthcare program.

Assuming the relevant standards are met, the rules could protect software used for malware prevention, network access control, business continuity, encryption, or email traffic filtering, as well as patches and updates. In addition, the protection could cover services associated with developing, installing, and updating cybersecurity software or services associated with managing and monitoring cybersecurity or responding to cyber-threats or attacks. Such services may be furnished directly by the donor or via third parties. However, neither the Stark exception nor the AKS safe harbor protect technology or services used predominantly in the normal course of a recipient's business, such as word processing programs, claims and billing applications, or general help desk services related to the use of a practice's IT.

With respect to finalizing these exceptions, it is also notable what CMS and the OIG opted *not* to finalize to facilitate the exchange of cybersecurity technology and related services and to maximize the healthcare industry's protection against cybersecurity threats. For example:

- While both CMS and the OIG initially proposed to exclude hardware donations or to create a narrow hardware exception that would have potentially imposed numerous conditions—including a cap on the value of the donated hardware, a financial contribution from the recipient, and/or performance of a risk assessment—the final rules do not adopt these conditions, instead permitting hardware donations if applicable requirements are satisfied. Accordingly, the CMS exception and OIG safe harbor could apply to encrypted servers, encrypted drives, and network appliances if the hardware is necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

- Neither agency imposed a monetary limit on the total amount of donations a donor can make to a recipient.

- Neither of the finalized rules limits the types of individuals and entities that may donate or receive cybersecurity donations. Thus, patients remain permissible donation recipients under the OIG's safe harbor, meaning that if the new safe harbor were satisfied, such donations would also qualify as an exception to the beneficiary inducement provision of the CMP Law.

- In contrast to the respective Stark exception and AKS safe harbor related to EHR, under the new cybersecurity exception and safe harbor, cost-sharing between the donor and recipient is optional. Donors may require recipients to contribute to the cost of the technology or services if they so choose. Both agencies caution, however, that if a donor gave a full suite of cybersecurity technology and related services to a high-referring practice at no cost but required a low-referring practice to contribute to the cost, then the donation could violate the condition set forth above prohibiting donors from accounting for the volume or value of a recipient's referrals.

Electronic Health Records Items and Services (42 CFR § 411.357(w) and 42 CFR § 1001.952(y))

CMS and the OIG also finalized revisions to the existing Stark EHR exception and AKS safe harbor, which protect the donation of interoperable EHR software or IT and training services. Although the agencies' initial proposals were largely aimed at reducing provider burden and facilitating more widespread adoption of EHR, both the exception and the safe harbor maintain their existing contribution provisions, which require all recipients, including small and rural physician organizations, to pay 15% of the donor's cost of the technology. CMS revised the timing of contribution payments, requiring physicians to pay the cost contribution amount *before* receiving an initial donation of EHR items and services or a donation of replacement items and services. In addition, for items or services donated after the initial or replacement donation, the cost contribution amount must be paid at "reasonable intervals." Except for slight differences in the contribution payment for updates to previously donated EHR, which the OIG no longer requires to be made in advance of receiving the update, the OIG's revisions to its EHR safe harbor were very similar to CMS's revisions to the Stark EHR exception.

Another important change is that both the EHR exception and safe harbor will now allow donations of replacement EHR technology. Donations of replacement items and services will be treated identically to new donations, meaning that arrangements for the donation of replacement EHR items and services must satisfy all applicable requirements, including the contribution requirement.

The final rules also eliminated the December 31, 2021 sunset provisions in both the Stark exception and AKS safe harbor. As a result, the Stark EHR exception and AKS EHR safe harbor are now permanent. To add flexibility, the OIG expanded the scope of protected donors under the EHR safe harbor to include individuals and entities providing services and submitting claims to a federal healthcare program, as well as entities comprised of individuals or entities providing services and submitting claims to a federal healthcare program, such as health systems or accountable care organizations.

CMS and the OIG also finalized several technical and clarifying edits to their respective EHR exception and safe harbor. For example, CMS's final rule clarifies that the EHR exception is, and has been, available to protect certain cybersecurity software and services, though CMS declined to expand the exception to additional services or hardware. CMS also removed language from the EHR exception that expressly prohibits information blocking (*i.e.*, limiting or restricting the use, compatibility, or interoperability with other EHR systems), in part because there are now other enforcement authorities better suited to addressing information blocking. Further, the final rule modifies the definition of "interoperable" to better align with the 21st Century Cures Act,[7] though CMS ultimately retained the existing definition for EHR. The OIG implemented similar clarifying revisions.

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,[8] the OIG finalized an exception to the definition of remuneration under the beneficiary inducements CMP Law for certain "telehealth technologies" furnished to end-stage renal disease (ESRD) patients receiving in-home dialysis covered under Medicare Part B. The OIG made several modifications to its proposed rule, including expanding the definition of telehealth technologies, adding physicians as protected donors, and eliminating several proposed conditions to more closely align the final rule with the statutory exception at 42 USC § 1320a-7a(i)(6)(J).

The OIG significantly broadened the definition of telehealth technologies to be "technology agnostic" and to include "hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for diagnosis, intervention, or ongoing care management." As

[7] 21st Century Cures Act of 2016, Pub. L. No. 114-25, § 4003(a), 130 Stat. 1033, 1165 (2016).
[8] Bipartisan Budget Act of 2018, Pub. L. No.115-123, § 50302(c), 132 Stat. 64, 191-92 (2018).

a result, many types of technology previously excluded under the proposed rule – such as telephones, fax machines, and electronic mail systems – are now permissible if the other exception requirements are met.

Compared to the proposed rule, the final rule imposes fewer restrictions on the donation of telehealth technologies to ESRD patients. Specifically, providers, physicians, or renal dialysis facilities must satisfy the following three conditions:

1. The provider, physician, or renal dialysis facility donating the technologies is either currently caring for the patient or has been selected or contacted by the patient to provide services;
2. The telehealth technologies are not offered as part of any advertisement or solicitation; and
3. The telehealth technologies are provided for furnishing telehealth services related to the individual's ESRD.

The OIG opted not to finalize a number of its proposed conditions, such as limiting the value of the telehealth technology and requiring providers, physicians, 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. The final rule also clarifies that the "telehealth services" furnished under the third condition above do not need to be reimbursable by Medicare.

Modernizing Stark and AKS: New Rules, Definitions and Clarifications

The goal of many of CMS's proposed changes to the Stark regulations was to clarify key terminology and increase flexibility with technical regulatory requirements. In large part, CMS adopted these proposals in the final rule. Although the new rules create additional flexibility and clarity, the Stark Law remains complex, and front-end contracting infrastructure remains important to ensure compliance.

The AKS final rules are aimed at modernizing several of its safe harbors and adding much-needed flexibility to broaden the range of conduct eligible for safe harbor protections.

STARK FINAL RULE: NEW DEFINITIONS, EXCEPTIONS, AND CLARIFICATIONS

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

CMS aimed to provide "bright-line" clarifications of three key terms, which are used throughout the regulatory text: "commercially reasonable," "volume or value," and "fair market value."

1. **Commercially Reasonable.** CMS adopted a hybrid of its proposed definition of commercially reasonable. Under the final rule, commercially reasonable means "the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties." CMS reiterated that the key question to ask when determining whether an arrangement is commercially reasonable is simply whether the arrangement makes sense as a means to accomplish the parties' goals. In addition, determining commercial reasonableness is not one of valuation. Overall, the new regulatory definition helps establish that economic losses do not automatically fail the commercially reasonability standard, but CMS stopped short of saying profitability should never be considered in evaluating commercial reasonability.

2. **Volume or Value.** Until now, CMS has not codified regulations defining the volume or value standard or the other business generated standard. In the final rule, CMS noted that the new special rules regarding the volume or value and other business generated standard supersede its previous guidance, including guidance with which they may be, or appear to be, inconsistent. CMS believes these special rules establish objective tests for determining whether compensation is determined in any manner that takes into account the volume or value of referrals or takes into account other business generated between parties to an arrangement.

   Under the final rule, compensation is only considered to take into account the volume or value of referrals or take into account the volume or value of other business generated when both the following are true:

   - The mathematical formula used to calculate the amount of compensation includes referrals or other business generated as a variable; and
   - The amount of the compensation correlates with the number or value of the physician's referrals to or the physician's generation of other business for the entity.

   The final rule provides specific language for compensation from an entity to a physician, as well as from a physician to an entity. With respect to employment arrangements and personal service agreements, CMS clarified in the preamble that a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services that are DHS are billed each time

the physician personally performs a service under the arrangement. CMS asserted that its position has not changed since the publication of Stark's Phase II rules. However, CMS declined to codify in the regulatory text wording that would directly address the controversial volume or value logic adopted by the court in the *U.S. ex rel. Drakeford v. Tuomey* case.[9]

The new definitions do not apply to the exceptions on medical staff incidental benefits, professional courtesy, community-wide health information systems, electronic prescribing items and services, EHR items and services, and cybersecurity technology and related services. The new definitions also do not apply to the special rules for unit-based compensation at § 411.354(d)(2) and (3), which continue to have their own tests for determining whether compensation takes into account the volume or value of referrals or of other business generated to assist. CMS and law enforcement in applying the policies in effect historically for compensation arrangements in place prior to these changes.

3. **Fair Market Value and General Market Value.** CMS finalized its proposal to eliminate the connection to the volume or value standard in the definitions of "fair market value" and "general market value." CMS believes an appropriate reading of the statutory language is that these concepts are distinct and must be individually satisfied. CMS also restructured the definition of fair market value to include a generally applicable definition, a definition applicable to the rental of equipment, and a definition applicable to the rental of office space. In finalizing its rules on general market value, CMS acknowledged that after reviewing comments from stakeholders, some of its proposals could have had an unintended limiting effect on the valuation community. Therefore, the finalized definition was modified to be consistent with general concepts and principles that exist in the valuation community.

   The generally applicable definition was modified slightly from the proposed text and is now finalized to mean "the value in an arm's-length transaction, consistent with the general market value of the subject transaction" without reference to "like parties and under like circumstances." CMS continues to believe that general market value is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties have with one another. CMS finalized the definition of general market value without reference to "volume or value" by providing specific regulatory language applicable to specific types of transactions: asset acquisitions, compensation for services, and the rental of equipment or office space. With respect to the purchase of an asset, general market value means "the price that an asset would bring on the date of acquisition of the asset as the result of *bona fide* bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other." With respect to compensation for services, general market value means "the compensation that would be paid at the time the parties enter into the service arrangement as the result of *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other." Finally, with respect to the rental of equipment or office space, general market value means "the price the rental property would bring at the time the parties enter into the rental arrangement as the result of *bona fide* bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other."

Narrowing the Designated Health Services Definition (42 CFR § 411.351)

CMS finalized its proposal to narrow the definition of "designated health services" such 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). CMS also extended this exclusion to hospital services furnished to inpatients that are paid under other prospective payment systems. Thus, in addition to the IPPS, this policy will also apply to the Inpatient Rehabilitation

[9] 792 F.3d 364 (4th Cir. 2015).

Facility Prospective Payment System (IRF PPS), the Inpatient Psychiatric Facility Prospective Payment System (IPF PPS), or the Long-Term Care Hospital Prospective Payment System (LTCH PPS). This policy will not extend to outpatient hospital services even though those services are also paid under a composite rate. CMS took the position that, for outpatient services, there is typically only one ordering physician, and it would be rare for a physician other than the ordering physician to refer an outpatient for additional hospital outpatient services that are compensated within the same ambulatory payment classification under the Hospital Outpatient Prospective Payment System.

Narrowing of the Indirect Compensation Arrangement Definition (42 CFR § 411.357(aa) and 42 CFR § 411.354(c))

In a departure from its proposal, CMS significantly narrowed the definition of "indirect compensation arrangement." This change will reduce the number of unbroken chains of financial relationships falling under the definition of an indirect compensation arrangement. Under the finalized rule, an indirect compensation arrangement only exists if the arrangement involves the physician receiving an individual unit of compensation that:

- Is not fair market value for the items or services provided;
- Includes the physician's referrals to the entity furnishing the DHS as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or
- Includes other business generated by the physician for the entity furnishing DHS as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity.

For purposes of this definition, a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases. The other conditions in the definition (such as the knowledge requirement) remain intact.

If an indirect compensation arrangement does exist, the arrangement can be protected, where applicable, by (1) the exception for indirect compensation arrangements, (2) the exception for risk sharing arrangements, if the entity with which the physician has an indirect compensation arrangement is an managed care organization or independent practice association, (3) a general exception at § 411.355 such as the in-office ancillary services exception, or (4) the newly established value-based arrangements exceptions.

Clarifying the Definition of Isolated Transaction (42 CFR § 411.351 and 42 CFR § 411.357(f))

CMS revised the definition of "isolated transaction" to reflect its view that the isolated transactions exception 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. In contrast, a one-time sale of property or physician practice is an example of a unique, singular transaction (with installment payments permitted in certain circumstances) that would fall under the scope of the isolated transactions exception. The final definition also includes the forgiveness of an amount owed: "An isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a *bona fide* dispute is not part of the compensation arrangement giving rise to the *bona fide* dispute." Thus, a settlement of a *bona fide* legal dispute is a separate compensation arrangement from any compensation arrangement between the parties giving rise to the dispute. The settlement of such a dispute does not retroactively bring the compensation arrangement that gave rise to the dispute into compliance with the Stark Law.

Narrowing the Ownership & Investment Interest Definition
(42 CFR § 411.354(b))

CMS finalized its proposal without modification to exclude titular ownership and any interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under Section 401(a) of the Internal Revenue Code from the list of items that are considered to be ownership or investment interests. Thus, a titular ownership interest that excludes the ability or right to receive the financial benefits of ownership or investment – including the distribution of profits, dividends, proceeds of the sale, or similar returns on investment – is not considered an ownership or investment interest. These changes should afford providers and suppliers with greater flexibility and certainty, especially in states where the corporate practice of medicine is prohibited.

Adding Flexibility: New Limited Remuneration Exception and Leeway to Remedy Stark Violations and Meet Writing and Signature Requirements
(42 CFR § 411.357(z), 42 CFR § 411.353(h) and 42 CFR § 411.354(e))

CMS finalized a new exception for limited remuneration to a physician at § 411.357(z), but with several modifications from the proposed regulatory text. First, the annual aggregate limit for remuneration to a physician was increased to $5,000 instead of the proposed limit of $3,500 (with annual adjustments for inflation). Second, the exception is available for payments to a physician to provide items or services through the physician's employees (or through *locums tenens* physicians), but not the physician's independent contractors. Third, the arrangement must be commercially reasonable even absent referrals made between the parties. Fourth, if remuneration is conditioned on the physician's referrals to a particular entity, the arrangement must comply with the requirements at § 411.357(d)(4) regarding patient choice. Finally, the per-click and percentage-based compensation provisions in the new rule apply only to timeshare arrangements for the use of premises or equipment.

CMS also clarified that the new limited remuneration exception is available to protect compensation arrangements involving the lease of office space or equipment from a physician.

With respect to other flexibilities to remedy Stark Law violations, CMS finalized a rule at § 411.353(h) that would provide parties a limited "grace period" of 90 days to reconcile payment discrepancies following the termination or expiration of a compensation arrangement. This assumes that the arrangement satisfied all requirements of an application exception during the duration of the arrangement after taking into account the reconciliation.

CMS finalized special rules on meeting the writing and signature requirements at § 411.354(e). Specifically, for exceptions that require a written arrangement, parties may obtain writings or signatures within 90 consecutive calendar days immediately following the date on which the compensation arrangement became non-compliant with the requirements of the applicable exception.

Modifications to the Set in Advance Requirement
(42 CFR § 411.354(d)(1))

Under the Stark Law special rules on compensation, compensation is deemed to be "set in advance" if the compensation is "set out in writing before the furnishing of items or services, office space, or equipment" and the formula for determining the compensation is set forth in sufficient detail so that it can be objectively verified. CMS codified its longstanding policy on modifying compensation during the course of an arrangement. The final rule specifies that compensation (or formula for determining the compensation) may be modified at any time during the course of a compensation arrangement if all of the following conditions are met:

- All requirements of an applicable exception in §§ 411.355 through 411.357 are met on the effective date of the modified compensation (or the formula for determining the modified compensation);
- The modified compensation (or the formula for determining the modified compensation) is determined before the furnishing of the related items, services, office space, or equipment; and

- Before furnishing the items, services, office space, or equipment, the formula for the modified compensation is set forth in a writing in sufficient detail so that it can be objectively verified.

Notably, CMS clarified that the 90-day grace period for the writing and signature requirements does not apply when parties are modifying compensation.

Updated Special Rules for Group Practices
(42 CFR § 411.352(i))

In an effort to eliminate potential barriers for participation by physicians in the delivery of value-based care and to clarify other components of the group practice rules, CMS finalized its proposal with respect to special rules for profit shares and productivity bonuses in a group practice. Although the rest of the regulatory changes in this final rule will be effective **January 1, 2021**, the changes related to group practice profit shares and productivity bonuses at § 411.352(i) will come into effect on **January 1, 2022**.[10]

In the final rule, CMS revised the concept of "overall profits" to mean the profits derived from *all the* DHS of any component of the group that consists of at least five physicians, which may include all the physicians in the group. CMS clarified that if there are fewer than five physicians in the group, overall profits means the profits derived from all the DHS of the group. Importantly, CMS reiterated that overall profits cannot be separated into separate categories of DHS; rather, the profits from all DHS of any component of the group must be aggregated before distribution.

As mentioned above, CMS finalized a new provision regarding the distribution of profits generated from a physician's participation in a VBE. Specifically, profits from DHS that are directly attributable to a physician's participation in a VBE may be distributed to such physician and will not be considered to directly relate to (or take into account) the volume or value of the physician's referrals.

CMS restructured and modified the regulatory text on productivity bonuses. Productivity bonuses may continue to be paid to physicians of a group based on services personally performed or services "incident to" such personally performed services provided that the bonus is not determined in a manner that is directly related to the volume or value of the physician's referrals. CMS revised the regulation to state that a productivity bonus will be deemed not to relate directly to the volume or value of a physician's referrals if it is based on the physician's total patient encounters or the relative value units personally performed by the physician. Additionally, CMS added a new provision that a productivity bonus will also not be deemed to relate directly to the volume or value of referrals if the services on which the productivity bonus is based are not DHS and would not be considered DHS if they were payable by Medicare.

Directed Referrals and Protecting Patient Rights
(42 CFR § 411.354(d)(4))

The existing Stark regulations permit certain compensation arrangements to include requirements that a physician refer patients to a particular provider, practitioner, or supplier, provided certain requirements are met including that the remuneration is set in advance, the requirement is set out in writing, and the arrangement includes wording preserving patient choice. The final rule continues to permit directed referrals with some modifications. The revised rules specify that (1) any changes to the compensation (or the formula determining compensation) must be made prospectively; (2) the compensation must be consistent with fair market value (eliminating language that the payment not take into account the volume or value of referrals); and (3) neither the existence of the compensation arrangement nor the amount of the compensation may be contingent on the number or value of the physician's referrals to a particular provider, practitioner or supplier. However, the

[10] CMS's rationale for the delay of the special rules at § 411.352(i) is its concern that the rules may require group practices that are relying on the current version of the regulations to adjust their compensation methodologies, and if so, they may not have sufficient time to do prior to the end of 2020.

arrangement may require the physician to refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner or supplier.

CMS *Does Not* Breathe Life into the Remuneration Unrelated to the Provision of DHS Exception (42 CFR § 411.357(g))

Based on concerns raised by commenters, CMS did not finalize any of its proposed revisions to the exception for remuneration unrelated to the provision of DHS. In its proposal, CMS had sought to bring utility to this exception by explaining when an item or service relates to the provision of patient care services. CMS only stated that it continues to evaluate the best way to restore utility to this exception and may finalize such a revision in future rulemakings.

CMS Decouples Stark, AKS and Federal and State Laws or Regulations Governing Billing or Claims Submission

Based on ongoing concerns with the burdens associated with the bootstrapping of the AKS to the Stark Law's exceptions, CMS finalized its proposal to remove the requirement that an arrangement not violate the AKS from all regulatory exceptions except for the fair market value compensation exception at § 411.357(l)(5). Specifically, CMS expressed concerned that if the requirement to comply with AKS was removed from the fair market value exception, certain abusive arrangements such as sham lease arrangements potentially could be protected since this exception does not contain the same detailed requirements found in other exceptions (*e.g.*, the statutory and regulatory exceptions for the rental of office space require, among other things, that the space rented or leased not exceed that which is reasonable or necessary for the legitimate purposes of the lease and is used exclusively by the lessee when in use).

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

CMS finalized its proposal to delete in their entirety the provisions setting forth the period of disallowance. The agency emphasized, however, that this action does not permit parties to a financial relationship to make referrals for DHS or to bill Medicare for the services when their financial relationship does not satisfy all requirements of an applicable exception. The analysis to determine when a financial relationship has ended is dependent in each case on the unique facts and circumstances of the financial relationship, including the operation of the financial relationship as negotiated between the parties. CMS believed this policy will encourage active, regular review of arrangements for compliance with the Stark Law.

Electronic Signatures (42 CFR § 411.354(e)(3))

CMS finalized a new provision that expressly permits the use of electronic or other signature that is valid under federal or state law to satisfy any signature requirement under such subpart.

Writing and Signature Requirements for Certain Physician Recruitment Arrangements (42 CFR § 411.357(e))

CMS clarified that when a physician practice receives no financial benefit under a recruitment arrangement, it is not necessary for a physician practice that hires a hospital-recruited physician to sign the writing documenting the recruitment arrangement, (*i.e.*, the recruited physician joins the physician practice but the hospital pays the recruitment remuneration to the physician directly, the physician practice receives the remuneration from the hospital but passes all the remuneration to the recruited physician, or the recruited physician joins the physician practice after the income guarantee period but before the physician's service repayment obligation is completed).

FINAL AKS RULE: NEW AND EXPANDED SAFE HARBORS

AKS Personal Services and Management Contracts (42 CFR § 1001.952(d)(1))

To add welcomed flexibility in creating *bona fide* business arrangements where parties provide legitimate services as-needed, the OIG finalized its proposal to remove the safe harbor's requirements for the agreement to specify the exact schedule of services; the precise length of each interval; and the charges for each interval if the services were going to be provided on a periodic, sporadic, or part-time basis. Next, as finalized, only the compensation methodology, rather than the aggregate compensation paid over the term of the agreement, must be set out in advance. These revisions bring this safe harbor more in line with the Stark personal service arrangements exception; and, once effective, will allow a number of common arrangements, such as medical director agreements paid on an hourly basis, to qualify for safe harbor protection. The OIG declined, however, to specify a particular compensation methodology, emphasizing that the legality of the arrangement would be determined based on a facts and circumstances analysis. The OIG also explained that the personal services and management contracts safe harbor does not specify a particular format for an agreement. Specifically, the OIG noted that the written agreement requirement can be met through (1) a single, formal signed agreement; or (2) through a collection of documents if it includes the required elements of the safe harbor and is signed by the parties.

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

While the current version of the AKS warranties safe harbor applies only to warranties for a single item, the final rules extend the safe harbor to cover bundled warranties for one or more items and related services. The OIG interpreted the revised definition of "warranty" to include warranties conditioned on clinical outcome guarantees. To meet this safe harbor, among other conditions, the bundled items and services must 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). The "same program/same payment" requirement protects against the risk of overutilization or cost-shifting that could result from bundling items and services that are reimbursed under different methodologies or payments. The revised safe harbor exempts beneficiaries from certain reporting requirements applicable to the buyer of the warrantied items or services.

The revised safe harbor adds protections against certain steering practices by prohibiting the conditioning of warranties on the exclusive use or minimum purchase of any items or services. Exclusivity and minimum-purchase requirements could lock buyers into a particular item that does not function as expected, and therefore, may not be in the patient's best interest to continue to use.

The safe harbor does not protect warranties covering only services; the OIG expressed concern that such warranties present a heightened risk of fraud and abuse because the determination of whether services meet the clinical outcome goals under the warranty are much more subjective for services than for items. The OIG also noted that the safe harbor protects only the warranty remedies, not the items or services being warrantied or any items or services used to determine whether a value-based outcome has been achieved. For example, a lab test confirming whether the warrantied outcomes have been achieved could still potentially, though not necessarily, implicate the AKS, depending on the facts and circumstances.

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 OIG finalized an extension of the mileage limit under this safe harbor for patients residing in rural areas from 50 miles to 75 miles. The OIG rejected commenters' suggestions to extend the distance to 150 miles, reasoning that such a limit would not be "local," nor would it adequately address the risk

of inducing beneficiaries to travel long distances to receive care they could have received locally. The OIG also found the bright-line rule easier to apply than other suggested approaches, such as using a standard based on patient need.

Regardless of whether the patient resides in an urban or rural area, the revised safe harbor also eliminates the mileage limit for patients being transferred to their residence (or another residence of the patient's choice) after being (1) discharged from an inpatient facility following inpatient admission, or (2) released from a hospital after being placed on observation status for at least 24 hours. A "residence" includes custodial care facilities such as long-term care facilities, homeless shelters, and the residence of friends and family caring for the beneficiary post-discharge. It does not include, however, transportation to another provider or facility because of the risk inherent in protecting transportation between healthcare providers in a position to refer to one another. This exemption from mileage limitations will not apply to patients discharged from an ambulatory surgery center or patients seen in an emergency department who were not under observation for at least 24 hours. The OIG clarified that transportation may be provided through ridesharing services or other means of local transportation that may be developed (*e.g.*, self-driving cars).

The OIG considered, but ultimately rejected, suggestions to generally expand the safe harbor to protect patient transportation for non-medical purposes related to improving and maintaining health (*e.g.*, transportation to grocery stores, gyms, or social services facilities). However, the OIG noted that non-medical transportation may be protected in the limited context of value-based arrangements under its new patient engagement and support safe harbor (see 42 CFR § 1001.952(hh), discussed more above) if such transportation directly connects to the coordination and management of care of the target patient population and meets the other conditions of the safe harbor.

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

In the final rules, the OIG also adopted regulatory language nearly identical to the statutory beneficiary incentive exception for accountable care organizations (ACOs).[11] The new safe harbor protects incentive payments to assigned beneficiaries made by an ACO under a CMS-approved beneficiary incentive program. For an incentive payment to satisfy this safe harbor, the payments must satisfy the requirements of Section 1899(m) of the SSA (42 U.S.C. § 1395jjj(m)), which governs incentive payments to beneficiaries for qualifying primary care services under the Medicare Shared Savings Program. Among the requirements, the qualifying primary care services must be furnished through an ACO by certain ACO professionals (*i.e.*, a primary care physician, physician assistant, nurse practitioner, or clinical nurse specialist), a federally qualified health center, or rural health clinic. The amount of the incentive payment must be the same for each beneficiary, and may not exceed $20 (or the maximum amount established by the Consumer Price Index) per qualifying service. The OIG clarified that requirements outside of this section, such as CMS regulations setting more detailed requirements for implementing an ACO Beneficiary Incentive Program,[12] do not need to be met in order to satisfy the new safe harbor; however, "it would be prudent for ACOs to review these regulations to ensure that their ACO Beneficiary Incentive Programs meet all applicable programmatic requirements." As an AKS safe harbor, incentive payments satisfying the proposed safe harbor would qualify as an exception under the beneficiary inducements provision of the CMP Law.

[11] 42 U.S.C. § 1320a-7b(b)(3)(K).
[12] See, e.g., 42 CFR §§ 425.304, 425.314.

AKS: Pharmaceutical Discounts and Pharmacy Benefit Manager Service Fees

OVERVIEW

With the stated goal of furthering transparency in drug pricing and lowering drug prices, the OIG issued a final rule amending the discount safe harbor at 42 CFR § 1001.952(h) to exclude from the safe harbor rebates from drug manufacturers to Medicare Part D (Part D) plan sponsors, including those offered through PBMs, and to add two new safe harbors related to drug reimbursement:

1. A safe harbor to protect point-of-sale reductions from a drug manufacturer to a Part D or Medicaid Managed Care Organization (Medicaid MCO); and

2. A safe harbor to protect drug manufacturer payments to PBMs for PBM services.

The OIG stated that such changes will increase transparency by allowing patients to choose drugs that minimize their out-of-pocket costs, providing Part D plans with more insight into PBM negotiations and increasing program integrity. In a change from the proposed rule, the effective date of the exclusion to the discount safe harbor has been pushed back from January 1, 2021, to **January 1, 2022**, in recognition of necessary changes to current industry practices to implement the new rules. Further, while the effective date of the new safe harbors was originally set as January 29, 2021, the effective date of these new safe harbors was delayed to **March 22, 2021** in a new rule issued by OIG.[13]

Discounts Safe Harbor
(42 CFR § 1001.952(h))

Generally, the AKS discount safe harbor at 42 CFR § 1001.952(h) protects discounts and rebates provided on items or services payable by federal healthcare programs if certain reporting requirements are met. The new changes categorically exclude rebates from drug manufacturers to Part D plan sponsors from allowable "discounts" under the safe harbor, except for such rebates required by law.

This new exclusion to the discount safe harbor applies only to Part D plans and the PBMs administering such plans. This is a change from the proposed rule exclusion, which also excluded rebates to Medicaid MCOs. Under the exclusion as finalized, rebates between drug manufacturers and Medicaid MCOs may continue to be protected under the discount safe harbor, including discounts and rebates to Medicaid MCOs that are contingent on formulary placement. Additionally, rebates for drugs payable under Medicare Part B continue to be protected under the discount safe harbor, if all safe harbor criteria are met.

In issuing the final rule, the OIG provided some insight into how other discount and rebate relationships between PBMs and drug manufacturers should be considered under the AKS. The OIG explained that a manufacturer "rebate" to a PBM that is retained by the PBM and not passed to the health plan is not, and has never been, covered by the discount safe harbor. The OIG also warned that "swapping arrangements" could violate the AKS. Swapping occurs if a discount is given on commercially insured products to induce referrals of products reimbursed by Part D. Also problematic are discounts given to a pharmacy owned by a Part D plan sponsor or PBM to induce referrals for federal healthcare program business from that sponsor or PBM.

The OIG also clarified that historically certain drug manufacturer rebates to Part D plans and other federal healthcare programs have been covered by the AKS discount safe harbor and may continue to meet other safe

[13] OIG Final Rule (scheduled to be published in the federal register on Feb 2, 2021) available at https://public-inspection.federalregister.gov/2021-02132.pdf.

harbors. Also, acknowledging that the new exclusion may preclude some value-based arrangements from meeting safe harbor protection where reductions in price cannot be provided at the point-of-sale (due to the use of data generated after the point of sale), the OIG reiterated that arrangements not fitting within a safe harbor do not necessarily violate the AKS.

Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products (42 CFR § 1001.952(cc))

The OIG implemented a new safe harbor for reductions on prescription pharmaceutical products that protects reductions in the price of pharmaceuticals offered by drug manufacturers and provided to Part D plan sponsors or Medicaid MCOs that are reflected at the point-of-sale. As such, rather than through rebates, drug manufacturers may issue price reductions through point-of-sale chargebacks to pharmacies or other mechanisms that allow the patient to receive a reduction in drug price at the time of dispensing. To utilize this safe harbor, the drug manufacturer and Part D plan sponsor, Medicaid MCO or PBM must ensure the following conditions are met:

- The reduction in price must be in writing and set out in advance of the first purchase that will reflect the reduced price;
- The full value of the reduction in price must be provided by the manufacturer to the dispensing pharmacy through point-of-sale chargebacks, unless provided as a rebate where required by law; and
- The reduction in price must be completely reflected in the price of the drug at dispensing.

In the final rule, point-of-sale chargebacks are defined as an amount "equal to the reduction in price agreed upon in writing between the plan sponsor under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product." This definition is intended to protect pharmacies from dispensing drugs at a loss due to gaming of the system by entities that fail to pass through reductions.

As required under the safe harbor, reductions in price must be reflected in full at the point-of-sale or, if earlier, at the pharmacy when patient cost-sharing amounts are determined. Any portion of the price reduction that is retained by the health plan sponsor or PBM will not be protected by the new safe harbor. Where a beneficiary is responsible for the entire amount under a deductible plan cost-sharing obligation, the beneficiary will pay the full discounted price of the drug, (*i.e.*, the drug's list price less the negotiated reduction in price). Accordingly, bundled arrangements where contingencies hinder application of the reduction at the point-of-sale will likely not qualify for safe harbor protection.

The OIG declined to define how this new point-of-sale chargeback system should be administered, saying that it wanted to provide industry stakeholders and parties flexibility to structure how the chargebacks will be implemented.

Another significant point of clarification provided within the final rule's commentary addressed drug manufacturer rebates offered to PBMs for formulary placement. In particular, many commenters focused on language in the proposed rule that "[r]ebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price." In the final rule, the OIG clarified that "reductions in price given to Part D plan sponsors or Medicaid MCOs that are conditioned on formulary placement of a particular drug can qualify for protection under the new safe harbor for point-of-sale reductions in price (and could have been protected for Part D plan sponsors under the discount safe harbor, and can continue to be protected under the discount safe harbor for Medicaid MCOs if all safe harbor conditions are met)." However, conditioning a reduction in price on a formulary not covering a competing drug would have to be reviewed on a case by case basis to determine permissibility.

Notwithstanding the acknowledgment that formulary placement could be negotiated as part of the protected point-of-sale price reductions, the OIG reiterated its concern about reductions in price tied to formulary placement that do not meet a safe harbor. For example, where PBMs request or demand price concessions that are contingent upon the PBM and manufacturer entering into an agreement for PBM service fees, these arrangements would not

be protected by the point-of-sale reduction in price safe harbor. Also, such arrangements would likely not fall within the protection of the new PBM service fee safe harbor as they could be considered a solicitation for remuneration.

PBM Service Fees
(42 CFR § 1001.952(dd))

The OIG also issued a new safe harbor for PBM service fees which protects fees paid by a drug manufacturer to a PBM for prescription benefit management services provided to the drug manufacturer related to the services the PBM provides to health plans. This safe harbor must meet all of the following requirements:

- The PBM and drug manufacturer must have a written agreement, signed by the parties, that covers all of the services the PBM provides to the manufacturer in connection with the PBM's arrangements with health plans and specifies each of the services to be provided by the PBM and the associated compensation for such services;
- Services must not involve counseling or promotion of a business arrangement or activity that would violate state or federal law;
- Compensation must be a fixed payment and not percentage-based;
- Compensation must be consistent with fair market value in an arm's length transaction and not be determined in a manner that takes into account the volume or value of referrals or federal program business generated; and
- The PBM must annually disclose to health plans the services rendered to drug manufacturers and disclose to the Secretary, upon request, the services rendered and associated fees.

The OIG declined to include a definition of "prescription benefit management services." Rather, in its commentary, the OIG provided a non-exhaustive list of services that may be considered prescription benefit management services, including contracting with a network of pharmacies; negotiating rebates and discount arrangements; developing and managing formularies, preferred drug lists and prior authorization programs; and controlling the costs of covered prescription drugs, among others. It is important to note that only services provided to drug manufacturers may be covered under the new PBM safe harbor and not services to the health plan. The services must be legitimate and cannot be duplicative of services the PBM provides to health plans for compensation.

As stated in the safe harbor, the PBM's compensation must be a fixed, flat fee, not based on a percentage of sales; and, it cannot be tied to volume or value of referrals. However, the OIG explained that per-unit-of-work fees may be allowed if they are fixed in advance, not based on the volume or value of federal healthcare business, and the unit-based compensation does not vary by volume during the course of the arrangement. For example, a payment of $x per unit of work could be protected by the safe harbor, but a payment of $x for the first 100 units of work and $x+1 for additional units would not be protected by the safe harbor.

Under the new safe harbor, PBMs must annually disclose to each health plan what services the PBM renders to manufacturers, and upon request, the PBM must disclose such services and the associated payment arrangement to the Secretary. The OIG acknowledged that when PBMs provide services to manufacturers for a fee, it can create tension between the PBM's obligations to the drug manufacturer and obligations to health plans. The OIG believes disclosure to health plans will increase transparency and help alleviate this tension.

Many commenters asked for clarification on whether payments by manufacturers to PBMs can be protected under the group purchasing organization (GPO) safe harbor. The OIG acknowledged that fees or rebates received by PBMs from drug manufacturers are not categorically excluded from protection under the GPO safe harbor. However, the OIG warned that safe harbor protection is available only if all elements of the safe harbor are met and specifically pointed out that meeting the GPO safe harbor requirements related to written agreements, disclosures, and no ownership of members would be potentially problematic for a PBM.

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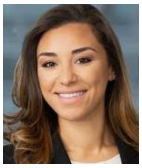

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