Health Care ADVISORY

November 25, 2020

CMS and OIG Significantly Update the Physician Self-Referral Law and Anti-Kickback Statute

The Department of Health and Human Services (HHS) released the text of a set of final rules on November 20, 2020, significantly updating the Physician Self-Referral Law (Stark Law), federal Anti-Kickback Statute (AKS), and civil monetary penalty (CMP) rules regarding beneficiary inducements. These changes come over a year after the Centers for Medicare & Medicaid Services (CMS) published the Stark Law Proposed Rule and the Office of Inspector General (OIG) published the AKS and CMP Proposed Rule, which we summarized in our Alston & Bird Health Care advisory here.

The CMS rule (the Stark Law final rule) and the OIG rule (the AKS and CMP final rule) are scheduled to be published in the *Federal Register* on December 2, 2020, and effective January 19, 2021, except for certain amendments to the Stark Law group practice requirements, which will take effect on January 1, 2022. This advisory focuses primarily on the changes in the final rules compared with the proposed rules. For more information on the background and proposed purposes of the rules, see our previous advisory.

THE STARK LAW FINAL RULE

Generally, the Stark Law prohibits a physician from making a referral to an entity for the furnishing of designated health services (DHS) if there is a financial relationship between the referring physician and the entity, absent an exception. In the Stark Law final rule, CMS finalized three new exceptions for certain value-based compensation arrangements between or among physicians, providers, and suppliers. It also includes several new rules and clarifications to existing Stark Law regulations, intended to address some of the more challenging aspects of Stark Law compliance.

Transition to Value-Based Care

New value-based care terminology

CMS finalized definitions for the following terms: value-based activity; value-based arrangement; value-based enterprise; value-based purpose; VBE participant; and target patient population. The definitions were finalized as proposed, aside from the following changes:

Value-Based Activity: In the proposed rule, CMS's definition of value-based activity stated that the making of a referral is *not* a value-based activity. Commentators expressed concern about this restriction, noting that the Stark regulations define a "referral" to includes the establishment of a plan of care that includes the provision of designated health services. In its final rule, CMS removed this restriction, noting that it was not their intention to exclude the development of a care plan that includes the furnishing of DHS from the definition of "value-based activity." However, CMS also revised the definition of "referral" to affirm its policy that, "as a general matter, referrals are not items or services for which a physician may be compensated under the physician self-referral law."

Value-Based Arrangement (VBA): CMS revised the language of its proposed definition by substituting "to which the only parties are" for "between or among" to make clear that all parties to the value-based arrangement must be VBE participants in the *same* value-based enterprise.

- CMS also noted that because the new VBA exceptions apply only to compensation arrangements, the VBA must be a compensation arrangement and not another type of financial relationship to which the Stark Law applies.
- In the proposed rule, CMS sought comment on whether to revise the definition of VBA to require care coordination and management in order to qualify as a VBA. However, the final definition does *not* require care coordination and management in order to qualify as a VBA.

Value-Based Enterprise (VBE): CMS finalized this definition as proposed, without modification. However, CMS clarified that a VBE may be a distinct legal entity (such as an ACO) or an informal affiliation, and may consist of only the two parties to a VBA. CMS noted that definition of VBE "is focused on the functions of the enterprise, as it is not our intention to dictate or limit the appropriate legal structures for qualifying as a value-based enterprise."

VBE Participant: CMS revised the language of its proposed definition by substituting "person" for "individual," citing the fact that the phrase "person or entity" is used more frequently throughout the Stark Law regulations. However, CMS noted that the word "entity" (as included in the definition of "VBE participant") is not limited to a DHS "entity" as defied at §411.351. CMS recognized that this could result in some confusion for stakeholders, and CMS may consider future revisions to replace the word "entity" throughout the Stark regulations in those instances where it is not intended to be limited to a DHS entity.

- The definition of "VBE participant" as finalized does *not* exclude any specific persons, entities, or organizations from potentially qualifying as a VBE participant. In the proposed rule, CMS indicated that it was considering whether to exclude laboratories, DMEPOS suppliers, and certain other providers/suppliers from the definition of "VBE participant," expressing concerns about compensation arrangements between physicians and these types of providers that may be intended to improperly influence or capture referrals without contributing to better coordination of care for patients. However, the agency was ultimately persuaded by comments that provided detailed examples of how laboratories and DMEPOS suppliers, in particular, contribute to value-based care. CMS noted that it "will continue to monitor the evolution of the value-based health care delivery and payment system to ensure that the inclusion of all types of providers and suppliers as VBE participants does not create a program integrity risk."

Value-Based Purpose: CMS finalized this definition as proposed, without modification. CMS initially sought comments on whether it would be desirable or necessary to codify what is meant by "coordinating and managing care," but ultimately did *not* finalize a definition of "coordinating and managing care."

Target Patient Population: CMS finalized this definition as proposed, without modification. CMS sought comments on whether to require patients in the target patient population have at least one chronic condition to align with OIG's proposals, but did not include this requirement.

New exceptions

VBAs (regardless of risk level): CMS added two additional requirements to its proposed exception that protects value-based activities, pursuant to any VBA, regardless of the level of risk involved:

- The arrangement must be "commercially reasonable" (in accordance with the newly finalized definitions discussed below).
- The parties must monitor whether they have furnished the value-based activities required under the arrangement and whether and how continuation of the value-based activities is expected to further the value-based purposes of the value-based enterprise.

VBAs with meaningful downside financial risk: This exception was published as proposed with one substantive change—CMS revised the definition of "meaningful downside financial risk" to mean that the physician is responsible to repay or forgo no less than ***10%*** of the total value of the remuneration the physician receives under the VBA (under the proposed rule this was set at 25%).

VBAs with full financial risk: This exception was published as proposed with one substantive change—instead of requiring the VBE to be at full financial risk within six months following the commencement of the VBA, CMS is giving VBEs *12 months* before requiring they be at full financial risk.

CMS noted that extending the "pre-risk period" to 12 months is consistent with the timeframe established in the Shared Savings Program pre-participation waiver, and, as with the Shared Savings Program preparticipation waiver, CMS does not believe that establishing a 12-month pre-risk period poses a risk of program or patient abuse.

Indirect Compensation Arrangements to which the Value-Based Exceptions Apply: To avoid a blanket prohibition on indirect compensation arrangements that enhance value-based health care delivery and payment, CMS finalized its proposal to make the VBA exceptions applicable to certain indirect compensation arrangements that include a VBA in the unbroken chain of financial relationships. Specifically, under the final rule, the VBA exceptions are available to protect the physician's referrals to the entity when an indirect compensation arrangement (as defined at §411.354(c)(4)(2)) includes a VBA to which the physician (or the physician organization in whose shoes the physician stands) is a direct party.

Other Changes to the Existing Stark Law Regulations

New definitions

CMS reiterated that the statutory and regulatory requirements regarding compensation arrangements that are (1) commercially reasonable; (2) determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by a physician; and (3) fair market value for items or services actually furnished are three separate and distinct requirements, each of which must be independently satisfied when required.

Commercially Reasonable: In the proposed rule, CMS sought to define "commercially reasonable," and ultimately finalized the following definition, combining parts of the two proposed definitions: "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 … even if it does not result in profit for one or more of the parties."

The Volume or Value Standard and the Other Business Generated Standard: CMS adopted the objective test that it proposed for determining whether compensation to/from a physician takes into account the volume or value of referrals or other business generated, with some revisions. CMS chose not to finalize proposed language that would have considered fixed-rate compensation for which there is a predetermined, direct correlation to the physician's prior referrals to implicate the volume or value standard, citing commenters who pointed out that the existing special rules for unit-based compensation essentially nullify this proposal. Instead, under the final rule, compensation is considered to take into account the volume or value of referrals (or other business generated) only if the formula used to calculate the compensation includes the physician's referrals (or other business generated) to the entity as a variable, resulting in an increase or decrease in the compensation that positively correlates with the number or value of the physician's referrals (or other business generated) to the entity (or negatively correlates, in the case of compensation paid by the physician). CMS noted that "[a]lthough our final regulations are "special rules" on compensation, we interpret them in the same manner as definitions." Put differently, CMS explained that "*[i]f the methodology used to determine the physician's compensation or the payment from the physician does not fall squarely within the defined circumstances, the compensation is not considered to take into account the volume or value of the physician's referrals or other business generated….*"

Patient Choice and Directed Referrals: Based on concern that the special rule on directed referrals (§411.354(d)(4)) may apply in fewer instances given the new volume or value standard, CMS finalized its proposal to include an affirmative requirement that the applicable compensation arrangement meet the conditions of the special rule for directed referrals, including in the new exception for limited remuneration to a physician. CMS also finalized its proposed addition to the directed referral requirements at §411.354(d)(4) that: "Regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician … neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier."

Fair Market Value: CMS finalized its proposal to revise its definition of "fair market value" to eliminate the connection to the volume or value standard. However, CMS did not finalize the proposed references to "like parties and under like circumstances" in the fair market value definition, resulting in a final definition of "the value in an arm's-length transaction, consistent with the general market value of the subject transaction." CMS emphasized that the "general market value of a transaction is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another." Also, for clarity, CMS finalized definitions of "general market value" specific to each of the types of transactions contemplated in the exceptions to the Stark Law—asset acquisition, compensation for services, and rental of equipment or office space.

Group practices

Interpretation of the "Volume or Value Standard" in the Group Practice Context: In its final rule, CMS affirmed that their interpretation of the terms "based on" and "related to" that remain in the regulatory text in §411.352(g) and (i) incorporate the volume or value standard. This means compensation to a physician who is a member of a group practice may not be determined in a manner that takes into account

the volume or value of referrals (except as otherwise provided in §411.352(i)), and the profit shares and productivity bonuses paid to a physician in the group may not be determined in any manner that takes into account the volume or value of the physician's referrals (unless the referrals are for "incident to" services)).

Special Rules for Profit Shares and Productivity Bonuses: *Note these final rule changes will become effective as January 1, 2022.*

CMS adopted its proposed rule for implementing the new VBE exceptions in the context of group practices, such that profits from DHS that are attributable to participation in a VBE will not be considered to directly take into account the volume or value of the physician's referrals. This allows greater flexibility for a group that desires to distribute VBE-related profits to its physicians.

CMS finalized its proposed updated definition of "overall profits" to mean "the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group." CMS clarified that a physician group practice may not distribute profits from designated health services on a service-by-service basis (i.e., a group practice is not permitted to distribute profits from one type of DHS to one subset of its physicians and distribute the profits from another type of DHS to a different subset of its physicians).

Additionally, under the revised §411.352(i)(1)(ii), if there are less than five physicians in the group practice, "overall profits" means "profits derived from all the designated health services of the group."

CMS finalized its proposal to remove Medicaid from the definition of "overall profits."

"Recalibrating" the scope and application of the regulations

AKS Cross-References: CMS did *not* finalize its proposal to remove the requirement that an arrangement not violate the AKS from the exception for fair market value compensation in §411.357(l)(5). CMS, in deciding to keep the reference to the AKS in-place as a safeguard, reasoned that the pliability offered by this exception is greater than overlapping exceptions (e.g., rental of office space and equipment rental), which could result in program abuse. However, CMS did finalize the removal of the requirement that arrangements not violate the AKS from several other exceptions included in its proposed rule.

Changes to Certain Definitions:

- Designated Health Services**:** CMS carved out services furnished by a hospital paid under certain prospective payment systems (PPS) from the definition of DHS. In other words, when a hospital service under the Acute Care Hospital Inpatient PPS, Inpatient Rehabilitation Facility PPS, Inpatient Psychiatric Facility PPS, or Long-Term Care Hospital PPS does not increase the amount of Medicare's payment to the hospital, they are not considered a "designated health service payable, in whole or in part, by Medicare."
- Remuneration: CMS finalized and updated the definition of "remuneration" to remove a parenthetical excepting surgical items, devices, or supplies from the carve-out to the definition of remuneration and added "in fact" to modify the same provision's "used solely" requirement.
- Isolated Financial Transaction**:** CMS, in addition to other modifications regarding bona fide disputes, finalized its proposal to clarify that the definition of an "isolated financial transaction" does not include a single payment for multiple services provided under an extended period."

Denial of Payment for Services Furnished Under a Prohibited Referral—Period of Disallowance:

- Period of Disallowance: CMS finalized its proposal to delete the sections detailing the period of disallowance in §411.353(c), reasoning that the attempt at a bright-line rule was impractical. CMS maintained that the notion in the CY 2008 PFS proposed rule stating that the period of disallowance should begin on the date the financial relationship ends or satisfies all the requirements of an applicable exception holds true.

- Special Rule for Reconciling Compensation: CMS also finalized a special rule under §411.353(h) to permit an entity to submit claims or bills for DHS and to permit payment to be made to the entity for the DHS if all payment discrepancies under the parties' otherwise compliant arrangement are rectified within 90 consecutive calendar days of the expiration or termination of the compensation arrangement, and post-rectification, the remuneration in its entirety has been paid according to the terms of the compensation arrangement.

Ownership or Investment Interests:

- Titular Ownership or Investment Interest**:** CMS finalized its proposed rule to update §411.354(b)(3)(vi) by including "titular ownership" in that provision's list of interests that are not considered ownership and investment interests. According to CMS, a titular ownership or investment is an interest that excludes the ability or right to receive the financial benefits of ownership and investment.

- Employee Stock Ownership Program**:** CMS finalized its proposed rule to update §411.354(b)(3)(vii) to include interests in an employee stock ownership plan ("ESOP") qualified under Internal Revenue Code 401(a) to the list of interests that are not considered ownership and investment interests. CMS reasoned that ESOPs are structured with particular safeguards under the Employee Retirement Income Security Act of 1974 (ERISA), which accordingly merits protection under the Stark Law.

Special Rules on Compensation Arrangements:

- Missing Signature/Writing: CMS finalized a proposed signature and writing-related rule designated at §411.354(e), which states that a writing or signature requirement is satisfied if: (1) the compensation arrangement satisfies all the requirements of an applicable exception other than the writing or signature requirement(s); and (2) the parties obtain the required writing or signature(s) within 90 consecutive calendar days immediately after the date on which the arrangement failed to satisfy the requirement(s) of the applicable exception.

- Modifications to Compensation: The newly codified §411.354(d)(1)(ii)) requires arrangements that are modified (or arrangements where the formula for determining compensation is modified) during the course of an arrangement to be set out in writing before the furnishing of items or services for which the modified compensation is to be paid. Notably, this finalized section does not allow the parties 90 days to reduce the compensation to writing.

- Electronic Signatures: Lastly, CMS codified at §411.354(e)(3) its policy that electronic signatures that are considered valid under federal and state law satisfy signature requirements for various Stark Law exceptions.

Exceptions for Rental of Office Space and Rental of Equipment: CMS finalized a rule to clarify its longstanding policy that a lessor (or any person or entity related to the lessor) is the only party that must be excluded from using the space or equipment under these sections.

Exception for Physician Recruitment: CMS finalized its proposal to modify the signature requirement at §411.357(e)(4)(i) to remove the requirement that a physician practice sign the writing documenting a recruitment arrangement if the practice does not retain any remuneration under the arrangement. Because the physician practice does not receive a financial benefit from the recruitment arrangement, CMS does not believe it is necessary for the physician practice to sign the writing.

Exception for Remuneration Unrelated to the Provision of Designated Health Services: CMS chose not to finalize proposed changes to the "Unrelated to DHS" exception. While commenters expressed support for increasing the utility of this exception, they also expressed concern that further definition and guidance would be needed to avoid increased risk of program or patient abuse. Given the need for additional review, this rule is not finalized at this time.

Exception for Payments by a Physician: CMS finalized its proposed rule changes related to the Payments by a Physician exception. CMS no longer believes that the exception should be limited by other regulatory exceptions but, instead, only limited to arrangements that are specifically excepted by other statutory exceptions. Under the final rule, parties would generally be able to rely on this exception to protect fair market value payments by a physician to an entity for items or services furnished by that entity, even if another regulatory exception may be applicable. The final exception does not apply to rental of office space or equipment arrangements but may be available to protect physician payments for the lease or use of space that is *not* office space (e.g. storage space, residential real estate). CMS further clarified that it does not believe pass-through arrangements (i.e., physician or an entity takes money from one party and passes the exact amount to another party) are financial arrangements subject to the Stark Law.

Exception for Fair Market Value Compensation: CMS finalized its proposal related to the Fair Market Value Compensation Exception with several modifications, including that the exception may be used for the lease of office space and not only for the use of office space; that it no longer requires that the arrangement not violate any federal or state law or regulation governing billing or claims submission; and that parties may rely on §411.357(z) [new exception for limited remuneration to physicians, discussed below] to protect an arrangement for the same items, services, office space, or equipment during the course of a year. CMS did *not* finalize the proposal to remove the requirement that the arrangement not violate the AKS; this requirement is retained in the final rule for this exception.

Electronic Health Records Items and Services: CMS finalized changes to the electronic health record (EHR) exception provisions, clarifying that cybersecurity software and service donations are permitted, removing the sunset provision, and modifying the definitions of "EHR" and "interoperable." CMS also modified the 15% physician contribution requirement (but did not eliminate it) and will allow certain donations of replacement technology. CMS chose not to finalize the proposed Information Blocking exception, stating that more recent authorities are better suited to enforce the prohibition against information blocking than a requirement of an exception to the Stark Law.

Exception for Assistance to Compensate a Nonphysician Practitioner: CMS finalized changes to this exception as proposed, and declined to expand the applicability of this exception to NPPs in additional practice specialties.

Other new exceptions to provide flexibility for nonabusive business practices

Through its administration of the SRDP and other stakeholder interaction, CMS identified certain nonabusive practices for which there is currently no applicable exception to the Stark Law. In response, CMS finalized two new exceptions that cover: (1) limited remuneration to a physician; and (2) nonmonetary cybersecurity technology and related services.

Limited Remuneration to a Physician: CMS finalized its proposed new exception at §411.357(z) for limited remuneration to a physician that does not exceed an aggregate of $5,000 per year (adjusted annually for inflation) regardless of whether the arrangement is in writing signed by the parties so long as certain other requirements are met. The exception may be used in succession with another applicable exception to protect an ongoing arrangement. All the requirements of the other applicable exception, including the set in advance requirement, would have to be met beginning on the date that the parties rely on the other exception, except that the parties would have up to 90 consecutive calendar days to document and sign the arrangement under §411.354(e)(4).

Cybersecurity Technology and Related Services: CMS's finalized rule includes a new exception to protect nonmonetary remuneration of cybersecurity technology and related services that are necessary and used predominantly to implement, maintain, and reestablish cybersecurity, as long as the agreement is in writing, the physician's eligibility is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties, and other requirements.

THE ANTIKICKBACK STATUTE AND BENEFICIARY INDUCEMENT FINAL RULE

The AKS prohibits offering, paying, soliciting, or receiving remuneration to induce or reward referrals or generate business that is reimbursable by a federal health care program.

The final rule modifies existing safe harbors to the AKS and adds new safe harbors and a new CMP exception to remove barriers to more effective coordination and management of patient care and delivery of value based care. The new safe harbors include protections for coordinated care and associated VBAs between clinicians, providers, suppliers, and others; donations of cybersecurity technology; and beneficiary incentives for certain telehealth technologies for in-home dialysis patients.

Safe Harbors for Value-Based Arrangements

As finalized, the OIG notes that the VBA Safe Harbors protect a "narrower universe" of arrangements than the CMS rules because the AKS is not a strict liability statute and the two laws have different objectives. They contemplate that some conduct may fall outside of the new safe harbors but still not violate the AKS. The OIG intentionally did not define "value" because they believe it is "not a one-size-fits all term … we believe industry stakeholders and those participating in value-based arrangements potentially protected by these safe harbors are best-positioned to determine value." However, like CMS's proposed Stark Law exceptions, the OIG's new AKS safe harbors operate in a tiered structure that is intended to provide greater flexibility to parties as they assume more downside financial risk.

The OIG chose not to expand the definition of a Value Based Enterprise (VBE) to include affiliates. The OIG considered, but did not implement, a prohibition on entities with common ownership from forming VBE. It also changed the proposed definition of VBE participant, which previously excluded certain entities, like pharmaceutical and device manufacturers. As finalized, these entities may participate in a VBE but generally cannot receive safe harbor protection, as discussed further below.

Care coordination arrangements

This safe harbor will protect in-kind remuneration exchanged between qualifying VBE participants under a VBA if the remuneration is intended to facilitate coordination and management of care to improve

quality, health outcomes, and efficiency. This safe harbor would *not* require parties to bear or assume downside financial risk.

OIG also made several changes from the proposed rule in implementing the final version, including:

- The proposed rule required VBEs to develop "specific, evidenced-based, valid outcome measures." OIG revised this to address concerns that this requirement was "overly restrictive." The final rule requires VBEs to develop "one or more legitimate outcome or process measures that the parties reasonably anticipate will advance the coordination and management of care for the target patient population based on clinical evidence or credible medical or health science support."
- The OIG added a requirement that value-based activities for which remuneration is used "can result in no more than incidental benefits to persons outside the target population."
- The final rule *removed* the proposed requirements that remuneration could not be funded by individuals or entities outside the VBE and that remuneration be provided directly from offeror to recipient
- The proposed rule said that recipient must pay at least 15% of offeror's cost. As finalized, the rule allows for the recipient to pay at least 15% of offeror's cost *or FMV*.
- The final rule does not include a proposed requirement that the VBA must have a direct connection to the coordination and management of care for target patient population, stating that this would be duplicative of other requirements.
- The final rule retains the requirement that the VBE assess its progress at least annually. But consistent with other changes, the OIG took out requirement that VBE assess its "progress toward achieving the evidence-based, valid outcome measure(s) in the value-based arrangement" to "progress toward achieving the legitimate outcome or process measures(s) in the value-based arrangement."
- While the proposed rule required termination if the VBE's accountable body or responsible person determined that VBA was unlikely to achieve the evidence-based, valid outcome measure(s), the final rule allows the VBE to cure problems through use of a corrective action plan.
- The final rule clarifies that VBEs must keep records for audit by OIG for *six years*.

Value-based arrangements with substantial downside financial risk

This safe harbor will protect both monetary and in-kind remuneration exchanged between a VBE that assumes substantial downside financial risk from a payor and a VBE participant that meaningfully shares in such risk pursuant to a VBA. By protecting both monetary and in-kind remuneration, this safe harbor offers greater flexibility than the safe harbor for care coordination arrangements in recognition of the VBE's assumption of substantial downside financial risk.

For a VBA to be protected under this safe harbor, a VBE must assume substantial downside financial risk from a payor under one of three methodologies, and a VBE participant must assume a meaningful share of the VBE's total risk under one of two methodologies. If applicable, the safe harbor protects both monetary and in-kind remuneration exchanged pursuant to VBAs between VBEs and VBE participants.

Various key conditions:

- Substantial Downside Financial Risk: The OIG reduced the risk threshold to 30%, revising how savings and losses must be calculated under different methodologies (e.g.. Episodic Payment Methodology, VBE Partial Capitation Methodology, etc.). With respect to Episodic Payment Methodology, the parties must design the clinical episode of care to cover items and services furnished collectively in more than one care setting. With respect to the revised VBE Partial Capitation Methodology, the new methodology provides that the VBE is at substantial downside financial risk if the VBE receives from the payor a prospective, per-patient payment that is: (1) designed to produce material savings; and (2) paid monthly, quarterly, or annually, for a predefined set of items and services furnished to the target patient population designed to approximate the expected total cost of expenditures for the predefined set of items and services. The OIG did not finalize the population-based payment methodology.
- Meaningful Share: The OIG revised the "meaningful share" methodologies, including:
    - Revising the first methodology of the "meaningful share" definition (the "Risk-Sharing Payment Methodology") to clarify that any risk assumed by a VBE participant pursuant to this methodology must be two-sided risk.
    - Lowering the risk threshold for the Risk-Sharing Payment Methodology from 8% to at least 5% of the losses and savings, as applicable, realized by the VBE pursuant to its assumption of substantial downside financial risk.
    - Revising the second methodology of the "meaningful share" definition to apply to prospective, per-patient payments for a predefined set of items and services furnished to the target patient population (the "Meaningful Share Partial Capitation Methodology").
    - Not finalizing the proposed methodology applicable to physician payments that meet the requirements of the Stark Law's regulatory exception for value-based arrangements with meaningful downside financial risk.
- Entities Ineligible for Safe Harbor Protection: The following entities may not exchange remuneration:
    - Pharmaceutical manufacturers, wholesalers, and distributors.
    - PBMs.
    - Laboratory companies.
    - Pharmacies that primarily compounded drugs or primarily dispense compounded drugs.
    - Manufacturers of devices or medical supplies.
    - Entities or individuals that manufacture, sell, or rent DMEPOS (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services, all of whom remain eligible).
    - Medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies.
- VBE's Assumption of Risk from a Payor: The safe harbor will provide two options to VBEs assuming substantial downside financial risk from a payor—a VBE can assume risk from the payor through an arrangement that meets the definition of "value-based arrangement," or a VBE can assume risk from a payor through a contract that places the VBE at substantial downside financial risk.

The VBE must also now be a distinct legal entity or represented by a VBE participant, other than a payor, that acts on the VBE's behalf.

- Remuneration Used to Engage in Value-Based Activities:
    - The safe harbor now requires the remuneration exchanged to be used *predominantly* (and not "primarily") to engage in value-based activities that are directly connected to the items and services for which the VBE has assumed (or has entered into a written contract or value-based arrangement to assume within the next 6 months) substantial downside financial risk.
    - Remuneration exchanged pursuant to a methodology for the assumption of risk does not need to meet this condition if the remuneration is part of a value-based arrangement that meets all other safe harbor conditions. That is, remuneration exchanged between either a VBE and a payor (as a VBE participant) pursuant to a methodology that meets the definition of "substantial downside financial risk," or between a VBE and a VBE participant (other than a payor) pursuant to a methodology that meets the definition of "meaningful share," need not be used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk.
    - Items and services to which the value-based activities must be directly connected are those for which the VBE has assumed (or has entered into a written contract or value-based arrangement to assume within the next 6 months) substantial downside financial risk (i.e. parties to a value-based arrangement may exchange remuneration during the phase-in period when the VBE has not yet assumed substantial downside financial risk but has entered into a written contract or value-based arrangement to assume such risk within the next 6 months).
- Direct Connection to Value-Based Purposes: The protected remuneration must be directly connected to at least one three defined value-based purposes.
- Reductions in Medically Necessary Items or Services: A value-based arrangement (not merely the remuneration exchanged) may not induce the VBE or VBE participants to reduce or limit medically necessary items or services furnished to any patient.
- Ownership or Investment Interests: This safe harbor will not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment interest.
- In Writing:
    - The parties must document the manner in which the VBE assumes risk from a payor and the VBE participant assumes a meaningful share of such risk (doesn't need to document offeror's costs).
    - The writing must be established in advance of, or contemporaneous with, the commencement of the value-based arrangement "and any material change," instead of "or any material change." The initial terms of the value based arrangement must be set forth in the signed writing, in advance of, or contemporaneous with the commencement of the arrangement, and any material change to the value-based arrangement also must be set forth in the signed writing in advance of, or contemporaneous with the commencement of the material change.

- This writing requirement does not apply to the contracts between a payor and a VBE in circumstances where the payor is not a VBE participant.

- Does Not Take into Account the Volume or Value of, or Condition Remuneration on, Business or Patients Not Covered Under the Value-Based Arrangement: The VBE or VBE participant offering the remuneration cannot take into account the volume or value of, or condition the remuneration on, referrals of patients outside of the target patient population or business not covered under the value-based arrangement.
- Preserve Clinical Decision Making: The value-based arrangement must not limit the VBE participant's ability to make decisions in the best interests of its patients at paragraph.
- Materials and Records**:** For a period of at least 6 years, the VBE or its VBE participants must maintain records and materials sufficient to establish compliance with the conditions of the safe harbor.
- Marketing of Items or Services or Patient Recruitment Activities**:** As with the care coordination arrangements safe harbor, rather than prohibiting all marketing and patient recruitment activities, the safe harbor prohibits the exchange of remuneration for the purpose of marketing items or services furnished by the VBE or VBE participants to patients or for the purpose of patient recruitment activities.
- Downstream Arrangements**:** The safe harbor protects only remuneration exchanged between a VBE and a VBE participant.

Value-based arrangements with full financial risk

This safe harbor will protect both monetary and in-kind remuneration exchanged between a VBE that assumes full financial risk from a payor and a VBE participant. This safe harbor does not require that the VBE participant "meaningfully share" in the VBE's downside risk. Because the VBE has assumed full financial risk, this proposed safe harbor imposes the fewest restrictions and allow a VBE the greatest flexibility with care coordination.

The definition of "full financial risk" now requires the VBE to be at risk on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least 1 year. "Prospective basis" means the VBE has assumed financial responsibility for the cost of all items and services covered by the applicable payor prior to the provision of items and services to patients in the target patient population.

Key provisions:

- Entities Ineligible for Safe Harbor Protection: For the full financial risk safe harbor, the following entities may not exchange remuneration:
    - Pharmaceutical manufacturers, wholesalers, and distributors.
    - PBMs.
    - Laboratory companies.
    - Pharmacies that primarily compound drugs or primarily dispense compounded drugs.
    - Manufacturers of devices or medical supplies.

- Entities or individuals that manufacture, sell, or rent DMEPOS (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services, all of whom remain eligible).
- Medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies.

- Methods to Assume Full Financial Risk from a Payor:
  - A VBE can assume risk from the payor through an arrangement that meets the definition of "value-based arrangement," or a VBE can assume risk from a payor through a contract that places the VBE at full financial risk. The first option for risk arrangements requires the payor to be a VBE participant, which is permitted under the final definition of "VBE participant." The payor (as a VBE participant) and the VBE can enter into a value-based arrangement for the VBE to assume full financial risk (remuneration exchanged pursuant to a payor's and a VBE's value-based arrangement could be protected by this safe harbor, including remuneration exchanged to implement the full financial risk methodology, if the value-based arrangement meets all applicable conditions of the safe harbor).
  - Under the second option, payors that do not wish to be part of the VBE may choose to enter into a written contract with the VBE that is not a value-based arrangement for the purposes of the VBE's assumption of full financial risk. Under this option, payors would not be VBE participants, the written contract between the payor and the VBE would not be a value-based arrangement, and the payor would not be subject to the other conditions of the safe harbor.
- Phase-in Period: The protected phase-in period for parties that have entered into a contract or a value-based arrangement to assume full financial risk was extended from the proposed six months to one year.
- Writing:
  - The writing requirement now states that the value-based arrangement must be set forth in writing (or a collection of them), signed by the parties, and specify all material terms, including the value-based activities and the term.
  - This writing requirement does not apply to contracts between a VBE and a payor that are not value-based arrangements.
- One-Year Minimum Term of Value-Based Arrangement**:** The term of the value-based arrangement must now be for a period of at least one year.
- Remuneration Used to Engage in Value-Based Activities**:** Remuneration exchanged must be used primarily to engage in the value-based activities set forth in the parties' signed writing.
- Direct Connection to Value-Based Purposes**:** The remuneration exchanged between the VBE and a VBE participant under this safe harbor must be connected to one or more defined value-based purposes.
- No Reduction in Medically Necessary Items or Services**:** The value-based arrangement (not merely the remuneration exchanged) must not induce the VBE or VBE participants to reduce or limit medically necessary items or services furnished to any patient.
- Taking into Account the Volume or Value of, or Conditioning Remuneration on, Business or Patients Not Covered Under the Value-Based Arrangement**:** The VBE or VBE participant offering

the remuneration cannot take into account the volume or value of, or condition the remuneration on, referrals of patients outside of the target patient population or business not covered under the value-based arrangement. This safeguard is identical to that included in the proposed care coordination arrangements and substantial downside financial risk safe harbors.

- Offer or Receipt of Ownership or Investment Interests**:** The full financial risk safe harbor will not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment interest.
- No Remuneration from Individuals or Entities Outside the Applicable VBE**:** While this proposed paragraph was not finalized, the OIG notes that remuneration exchanged outside of a value-based arrangement would not be protected by any of the value-based safe harbors.
- Utilization Review and Quality Assurance Programs**:** VBEs seeking protection under this safe harbor must provide or arrange for a quality assurance program for services furnished to the target patient population that: (1) protects against underutilization of items and services furnished to the target patient population; and (2) assesses the quality of care furnished to the target patient population.
- No Marketing of Items or Services or Patient Recruitment Activities**:** Rather than prohibiting all marketing and patient recruitment activities, the final rule prohibits the exchange or use of remuneration for the purpose of marketing items or services furnished by the VBE or VBE participants to patients or for the purpose of patient recruitment activities.
- Materials and Records**:** The final rule includes new language to specify that, for a period of at least 6 years, the VBE or its VBE participants must maintain materials and records sufficient to establish compliance with the conditions of the safe harbor.
- Downstream Arrangements**:** The exchange of remuneration must be between the VBE and a VBE participant. This safe harbor protection is not extended to remuneration that passes from one VBE participant to another VBE participant or a downstream contractor.
    - The concern here is that without the VBE as a party, where neither party has assumed full financial risk and may continue to bill the applicable payor on a fee-for-service-basis, there is a heightened concern about traditional FFS fraud and abuse risks.
    - Note: A VBE participant seeking to exchange remuneration with another VBE participant may look to the care coordination arrangements safe harbor or other safe harbors, such as the personal services and management contracts and outcomes-based payments safe harbor.

Arrangements for patient engagement and support to improve quality, health outcomes, and efficiency

The final rule creates a new patient engagement and support safe harbor at paragraph 1001.952(hh). Key provisions:

- Entities Ineligible for Safe Harbor Protection: The following entities are ineligible to use the safe harbor to furnish protected remuneration to patients:
    - Pharmaceutical manufacturers, wholesalers, and distributors.
    - PBMs.
    - Laboratory companies.

- Pharmacies that primarily compound drugs or primarily dispense compounded drugs.
- Manufacturers of devices or medical supplies (except with respect to digital health technology, as described below).
- Entities or individuals that sell or rent DMEPOS (other than a pharmacy, a medical device or supply manufacturer that also sells or rents DMEPOS, or a physician, provider, or other entity that primarily furnishes services, all of whom remain eligible).
- Medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies.
- Medical device manufacturers, distributors, or wholesalers with ownership or investment interests held by physicians. NOTE: The final rule permits manufacturers of devices and medical supplies to furnish patient engagement tools or supports that constitute digital health technology, as defined at paragraph 1001.952(ee)(14).

- Limitations on Recipients**:** Safe harbor protection is limited to tools and supports provided to patients in a target patient population. To qualify for safe harbor protection, a tool or support must be furnished by a VBE participant to a patient in the target patient population of a value-based arrangement to which the VBE participant is a party.
- Furnished Directly to the Patient**:** A tool or support must be furnished directly to the patient by a VBE participant. The final rule also extends safe harbor protection to a VBE participant that provides patient engagement tools or supports through a third party that qualifies as an "eligible agent," as defined in paragraph 1001.952(hh)(9).
- Funding Limitations:
  - The final regulation text states that the patient engagement tool or support must not be funded or contributed by a VBE participant that is not a party to the applicable value-based arrangement or by an entity listed at paragraph 1001.952(hh)(1)(i) through (viii).
  - The VBE participant must be a party to the "applicable valuebased arrangement." In other words, the patient receiving the tool or support must be a member of the target patient population of a VBA to which the VBE participant is a party.
  - The safe harbor does not protect any patient engagement tools and supports funded by or involving contributions from ineligible entities (identified at paragraph 1001.952(hh)(1)(i) through (viii)).
- Nature of Remuneration:
  - In-Kind Remuneration
    - The final rule protects patient engagement tools and supports that are in-kind items *only*, goods, and services provided they meet all applicable safe harbor conditions.
    - Provided that all safe harbor requirements are satisfied, the final rule protects a broad range of tools and supports that may include, among others, health-related technology, patient health-related monitoring tools and services, and supports and services designed to identify and address a patient's social determinants of health.
    - Preventive items, goods, or services can be protected under this safe harbor.

- Cash, cash equivalents, and most gift cards are excluded in the final rule because the safe harbor is limited to in-kind remuneration.
    - The final rule protects in-kind tools and supports that identify and address a patient's social determinants of health, provided that the tools and supports otherwise meet all applicable safe harbor conditions, including, among others, the $500 annual cap, the requirement for a direct connection to the coordination and management of the care of the target patient population, the requirement that the tool or support is recommended by the patient's licensed health care professional, and the requirement that the tool or support advances at least one of the enumerated goals to ensure that protected tools and supports have a close nexus to care coordination, quality of care, and health outcomes for patients.
- Health-related technology and patient health-related monitoring tools and supports can be protected remuneration if all safe harbor conditions are met, but these were not specifically enumerated in the final rule.

- Marketing and Patient Recruitment:
    - Neither the VBE participant, nor an eligible agent of the VBE participant, may use the patient engagement tools or supports to market other reimbursable items or services or for patient recruitment purposes.
    - The marketing prohibition only applies with respect to the marketing of items and services reimbursable by federal health care programs. Providing remuneration to patients in order to market items or services not reimbursable by federal health care programs is unlikely to implicate the AKS and therefore would not need safe harbor protection.
    - This condition does not preclude a VBE participant from educating patients, such as providing objective patient educational materials to a patient or engaging in objective patient informational activities with respect to patients in the target population.
- Direct Connection:
    - Any protected tool or support must have a "direct connection" to the coordination and management of care of the target patient population.
    - The phrase "direct connection" appears to mean that the VBE participant has a good faith expectation that the tool or support will further the coordination and management of care for the patient.
- Medical Necessity**:** The tool or support must not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a federal health care program.
- Licensed Health Care Professional Recommendation:
    - The tool or support must be recommended by the patient's licensed health care "professional" rather than "provider."
    - The term "professional" emphasizes the importance of a health care professional's medical judgment, as well as the patient's relationship with a health care professional.
    - The OIG did not finalize a written certification requirement.

- No Selection Based on Payor**:** The availability of patient engagement tools and supports cannot be determined in a manner that takes into account the type of insurance coverage of the patient.
- Monetary Cap:
    - Tools and supports protected under this safe harbor are subject to an annual cap of $500, with no exception for demonstrated financial need.
    - The final rule does contain an inflation adjuster.
- Materials and Records**:** Materials and records sufficient to establish compliance with the safe harbor must be made available to the Secretary and kept for a period of at least 6 years.

Other New Safe Harbors

CMS-sponsored model arrangements and CMS-sponsored model patient incentives

As envisioned by the proposed rule, the OIG implemented a new safe harbor to permit remuneration between and among parties to arrangements under certain models or other initiatives being tested or expanded by CMS. The final rule was promulgated with a few modifications, including clarification that financial arrangements and incentives qualifying for the safe harbor are subject to CMS approval.

Additionally, some arrangements not anticipated in the proposed rule may qualify for the safe harbor under the final rule if expressly specified in the participation documents. For example, if specified in the participation documents, incentives may be furnished by an individual other than the CMS-sponsored model participant or its agent or may be given under a standard other than a "direct connection to the patient's health care." The final rule also includes a paragraph specifying the timeframes for when the safe harbor protection begins and ends under different circumstances.

Cybersecurity technology and related services

The OIG implemented a new safe harbor to protect non-monetary donations of certain cybersecurity technology and related services to help strengthen the health care industry against the threat of cyberattacks. To qualify for safe harbor protection, the donations must, among other things, be "necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity." The parties must codify the terms of the donation in writing, such as the scope of the donation and the parties' responsibilities (including any contribution required by the recipient of the donation). The OIG made clear in the final rule that donors may not directly take into account the volume or value of referrals or other business generated between the parties or the amount or nature of the technology or services to be donated when determining the eligibility of a potential recipient for donated technology or services.

The OIG declined to include several requirements or limitations that it had considered in the proposed rule. For example, the OIG declined to include a monetary cap or a requirement that the recipient contribute to the overall cost of the donation. The OIG also chose not to limit or restrict the types of individuals or entities eligible to be donors or recipients and not to categorically exclude hardware from the safe harbor's protection (or to require a risk assessment for hardware donations). Additionally, the OIG decided not to include a "deeming" provision in the final cybersecurity rule.

Amended Safe Harbors

Electronic health records

As proposed, the OIG removed the EHR safe harbor's "sunset provision" (under which the safe harbor would have terminated at the end of 2021) and clarified that donations of certain cybersecurity technology and services (excluding hardware) have always been protected within the EHR safe harbor (separately from the new cybersecurity safe harbor). The OIG also updated the definition of "interoperable," including clarifying that certification by a certifying body authorized by ONC deems technology "interoperable," but is not necessary for the technology to be "interoperable." The OIG further expanded the scope of the safe harbor to protect additional entities as "donors." The OIG declined, however, to add an "information blocking" prohibition or to make any changes to the 15% contribution requirement or the definition of "electronic health information."

Finally, through the final rule, the OIG deleted two existing safe harbor elements. First, the OIG deleted a provision that prohibited donors from taking actions to restrict the use, compatibility, or interoperability of donated EHR items or services. Second, to allow for donations of replacement EHR technology, the OIG deleted a condition that prohibited the donation of equivalent items or services.

Personal services and management contracts and outcomes-based payments

In the final rule, the OIG finalized, without modification, its proposed changes to the Personal Services and Management Contracts safe harbor to increase flexibility for part time or sporadic arrangements and arrangements for which aggregate compensation is not known in advance.

The OIG also finalized new protection for outcomes-based payments with a few modifications. The OIG clarified that the protection is intended to be flexible and provided more clarification about situations that may qualify for protection under the safe harbor, such as types of payment arrangements and outcome measures that are likely to comply. The final rule includes a provision that the parties must periodically assess and revise benchmarks and remuneration to ensure compliance with the safe harbor. Moreover, the final rule requires arrangements for outcomes-based payments, including a general description of the types of services to be performed and the applicable outcome measures, be in writing. As proposed, the OIG excluded certain types of entities, such as pharmaceutical companies and PBMs, from the safe harbor's protection.

Warranties

The warranties safe harbor protects remuneration consisting of the payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a provider or beneficiary). The OIG proposed to modify the safe harbor to protect warranties for one or more items and related services (e.g., bundled items) upon certain conditions. This change expands the current warranties safe harbor, which only protects warranties offered on a single product. The OIG proposed several conditions necessary for bundled warranty arrangements to receive protection, including that all federally reimbursable items and services subject to bundled warranty arrangements must be reimbursed by the same federal health care program.

In the final rule, the OIG clarified that all bundled items in the warranty must be reimbursable in the same federal health care program payment, but that does not mean all the items and services must be reimbursable only in a single payment. Warranty remedies are capped at the total amount of the items under the warranty, which is a better remedy than previously where remedy was capped at only single

item covered by the warranty. The reason for having a limit is to prevent vendors from paying excessive remuneration to induce further federal health care business.

The OIG also finalized the definition of "warranty" instead of referencing 15 USC section 2301(6) to clarify that the warranties safe harbor applies to FDA-regulated drugs and devices whereas 15 USC section 2301(6) does not.

Local transportation

The OIG finalized its proposals to modify the local transportation safe harbor to: (1) expand the distance that residents of rural areas may be transported from 50 to 75 miles; and (2) remove any mileage limit on transportation of a patient from a health care facility from which the patient has been discharged to the patient's residence.

In the final rule, OIG clarified that mileage limits do not apply when the patient is discharged from an inpatient facility following inpatient admission *or released from a hospital after being placed in observation status for at least 24 hours*.

Other Notable Changes

Accountable care organization beneficiary incentive programs

The OIG adopted its proposal to codify Section 50341(b) of the Budget Act of 2018, which states that "illegal remuneration" under the AKS does not include "an incentive payment made to a Medicare fee-for-service beneficiary by an [accountable care organization (ACO)] under an ACO Beneficiary Incentive Program" if the payment is made in accordance with the requirements of the statute and conditions as established by the Secretary. The OIG's codification is nearly identical to the Budget Act's statutory language.

Beneficiary inducement CMP exception (telehealth for in-home dialysis)

The OIG proposed to codify a statutory exception to the beneficiary inducement statute that would exclude specific telehealth technologies related to in-home dialysis from the definition of "remuneration." The OIG proposed as a condition of this exception that a person must not bill federal health care programs, other payors, or individuals for the telehealth technologies, claim the value of the item or service as bad debt, or otherwise shift the cost of the telehealth technologies.

In the final rule, the OIG removed most of the additional proposed conditions and regulatory language that are not in the statutory exception. This resulted in several changes between the proposed and final versions:

- "Telehealth technologies" now has a broader definition and is now "technology" agnostic, meaning that it can be any technology that fulfills the necessary conditions: multimedia communications equipment, including audio and video equipment permitting two-way, real-time interactive communication with the patient.
- Includes any hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for the diagnosis, intervention, or ongoing care management.

- This definition differs from Medicare definitions because there is no definition in this statutory text (unlike Medicare, which has an explicit definition).
- The definition now includes broader forms of technologies that enable asynchronous communications between the patient and a distant site physician or practitioner, like Bluetooth-enabled stethoscopes and thermometers
- Additionally, the final rule includes physicians as a type of practitioner that can donate telehealth technologies to a patient.

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Alston & Bird has launched the **Digital Transformation of Health Care**, a new initiative that advances our commitment to an industry approach to providing legal services in the health care space. Our health care and technology teams can assist with establishing or significantly growing telehealth capabilities and navigating the regulatory landscape.

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