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Health Care ADVISORY ■

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CMS and OIG Release Proposed Rules on Stark Law and Anti-Kickback Statute Reforms

The Department of Health and Human Services (HHS) recently announced proposed changes to the regulations implementing the Physician Self-Referral Law (Stark Law), federal Anti-Kickback Statute (AKS), and Civil Monetary Penalty (CMP) Rules Regarding Beneficiary Inducements. These changes come from a pair of proposed rules issued by the Centers for Medicare & Medicaid Services (CMS) (Stark Law Proposed Rule) and the Office of Inspector General (OIG) (AKS and CMP Proposed Rule).

Although the Proposed Rules reflect a coordinated effort between CMS and OIG, the two agencies emphasize that the AKS and Stark Law are distinct and separate enforcement vehicles. Both agencies state that the AKS may act as a "backstop" to protect against arrangements that meet a Stark Law exception but are nonetheless considered potentially abusive.

These highly anticipated Proposed Rules are a part of HHS's Regulatory Sprint to Coordinated Care—an initiative launched in 2018 with the goal of promoting value-based care by reducing regulatory burdens on providers. CMS and OIG recognize that the AKS and Stark Law are often viewed as barriers to innovative care coordination arrangements, which often involve those in a position to refer federal health care program beneficiaries to each other. CMS and OIG solicited public input on how best to eliminate these barriers by issuing requests for information in June and August 2018. After collectively receiving 734 comments from various stakeholders, on October 9, 2019, CMS and OIG each issued a notice of proposed rulemaking. *The deadline for the submission of comments to CMS and OIG on the Proposed Rules is December 31, 2019*.

The Stark Law Proposed 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 Proposed Rule, CMS includes three new exceptions for certain value-based compensation arrangements between or among physicians, providers, and suppliers. It also includes a laundry list of new rules and clarifications to existing Stark Law regulations, which are intended to address some of the more challenging aspects of Stark Law compliance.

New Exceptions for Value-Based Compensation Arrangements

New terminology

The Proposed Rule attempts to define the universe of value-based arrangements (VBAs) through the use of new terms. The key new terminology includes:

- **Value-Based Arrangement (VBA):** A VBA is an arrangement for the provision of at least one value-based activity for a target patient population between or among (1) the value-based enterprise (VBE) and one or more of its VBE participants; or (2) VBE participants in the same VBE.
- **Value-Based Enterprise (VBE):** A VBE exists when there are two or more VBE participants (1) collaborating to achieve at least one value-based purpose; (2) each of which is a party to a VBA with the other or at least one other VBE participant in the VBE; (3) that have an accountable body or person responsible for oversight of the VBE; *and* (4) that have a governing document.
- **Value-Based Purpose:** A value-based purpose can be any of the following: (1) coordinating and managing care; (2) improving quality of care; (3) appropriately reducing the cost to payors without reducing the quality of care; or (4) transitioning from fee-for-service health care delivery and payment mechanisms to delivery and payment mechanisms based on the quality of care and control of costs.
- **Value-Based Activity:** The following activities are all value-based activities, provided the activity is reasonably designed to achieve a value-based purpose of the VBE: (1) providing an item or service; (2) taking an action; or (3) refraining from taking an action. CMS explicitly notes that making a referral is *not* a value-based activity.

VBAs (regardless of risk level)

This exception would protect remuneration for value-based activities, pursuant to any VBA, regardless of the level of risk involved. For this exception to apply:

- The arrangement must be in writing (including specific requirements to outline the arrangement).
- The performance/quality metrics used to measure the recipient, if any, must be objective and measurable.
- The remuneration methodology must be set in advance.
- The remuneration must be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
- The remuneration must not be an inducement to reduce or limit medically necessary care.
- The remuneration must not be conditioned on referrals of patients who are not part of the target patient population, and if remuneration is otherwise conditioned on referrals, the arrangement must satisfy the special rules on compensation.
- The records of the methodology for determining the amount of remuneration must be maintained for at least six years.

VBAs with meaningful downside financial risk

This exception would protect remuneration paid under a VBA so long as the arrangement is in writing (does not include specific requirements to outline the arrangement) and the physician is at "meaningful downside financial risk" for failure to achieve the value-based purpose(s) of the VBE during the duration of the VBA. A physician is at meaningful downside risk if he or she (1) is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the VBA; or (2) is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

CMS proposes conditions similar to those proposed for the VBA exception: (1) remuneration methodology must be set in advance; (2) remuneration must result from value-based activities; (3) restrictions on remuneration to induce reduction or limitation of medically necessary care; (4) requirements for consideration of volume or value of referrals; and (5) recordkeeping requirements.

VBAs with full financial risk

This exception would protect remuneration paid under a VBA between VBE participants if the VBE is at full financial risk (or is contractually obligated to be at full financial risk within the six months following the commencement of the VBA) during the entire duration of the VBA. A VBE is at "full financial risk" if the VBE is 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 period of time.

CMS proposes conditions similar to those proposed for the VBA exception: (1) remuneration must result from value-based activities; (2) restrictions on remuneration to induce reduction or limitation of medically necessary care; (3) requirements for consideration of volume or value of referrals; and (4) recordkeeping requirements.

Other Proposed Changes to Existing Stark Law Regulations

CMS also proposes several new rules and clarifications to existing Stark Law regulations that are intended to address some of the most challenging aspects of Stark Law compliance.

New definitions

- **Commercial Reasonableness:** CMS proposes two alternative definitions: (1) the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements; or (2) the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty. CMS reiterates that the key question of determining commercial reasonableness is whether the arrangement "makes sense" as a means to accomplish the parties' goals. CMS believes the determination is not one of valuation or profitability—the determination should be made from the perspective of the parties involved in the arrangement.
- **Fair Market Value and General Market Value:** CMS proposes to revise its definition of "fair market value" to eliminate the connection to the volume or value standard. CMS also proposes to establish a definition of "general market value" that is consistent with the recognized principle of "market" valuation to address the discrepancy that the current regulatory definition is likely at odds with general valuation principles.

- **Volume/Value Standard:** CMS proposed an objective test for determining whether compensation takes into account the volume or value of referral or other business generated. Under this test, compensation takes into account the volume or value only if the formula used to calculate the physician's compensation includes physicians' referrals to the entity or other business as a variable *or* there is a predetermined, direct correlation between the physician's previous referrals or other business generated and the prospective rate of compensation. CMS explicitly rejects any interpretation of *U.S. ex rel. Drakeford v. Tuomey Healthcare System Inc.*, 675 F.3d 394 (4th Cir. 2012), that would prohibit either employment arrangements or independent contractor arrangements where a portion of the compensation is based on work relative value units (wRVUs).

Group practices

CMS is proposing to make a conforming change to the group practice rule to ensure consistency with the new value-based rules. Specifically, profits from DHS that are attributable to participation in a VBE would not be considered to directly take into account the volume or value of the physician's referrals.

In addition, CMS proposes revisions to the profit-sharing rules to specify that a group practice may not distribute DHS profits on a service-by-service basis, but rather must allocate *all* DHS profits generated by a group of at least five physicians back to the applicable group.

Finally, CMS has proposed to remove a number of references to Medicaid throughout the group practice rule, given that the definition of DHS only includes services payable by Medicare.

New exceptions

CMS proposes to add a new exception for limited remuneration to a physician that does not exceed an aggregate of $3,500 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. CMS is proposing to protect nonmonetary remuneration of certain types of cybersecurity technology and related services. CMS proposes to include software or other type of information technology within the scope of covered technology. As an alternative, CMS proposes to permit the donation of certain cybersecurity hardware under certain circumstances.

CMS proposes to update electronic health record (EHR) exception provisions related to interoperability and data lock-in, clarify that cybersecurity software and service donations are permitted, remove the sunset provision, and modify definitions of "EHR" and "interoperable." CMS also proposes to modify the 15 percent physician contribution requirement and allow certain donations of replacement technology. CMS proposes a new rule that would create a 90-day grace period for the writing or signature requirement of any compensation exception if certain requirements are met.

New interpretations/clarifications

The proposed rule modifies the definition of designated health services (DHS) to clarify that an inpatient hospital service only constitutes DHS payable by Medicare if the furnishing of the service affects the amount of Medicare's payment to the hospital under the Inpatient Prospective Payment System (IPPS). This potentially avoids any DHS referrals by a consulting specialist who has a noncompliant financial relationship with a hospital.

CMS proposes that compensation would relate to DHS if the item or service relates to patient care services. This would be a significant expansion of this exception, which has historically been of limited utility.

Other notable changes

Under the proposed rule, lack of an AKS violation would no longer be an element of any Stark Law exception. CMS proposes to delete its current rules on the period of disallowance of payment, stating that, in practice, these rules have turned out to be "overly prescriptive and impractical." Instead, CMS proposes making determinations about when a financial relationship has ended on a case-by-case basis.

Seeking Comments

CMS requests comments on the role of price transparency in the context of the Stark Law and whether inclusion of a price transparency requirement in a value-based exception would provide additional patient protection.

CMS is considering whether to exclude from the VBA exceptions a compensation arrangement involving a: (1) pharmaceutical manufacturer; (2) durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) manufacturer, distributor, or supplier; (3) laboratory; (4) pharmacy benefits manager; (5) wholesaler; or (6) distributor. CMS seeks comment on the role these entities play in care coordination and value-based payment models. Specifically, CMS seeks information on how they may be important or necessary for care coordination and whether their role may raise undue risk of program or patient abuse.

CMS solicits comments on whether the proposal to exclude from the definition of DHS services that do not affect the amount of Medicare's payment to the hospital under an IPPS should be extended to analogous services provided by hospitals not paid under the IPPS. CMS also seeks comment on whether it should extend the proposal to outpatient hospital services or other categories of designated health.

The AKS and CMP Proposed 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 proposed rule is intended to modify existing safe harbors to the AKS and add 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 proposed 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 VBAs

The OIG proposes three new AKS safe harbors for certain remuneration exchanged between or among participants in a VBA. Like CMS's proposed Stark Law exceptions, these safe harbors operate in a tiered structure that offers greater flexibility to parties as they assume more downside financial risk.

The proposed rule attempts to define the universe of VBAs, and its definitions mostly parallel those proposed by CMS. The following are unique to the OIG's proposed rule:

- Unlike CMS, the OIG is affirmatively proposing to make certain entities ineligible from being VBE participants: pharmaceutical manufacturers; manufacturers, distributors, or suppliers of DMEPOS; and laboratories.

- Under the proposed rule, "coordination and management of care" means the deliberate organization of patient care activities and sharing of information between two or more VBE participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population. Several of the OIG's proposed safe harbors include a requirement that the remuneration has a direct connection to the coordination and management of care for the patient population.

Care coordination arrangements

This safe harbor would 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. To fit into this safe harbor, the following requirements would need to be met:

- The VBE must establish specific evidence-based, valid outcome measures against which the recipient of remuneration would be measured.
- The arrangement must be commercially reasonable.
- The arrangement must be in writing (including specific requirements to outline the arrangement).
- The VBA must have a direct connection to the coordination and management of care for the target patient population. The VBA could not limit the parties' ability to make decisions in the best interests of their patients. VBAs could not include marketing items or services to patients or patient recruitment activities.
- The remuneration provided must be in-kind only, and it must be used primarily to engage in value-based activities that are directly connected to the coordination and management of care of the target patient population.
- The remuneration cannot be funded by an individual or entity outside the VBE.
- The remuneration must not be an inducement to furnish medically unnecessary items or services or to reduce or limit medically necessary care.
- The offeror of the remuneration cannot consider the volume or value of, or condition an offer of remuneration on: (1) referrals of patients who are not part of the VBA's target patient population; or (2) business not covered under the VBA.
- The recipient must contribute at least 15 percent of the offeror's cost for the in-kind remuneration.
- The VBE must monitor and assess (at least annually) the coordination and management of care for the target population, deficiencies in the delivery of care, and progress toward achieving the evidence-based, valid outcomes measured in the VBA.
- The proposed safe harbor does not protect the exchange of remuneration if the offeror knows or should know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose.
- The VBE or VBE participants must make available to the Secretary of HHS all materials and records sufficient to establish compliance with the conditions of the safe harbor.

VBAs with substantial downside financial risk

This safe harbor would 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 would offer greater flexibility than the safe harbor for care coordination arrangements in recognition of the VBE's assumption of substantial downside financial risk. To qualify for this safe harbor, the following requirements must be met:

- The VBE has substantial downside financial risk. The OIG considers a VBE to be at "substantial downside financial risk" if there is: (1) shared savings with a repayment obligation to the payor of at least 40 percent of shared losses; (2) a repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss; (3) a prospectively paid population-based payment arrangement of at least 20 percent of any total loss; or (4) a partial capitated payment from the payor reflecting a discount of at least 60 percent of the total expected fee-for-service payment for the items and services.
- The VBE participant meaningfully shares in the risk. A VBE participant "meaningfully shares" in the substantial downside financial risk if the VBE participant assumes a certain percentage of the VBE's overall financial risk, is subject to a partial or full capitation payment or similar payment methodology, or, in the case of a physician, meets the proposed Stark Law exception for VBAs with meaningful downside financial risk described above.
- The remuneration for value-based activities must be used primarily 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.
- The remuneration exchanged must be directly connected to one or more of the VBE's value-based purposes, at least one of which must be the coordination and management of care for the target patient population.
- The remuneration is not an ownership or investment interest. This safe harbor would not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment interest.
- The remuneration cannot be funded by an individual or entity outside the VBE.
- The remuneration must not be an inducement to furnish medically unnecessary items or services or to reduce or limit medically necessary care.
- The OIG is proposing conditions similar to those proposed for the care coordination arrangements safe harbor regarding (1) writing; (2) consideration of volume or value of referrals; (3) limitations on VBE participants' ability to make decisions in the best interest of their patients; (4) marketing to patients; and (5) maintenance of documentation.

VBAs with full financial risk

This safe harbor would 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, which the OIG believes presents fewer traditional fee-for-service fraud and abuse risks, this proposed safe harbor would impose the fewest restrictions and allow a VBE the greatest flexibility with care coordination.

For the purposes of this safe harbor, a VBE assumes full financial risk if it is financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population and is prospectively

paid by the payor. The proposed rule would require that VBEs under this safe harbor not claim payment for any items or services covered under the VBA. The VBE must provide or arrange for an operational utilization review program and a quality assurance program that protects against underutilization and specifies patient goals.

The OIG is proposing conditions similar to those proposed for the care coordination arrangements safe harbor regarding (1) writing; (2) consideration of volume or value of referrals; (3) limitations on VBE participants' ability to make decisions in the best interest of their patients; (4) marketing to patients; and (5) maintenance of documentation.

Seeking comments

The OIG requests comments on elements of the VBAs, including whether:

- A VBE or its participants should be required to have a compliance program that covers at least those VBAs for which safe harbor protection is sought and whether the accountable body or person should have responsibility for the compliance program.
- The definition of "target patient population" should be limited to patients with a chronic condition or, alternatively, limiting any or all the proposed safe harbors that use the "target patient population" definition to VBAs for patients with a chronic condition.
- Some or all the entities excluded from the definition of "VBE participant" should be included in the definition of "VBE participant." Additionally, it seeks comments on whether there are other entities that should be excluded from the definition, such as all pharmacies or compounding pharmacies specifically, and on beneficial arrangements pharmacies may want to undertake under the new value-based framework and any safeguards that could be implemented if such entities were permitted to participate in VBAs.

Other Proposed Changes to Existing AKS Regulations

The OIG also proposes three other new safe harbors and additional changes to existing AKS regulations.

Arrangements for patient engagement and support

This safe harbor would protect certain arrangements for the provision of patient engagement tools and supports furnished by VBE participants to patients in a target patient population. To qualify for this safe harbor, the VBE participant must provide an in-kind preventive item, good, or service (such as health-related technology, patient-health-related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health). The item, good, or service must have a direct connection to the coordination and management of care of the target patient population. Under the proposed rule, the engagement tool or support must be recommended by the patient's licensed health care provider, and it must be provided directly by the VBE participant (not an outside provider). The aggregate retail value of tools and supports provided to a patient cannot exceed $500 per year, with certain limited exceptions.

Remuneration exchanged in CMS-sponsored models

This safe harbor would permit remuneration between and among parties to arrangements under a model or other initiative being tested or expanded by the Center for Medicare and Medicaid Innovation (CMMI) or under the Medicare Shared Savings Program (MSSP) and to permit remuneration in the form of incentives and supports provided by CMS model participants and their agents under a CMS-sponsored model to patients covered by the model.

Donation of cybersecurity technology and services

This safe harbor would protect donations of certain cybersecurity technology and related services with appropriate safeguards. The OIG intends this safe harbor to help improve the cybersecurity posture of the health care industry by removing barriers to allow parties to address the threat of cyberattacks.

Amended Safe Harbors

Electronic health records items and services

The OIG proposes to modify the existing safe harbor protection for donations of electronic health records (EHR) software by: (1) amending the requirements relating to interoperability; (2) clarifying that certain cybersecurity software and services have always been protected; (3) eliminating the sunset provision; (4) modifying certain definitions; and (5) deleting the condition that prohibits the donation of equivalent items or services to allow donations of replacement EHR technology. The OIG is also considering reducing or eliminating the 15 percent recipient contribution requirement.

Personal services and management contracts and outcomes-based payments

The OIG proposes to modify the personal services and management contracts safe harbor to: (1) substitute a requirement that the methodology for determining compensation be set in advance in place of the requirement that aggregate compensation under these agreements be set in advance; (2) eliminate the requirement that, if an agreement provides for the services of an agent on a periodic, sporadic, or part-time basis, the contract must specify the schedule, length, and exact charge for such intervals; (3) create a new provision to protect certain outcomes-based payments; and (4) make certain technical changes.

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 proposes to modify the safe harbor for items covered by warranties 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 and in the same payment. Additionally, the OIG proposes to amend the warranty exception to exclude beneficiaries from the reporting requirements applicable to buyers and to define "warranty" directly rather than by reference to 15 U.S.C. § 2301(6).

Local transportation

The OIG proposes 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. The OIG provides guidance on ride-sharing services without any proposed changes to the rules, noting that nothing in the safe harbor excludes them from protection.

Other Notable Changes

Accountable care organization beneficiary incentive programs

The OIG proposes 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, with two exceptions. First, the text of the proposed safe harbor would make it clear that an ACO may furnish incentives only to assigned beneficiaries. Second, the safe harbor language would change the statutory text from "if the payment is made" to "if the incentive payment is made."

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

The OIG proposes to codify a statutory exception to the beneficiary inducements CMP rule that would exclude specific telehealth technologies related to in-home dialysis from the definition of "remuneration." The OIG proposes 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.

Seeking Comments

In addition to the above proposals and comment solicitation on elements of the VBAs, the OIG requests comments on numerous other areas of the proposed rule. Alston & Bird frequently assists clients in submitting comments as well as bringing our clients' specific needs to the fore so that they get the right amount of attention.

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