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SIDLEY UPDATE

HHS Proposes Anti-Kickback Statute and Stark Law Reforms to Support Value-Based and Coordinated Care Arrangements

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On October 9, 2019, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS)(collectively, HHS) released a pair of proposed rulemakings that set forth changes under the Federal Anti-Kickback Statute (AKS), Civil Monetary Penalties Law (CMP) and Physician Self-Referral Law (the Stark Law) regulations to promote value-based and coordinated care arrangements. The proposed reforms are part of HHS's Regulatory Sprint to Coordinated Care, which launched in 2018 with the goal of removing regulatory obstacles to better-coordinated and value-based care, and address comments received in response to requests for information (RFI) issued by OIG in June and August 2018.

There are substantial technical requirements that must be satisfied for eligible participants to avail themselves of the protections under the newly proposed and modified safe harbors. Significantly, a number of the proposed reforms explicitly exclude protection for pharmaceutical manufacturers and manufacturers of durable medical equipment, prosthetics, orthotics or supplies (DMEPOS), laboratories, as well as other industry stakeholders that may have an interest in value-based arrangements or otherwise contributing to care coordination. The proposed rules are scheduled to appear in the *Federal Register* on October 17, 2019. Comments are due on December 31, 2019, 75 days after the date of publication.

Proposed AKS and CMP Reforms. The AKS and CMP reforms, available here, include several proposed new safe harbors, along with substantial amendments to a number of existing safe harbors, as described below.

New AKS Safe Harbors – OIG proposes to adopt the following new AKS safe harbors:

1. **Value-Based Arrangements**. OIG proposes to adopt three new safe harbors, each with substantial technical components, to protect remuneration exchanged between parties to a "value-based arrangement." The first of the safe harbors would protect certain forms of in-kind remuneration, including services and infrastructure, exchanged pursuant to care coordination arrangements that improve quality, health outcomes and efficiency. The second would apply to in-kind and monetary remuneration where the value-based arrangement involves substantial downside financial risk. The third would apply to in-kind and monetary value-based

arrangements involving full financial risk.

Importantly, these proposed "value-based arrangement" safe harbors would apply only to arrangements involving "value-based enterprise participants," which is defined to exclude "a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of durable medical equipment, prosthetics, orthotics, or supplies; or a laboratory." OIG also solicits comment on whether the definition should exclude pharmacy benefits managers (PBMs), pharmacies, wholesalers, distributors, pharmacies and "some or all" device manufacturers. Notably, OIG questions whether "traditional device manufacturers" have a role in care coordination and management. It also acknowledges the challenge of an overly broad definition of "device manufacturer," which could result in excluding devices or technologies that support care coordination by providing digital and remote monitoring.

2. **Patient Engagement Tools and Services**. OIG proposes to adopt a new safe harbor for in-kind "patient engagement tools or support" furnished by a so-called "VBE participant" to a patient within a target patient population. "Tools or support" is limited to in-kind, preventive items, goods or services, or items, goods or services such as health-related technology, patient-health-related monitoring tools and services, or supports and services designed to identify social determinants of health, that have a direct connection to coordination and management of care of the target patient population. As with the value-based arrangement safe harbors, the safe harbor for patient engagement tools would not apply to pharmaceutical and DMEPOS manufacturers, among others, given the narrowly drawn definition of "VBE participant."
3. **CMS-Sponsored Models**. OIG proposes to adopt a new safe harbor that would protect remuneration, including patient incentives or remuneration between parties, provided in connection with a CMS-sponsored model arrangement, which is defined to include 1115A models and the Medicare shared savings program. The objective for the proposed safe harbor is to standardize and simplify AKS and CMP compliance for participants in CMS-sponsored models which CMS has determined should have protection that would be afforded by the safe harbor.
4. **Donations of Cybersecurity Technology and Services**. To reduce potential cybersecurity threats, OIG proposes to adopt a new safe harbor that would protect the donation of nonmonetary remuneration in the form of cybersecurity technologies, limited to software or other types of information technology, used "predominantly to implement and maintain effective cybersecurity."
5. **Accountable Care Organization (ACO) Beneficiary Incentive Program**. OIG proposes to adopt a new safe harbor that would exclude from the definition of "remuneration" certain incentive payments made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program, provided that the incentive payment is made consistent with the applicable requirements of the statute establishing the Medicare Shared Savings Program.

Modifications to the Existing AKS Safe Harbors – OIG also proposes substantial amendments to the following existing AKS safe harbors:

1. **Electronic Health Records (EHR) and Services**. OIG proposes modifications to the existing

safe harbor for EHR items and services to add protections for certain cybersecurity-related technology, update provisions regarding interoperability and remove the existing sunset date (December 31, 2021) for the safe harbor. Notably, CMS proposed almost identical changes to the Stark Law EHR regulatory exception.

2. **Personal Services and Management Contracts**. OIG proposes several important reforms to add flexibility for outcomes-based payments and eliminate common compliance challenges under the current personal services and management contracts safe harbor. First, OIG proposes to eliminate the current element for aggregate compensation to be set in advance and to replace the requirement with a proposal that requires that the methodology for determining compensation be set in advance. Second, OIG proposes to eliminate the existing element that, if an agreement provides for 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.

   In addition, OIG proposes adding new provisions to protect certain outcomes-based payments. Importantly, the protection for outcomes-based payments includes a carve-out that would exclude any payments made, directly or indirectly, by a pharmaceutical manufacturer, a DMEPOS manufacturer, distributor or supplier, or a laboratory. OIG is also considering excluding device manufacturers, PBMs, wholesalers and distributors. Other elements under the current personal services safe harbor would continue to apply.

3. **Warranties**. OIG proposes substantial revisions to the AKS safe harbor for warranties, possibly signaling that the agency considers this safe harbor to be a potentially appropriate one for certain value-based arrangements, as alluded to in prior OIG advisory opinions. Among other changes, OIG proposes to modify the safe harbor to expressly protect warranties for a bundle of "items and services," to allow manufacturers and suppliers "to warrant that certain services, in combination with one or more items, will result in a specified level of performance." OIG also clarifies that, where a warranty applies to multiple items and related services, the federally reimbursable items and services subject to the warranty must be reimbursed by the same federal health care program "and in the same Federal health care program payment." Further, a warranty must not be conditioned on a buyer's exclusive use of or minimum purchase of any items or services.

   OIG also proposes to exclude beneficiaries from the reporting requirements applicable to buyers and to adopt a revised definition of "warranty" that turns, in part, on whether an item or bundle of items "fails to meet the specifications set forth in [a written] undertaking" or "meet a specified level of performance over a specified period of time." OIG clarifies these provisions "provide protection for warranty arrangements conditioned on clinical outcome guarantees," provided the arrangement meets all other elements of the safe harbor.

4. **Local Transportation**. OIG proposes to modify the existing safe harbor for local transportation to expand the distance which residents of rural areas may be transported and to remove any mileage limit on transportation of a patient from a healthcare facility from which the patient has been discharged to the patient's residence. OIG is also soliciting comments on whether the safe harbor could be expanded to foster innovative arrangements that are likely to improve health outcomes and involve transportation for purposes other than to obtain

medically necessary items or services.

Modification to Existing CMP Safe Harbors – OIG also proposes to amend the CMP regulations to create a safe harbor to reflect a new statutory exception to the prohibition on beneficiary inducements for the provision of certain telehealth technologies related to in-home dialysis services.

Proposed Stark Law Reforms. The Stark Law reforms, available here, include new exceptions for value-based arrangements and provide new guidance and clarifications on several key requirements under the Stark Law for physicians and healthcare providers. These proposals include the following additions and clarifications, among others:

1. **Value-Based Arrangements**. CMS proposes to adopt three new exceptions for "value-based arrangements" that satisfy specified requirements, based on the characteristics of the arrangement and the level of financial risk undertaken by the parties. The proposals include exceptions for value-based arrangements that involve: (i) "full financial risk"; (ii) meaningful downside financial risk to the physician; and (iii) any level of risk undertaken by the participants. As with the proposed AKS safe harbors, these proposed "value-based arrangement" exceptions would apply only to arrangements with a value-based purpose involving "value-based enterprise participants." CMS solicits comment on whether the definition should exclude laboratories, DMEPOS suppliers, pharmaceutical manufacturers, PBMs, wholesalers, distributors, pharmacies and device manufacturers. CMS also seeks comment on whether the value-based arrangements exceptions should include a price transparency element to encourage active participation of patients in selecting their healthcare providers and suppliers.
2. **Clarifications Addressing Commercial Reasonableness, Fair Market Value and When an Arrangement Takes into Account the Volume or Value of Referrals**. CMS acknowledges that many of the Stark Law statutory and regulatory exceptions include one, two or all of the following requirements: the compensation arrangement itself is commercially reasonable, the amount of the compensation is fair market value and the compensation paid under the arrangement is not determined in a manner that takes into the account or volume or value of referrals.

   CMS proposes to define "commercially reasonable," which is not currently defined, to mean that an arrangement "furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements," or, alternatively, that an 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 also undertook a fresh review of the statutory definition of "fair market value" and the structure of the existing exceptions and now proposes to define "fair market value," in part, as "the value in an arm's-length transaction, with like parties and under like circumstances, of like assets or services, consistent with the general market value of the subject transaction." "General market value" would be defined, in part, as the price that assets would bring as a result of bona fide bargaining. CMS also proposes to establish new, bright-line standards to identify when an arrangement "take[s] into account the volume or value of referrals." Specifically, compensation from an entity to a physician (or immediate family member) takes into account the volume or value of referrals only if the

formula used to calculate the compensation includes the physician's referrals 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 referrals to the entity. The converse would be true for compensation from a physician (or immediate family member) to an entity.

3. **Limited Remuneration to a Physician**. CMS proposes to adopt a new exception to protect remuneration that is unlikely to cause overutilization or similar harm to the Medicare program. Specifically, CMS proposes a new exception for remuneration from an entity to a physician for the provision of items or services by the physician to the entity that does not exceed $3,500 per calendar year, provided that the compensation does not take into account the volume or value of referrals between the parties and does not exceed fair market value, and the arrangement between the parties is commercially reasonable. Additional requirements would apply for compensation for the lease of office space or equipment.
4. **EHR Items and Services**. CMS proposes modifications to the existing exception for EHR items and services that mirrors the proposed changes to the AKS safe harbor regulations.
5. **Cybersecurity Technology and Related Services**. CMS proposes to adopt a new exception that closely mirrors a similar AKS safe harbor to protect nonmonetary remuneration in the form of cybersecurity technologies, limited to software or other types of information technology, used "predominantly to implement and maintain effective cybersecurity."

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