

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

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On November 20, 2020, 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 final 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 as well as reduce other unnecessary regulatory burdens. The 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 proposed rules issued by HHS on October 9, 2019.

In the final AKS rule, OIG largely adopted its proposal to deem the following entities ineligible for protection under the new value-based and outcomes arrangements safe harbors: (1) pharmaceutical manufacturers, distributors, and wholesalers, (2) manufacturers of devices or medical supplies, (3) medical device distributors and wholesalers that are not otherwise a manufacturer of a device or medical supplies, (4) entities that sell or rent durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), (5) pharmacy benefit managers (PBMs), and (6) certain other industry stakeholders that may have an interest in value-based arrangements or otherwise contributing to care coordination (referred to collectively here as Ineligible Entities). Notwithstanding this, the new AKS safe harbor for care coordination arrangements nevertheless protects certain digital technology arrangements and is available to manufacturers of devices or medical supplies and DMEPOS companies. In contrast, the Stark Law final rule does not exclude any individuals or entities from qualifying for the new exceptions available for value-based arrangements.

Despite HHS's goals, the rules finalize substantial technical requirements that must be satisfied for eligible participants to avail themselves of the protections under the new and modified safe harbors and exceptions, which could limit their potential applicability.

The final rules go into effect 60 days after the date of publication in the *Federal Register* (publication is scheduled for December 2).

**AKS and CMP Reforms.** The AKS and CMP reforms, available [here](#), include finalization of seven proposed new safe harbors along with substantial amendments to four existing safe harbors and a new exception under the Beneficiary Inducements CMP. Note that failure to satisfy a statutory exception or safe harbor does not render an arrangement violative of the AKS. Rather, whether a violation has occurred depends on the facts and circumstances of the particular arrangement.

*New AKS Safe Harbors* – OIG finalized its proposal to adopt the following new AKS safe harbors.

1. **Value-Based Arrangements.** OIG finalized with limited modifications three new safe harbors, each with substantial technical components, to protect remuneration exchanged between parties to a value-based enterprise (VBE). The first new safe harbor protects 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 new safe harbor protects in-kind and monetary remuneration where the value-based arrangement involves substantial downside financial risk. The third new safe harbor protects in-kind and monetary value-based arrangements involving full financial risk. With limited exception, Ineligible Entities cannot obtain protection under the three new value-based arrangements safe harbors. There is a limited exception for certain technology companies, which may include manufacturers of medical devices and supplies and DMEPOS companies, who are eligible for protection only under the first new safe harbor for care coordination arrangements that involve digital health technology, for instance, remote monitoring, telehealth and other communications, and software and applications that support services to coordinate patient care.
2. **Patient Engagement Tools and Support.** OIG finalized with limited modification a new safe harbor that protects any patient engagement tool or support furnished by a VBE participant to a patient in the target patient population of the value-based arrangement to which the VBE participant is a party. Ineligible Entities generally cannot obtain protection under this safe harbor, with the limited exception of certain manufacturers of medical devices and supplies (but not DMEPOS companies) with respect to digital health technology.
3. **CMS-Sponsored Models.** OIG finalized its proposal to adopt a new safe harbor that protects patient incentives or remuneration between parties where provided between or among “CMS-sponsored model” parties under a “CMS-sponsored model arrangement” for which CMS has determined that this safe harbor is available. A “CMS-sponsored model” refers to a model being tested or expanded under the Social Security Act. A “CMS-sponsored arrangement” refers to a financial arrangement between or among CMS-sponsored model parties to engage in activities under the CMS-sponsored model.
4. **Donations of Cybersecurity Technology and Services.** To reduce potential cybersecurity threats, OIG finalized its proposal to adopt a new safe harbor that protects the donation of nonmonetary remuneration in the form of cybersecurity technologies that are necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity. Notably, CMS finalized a similar new Stark Law exception.
5. **Accountable Care Organization (ACO) Beneficiary Incentive Programs.** OIG created a new safe harbor that excludes 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.

*Modifications to Existing AKS Safe Harbors – OIG also adopts the following substantial amendments to existing AKS safe harbors.*

1. **Personal Services and Management Contracts.** OIG finalized a proposal to eliminate common challenges under the personal services and management contracts safe harbor. First, OIG finalized its proposal to eliminate the requirement that aggregate compensation be set in advance and to instead require only that the *methodology* for determining compensation be set in advance. Second, OIG finalized its proposal to eliminate the existing requirement 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. These safe harbor revisions are not limited to specific entities.

OIG also finalized its proposal to add new provisions to the personal services safe harbor that protect certain outcomes-based payments that meet specified requirements. Ineligible Entities may not obtain protection for such arrangements under the outcomes-based provisions of this safe harbor.

2. **Warranties.** OIG finalized substantial revisions to the AKS safe harbor for warranties. Among other changes, OIG finalized its proposal to modify the safe harbor to protect warranties for a bundle of “items and services,” not just a single item, so long as the items and services subject to the warranty are reimbursed by the same federal healthcare program and in the same federal healthcare program payment. Further, OIG finalized its proposal that a protected warranty must not be conditioned on a buyer’s exclusive use of or minimum purchase of any items or services. Finally, the final rule expands the definition of “warranty” to mean (1) any written affirmation of fact or written promise on the quality of the workmanship, which affirmation or promise is in connection with the sale of an item or bundle, or services in combination with one or more related items, by a manufacturer or supplier to a buyer, or (2) in certain circumstances, any written undertaking concerning remedial action with respect to sale by a manufacturer or supplier of an item or bundle of items or services in combination with one or more related items, or (3) a manufacturer’s or supplier’s agreement to replace another manufacturer’s or supplier’s defective item or bundle of items.
3. **Local Transportation.** In recognition of the important role transportation plays in patient access to care and healthcare outcomes, OIG expanded mileage limits for rural areas (up to 75 miles) and eliminated mileage limits for transportation for patients discharged from an inpatient facility or released from a hospital after being placed in observation status for at least 24 hours. This safe harbor is available for transportation through rideshare arrangements.

Other modifications include expanded AKS safe harbor protection for certain electronic health record arrangements and new CMP safe harbor protection for the provision of certain telehealth technologies related to in-home dialysis services.

**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, healthcare providers, and other industry stakeholders. As the Stark Law is a strict

liability statute, compliance with at least one exception is required to avoid liability (unlike the AKS, where failure to satisfy the requirements of a statutory exception or regulatory safe harbor does not necessarily result in a violation).

The final rule implements the following additions and clarifications, among others.

1. **Value-Based Arrangements.** CMS finalized its proposal 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. Specifically, the final rule includes 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 AKS safe harbors, these value-based arrangement exceptions will apply only to arrangements with a value-based purpose involving “value-based enterprise participants.” Furthermore, a physician must be a direct party (through a compensation arrangement) to the value-based arrangement. Significantly, CMS did not finalize any of its proposed restrictions on the types of individuals and entities that may take advantage of these new exceptions. CMS had previously requested comment on whether it should exclude laboratories, DMEPOS suppliers, pharmaceutical manufacturers, PBMs, wholesalers, distributors, pharmacies, and device manufacturers. CMS also did not finalize any of the price transparency requirements discussed in the proposed rule.
2. **Clarified definitions for commercial reasonableness, fair market value, and when an arrangement takes into account the volume or value of referrals.** CMS again acknowledged that many of the statutory and regulatory exceptions include one, two, or all of the following requirements: (1) the compensation arrangement itself is commercially reasonable, (2) the amount of the compensation is fair market value, and (3) the compensation paid under the arrangement is not determined in a manner that takes into the account the volume or value of referrals.

In an attempt to ensure that the Stark Law exceptions establish clear, bright-line rules, CMS has finalized the following definitions for these terms:

- a. *Commercially Reasonable:* “[T]he particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.”
- b. *Fair Market Value:* “The value in an arm’s length transaction, consistent with the general market value of the transaction.” Additional requirements are set forth for the rental of equipment and office space. “General market value” is defined separately with respect to assets, compensation, and the rental of equipment or office space.
- c. *Takes Into Account:* Compensation “takes into account the volume or value of referrals only if the formula used to calculate the physician’s (or immediate family member’s) compensation includes the physician’s referrals to the entity as a variable, resulting in an increase or decrease in the physician’s (or immediate family member’s) compensation that positively correlates with

the number or value of the physician's referrals to the entity."

- 3. Limited Remuneration to a Physician.** CMS finalized its proposal to adopt a new exception to protect remuneration that is unlikely to cause overutilization or similar fraud and abuse concerns. Specifically, CMS adopted a new exception for limited remuneration from an entity to a physician for the provision of items or services by the physician that does not exceed \$5,000 (an increase from the originally proposed amount of \$3,500) per calendar year (to be adjusted each year for inflation), provided that, among other requirements, the compensation does not take into account the volume or value of referrals between the parties, it does not exceed fair market value, and the arrangement is commercially reasonable. Notably, this exception does not require a signed written agreement to be executed. Furthermore, in another change from the proposed rule, CMS is allowing this exception to protect certain compensation arrangements involving office space or equipment leased from a physician.

## CONTACTS

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work, or

<b>Meenakshi Datta</b> , Partner	+1 312 853 7169, <a href="mailto:mdatta@sidley.com">mdatta@sidley.com</a>
<b>Mark B. Langdon</b> , Partner	+1 202 736 8162, <a href="mailto:mlangdon@sidley.com">mlangdon@sidley.com</a>
<b>Trevor L. Wear</b> , Partner	+1 312 853 7101, <a href="mailto:twear@sidley.com">twear@sidley.com</a>
<b>Donielle McCutcheon</b> , Partner	+1 312 853 7282, <a href="mailto:dmccutcheon@sidley.com">dmccutcheon@sidley.com</a>
<b>Jon S. Zucker</b> , Partner	+1 202 736 8571, <a href="mailto:jzucker@sidley.com">jzucker@sidley.com</a>
<b>Joseph R. LoCascio</b> , Senior Managing Associate	+1 312 853 7139, <a href="mailto:joseph.locascio@sidley.com">joseph.locascio@sidley.com</a>

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