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New HHS Rules for AKS Safe Harbors and Stark Law Exceptions

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Health Care

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On Friday, November 20, 2020, the Centers for Medicare and Medicaid Services ("CMS") and the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") finalized two rules: (1) the "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements" rule (the "AKS Final Rule"), adopting changes to the safe harbor provisions of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b),[1] and (2) the "Modernizing and Clarifying the Physician Self-Referral Regulations" rule (the "Stark Final Rule"), adopting changes to the physician self-referral law known as the Stark Law, 42 U.S.C. § 1395nn.[2] The two rules come as part of HHS's Regulatory Sprint to Coordinated Care, an agenda aiming to remove potential regulatory barriers to care coordination and value-based care. The two rules were initially proposed in October 2019, but they have been undergoing detailed review by OMB. The new rules go into effect on January 19, 2021.[3]

In its press release, HHS stated that these rules are intended to update implementation of the Stark Law and the AKS to account for new, innovative arrangements for the delivery and payment of health care. At the time these two statutes were initially adopted, items and services

[1] CMS, *Modernizing and Clarifying the Physician Self-Referral Regulations*, CMS-1720-F (Nov. 20, 2020), https://www.federalregister.gov/public-inspection/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations.

[2] OIG, *Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements*, RIN 0936-AA10 (Nov. 20, 2020), https://www.federalregister.gov/public-inspection/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the.

[3] One change in the Stark Final Rule, related to the payment of profit shares to physicians in group practices, will be effective as of January 1, 2022.

were primarily reimbursed under a fee-for-service model. Since then, however, care delivery has shifted towards new fee arrangements that incentivize value-based care rather than the volume of patients treated.

In addition to publishing these two rules, the OIG simultaneously published another AKS Final Rule (the "Rebates Final Rule") amending the existing discount safe harbor and creating new safe harbors for point-of-sale discounts and certain fixed fee arrangements.[4] Although these changes are also related to the AKS safe harbors, OIG intends these modifications as a way to control out-of-pocket drug costs, rather than to promote value-based arrangements. The change to the discount safe harbor is effective January 1, 2022, while the other changes go into effect 60 days after publication of the Rebates Final Rule in the *Federal Register*.

Safe Harbor for Certain Value-Based Arrangements

The two value-based rules finalize new exceptions to the Stark Law and new AKS safe harbors (together, the "value-based safe harbors") to protect certain arrangements that seek to provide value-based health services to a target patient population, including through: "coordinating and managing care," "improving the quality of care," "reducing the costs to or growth of expenditures of payors without reducing the quality of care," or transitioning from volume-based care to value-based care.[5]

Although the rules aim to achieve the same goals and share many similarities, they vary slightly in technical aspects and requirements. For example, the AKS Final Rule excludes certain entities from protection under the value-based safe harbors in order to balance risks of increased fraud and abuse. These excluded entities are:

- pharmaceutical manufacturers, distributors and wholesalers
- pharmacy benefit managers ("PBMs")
- laboratory companies
- pharmacies that primarily compound drugs or primarily dispense compounded drugs
- entities that sell or rent durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS")
- medical device and supply manufacturers

[4] OIG, Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, RIN 0936-AA08 (Nov. 20, 2020), https://www.hhs.gov/sites/default/files/rebate-rule-discount-and-pbm-service-fee-final-rule.pdf.

[5] *See* 42 C.F.R. § 1001.952(ee)(14)(x); 42 C.F.R. § 411.351. Throughout this document, citations to provisions of the Code of Federal Regulations are as amended by the new final rules.

- medical device distributors or wholesalers that are not otherwise manufacturers of devices or medical supplies.

These entities are excluded because OIG believes they present a "heightened risk of fraud and abuse" due to their dependence on "practitioner prescriptions and referrals." OIG did not, however, finalize its proposal to exclude these entities from the definition of a value-based enterprise ("VBE")[6] participant. Instead the AKS Final Rule prohibits the listed entities from relying on the safe harbor to protect remuneration exchanged with a VBE or other VBE participants.

Companies seeking to benefit from the safe harbors must comply with several regulatory requirements intended to provide assurances that remuneration under the arrangement is tied to a value-based purpose. The rules create three tiers to the safe harbor, imposing less onerous requirements on arrangements in which the VBE takes on a greater portion of the financial risk of the arrangement. This tiered approach recognizes that "arrangements involving higher levels of downside financial risk for those in position to make referrals or order products or services could curb . . . incentives to order medically unnecessary or overly costly items and services."

VBE participants that take on either "full financial risk" or substantial "downside financial risk" must generally set forth the arrangement in writing,[7] ensure that remuneration is connected with a value-based purpose, and complete some oversight and monitoring of the arrangement.[8] The safe harbor also provides protections for value-based arrangements in which the VBE or VBE participant is *not* accepting significant financial risk, but to take advantage of the safe harbor companies must set forth extensive details about the arrangement in writing and monitor the arrangement annually and assess it against outcome or process benchmarks.[9]

All three tiers protect in-kind remuneration (e.g., technology or services), and under the Stark Final Rule, all three tiers protect monetary remuneration as well. However, in the AKS Final Rule, the OIG finalized its proposal to limit protection for monetary remuneration to only those value-based arrangements with full or substantial assumption of risk. Monetary remuneration can include arrangements for shared savings or losses, bundled payments, or performance bonus payments. The OIG notes, however, that under the AKS, parties to arrangements involving monetary remuneration may be eligible for the new protections for

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[6] The rules define a "value-based enterprise" as two or more participants "[c]ollaborating to achieve at least one value-based purpose," "[e]ach of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise," "[t]hat [has] an accountable body or person responsible for financial and operational oversight of the value-based enterprise," and "[t]hat [has] a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s)." *See* 42 C.F.R. § 1001.952(ee)(14)(viii); 42 C.F.R. §411.351.

[7] The Stark Law exception for VBE participants that take on "full financial risk" does not require the arrangement to be in writing. *See* 42 C.F.R. § 411.357(aa)(1).

[8] *See* 42 C.F.R. § 1001.952(ff)-(gg); 42 C.F.R. § 411.357(aa)(1)-(2).

[9] *See* 42 C.F.R. § 1001.952(ee)(1)-(10); 42 C.F.R. § 411.357(aa)(3).

outcomes-based payments under the "personal services and management contracts" safe harbor.

The two final rules require that companies continue to meet some of the standard criteria to qualify for a safe harbor under the AKS or the Stark Law, including that remuneration provided under a value-based arrangement is not used to recruit patients or to market items or services reimbursed by federal health care programs, the remuneration does not take into account the volume or value of patient referrals *outside of* the target patient population covered by the value-based arrangement, and the arrangement does not induce the parties to reduce or limit medically necessary items or services. But the Stark Final Rule also eases, for value-based arrangements, traditional requirements that compensation be set in advance, consistent with fair market value, and without consideration for the volume or value of referrals.

The safe harbors do not protect the exchange of remuneration between entities downstream of the VBE, including remuneration exchanged between VBE participants, a VBE participant and a downstream contractor, or between downstream contractors. The value-based safe harbors also do not protect remuneration provided to patients, whether in-kind or monetary, and the AKS Final Rule revises the definition of a "VBE participant" to expressly exclude patients. In-kind remuneration to patients may still be available under the new "patient engagement and support" safe harbor. Arrangements that would be protected by the value-based safe harbors, if all the other regulatory conditions are met, could include the following:

- A hospital provides physician offices with care coordinators to help furnish individually tailored case management services for patients that are transitioning from one delivery point to the next and require post-acute care
- A hospital provides post-acute providers with incentives and support to reward outcome measures that effectively and efficiently coordinate care across settings and reduce hospital readmissions

The value-based safe harbors will be effective 60 days after the rules are published in the *Federal Register* and will protect arrangements only prospectively. Conduct will continue to be evaluated under the statute and regulations that were in place at the time of the conduct.

Four Additional New Safe-Harbors Under the AKS

Aside from the value-based safe harbors adopted under both the AKS and the Stark Law, the AKS Final Rule and Rebates Final Rule also create five new safe harbors under the AKS.

Point of Sale Safe Harbor

In the Rebates Final Rule, HHS finalized a new discount safe harbor to protect certain price reductions offered by manufacturers on prescription drugs at the point of sale. Under the safe harbor, manufacturers can offer a price reduction for drugs payable by a Medicare Part D plan or Medicaid MCO under the following conditions:

- The reduction in price is set in advance and in writing with the manufacturer and the plan sponsor or a PBM acting on behalf of the sponsor;

- the price reduction does not involve a rebate "unless the full value of the reduction in price is provided to the dispensing pharmacy by the manufacturer, directly or indirectly, through a point-of-sale chargeback or series of point-of-sale chargebacks, or is required by law;" and
- the price reduction is "completely reflected in the price of the prescription pharmaceutical product at the time the pharmacy dispenses it to the beneficiary."

Importantly, CMS revised its proposed definition for the term "chargeback" after comments raised the concern that the proposed definition could lead to gaming. The proposed definition calculated the chargeback to be equal to the "discounted price of the drug," but the final rule instead calculates the "chargeback" as "equal to the reduction in price agreed upon in writing."[10] The change was made to ensure that "the pharmacy is made whole for the difference between acquisition cost, plan payment, and beneficiary out-of-pocket payment."[11]

Safe Harbor for Fixed-Fee Service Arrangements with PBMs

In the Rebates Final Rule, CMS also finalized, with only minor revisions, a safe harbor to protect payments by a manufacturer to a PBM for services that the PBM provides to the manufacturer related to the pharmacy benefit management services the PBM provides to health plans.[12] The arrangement can qualify for the safe harbor if the following criteria are met:

- there is a written and signed agreement between the PBM and manufacturer covering all of the services and specifying the compensation for services;
- the services "do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law;"
- compensation paid under the agreement is "consistent with fair market value in an arm's length transaction," is "a fixed payment, not based on a percentage of sales," and does not "take[] into account the volume or value of any referrals or business otherwise generated between the parties, or between the manufacturer and the PBM's health plans, for which payment may be made in whole in part by" a Federal health care program; and
- the PBM discloses to health plans annually, in writing, the services that it provides to manufacturers related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan.[13]

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[10] *See* 42 C.F.R. § 1001.952(cc)(2)(ii).

[11] HHS, Fact Sheet: Trump Administration Finalizes Proposal to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients (Nov. 20, 2020), https://www.hhs.gov/about/news/2020/11/20/fact-sheet-trump-administration-finalizes-proposal-to-lower-drug-costs.html

[12] *See* 42 C.F.R. § 1001.952(dd)(1).

[13] *See* 42 C.F.R. § 1001.952(dd).

Patient Engagement and Support Safe Harbor

The AKS Final Rule creates a new safe harbor allowing VBEs to furnish patient engagement tools and supports directly to patients in the target patient population of a value-based arrangement.[14] The tools or supports must be in-kind, they must have a direct connection to the coordination and management of care of the target patient population, and remuneration to a given patient cannot exceed an aggregate retail value of $500 annually.[15] Monetary remuneration, such as gift cards, cash, and cash equivalents, are excluded from protection under this safe harbor.[16]

Under the AKS Final Rule, entities that are ineligible under the value-based safe harbor are also ineligible for this patient engagement and support safe harbor.[17] As with the value-based safe harbor, OIG leaves open a path for device and supply manufacturers and DMEPOS companies to provide digital health technology under this safe harbor. OIG explains that its decision to create this limited pathway was based on the "the important role that digital health technology plays in advancing [HHS's] goals in connection with the Regulatory Sprint" and that the policy "would advance the benefits of improved care coordination without undue risk to patients or programs."

As an example, HHS has stated that this harbor could protect a situation in which a primary care physician provides patients with a smart tablet or other electronic equipment capable of two-way, real-time interactive communication in order to facilitate communication through telehealth and provide in-home services.

CMS-Sponsored Model Safe Harbor

The AKS Final Rule creates a new safe harbor that provides protection for incentives and remuneration exchanged between and among certain CMS-sponsored model parties under a CMS-sponsored model arrangement.[18] CMS-sponsored models are models "being tested or expanded by the Innovation Center under section 1115A of the [Social Security] Act or under the Medicare Shared Savings Program under section 1899 of the Act." To qualify for the safe harbor, the parties must advance one or more goals of the CMS-model arrangement, and the incentive provided to the patient must have a direct connection to the patient's health care.[19] This safe harbor is intended to reduce the need for OIG to issue separate and distinct fraud and abuse waivers and to encourage participation in the CMS programs. CMS chose not to similarly create a new exception in the Stark Final Rule, despite requests from commenters, stating

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[14] *See* 42 C.F.R. § 1001.952(hh)

[15] *See* 42 C.F.R. § 1001.952(hh)(3), (5).

[16] 42 C.F.R. § 1001.952(hh)(3)(iii).

[17] *See* 42 C.F.R. § 1001.952(hh)(1)

[18] *See* 42 C.F.R. § 1001.952(ii).

[19] *See* 42 C.F.R. § 1001.952(ii)(2).

instead that "compensation arrangements" in a CMS-sponsored model "can be structured to satisfy the requirements of at least one of the [value-based] exceptions."

Cyber-Security Technology and Services Safe Harbor

The AKS and Stark Final Rules create a new safe harbor to protect donations of cyber-security technology and services used to implement, maintain, or reestablish effective cyber-security.[20] The safe harbor "protect[s] arrangements intended to address the growing threat of cyberattacks impacting the health care ecosystem." To qualify for the safe harbor, the donor cannot take into account the volume or value of referrals, and the recipient cannot make receipt of the donation a condition of continued business.[21] The parties must also set forth in writing and sign a general description of the technology and services being provided.[22]

Modification to Pre-Existing Safe Harbors under the AKS

The AKS and Rebates Final Rules also modify several existing AKS safe harbors.

Safe Harbor for PBM Rebates

The Rebates Final Rule amends the existing discount safe harbor and eliminates protections for rebates or other price reductions from manufacturers to plan sponsors under Medicare Part D or PBMs acting on their behalf, unless the price reduction is otherwise required by law.[23] Notably, OIG had originally proposed to also exclude rebates paid to Medicaid managed care organizations ("MCOs") but declined to finalize the exclusion in the final rule. The discount safe harbor will continue to protect discounts on prescription drugs offered to other entities such as wholesalers, hospitals, physicians, pharmacies, and third-party payors in other federal health care programs. The effective date for the change to the discount safe harbor is January 1, 2022, a change from the proposed effective date of January 1, 2020, to ensure sufficient time to implement the changes and in response to concerns raised by commenters.

Personal Services and Management Contracts

The AKS Final Rule modifies the existing safe harbor for personal services and management contracts to increase flexibility for part-time or sporadic arrangements and arrangements for certain outcome-based payments.[24] This flexibility is created by (i) removing the current requirement that aggregate compensation be set in advance, and instead requiring that only the *methodology* for determining compensation be set in advance, and (ii) eliminating the "requirement that if an agreement provides for the services of an agent on a periodic,

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[20] *See* 42 C.F.R. § 1001.952(jj); 42 C.F.R. § 411.357(bb).

[21] *See* 42 C.F.R. § 1001.952(jj)(1)-(2).; 42 C.F.R. § 411.357(bb)(i)-(ii).

[22] *See* 42 C.F.R. § 1001.952(jj)(3); 42 C.F.R. § 411.357(bb)(iii).

[23] *See* 42 C.F.R. § 1001.952(h)(viii).

[24] *See* 42 C.F.R. § 1001.952(d)(1).

sporadic, or part-time basis, the contract must specify the schedule, length, and the exact charge for such intervals." The rule also creates new protection for "outcomes-based payments" for the achievement of outcomes "based on clinical evidence or credible medical support and with specified benchmarks related to quality of care, a reduction in costs, or both."[25] OIG excludes pharmaceutical companies, PBMs, laboratory companies, compounding pharmacies, manufacturers of a device or medical supply, medical device distributors or wholesalers, and DMEPOS companies from the "outcomes-based payments" safe harbor protection.

Electronic Health Record ("EHR") Safe Harbor

The AKS and Stark Final Rules add protections into the existing EHR safe harbor for cyber-security technology provided as part of an EHR arrangement.[26] The rules are intended to clarify any uncertainty regarding whether the existing safe harbor covers related cyber-security technology, and further brings this update in line with the new cyber-security technology safe harbor. The rule also updates certain interoperability provisions and removes the sunset period for this safe harbor.

Warranties Safe Harbor

The AKS Final Rule modifies the existing safe harbor for warranties to revise the definition of a warranty and extend warranty protection for bundled warranties covering "one or more items and related services" under certain conditions.[27] The modification "offer[s] greater flexibility to buyers and sellers to enter into innovative arrangements that warranty the value of an entire bundle of items or that include bundled items and services."

Other Changes to Stark Law Regulations

The Stark Final Rule also finalizes a number of changes to "provide[] clarity and guidance on a wide range of other technical compliance requirements intended to reduce administrative burden that drives up costs."[28] As a part of this effort, CMS adopted bright-line and objective standards for some of the fundamental and frequently used terms and requirements of the Stark Law. Notably, CMS defined the term "commercially reasonable" to mean that "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."[29] "[A]n arrangement may be commercially reasonable even if

[25] 42 C.F.R. § 1001.952(d)(2)(i).

[26] *See* 42 C.F.R. § 1001.952(y); 42 C.F.R. § 411.357(w).

[27] *See* 42 C.F.R. § 1001.952(g).

[28] CMS, *Fact Sheet: Modernizing and Clarifying the Physician Self-Referral Regulations Final Rule (CMS-1720-F)* (Nov. 20, 2020), https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-final-rule-cms-1720-f

[29] 42 C.F.R. § 411.351.

it does not result in profit for one or more of the parties." CMS explains that "many of the statutory and regulatory exceptions" to the Stark Law require that the compensation arrangement be commercially reasonable but that prior to this Rule, no definition of the phrase had been codified in the regulations.

The Stark Final Rule also largely decouples the Stark rules from the AKS, removing requirements that arrangements must comply with the AKS in order to comply with the Stark regulations. The change is intended in part to better reflect the intent of Congress, which "did not require compliance with the anti-kickback statute or any other law in existence at the time of enactment of the [Stark Law]." Notwithstanding this significant clarification, CMS continues to require that companies comply with the AKS in order to qualify for the "fair market value compensation" exception, because the Stark regulations do not have the corresponding AKS safeguards around fair market value compensation.

The Stark Final Rule also creates a new exception for remuneration paid to a physician for items and services provided by the physician.[30] The exception is intended to account for circumstances in which physician "services [are] provided sporadically or for a low rate of compensation" or where "services [are] provided during a short period of time," for example, where a physician steps in to serve as interim medical director during the hiring process of a new medical director. The exception applies to arrangements in which items or services are actually provided by a physician, the amount of remuneration does not exceed $5,000 annually, the arrangement is commercially reasonable even if no referrals were made between parties, the remuneration does not take into account the volume or value of referrals or other business generated by the physician; and the remuneration does not exceed the fair market value for the items or services.[31]

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[30] *See* 42 C.F.R. § 411.357(z).

[31] *See* 42 C.F.R. § 411.357(z)(1).

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