

SPRINTING TOWARD VALUE: OIG OVERHAULS ANTI-KICKBACK SAFE HARBORS TO BENEFIT PATIENTS AND PROVIDERS

On November 20, 2020, the Health and Human Resources Office of Inspector General ("OIG") issued the long-awaited final rule to overhaul various aspects of the Anti-Kickback Statute and Civil Monetary Penalties Laws ("Final Rule"). The Final Rule issued several new safe harbors and modified existing safe harbors under the Anti-Kickback Statute.

As we noted in our firm's initial [alert](#) on November 20 and our corresponding overview [webinar](#), the Final Rule provides a much-needed framework for protecting certain value-based arrangements that incentivize care coordination, quality of care and cost containment.

This article is intended to briefly summarize the Final Rule and its effect on patient relationships impacted by the Anti-Kickback Statute ("AKS") and Civil Monetary Penalties Law ("CMP"). Hall Render will be publishing additional analyses of other modifications addressed by the Final Rule.

FINALIZED AKS REVISIONS

Key Definitions

OIG has finalized several new AKS Value-Based Safe Harbors related to various conduct and arrangements. When interpreting the Safe Harbors, understanding the definitions that underpin these new AKS Safe Harbors is critical. These definitions cross-reference each other in multiple ways.

Value-Based Enterprise. The network of individuals and entities that collaborate together to achieve one or more value-based purposes. This network could range from a collaboration by two individual physician practices to a network of hospital systems, post-acute providers, and physician practices. OIG stated that this definition is intended to be flexible and allow a broad range of participation and business structures. Note that pharmaceutical and medical device manufacturers, distributors and wholesalers, PBMs, laboratory companies, compounding pharmacies and DMEPOS companies are permitted to participate in value-based enterprises as value-based participants; **however**, neither these participants nor remuneration to or from these participants are afforded Safe Harbor protection.

Engagement Tools and Supports. In-kind, preventive, monitoring and assessment items, goods or services 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. These tools and supports must have a direct connection to the coordination and management of care for the target patient population.

Target Patient Population. An identified patient population selected by a value-based enterprise or its participants using legitimate and verifiable criteria that is set forth in writing in advance of commencement of the value-based arrangement and further the value-based purposes of the value-based enterprise. OIG indicated that the "legitimate and verifiable criteria" standard will afford parties greater flexibility in determining the target patient population than an "evidence-based criteria" standard.

New Safe Harbors

- Care Coordination Arrangements to Improve Quality, Health Outcomes and Efficiency Safe Harbor.** This Safe Harbor is one of three new Safe Harbors intended to specifically address value-based arrangements. This Safe Harbor is limited to in-kind remuneration exchanged between qualifying value-based enterprise participants of value-based arrangements that "squarely satisfy" several requirements, including that the recipient of the in-kind remuneration must pay at least 15% of the offeror's costs (or of the fair market value) for the remuneration.
- Value-Based Arrangements with Substantial Downside Financial Risk Safe Harbor.** This Safe Harbor protects both in-kind and monetary remuneration exchanged amongst value-based enterprises that have assumed "substantial" downside financial risk and the participants that meaningfully share in that risk. In the final rule, OIG has limited the safe harbor to protecting the exchange of remuneration between a value-based enterprise and a value-based enterprise participant ("VBE participant"). OIG declined to extend

safe harbor protection to remuneration exchanged between one VBE participant with another VBE participant or to any downstream financial arrangements to which the value-based enterprise is not a party.

- 3. Value-Based Arrangements with Full Financial Risk Safe Harbor.** The OIG has recognized that value-based enterprises assuming full financial risk do not contain significant, traditional fraud and abuse risks and therefore has finalized a separate Safe Harbor with additional flexibility for these types of arrangements. The highest financial risk warrants the highest ability for innovation regarding coordinate care arrangements.
- 4. Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes and Efficiency Safe Harbor.** This Safe Harbor permits in-kind patient engagement tools and/or supports furnished directly by a value-based enterprise participant to a patient in a target patient population that are directly connected to the coordination and management of care when all elements of the Safe Harbor are satisfied.
- 5. CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives Safe Harbor.** This Safe Harbor permits remuneration between parties testing an initiative by the Medicare Innovation Center and/or the Medicare Shared Savings Program. It also permits the provision of incentives and supports to patient participants in these CMS-sponsored models. A goal of this Safe Harbor is to reduce OIG's burden in issuing specific fraud and abuse waivers for each new CMS-sponsored model that may be rolled out in the future.
- 6. Donations of Cybersecurity Technology and Services Safe Harbor.** Given the recent increase in cybersecurity breaches, this Safe Harbor permits the donation of any software or other types of information technology, including single-function hardware that is specific to cybersecurity, that serves to protect information by preventing, detecting and responding to cyberattacks.

Modifications to Existing Safe Harbors

- 1. Electronic Health Records Items and Services Safe Harbor.** OIG has added protections for certain cybersecurity technology included as a part of the broader electronic health record ("EHR") arrangement. In addition, the Final Rule addresses updates regarding interoperability of EHR platforms. Lastly, OIG has removed the sunset date associated with this Safe Harbor so that this Safe Harbor will be available indefinitely.
- 2. Personal Services and Management Contracts Safe Harbor.** OIG modified this Safe Harbor to add flexibility for part-time arrangements by no longer requiring the aggregate compensation be set in advance, only that the compensation methodology be set in advance. In addition, OIG the specific schedule of services does not have to be set in advance. These modifications are intended to align the Personal Services and Management Contracts Safe Harbor with the corollary Stark Law exception of personal service arrangements. The Final Rule also created a "new" Safe Harbor within the Personal Services and Management Contracts Safe Harbor for the protection of "outcomes-based" payments, including rewards for successfully achieving outcomes measures. This Safe Harbor also permits recoupment or reduction in payments for failure to achieve an outcome measure.
- 3. Warranties Safe Harbor.** OIG finalized its proposal to expand this Safe Harbor to include bundled arrangements for items and related services. This expansion increases the utility of supply chain purchases under a written warranty by including related services that support the use of those goods. However, it does not go so far as to protect warranties for services only (items must be included as well). Further, OIG has clarified the definition of "warranty" to apply to FDA-regulated drugs and devices.
- 4. Local Transportation Safe Harbor.** OIG has modified this Safe Harbor to expand the rural area mileage restrictions for patient transportation from 50 miles to 75 miles. In addition, there are no mileage limitations on the transportation of patients to a residence of their choice upon discharge from an inpatient admission (or 24-hour observation).

Finally, OIG codified the statutory exception to the definition of "remuneration" as it relates to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program.

CMP REVISIONS FOR BENEFICIARY INDUCEMENTS

The CMP imposes restrictions on remuneration to Medicare and Medicaid beneficiaries. OIG has revised the CMP definition of "remuneration" to add a new exception for the provision of items and services that relate to telehealth technologies provided to certain in-home dialysis patients. This exception permits renal dialysis facilities and providers to provide telehealth technologies to patients that are currently

receiving in-home dialysis from that provider or facility.

In addition, conduct that satisfies the AKS Safe Harbor for patient engagement and support arrangements, as well as the local transportation Safe Harbor, also constitute exceptions to the beneficiary inducement CMP's definition of "remuneration."

PRACTICAL TAKEAWAYS

The Final Rule shows OIG is serious about affording providers, practitioners and suppliers with additional opportunities to improve the quality of patient care during the transition from volume to value-based reimbursement. These new and modified Safe Harbors take effect on January 19, 2021. Health care organizations wishing to avail themselves of these Safe Harbors need to move quickly to react and adapt their arrangements, as well as create new arrangements under the value-based construct, accordingly.

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