SPRINTING TOWARD VALUE: OIG PROPOSES REGULATIONS BENEFITING PATIENTS AND PROVIDERS

On October 9, 2019, the Health and Human Services Office of Inspector General ("OIG") released a proposed rule pertaining to various Anti-Kickback Statute and Civil Monetary Penalties Law new regulations and modifications ("Proposed Rule"). The Proposed Rule is one component of the Department of Health and Human Services's ("HHS's") recently launched "Regulatory Sprint to Coordinated Care" and is intended to provide additional flexibility to health care providers, practitioners and suppliers as they continue to face the transition from volume to value reimbursement.

In conjunction with the Regulatory Sprint to Coordinated Care, OIG previously published a Request for Information ("RFI") regarding potential Anti-Kickback Statute ("AKS") and Civil Monetary Penalties Law ("CMP") initiatives that would ease the burden of this volume to value transition.

This article is intended to briefly summarize the proposed changes that affect patient relationships impacted by the AKS and CMP. Hall Render will be publishing additional analyses of other modifications addressed by the Proposed Rule, as well as the proposed changes to the Stark regulations by CMS.

PROPOSED AKS REVISIONS

The AKS prohibits anyone from soliciting, receiving, offering or paying any remuneration or generating business in return for a referral for an item or service that may be paid for by a federal health care program.

Key Definitions

OIG has proposed several new AKS Safe Harbors related to various conduct and arrangements. When interpreting the proposed Safe Harbors, understanding the definitions that underpin these proposals is critical. Note that all of these definitions are proposed and are subject to modification pending the comments received by OIG.

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.

Engagement Tools and Supports. In-kind, preventive, patient monitoring and assessment items, goods or services as well as 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 furthers the value-based purposes of the value-based enterprise.

Proposed New Safe Harbors

1. **Care Coordination Arrangements to Improve Quality, Health Outcomes and Efficiency Safe Harbor**. This proposed Safe Harbor is one of three proposed new Safe Harbors intended to specifically address value-based arrangements. This proposed Safe Harbor is limited to in-kind remuneration exchanged between qualifying value-based enterprise participants of value-based arrangements that "squarely satisfy" several proposed requirements.
2. **Value-Based Arrangements with Substantial Downside Financial Risk Safe Harbor**. This proposed Safe Harbor would protect 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. OIG noted that it is considering extending this Safe Harbor to remuneration that passes from one value-based enterprise to another.

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3. **Value-Based Arrangements with Full Financial Risk Safe Harbor**. OIG has recognized that value-based enterprises assuming full financial risk do not contain significant, traditional fraud and abuse risks and therefore has proposed 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, as proposed, would permit 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 proposed Safe Harbor would permit 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 proposes to permit the donation of any software or other types of information technology, other than hardware, that serves to protect information by preventing, detecting and responding to cyberattacks. Note that CMS has proposed a similar exception to the Stark Law.

Modifications to Existing Safe Harbors

1. **Electronic Health Records Items and Services Safe Harbor**. OIG has proposed to add protections for certain cybersecurity technology included as a part of the broader electronic health record ("EHR") arrangement. In addition, the Proposed Rule addresses updates regarding interoperability of EHR platforms. Lastly, OIG has proposed to entirely remove the sunset date associated with this Safe Harbor but is also soliciting comments as to whether the sunset date should be extended and not removed.

2. **Personal Services and Management Contracts Safe Harbor**. OIG has proposed to modify 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 has proposed that the specific schedule of services would not have to be set in advance. These proposed modifications are intended to align the Personal Services and Management Contracts Safe Harbor with the corollary Stark Law exception for personal service arrangements. The Proposed Rule also contemplates additional flexibility for arrangements that include outcomes-based payments.

3. **Warranties Safe Harbor**. OIG has proposed to expand this Safe Harbor to include bundled arrangements for items and related services. This expansion could increase the utility of supply chain purchases under a written warranty by including related services that support the use of those goods. Further, OIG has clarified the definition of "warranty" to apply to FDA-regulated drugs and devices. This proposed expansion is intended to enhance innovative and mutually beneficial arrangements between manufacturers/suppliers and their hospitals and health system buyers.

4. **Local Transportation Safe Harbor**. OIG has proposed to modify this Safe Harbor to expand the rural area mileage restrictions from 50 miles to 75 miles. In addition, it is proposed that there would be no limit on mileage for transportation of patients to a residence of their choice upon discharge from an inpatient admission. OIG is also considering permitting transportation to the *location* of the patient's choice (which would permit transportation to another health care provider upon discharge).

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

PROPOSED CMP REVISIONS FOR BENEFICIARY INDUCEMENTS

The CMP imposes restrictions on remuneration to Medicare and Medicaid beneficiaries. OIG has proposed to revise 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 would permit renal dialysis facilities and providers to provide telehealth technologies to patients that

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are currently receiving in-home dialysis from that provider or facility.

In addition, if the above referenced AKS Patient Engagement and Support Arrangements Safe Harbor and modifications to the local transportation Safe Harbor are finalized, conduct that satisfies these Safe Harbors would also constitute exceptions to the beneficiary inducement CMP's definition of "remuneration."

PRACTICAL TAKEAWAYS

The Proposed Rule shows OIG's intention to afford providers, practitioners and suppliers with additional opportunities to improve the quality of patient care during the transition from volume to value-based reimbursement. However, it is important to note that the Proposed Rule cannot be viewed as final in any way. OIG specifically instructed that, until final determination is made regarding the arrangements described in the Proposed Rule, these types of arrangements should not be considered exempt from liability under the AKS. Any resulting Safe Harbors from future final regulations would only offer prospective protection.

If you are interested in submitting a comment or would like additional information about this topic, please contact:

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