

On October 9th, the Trump Administration released two proposed rules aimed at improving the Medicare program's ability to support value-based arrangements, care coordination, and population health efforts. The *Modernizing and Clarifying the Physician Self-Referral Regulations* updates a number of provisions in the physician self-referral law (commonly known as the Stark law) and *Revisions to the Safe Harbors under the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalties Rules Regarding Beneficiary Inducement* (commonly known as AKS or CMP rules) clarifies when providers are allowed protection from liability and penalty under these laws.

Stark Reforms

The Stark Law prohibits physicians from making referrals for certain healthcare services if the physician (or an immediate family member) has a financial relationship with the entity performing the service. While there are some statutory and regulatory exceptions, in general, physicians cannot refer a patient to a facility or service with which the physician has a financial interest.

In an era where hospitals, physicians, payers and other entities are working to coordinate care in order to reduce over-utilization, improve quality and reduce costs, these prohibitions can be problematic.

Below is a summary of the proposed reforms to the Stark regulations:

- **Exceptions for Value-Based Arrangements** — The proposed rule makes exceptions for value-based arrangements and would allow physicians and other health care providers to design and enter into value-based arrangements without fear that legitimate activities to coordinate and improve the quality of care for patients and lower costs would violate the Stark Law.

CMS is seeking comments on the role of price transparency in Stark Law regulations, and whether to require cost-of-care information at the point of referral for an item or service. The health agency stated that the additional cost information could empower patients to have conversations about costs with their physicians at the point of care and serve as an additional safeguard at the point of referral.

- **New Guidance and Clarification** — The proposed rule provides guidance on several key requirements that must often be met for physicians and healthcare providers to comply with the Stark Law. Additionally, the proposed rule provides clarity and guidance on a wide range of other technical compliance requirements intended to reduce administrative burden.
- **Other New Exceptions** — The proposed rule includes exceptions that would provide new flexibility for certain arrangements — such as donations of certain cybersecurity technology that safeguard the integrity of the healthcare ecosystem — regardless of whether the parties operate in a fee-for-service or value-based payment system.
- **Price Transparency** — The proposed rule also addresses the price transparency directives in the June 24, 2019 Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First. *CMS is considering whether to include a requirement related to price transparency in every proposed exception for value-based arrangements. The agency states that because of limits on currently available pricing data, such a requirement could help break down barriers to cost-of-care discussions.*

- **Compliance** — CMS also writes that it plans to add additional program integrity requirements. The agency sought comment on whether to require the value-based entities and participants to monitor that they are achieving the value-based purposes, what that monitoring would entail, and the burden of cost of such monitoring.

Anti-Kickback Modifications

The Anti-kickback statute prohibits the exchange of remuneration (defined as anything of value) for referrals for services that are payable by Medicare. The Civil Monetary Penalty (CMP) statute prohibits beneficiary inducements and provides for the imposition of financial penalties for violations.

The proposed rule would create a number of safe harbor protections similar to CMS's rule on the Stark Law. The new safe harbors would create a **range of flexibilities for providers engaged in value-based arrangements**, ranging from flexibility on in-kind remuneration for coordinated care to permitting monetary remuneration for providers with full financial risk in a value-based care arrangement. It would also create an exception to CMP for inducing the use of **telehealth technologies for patients undergoing in-home dialysis**. Given the benefits of sharing cybersecurity and electronic health record (EHR) technology, the rule would create a **safe harbor for transfers of cybersecurity and EHR** goods and services between entities.

Specifically, the rule proposes safe harbors for the following scenarios:

- **Exceptions for Value-Based Arrangements** — OIG would create a number of new safe harbors in the AKS protecting value-based arrangements. These arrangements would generally be targeted at a specific patient population under a framework designed to encourage high-value care for that population. Furthermore, OIG is considering limiting the definition of targeted patient population in this case to only patients with chronic conditions. Value-based arrangements would be protected under three safe harbors
 - Care coordination arrangements to improve quality, health outcomes, and efficiency;
 - Value-based arrangements with substantial downside financial risk; and
 - Value-based arrangements with full financial risk.
- **CMS-Sponsored Models** — Precluding the need for CMS to obtain waivers from OIG, the proposal would create a safe harbor for activities associated with a CMS-sponsored model such as those run by the Center for Medicare and Medicaid Innovation (CMMI).
- **Patient Engagement** — The rule would create a new safe harbor for patient engagement, allowing providers participating in a value-based arrangement to offer in-kind patient engagement tools and supports to patients. Monetary inducements for patients would not be permitted.
- **Cybersecurity Donations** — This safe harbor, a similar version of which is also being proposed in CMS's Stark Law rule, would protect the transfer of cybersecurity technology and services between entities to implement and maintain cybersecurity. The safe harbor is not intended to protect the transfer of technology and services with general use — which OIG believes could be used to disguise a bribe or other such payment.

- **Electronic Health Records** — Similar to a requirement in the rule published simultaneously by CMS, OIG’s rule would modify the current safe harbor for the donations of EHRs and associated services by requiring donated items and services to be interoperable. It would also update the safe harbor to use more up-to-date definitions of information blocking and would clarify that cybersecurity software and services have always been covered under the existing safe harbor for EHRs. Finally, it would eliminate the sunset provision on the EHR safe harbor.
- **Other Safe Harbors** — The rule also includes proposed safe harbors relating to local transportation, personal services, management contracts. Furthermore, it would implement two requirements from the Bipartisan Budget Act of 2018, one protecting beneficiary inducements for using telehealth in conjunction with in-home dialysis and the other protecting incentive payments by accountable care organizations (ACO) to their assigned beneficiaries.