Proposed Changes to Stark and Anti-Kickback Regulations

On October 9, 2019, agencies in the U.S. Department of Health and Human Services (HHS) coordinated the release of proposed changes to the regulations promulgated pursuant to the federal Anti-Kickback Statute (AKS), the civil monetary penalty (CMP) Law, and the physician self-referral law or "Stark Law." HHS' Office of Inspector General (OIG) proposed to significantly expand the safe harbors under the AKS and revise the regulations under CMP Law. At the same time, the Centers for Medicare & Medicaid Services (CMS) proposed to expand similar exceptions under the Stark Law.

These proposals are part of what HHS calls its "Regulatory Sprint" initiative, which strives to remove regulatory obstacles to value-based care and encourage coordination of care between providers. In general, the AKS and the Stark Law are designed to prevent health care providers from referring patients to businesses with which they have a financial relationship or from referring patients to other providers for financial gain. The CMP Law prohibits offering inducements to Medicare and Medicaid beneficiaries to choose healthcare providers or services. However, these laws are quite strict and the penalties for violating them are severe, which stifles initiatives among providers to coordinate care and improve quality for fear that they also could run afoul of the law. The proposed changes would create and expand safe harbors and exceptions to the AKS, the CMP Law and the Stark Law in order to encourage care coordination and value-based care.

The AKS Proposed Rule modifies several existing safe harbors and creates new safe harbors under the AKS. For example:

- The AKS Proposed Rule includes three proposed new safe harbors to permit and protect remuneration exchanged between or among clinicians, providers, suppliers, and others participating in a value-based arrangement that fosters better coordinated and managed patient care. These proposed safe harbors vary, among other ways, by the types of remuneration protected (in-kind or in-kind and monetary), the level of financial risk assumed by the parties, and the types of safeguards included as safe harbor conditions.

- The proposed rule includes a new safe harbor for donations of cybersecurity technology. Although the types of donors are not limited, the OIG clearly envisions that larger entities such as hospitals would provide free cybersecurity software and services to physician practices and other small providers, which the OIG considers to be the "weakest links" and susceptible to cyberattacks. Donors cannot select recipients based on the value of referrals from a recipient. Conversely, a potential recipient cannot demand, explicitly or implicitly, a donation of cybersecurity technology and services as a condition of doing business with the donor.

- It also amends the existing safe harbor for electronic health records (EHR) arrangements to add protections for certain cybersecurity technology included as part of an EHR arrangement and to update provisions regarding interoperability. This existing safe harbor was scheduled to sunset on December 31, 2021, but this proposal deletes the sunset date.

- The proposed rule amends the existing safe harbor for warranties to expand it to protect bundled warranties for one or more items and related services.
- It amends existing safe harbors for personal services and management contracts to add flexibility with respect to outcomes-based payments and part-time arrangements.
- It clarifies that providing telehealth technologies related to in-home dialysis services is not patient inducement if they are not offered as part of any advertisement or solicitation.

The AKS Proposed Rule also modifies the CMP Law to permit providers to offer certain patient engagement and support arrangements to improve quality of care and health outcomes:

- The AKS Proposed Rule amends an existing AKS safe harbor for local transportation and changes the definition of "remuneration" under the CMP Law (1) to expand the distance which residents of rural areas may be transported to 75 miles and (2) to remove any mileage limit on transportation of a patient from a healthcare facility from which the patient has been discharged to the patient's residence.
- It adds a "patient engagement and support safe harbor" under the AKS and amends the definition of "remuneration" under the CMP Law allowing providers to offer tools and support to their patients that will promote the patients' involvement in their care, adhere to care protocols, and empower them to make informed health care decisions.
- It also adds a new exception for "telehealth technologies" offered to certain patients receiving in-home dialysis.

The Stark Proposed Rule modifies existing exceptions and adds new exceptions to the Stark Law as well as provides some much-needed guidance and definitions. Some of these parallel proposed changes to the AKS, such as:

- The Stark Proposed Rule proposes a new exception for certain value-based compensation arrangements between or among physicians, providers, and suppliers.
- The Stark Proposed Rule creates a new exception for donations of cybersecurity technology and related services.
- The Stark Proposed Rule amends the existing exception for EHR items and services.

However, other changes are unique to the Stark Law:

- The Stark Proposed Rule creates a new exception for certain arrangements under which a physician receives limited remuneration (up to $3,500 per year) for items or services actually provided by the physician.
- This proposed rule provides much-needed guidance for physicians as well as other health care providers and suppliers whose financial relationships are governed by the Stark Law as to the

meaning of key terms such as “fair market value,” “commercial reasonableness,” and compensation that “takes into account” the volume or value of referrals and is “set in advance.” For example, the proposed rule clarifies that the fair market value requirement is separate and distinct from the volume or value standard. It also defines commercial reasonableness not by profitability but simply whether the arrangement makes sense as a means to accomplish the parties’ goals.

- It allows group practices to distribute profits from designated health services that are directly attributable to a physician’s participation in a value-based enterprise even if such distribution directly takes into account the volume or value of the physician’s referrals. As CMS explained, “a group practice could distribute directly to a physician in the group the profits from designated health services furnished by the group that are derived from the physician’s participation in a value-based enterprise, including profits from designated health services referred by the physician, and such remuneration would be deemed not to directly take into account the volume or value of the physician’s referrals.”

- CMS clarifies that the exception for isolated transactions is not available for payments for multiple services provided over an extended period of time, even if there is only a single payment for all the services.

- It updates the group practice rules by eliminating the references to Medicaid in the definition of overall profits.

These proposed regulations are not yet in effect and may change in the final version. If you wish to have input into these proposed changes, comments may be submitted up to 75 days after publication of the proposed rules in the Federal Register. Please reach out to us if we can assist in drafting comments or if we can help you determine how these changes may impact your business.

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