

insights

TYPES NOT MAPPED YET October 11, 2019 | TTR not mapped yet | Milada R. Goturi

HHS proposes significant changes to Stark, Anti-Kickback and CMP regulations

On October 9, 2019, the Department of Health and Human Services (“HHS”) proposed [significant amendments](#) to the Stark Law, Anti-Kickback Law and Civil Monetary Penalty (“CMP”) Law. These proposed amendments are intended to modernize and clarify these laws, encourage value-based arrangements and care coordination and reduce some of the regulatory burdens on healthcare providers. The proposed amendments reflect efforts of the Centers for Medicare and Medicaid Services (“CMS”) and the HHS Office of Inspector General (“OIG”) to address the transition to value-based health care systems.

Stark Law

CMS proposed new compensation exceptions and clarifications to several existing Stark Law requirements. In the [Fact Sheet](#) announcing the proposed rules, CMS indicated that these changes are designed to “support the necessary evolution of the American healthcare delivery and payment system care” and are intended to “unleash innovation by permitting physicians and other healthcare 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.”

Specifically, the proposal includes the following:

- New compensation exceptions for value based arrangements, for limited remuneration to a physician and for cybersecurity technology and related services
- New and modified guidance on several key Stark Law compliance concepts, including commercial reasonableness, the volume or value standard and fair market value
- Several clarifications related to Stark Law compliance requirements, among which are group practice requirements and the distribution of DHS profits and guiding principles for calculating the period of disallowance

Anti-Kickback Statute

OIG proposed significant changes to the Anti-Kickback Law by adding six new safe harbors among which are three new safe harbors for value-based arrangements, as well as new safe harbors for donations of cybersecurity technology, CMS-sponsored models and services, and for certain tools and supports furnished under patient engagement arrangements.

The OIG also proposed to update several existing safe harbors:

- The **personal services and management contracts safe harbor** will add greater flexibility for outcome-based payments and part-time arrangements
- The **electronic health records safe harbor** will promote interoperability
- The **warranty safe harbor** will protect more than one item or service
- The **local transportation safe harbor** will expand and modify mileage limits for rural areas

Civil Monetary Penalty Law



With respect to proposed changes to the CMP rules, the proposal incorporates a new exception for beneficiary inducements regarding telehealth technologies provided to certain in-home dialysis patients. OIG also noted that the proposed changes to the local transportation safe harbor and new patient engagement safe harbor would also serve as exceptions under CMP's prohibition of beneficiary inducement.

Next steps

The public currently has the opportunity to provide feedback to HHS on the proposed regulations before the final regulations will be enacted. HHS will be accepting feedback on these proposed changes up until 75 days from the date of publication in the Federal Register, which is currently scheduled for October 17.

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