



CMS and OIG issue long-awaited rules proposing changes to the Stark Law, Anti-Kickback Statute and Beneficiary Inducement Civil Monetary Penalty Law

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On October 9, 2019, the Centers for Medicare and Medicaid Services (CMS) and Department of Health and Human Services Office of Inspector General (HHS-OIG) [issued](#) long-awaited proposed changes “to modernize and clarify the regulations that interpret the Physician Self-Referral Law (the ‘Stark Law’) and the Federal Anti-Kickback Statute.” Each proposed rule is lengthy. However, both CMS and OIG issued fact sheets along with their proposed rules to highlight the changes being proposed. The CMS fact sheet describing the proposed changes to the Stark Law can be found on [CMS’ website](#). The OIG fact sheet describing the proposed changes to the Anti-Kickback Statute (AKS) and Beneficiary Inducement Civil Monetary Penalty (CMP) Law is on [OIG’s website](#).

CMS’ [proposed rule](#):

- includes new exceptions for value-based arrangements, donations of cybersecurity technology
- provides guidance on how to determine whether compensation paid to a physician is fair market value
- provides “clarity and guidance” on technical compliance requirements that is intended to reduce administrative burden
- solicits comments about price transparency in the context of the Stark Law and whether to require cost-of-care information at the point of a referral for an item or service

OIG's [proposed rule](#) includes:

- six new AKS safe harbors (three of which are for value-based arrangements)
- modifications to four existing AKS safe harbors
- a codification of the statutory exception to the AKS definition of “remuneration” related to ACO Beneficiary Incentive Programs for Medicare Shared Savings Programs
- amendment to the definition of “remuneration” in the CMP rules related to an exception for telehealth technologies furnished to certain in-home dialysis patients

Authors
