



## Changes coming to the Stark Law and Anti-Kickback Statute regulations

January 31, 2020

On October 9, 2019, the Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services Office of Inspector General (OIG) issued long-awaited proposed changes “to modernize and clarify the regulations that interpret” the Physician Self-Referral Law (Stark Law) and the federal Anti-Kickback Statute (AKS).

CMS and OIG are expected to finalize these proposed changes in 2020. These changes are anticipated to clarify and simplify the process that entities use to understand if their physician arrangements are in compliance with both regulations. Providers should be prepared to evaluate and update their arrangements as necessary to ensure they follow CMS and OIG’s suit in a move towards a value-based care system.

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 are 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
- an amendment to the definition of “remuneration” in the Beneficiary Inducement Civil Monetary Penalty rules related to an exception for telehealth technologies furnished to certain in-home dialysis patients

Bricker & Eckler published a series of articles summarizing many of the proposed changes to the regulations, which are linked below.

#### Key Stark Law definitions

CMS’ proposed changes to the regulations interpreting the Stark Law include bright-line rules to clarify several key terms used in the Stark Law exceptions. Specifically, CMS proposes changes to the terms “commercial reasonableness,” “takes into account the volume or value of referrals or other business generated,” and “fair market value.” [Read more >>](#)

#### Scope and application of Stark Law regulations

CMS is proposing to recalibrate the scope and application of the Stark Law regulations. These clarifications provide helpful insight into how CMS interprets the Stark Law and, in some instances, proposes to modify the existing regulations. [Read more >>](#)

#### Profit shares for group practices

CMS proposed changes to the special rules for profit shares and productivity bonuses paid by group practices to physicians. [Read more >>](#)

#### Donation of EHR and cybersecurity technology/services

OIG and CMS have both proposed modifications to the existing AKS safe harbor and Stark Law exception for the donation of electronic health records (EHR) items and services. The agencies have also proposed a new safe harbor and new exception for donations of cybersecurity technology and services. [Read more >>](#)

#### Value-based care exceptions

CMS has proposed three new compensation exceptions for direct and indirect value-based arrangements: full financial risk exception, meaningful downside financial risk exception and value-based arrangements exception. OIG also has proposed three new safe harbors: full financial risk safe harbor, substantial downside financial risk safe harbor and care coordination safe harbor. [Read more >>](#)

#### Correcting administrative and operational errors

CMS has proposed clarifications addressing whether mistaken payments of excess or insufficient compensation that differ from the amount indicated in the written agreement result in noncompliance. It has also clarified how certain administrative and operational mistakes can be resolved. [Read more >>](#)

#### Anti-Kickback Statute safe harbors

OIG has proposed changes to the AKS’s regulatory safe harbors, including the personal services and management contracts safe harbor, warranty safe harbor and local transportation safe harbor. [Read more >>](#)

#### Limited remuneration to a physician

CMS has proposed a new exception for limited remuneration to a physician. This exception is designed to offer protection for certain non-abusive arrangements that cannot satisfy existing Stark Law exceptions due to reasons including the dollar limit, documentation, signature and/or the “set in advance” requirement. [Read more >>](#)

