

NEWS ALERT

HEALTH CARE



Breaking Down the New Stark Law and Anti-Kickback Statute Final Rules

By Julia P. Boisvert and Stephanie S. Sobkowiak | December 22, 2020

In late November, the Centers for Medicare and Medicaid Services and the Office of the Inspector General released their final rules revising the Physician Self-Referral Law (the “**Stark Law**”) and the Anti-Kickback Statute. The changes are sweeping and while they are generally designed to facilitate coordinated care, some of the changes will impact providers more broadly. Most provisions of the final rules are effective on January 19, 2021. The following is a brief overview of the hundreds of pages of rules and commentary:

The Stark Law Final Rule

- **New Value-Based Exceptions:** New exceptions were created to permit compensation arrangements in the context of value-based arrangements designed to coordinate and improve the quality of care for patients and to lower costs.
- **New Cybersecurity Exception and Modification to Existing EHR Exception:** A new exception was created related to donations of cybersecurity technology. In addition, the existing exception related to donations of electronic health record systems was expanded, and the sunset provision was (finally) removed.
- **New Exception for Limited Remuneration to a Physician:** A new exception was created for arrangements where a physician receives remuneration of no more than \$5,000 per calendar year (adjusted annually for inflation) as a fair market value exchange for items or services provided by the physician.
- **Clarification Regarding Group Practices and Designated Health Services (DHS) Profit Sharing:** The Stark Law Final Rule clarifies the manner in which group practices may distribute overall profits derived from DHS within the group. Distributing overall profits from DHS on a “split-pool” basis, where different pools of DHS are shared differently among physicians, is no longer allowed. Instead, in order to qualify as a group practice, the group must aggregate, prior to distribution, the overall profits derived from all DHS of the entire group, or the overall profits from all DHS of any subgroup consisting of five or more physicians. This clarification may have important implications for group practices and, in particular, multi-specialty groups. On the bright side, unlike the other parts of the Final Rule, this clarification is not effective until January 1, 2022.
- **New or Revised Definitions and Other Clarifications:** The Stark Law Final Rule creates a new definition for the term “commercially reasonable” and “general market value” and further revises key definitions such as “volume or value” and “fair market value,” among others. CMS’s stated intention in making these changes is to modernize and clarify the Stark Law to reduce unnecessary burdens while still protecting the Medicare program from fraud and abuse.

The Anti-Kickback Statute Final Rule

- **New Value-Based Safe Harbors:** Three new safe harbors were created for remuneration exchanged among eligible entities in value-based arrangements.
- **New CMS-Sponsored Model Safe Harbors:** CMS finalized a new safe harbor for CMS-sponsored models (such as the BPCI Advanced program) to create greater predictability for model participants and greater uniformity across models. With this safe harbor, the need for separate fraud and abuse waivers for new innovative models should be reduced.

- **Modifications to Existing Safe Harbors and Other New Safe Harbors:** Modifications were made to the safe harbors for Personal Services and Management Contracts, Warranties, and Local Transportation. Additional new safe harbors include a safe harbor for Cybersecurity Technology and Services and for Accountable Care Organization Beneficiary Incentive Programs (codifying a statutory provision).

For more detail on any of these changes and how they may impact your organization, please contact Stephanie S. Sobkowiak at 203.772.7782 or ssobkowiak@murthalaw.com or Julia Boisvert at 860.240.6018 or jboisvert@murthalaw.com.

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