

PUBLICATION

Regulatory Sprint: OIG and CMS Release Long-Awaited Changes to the Anti-Kickback Statute and Stark Law

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The proposed rules released by the Department of Health and Human Services Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) on Wednesday, October 9, 2019 include new exceptions and safe harbors, as well as clarifications to the Physician Self-Referral (Stark) Law, the Anti-Kickback Statute and the civil monetary penalty prohibition against beneficiary inducements. These much-anticipated proposed rules aimed at removing regulatory barriers to coordinated care and value-based care provide some of the most extensive changes to these laws in response to the HHS's Regulatory Sprint to Coordinated Care.

This brief overview of the proposed rules is the first of a series of articles that will include Baker Donelson's extensive analysis of the changes and their potential impact.

Anti-Kickback Statute

The OIG proposes new safe harbors and modifications to existing safe harbors to promote outcome-based payment arrangements that reward improvements in patient health. Notably, the OIG's proposed rule includes three new safe harbors for value-based arrangements protecting arrangements for improved care quality and outcome and efficiency, and arrangements under which the value-based enterprise (VBE) is at substantial or full downside financial risk. The OIG also proposes to expand protections under the Anti-Kickback Statute and the civil monetary penalty law for improved coordination of patient care and health outcomes. Under the proposed rules, CMS-sponsored models, such as the Innovation Center models, can now operate under a safe harbor which would likely replace the current model-by-model fraud and abuse waiver process.

Acknowledging the increased use of technology in patient care and the need for the safe protection of patient information, the OIG's proposed rule includes a new safe harbor for cybersecurity technology and services donations and modifications to the electronic health records safe harbor. The OIG's proposed rule also includes modifications to the personal services and management contracts safe harbor to include a change in the requirement for compensation to be set in advance and the protection of outcome-based payment arrangements. Notably, the OIG states that the proposed protection for outcome-based payment arrangements would not apply to pharmaceutical manufacturers; manufacturers, distributors, and suppliers of durable medical equipment, prosthetics, orthotics or supplies (DMEPOS); and laboratories. Other proposed changes include new protections for bundled warranty arrangements that apply to at least one item and service, a new statutory exception for telehealth technologies furnished to in-home dialysis patients, and modifications to the local transportation exception.

Physician Self-Referral (Stark) Law

CMS issued its proposed rule focused on modernizing and clarifying the Stark Law. Similar to the OIG's proposed rule, CMS's proposed rule creates new and permanent exceptions to the Stark Law for value-based arrangements. While the OIG's definition of VBE expressly excludes manufacturers, distributors, and suppliers of DMEPOS, CMS seeks comments on whether or not to exclude DMEPOS providers from the definition of VBE and seeks comments on the roles that DMEPOS providers play in the coordination of care. Noting the continued importance of price transparency and its impact on a patient's freedom of choice, CMS seeks

comments about the role of price transparency in coordinated care – specifically, whether to include a requirement for price transparency in the value-based arrangement exceptions.

CMS proposes new exceptions for cybersecurity donations and for limited remuneration to a physician, as well as modifications to the current electronic health records exception. As expected, CMS also proposes clarifications to definitions and important Stark Law terms that the industry has grappled with for years – including commercial reasonableness, the volume or value standard as well as fair market value. CMS also discusses the period of disallowance, application of the isolated transaction exceptions and other clarifications to compensation exceptions.

Industry Input and Impact

The proposed rules provide an opportunity to give feedback to CMS and OIG on the expansive modifications to laws that have widespread influence throughout the health care industry. CMS and the OIG consider each comment received in promulgating final rules – and these final rules will have far-reaching impacts for health care as the transition to value-based care continues. The rules are scheduled to be published in the *Federal Register* on October 17, 2019. Based on that publication date, comments will be due by December 31, 2019.

If you would like to discuss the proposed rules, please contact the authors of this alert or a member of the Health Law Regulatory Team.