CLIENT ALERTS & INSIGHTS

HHS Proposes Changes to Stark Law and Federal Anti-kickback Regulations to Advance Value-Based Care and Coordination of Care

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On October 9, 2019, the Centers for Medicare and Medicaid Services ("CMS") and the Office of Inspector General for the Department of Health and Human Services ("OIG") announced proposed changes to modernize and clarify the Physician Self-Referral Law (the "Stark Law"), the Federal Anti-kickback Statute, and Beneficiary Inducement Civil Monetary Penalty Law ("CMPL") regulations.

The primary focus of these proposed changes is to reduce regulatory barriers and accelerate the transition from volume-based care to value-based care and improve the coordination of care among providers and across treatment settings. The proposed changes if adopted will represent some of the most significant revisions in years and a fundamental shift in the healthcare industry. This client alert will be followed by several more in-depth analyses of the proposed revisions.

The "Regulatory Sprint to Coordinated Care"

The Department of Health and Human Services ("HHS") launched the "Regulatory Sprint to Coordinated Care" in 2018 (the "Regulatory Sprint"). The Regulatory Sprint is aimed at removing potential regulatory barriers to care coordination and value-based care in several key Federal health care laws, including the Stark Law and the Federal Anti-kickback Statute.

As part of the Regulatory Sprint, HHS identified the Stark Law, the Federal Anti-kickback Statute, and the CMPL as potentially inhibiting arrangements beneficial to the advancement of the transition to value-based care and coordination of care among providers. Due to the broad reach of and the dire consequences of noncompliance with these laws, HHS was concerned that providers and suppliers may be discouraged from entering into innovative arrangements that could improve quality and health outcomes, produce health system efficiencies, and lower or slow the growth of healthcare costs.

Proposed Rules

As evidenced by the joint release of the proposed rules by CMS and the OIG, the agencies worked closely together to design the proposed revisions to promote coordinated patient care and improve quality and health outcomes, produce health system efficiencies, and lower or slow the growth of costs, while still safeguarding against the fraud and abuse that the Stark Law, the Federal Anti-kickback Statute, and CMPL were enacted to address.

The proposed revisions include:

- Value-Based Care Safe Harbors and Exceptions. CMS and the OIG proposed new Stark Law exceptions and Federal Anti-kickback safe harbors for value-based arrangements that meet certain requirements that depend on the type of remuneration provided, the level of financial risk, and the safeguards included.
- New Exception and Safe Harbor for Cybersecurity Technology. CMS and the OIG proposed a new Stark Law exception and Federal Anti-kickback safe harbor for donations of cybersecurity technology and services.
- Revisions to Electronic Health Records ("EHR") Items and Services Exception and Safe Harbor. CMS and the OIG proposed modifications to the existing Stark Law exception and Federal Anti-kickback Statute safe harbor for EHR items and services.
- New Stark Law Defined Terms or Regulatory Modifications.
    - Stark Law Key Defined Terms.
        - CMS proposed new definitions for several key terms under the Stark Law, including commercial reasonableness, the volume or value of referrals, and fair market value.
        - CMS proposed to modify the definition of "designated health services" to clarify that an inpatient hospital service is a "designated health service" under the Stark Law only if the service affects the amount of reimbursement the hospital receives from Medicare.
    - "Group Practice" Requirements. CMS proposed modifications to the definition of "group practice" related to its revisiting the definitions of commercially reasonable, fair market value, and the volume and value of referrals, and to the transition to a value-based health care system, including modifications to the rules regarding productivity bonuses and profit shares.
    - Temporary Non-compliance. CMS proposed to increase the grace period for non-compliance with certain writing requirements to 90 days.
    - Period of Disallowance. CMS proposed deleting the existing rules regarding the period of disallowance - the period during which a physician is prohibited from making referrals of DHS to an entity. CMS determined the existing regulations did not provide the intended clarity when trying to make this determination. However, CMS maintains that the period of disallowance begins when a relationship fails to comply with an exception and ends when the relationship ends or is brought into compliance.
    - Decoupling the Stark Law from the Federal Anti-kickback Statute. A number of the existing Stark Law exceptions have a requirement that the relationship comply with the Federal Anti-kickback Statute. CMS proposed deleting this requirement for a number of reasons, including the consequences of injecting the intent-based nature of the Federal Anti-kickback Statute into the strict liability Stark Law and CMS's determination that most if not all arrangements that violated the Federal Anti-kickback Statute would not comply with the other requirements of the applicable exception.

- Other New or Revised Stark Law Exceptions
  - Limited Remuneration to a Physician Exception. CMS proposed a new Stark Law exception for certain remuneration to a physician that does not exceed $3,500 annually in the aggregate.
  - Revisions to Existing Compensation Relationships Exceptions. CMS proposed also various revisions to the space lease, recruitment, fair market value, compensation unrelated to the provision of DHS, and payments by physicians exceptions.

- Other New or Revised Federal Anti-Kickback Safe Harbors and CMPL Exceptions.
  - Patient Engagement. The OIG proposed a new safe harbor for certain tools and supports furnished to patients to improve quality, health outcomes, and efficiency.
  - CMS Sponsored Models. The OIG proposed a new safe harbor for certain remuneration provided in connection with CMS-sponsored models to help reduce the need for separate and distinct fraud and abuse waivers for new CMS-sponsored models.
  - Personal Services and Management Contracts Safe Harbor. The OIG proposed modifications to the Personal Service and Management Contracts Safe Harbor to add flexibility with respect to outcome-based payments and part-time arrangements.
  - Location Transportation Safe Harbor. The OIG proposed modifications to the Local Transportation Safe Harbor to expand and modify mileage limits for rural areas and for transportation for patients discharged from inpatient facilities.
  - Warranties. The OIG proposed modifications to the Warranties Safe Harbor to revise the definition of "warranty" and provide protection for bundled warranties for multiple items and related services.

- CMPL Exceptions
  - ACO Beneficiary Incentive Programs. The OIG proposed to codify the statutory exception to the definition of "remuneration" under the CMPL related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program.
  - Telehealth for In-home Dialysis. The OIG proposed an exception to the regulatory definition of "remuneration" under the CMPL for "telehealth technologies" furnished to certain in-home dialysis patients.

Comments on the proposed changes from the public will be due 75 days from the date of publication in the Federal Register. As both sets of changes to the regulations are currently scheduled to be published in the Federal Register on October 17, 2019, the comments are expected to be due no later than December 31, 2019.

Questions?

If you have questions regarding the proposed revisions or the notice and comment process, please contact a member of Benesch's Health Care & Life Sciences Practice Group.

Additional Information

HHS's press release can be found here.

The OIG's proposed rule can be found here.

Further information on the OIG's proposed changes can be found here.

CMS's proposed rule can be found here.

Further information on CMS's proposed changes can be found here.