SQUIRE PATTON BOGGS

Proposed Changes to the Anti-Kickback Statute, Stark Law and Civil Monetary Penalties Law Address Value-Based Healthcare Environment

On October 9, the Department of Health and Human Services (HHS) released proposed rules (the Proposed Rules) aiming to update the Anti-Kickback Statute (the AKS), Stark Law and Civil Monetary Penalties Law (CMPL) to address today's value-based and coordinated healthcare environment. The proposals reflect a recognition on HHS's part that the healthcare landscape of today is significantly different from when these laws were adopted. Overall, HHS's Proposed Rules appear directed at ensuring that the AKS, the Stark Law and the CMPL will not stand as an impediment to the shift toward value-based care and increased coordination of patient care among providers and across care settings. Consequently, the Proposed Rules introduce new exceptions and safe harbors, as well as re-evaluate certain existing provisions.

Background

The Proposed Rules were developed as part of HHS's Regulatory Sprint to Coordinated Care program. The aim of the Regulatory Sprint program is to remove potential regulatory barriers to care coordination and value-based care under certain federal healthcare laws, including the AKS and Stark Law.

HHS's stated aims under the Regulatory Sprint include encouraging and improving (i) a patient's ability to understand treatment plans and make empowered decisions; (ii) provider's alignment on end-to-end treatment; (iii) incentives for providers to coordinate, collaborate and provide patients tools to be more involved in their own care; and (iv) information sharing among providers, facility and other stakeholders in a manner that facilitates efficient care while preserving and protecting patient access to data.

In 2018, as part of the Regulatory Sprint, the HHS Office of Inspector General (OIG) and Centers for Medicare and Medicaid Services (CMS) issued a request for information (RFI), with the OIG seeking comments regarding the AKS and CMPL, and CMS seeking comments regarding the Stark Law. The purpose of each RFI was to obtain feedback on how these laws may be modified (including the adoption of new safe harbors and exceptions) to better foster arrangements that would promote care coordination and advance the delivery of value-based care while still protecting patients and federal programs. The Proposed Rules were developed in consideration of the comments received through the RFI process.

Stark Law

Under CMS's Proposed Rules provisions, CMS aims to adopt new Stark Law exceptions, and proposes to revise or reconsider certain of its existing Stark Law definitions and exceptions. The stated intent of these changes is to (i) alleviate the undue impact of the Stark Law on parties that participate in alternative payment models; (ii) to facilitate care coordination; and (iii) to balance genuine program integrity concerns against the burden of the Stark Law's billing and claims submission prohibitions.

New Exceptions

Value-Based Arrangements: CMS proposes a new exception to address arrangements identified as "value-based arrangements" among value-based enterprise participants. The exception would apply to value-based arrangements incorporating "full financial risk" between participants, arrangements with "meaningful downside" financial risk to physicians and value-based arrangements regardless of risk level. The exception would apply differing requirements depending upon which category of value-based arrangement the relationship applies.

Limited Remuneration to a Physician: CMS also proposes a new exception that would permit payment of limited remuneration from an entity to a physician up to US$3,500 per calendar year (updated annually based on CPI). This exception would allow certain limited payments to physicians for items and services actually provided by the physician to the entity with fewer restrictions than typically found under other exceptions (e.g., the proposed exception has no writing requirement).

Cybersecurity Technology and Related Services: This proposed exception permits the provision of nonmonetary remuneration consisting of technology and services necessary and used predominantly to implement, maintain or reestablish cybersecurity. For purposes of the exception, "technology" is defined as software or other types of information technology **other than** hardware.

Definitions: CMS proposes to make several changes to the Stark Law's regulatory definitions presented under 42 C.F.R. § 411.351. These changes include the adoption of new definitions related to the proposed Value-Based Arrangements Exceptions, such as a definition of "value-based arrangement" and "value-based enterprise." Other changes include narrowing the definition of "designated health services" (excepting certain hospital services paid under the IPPS), introducing a definition for "commercial reasonableness" and revising the definition of "fair market value."

Group Practice Requirements: CMS proposes changes to the Stark Law's group practice requirements under 42 C.F.R. § 411.352, clarifying provisions regarding productivity bonuses and profit shares, and adding a provision regarding value-based enterprise participation.

Period of Disallowance: CMS proposes to revise 42 C.F.R. § 411.353 to remove the period of disallowance rules under subsection (c) in their entirety.

Financial Relationship, Compensation and Ownership or Investment Interests: CMS proposes to revise its Stark Law regulations defining when a financial relationship exists. These revisions would clarify the definition of titular ownership, and revise provisions concerning indirect compensation relationships to address indirect value-based arrangements. The Proposed Rules also include changes to the temporary noncompliance provisions, permitting otherwise compliant arrangements to meet the writing requirement of a particular exception if the arrangement is reduced to writing within ninety (90) days of inception.

Compensation Arrangement Exceptions: The Proposed Rules contain many revisions to existing exceptions under 42 C.F.R. § 411.357 for compensation arrangements. These changes include a potential revisiting of the Payments by a Physician Exception under 42 C.F.R. § 411.357(i), with CMS liberalizing its interpretation of the exception's applicability. Additionally, CMS retracts is prior statements that office space is neither an "item" nor "service" under the exception.

"De-Coupling" From the Anti-Kickback Statute: CMS proposes to amend several provisions in the Stark Law regulations by removing reference to compliance with AKS as an element of compliance with the particular Stark Law regulatory provision.

Anti-Kickback Statute/CMPL

As part of its Proposed Rules provisions, the OIG has proposed several new AKS safe harbors relating, in part to value-based arrangements. The OIG also proposes to revise certain existing safe harbors, and to amend provisions of the CMPL to ease beneficiary inducement limitations. Similar to CMS, the OIG's stated goal of its proposed rule is to "remove potential barriers to more effective coordination and management of patient care and delivery of value-based care that improves quality of care, health outcomes and efficiency."

New Safe Harbors

Care Coordination Arrangements to Improve Quality, Health Outcomes and Efficiency Safe Harbor: This safe harbor would be designed to cover certain care coordination arrangements, protecting in-kind, nonmonetary remuneration exchanged between qualifying value-based enterprise participants with compliant value-based arrangements. Unlike some of the new Stark Law exceptions, this safe harbor would not require the parties to assume downside financial risk.

Value-Based Arrangements With Substantial Downside Financial Risk Safe Harbor: This safe harbor would protect both monetary and in-kind remuneration for value-based arrangements where the participants have assumed substantial downside financial risk and meaningfully share in such risk.

Value-Based Arrangements With Full Financial Risk Safe Harbor: This safe harbor would protect arrangements where the value-based enterprise assumes full financial risk under the arrangement. The OIG states that this safe harbor is intended to offer the greatest ability to innovate with respect to coordinated care arrangements.

Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes and Efficiency Safe Harbor: The stated goal of this safe harbor is to remove barriers presented by the AKS and CMPL to providers offering patients beneficial tools and supports to improve quality, health outcomes and efficiency by promoting patient engagement.

Safe Harbor for CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives: This safe harbor would protect remuneration between parties in arrangements participating under a model or other initiative being tested or expanded by CMS.

Cybersecurity Technology and Related Services Safe Harbor: This safe harbor would protect certain donations of cybersecurity technology and related services, provided the donation contains certain safeguards.

ACO Beneficiary Incentive Program: The OIG also proposes to amend its safe harbor regulations clarifying that "remuneration" does not include an incentive payment made by an ACO to an assigned beneficiary under a beneficiary incentive program established under the Medicare Shared Savings Program.

Modifying Existing Safe Harbors

The OIG also proposes to modify certain existing safe harbors. Specifically, the OIG plans to modify the Safe Harbor for Electronic Health Records Items and Services to add protections for certain cybersecurity technology, to update provisions regarding interoperability and to remove the sunset date. Additionally, the OIG proposes to modify the Personal Services and Management Contracts Safe Harbor to add flexibility with respect to outcomes-based payments and part-time arrangements. The OIG also proposes to expand and modify mileage limits under the Local Transportation Safe Harbor and to modify the definition of "warranty" under the Warranties Safe Harbor.

CMPL Changes

The OIG proposes to amend the definition of "remuneration" under the CMPL regulations to permit provision of "telehealth technologies" to certain in-home dialysis patients.

The Proposed Rules changes will likely have a significant impact on arrangements in the healthcare space. Overall, the changes, if adopted, would seem to loosen regulatory restrictions on healthcare-related financial arrangements, and may present significant opportunities for a variety of stakeholders.

Both the OIG and CMS are soliciting comments for the proposed rules. Such comments will be due 75 days from the date of publication in the Federal Register (expected to be October 17, 2019).

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