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HHS Releases Proposed Stark Law, Anti-Kickback Statute, and Civil Monetary Penalties Law Reforms

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On October 9, 2019, the Department of Health and Human Services ("HHS") issued proposed changes to the regulations implementing the Physician Self-Referral Law (the "Stark Law"), the Anti-Kickback Statute (the "AKS"), and the Civil Monetary Penalties Law ("CMP Law"). The proposed rules are part of HHS's "Regulatory Sprint to Coordinated Care," an initiative to reduce regulatory burdens on the expansion of value-based care. The rules also follow the requests in 2018 by both the Centers for Medicare & Medicaid Services ("CMS") and the Office of the Inspector General ("OIG") seeking input from the public on the impact of the Stark Law, and the AKS and the beneficiary inducement provisions of the CMP Law, respectively.

CMS and OIG coordinated their proposed changes to the Stark Law and the AKS regulations. As such, it is recommended that stakeholders review and submit comments on both proposed rules. Comments are due within 75 days of publication of the proposed rules in the Federal Register, which should be on or around December 31, 2019. Proskauer's Health Care team can assist with developing and submitting comments to the proposed rules.

Below is a general summary. Look for our future posts that will dig deeper into a handful of topics most relevant to our clients.

Proposed Changes to the Stark Law Regulations

CMS's proposed changes to the Stark Law regulations include new exceptions, amendments to the existing exception on electronic health records, and general clarifying guidance for those whose financial relationships are governed by the Stark Law.

1. New Exceptions

1. **Value-Based Compensation Arrangements**. CMS proposed three new exceptions at 42 C.F.R. § 411.357(aa) for certain remuneration exchanged between or among eligible participants in a value-based arrangement, which vary based on the level of financial risk assumed by the arrangement's participants. CMS hopes that these new exceptions will encourage innovative arrangements, improve quality outcomes, produce health system efficiencies, and lower costs.
2. **Limited Remuneration Arrangements**. CMS seeks to add a new exception at § 411.357(z) to protect remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed an aggregate of $3,500 per calendar year (as adjusted for inflation).
3. **Donations of Cybersecurity Technology**. In an effort to increase cybersecurity donations while balancing the risk of program or patient abuse, the proposed exception at § 411.357(bb) would impose a number of requirements, including that the donation be necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

2. Modifications to Existing Exception on Electronic Health Records

CMS proposed certain changes to the electronic health record ("EHR") exception at § 411.357(w) to broaden the reach of the exception and to either eliminate the sunset provision (so as to make the exception permanent) or extend the sunset date past December 31, 2021.

3. Clarifying Guidance on Fundamental Terminology

Many of the Stark Law's exceptions include one, two, or all of the following requirements: the compensation arrangement itself is commercially reasonable; the amount of the compensation is fair market value; and the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals (or, in some cases, other business generated between the parties). The industry has constantly sought further guidance from CMS on these concepts.

In the proposed rule, CMS mentions that it understands the desire for bright-line rules and, as a result, CMS provides clarity on this fundamental terminology. If finalized, these concepts will be an important benchmark for measuring stakeholder compliance and for CMS's enforcement capability.

Proposed Changes to the AKS and CMP Law Regulations

The OIG's proposed changes to the AKS regulations include new exceptions to the definition of "remuneration" and amendments to certain existing exceptions. OIG notes that its guiding principles were to (1) "design proposed safe harbors that allow for beneficial innovations in healthcare delivery," (2) "avoid promulgating safe harbors and exceptions that drive such innovation to limited channels that may not reflect up-to-date understandings in medicine, science, and technology," and (3) "design proposed safe harbors useful for a range of entities engaged in the coordination and management of patient care. . ."

1. New AKS Exceptions

The OIG proposed additional safe harbors to the AKS, which would be added to 42 C.F.R. § 1001.952, and provide only prospective protection for relevant arrangements. These include:

1. **Value-Based Arrangements**. These safe harbors would protect remuneration within a value-based arrangement that fosters coordinated and managed patient care: Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency (§ 1001.952(ee)); Value-Based Arrangements with Substantial Downside Financial Risk (§ 1001.952(ff)); Value-Based Arrangements with Full Financial Risk (§ 1001.952(gg)).
2. **Patient Engagement**. The proposed new safe harbor (§ 1001.952(hh)) would protect certain tools and supports furnished under patient engagement and support arrangements to improve quality, health outcomes, and efficiency.
3. **CMS-Sponsored Models**. The proposed new safe harbor (§ 1001.952(ii)) would protect certain remuneration provided in connection with a CMS-sponsored model, with the goal of preventing the need for OIG to issue separate waivers for each new CMS-sponsored model.
4. **Cybersecurity Technology and Services**. The proposed new safe harbor (§ 1001.952(jj)) would protect certain donations of cybersecurity technology and services.
5. **ACO Beneficiary Incentive Programs**. The proposed new safe harbor (§ 1001.952(kk)) codifies the statutory AKS exception to the definition of remuneration relating to the ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program.

2. Modifications to Existing AKS Exceptions

The proposed rules would modify a number of existing safe harbors, including by adding protections for certain EHR cybersecurity technology (§ 1001.952(y)), revising the definition of "warranty" in the warranty safe harbor (§ 1001.952(g)), and expanding and modifying mileage limits for rural areas and for transportation for discharged patients for the local transportation safe harbor (§ 1001.952(bb)). In addition, the proposed rule would add flexibility under the personal services and management contracts safe harbor (§ 1001.952(d)) for outcome-based payments and part-time arrangements, including by eliminating the requirement from the safe harbor that aggregate payments and the specific dates and times of services be set in advance. This would bring the safe harbor into alignment with the Stark personal services exception, thereby simplifying compliance for the contracting parties.

3. New CMP Law Exception

The OIG proposed to amend the definition of "remuneration" in the CMP rules at 42 C.F.R. §1003.110 by interpreting and incorporating a new statutory exception to the prohibition on beneficiary inducements for "telehealth technologies" furnished to certain in-home dialysis patients. In addition, if adopted, the new AKS safe harbor for patient engagement (§ 1001.952(hh)) and the modifications to the local transportation safe harbor (§ 1001.952(bb)) would, by operation of law, become exceptions to the CMP Law's definition of "remuneration."

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