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CMS Releases Final Rules Implementing Stark Law Changes to Reflect Value-based Healthcare Delivery and Payment Environment

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On Wednesday, December 2, the Centers for Medicare and Medicaid Services (CMS) published final rules implementing many of the Stark Law changes first proposed in October 2019 (the Final Rules).[1]

These changes have been adopted to address the shift to a value-based and coordinated healthcare environment. The Final Rules represent CMS' recognition that the healthcare delivery and payment environment has changed from the "fee-for-service" model under which the Stark Law was developed, and that, in its current form, the Stark Law can impede the development of value-based relationships. In connection with this change, the Final Rules introduce new Stark Law exceptions and revise or reevaluate many existing Stark Law exceptions and definitions.

Background

The Final Rules were developed as part of the US Department of Health and Human Services' (HHS) Regulatory Sprint to Coordinated Care program (the Regulatory Sprint), which aims to remove potential regulatory barriers to care coordination and value-based care under certain federal healthcare laws, including the Stark Law.

In 2018, as part of the Regulatory Sprint, CMS issued a request for information (RFI) seeking comments regarding the Stark Law. The purpose of the RFI was to obtain feedback on how the Stark Law may be modified (including the adoption of new exceptions) to better foster arrangements that would promote care and coordination and advance the delivery of value-based care while still protecting patients and federal programs. The Final Rules were developed in consideration of the comments received through the RFI process and comments received regarding the proposed rules.

CMS has identified four broad policies that the Final Rules implement:

- Finalizing new, permanent exceptions for value-based arrangements that will permit physicians and other healthcare providers to design and enter into value-based arrangements
- Finalizing additional guidance on key requirements of Stark Law exceptions to make it easier for physicians and other healthcare providers to make sure they comply with the law
- Finalizing other new exceptions to provide protection for non-abusive, beneficial arrangements between physicians and other healthcare providers (e.g., donations of cybersecurity technology)
- Reducing administrative burdens that drive up costs by taking money previously spent on administrative compliance and redirecting it to patient care[2]

In CMS' view, the Final Rules include "a comprehensive package of reforms to modernize the regulations that interpret the Stark Law while continuing to protect the Medicare program and patients from bad actors" and will "support the necessary evolution of the American healthcare delivery and payment system."[3]

Exception for Value-based Arrangements

The Final Rules implement a new exception for "value-based arrangements" among value-based enterprise participants. This new exception applies whether the arrangement relates to care to Medicare beneficiaries, non-Medicare patients or a combination of both, and contains separate requirements for arrangements incorporating "full financial risk," "meaningful downside risk" (i.e., at least 10% of the value the physician receives is subject to repayment), and for value-based arrangements regardless of risk level. Generally, the exception's requirements become stricter for arrangements involving less financial risk. For example, the exception does not contain a writing requirement for arrangements involving full financial risk (unless the arrangement contains a referral requirement), whereas arrangements with little or no downside risk must be in writing and are subject to monitoring requirements to be eligible for the exception's protection. Notably, unlike most exceptions for compensation arrangements, the value-based arrangement exception applies to arrangements where the relationship between the physician and Stark entity is indirect.

New Exceptions for Certain "Non-abusive Business Practices"

In addition to finalizing the new exception for value-based arrangements, CMS finalized new exceptions to protect certain arrangements between physicians and healthcare providers that CMS views as non-abusive.

1 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations. 85 Fed. Reg. 77,492 (Dec. 2, 2020) (to be codified at 42 C.F.R. pt. 411).

2 www.cms.gov/newsroom/press-releases/cms-announces-historic-changes-physician-self-referral-regulations, accessed on December 16, 2020.

3 www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-final-rule-cms-1720-f, accessed on December 16, 2020.

Limited Remuneration to a Physician Exception

CMS finalized a new exception that would permit payment of limited remuneration to physicians for items and services actually provided by the physician to the entity. Given that the exception applies to limited arrangements (US$5,000 maximum), it contains fewer restrictions than typically found under other exceptions. For example, the new Limited Remuneration Exception contains no writing requirement, or requirement that compensation be set in advance. The exception limits compensation to US$5,000 annually, which limit will be adjusted annually based on increases in the Consumer Price Index-Urban All Items. This is a notable increase from the US$3,500 limit originally proposed by CMS.

Cybersecurity Technology and Related Services

CMS also finalized a new exception to permit the provision and donation of nonmonetary remuneration consisting of technology and services necessary and used predominantly to implement, maintain or reestablish cybersecurity. Unlike the exception for certified electronic health record technology (CHERT) donations, this cybersecurity exception does not require that the recipient pay any portion of the costs for the cybersecurity technology and/or services. Furthermore, as finalized, the exception applies to the provision of hardware that is necessary and used predominantly to implement, maintain or reestablish cybersecurity. This differs from the exception's originally proposed version, which expressly did not apply to hardware.

Changes to Certain Fundamental Terms

The Final Rules make changes to some of the fundamental terms used for Stark Law analysis, namely implementing a definition for "commercially reasonable," clarifying the standards for "volume or value" and "other business generated," and revising the definition of fair market value. Under the new definition for "commercially reasonable," CMS makes it clear that an arrangement need not be profitable to be commercially reasonable. The Final Rules also narrow the definition of "Designated Health Services" to exclude certain services furnished to hospital inpatients if the furnishing of the service does not increase the amount of Medicare's payment under certain prospective payment systems.

Group Practices

The Final Rules revise the rules for group practice productivity bonuses and profit shares under 42 C.F.R. § 411.352 to provide group practices greater flexibility in distributing payments relating to value-based arrangements. CMS also clarifies the definition of "overall profits" for group practices, making it clear that the term means the profits derived from all designated health services of any component of the group practice consisting of at least five physicians. In connection with this, CMS confirms that DHS profits may not be distributed on a service-by-service basis. Unlike the other provisions of the Final Rule, these revisions to the group practice definition become effective on January 1, 2022.

Revisions and Changes to Other Exceptions and Provisions

In addition to adding new exceptions and revising key definitions, the Final Rules implement changes and clarifications to many existing Stark Law exceptions and concepts. Some of the key changes are as follows:

"De-coupling" From the Anti-Kickback Statute

CMS finalized its proposal to amend several Stark Law exceptions to remove reference to compliance with the Anti-Kickback Statute as an element of compliance with the Stark Law exception. Notably, this requirement was not removed from the exception for fair market value compensation under 42 C.F.R. § 411.357(l).

Period of Disallowance

CMS finalized its proposal to revise 42 C.F.R. § 411.353 to remove the period of disallowance provisions in their entirety.

Special Rules on Compensation Arrangements

CMS finalized its proposed changes to the temporary noncompliance provisions, permitting otherwise compliant arrangements to meet the writing and signature requirements of a particular exception if the arrangement is reduced to writing and signed within 90 days of inception. CMS also finalized requirements under 42 C.F.R. § 411.354(d)(1)(ii) for modifying compensation (or the formula used to calculate compensation) during the course of an arrangement.

Payments by a Physician Exception

CMS clarified its position on the applicability of the exception for payments by a physician under 42 C.F.R. § 411.357(i). Specifically, CMS stated its position that the exception is not available for arrangements that may be covered under the statutory exceptions set forth under 42 C.F.R. § 411.357(a) through § 411.357(i), but is available for arrangements that may be covered under the regulatory exceptions set forth at 42 C.F.R. § 411.457(j) *et seq.* This differs from past statements from CMS that suggested the exception's application was much more limited.

Fair Market Value Exception

CMS revised the exception for fair market value compensation under 42 C.F.R. § 411.357(l) to now make it available for the lease of office space or equipment (subject to limitations on percentage-of-revenue or per-unit-of-service payment terms). While compliance with the Anti-Kickback Statute remains an element for this exception, the requirement that the arrangement not violate laws governing billing or claims submission has been removed.

Other Changes

The Final Rules also contain revisions and clarifications for other Stark Law exceptions, including the exceptions for rentals of office space or equipment under 42 C.F.R. § 411.357(a) and (b) (clarifying that only the lessor is the party that must be excluded from using the space or equipment), the exception for electronic health records items and services under 42 C.F.R. § 411.357(w) (removing the sunset provision and clarifying certain terms), and the exception for assistance to compensate a nonphysician practitioner under 42 C.F.R. § 411.357(x) (clarifying terms). CMS did not finalize the changes it originally proposed for the exception for remuneration unrelated to the provision of designated health services, set forth under 42 C.F.R. § 411.357(g), stating that it will continue to evaluate the best way to restore utility to that exception.

Effective Date

Except for the changes to the group practice provisions described above, the Final Rules' provisions will go into effect January 19, 2021. The group practice provisions will go into effect January 1, 2022.

Overall, the Final Rules' changes represent some of the most significant changes to the Stark Law's regulatory structure since its inception. Generally, the changes appear to loosen many regulatory restrictions on healthcare-related financial arrangements, and may present significant opportunity for a variety of stakeholders. While it will take time to ascertain fully whether the Final Rules' changes are enough to bring the Stark Law in line with today's value-based healthcare environment, the changes do seem to be a step in the right direction.

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