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MAJOR CHANGES TO STARK LAW AND ANTI-KICKBACK STATUTE REGULATIONS PERMIT 'VALUE-BASED ARRANGEMENTS' AND CLARIFY EXISTING REGULATORY REQUIREMENTS

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On Dec. 2, 2020, the U.S. Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS) and Office of Inspector General (OIG) each published final rules modernizing and clarifying regulations concerning the Physician Self-Referral Law (42 U.S.C. § 1395nn), commonly referred to as the "Stark law," and the anti-kickback statute (AKS) (42 U.S.C. § 1320a-7b), respectively. The new rules contain sweeping changes to facilitate the development of "value-based arrangements," lessen the burden of regulatory compliance, and provide more clarity. This alert is intended as a primer on the most significant changes implemented through the new regulations. Most of the regulatory changes implemented through the final rules will be effective Jan. 19, 2021.

VALUE-BASED ARRANGEMENTS

The key initiative behind the regulatory changes implemented in the final rules is to ease the transition of healthcare services to value-based arrangements and move the Medicare program away from its traditional emphasis on fee-for-service arrangements. Accordingly, CMS and the OIG created three value-based exceptions under the Stark law and safe harbors under the AKS.

The new Stark law exceptions and corresponding AKS safe harbors protect three different forms of value-based arrangements: (i) arrangements in which participants bear full financial risk for healthcare items or services required for a target population, (ii) arrangements with substantial downside risk for physicians, and (iii) certain value-based arrangements that involve neither full nor substantial downside risk but are closely monitored to ensure that value-based objectives are achieved. The regulatory requirements associated with each of those exceptions depend on the risk level; arrangements involving more risk for providers and suppliers contain fewer requirements. Thus, an arrangement with full financial risk contains the fewest number of requirements for compliance.

To be eligible for the new value-based exceptions, the providers involved must form a "value-based enterprise," which is two or more participants (e.g., clinicians, providers, and suppliers) who collaborate to achieve a value-

based purpose. “Value-based purpose” is defined in the regulations as any of the following: (i) coordinating and managing the care of a target patient population; (ii) improving the quality of care for a target patient population; (iii) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or (iv) transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target population. The providers and suppliers participating in the value-based enterprise must agree upon a written document describing how the enterprise will achieve its value-based purposes, and the value-based enterprise must have an accountable body or person responsible for oversight of the enterprise’s finances and operations.

Notably, the Stark law exceptions and AKS safe harbors for value-based arrangements are not identical. As a result, a separate analysis of each statute’s regulations must be completed in order to ensure that a specific value-based arrangement is compliant.

OTHER NEW EXCEPTIONS AND SAFE HARBORS

In addition to the value-based arrangements, CMS and the OIG finalized the creation of two other notable exceptions and safe harbors.

Limited Remuneration to a Physician. This new Stark law exception permits an entity to, without a signed agreement, pay a physician (but not the physician’s immediate family member) up to an aggregate of $5,000 per calendar year in exchange for items or services received from the physician, if certain conditions are met. As with many other exceptions, the compensation paid to the physician must not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician, must not exceed the fair market value of the items or services, and must be commercially reasonable even if no referrals were made between the parties. This exception even protects arrangements under which the physician provides items or services through hired employees, through a wholly owned entity, or through *locum tenens* physicians. Though limitations apply, this exception creates a potential solution when payments are made to physicians without a written agreement.

Cybersecurity Technology and Related Services. The CMS and the OIG also published a cybersecurity exception and safe harbor for the donation of technology and services. The cybersecurity exception and safe harbor is broader in scope and does not include all the restrictions contained in the current electronic health records exception and safe harbor. For example, the cybersecurity exception and safe harbor permit the donation of hardware in certain circumstances. This new exception will give entities more flexibility in assisting affiliated physicians and physician groups in developing and strengthening their physician practices’ cybersecurity efforts.

REVISIONS TO EXISTING EXCEPTIONS AND SAFE HARBORS

CMS and the OIG’s regulatory revisions also contain several important alterations to existing rules and definitions. Although this alert does not provide an exhaustive list of those regulatory changes, below is a brief description of some of the most significant revisions.

Local Transportation Safe Harbor. The local transportation safe harbor currently protects free or discounted local transportation services for federal healthcare program beneficiaries, up to a distance of 25 miles traveled one-way or 50 miles if the patient resides in a rural area. The OIG has expanded the rural-area mileage restriction from 50 miles to 75 miles. Further, the revised safe harbor removes mileage limitations completely for the transportation of patients to their residence upon discharge from an inpatient admission or from 24-hour observation.

Definition of Commercially Reasonable. The final rule contains a new definition of “commercially reasonable,” a concept incorporated into many Stark law exceptions. Under the revised regulations, an arrangement is commercially reasonable when “the particular arrangement furthers a legitimate business purpose of the parties to

the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty." The new regulations also say that "an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties." In the commentary to the final rule, CMS stated that an arrangement may be commercially reasonable even if unprofitable where the arrangement addresses an otherwise unmet community need for a particular service.

Definition of the Volume or Value Standard and the Other Business Generated Standard. Adopting a new approach, CMS revised the Stark law regulations to specifically define when compensation takes into account the volume or value of referrals or other business generated between the parties. The final regulations state that compensation takes into account the volume or value of referrals when the formula used to calculate the amount of compensation includes referrals or other business generated as a variable and when the amount of compensation correlates with the number or value of the physician's referrals or business generated. It remains to be seen how courts and law enforcement officials will interpret and apply the new formula-based approach to this Stark law requirement

Temporary Noncompliance with Writing and Signature Requirements. In the final rules, CMS provided a period of leniency for "temporary noncompliance" with signature and writing requirements for 90 days after the date such requirement begins. This provision may prove helpful for transactions needing to be completed urgently or within an emergency. Please note that this change applies only to the writing and signature requirements in the Stark exceptions, and in order for an arrangement to be protected under an exception, all other elements of that exception must be met, including the requirement that the compensation be set in advance.

SUMMARY

In summary, the CMS and OIG final rules provide significant alterations to existing exceptions and new opportunities to form value-based arrangements. These new regulations may increase the willingness of providers to pursue value-based care models, and many revisions the OIG and CMS implemented may provide greater clarity in application of the Stark law and AKS. If you have any questions about how these new regulations will affect your business, we are happy to work through those questions with you.

FOR MORE INFORMATION

If you have questions or want more information regarding the provisions summarized in this alert, please review the AKS final rule here and the Stark law final rule here or contact your legal counsel. If you do not have regular counsel for such matters, Foulston Siefkin LLP would welcome the opportunity to work with you to meet your specific business needs. Foulston's healthcare lawyers maintain a high level of knowledge regarding federal and state regulations affecting the healthcare industry. At the same time, our healthcare practice group's relationship with Foulston's other practice groups, including the taxation, general business, labor and employment, and commercial litigation groups, enhances our ability to consider all of the legal ramifications of any situation or strategy. For more information, contact **Brooke Bennett Aziere** at 316.291.9768 or baziere@foulston.com, or **Alex Schulte** at 913.253.2155 or aschulte@foulston.com. For more information on the firm, please visit our website at **www.foulston.com**.

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