KEY TAKEAWAYS FROM THE STARK LAW FINAL RULE

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On January 19, 2021, the final rule modernizing and clarifying the regulations interpreting the Medicare physician self-referral law (Stark Law) takes effect. The Centers for Medicare and Medicaid Services ("CMS") issued the final Stark Law rule in conjunction with the Office of Inspector General ("OIG") final rule that updated the safe harbors under the federal Anti-Kickback Statute ("AKS") and added a new exception to the Beneficiary Inducements Civil Monetary Penalties Law ("CMP"), which we discuss in a corresponding alert here. The interwoven regulations are part of the "Regulatory Sprint to Coordinated Care" to remove potential regulatory barriers to care coordination and value-based care.

With changes in the healthcare landscape, the existing regulations were viewed increasingly as outmoded due to their focus on combating overutilization in a fee-for-service, volume-based system. Integrated care models, in contrast, protect against overutilization by aligning clinical decisions and outcomes with economic performance. The intent of the regulatory revisions is to support the transition from reimbursement mechanisms based on the volume of items and services, to those based on the quality of, and cost control over, care for a target patient population.

Among the many changes in the Stark Law final rule, the following are some of the most significant:

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1. New Value-Based Exceptions

The final rule creates new exceptions to the Stark Law for value-based arrangements that satisfy specified requirements based on the characteristics of the arrangement and the level of financial risk assumed by the parties. A "value-based enterprise" is essentially a network of individuals and entities (such as clinicians, providers and suppliers) that have agreed to collaborate to achieve one or more value-based purposes. A "value-based purpose" is one or more of the following: coordinating and managing care; improving the quality of care; appropriately reducing healthcare costs or growth in expenditures without reducing the quality of care; or transitioning from delivery and payment mechanisms based on the volume of items and services, to the quality of care and control of costs for a target patient population. The final rulemaking identifies exceptions based upon three levels of risk: value-based arrangements with full financial risk; value-based arrangements with meaningful downside financial risk; or any value-based arrangement, without regard to the level of risk, provided specified requirements are met.

To illustrate, the value-based exceptions could facilitate an arrangement designed to prevent the readmission of patients following hip surgery by requiring the participants – networks of physicians and other providers such as hospitals and skilled nursing facilities – to contribute to the repayment of shared losses relating to patient readmissions. The financial risk incentivizes the value-based enterprise to monitor for appropriate utilization, referral patterns and quality performance, thereby reducing the risk of program or patient abuse. Without an exception, the arrangement could risk implicating Stark's self-referral requirements, which generally prohibit physicians from making referrals to other providers with whom they have a financial relationship.

2. New Definitions. The final rule also defines important terms – including commercial reasonableness, fair market value, and compensation that "takes into account" the volume or value of referrals – that are fundamental to the physician self-referral law. Among the highlights:

- The term "commercially reasonable" means that "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." Assuming the definition is otherwise satisfied, an arrangement also "may be commercially reasonable even if it does not result in profit for one or more of the parties." This is the first time CMS has provided a regulatory definition of the concept of commercial reasonableness under the Stark Law.
- The term "fair market value" generally means "the value in an arm's-length transaction, consistent with the general market value of the subject transaction." The final rule removes the prior language referencing the "volume or value" standard, while still making clear that fair market value must be assessed, irrespective of whether the seller and purchaser are in a position to generate business for each other. The revisions provide a definition of "fair market value" for general application; separate definitions applicable to the rental of equipment and the rental of office space; and revise the definition of "general market value" with respect to the purchase of an asset, compensation for services, and the rental of equipment or office space.
- Compensation between an entity furnishing designated health services and a physician (or immediate family member) "takes into account" the volume or value of referrals or other business generated, in general, if the formula used to calculate the compensation includes the physician's referrals to, or other business generated for, the entity as a variable, resulting in an increase or decrease in compensation that correlates with the number or value of the physician's referrals

to or generation of other business for the entity. This, too, represents a first attempt by CMS to clarify fundamental terms whose interpretation and application has sometimes proven elusive.

3. Greater Flexibility. The final rule revises a number of requirements that have been subject to criticism as unnecessarily rigid or otherwise needlessly placing providers at risk of technical noncompliance under the Stark Law's strict liability standard. For example, under the final rule:

- Even where compensation must be "set in advance" to meet a given Stark exception, parties will have flexibility to modify the compensation, provided the modified compensation (or a formula for determining it) is set in advance, documented in writing and meets all the other requirements of an applicable exception; and
- The special rule on writing and signature requirements allows parties up to 90 calendar days to obtain the required writing or signature; this change is relevant to multiple Stark exceptions, including those for office space rental, equipment rental, personal services arrangements, physician recruitment, the special rule for rural hospitals, fair market compensation, electronic prescribing items and services, and electronic health records items and services.

4. Other New Exceptions and Revisions
The final rule also establishes a new exception related to the donation of cybersecurity technology and services, recognizes a new exception for certain arrangements under which a physician receives limited remuneration (not exceeding $5,000), and amends the existing exception for electronic health records items and services to align more closely with the interoperability and information blocking provisions of the 21st Century Cures Act. Additionally, it includes revisions to the group practice rules; special rules for profit shares and productivity bonuses; revisions to the definition of "designated health services" in the context of inpatient services, and many other revisions and clarifications.

The final rule, which is available to view here, provides detailed guidance for physicians and health care providers and suppliers whose financial relationships are subject to the Stark Law and regulations.

If you need assistance in analyzing or applying these changes in the context of current or prospective arrangements, please contact Jane Bello Burke (518.433.2404), Joshua Feinstein (716.848.1318) or Roopa Chakkappan (716.848.1258).

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