VALUE-BASED SAFE HARBORS AND EXCEPTIONS TO THE ANTI-KICKBACK STATUTE AND STARK LAW

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On 2 December 2020, the U.S. Department of Health and Human Services' (HHS) issued two Final Rules in conjunction with its "Regulatory Sprint to Coordinated Care," which will markedly change the regulatory fraud and abuse landscape for "value-based" arrangements:

- The HHS Office of the Inspector General (OIG) published a Final Rule that introduces new safe harbor protections under the federal Anti-Kickback Statute (AKS) for certain coordinated care and risk-sharing value-based arrangements between or among clinicians, providers, suppliers, and others that squarely meet all safe harbor conditions (AKS Final Rule).
- The HHS Centers for Medicare & Medicaid Services (CMS) published a Final Rule that finalizes similar exceptions to the Physician Self-Referral Law (Stark Law) for certain value-based compensation arrangements between or among physicians, providers, and suppliers (Stark Final Rule, and together with the AKS Final Rule, the Final Rules).

These Final Rules introduce an entirely new framework for structuring permissible arrangements and affiliations between and among health care providers and payors. They introduce a host of new definitions, safe harbors, and exceptions that are designed to play a central role toward innovating care coordination and health care payment models for years to come.

The Final Rules include three AKS safe harbors and three Stark Law exceptions that reflect a sliding scale of regulatory flexibility for value-based arrangements. This sliding scale is based on a degree of risk sharing that is incorporated into the agreement. Intuitively, the greater the amount of risk sharing incorporated into the arrangement, the more flexibility provided under the safe harbor or exception.

LIMITED OR NO RISK SHARE ARRANGEMENTS

- The *AKS Care Coordination Arrangements* safe harbor protects in-kind (nonmonetary) remuneration within compliant value-based arrangements that further patient care coordination purposes. This safe harbor requires no assumption of downside risk by parties to a value-based arrangement.
- *The Stark Value-Based Arrangements* exception protects physician compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken though the arrangement.

SIGNIFICANT RISK SHARE ARRANGEMENTS

- *The AKS Value-Based Arrangements with Substantial Downside Financial Risk* safe harbor protects both monetary and in-kind remuneration and offers greater flexibility than the AKS Care Coordination Arrangements safe harbor in recognition of the assumption of an intermediate level of downside risk in a payor arrangement.
- *The Stark Meaningful Downside Risk* exception is meant to protect remuneration paid under a value-based arrangement where both the physician and value based enterprise (VBE) take on downside financial risk under a payor arrangement.

FULL FINANCIAL RISK SHARE ARRANGEMENTS

- *The AKS Value-Based Arrangements with Full Financial Risk* safe harbor is intended to protect arrangements (including in-kind and monetary remuneration) involving VBEs that have assumed “full financial risk” for a target patient population.
- *The Stark Full Financial Risk Exception* only applies to arrangements that involve a VBE taking on full downside risk in a value-based arrangement with an applicable payor. However, unlike the meaningful downside risk exception, it does not require a physician participating in the arrangement to also assume financial risk.

These safe harbors and exceptions are intended to cover a broad array of arrangements, offering flexibility for payors and providers to “design their own model” through selecting, for example, the patient populations, value-based purposes and activities, quality measures, payment methodologies, referral requirements, and other components that fit the “value-based purpose” the parties are seeking to achieve. For arrangements that are designed and implemented to fit within the parameters set forth in the Final Rules, those arrangements will not be subject to certain traditional fraud and abuse safeguards such as a requirement that an arrangement be set at fair market value, and without a broad prohibition on remuneration under an arrangement taking into account the volume or value or referrals. However, these flexibilities can only be taken advantage of through carefully structured arrangements that satisfy a series of requirements set forth in the Final Rules.

These changes and requirements are discussed in detail in K&L Gates' White Paper: Value-Based Safe Harbors and Exceptions to the Anti-Kickback Statute and Stark Law. This White Paper is available here.

K&L Gates' Health Care practice routinely assists health systems, hospitals, and other providers and suppliers with legal advice and strategic considerations regarding setting up and operationalizing value-based arrangements and clinically integrated networks.

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