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Proposed Stark regulations have an immediate compliance impact

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In October 2019, the Centers for Medicare & Medicaid Services (CMS)[1] and Health and Human Services Office of Inspector General (OIG)[2] issued highly anticipated proposed rules as part of the Regulatory Sprint to Coordinated Care, which aims to reduce regulatory barriers and encourage transition to value-based care. The proposed rules are notable, because both agencies respectively acknowledge the broad reach of the federal Anti-Kickback Statute (AKS) and the Stark Law (aka, the federal Physician Self-Referral Law) as potentially inhibiting beneficial and non-abusive arrangements, and both agencies propose significant modifications to help address these issues. Much of the attention has been focused on the proposed new AKS safe harbors and Stark Law exceptions for value-based arrangements, and these are certainly significant developments.

Equally important, however, and critically important to current compliance efforts, the proposed Stark Law regulations include a number of clarifications by CMS of its *existing* position with respect to two key phrases that historically created compliance uncertainty: "commercially reasonable" and "taking into account the volume or value of referrals or other business generated." These clarifications are extremely helpful, because they help mitigate risk of exposure that has been increasing in recent years for standard and legitimate compensation methodology approaches. CMS also provides clarification of its existing position with respect to the Isolated Transactions exception.

Stark Law overview

Unless an exception applies, the Stark Law prohibits physician referrals to an entity providing "designated health services" (DHS), such as inpatient or outpatient hospital services, outpatient prescription drugs, physical therapy, or other enumerated services, where the physician (or an immediate family member) has a financial relationship with the entity. It also prohibits the entity from billing for services rendered as a result of prohibited referral.

The Stark Law is a strict liability statute, meaning intent of the parties is generally irrelevant. If the Stark Law applies to a financial relationship, such as when a hospital or other DHS entity contracts with a physician for on-call coverage, medical director services, or professional services, failure to meet just one component of an applicable exception can "taint" all referrals from the physician to the entity. The highly technical and unforgiving nature of the Stark Law and its exceptions, coupled with confusion regarding some of the fundamental terminology and increasingly aggressive relators and enforcement agencies claiming False Claims Act[3] (FCA) liability based on alleged Stark Law violations, has exacerbated compliance uncertainty for healthcare providers.

Fundamental terminology: "Commercially reasonable"

One core concept in many of the Stark Law compensation arrangement exceptions is that the arrangement must

be commercially reasonable, without regard to the referrals or other business generated by the physician. However, the term *commercially reasonable* has not previously been defined in the regulations.

In addition to proposing a definition for the term, CMS clarifies its current position that compensation arrangements with physicians can be considered commercially reasonable without regard to referrals or other business generated by the physician, even if they are unprofitable when comparing the collections received for the physician services performed to the compensation paid to the physician for performing those services. CMS also proposes to include an express statement on this point in the regulatory definition. In explaining its position, CMS refers to what it calls a "widespread misconception" to the contrary, and notes that there are compelling reasons to compensate physicians at a loss in some circumstances (e.g., to meet a community need or licensure or regulatory obligations).

This clarification is significant, given that a number of FCA cases include allegations pointing to compensation arrangements at a loss as evidence that compensation paid to physicians was not commercially reasonable when one considers the value of the referrals or other business generated by the physician, and hence there is a Stark Law violation. The government and relators have repeatedly argued that if hospitals lose money on arrangements with physicians when considering just collections for physician services compared to physician compensation, then it must mean the hospital is taking into account the referrals or other business generated by the physicians (as discussed below).

CMS's clarification should provide significant support in defending against allegations of wrongdoing in the context of legitimate arrangements, where it is alleged that the arrangement is not commercially reasonable simply because a physician is compensated in excess of the professional collections generated by the physician. Entities that contract with physicians at a loss are well advised to consider documenting the rationale for doing so (e.g., the business case, clinical needs, operational considerations) to help demonstrate that the arrangement is commercially reasonable for reasons unrelated to the referrals or other business generated by these physicians.

Fundamental terminology: "Volume or value"

Another core concept in many of the Stark Law compensation exceptions is that the physician's compensation is not determined in a manner that takes account of the volume or value of referrals or other business generated by the physician. In the proposed regulations, CMS re-affirms its longstanding position that productivity-based physician compensation does *not* take into account volume or value of referrals (or other business) solely because corresponding hospital services are billed each time the physician personally performs a service. CMS clarifies that this position applies to both employment and independent contractor relationships.

This clarification is significant given recent adverse case law, particularly for physicians that perform professional services in hospital settings, where the technical component provided by the hospital is considered a referred service. In *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*[4] and other FCA cases,[5] whistleblowers advanced the argument that a personal productivity bonus paid to a physician, based on the physician's work-relative value units (wRVUs) or patient encounters, impermissibly takes account of the physician's referrals or other business generated for the hospital by the physician, and these arguments had been gaining traction.

Thankfully, CMS rightly refutes such an argument. Compensation based on personal productivity is a standard compensation methodology used across the country. Contrary to the claims of whistleblowers, paying physicians based on their personal productivity can be viewed as a compliance safeguard against fraud and abuse, because it protects against overcompensating a physician who is not putting in sufficient work effort to justify the

compensation received. By contrast, compensation based on a fixed annual amount might not appropriately reflect a physician's personal labor over time.

Isolated Transactions exception

The Stark Law regulations provide an exception for remuneration paid to physicians as part of an "isolated financial transaction" if certain requirements are met, including that the transaction involve only a single payment that is consistent with fair market value for the items or services provided. Because this is one of the few compensation arrangement exceptions that does not require that the arrangement be in writing, it has long been a compliance "life saver" for healthcare providers. It has often been used to protect legitimate, but unwritten arrangements (e.g., when a physician starts providing services before negotiations on compensation terms are finalized) to address immediate patient care needs.

This exception has been particularly important in states with a strong corporate practice of medicine prohibition, which sometimes prohibits hospitals from employing physicians. (Under the Stark Law, there is more flexibility with respect to employment relationships, including no writing requirement and no requirement that compensation be set in advance, so this exception is often used as a fallback when the physician begins providing services before the details of an arrangement have been completely worked out).

In the proposed rule, CMS takes the position that the Isolated Transactions exception is not intended to protect arrangements where a single payment is made for ongoing services provided and proposes revisions to the regulatory exception to include an affirmative statement to that effect. CMS asserts that this proposed change is a "clarification" of its long-standing policy, although it represents a significant departure from the interpretation that has been widely held within the industry (as CMS acknowledges in the preamble).

The proposed rule is just that—proposed—and therefore it is premature to anticipate what the final regulatory text will state. There is a possibility that, in response to submitted comments, CMS will retract its current position or otherwise revise the final regulations to reflect concerns raised by stakeholders.

However, because CMS has also couched its position as a "clarification" of its existing policy, and did so at length, providers that wish to rely on this exception moving forward (to protect arrangements involving a single payment made in exchange for services provided during an ongoing period) face heightened risk. Until or unless CMS retracts its current position as stated in the proposed rule, if a physician and a DHS entity do not enter into a formal executed agreement prior to commencement of services, providers might be better off looking instead for evidence of one or more writings that describe the arrangement, including the items and services to be provided, the compensation (which is set in advance), and other terms, thus taking advantage of the additional flexibility CMS has provided in recent years on combining various documents to satisfy these elements.

For example, parties can currently look to a collection of writings, including contemporaneous documents evidencing the course of conduct of the parties, such as email correspondence, signed checks, and other documentation, to demonstrate that an agreement is in writing.[6] The current regulations also allow for "temporary noncompliance with signature requirements" where all other components of an exception are met and the parties obtain signatures within 90 days. (Under the proposal rule, this temporary noncompliance concept would be moved to 42 C.F.R. § 411.354 and expanded to apply to both the signature and writing requirements).[7]

In addition, in the preamble to the proposed rule, CMS notes that compensation does not need to be in writing to be "set in advance," and "broadly speaking, records of a consistent rate of payment over the course of the arrangement, from the first payment to the last, typically support the inference that compensation was set in

advance."[8]

DHS entities entering into a physician arrangement under circumstances where it is not possible to finalize an agreement prior to commencement of services may also wish to evaluate whether it makes sense to start making periodic payments to the physician while the agreement is otherwise being finalized and going through the entity's contract approval process. That determination would likely turn on the specific factual context and may be better made on a case-by-case basis. However, in certain cases where an arrangement is determined to be low risk, it could help to establish compliance with the requirements of other Stark Law exceptions, in lieu of withholding making any payment and using a one-time "catch-up" payment in reliance on the Isolated Transactions exception.