Proposed Stark & Anti-Kickback Regulations Are A Big Deal

Insights 10.16.19

Proposed anti-kickback statute and Stark law regulations issued on October 9, 2019 signal potentially significant easing of compliance concerns throughout the healthcare community. The highly-anticipated proposed regulations would create new anti-kickback safe harbors (for certain "value based" arrangements, and other activities) and ease compliance with existing ones, and would create similar new Stark law exceptions (there is also a new safe harbor under the civil monetary penalties law ("CMP")). Notably, the proposed Stark law regulations would also facilitate compliance with current regulations by adopting provider-friendly interpretations of terms such as "fair market value" and "commercially reasonable" that are used throughout the regulations, and have been a breeding ground of uncertainty.

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Value Based Arrangements

In an effort to remove regulatory obstacles to value based payment arrangements, the Centers for Medicare and Medicaid Services ("CMS"), which has jurisdiction over the Stark law, proposes three new Stark law exceptions, and the Office of Inspector General of the Department of Health and Human Services ("OIG"), which has jurisdiction over the anti-kickback statute, proposes three corresponding new safe harbors to the anti-kickback statute.

The proposed regulations use a common set of terms to refer to a "value based arrangement", which is "an arrangement for the provision of at least one value based activity for a target population." The value based arrangement must involve a "value based enterprise." In the preamble to the Stark regulation, CMS explained, "We intend the definition of value based enterprise to include only organized groups of health care providers, suppliers, and other components of the health care system collaborating to achieve the goals of a value based health care system." A value based enterprise must be made up of two or more parties "collaborating to achieve at least one value based purpose," which can refer to coordinating and managing patient care; improving care; appropriately reducing costs; and transitioning from a payment system based on volume to one based on value. Under the proposed Stark regulations, the scope of permitted "participants" in a value based enterprise contains no exclusions; however, the anti-kickback statute regulations exclude pharmaceutical manufacturers; DMEPOS manufacturers, distributors and suppliers; and laboratories.

There are proposed Stark law exceptions and safe harbors for *full* financial risk arrangements, as well as for arrangements where the physician has *meaningful* or *substantial* downside financial risk. The two sets of regulations set forth

different quantitative thresholds for taking on "meaningful" and "substantial" downside risk, respectively, so parallel analyses are necessary to ensure that a particular value based arrangement satisfies both a Stark law exception and a safe harbor.

The burden of complying with each exception would depend on the level of risk, and arrangements involving greater risk are subject to fewer requirements. Again, however, the requirements do not line up across the proposed Stark law regulations and the proposed anti-kickback safe harbors, so two analyses are necessary to determine whether a particular value based arrangement satisfies an exception *and* a safe harbor.

The OIG has proposed a separate safe harbor for in-kind remuneration that is used for care coordination and care management activities. By way of example, the OIG suggested that the safe harbor could be used to allow a value based enterprise participant to share a care coordinator with another value based enterprise participant. In addition to satisfying other requirements, the arrangement must require the recipient to pay for at least 15% of the cost of the in-kind remuneration. The safe harbor does *not* require a party to take on financial risk.

Finally, the proposed Stark regulations contain an additional exception for a value based arrangement that involves neither full nor meaningful financial risk, and does not require the parties to take on downside risk at all. While there is no clear analog to this exception among the new safe harbors, CMS sought comment on whether to include additional requirements to align this exception with the safe harbor for in-kind remuneration used for care coordination and care management activities.

Patient Engagement and Support Safe Harbor

The OIG has proposed a new anti-kickback statute safe harbor for providing patient engagement tools and support to improve quality, health outcomes, and efficiency, but the proposed safe harbor would be available only to "value based enterprise" participants (as this term is used in the OIG's proposed new value based arrangement exceptions). The OIG indicates it seeks to promote "well-coordinated care" with a goal to help "patients to actively participate and engage in their preventive care, treatment, and general health," and notes the significant potential cost-savings to the Medicare and Medicaid programs from such care.

The safe harbor would protect the provision of in-kind preventive items or services such as health-related technology, health-related monitoring tools and services, or support services to identify and address social determinants of health, if they are recommended by the patient's licensed provider, have a direct connection to coordination or management of care, and advance certain healthcare goals, e.g., treatment plan compliance. The value of these items or services is generally capped at $500 per year, unless an exception is based on an individualized financial needs determination. The safe harbor would not permit providing cash or cash equivalents, or items or services used for marketing or resulting in medically unnecessary or inappropriate care.

Local Transportation Safe Harbor

The proposed regulations would modify the local transportation safe harbor to (1) extend the distance residents of rural areas may be transported from 50 to 75 miles; and (2) remove the 25-mile limit on transportation of a patient upon discharge, to the patient's residence. The OIG is considering expanding the safe harbor to include transportation for health-related, non-medical purposes, e.g., to food stores or banks, social service facilities, exercise facilities, and chronic disease support groups. The OIG also clarifies that it is permissible to provide local transportation through ride-sharing services, so long as the requirements of the local transportation safe harbor are satisfied, and explains that the safe harbor protects not just the transportation, but also the support necessary to get patients safely to their destination, e.g., assisting the patient with a wheelchair, oxygen equipment, and ambulating in and out of the pickup and drop-off points.

CMS-Sponsored Model Arrangements and Patient Incentives

The OIG proposes a new safe harbor for delivery and payment arrangements, as well as beneficiary incentives, provided in connection with models under either the CMS Innovation Center or the Medicare Shared Savings Program. The proposed

safe harbor would be an alternative to the current model-by-model fraud and abuse waiver process, and would provide greater efficiency and consistency across all eligible models. The safe harbor would be applicable to each CMS-sponsored model, if CMS notifies participants the safe harbor applies. CMS may also choose to impose additional conditions to using the safe harbor for particular models.

In addition to any CMS imposed conditions, the proposed safe harbor includes several requirements, e.g., the arrangement or patient incentive (as applicable) must advance one or more goals of the CMS-sponsored model, and any patient incentives must have a direct connection to the patient's healthcare. CMS does not propose a corresponding Stark exception. However, the proposed value based arrangements exceptions to Stark, and the corresponding proposed anti-kickback statute safe-harbors, are not limited to CMS-sponsored models. So, depending on the nature of the arrangement, those exceptions and safe harbors might protect participants in CMS-sponsored (or other alternative payment models).

Personal Services Safe Harbor

The OIG proposes significant modifications to the existing safe harbor for personal services and management contracts. For example, the requirement that the *aggregate compensation* be set in advance would be replaced with the requirement that the *methodology* for determining compensation be set in advance. This is an extremely advantageous change, as it is more in line with the corresponding Stark personal services exception, and would cover common wRVU-based compensation structures (and other formula-based arrangements where the exact dollar amount of compensation is not fixed in advance). Another proposed change would eliminate the requirement that periodic, sporadic or part-time arrangements must specify the exact schedule, precise length, and the exact charge for those intervals (again, more in line with the corresponding Stark personal services exception).

The OIG also proposes to exclude from the definition of "remuneration" certain outcome-based payments, in recognition of newer payment models intended to facilitate better care coordination, provider engagement across care settings, and that promote the shift to value. The OIG proposes defining outcome-based payments to mean payments for (1) improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or (2) achieving one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved, quality of care for patients. This would potentially cover shared savings and shared losses, gainsharing, pay-for-performance, and episodic or bundled payments. The parties would be required to regularly monitor and assess performance on each outcome measure, and periodically "rebase" (reset) the benchmark or outcome measure for outcomes-based payments when feasible, to account for improvements achieved.

Payments made by a pharmaceutical manufacturer, a DMEPOS manufacturer, distributor, or supplier, or a laboratory, whether directly or indirectly, would be excluded, and the OIG is considering excluding pharmacies, PBMs, wholesalers and distributors, and also possibly limiting protection for outcomes-based payment arrangements to value based enterprise participants. Payments that relate solely to achieving internal cost savings for the principal would also be excluded. So, for example, the safe-harbor would not protect outcomes-based payment arrangements between a hospital and physician group where the parties share financial risk or gain only with respect to items or services reimbursed to the hospital under the Medicare prospective payment system for acute inpatient hospitals, but if it involved sharing financial risk or gain across care settings (e.g. inpatient stay plus the 60-day post-discharge period), then it could qualify as an outcome-based payment if the other safe harbor requirements are met.

Cybersecurity Technology and Related Services

The OIG and CMS have coordinated to propose a new anti-kickback statute safe harbor and a new exception to the Stark law to allow for donations of cybersecurity technology and related services (but excluding hardware and monetary support). The proposals are intended to help improve cybersecurity by "removing a real or perceived barrier that would allow parties to address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records and other information essential to the delivery of healthcare."

The proposals would permit non-monetary donations of cybersecurity technology and services if certain conditions are met, e.g., the technology and services must be "necessary and used predominantly" to implement, maintain or reestablish cybersecurity, and the donation of technology or services may not take into account the volume or value of referrals or other business generated between the parties. Likewise, the recipient of the technology or services may not condition doing business with the donor on such donation. The arrangement must be documented in writing, and meet other requirements.

Electronic Health Records

The OIG and CMS also collaborated to make recommended changes to the safe harbor and Stark law exception for the donation of interoperable electronic health records ("EHR") software or information technology and training services. Among other things, the proposals would eliminate the current sunset provision included in each regulation, to make the safe harbor and exception permanent. The proposed modifications are primarily designed to incorporate definitions used in the 21st Century Cures Act and related regulations. Practically, the revised definitions are intended not to be substantially different from the existing definitions, but to reflect updated terminology and understandings, as well as to provided consistency between the separate regulations. The OIG and CMS have also invited comments on modifications to the existing requirement that a recipient of EHR technology contribute 15 percent of the donor's cost. While no specific text has been proposed, comments have been requested regarding whether the contribution requirement should be reduced or even eliminated for certain providers.

Telehealth Technologies for In-Home Dialysis

The OIG provides guidance on how it interprets the statutory exception in the CMP law for certain telehealth technologies provided to end stage renal disease ("ESRD") patients. The OIG clarifies that it interprets the regulation as requiring the telehealth technologies be furnished to the patient by the provider of services or the renal dialysis facility that is currently providing the related care to the patient, to prevent arrangements in which telehealth technologies are provided to non-patients in an effort to convert them into patients. The OIG also proposes to exclude provision of technology that has "excessive" value, and defines "telehealth technologies" by building off the definition of "interactive telecommunications system" used for Medicare Part B, and would include any "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time, interactive communication between the patient and distant site physician or practitioner," e.g., smart phones.

Warranties

The OIG proposes to update the safe harbor for warranties to (1) protect warranties for one or more items and related services upon certain conditions; (2) revise reporting requirements; and (3) define "warranty" directly, not by reference to another statute. In OIG's view the current safe harbor does not protect arrangements where a warranty applies to bundled items and services, such as wound care products and related support services (see Advisory Opinion No. 01-08). The proposed regulation would modify the safe harbor to permit these arrangements where certain conditions are met. The OIG's proposed changes to reporting requirements would accommodate outcomes-based warranty arrangements where the efficacy of an item might not be known in the current reporting period and exclude beneficiaries from reporting requirements applicable to buyers.

ACO Beneficiary Incentive Program

By statute, accountable care organizations ("ACOs") participating in certain CMS-approved, two-sided risk models may provide incentive payments to beneficiaries who receive qualifying primary care services. The proposed new safe harbor codifies the existing statutory exception through wording very similar to the existing statute, although the proposed safe harbor clarifies that an ACO may provide incentive payments only to beneficiaries assigned to the ACO by CMS.

OTHER KEY PROPOSED STARK CHANGES

Although much of the focus and attention surrounding the new proposed Stark Law regulations has been the creation of new exceptions to help support the transition to value based reimbursement, CMS has also proposed significant changes to the existing exceptions – an exercise it describes as "recalibrating the scope and application" of the Stark regulations. Many of the proposed changes are a direct response to a series of False Claims Act ("FCA") whistleblower cases that have been decided over the last 10 years including the 2015 decision in *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, and provide helpful clarifications of the existing regulations. Below is a high-level summary of several of the most significant definitional and special regulation changes:

Isolated Financial Transactions: The Stark Law provides an exception for remuneration paid to physicians as part of an "isolated financial transaction" so long as certain requirements are satisfied, including that the transaction involves only a single payment, consistent with fair market value for the items or services provided. Because the exception does not require the arrangement to be in writing, it has long been used by healthcare providers to protect unwritten arrangements of various types, so long as the arrangement entails only a single payment.

In the proposed regulation, CMS describes at length its position that the isolated transactions exception is not intended to protect arrangements where a party makes a *single* payment for *multiple* services provided over an extended period of time. To clarify this position, CMS proposes modifying the definition of "isolated financial transaction" to include an affirmative statement that an "isolated financial transaction" cannot include "a single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated)."

Although CMS asserts the new text is just a "clarification" of its long-standing policy, it represents a significant departure from an interpretation of the exception that (1) has been widely held within the industry (as CMS recognizes in its commentary), and (2) is well-supported by the plain wording of the regulations. The Stark regulations currently define a transaction as "an instance or process of two or more persons or entities doing business," meaning that the term "transaction" includes not only "instances" of business, but also ongoing business arrangements. Under the current regulations, the definition of a "transaction" is subsumed within the definition of an "isolated financial transaction," which "means one involving a single payment between two or more persons or entities…." Both the statute and regulation provide examples of "isolated transactions" that include the one-time sale of property or a practice, but these are offered as examples, without any indication or suggestion that they are intended to be exhaustive. Accordingly, by the plain wording of the regulations, it is far from clear that the exception, as currently written, would prohibit a single, fair market value payment for services performed over a period of time (assuming the other requirements of the exception are satisfied).

Commercial Reasonableness: A key element of most Stark Law exceptions is that the arrangement be commercially reasonable. This requirement has been the subject of numerous FCA actions over the last several years and has been source of significant enforcement action. Despite the importance of this requirement, the Stark Law itself has never included a definition for the term.

In response to requests from stakeholders and confusion generated from prior FCA litigation, CMS has proposed to define "commercially reasonable" as meaning that "the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements." Importantly, the definition goes on to state that "[a]n arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties." This last clarification is very significant because the question of whether an arrangement can be commercially reasonable even if a hospital loses money has been the subject of significant controversy in multiple recent FCA actions. The government and private whistleblowers have repeatedly argued that if hospitals lose money on arrangements with physicians when considering the collections for physicians' services compared to the physicians' compensation, then it must mean the hospital is taking account of referrals or other business generated by the physicians (something that is prohibited under the Stark law).

Volume or Value Standard and the Other Business Generated Standard: The requirement that compensation to physicians cannot take into account the "volume or value" of referrals made by the physicians is a central concept within the Stark Law

and has been the subject of controversy in recent FCA cases. As with the term "commercial reasonableness," despite being a key term within the Stark law, there has never been a definition of the "volume or value" standard within the regulations. Except in connection with the special rules on compensation for unit-based compensation (which contain exclusions from the standard).

CMS now proposes that compensation will be considered to take into account the volume or value of referrals *only* when the "mathematical formula used to calculate the amount of the compensation" includes a variable identifying the specific number of referrals or other business generated by the physician and "the amount of the compensation correlates with the number or value of the physicians referrals." Importantly, CMS also clarifies that (despite some questions raised by the holdings in *Tuomey* and other FCA cases) when a hospital is paying physicians productivity based compensation, it is not considered to take into account the value or volume of the physicians' referrals solely because corresponding hospital services are billed by the hospital each time the physician provides a service in the hospital or outpatient department/clinic.

Independent Compensation Arrangements: The proposed regulation would significantly limit which financial relationships are considered indirect compensation arrangements, which then create a financial relationship for purposes of the Stark law. The current definition requires that the compensation link closest to the physician "varies with or takes into account the volume or value of referrals or other business generated;" and the proposed definition would remove the "varies with" phrase. This change, in addition to the significant limitation regarding which compensation methodologies are considered to "take into account" referrals or other business generated (discussed above), may mean that many indirect financial relationships that would previously require scrutiny will no longer be subject to the Stark Law.

Designated Health Services: CMS proposes clarification of what constitutes a "designated health service" for hospital inpatients. The change could significantly reduce the number of hospital inpatient claims "tainted" by prohibited financial relationships. CMS proposes that any individual service provided by a hospital to an inpatient (such as an X-ray or diagnostic test) does not constitute a designated health service if the service does not affect the amount Medicare pays for the inpatient under the inpatient prospective payment system ("IPPS"). This would mean that if a physician who ordered a diagnostic test had a financial relationship with a hospital that failed to comply with a Stark exception, the hospital would not be prohibited from billing for the admission so long as the physician who ordered the inpatient admission did not have an impermissible financial relationship with the hospital, and the diagnostic test ordered did not affect the hospital's payment.

Period of Disallowance: Currently the Stark Law contains a process providers can use to calculate the "period of disallowance," i.e., the period when, as a result of a prohibited financial relationship, a physician cannot make referrals of designated health services and entities cannot bill Medicare for the referred designated health services. A general principle under the Stark Law is that a period of disallowance starts on the date a financial relationship fails to meet the requirements of an applicable exception and ends when the financial relationship ends or is brought into compliance, and the current regulations *deem* certain kinds of financial relationships to last a specific period of time for purposes of calculating the period of disallowance. By removing these provisions CMS is arguably creating more flexibility for providers to determine the appropriate period of disallowance on a case-by-case basis, but it may also introduce confusion by eliminating a provision that was intended to act as a bright line regulation.

Of note, in the commentary addressing the period of disallowance, CMS expressly acknowledges that "imperfect performance" does not necessarily create a Stark law violation, stating that "parties who detect and correct administrative or operational errors or discrepancies during the course of the arrangement are not necessarily 'turning back the clock'," and providing an example of payment errors that are corrected over the course of the arrangement. This firm has long taken the position that such imperfect performance is defensible.

Fair Market Value and General Market Value: CMS proposes to update the regulatory definition of "fair market value" to more closely align with the statutory definition. The updated definition addresses two distinct concepts – fair market value and general market value (now more closely tied to the valuation definition of "market value"). Fair market value is the hypothetical value of an asset or service in an arms' length transaction, with like parties under like circumstances, consistent

with general market value. The updated definition makes clear that general market value is the specific value to the actual parties of a transaction set to occur within a specific timeframe as a result of bona fide bargaining between the buyer and the seller.

Group Practices: Among other things, CMS proposes to "clarify" its interpretation of how "overall profits" from designated health services may be distributed to physicians in the group. The current regulations permit distribution of the group's overall profits, defined as the "entire profits derived from designated health services," and a common interpretation has been to permit distribution on a service-by-service basis (e.g., profits from laboratory services distributed one way and profits from diagnostic imaging services distributed another way). CMS proposes revising the regulatory language to prohibit distributing overall profits based on particular designated health services service lines.

Limited Remuneration to a Physician (Proposed New Exception): In addition to the proposed new Stark law exceptions corresponding to the proposed new safe harbors, as addressed above, CMS has proposed an additional exception for compensation up to $3,500 in a calendar year (adjusted for inflation annually), paid to a physician for items or services provided by the physician, and no writing is needed. Other requirements apply, e.g., compensation must be fair market value, and compensation for leasing space or equipment may not be based on percentage of revenue or per-unit formula. This proposed exception is intended to provide additional flexibility to protect short term arrangements (90 days or less), or payments otherwise made outside of a written agreement (e.g., where a physician receives an hourly rate of payment that is higher than the amount stated in the written agreement).

This would create another solution for arrangements that do not squarely fit within another exception. In addition, if CMS does not change course from its proposed changes to the isolated transactions exception, this limited remuneration exception, along with other new proposed modifications, will be critical to protect at least some payments made to physicians for services without a written agreement.

Temporary Noncompliance with Writing and Signature Requirements: CMS has previously provided flexibility for obtaining signatures after an arrangement begins, and clarified that a collection of writings could be combined to satisfy the writing requirement in lieu of a formal executed agreement. The proposed regulations would go further, to allow compliance with both the signature and writing requirements up to 90 days after the arrangement begins. This change is helpful, as it recognizes that services might need to begin before an agreement can be memorialized. CMS, however, emphasizes that all other applicable requirements must be met, including that the compensation be set in advance. This raises the question of how parties would prove compensation was set in advance if the arrangement was not reduced to writing, particularly in more complex compensation arrangements, although documenting that the parties previously agreed to the compensation and other terms prior to commencement of the arrangement might be a reasonable approach. CMS also notes that records of a consistent rate of payment would support the inference that compensation is set in advance.

Other Modifications of Note to Existing Exceptions: CMS proposes changes to a number of other existing exceptions, such as revisions to the exception for recruiting non-physician practitioners. These exceptions are not addressed in detail here but, along the same theme as many other changes, provide additional flexibility. For example, with respect to office and equipment leases, CMS proposes to revise the "exclusive use" requirement to clarify that multiple lessees may use the space or equipment to the exclusion of the lessor. CMS also proposes to allow the use of the fair market value compensation exception for space leases, providing more flexibility with respect to the term of a lease, and such exception would be revised to incorporate the restriction on compensation methodologies for rental payments currently included in other exceptions.

Also, CMS proposes to revise the exception for remuneration unrelated to designated health services to clarify that remuneration from a hospital to a physician does not relate to the provision of designated health services if it is for items or services that are not related to patient care services (e.g., serving on a governing body along with non-licensed individuals).

Save the Date for an HLB webinar that further expands on these issues scheduled on October 29, 2019. More information coming soon.

For more information, please contact *Charles Oppenheim*, *David Hatch*, *Sandi Krul*, *Robert Miller* or *Brett Moodie* in Los Angeles, *Ben Durie* or *Stephanie Gross* in San Francisco, *Amy Joseph* in Boston, or your regular Hooper, Lundy & Bookman contact.

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