Final Anti-Kickback and Stark Rules: Value-Based Arrangements and Beyond

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Sweeping new federal physician self-referral law (referred to as the "Stark" law) regulations and federal anti-kickback statute safe harbors released November 20, 2020 contain broad new exceptions for "value based arrangements," and ease regulatory compliance in other areas, as well as adding welcome clarity to both sets of laws. In addition, a new exception to the civil monetary penalties law has been added for in-home dialysis telemedicine. The new rules are effective January 19, 2021, other than certain revisions with respect to group practices under the Stark law, which are effective January 1, 2022.

Save the date for an HLB webinar that will address key highlights of the new regulations, and offers practical tips for compliance. It is scheduled for December 1, 2020. Click here to register.

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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"), with jurisdiction over the Stark law, has established three new exceptions, and the Office of Inspector General of the Department of Health and Human Services ("OIG"), with jurisdiction over the anti-kickback statute, has created three corresponding safe harbors.

The regulations protect "value based arrangements," defined as arrangements involving at least one "value based activity" for a target population. The value based arrangement must involve a "value based enterprise," which is two or more participants (*e.g.*, clinicians, providers, and suppliers) who collaborate to put patients at the center of care, through care coordination, increased efficiencies in delivering care, and improved outcomes.

The new Stark law exceptions and corresponding anti-kickback statute safe harbors protect arrangements involving *full* financial risk and *meaningful* or *substantial* downside financial risk. There is also a new Stark law exception for value-based arrangements that involves neither full nor meaningful financial risk, and does not require the parties to take on downside risk at all, as well as a new safe harbor for in-kind remuneration that is used for care coordination and care management activities, where the physician is not at risk. In each case, the compliance burden depends on the risk level, and arrangements involving greater risk are subject to fewer regulatory requirements.

Unfortunately, the requirements for the Stark exception are not identical to those of the anti-kickback safe harbor. Among other differences, the Stark regulations focus on "physician risk arrangements and remuneration," while the safe harbors to the anti-kickback statute focus on "risk assumed at the value based enterprise level." As a result, two analyses are necessary to determine whether a particular value based arrangement satisfies an exception and a safe harbor.

Notably, good intentions alone might not protect the parties to a value based arrangement. To remain within the anti-kickback statute safe harbor for in-kind remuneration used for care coordination and care management activities or the Stark exception for value based arrangements, the value based arrangement must not only be reasonably designed to achieve its goals, it must also work in practice, and the parties must monitor their arrangements. If problems are identified, the parties must "act quickly to rectify the ineffectiveness of their value-based activities" and modify or terminate them.

OTHER NEW SAFE HARBORS AND CORRESPONDING STARK LAW EXCEPTIONS

Patient Engagement and Support Safe Harbor: The OIG has finalized a new anti-kickback statute safe harbor for providing patient engagement tools and support to improve quality, healthy outcomes, and efficiency, but the safe harbor is available only to "value based enterprise" participants (as this term is used in the value based arrangements exception) in a target patient population. This safe harbor protects the provision of in-kind preventive items or services, and the OIG declined to include examples, so as to be agnostic about the types of tools and supports the safe harbor protects. The value of these items or services is capped at $500 per patient, per year.

CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives: The OIG has added anti-kickback statute safe harbors for delivery and payment arrangements, and patient incentives, provided in connection with models under either the CMS Innovation Center or the Medicare Shared Savings Program. The safe harbor does not replace the existing fraud and abuse waivers (which remain in effect), but instead should reduce the future need for model-specific waivers. Under the safe harbor, only CMS-sponsored model arrangements and patient incentives are protected, and they must: (1) advance one or more goals of the CMS-sponsored model; and (2) have either a direct connection to the patient's health care, or to a different standard (in which case the different standard must be met).

While CMS has not adopted a corresponding Stark law exception, the newly adopted Stark law value-based arrangements exceptions (discussed above) could potentially protect participants in CMS-sponsored models (or other alternative payment models) depending on the nature of the arrangement.

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 anti-kickback statute safe harbor follows the statutory exception, and protects incentive payments for beneficiaries assigned to the ACO by CMS.

Cybersecurity Technology and Related Services: A new anti-kickback statute safe harbor and Stark law exception allow for donations of cybersecurity technology and related services, as long as certain conditions are met. For example, the technology and services must be "necessary and used predominantly to implement, maintain or reestablish effective cybersecurity," and 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.

Telehealth Technologies for In-Home Dialysis: The OIG added an exception to beneficiary inducement prohibitions of the civil monetary penalties ("CMP") law to allow certain "telehealth technologies" to be provided to beneficiaries suffering from end-stage renal disease who receive in-home dialysis services. "Telehealth technologies" is defined as "hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for the diagnosis, intervention, or ongoing care management."

REVISED SAFE HARBORS AND CORRESPONDING STARK LAW EXCEPTIONS

Local Transportation Safe Harbor: The OIG has modified the local transportation anti-kickback statute safe harbor to (1) extend the distance residents of rural areas may be transported from 50 to 75 miles (with certain exceptions); and (2) remove the 25-mile limit on transportation of a patient, upon discharge, to the patient's residence. The OIG makes clear that it is permissible to provide local transportation through ride-sharing services, as long as the requirements of the local transportation safe harbor are satisfied.

Personal Services, Management Contracts and Outcomes-Based Payment Arrangements: The existing anti-kickback statute safe harbor for personal services arrangements has been greatly eased and more closely aligned with its Stark law exception counterpart. The changes include: (1) replacing the requirement that the *aggregate* compensation be set in advance (which had meant the parties had to know the exact dollar amount to be paid over the term of the arrangement) with a requirement that the *methodology* for determining compensation be set in advance, and (2) eliminating the requirement that part-time arrangements must specify the exact schedule, precise length, and exact charge for each interval.

The revised safe harbor also now protects certain fair market value outcome-based arrangements that reward or penalize the achievement of legitimate outcome measures. To be a legitimate outcome measure, the measure must (1) be selected based on clinical evidence or credible medical support and (2) have benchmarks that are used to quantify either (x) improvements in or maintaining improvements in the quality of patient care, (y) a material reduction in costs to or growth in expenditures of payors while maintaining or improving quality of care for patients or (z) both. Parties must periodically assess and, as necessary, revise their benchmarks and payments to ensure they are consistent with fair market value. Certain parties are precluded from using this safe harbor, including some in laboratory, pharma and the durable medical equipment business.

Warranties: The OIG has updated anti-kickback statute safe harbor for warranties in various ways. Among other things, the updated safe harbor now (1) applies to warranties that bundle multiple items and services, if they are reimbursed using the same payment methodology; and (2) defines "warranty" directly, not by reference to another statute.

Electronic Health Records: The existing anti-kickback statute safe harbor and Stark law exception for the donation of electronic health record information technology and training was expanded to eliminate the sunsetting date, and to allow the 15% cost-sharing collected from recipients to be collected at a "reasonable interval," rather than requiring it to be paid in advance.

OTHER STARK LAW-SPECIFIC CHANGES

While the value-based exceptions have stolen the spotlight, the new Stark law regulations contain other significant changes. For the most part these changes, collectively, represent a counter-blow to a series of False Claims Act ("FCA") whistleblower cases that have vexed healthcare providers through their expansive readings of the Stark law, *e.g.*, United States ex rel. Drakeford v. Tuomey Healthcare System, Inc. Below are some of the highlights from these changes:

Isolated Financial Transactions*:* The Stark law provides an exception for remuneration to a physician in an "isolated financial transaction" if certain requirements are satisfied, including that the transaction involves only a single payment, consistent with fair market value. Because the exception does not require a writing, it has been used to protect various unwritten arrangements, when they entail a single payment. Now, CMS has significantly modified the exception to foreclose its use to protect a single payment when it is in exchange for "multiple or repeated services (such as a payment for services previously provided but not yet compensated)."

Temporary Noncompliance with Writing and Signature Requirements*:* CMS provides significant new leniency by allowing "temporary noncompliance" with both the signature and writing requirements for up to 90 days after an arrangement begins that otherwise requires a signed, written agreement. This change is enormously helpful, as it recognizes that services might need to begin before an agreement can be memorialized. Importantly, the 90 day grace period only applies to the writing and signature requirements – meaning that all other applicable requirements must be met, including that compensation is set in advance.

Commercial Reasonableness: The final regulations define for the first time that an arrangement is "commercially reasonable" if "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." 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 essentially refutes multiple recent False Claims Act cases in which it was 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 arrangement is not "commercially reasonable" unless the hospital is taking account of referrals or other business generated by the physicians (something that is prohibited under the Stark law).

Fair Market Value and General Market Value: CMS has finalized what it considers slight modifications to the existing definitions of fair market value and general market value. For example, with respect to general market value, the final rule includes three separate definitions for asset purchases, compensation for services, and equipment or office space rental, respectively. In addition, CMS has removed the reference to volume or value of other business generated from the definition, to "disentangle" this concept.

Taking Into Account Volume or Value of Referrals or Other Business Generated Standard *:* Although the requirement that compensation not take into account volume or value of referrals or other business generated is fundamental to many Stark law exceptions, to date this phrase has not been defined by regulation. In an effort to provide an objective, bright line standard, the final regulations include an express definition. Essentially, the test is whether the formula by which compensation is calculated includes referrals or other business generated as a "variable," resulting in a change in compensation that correlates with the number or value of referrals or other business generated (with certain limited exceptions). If an arrangement does not fall squarely within this definition, then it will be deemed not to take into account the volume or value of referrals or other business generated.

Indirect Compensation Arrangements: The final regulations significantly narrow the scope of what constitutes an indirect compensation arrangement, which will substantially limit the number of arrangements subject to scrutiny under the Stark law. CMS acknowledges that the historical approach – which casts a wide net when identifying indirect compensation arrangements subject to the Stark law and then "weeds outs most" under an applicable exception, is unnecessarily burdensome. This new approach essentially raises the bar for what constitutes an "indirect compensation arrangement" in the first place. Moving forward, the fact that "aggregate" compensation received by a physician varies with the volume or value of referrals or other business generated will not be sufficient on its own. To create an indirect compensation arrangement, the individual unit of compensation must not be fair market value, or must include the physician's referrals or business generated as a variable (in line with the new volume or value standard addressed above).

Designated Health Services: CMS finalized a clarification of what constitutes a "designated health service" for hospital inpatients. Now, 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 a prospective payment system. This would mean that if a physician orders a diagnostic test for an inpatient, but did not admit the patient, 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: CMS is deleting the Stark Law's current process that providers can use to calculate the maximum "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. By removing these provisions, CMS is arguably creating more flexibility 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.

Group Practices: The final regulations include a number of changes to the group practice provision. One notable change is an express statement that "overall profits" means a group practice's "entire profits" — thus prohibiting different distribution methods based on different service lines. CMS acknowledges that although it views this change as a "clarification" only of its existing policy, the current regulation text does not "fully and exactly" reflect that policy. In addition, from a practical perspective group practices need sufficient time to adjust compensation methodologies, so the revised regulations will not take effect until January 1, 2022.

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 revised the "exclusive use" requirement to clarify that multiple lessees may use the space or equipment to the exclusion of the lessor. Also, CMS now allows the use of the fair market value compensation exception for space leases, providing more flexibility with respect to the term of a lease, and incorporated the restriction on compensation methodologies for rental payments currently included in other exceptions.

CMS revised 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).

Limited Remuneration to a Physician: CMS has finalized an exception for compensation up to $5,000 in a calendar year (adjusted for inflation annually), paid to a physician for items or services provided. No writing is needed, although other requirements apply, including fair market value and commercial reasonableness requirements. This exception creates another potential solution to protect at least some payments made to physicians for services without a written agreement, albeit fairly limited.

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