Along with proposed Stark Law exceptions designed to accommodate value-based care models, the Centers for Medicare & Medicaid Services (CMS or the agency) adopted additional revisions to the Stark Law regulations (the final rule) on an incredibly busy November 20th. The revisions include extensive clarifications on many elements of the Stark Law that have long been viewed as burdensome or unclear for compliance-oriented health care providers (e.g., commercial reasonableness and volume or value of referrals). The final rule describes these changes as relating to “fundamental terminology and requirements” of the law and, following feedback from an October 2019 proposed rule (the proposed rule), are part of the Trump administration's goal to reduce regulatory barriers through a "Regulatory Sprint to Coordinated Care." This alert (which is part one of a two-part alert addressing new Anti-Kickback Statute (AKS) and Stark Law regulations) summarizes some of the most significant Stark Law regulatory changes.

The measures discussed here—new exceptions, revisions to existing exceptions, and accompanying guidance—do not expressly relate to value-based care, but help clarify or reduce some of the hurdles and technical pitfalls that commonly hinder relationships between providers and physicians. In general, the final rule adopts and implements most of the changes that the agency had proposed, which had been favorably received by health care providers.

Part two of this alert will focus on HHS’s implementation of AKS and Stark safe harbors and exceptions specifically designed to accommodate the industry shift toward value-based care. We also have summarized in other alerts two concurrently published final rules, one from the OIG on pharmaceutical manufacturer rebate arrangements and one from CMS on a drug payment model to tie Medicare Part B payments for certain drugs to the lowest price charged in other similar countries.

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Summary of Stark Law revisions and guidance: fundamental conditions
New definition of “commercially reasonable.” A “commercially reasonable” arrangement is one that “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.

In recent years, a provider’s "profit" (or lack thereof) on a physician’s professional services has been a key area of focus in a number of high-profile Stark Law enforcement cases. In particular, enforcement litigation gave rise to a perception that compensation to a physician exceeding the reimbursement that an entity collects for the physician’s professional services may presumptively render an arrangement not "commercially reasonable," which was not defined in the law except in extremely limited preamble commentary. The final rule adopted the proposed definition, focusing on whether the arrangement furthers the legitimate business purposes of the parties and has similar terms as like arrangements among like parties.[1] While the agency stated in commentary that “commercially reasonable” is not a question of “whether the arrangement is profitable” (reiterating a stance from proposed rule commentary on this point), the definition states that something may be commercially reasonable “even if it does not result in profit[.]” In finalizing this aspect of the definition, the agency declined to specify in regulatory text that profitability is irrelevant in all circumstances (citing as an example in commentary, “a case where the parties enter into an arrangement aware of its certain unprofitability and there exists no identifiable need or justification—other than to capture the physician’s referrals—for the arrangement”).[2] This example seems to suggest that providers’ awareness of inevitable financial losses could still bear on the question of commercial reasonableness, but only if there is no legitimate business justification for that fact.

Volume or value of referrals: objective test adopted. Despite some reference to the parties’ state of mind with respect to commercial reasonableness, the agency finalized its proposed ”objective test” for volume/value. The final rule specifies that compensation "takes into account the volume or value of referrals” only if the mathematical formula used to determine the physician’s compensation includes the physician’s designated health services (DHS) referrals to the entity as a variable and there is a positive correlation between referrals and compensation (or a negative correlation for compensation paid by a physician).[3]

The change suggests that there would be no "volume or value" problem in two often-analyzed situations. First, even if there is an observable correlation between compensation and referrals, in practice, if referrals are not included in the compensation calculations, compensation will not be deemed to “take into account” referrals. The agency emphasized that correlation to referrals is not sufficient, on its own, to create an issue. The formula must also contain DHS referrals as a variable in some respect. Second, considering or anticipating a physician's referrals, in a general sense, when entering into an arrangement also will not create a problem under the “takes into account” condition, either. As a result, the parties’ general state of mind when entering into an arrangement should not bear on this question of “takes into account.”

As a matter of Stark Law mechanics, this change also cements longstanding commentary that incentive compensation for personal productivity (such as wRVU-based bonuses) do not create a “volume or value” problem, regardless of the setting or type of relationship. That is because personally performed services are not DHS “referrals” and therefore a formula based on wRVU for such services would not include referrals. (The agency explained that it would not delete the productivity compensation deeming rule in the employment exception, however, even though it does not appear in other exceptions, because it appears in the statute that way.)

In addition, touching on but not technically feeding into the “takes into account” analysis, the agency issued additional conditions with respect to referrals that are directed to a particular provider under an agreement (as is common, for example, in physician employment agreements). There has long been a Stark Law regulatory provision allowing contractual referral requirements if certain conditions were met. [4] The final rule added a requirement to this existing provision stating that the existence of the compensation arrangement and the amount of compensation cannot be “contingent on the number or value of the physician’s referrals to a particular provider[.]” This provision would preclude a provider, for example, from requiring that a physician admit a certain number of patients to a hospital in a given year or
else risk losing some or all of his or her compensation. However, the provision does expressly allow requiring physicians to refer an established ratio or percentage of patients to a particular provider. The final rule also adds compliance with the directed referrals provision as requirement of a number of new and existing Stark Law exceptions (e.g., adding it to the bona fide employment exception and the new value-based exceptions), if referrals are directed under the relevant arrangement.

Finally, the final rule revised the incredibly complex definition of an “indirect compensation arrangement,” which is highly relevant to situations where physicians do not directly receive payment from a DHS provider, but rather are paid by another entity linked to the provider by one or more intermediate financial relationships. For nearly two decades, the existence of an indirect compensation arrangement (ICA) has depended on (in addition to other elements) whether aggregate compensation received by the physician “varies with, or takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.” This standard has created confusion for several reasons, including the fact that Stark law exceptions (which would be necessary if an ICA is determined to exist) generally require that compensation not be “determined in a manner that takes into account the volume or value of referrals.”

The revised ICA definition drops “takes into account” and now references only “varies with,” relying on the subtle distinction between those concepts. In addition to variability, for an ICA to exist (and thus for the Stark Law to apply), the individual unit of compensation (which might be a per-service payment or an annual salary, among other structures) must either be above fair market value (FMV) for items and services actually provided or include as a variable and positively correlate with the physician’s DHS referrals or other business generated. It is notable that the final rule expressly incorporates an FMV component for the first time.

In practice, it appears for example that FMV productivity compensation for personally performed services will not create an ICA. More generally, the practical consequence of the way this new definition fits together with Stark Law exceptions is that indirect relationships not creating an ICA (and therefore not needing an exception) would not need to satisfy the writing and certain other basic elements of applicable exceptions.

**Simplified FMV definition, but retaining a reference to parties not being in a position to refer to each other.** CMS adopted the new definition of FMV as it had proposed. This definition is more streamlined, referencing: “the value in an arm’s-length transaction, consistent with the general market value of the subject transaction.” There are several sub-provisions specific to various types of arrangements (such as leases and compensation for services). But the agency declined to bend to commenters critical of the definition of “general market value” upon which the FMV definition relies). General market value will continue to be defined by reference to bona fide bargaining between often times hard to identify well-informed parties “not otherwise in a position to generate business for each other.” Commenters had expressed concern that many arrangements by their very nature must be between parties in a referral relationship. For example, medical directors most often need admitting privileges to a hospital. There are few if any points of comparison for such arrangements that do not involve parties in a position to generate business for each other. In addition, commenters cited the agency’s clear statement in the proposed rule that FMV and the “volume and value of referrals” are distinct, non-overlapping concepts. How this final definition will affect the process of valuation of physician compensation remains to be seen.

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Reducing other Stark Law trip wires
• The final rule adopted a more flexible position on the meaning of compensation needing to be “set in advance.”

The final rule essentially codifies recent commentary from the agency that, among other things, takes a more permissive view toward arrangements that are amended multiple times. Where “set in advance” is applicable, compensation would still need to be established before the furnishing of the items, services, etc., to which the compensation applies.

• "Limited remuneration" exception (to US$5,000 per calendar year). The final rule adopted an exception for arrangements involving low-value payments to physicians.[5] While the exception would require fair market value payment and other basic safeguards, the key aspects of this exception are the lack of set in advance, writing, and term requirements. Nor is this exception limited to any particular kind of compensation (e.g., services, leases, etc.). The $5,000 limit was increased from $3,500 which appeared in the proposed rule. This value will be adjusted for inflation, in a similar manner to the financial limit in the non-monetary compensation exception.

• Inadvertent payment errors do not necessarily cause noncompliance, depending on how they are discovered and addressed. The final rule added a regulatory provision to codify CMS guidance from the proposed rule on this point (but that had not been included in regulatory text). Overpayments and underpayments as compared with the established terms of an arrangement, resulting from administrative mistakes, have been a frequent Stark Law challenge for providers. The new “special rule for reconciling compensation” allows payment discrepancies to be resolved during the term of an arrangement and for up to 90 days following its termination.[6]

• Late writings: a new provision allows arrangements to be reduced to writing up to 90 days following the beginning of the relationship.[7] However, compensation would still need to be set in advance under exceptions with that condition, even if it is not specified in a full written arrangement.

• Trimmed liability for DHS furnished to an inpatient. Services such as diagnostic imaging and laboratory services furnished to a hospital inpatient will not be considered to be Stark Law DHS if they do not affect Medicare reimbursement under the Inpatient Prospective Payment System (IPPS).[8] One impact of this change is with respect to specialists ordering diagnostic services pursuant to a consultation requested by an attending physician. If the hospital has a noncompliant financial arrangement with the specialist, IPPS reimbursement will not be disallowed simply on account of the specialist ordering services that do not change IPPS reimbursement (assuming that financial relationships with other relevant physicians remain compliant).

• Changes to exceptions available for leases. The "fair market value arrangements" exception is amended to also apply to leases (whereas it currently expressly precludes them).[9] Given the differences in existing exceptions, a practical impact of this change is to allow additional protection for leases that have a term of less than one year.

• Regained relevance for "payments by a physician" exception. The Stark Law statute has a very basic exception for situations when a physician makes payment to an entity (as compared to an entity paying a physician), that applies to any payment for clinical laboratory services or any fair market value payment for anything else. The regulatory equivalent of this exception had applied only if no other Stark Law exception is applicable. In prior commentary, for anything other than clinical laboratory services, CMS explained its view that the "payments by a physician" exception was essentially foreclosed by the regulatory publication of the "fair market value arrangements" exception, which applies to payments made either to or by a physician. Consistent with the proposed rule, the final rule changes the existing landscape by limiting the payments by a physician exception to arrangements for which no statutory exception (such as leases) is applicable.[10] Because there is no
statutory "fair market value arrangements" exception, the "payments by a physician" exception (with no writing or "volume or value" requirements) is now more available, specifically for arrangements where the physician is paying the DHS entity (as opposed to the physician being paid).

- **Wider use of carve-out for specimen collection supplies.** Previously, specimen collection supplies that are considered “surgical" could not qualify for the relevant carve-out to the definition of "remuneration." For example, in a 2013 advisory opinion, CMS had found that certain biopsy brushes would be considered surgical and would therefore not qualify for this protection. The final rule deleted the existing regulatory language stating that the carve-out for collection supplies does not include surgical items, and seemingly allows for more flexibility with respect to items such as biopsy brushes.[11]

If you have questions about the final rule, please do not hesitate to contact the Hogan Lovells lawyer with whom you regularly work or any Hogan Lovells lawyer listed on this alert.

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[11] 42 Code of Federal Regulations 411.351 (definition of “remuneration”). CMS did not discuss the impact, if any, if the surgical collection supplies are used in connection with a billable physician service. In addition, on a very general level, CMS stated that how an item is actually used affects the determination of whether or not is "used solely" for specified purposes (with the very basic hypothetical example of a collection device used as a doorstop not being "used solely" to collect specimens).
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