Analyzing the Proposed 2019 Stark Reforms

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The United Stated Department of Health and Human Services ("HHS") published a notice of proposed rulemaking (NPRM) containing proposed changes to the Physician Self-Referral Law ("Stark Law," or "Stark") on October 17, 2019.

These changes, part of HHS's "Regulatory Sprint to Coordinated Care," were intended to reduce regulatory red-tape, facilitate care coordination, and advance value-based care. In general, the NPRM proposed new exceptions applicable to arrangements involving value-based payment, and a variety of technical changes to the existing rules implementing the Stark Law.

Certain proposals would reduce Stark's burden by adding greater flexibility and predictability, while others would potentially have negative implications for some providers. In this article we review many of the proposed changes and identify potential implications and possible areas of comment for health care entities. A separate article, which can be found here, reviews the Stark and Anti-Kickback Statute ("AKS") proposals related to value-based care.

The deadline for submitting comments on the Stark and AKS proposals is **December 31, 2019**. Physician practices, hospitals, and other entities that are impacted by the Stark Law or AKS should not miss this opportunity to have their voice heard.

I. Introduction and Overview

The Stark Law prohibits physicians from referring patients to an entity for certain designated health services ("DHS") if the physician (or the physician's immediate family member) has a financial relationship with the entity, unless an exception applies The law is frequently cited as creating actual or perceived barriers to innovation because of its large potential penalties, highly technical exceptions, and strict liability nature. CMS proposes significant modifications to the law's implementing regulations based on its experience with the voluntary Self-Referral Disclosure Protocol ("SRDP") and its overall policy goal of encouraging arrangements involving value-based care, which improve the quality of care, reduce costs, and involve financial risk.

At a high level, some of the important proposed changes in the NPRM include:

- Revising key regulatory definitions, including "fair market value," "volume or value," "commercial reasonableness," and "set in advance."
- Revising rules for distributing group practice profits.
- Modifying rules on ending or resolving unintentional noncompliance with contracts
- Changing key Stark Law exceptions, including those for leases of space and equipment, recruitment, payments unrelated to DHS, and payments by a physician.

Authors

William P. Hoffman
Shareholder
whoffman@polsinelli.com

Neal D. Shah
Shareholder
nshah@polsinelli.com

Breanna M. Caldwell
Associate
bcaldwell@polsinelli.com

- Proposing a new exception for "limited remuneration" and making modifications to the "temporary noncompliance" rules that, combined with other changes, would significantly reduce risk for arrangements that are not immediately recorded in writing.
- Modifying the EHR donation exception to allow donations of cybersecurity, limit information blocking, and potentially reduce the physician contribution requirement.
- Providing CMS's perspective on federal judicial interpretations of the Stark Law related to productivity payments, practice losses, and the application of the Stark Law to Medicaid.

The discussion below highlights proposals in the NPRM that may be helpful to DHS entities and proposals that may be viewed as detrimental, and suggests opportunities to comment.

II. Proposals That Would Reduce Regulatory Burden

A. Changes to Key Definitions

The NPRM includes a number of changes to key terms. For some of these terms, CMS has never codified definitions even though they appear in multiple Stark Law exceptions. For some other terms, CMS proposes modifying their longstanding interpretations of key terms.

1. Consideration of Unique Circumstances. CMS proposes modifying the definition of "fair market value" and adding a definition of "commercial reasonableness." Overall, these changes would help parties establish that compensation arrangements were compliant because of their unique business goals, even if they differed from survey data or resulted in a practice loss.

Many Stark Law exceptions require compensation to be "fair market value." The Stark Law states that "fair market value" in part means compensation "consistent with general market value." CMS's existing regulations define "general market value" as the value of an asset or services negotiated by parties who were not in a position to refer to one another, and state that this "usually" means the price of similar transactions. This interpretation has caused concern over the years, as parties worried about justifying amounts paid in deals that made business sense disregarding referrals, but may have differed from similar transactions (e.g., physician compensation arrangements that differed from national surveys covering the applicable specialty and region).

The NPRM would create a two-part test in which "fair market value" would mean:

> "*[T]he value in an arm's-length transaction with like parties and under like circumstances, of assets or services, consistent with the general market value of the subject transaction;*" while "*general market value*" would mean "*the price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement.*"

This modification to the definition of "general market value" would allow parties to incorporate their own business objectives into the assessment of fair market value. CMS notes in the NPRM that "the concept of fair market value relates to the value of an asset or service to hypothetical parties in a hypothetical transaction (that is, typical transactions for like assets or services, with like buyers or sellers, and under like circumstances), while general market value (or market value) relates to the value of an asset or service *to the actual parties to a transaction* that is set to occur within a specified timeframe." For leases of equipment and leases of office space, "fair market value" must also be based on the value of "rental property for general commercial purposes," notwithstanding the intended use of the equipment or space or any additional value due to the proximity or convenience of space to a lessor in a position to refer patients to the lessee. Therefore, under CMS's revised proposed definition, parties could justify compensation higher or lower than the "usual" amount for the asset or service based on their actual business contexts.

Several Stark Law exceptions also require that compensation must be "commercially reasonable." In the past, arrangements have been challenged as not "reasonable" where an entity pays more for a physician's services than the physician generates in professional revenue (i.e., a "practice loss"). This has caused problems for arrangements involving physicians with unpredictable patient volume, specialized skill sets, practices in rural or underpopulated regions, or who otherwise did not reliably turn a profit. Under the NPRM, for the first time CMS would codify a definition of "commercially reasonable" as follows:

> "*Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.*"

CMS acknowledges several reasons for arrangements to be considered commercially reasonable despite practice losses, including community need, providing timely access to health care services, fulfilling licensure or regulatory obligations, providing charity care, and quality improvement; notably, entire hospital service lines could operate at a loss and still be "commercially reasonable." However, CMS emphasizes that some arrangements still are not "commercially reasonable," like duplicative arrangements or criminal activities. Arrangements must still be commercially reasonable "even if no referrals were made."

These changes would significantly improve the ability of entities to incorporate their own business goals in setting compensation. DHS entities could not pay for the value of generating referrals, but would be able to negotiate favorable deals even if such deals resulted in practice losses or compensation that differed from applicable survey amounts.

2. Clarifying the "Volume or Value" Standard. One challenge in value-based care delivery and payment models is that compensation incentivizing reduced utilization of services may be considered to "vary with" or "take into account" the volume or value of referrals or other business generated, a requirement of certain Stark Law exceptions. CMS proposes a special rule clarifying that the "volume or value" standard is only intended to prohibit relationships where the economic benefit to the physician relates to increased referrals. Compensation from a DHS Entity to a physician would take into account "volume or value" if:

> *1) The formula used to calculate the compensation includes the physician's referrals as a variable, resulting in an increase or decrease that positively correlates with the number or value of the physician's referrals to the entity; or 2) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.*

Conversely, compensation from a physician (or immediate family member) to a DHS Entity (e.g., a rent payment) would take into account "volume or value" if:

> *1) The formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease that negatively correlates with the number or value of the physician's referrals to the entity; or 2) "There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined."*

CMS notes that this standard would be violated if a physician's increased referrals would lead to increased compensation (or a decreased obligation to pay). It would not be violated in cases where a physician's compensation increased due to reduced referrals (such as a bonus for earning savings), or cases where a physician's compensation decreased due to increased referrals (such as a withhold for failing to achieve cost savings).

CMS also clarifies that it does not intend to link the "fair market value" and "volume or value" standards. This contradicts the position of some regulators and courts that compensation above fair market value necessarily reflects the volume or value of a physician's referrals or business generated.

3. Limiting the Scope of Liability Under the Stark Law. CMS proposes to change the sweeping definition of "DHS" in two important ways that would narrow the impact of the Stark law.

First, CMS would clarify in the regulatory definition that "DHS" only includes "DHS payable, in whole or in part, by Medicare." This would clarify CMS's position on a longstanding disagreement within the health care bar about whether or not the Stark Law applies to referrals of *Medicaid* covered services.

Second, CMS would clarify that a service furnished to a hospital inpatient is not "DHS" regulated by the law if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System ("IPPS"). This change could significantly reduce the liability of hospitals that have relationships with physicians who may provide services covered under an inpatient DRG, such as hospitalists or radiologists.

4. Other Changes to Definitions. CMS proposes several definition changes that have less significance, but are nevertheless important regulatory modifications. The agency solicits comments on all of these issues:

- Revising the definitions of "Electronic Health Record" and "Interoperable" to align with other changes made by the Office of the National Coordinator ("ONC") and adding a definition of "Cybersecurity."
- Aligning the definition of "physician" with the statutory definition at 42 U.S.C. § 1395x(r).
- Clarifying that a "referral" is not an "item or service" that can be covered under an exception.
- Adding language expressly allowing "directed referrals" subject to regulatory standards in the exceptions for equipment leases, personal services, remuneration unrelated to DHS, and fair market value compensation; and
- Codifying CMS's position in an earlier advisory opinion by revising the definition of an "ownership or investment interest" to exclude a "titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment."

B. New or Expanded Exceptions

The NPRM adds or expands various exceptions under the law.

1. Significantly Limiting Temporary or Minor Noncompliance. Three proposals in the NPRM could nearly eliminate the most common technical Stark Law violation – the failure to obtain a "signed writing" for a contract.

First, the NPRM would broaden the "special rule" on temporary noncompliance with signature requirements. Currently, an arrangement will not violate a Stark Law exception if: 1) *the only* noncompliance is a failure to obtain a signature on a document; and 2) the parties obtained signatures within 90 days. The NPRM would expand this rule to cover temporary noncompliance with the entire writing requirement. Parties could comply with the Stark Law if they had evidence of a "signed writing" – including a collection of contemporaneous documents evidencing the parties' conduct - within 90 days of the start date. This could be done using contemporaneous evidence of the parties' course of conduct, if sufficiently detailed.

Second, the NPRM clarifies the "set in advance" rule to establish that parties are not required to set out the compensation (or a formula used to calculate the compensation) in writing in advance of providing services. Therefore, the failure to have written evidence of compensation terms prior to starting performance under an arrangement would no longer cause a Stark Law violation.

Combined, these provisions would mean parties who agreed on compensation without a signed writing could still meet a Stark Law exception if: 1) the parties agreed on compensation before furnishing items or services; 2) the parties assembled written documentation of the arrangement within the first 90 days, including at least one "signed" document; and 3) the written documentation specifies an amount or rate of compensation that is consistent with the first payment and did not change – even if a party began performing services before any description of compensation was set out in writing.

Third, CMS proposes a new exception for limited remuneration, which would allow physicians to be paid for items or services if no other exception applies. A DHS Entity could pay a physician remuneration worth up to $3,500 per year, so long as: 1) the remuneration does not take into account the volume or value of referrals or other business generated by the physician; 2) the compensation is fair market value for the items or services; and 3) the arrangement is commercially reasonable. Fees could not be based on a percentage of revenue generated as a result of the arrangement or per-unit fees reflecting services provided to patients referred by the lessor (or other party providing space, equipment, personnel, items, or supplies under the arrangement). The $3,500 cap would only apply to compensation paid under an otherwise non-compliant arrangement (i.e., after the arrangement becomes compliant, any compensation would not be counted towards the cap).

Combined, these provisions should make it easier to address situations where parties begin performance under an agreement before all of the material terms are reduced to writing. The proposal suggests that, with a 90-day grace period for a "signed writing" and clarified "set in advance" rules, parties could begin operating under a contract before it is documented. Even if the parties do not initially meet the requirements of an exception, the "limited remuneration" exception would allow added flexibility to protect arrangements that are brought into compliance later in the year. As the year progresses, parties will often generate additional documentation evidencing their consistent course of conduct, which may create a "signed writing" to bring the arrangement into compliance before the $3,500 cap is met.

2. Reducing Burden Under Existing Exceptions. The NPRM also includes a variety of technical modifications to existing regulatory exceptions that were designed to reduce the likelihood of an unintentional violation, including the following modifications:

- Clarifying the office space and equipment lease exceptions' requirement of use "exclusively by the lessee when being used by the lessee" only requires the lessee to exclude the lessor, while permitting lessees to share the space with other lessees, or sub-license the space further
- Removing the physician recruitment exception's requirement that a physician must sign a recruitment support agreement between a hospital and a practice, so long as the practice passes all compensation through directly to the physician.
- Modifying the "certain arrangements with hospitals" exception, which currently only applies to remuneration "unrelated to furnishing DHS." Under the NPRM, CMS would clarify that remuneration would be "unrelated to DHS" for any items or services "unrelated to patient care services," so the exception could cover arrangements for administrative business operations that are typically provided by non-medical professionals. CMS also proposes amending the regulation to include a list of items and functions that it believes are related to patient care
- Permitting the "payments by physicians" exception to protect any fair market value payment by a physician to a DHS Entity for items or services, even if another exception could apply. This exception would not cover rental of office space, but would cover rental of any other space.
- Permitting the "fair market value arrangements" exception to be used with rentals of office space, and allowing certain leases with a term of less than a year.

3. Disagreeing with Contrary Judicial Positions. CMS takes the surprising step of disagreeing with a number of judicial opinions in the NPRM. Several of CMS's positions directly respond to certain opinions and propose different interpretations, but it is unclear whether this guidance would take precedence over contrary judicial decisions. These positions include the following:

- CMS reiterates its position that a productivity bonus paid to employees or physicians operating under personal service agreements and based on the personally performed services of those employees or contractors, would not take into account the volume or value of referrals even if those services generate a facility fee or other DHS. This arguably conflicts with the holdings of federal court cases, including *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.* (5th Cir. 2015) and *United States ex rel. Bookwalter v. UPMC* (3rd Cir. 2019). CMS acknowledges *Tuomey* but restates its earlier position; CMS does not propose any changes to regulatory text reflecting this position.
- Some courts have found that the Stark Law may apply to state Medicaid programs. (See e.g., *U.S. ex rel. Parikh v. Citizens Medical Center* (S.D.Tex. 2013)). CMS proposes changes that would seem to limit the Stark Law's application to Medicaid, including a proposed modification to the definition of DHS stating that it only included DHS "payable by Medicare."

- CMS's proposed definition of "commercially reasonable" states that an arrangement is not required to "result in profit for one or more of the parties" in order to be reasonable (rejecting the so-called "practice loss" rule). The practice loss rule has traditionally created large compliance challenges for parties (including health systems) who may have legitimate business reasons to accept losses in an arrangement. (See *Tuomey and Parikh*, cited above).

The practical impact of these changes remains unclear, particularly in the absence of regulatory language. In fact, the recent Supreme Court case Allina v. Azar casts further doubt on the legal impact of positions that are taken by CMS in guidance but not adopted through formal rulemaking. CMS could strengthen its proposal by codifying its position on these issues. Short of that, its statements could at least help parties argue that their practices comply with the Stark Law.

4. Redesigning EHR Donation Rules. CMS proposes several changes to its rules around donations of electronic health record ("EHR") technology. These include the following:

- Proposing new definitions of terms including "electronic health record," "interoperable," and "information blocking" to align with the 21st Century Cures Act and other CMS changes.
- Clarifying that CMS intends to protect donations of cybersecurity and soliciting comments on a new exception at 42 C.F.R. § 411.357(bb).
- Clarifying that the EHR exception could cover donations of cybersecurity software and services that meet the requirements of the EHR donation exception, if provided to protect the EHR system.
- Allowing the donated software and services to have non-EHR functionality if the predominant purpose of the software or services is cybersecurity associated with the EHR.
- Modifying the exception to specify that information technology and training services may also be donated if related to the EHR.
- Soliciting comments on the requirement for physicians to pay at least 15% of the cost of donated technology, including whether the requirement should be reduced or eliminated for small or rural practices, for all physicians, or for updates to previously donated EHR technology; and
- Proposing the removal or extension of the current EHR donation exception sunset date of December 31, 2021.

III. Proposals That Could Disadvantage Entities

Although many of CMS's proposals may reduce regulatory burden, the NPRM also presents new challenges for some entities that may require additional review and potential restructuring of longstanding arrangements. These include proposed changes to rules on distributing group practice profits from DHS, limitations on using the "isolated transactions" exception to resolve contractual administration disputes or errors, and new requirements to address compensation errors during the term of the agreement under the "period of disallowance" rules.

A. Modified or Eliminated Rules and Exceptions

1. Modifications to Rules Regarding Profit Shares in Group Practices. Under the Stark law, compliance with certain exceptions, including the in-office ancillary services exception, requires that a physician group must qualify as a "group practice" as defined in the law and rule. Under the group practice definition a physician group practice may not pay a physician compensation (including profit distributions) based directly or indirectly on the volume or value of the physician's DHS referrals to the group practice. However, in the law's current implementing regulations, CMS provides that a group practice may distribute the overall DHS profits of the group or a "pod" of at least five physicians using certain methodologies.

Since the 2001 "Phase I" final rule implementing the Stark Law, organizations seeking to qualify as a "group practice" have crafted various compensation arrangements in reliance on the rule's current provisions governing profit shares, including arrangements using pods. In the NPRM, CMS observes that there has been confusion in the industry about whether a group practice may define pods by category of DHS (e.g., whether a practice could allocate its profits from physical therapy services to a pod of five or more physicians).

In an effort to clarify this confusion, CMS states in the NPRM that it interprets (and has always interpreted) these rules to implicitly state that "a physician practice that wishes to qualify as a group practice could not distribute profits from DHS on a service-by-service basis." This means, for example, that a group practice may not "distribute the profits from clinical laboratory services to one subset of its physicians or using a particular methodology and distribute the profits from diagnostic imaging to a different subset of its physicians." Therefore, if a group practice (or a subset of five or more physicians in a group practice) shares DHS profits, the proposal suggests the group would be required to fund the pool with all of the group practice's DHS profits, *and* distribute them in a manner that complies with the group practice profit distribution rules (e.g., per capita). It remains to be seen whether CMS will allow group practices to define pods receiving distinct treatment using other criteria, such as location, seniority, equity class, or other standards.

This proposed clarification and change could have serious implications for existing group practices, particularly multispecialty practices that provide many different categories of DHS. Practices should review their compensation structures and understand the financial implications of potential requirements of the change. Given that the proposed change would likely require changes to group practice compensation models, this proposed change has great potential to disrupt current industry practices. Given that the in-office ancillary services exception to the Stark Law permits the greatest methodological flexibility in physician ownership and compensation arrangements involving DHS Entities, organizations that currently or may in the future, seek to use this flexibility may wish to consider commenting on the practical impact (and potential drawbacks) of the proposal.

2. Modifications to the Isolated Transactions Exception. The "isolated transactions" exception protects a one-time transaction or series of transactions under certain conditions. Prior to the publication of the NPRM, CMS had offered little practical guidance regarding the intended use of this exception. As a result, it was unclear whether the regulation permitted DHS Entities to use this exception to pay physicians a lump-sum payment for services rendered in the past (e.g., to pay for services without a written agreement, resolve compensation disputes, or address contractual administration errors through settlements). CMS is proposing a regulatory change that could close the door on this interpretation, clearly stating that "the exception for isolated transactions is not available to retroactively cure noncompliance with the physician self-referral law." If finalized, this proposal would deprive parties of a commonly used tool to bring arrangements back into compliance. However, parties may be able to cure at least some non-compliance under the newly proposed exception for "limited remuneration" discussed above.

3. Deletion of the Period of Disallowance. CMS proposes removing the "period of disallowance" rules, which currently state that an arrangement ends when all excess compensation is refunded. CMS now states that the date when a prohibited financial relationship ends should be determined on a case-by-case basis, and that: "the analysis to determine when a financial relationship has ended is dependent in each case on the unique facts and circumstances of the financial relationship."

This interpretation has implications for correcting contractual non-compliance and the timing of self-disclosures through the SRDP. There has been some confusion in the industry about the start of the "period of disallowance"; for example, whether an arrangement has violated the Stark Law and must be disclosed on the date the parties act out of compliance with a written contract. In light of the changes to the "isolated transactions" exception, parties may also wonder whether they have an opportunity to cure accidental or inadvertent non-compliance with a contract (e.g., missing a rent payment or overpaying a physician due to a clerical error).

In an effort to draw a bright line between "turning back the clock" to address non-compliance and "fix[ing] a mistake," CMS states: *"An entity that detects a problem in an active financial relationship and corrects the problem while the financial relationship is still active is addressing a current problem and is not "turning back the clock" to fix past noncompliance. On the other hand, once the arrangement has ended, we believe that parties cannot retroactively "cure" previous noncompliance by recovering or repaying problematic compensation."*

It appears that CMS is simply trying to create a bright line because it is unclear why curing an inactive arrangement is worse than an active arrangement from a policy perspective. There are still many open questions about applying this test. For example, can a DHS Entity fix compensation paid in prior years to a continuously employed physician if the compensation methodology has changed? Or, if an arrangement expires on December 31st and a clerical error is discovered on January 1st of the following year, are the parties required to treat this as a Stark Law violation? The inability to cure inactive arrangements under this rule will likely negatively impact providers based somewhat arbitrarily on the date they discover the non-compliance.

IV. Conclusion

In the NPRM, CMS has set out some of the most ambitious and far-reaching modifications in decades. The proposals could change everything from core defined terms affecting every compensation arrangement, to common compliance strategies, to new partnership opportunities. While these proposed changes are generally positive for many entities, several of the proposed changes could have serious, potentially detrimental impacts for certain organizations. These entities may include physician group practices with in-office ancillary services, and entities that administer many complicated physician compensation agreements (including many health systems). The deadline for submitting comments to the NPRM is December 31, 2019.