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Healthcare

The Other Half of the Stark Sprint Regulations - Valuable (but Not Value-Based) Proposals

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10.28.19

The Sprint Regulations' value-based exceptions and related amendments have attracted much well-deserved attention. However, value-based matters aside, the Sprint Regulations portend significant positive changes to the Stark Law.

CMS would re-define key terms, clarify *volume or value* and *commercially reasonable*, create new exceptions, streamline existing exceptions and breathe new life into exceptions previously left for dead. The proposals reflect a more mature assessment by the agency of the scope and purpose of the Stark Law.

With the benefit of almost three decades of rulemaking, hundreds of submissions under the Self-Referral Disclosure Protocol and the growing body of often troubling Stark case law, CMS revisits a number of assumptions and offers new solutions in an admirable attempt to bring some measure of reason and common sense to a deeply flawed statute.

Unfortunately, the agency's ability to solve the "Stark problem" is limited. The breadth and complexity of the statute virtually ensures that its parameters will remain incomprehensible – a gift for lawyers and a curse for the rest of the world. Only Congress can fix it.

The key modifications CMS proposes in the Sprint Regulations are summarized below. Comments on the proposed regulations are due by December 31, 2019.

The Definitions

Fair Market Value
CMS carefully assesses the definition of "fair market value" and reaches two important conclusions:

- First, the fair market value requirement should be separate and distinct from the "volume and value of referrals" and "other business generated" standards.
- Second, the term "general market value" as used in the Stark Law should not vary from generally accepted principles in the valuation community.

Consequently, the proposed definition of fair market value eliminates the references to *bona fide* bargaining between parties who are not otherwise in a position to generate business for each other, and to *bona fide* service agreements where the compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.

As proposed:

- "Fair market value" means "the value in arm's-length transactions with like parties and under like circumstances, of like assets or services, consistent with the general market value of the subject transaction."
- "General market value" is defined as "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 asset or at the time the parties enter into the service arrangement."

CMS also proposes separate definitions of fair market value for rental of office space and rental of equipment.

- Fair market value for rental of equipment still refers to the value of rental property for general commercial purposes not taking into account its intended use;
- Fair market value for rental of office space still includes the condition that the value is not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

Volume or Value of Referrals

Many Stark exceptions require that compensation not take into account the "volume or value of referrals" or "other business generated" between the parties. Historically, CMS has offered little guidance regarding the application of the volume or value standard.

In the Sprint Regulations, the agency proposes an "objective test" to serve as a "bright line" that "defines exactly when compensation will be considered to take into account the volume or value of referrals or other business generated between the parties." While categorized as special rules on compensation, the proposed clarifying language appears to more akin to a definition, based on CMS's commentary:

If the methodology used to determine the physician's compensation or the payment from the physician does not fall squarely within the defined circumstances, the compensation would not take into account the volume or value of the physician's referrals or the other business generated by the physician, as appropriate, for purposes of applying the exceptions to the physician self-referral law.[1]

The proposed special rule on compensation states that compensation from an entity furnishing designated health services (DHS) to a physician takes into account the volume or value of referrals (or other business generated) only if one of the following applies:

- The formula used to calculate the physician's compensation includes the physician's referrals to (or other business generated for) the entity as a variable, resulting in an increase or decrease in the physician's compensation that positively correlates with the number or value of the physician's referrals to (or generation of other business for) the entity.

  An example of such a formula is the following: a physician is paid a percentage of collections that includes amounts collected for DHS that the physician ordered but did not personally perform.

- There is a predetermined direct correlation between the physician's prior referrals to (or other business previously generated for) the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

  This would apply to fixed rate compensation (such as a fixed annual salary or an unvarying per-unit rate of compensation) where there is a "predetermined, direct and meaningful 'if X, then Y' correlation between the volume or value of the physician's prior referrals (or other business previously generated) and the prospective rate of compensation to be paid over the relevant period."

  In this connection, the agency notes that *"[m]erely hoping for or even anticipating future referrals or other business is not enough to show that compensation is determined in a manner that takes into account the volume or value of referrals or other business generated by the physician for the entity."*[2]

- For purposes of this section, a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

With respect to arrangements where the physician is compensating the entity furnishing DHS, the converse applies: compensation from the physician takes into account the volume or value of referrals only if:

- The formula used to calculate the compensation includes the physician's referrals to (or other business generated for) the entity as a variable, resulting in an increase or decrease in the compensation that negatively correlates[3] with the number or value of the physician's referrals to (or generation of other business for) the entity; or

- There is a predetermined direct correlation between the physician's prior referrals to (or other business previously generated for) the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

In response to concerns raised about the interpretation of the volume or value standards in cases such as *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.* and *U.S. ex rel Bookwalter v. UPMC*, CMS also clarified that a physician's compensation does not take into account the volume or value of referrals or other business generated *solely* because corresponding hospital services are billed each time the physician personally performs a service.

This clarification may provide some comfort for productivity-based compensation arrangements between hospitals and physicians where the physicians personally perform surgeries or procedures at the hospital.

While CMS requests comments on the proposed special rule, it also notes that its commentary should "supersede" prior guidance.[4] This suggests that the agency's statements can be immediately relied upon as a clarification of its interpretation of the volume or value standard.

Commercially Reasonable

Despite being a required element in several Stark exceptions, the term "commercial reasonableness" until now has never been defined by CMS. The Sprint Regulations address that deficiency. CMS proposes to define the term to mean "that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements."

CMS adds that "[a]n arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties." There are two issues of note:

- First, this definition does not require that there be a business purpose unrelated to the volume or value of referrals. However, certain exceptions (such as the *bona fide* employment exception) specifically require that the arrangement must be commercially reasonable even in the absence of referrals.

  The agency does not propose to modify those exceptions to remove the reference to referrals.

- Second, the proposed definition specifically acknowledges that profitability is not the touchstone for commercial reasonableness. In several False Claims Act cases the government and on occasion the courts have suggested that any arrangement that involves a financial loss is not commercially reasonable.

  The agency rejects this position, stating: "We wish to clarify that compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable."[5] CMS's proposed definition appropriately permits consideration of a range of factors, including an entity's charitable mission, in the determination of commercial reasonableness.

Designated Health Services

The Sprint Regulations propose to exclude from the definition of DHS hospital inpatient services "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)."

To illustrate, if a physician who is a party to a noncompliant financial arrangement with a hospital serves as a consultant for a hospital inpatient and orders diagnostic tests, but that service does not affect the DRG determining the payment to the hospital, then Medicare payments for that hospital inpatient stay would not be subject to the Stark billing prohibition.

This is a significant change that aligns the definition of DHS more closely with the purpose of the statute and reduces the scope of the referral and billing prohibitions.

Isolated Financial Transaction

While most of the Sprint Regulations' proposed changes are provider friendly, the agency's changes to the definition of isolated financial transaction would narrow the scope of the corresponding exception. The agency proposes to modify the definition to exclude "a single payment for multiple or repeated services (such as a payment for service previously provided but not yet compensated)."[6]

While the isolated transaction exception would remain useful, some of the more creative applications would be curtailed by this amendment. As CMS notes in the commentary, the isolated transaction exception "is not available to retroactively cure noncompliance" with the Stark Law.[7]

Ownership or Investment Interests

The Sprint Regulations carve out from the definition of ownership or investment interests both (1) "titular" interests that exclude the right to financial benefits of ownership, such as profits, dividends, proceeds of sale and other returns on investment, as well as (2) interests arising from employee stock ownership plans.

Exceptions for Indirect Compensation

The definition of "indirect compensation arrangement" is modified to explicitly state that the only exceptions available to protect indirect arrangements are the indirect compensation exception and those general exceptions that cover both ownership and compensation arrangements (i.e., the physician services, in-office ancillary services, services of certain managed care organizations, and the academic medical centers exceptions).[8]

Although presented as a confirmation of CMS's existing position, this limitation is inconsistent with the express language of several existing exceptions.[9] Most notably, the risk-sharing exception clearly encompasses both direct and indirect compensation arrangements.

It is odd that CMS would propose to narrow the Stark risk-sharing exception as a part of its sprint to coordinated care without at least discussing the rationale for such a change. The proposed modification to the definition is even more puzzling given that the agency proposes that an indirect compensation arrangement may be protected by the new exception for value-based arrangements if the unbroken chain of financial relationships includes a "value-

based arrangement" to which the physician (or physician organization in whose shoes the physician stands) is a direct party.

Group Practice

The Sprint Regulations propose a number of clarifications to the Stark group practice requirements, including:

- Confirming that profit allocations and productivity bonuses may indirectly take into account the volume or value of referrals.
- Revising the definition of "overall profits" to mean the profits derived from all DHS of any component of the group that consists of at least five physicians.
- Clarifying that the profits from all of the DHS of the group (or a subset of at least five physicians in the group) must be aggregated and then distributed. In short, a group practice could not distribute profits from DHS on a service-by-service basis.
- Removing the reference to Medicaid from the provision deeming certain methods for distributing profit shares to be permissible. Revenues derived from DHS could be distributed based on the distribution methodology used for revenue attributed to services that are not Medicare DHS and that would not be considered DHS if they were payable by Medicare.
- Revising the description of how productivity bonuses may be paid to be consistent with the provisions addressing the distribution of overall profits.

Writing and Signature Requirements

The Sprint Regulations provide greater flexibility to meet the Stark exceptions' writing requirements. CMS proposes a special rule stating that the writing requirement as well as the signature requirement are deemed to be satisfied if the arrangement satisfies all other elements of an applicable exception, and the parties obtain the required writing or signature within 90 consecutive calendar days. The agency also confirms that the writing requirement can be satisfied through a collection of documents.

The writing grace period would not eliminate the requirement for compensation to be set in advance (if an element of the applicable exception). However, the agency indicates that the compensation terms do not have to be documented before the items or services are furnished to meet the "set in advance" requirement.

For example, compensation would be considered set in advance if the parties agree on a rate before items or services are furnished and assemble adequate documentation before the end of the 90-day grace period to satisfy the writing requirement and demonstrate a consistent rate of compensation over the course of the arrangement.

Period of Disallowance

The Sprint Regulations propose to eliminate the Stark rules addressing the period of disallowance. While confirming the general principle that the period of disallowance under Stark "should begin on the date when a financial relationship fails to satisfy all requirements of any applicable exception and end on the date when the financial relationship ends or satisfies all requirements of an applicable exception," the agency's comments reinforce the need for a case-by-case analysis.

In other words, by eliminating the period of disallowance rules, CMS is expressly acknowledging that there are no bright-line rules for determining when a non-excepted financial relationship has ended.

In one of the more interesting portions of the commentary, CMS offers guidance about how to remedy "administrative and operational failures" that may arise in the course of an arrangement:

Through submissions to the SRDP and other interactions with stakeholders, we are aware of questions regarding whether administrative errors, such as invoicing for the wrong amount of rental charges (that is, an amount other than the amount specified in the written lease arrangement) or the payment of compensation above what is called for under a personal service arrangement due to a typographical error entered into an accounting system, create the type of "excess compensation" or "insufficient compensation" described in our preamble guidance and the period of disallowance rules. **This was never our intent.** However, the failure to remedy such operational inconsistencies

could result in a distinct basis for noncompliance with the physician self-referral law.[10]

The agency goes on to explain that if the parties discover an unintentional error that affected compensation or another key element of an arrangement, they can avoid triggering the Stark referral and billing prohibitions if they correct the error during the term of the arrangement. If, however, the error is not discovered and remedied during the term, the parties cannot "unring the bell" by correcting the error at a later date.

While this guidance regarding clerical errors or technical omissions is certainly welcome, the draconian distinction between the treatment of errors discovered and corrected during the term of an arrangement and errors discovered and corrected after the term has ended is troubling.

The Compensation Exceptions

New Exception "Z"-- Limited Remuneration to a Physician
The Sprint Regulations introduce a new exception that covers remuneration paid to a physician for items or services that do not exceed $3,500 per calendar year provided the compensation does not exceed fair market value, is not determined in a manner that takes into account the volume or value of referrals or other business generated by the physician, and the overall arrangement is commercially reasonable.

The significance of this proposed exception is that there are no writing, signature or set-in-advance requirements. The exception recognizes that limited remuneration may not pose a risk of program or patient abuse if certain other requirement are met.

The aggregate limit under Exception Z will be adjusted annually for inflation. The exception does not apply to payments to an immediate family member of a physician.

In addition, if the arrangement involves the lease or use of office space, equipment, personnel, items or services, the compensation must not be determined using a formula based on a percentage of revenue or collections attributable to services performed using the space, equipment, personnel,

items, supplies or services, or using per-unit-of-service fees reflecting services provided to patients referred by the lessor to the lessee, or patients referred by the owner of the premises, equipment, personnel, items, supplies or services.

CMS also notes that Exception Z can be used in conjunction with other Stark exceptions, creating the possibility that a personal services arrangement that fails to comply with an exception for the first few months of the term could rely on Exception Z if the amount paid during the first few months did not exceed $3,500.

Decoupling the Anti-Kickback Statute

The Sprint Regulations eliminate from the Stark exceptions the requirement that the arrangement not violate the Anti-Kickback Statute, and that the claim or bill otherwise complies with applicable law. This proposal affects numerous exceptions including the exceptions for temporary noncompliance, academic medical centers, fair market value compensation, indirect compensation, risk-sharing arrangements, nonmonetary compensation, medical staff incidental benefits, physician recruitment, timeshare arrangements, and electronic health records.

The proposal would essentially remove an intent-based requirement from the Stark exceptions. Of course, the Anti-Kickback Statute would continue to apply to any given arrangement on its own terms.

Required Referrals

One of the special rules on compensation allows an entity to include in employment agreements, personal services agreements or managed care contracts a provision requiring the physician to refer within a designated network or system. The referral requirement must be in writing and include exceptions for patient choice, payor preference and the physician's clinical judgment.

The Sprint Regulations make this provision an explicit element in the exceptions for academic medical centers, employment, personal services arrangements, physician incentive plans, fair market value compensation, and indirect compensation arrangements.

Office Space and Equipment Leases

The Sprint Regulations propose to amend the "exclusive use" requirement in the exceptions for office space and equipment leases to permit multiple lessees to use the space. In short, the exclusive use requirement limits only the lessor's use of the lessee's space. However, neither the lessor nor any person related to the lessor may use the space even as an invitee of the lessee.

Fair Market Value Compensation

The Sprint Regulations would modify the fair market value compensation exception to cover arrangements for the rental of office space or equipment for a term of less than one year. The parties could enter into only one such arrangement over the course of a year. However, the duration of the short-term arrangement could be extended on the same terms.

Compensation Unrelated to DHS

Historically CMS has essentially attempted to eviscerate the statutory exception for remuneration unrelated to DHS. In the Sprint Regulations, the agency changes course, proposing that remuneration would not relate to the provision of DHS if it is not determined in any manner that takes into account the volume or value of the physician's referrals and is "not related to the provision of patient care services."

A service would be deemed to not relate to the provision of patient care services "if the service could be provided by a person who is not a licensed health care professional." Items related to the provision of patient care services would include but would not be limited to "any item, supply, device, equipment, or space that is used in the diagnosis or treatment of patients and any technology that is used to communicate with patients regarding patient care services."

The commentary offers examples of payments that would not qualify for the exception as proposed:

- Payments for emergency department call coverage, medical director or utilization review services; and
- Payments for rental of medical equipment, purchase of medical devices, and rental of office space where patient care services are provided.

An example of remuneration from a hospital to a physician that CMS indicated would qualify as unrelated to DHS is a payment or other in-kind benefit that a physician receives for serving as a member of the hospital's governing body, provided the remuneration is not determined in a manner that takes into account the volume or value of the physician's referrals. Another example of remuneration unrelated to DHS is a hospital's payment to a physician for the purchase of office furniture.[11]

CMS seeks comments on other ways to distinguish between remuneration that is related and unrelated to the provision of DHS.

Payments by a Physician

The Sprint Regulations propose to rescue another exception that CMS has historically disfavored: payments by a physician for items or services at fair market value. Historically CMS took the position that this exception was not available for arrangements where any other Stark exception could apply.

CMS now proposes to allow this exception to protect compensation arrangements other than those addressed in one of the *statutory* compensation exceptions. This means that the exception for payments by a physician could still not apply to arrangements involving leases of office space or equipment, for example, but could potentially protect an arrangement such as a physician's purchase of administrative services from a hospital, because there are no statutory exceptions that might otherwise apply.

Physician Recruitment

CMS acknowledges that the agency has reviewed several arrangements where the recruitment exception was unavailable because the physician practice did not sign the recruitment agreement, even though the practice did not receive any payments under the agreement. The Sprint Regulations would modify the recruitment exception to require the practice to sign the recruitment agreement only if payment is made to the practice and the practice does not pass directly through to the recruited physician all of the remuneration received from the hospital.

Assistance to Compensate a Non-Physician Practitioner (NPP)

The Sprint Regulations include clarifications concerning the exception that protects remuneration provided by a hospital, Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) to a physician to compensate an

NPP to provide "patient care services". To avoid confusion with the already defined term "patient care services" (which refers to physician services), CMS offers a new term, "NPP patient care services," defined as direct patient care services furnished by an NPP and any task performed by an NPP that promotes the care of patients.

To address questions about the timing of the arrangements that are permissible under this exception, the Sprint Regulations propose to require the compensation arrangement between the hospital/FQHC/RHC and the physician begin before the physician or physician organization enters into the compensation arrangement with the NPP.

FOOTNOTES

1 84 Fed. Reg. 55766, at 55794 (Oct. 17, 2019). These special rules would not apply to the exceptions for value-based arrangements.
2 84 Fed. Reg at 55794 (emphasis added).
3 A negative correlation between two variables exists when one variable increases as the other variable decreases, or one variable decreases as the other variable increases. The example given in the commentary is that under a rental formula for office space leased by a physician from a hospital, the rental rate decreases as the number of the physician's referrals for hospital outpatient services increases. 84 Fed. Reg. at 55794.
4 84 Fed. Reg. at 55792.
5 84 Fed. Reg. at 55790.
6 84 Fed. Reg. at 55840, proposed definition set forth in 42 CFR § 411.351.
7 84 Fed. Reg. at 55808.
8 84 Fed. Reg. at 55842, proposed 42 CFR 411.§ 354(c)(4).
9 For example, the physician recruitment exception and the fair market value arrangement exception both indicate that they may apply to arrangements that could satisfy the indirect compensation arrangement definition.
10 84 Fed. Reg. at 55810 (emphasis added).
11 84 Fed. Reg. at 55816-17.

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