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CMS issues long-awaited Stark proposed rulemaking

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On October 17, 2019, the Centers for Medicare & Medicaid Services (CMS) published a notice of proposed rulemaking (the proposed rule) to update and amend the Stark Law regulations.[1] Stakeholders have long awaited this proposed rule after CMS issued a Request for Information (RFI) on June 25, 2018, for public input on how to address the regulatory burdens of the Stark Law. Considering those comments, CMS issued this proposed rule to introduce new exceptions addressing value-based care arrangements, and to clarify and introduce new exceptions addressing non-abusive compensation arrangements. More than 330 pages long, the proposed rule is the first stand-alone Stark rulemaking in over a decade. This article explores a selection of aspects of the proposed rule.

Simultaneously with the proposed rule, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued a companion notice of proposed rulemaking introducing new exceptions, amendments, and clarifications to the Anti-Kickback Statute (AKS) and Civil Monetary Penalties (CMP) regulations. A companion article summarizing and discussing the OIG proposed rule ("OIG proposed rule revises federal Anti-Kickback Statute and CMP Law") can be found in this issueof *Compliance Today*.

The Stark Law background

The Stark Law prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare and prohibits the entity from billing for those referred services, if the physician or a family member has a financial relationship with the entity performing or billing for the DHS.[2] If an arrangement implicates the Stark Law, it *must* fit within an exception in order to be protected from liability. This restrictive and unforgiving prohibition has been a large burden on entities and providers over time, especially as healthcare reimbursement transitions from pay-for-performance to value-based, coordinated care arrangements. Recognizing that the Stark Law is, in fact, a law that can only be amended by Congressional action, CMS has proposed new exceptions and clarifying language to these regulations in an attempt to ease the regulatory burden on stakeholders.

Coordinated care arrangements

CMS received numerous comments in response to the RFI regarding the transformation of healthcare compensation methodologies, specifically the transition from fee-for-service (FFS) to new value-based, coordinated care arrangements. These new arrangements complement payment models focused on efficiencies and outcomes, versus rendered services. Stakeholders requested regulatory updates to protect arrangements compensating efficiencies and outcomes. In response, the proposed rule issued new definitions for these arrangements and introduced three exceptions to protect compensation arrangements that satisfy certain requirements based on the type of arrangement or value-based enterprise (VBE) and level of the parties' financial risk. If finalized, these definitions and exceptions are meant to eliminate the need for new CMS-sponsored waivers for value-based arrangements.

Value-based care definitions

CMS introduced definitions for limited terms critical to three exceptions proposed to protect certain coordinated care arrangements.[3]

- A "value-based activity" would mean any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the VBE: (1) the provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action. The making of a referral is not a value-based activity.
- A "value-based arrangement" would mean an arrangement for the provision of at least one value-based activity for a target patient population between or among: (1) the VBE and one or more of its VBE participants; or (2) VBE participants in the same VBE.
- A "value-based enterprise" would mean two or more VBE participants: (1) collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the VBE; (3) that have an accountable body or person responsible for financial and operational oversight of the VBE; and (4) that have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s).
- A "value-based purpose" would mean: (1) coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to, or growth in expenditures of, payers without reducing the quality of care for a target patient population; or (4) transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided, to mechanisms based on the quality of care and control of costs of care for a target patient population.
- A "VBE participant" would mean an individual or entity that engages in at least one value-based activity as part of a VBE.
- "Target patient population" would mean an identified patient population selected by a VBE or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and furthers the VBE's value-based purpose(s).

Proposed exceptions for value-based arrangements

The specifics of the three notable exceptions in the proposed rule are described below.

Full financial risk exception

The Full Financial Risk exception would apply to value-based arrangements between VBE participants in a VBE that have assumed "full financial risk" for the cost of patient care items and services covered by the applicable payer for each patient in a target patient population for a specified period of time. In other words, the VBE must be financially responsible on a prospective basis for the cost of all patient care items and services referenced above. For Medicare beneficiaries, the VBE must, at a minimum, be responsible for all Parts A and B items and services. The financial risk may take the form of capitation payments or global budget payments. The specific proposed requirements are:[4]

i. The VBE is at full financial risk (or is contractually obligated to be at full financial risk within the six months following the commencement of the value-based arrangement) during the entire duration of the

value-based arrangement;

ii. The remuneration is for, or results from, value-based activities undertaken by the recipient of the remuneration for patients in the target patient population;

iii. The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient;

iv. The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement;

v. If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of 42 C.F.R. § 411.354(d)(4)(iv); and

vi. Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least six years and made available to the Secretary upon request.

Remuneration under the VBE arises from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. CMS clarified that gainsharing payments, shared savings distributions, and similar payments could meet this requirement. Additionally, the proposed exception would not protect payments for referrals or any other actions or business unrelated to the target patient population. Examples of unprotected arrangements include general marketing or sales arrangements.

Value-based arrangements with meaningful downside financial risk to a physician exception

This exception would apply to remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk to achieve the value-based purpose(s) of the VBE. Remuneration could be paid to or from the physician, but in any event, the meaningful downside risk must span the entire term of the arrangement. The meaningful downside risk would mean that the physician is either responsible to pay the entity no less than 25% the value of the remuneration the physician receives under the value-based arrangement; or the physician is financially responsible to the entity on a prospective basis for the cost of all or certain patient care items or services. The specific proposed requirements are:[5]

i. The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the VBE during the entire duration of the value-based arrangement;

ii. A description of the nature and extent of the physician's downside financial risk is set forth in writing;

iii. The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid;

iv. The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population;

v. The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient;

vi. The remuneration is not conditioned on referrals of patients who are not part of the target patient

population or business not covered under the value-based arrangement;

vii. If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of § 411.354(d)(4)(iv); and

viii. Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least six years and made available to the HHS Secretary upon request.

Value-based arrangements exception

The proposed rule introduced this broader exception, aimed at protected value-based compensation arrangements, regardless of the level of risk involved. This proposed exception protects both monetary and nonmonetary remuneration between the parties. Given the far-reaching implications of this proposed exception and that financial risk is not a requirement, CMS included certain historical conditions to protect the program and patients from abuse, such as reducing the arrangement to writing and requiring compensation be set in advance. The writing must include descriptions of:

- The value-based activities to be undertaken under the arrangement,
- How the value-based activities are expected to further the value-based purpose(s) of the VBE,
- The target patient population for the arrangement,
- The type or nature of the remuneration,
- The methodology used to determine the remuneration, and
- The performance or quality standards against which the recipient will be measured, if any.

Additionally, the specific proposed requirements are:[6]

i. The arrangement is set forth in writing and signed by the parties (as described in more detail above);

ii. The performance or quality standards against which the recipient will be measured, if any, are objective and measurable, and any changes to the performance or quality standards must be made prospectively and set forth in writing;

iii. The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid;[7]

iv. The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population;

v. The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient;

vi. The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement;

vii. If the remuneration paid to the physician is conditioned on the physician's referrals to a particular

provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of 42 C.F.R. § 411.354(d)(4)(iv); and

viii. Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least six years and made available to the Secretary upon request.

The arrangements protected under this proposed exception would be under an "implicit ongoing obligation" to monitor the arrangement for compliance.[8] To illustrate, if at any point in the arrangement, an entity detects that it will not be able to reasonably achieve the results of the VBE, then the value-based activities under the arrangement would no longer be reasonably designed to achieve the value-based purpose of improving care. CMS would no longer consider it a value-based arrangement. Thus, ongoing monitoring would be crucial to ensuring that an arrangement seeking protection under this proposed exception does not fall out of compliance, thereby exposing the parties to liability.

Clarifying critical definitions and terms

CMS introduced new definitions for fundamental terminology and requirements used throughout the Stark Law.

Commercially reasonable

CMS proposes two alternative definitions for the term "commercially reasonable" and seeks comments from stakeholders as to which might provide clearer guidance regarding how to structure arrangements. *Commercially reasonable* shall mean:

1. "[T]hat the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements;" or
2. "[T]hat the arrangements make commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty."[9]

CMS also would clarify in regulation text that an arrangement still may be considered commercially reasonable even if it does not result in profit for one or more of the parties. The proposed *commercially reasonable* definitions are similar to those expressed in previous agency commentary.[10]

Fair market value

As for the definition of fair market value (FMV), CMS clarifies that FMV is meant to be separate and distinct from the volume or value standard, therefore the proposed rule disconnects the two concepts. The proposed rule sets forth the following three definitions of FMV to be applied in different circumstances:

1. Applied generally, FMV means "the 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."
2. Applied to equipment rental, FMV means "the value, in an arm's-length transaction with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction."
3. Applied to the rental of office space, FMV means "the value in an arm's-length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), without adjustment 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, and consistent with the general market value of the subject transaction."[11]

CMS also would revise the definition of "general market value," currently included in the definition of FMV, to mean:

> [t]he 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; or, in the case of the rental of equipment or office space, the price that rental property would bring as the result of bona fide bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement.

Volume or value of referrals and other business generated

CMS proposes a bright-line rule for the "volume or value of referrals" standard and the "other business generated" standard:

> Only when the mathematical formula used to calculate the amount of the compensation includes, as a variable, referrals or other business generated, and the amount of the compensation correlates with the number or value of the physician's referrals to, or the physician's generation of other business for the entity, is the compensation considered to take into account the volume or value of referrals or take into account the volume or value of other business generated.[12]

This change would be reflected in two separate special rules for the volume or value standard, as well as two separate special rules for the other business generated standard, instead of a single definition for either standard. The separate special rules are meant, in part, to address circumstances where compensation flows from an entity to a physician, as well as from a physician to an entity.

Two new proposed exceptions for non-abusive business practices

New exceptions were introduced to provide protection for certain arrangements that pose little risk of program abuse but may not otherwise be protected by current exceptions.

Limited remuneration for items or services provided by a physician

CMS proposed an exception for limited remuneration paid to a physician from an entity for the physician's provision of items or services.[13] The remuneration cannot exceed $3,500 annually per physician and cannot be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician. Additionally, the compensation cannot exceed FMV for the items or services and the arrangement must be commercially reasonable. There are additional requirements if the compensation is for the lease of office space or equipment or for the use of premises, equipment, personnel, items, supplies, or services. This exception is meant to address the arrangements disclosed to CMS via the Self-Referral Disclosure Protocol (SRDP) that were not otherwise protected by current exceptions but did not present risk of program or patient abuse.

Donation of cybersecurity technology

CMS proposed an exception for the donation of cybersecurity technology and related services. Specifically, the donation of cybersecurity technology and/or related services would be protected if necessary and used predominantly to implement, maintain, or reestablish cybersecurity; the arrangement is documented in writing; the receipt of technology or services is not a condition of doing business; and the eligibility for the donation is not condition in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.[14]

Additional clarifications

The proposed rule addressed a number of additional concepts that could significantly impact future rulemaking. Below are brief discussions of select proposals.

Price transparency

CMS introduced the concept of price transparency and sought feedback from stakeholders regarding whether requiring price transparency at the point of a referral should be included in future regulatory changes. Out-of-pocket patient costs were emphasized in the request for comments. The goal behind this is to target the objective of the Stark Law, which at its core is meant to reduce or eliminate a physician's conflict of interest when providing care to Medicare beneficiaries.

Decoupling Stark Law from AKS

The proposed rule seeks to decouple the Stark Law from the AKS. Because the two laws have different intent requirements and are regulated by different agencies, CMS proposed to remove the references to AKS compliance throughout the regulation. This does not mean that stakeholders do not have to be concerned with AKS compliance, but it does mean that regulators have recognized that the two laws are independent and should be treated as such. If this proposal does not get finalized, the AKS compliance aspects present in the regulations would remain, and CMS stated that it would also add AKS compliance where necessary to any new exceptions.

Interoperability of electronic health records

CMS proposed to revise the existing exception for the donation of electronic health records software, information technology, and training services by updating interoperability and data lock in requirements. The proposed rule also considers removing the sunset provision, modifying definitions, and considers eliminating the 15% technology cost contributions by recipient requirement.

Group practice definitions

CMS addressed a few changes to the rules for qualifying as a "group practice" in response to concern from RFI commenters. Specifically, they discussed clarifying the "volume or value standard" and the special rules for profit shares and productivity bonuses.[15]

Designated health services

The proposed rule discussed the definition of DHS and (in keeping with the intent of the statute to prevent Medicare trust fraud, waste, and abuse) clarified that services provided to hospital inpatient Medicare beneficiaries that would not otherwise change the reimbursement received from Medicare would not be considered DHS. For example, if a Medicare beneficiary is admitted to a hospital, the Medicare payment to the hospital would be controlled by the diagnosis-related group (DRG). As such, if the patient's attending physician

consulted with a specialist who ordered an X-ray, that X-ray would not change the amount of Medicare reimbursement established by the DRG under the Inpatient Prospective Payment System (IPPS). Unless that X-ray were to be an outlier payment, the hospital's Medicare reimbursement under the IPPS would not change. Thus, CMS would not consider that X-ray to be DHS. The reasoning behind this rule is that because the payment would not change, CMS does not believe the prescribing physician would have a financial incentive to order the service.

Conclusion

This article has touched on some of the select proposals and concepts in the proposed rule; however, there is much more contained in the proposed rule. Stakeholders had until December 31, 2019, to submit comments on this proposed rule. CMS encouraged stakeholders to submit comments providing feedback on certain proposals, especially those definitions and concepts in which alternating proposals are offered. Unless and until CMS issues a final rule regarding these exceptions and clarifying language to the Stark Law regulations, stakeholders will not be able to use them to protect arrangements and the associated commentary will be of limited use.

Takeaways

- This proposed rule is the first stand-alone Stark Law rulemaking in over a decade.
- CMS attempted to balance program integrity concerns with the regulatory burden of the Stark Law in this proposed rule.
- CMS proposes first-of-its-kind exceptions aimed at protected value-based care arrangements.
- This proposed rule is not final, so stakeholders should be cautious in proceeding with arrangements that rely on this proposed rule until a final rule is issued.
- CMS hopes to issue the final rule in 2020.

1 Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55,766 (proposed Oct. 17, 2019) (to be codified at 42 C.F.R. § 411).
2 42 U.S.C. § 1395nn (2018) .
3 84 Fed. Reg. at 55,773-77 .
4 *See generally* 84 Fed. Reg. at 55,846 (to be codified at 42 C.F.R. § 411.357(aa) (1)).
5 *See generally* 84 Fed. Reg. at 55,846 (to be codified at 42 C.F.R. § 411.357(aa) (2)).
6 *See generally* 84 Fed. Reg. at 55,847 (to be codified at 42 C.F.R. § 411.357(aa) (3)).
7 84 Fed. Reg. at 55,814 (discussion of the "set in advance" requirement) .
8 84 Fed. Reg. at 55,784 .
9 84 Fed. Reg. at 55,790 .
10 *See, e.g.*, Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16,054, 16,093 (proposed Mar. 26, 2004) (to be codified at 42 C.F.R. pt. 411).
11 84 Fed. Reg. at 55,796 .
12 84 Fed. Reg. at 55,791-93 .
13 84 Fed. Reg. at 55,846 (to be codified at 42 C.F.R. § 411.357(z)).
14 84 Fed. Reg. at 55,847 (to be codified at 42 C.F.R. § 411.357(bb)).
15 84 Fed. Reg. at 55,799-802 .