Proposed Stark Law Changes: Health Care Industry Implications

Lifting of restrictions would support shift to value-based payment models

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On October 9, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule to modernize and clarify the Stark Law.[1] The Stark Law governs those physicians (or their immediate family members) who have a financial relationship (i.e., an ownership investment interest or a compensation arrangement) with an entity, and prohibits those individuals from making Medicare referrals to those entities for the provision of designated health services.[2] Notably, the law contains a large number of exceptions, which describe ownership interests, compensation arrangements and forms of remuneration to which the Stark Law does not apply.

The majority of the proposed changes to the Stark Law acknowledge the shift of health care reimbursement, from ***volume-based*** to ***value-based*** payment models. Under the proposed rule, CMS seeks to establish new exceptions and new definitions, as well as provide additional flexibility to support this necessary evolution of the U.S. health care delivery and payment system.[3] This article will discuss CMS' proposed to changes to the definitions of ***fair market value*** and ***commercial reasonableness***; summarize the proposed new exceptions; and, review the potential implications of these rule changes on the health care industry.

Fair Market Value

The proposed revision of the fair market value definition seeks to clarify previous definitions and guidance on fair market value and separate the term and definition from other intertwined terms. CMS proposed three separate fair market value definitions as set forth below. Of note, the revised definition of fair market value eliminates the connection to the volume or value standard, as CMS considers that to be a "separate and distinct" requirement.[4]

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In addition to the delineated definitions set forth below, CMS proposed a definition for ***general market value***, separate and apart from ***fair market value***. In juxtaposing the two terms, CMS provided clear guidance on the relationship—fair market value regards ***hypothetical*** transactions of a similar type, while general market value is ***specific to a transaction*** with identified parties.[4] (See table on facing page.)

Significantly, CMS noted their understanding that the fair market value and the general market value of a transaction may not always be identical and provided examples as to when physician compensation may "veer from values identified in salary surveys and other hypothetical valuation data that is not specific to the actual parties to the subject...transaction."[4]

Commercial Reasonableness

Regarding the threshold of commercial reasonableness, CMS recognized that it has only addressed the concept once, in a 1998 proposed rule, interpreting the term "commercially reasonable" to mean an arrangement that appears to be:

> *"...a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals."*[4]

In an effort to finally define the term, CMS proposed two alternative proposed definitions for the term "commercially reasonable:"

(1) "the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements;" or,

(2) "the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty."[4]

Significantly, CMS unequivocally stated that an arrangement may be commercially reasonable "***even if it does not result in profit*** for one or more of the parties."[4] [Emphasis added.] CMS was compelled by commenters who identified a number of reasons why parties may enter into non-profitable transactions, for example:

- Community need;
- Timely access to health care services;

Current and Proposed Fair Market Value and General Market Value Definitions

	Old Definition[5]	Proposed New Definition[4]	
		General	Rental of Equipment or Office Space
Fair Market Value	The value in arm's-length transactions Consistent with the general market value	▪ With like parties and under like circumstances ▪ Of like assets or services ▪ Consistent with the general market value of the subject 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
General Market Value	The price that an asset (or the compensation that would be included in a service agreement) would bring as the result of bona fide bargaining between well-informed buyers and sellers (or parties to the agreement) who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.	▪ 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	▪ 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

- Fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA);
- The provision of charity care; and,
- The improvement of quality and health outcomes.[4]

Volume or Value Standard and the Other Business Generated Standard

Many Stark Law exceptions require that the compensation arrangement at issue "not [be] determined in a manner that takes into account the volume or value of referrals by the physician...[or be] determined in a manner that takes into account other business generated between the parties." In response to commentator concerns, CMS proposed four "objective tests [i.e., mathematical formulas] for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated by the physician." CMS also set forth "the narrowly-defined circumstances under which [the agency] would consider fixed-rate compensation...to be determined in a manner that takes into account the volume or value of referrals or other business generated."[4]

New Stark Law Exceptions

In addition to these new definitions related to the Stark Law, CMS introduced a number of new exceptions to the Stark Law, the most pertinent of which are set forth below.

- **Value-Based Arrangements.** The proposed rule would create permanent exceptions to the Stark Law for value-based arrangements (VBAs). As part of the new exceptions, CMS introduced a number of new definitions, including those for VBA, value-based activity, value-based purpose, value-based enterprise (VBE), VBE participant and target patient population.[6] The exceptions would only apply to compensation arrangements, but would apply to all patients, not just Medicare beneficiaries. These exceptions were proposed in order to reduce regulatory hurdles for providers seeking to pursue legitimate VBAs that are intended to coordinate care, improve the quality of care and lower costs for patients.[3]

  Of note, CMS proposed not to require that remuneration associated with a VBA: (1) be consistent with fair market value; or, (2) not take into account the volume or value of a physician's referrals or the other business generated by the physician for the entity, although the agency is soliciting comments on these points.[7]

- **Limited Remuneration to a Physician.** CMS proposed a new exception for limited remuneration to a physician for items or services actually provided by the physician, on an "infrequent or short-term basis," in an aggregate amount not exceeding $3,500 per calendar year (as adjusted by inflation) if:

Continued on page 18

1. The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician;
2. The compensation does not exceed the fair market value of the items or services;
3. The arrangement is commercially reasonable; and,
4. Arrangements for the rental or use of office space or equipment do not violate the prohibitions on per-click and percentage-based compensation formulas.[7]

Of note, the remuneration does not need to be set in advance, and the arrangement does not need to be set forth in writing, in order to comply with this exception.

- **Cybersecurity Exception.** CMS also proposed the establishment of a new exception for donations of cybersecurity technology and related services that are "necessary to implement, maintain, or reestablish security," provided the various exception conditions are met.[8] CMS believes that the cybersecurity exception will be widely used by physicians because it helps address the growing threat of cyberattacks on data systems and health records.
- **Price Transparency.** In contrast to the above paragraphs, which discuss new exceptions, CMS did not make any specific proposals related to price transparency, but instead used the proposed rule to solicit comments as to the pursuit of the Trump Administration's price transparency objectives[9] and whether to require cost-of-care information at the point of a referral for a health care item or service provided to patients.[4] Should the price of health care items and services become easily accessible and comparable, this increased choice may serve to increase competition among providers and apply price pressures on those health care organizations charging patients more for these items/services.

Implications

Historically, the application of the Stark Law has, at times, been at odds with the goals of health care reform. Specifically, the discord between the objectives of fraud and abuse laws, and the objectives of value-based reimbursement models, reflected the disjointed approach to health care reform by the numerous federal agencies tasked with regulation of the health care industry. Ultimately, this disjointed approach resulted in a scenario wherein the left hand didn't know what the right hand was doing.[10]

The proposed rule changes from CMS clearly aim to remedy this catch-22 situation, making it easier for providers to provide value-based care without running afoul of the Stark Law. The agency has made significant strides in attempting to reduce the burden of compliance while also maintaining strong safeguards against fraud and abuse.[1]

Perhaps the most significant takeaways from the proposed rule stem from CMS' acknowledgment that not all physicians, or compensation arrangements are the same; and, that compensation arrangements may have qualitative benefits that outweigh quantitative costs, i.e., profitability. CMS' proposals recognize that an arrangement may have inherently subjective, qualitative elements, e.g., there are plausible scenarios wherein a compensation arrangement deviates from industry normative benchmark data to account for the specific facts and circumstances related to a given transaction. This further demonstrates the need for physicians to obtain health care compensation valuation opinions that utilize an evidence-driven methodology, including both qualitative and quantitative assessments of the specific facts and circumstances related to the transaction, a documentation of the consideration of these facts and circumstances, and an articulation of their ultimate applicability to the transaction.

CMS' proposed rules were published in the Federal Register on October 17, 2019, and all comments on the proposed rule will be due 75 days from the date of publication (by December 31, 2019). Upon the end of the comment period, CMS has no official timeline by which it must publish the final rule. ◄

References

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2. "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(a).
3. "Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule" U.S. Centers for Medicare & Medicaid Services, October 9, 2019, https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-proposed-rule (Accessed 10/22/19).
4. "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55777, 55790-55799.
5. "Definitions" 42 CFR § 411.351.
6. "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55773.
7. "Medicare 55777; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55829.
8. "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55835.
9. The order articulated the Administration's goal to give patients access to price and quality information to find low-cost, high-quality care. "Executive Order on Improving Price and Quality Transparency in American Health care to Put Patients First" The White House, June 24, 2019, https://www.whitehouse.gov/presidential-actions/executive-order-improving-price-quality-transparency-american-health care-put-patients-first/ (Accessed 10/23/19).
10. For more information, see "Beyond FMV: Commercial Reasonableness of Physician Compensation Post-MACRA, by Robert James Cimasi, MHA, ASA, FRICS, MCBA, CVA, CM&AA, Todd A. Zigrang, MBA, MHA, FACHE, ASA, John R. Chwarzinski, MSF, MAE, and Jessica L. Bailey-Wheaton, Esq., B*usiness Valuation Review*, Vol. 37, Issue 1 (Spring 2018), p. 20-46.