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Proposed Stark Law Changes: Healthcare Valuation Implications

On October 9, 2019, the *Centers for Medicare & Medicaid Services* (CMS) issued a proposed rule to modernize and clarify the *Stark Law*.[1] The proposed rule changes were published in conjunction with the *Office of Inspector General* (OIG) of the *Department of Health and Human Services* (HHS), which published proposed rule changes to the *Anti-Kickback Statute* (AKS), and are part of the larger effort by HHS (of which CMS is part) to modernize and clarify fraud and abuse laws as part of the *Regulatory Sprint to Coordinated Care* initiative[2] and CMS's *Patients over Paperwork* initiative.[3] The initiatives are aimed at reducing regulatory barriers and accelerating the transformation of the healthcare system into one that better pays for value and promotes care coordination.[4] Recognizing the rapidly changing healthcare system, CMS is proposing new rules, and rule changes, that are more consistent with emerging *value-based* healthcare delivery and payment models, and which may allow for better coordination of care.[5]

These proposed rule changes have potentially significant implications, and may serve to create additional opportunities for healthcare valuation professionals, with CMS recognizing and confirming the close link between "*the regulated [healthcare] industry and its complementary parts, such as the health care valuation community...*"[6]

This *Health Capital Topics* article will summarize the Stark Law proposed rule in brief; discuss CMS's proposed changes to the definitions of *Fair Market Value* and *Commercial Reasonableness*; and, review the potential implications of these rule changes on healthcare valuation.

Stark Law Proposed Rule

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* (DHS).[7] 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.[8]

The majority of the proposed changes to the Stark Law acknowledge the shift of healthcare reimbursement, from *volume-based* to *value-based* payment models.[9] 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. healthcare delivery and payment system.[10] Of note, the exceptions and definitions described herein apply only to the Stark Law; although OIG and CMS worked closely on their respective proposed rules, that guidance does not apply beyond the law at issue. For example, only the Stark Law addressed *fair market value* and *commercial reasonableness*; consequently, those proposed definitions will not apply to agreements that are not subject to Stark.

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, i.e., *general market value* and the *volume or value* standard. Historically, the Stark Law has defined *fair market value* generally (with additional modifications of the definition as applies to equipment leases and office space leases[11]), as follows:

> "*the value in arm's-length transactions, consistent with the general market value....Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.*"[12]

CMS proposes to provide three separate *fair market value* definitions: (1) generally; (2) for the rental of equipment; and, (3) for the rental of office space.[13] However, the agency emphasizes that "*the proposed structure of the definition merely reorganizes for clarity, but does not significantly differ from the [previous] statutory language...*"[14]

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These three separate *fair market value* definitions are as follows:

(1) **General**: The value in an arm's-length transaction –

(a) With <u>like parties</u> and under like circumstances;

(b) Of like assets or services; and,

(c) Consistent with the general market value of the subject transaction.

(2) **Rental of Equipment**: With respect to the rental of equipment, the value in an arm's-length transaction –

(a) With <u>like parties</u> and under like circumstances;

(b) Of rental property for general commercial purposes (not taking into account its intended use); and,

(c) Consistent with the general market value of the subject transaction.

(3) **Rental of Office Space**: With respect to the rental of equipment, the value in an arm's-length transaction –

(a) With <u>like parties</u> and under like circumstances;

(b) Of rental property for general commercial purposes (not taking into account its intended use);

(c) 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,

(d) Consistent with the general market value of the subject transaction.[15]

Of note, the revised definition of *fair market value* eliminates the connection to the *volume or value* standard.[16] CMS clarified that requirement that certain compensation arrangements "*not take into account the volume or value of referrals (or the volume or value of other business generated by the physician...)*" is "*separate and distinct*" from *fair market value* requirements.[17] Thus, CMS no longer believes it necessary to include the *volume or value* language (discussed separately below) as it appears in connection to the *fair market value* definition.[18]

In addition to the delineated definitions set forth above, CMS proposed a definition for *general market value*. Currently, the Stark Law requires that *fair market value* "*be consistent with the general market value*," and defines the term as:

> "*...the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed 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.*"[19]

CMS proposed defining *general market value* separate and apart from *fair market value*, and, similar to fair market value, has different definitions depending on if it applies *generally* or to *rental of equipment or office space*,[20] as follows:

(1) **General**: "*the price that assets or services would bring as the result of bona fide bargaining between <u>the buyer and seller in the subject transaction</u> on the date of acquisition of the assets or at the time the parties enter into the service arrangement.*"[21] [Emphasis added.]

(2) **Rental of Equipment or Office Space**: "*the price that rental property would bring as the result of bona fide bargaining between <u>the lessor and the lessee in the subject transaction</u> at the time the parties enter into the rental arrangement.*"[22] [Emphasis added.]

In reconciling the terms *fair market value* and *general market value*, CMS interpreted Congress's original intent behind general market value was "*to ensure that the fair market value of the remuneration...is generally consistent with the valuation that would result using accepted general market principles.*"[23] In other words, CMS equates *general market value* with "*'market value,' the term uniformly used in the valuation industry.*"[24] CMS states that their own research indicates that the valuation industry defines the term *market value* as "*the valuation of a planned transaction between two identified parties for identified assets or services, and intended to be consummated within a specified timeframe,*"[25] and notes that it "*is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another.*"[26] CMS recognizes that the previous definition of *general market value* was "*likely at odds with general valuation principles*" and "*unconnected to the recognized valuation principle of "market value*," and states their intention that the new proposed definition is more "*consistent with the recognized principle of 'market' valuation...*"[27]

In further juxtaposing *fair market value* and *general market value* (a/k/a *market value*), CMS provided clear guidance on the relationship, as well as the interplay, between the two terms. Specifically, CMS views *fair market value* as relating to "*the value of an asset or service to <u>hypothetical parties</u> in a <u>hypothetical transaction</u> (that is, <u>typical transactions</u> for <u>like assets or services</u>, with <u>like buyers and sellers</u>, and under <u>like circumstances</u>)*" [emphasis added], while *general market value* relates to "*the value of <u>an asset or service</u> to <u>the actual parties</u> to <u>a transaction</u>...*"[28] To state it simply, *fair market value* regards hypothetical transactions of a similar type, while *general market value* is specific to a transaction with identified parties.

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As noted above, the *fair market value* of the subject transaction must be "*consistent with the general market value*."[29] However, CMS significantly noted their understanding that the hypothetical *fair market value* and *general market value* of a transaction may not always be identical, and provided examples as to when a transaction 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*,"[30] to wit:

> "*...assume a hospital is engaged in negotiations to employ an orthopedic surgeon. Independent salary surveys indicate that compensation of $450,000 per year would be appropriate for an orthopedic surgeon in the geographic location of the hospital. However, the orthopedic surgeon with whom the hospital is negotiating is one of the top orthopedic surgeons in the entire country and is highly sought after by professional athletes with knee injuries due to his specialized techniques and success rate. Thus, although the employee compensation of a hypothetical orthopedic surgeon may be $450,000 per year, this particular physician commands a significantly higher salary and the general market value (or market value) of the transaction may, therefore, be well above $450,000...In this example, compensation substantially above $450,000 per year may be fair market value.*"[31]

Commercially Reasonable

As regards 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*."[32]

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*."[33]

Simply stated, "*the key question to ask when determining whether an arrangement is commercially reasonable is...whether the arrangement makes sense as a means to accomplish the parties' goals*."[34] CMS also reiterates the agency's prior guidance that the determination of commercial reasonableness "*should be made from the perspective of the particular parties involved in the arrangement*."[35]

Significantly, CMS unequivocally noted that an arrangement may be *commercially reasonable* "*<u>even if it does not result in profit</u> for one or more of the parties*."[36] [Emphasis added.] CMS was compelled by commenters who identified a number of reasons why parties may enter into non-profitable transactions, e.g.:

(1) "*community need*;"

(2) "*timely access to health care services*;"

(3) "*fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA)*;"

(4) "*the provision of charity care*;" and,

(5) "*the improvement of quality and health outcomes*."[37]

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*."[38] In response to commentator concerns, CMS proposed "*objective tests 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*."[39]

CMS's proposed approach "*creates [a] bright-line rule*," such that "*only when the mathematical formula used to calculate the amount of the compensation <u>**includes as a variable** referrals or other business generated</u>, <u>and</u> the <u>amount of the compensation **correlates** with the number or value of the physician's referrals</u> to <u>or</u> the <u>physician's generation of other business for the entity</u>, 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*"[40] [Emphasis added.] This approach is manifested by four proposed "*special rules*" for compensation arrangements, two of which relate to the volume or value standard, and two of which relate to the other business generated standard.[41]

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.*"[42] In other words, CMS would consider a fixed-rate compensation arrangement to violate the volume or value (or other business generated) standard if there was a "*predetermined, direct positive or negative correlation between the volume or value of the physician's prior referrals (or other business previously generated...) and the exact rate of compensation paid*."[43]

Perhaps the most significant statement made by CMS in this section was its discussion of these two standards in light of fraud and abuse cases, such as *United States ex rel. Drakeford v. Tuomey*, which have held that, within the context of inpatient and outpatient hospital services, any *ancillary service and technical component*

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(associated with a physician's professional services, i.e., a "*facility fee*") services performed in connection with personally performed services constituted an impermissible referral.[44] CMS reaffirmed its previous position that "*[w]ith respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services...are billed each time the employed physician personally performs a service*."[45] CMS then extended this guidance to personal service arrangements.[46]

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).[47] As part of the new exceptions, CMS introduced a number of new definitions, including those for value-based activity, VBA, value-based enterprise, value-based purpose, VBE participant, and target patient population.[48] The exceptions would only apply to compensation arrangements, but would apply to all patients, not just Medicare beneficiaries.[49] These exceptions are proposed in order to present lower (and fewer) regulatory hurdles to providers seeking to pursue legitimate VBAs that are intended to coordinate care, improve the quality of care, and lower costs for patients.[50] Nevertheless, the proposed rule keeps in place some traditional protections against overutilization and associated harms.[51]

Significantly, CMS noted that remuneration under a VBA may not "*always involve one-to-one payments for items or services provided by a party to an arrangement*"; in fact, "*such payments are made...in consideration of the physician refraining from following his or her past patient care practices rather than for direct patient care items or services furnished by the physician*."[52] This comment recognizes that providers may sometimes be compensated for services not personally performed, or performed at all.

Also 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.[53]

Limited Remuneration to a Physician

CMS proposes 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:

(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.[54]

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.[55]

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*."[56] For the exception to apply, a number of conditions must be met, including: (1) that the volume or value of referrals not be considered;[57] and, (2) the receipt of such technology may not be a condition of doing business with the donor.[58] 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.[59] CMS also proposed allowing for the donation of cybersecurity hardware, but only if that hardware was determined to be "*reasonably necessary*" based on the donor's risk assessments of its organization, as well as of the potential donee.[60]

Price Transparency

In contrast to the above paragraphs, which discuss new exceptions, CMS did not make any proposals related to price transparency, but instead used the propose rule to solicit comments as to the pursuit of the Trump Administration's price transparency objectives[61] and whether to require *cost-of-care* information at the point of a referral for a healthcare item or service provided to patients.[62] The idea of requiring *cost-of-care* information is part of CMS's larger priority goal of *price transparency* aimed at lowering the rate of growth in healthcare costs and giving patients a better understanding of healthcare costs before embarking on a referral.[63] Any action ultimately undertaken by CMS to improve price transparency in healthcare services may have significant ramifications; according to the *Council of Economic Advisors 2019 Report*, 73% of the 100 highest-spending categories are considered to be *shoppable* by the patient (meaning that patients can schedule when they receive the services, and thus have an opportunity to price compare).[64] Should the price of healthcare items and services be easily accessible and comparable, this increased choice may serve to increase competition among providers, and apply price pressures on those healthcare organizations charging patients more for these items/services.

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IMPLICATIONS

Historically, the application of the Stark Law (and the AKS) has, at times, been at odds with the goals of healthcare reform. Specifically, the discord between the objectives of fraud and abuse laws, and the objectives of value-based reimbursement models (e.g., VBAs) reflected the disjointed approach to healthcare reform by the numerous federal agencies tasked with regulation of the healthcare industry. For example, HHS and CMS have pushed value-based healthcare initiatives, which require provider alignment and collaboration, while the OIG and the *Department of Justice* (DOJ), have more intensely scrutinized these arrangements as they relate to the Stark Law and AKS, and their potential liability under the *False Claims Act*. Ultimately, this disjointed approach resulted in a scenario wherein the *left hand didn't know what the right hand was doing*.[65]

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.[66] The agency has made significant strides in attempting to reduce the burden of compliance while also maintaining strong safeguards against fraud and abuse.[67]

At the same time, there remain a number of uncertainties related to the proposed rule. In some situations, numerous definitions or approaches are proposed, while, in other parts of the proposed rule, definitions seem to lack clarifying language regarding the terms used within the definitions. While CMS spends a considerable amount of verbiage defining *fair market value* (and *general market value*), it appears that the ultimate implications of these changes may be minimal. These remaining issues render potential future ramifications of CMS's clarification indeterminate.

Perhaps the most significant takeaways from the proposed rule stem from CMS's 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's statement highlighting the difference between *fair market value* and *general market value* recognizes that an arrangement may have inherently *subjective*, *qualitative* elements, e.g., there are plausible scenarios that may require a valuation professional to deviate from industry normative benchmark data to account for the specific facts and circumstances related to a given transaction. This further demonstrates the need for valuation professionals in the healthcare industry who utilize an evidence-driven methodology that includes both *qualitative* and *quantitative* assessments of the specific facts and circumstances related to the transaction; document their consideration of these facts and circumstances; and, articulate their ultimate applicability to the transaction in support of their opinion.

HCC will continue to closely monitor and report, in future *Health Capital Topics*, the progression of these fraud and abuse law reforms, as well as the implications of these prospective changes on transactions involving healthcare enterprises, assets, and services.

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