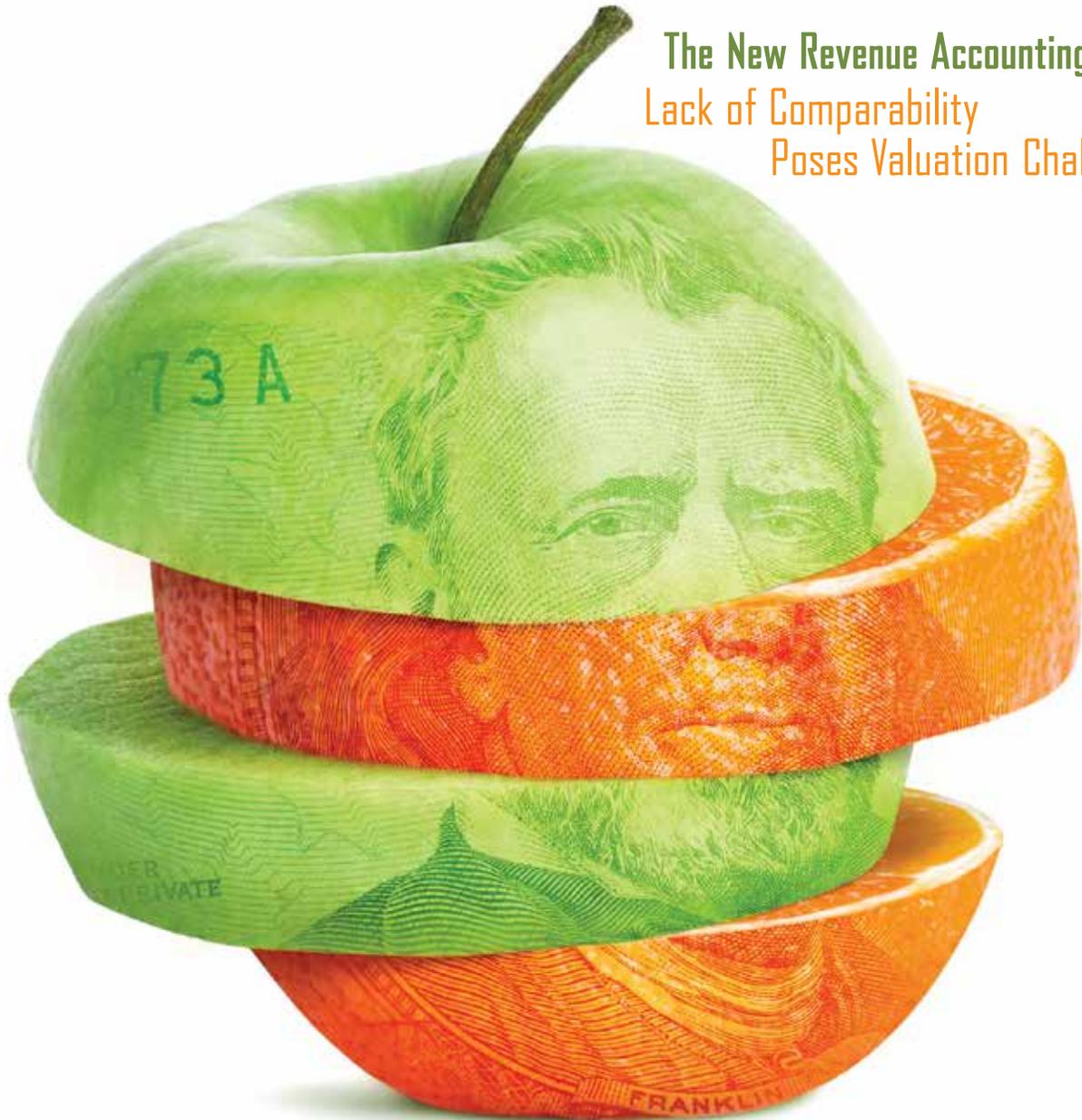


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**The New Revenue Accounting Standard:  
Lack of Comparability  
Poses Valuation Challenges**



# Healthcare Valuation Implications of the Stark Law Proposed Rule

By Todd A. Zigrang, MBA, MHA, FACHE, CVA, ASA and Jessica L. Bailey-Wheaton, Esq.

On October 9, 2019, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule to modernize and clarify the Stark Law.<sup>1</sup> 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).<sup>2</sup> 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.<sup>3</sup>

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.”<sup>4</sup> This article will summarize the Stark Law proposed rule; discuss CMS’s proposed changes to the “Big Three” Stark Law definitions: fair market value, commercial reasonableness, and the volume or value standard; and review the potential implications of these rule changes on healthcare valuation.

## Fair Market Value (FMV)

The proposed revision of the FMV definition seeks to clarify previous definitions and guidance on FMV, and separate the term and definition from other intertwined terms. CMS proposed three separate FMV definitions, as set forth in Table 1. However, the agency emphasized that “the proposed structure of the definition merely reorganizes for clarity, but does not significantly differ from the [previous] statutory language.”<sup>5</sup>

Of note, the revised definition of FMV eliminates the connection to the volume or value standard,<sup>6</sup> as CMS considers that to be a “separate and distinct” requirement.<sup>7</sup>

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). “HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordinated Care”, U.S. HHS, October 9, 2019, <https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html>.

2 Limitation on Certain Physician Referrals, 42 U.S.C. § 1395nn(a). DHS includes the following services: “(i) Clinical laboratory services. (ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services. (iii) Radiology and certain other imaging services. (iv) Radiation therapy services and supplies. (v) Durable medical equipment and supplies. (vi) Parenteral and enteral nutrients, equipment, and supplies. (vii) Prosthetics, orthotics, and prosthetic devices and supplies. (viii) Home health services. (ix) Outpatient prescription drugs. (x) Inpatient and outpatient hospital services.” 42 C.F.R. § 411.351 (2015) (“Definitions”).

3 42 U.S.C. § 1395nn.

4 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55789 (October 17, 2019).

5 Ibid., 55797.

6 The current FMV definition states in part that the “price or compensation [may not be] determined in any manner that takes into account the volume or value of anticipated or actual referrals.”

7 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55777, 55797–55799 (October 17, 2019).



In addition to the delineated definitions set forth above, CMS proposed a definition for general market value, separate and apart from FMV (see Table 1). In reconciling the terms FMV and general market value, CMS interpreted that 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."<sup>10</sup> In other words, CMS equates general market value with "market value,' the term uniformly used in the valuation industry."<sup>11</sup> 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,"<sup>12</sup> 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."<sup>13</sup> It is unclear what "research" CMS reviewed in determining that "market value" is a common valuation industry term; while it is a term of art in real estate valuation, there is no such term utilized in business valuation. Further, the definitions of market value cited by CMS are quite similar to those of "investment value,"<sup>14</sup> a standard of value separate and apart from FMV.

CMS provided clear guidance on the relationship, as well as the interplay, between FMV and general market value in the proposed rule. Specifically, CMS views FMV as relating 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 and sellers, and under like circumstances*)" [emphasis added], while general market value relates to "the value of *an asset or service to the actual parties to a transaction.*"<sup>15</sup> To state it simply, FMV regards hypothetical transactions of a similar type,

while general market value is specific to a transaction with identified parties.

Significantly, CMS noted their understanding that the FMV and the 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,"<sup>16</sup> 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.<sup>17</sup>

### Commercial Reasonableness

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

10 Ibid., 55798.

11 Ibid.

12 Ibid.

13 Ibid.

14 See Shannon Pratt, *Valuing a Business: The Analysis and Appraisal of Closely Held Companies*, 5th ed. (New York: McGraw-Hill, 2008), 43, citing Chicago Appraisal Institute, *The Dictionary of Real Estate Appraisal*, 4th ed. (Chicago: Chicago Appraisal Institute, 2002), 152; Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, *Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services* (Hoboken, NJ: John Wiley & Sons, 2014), 24–25.

15 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55799 (October 17, 2019).

16 Ibid.

17 Ibid.

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.<sup>18</sup>

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.”<sup>19</sup>

Interestingly, CMS did not comment on the significance of the distinction between these two definitions, and most of the commentators did not state a preference for one definition over another. Among those who did comment on the two definitions, there was not a clear preference.<sup>20</sup>

Significantly, CMS unequivocally noted that an arrangement may be commercially reasonable “*even if it does not result in profit* for one or more of the parties.”<sup>21</sup> [Emphasis added.] CMS was compelled by commenters who identified several reasons why parties may enter into unprofitable transactions, such as:

- (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.”<sup>22</sup>

### Volume or Value and Other Business Generated Standards

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.”<sup>23</sup>

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.”<sup>24</sup>

CMS’s proposed approach “creates [a] bright-line rule,” such that “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.”<sup>25</sup> [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.<sup>26</sup>

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.”<sup>27</sup> 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.”<sup>28</sup>

18 Ibid., citing Medicare and Medicaid Programs; Physician Referrals to Health Care Entities With Which They Have a Financial Relationship: Proposed rule, 63 Fed. Reg. 1700.

19 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55790, 55840 (October 17, 2019).

20 “Medicare Program; Physician Self-Referral Rulemaking Documents,” regulations.gov, accessed January 12, 2020, <https://www.regulations.gov/docketBrowser?rpp=50&so=DESC&sb=postedDate&po=0&dct=PS&D=CMS-2018-0082>.

21 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55790, 55840 (October 17, 2019).

22 Ibid., 55790.

23 Ibid., 55791.

24 Ibid.

25 Ibid., 55793.

26 Ibid.

27 Ibid., 55794.

28 Ibid.

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 services (associated with a physician's professional services, i.e., a "facility fee") performed in connection with personally performed services constituted an impermissible referral.<sup>29</sup> 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."<sup>30</sup> CMS then extended this guidance to personal service arrangements.<sup>31</sup>

### New Stark Law Exceptions

In addition to these new Stark definitions, CMS introduced several new Stark exceptions, the most pertinent of which are summarized below.

#### Value-Based Arrangements

The proposed rule would create permanent Stark exceptions for value-based arrangements (VBAs).<sup>32</sup> As part of the new exceptions, CMS introduced a number of new definitions, including those for value-based activity (VBA), value-based enterprise (VBE), value-based purpose, VBE participant, and target patient population.<sup>33</sup> The exceptions would only apply to compensation arrangements, but would apply to all patients, not just Medicare beneficiaries.<sup>34</sup> 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.<sup>35</sup>

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."<sup>36</sup> 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 FMV; 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.<sup>37</sup>

#### 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 FMV 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.<sup>38</sup>

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.<sup>39</sup>

29 Opposition of the United States of America to Petition by Tuomey Healthcare System, Inc. for Permission to Appeal Interlocutory Order, *United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc.*, No. 10-254 (4th Cir., Sept. 20, 2010), 8-9.

30 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55795 (October 17, 2019).

31 *Ibid.*

32 "Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule," U.S. Centers for Medicare and Medicaid Services, October 9, 2019, <https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-proposed-rule>.

33 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations", 84 Fed. Reg. 55773 (October 17, 2019).

34 "Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule" (see n. 30).

35 *Ibid.*

36 Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations", 84 Fed. Reg. 55773 (October 17, 2019).

37 *Ibid.*, 55829.

38 *Ibid.*

39 *Ibid.*, 55828.

## Implications

Historically, the application of the Stark Law (and other fraud and abuse laws) 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

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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.

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.<sup>40</sup> The agency has made significant strides in attempting to reduce the burden of compliance while also maintaining strong safeguards against fraud and abuse.<sup>41</sup> 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 FMV 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. **VE**



*Todd A. Zigrang, MBA, MHA, FACHE, CVA, ASA, is president of Health Capital Consultants, where he focuses on the areas of valuation and financial analysis for hospitals and other healthcare enterprises. Mr. Zigrang has significant physician-integration and financial analysis experience, and has participated in the development of a physician owned, multispecialty management service organization and networks involving a wide range of specialties, physician owned hospitals, as well as several limited liability companies for acquiring acute care and specialty hospitals, ASCs, and other ancillary facilities. Email: tzigrang@healthcapital.com.*



*Jessica L. Bailey-Wheaton, Esq., serves as vice president and general counsel of Health Capital Consultants, where she conducts project management and consulting services related to the impact of both federal and state regulations on healthcare exempt organization transactions, and provides research services necessary to support certified opinions of value related to the fair market value and commercial reasonableness of transactions related to healthcare enterprises, assets, and services. Email: jbailey@healthcapital.com.*

<sup>40</sup> "HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordinated Care," U.S. Department of Health & Human Services, October 9, 2019, <https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html>.

<sup>41</sup> Ibid.