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Stark Law Overhaul:
An In-Depth Review of the 2020 Rulemaking

White Paper No. 4
Key Standards (Part II):
"Fair Market Value" and "Commercial Reasonableness" Standards, and Indirect Compensation Arrangements

Key Standards (Part II): **"Fair Market Value" and "Commercial Reasonableness" Standards, and Indirect Compensation Arrangements**

In December 2020, the Centers for Medicare & Medicaid Services (CMS) finalized its long-awaited changes to the agency's regulations governing the federal physician self-referral law, commonly known as the Stark Law (Final Rule).[1] The Final Rule represents the most significant Stark Law rulemaking in more than a decade. The Health Care Group at Dentons US is presenting a series of seven webinars, each with a companion white paper, addressing the principal components of the Final Rule. This is the fourth such white paper.

Our last white paper covered the Final Rule's impact on the first of the Stark Law's three key substantive standards, the so called "volume or value" standard (Volume/Value Standard). That Standard generally focuses on whether the compensation provided for under the arrangement at issue takes into account the volume or value of the physician's referrals to, or other business generated for, an entity that furnishes designated health services (DHS Entity).

This white paper covers the Final Rule's impact on the second and third key substantive standards: specifically, whether the compensation at issue is consistent with "fair market value" (FMV Standard), and whether the arrangement is "commercially reasonable" (Commercial Reasonableness Standard). This white paper also addresses the significant changes the Final Rule made to the definition of an "indirect compensation arrangement" (ICA), the most complicated of the Stark Law's four categories of financial relationships.

1 The Stark Law is codified at 42 U.S.C. §§ 1395nn, 1396b(s), and 42 C.F.R. § 411.350 *et seq*. The Final Rule was published at 85 Fed. Reg. 77492 (Dec. 2, 2020).


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I. Fair Market Value Standard

A. Introduction

Numerous Stark Law exceptions and special rules include a requirement that the compensation at issue "is,"[2] "is consistent with"[3] or "does not exceed"[4] the "fair market value" (FMV) of the items, services or space being provided in return for such compensation. Specifically, the FMV Standard appears in:

- a dozen Stark Law exceptions for compensation arrangements—including the exceptions covering the rental of office space,[5] the rental of equipment,[6] bona fide employment relationships,[7] personal service arrangements[8] and indirect compensation arrangements[9]—as well as the exception for services provided by an academic medical center;[10]
- the Unit-Based Special Rules[11] and the Required Referrals Special Rule;[12] and
- as of January 19, 2021, the regulatory definition of an ICA.[13]

The Final Rule makes certain changes to the definitions applicable to the FMV Standard, and provides guidance on its application. Some of these changes—e.g., the reorganization of the definitions of "fair market value" and "general market value"—are not particularly noteworthy, but are summarized below in the interests of context and completeness. Two other changes, however, are significant. The first is CMS's attempt to disentangle the FMV and Volume/Value Standards. The second is the agency's clarification of the role and import of market survey data in the assessment of FMV.

2 42 C.F.R. § 411.357(p)(1)(i).

3 *Id.* § 411.357(h)(5).

4 *Id.* § 411.357(d)(1)(v).

5 42 U.S.C. § 1395nn(e)(1)(A); 42 C.F.R. § 411.357(a).

6 42 U.S.C. § 1395nn(e)(1)(B); 42 C.F.R. § 411.357(b).

7 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c).

8 42 U.S.C. § 1395nn(e)(3); 42 C.F.R. § 411.357(d).

9 42 C.F.R. § 411.357(p). The FMV Standard also can be found in the exceptions for (i) isolated transactions, 42 U.S.C. § 1395nn(e)(6) and 42 C.F.R. § 411.357(f); (ii) group practice arrangements with a hospital in which DHS are furnished by the group but billed by the hospital, 42 U.S.C. § 1395nn(e)(7) and 42 C.F.R. § 411.357(h); (iii) payments by a physician (or immediate family member), 42 U.S.C. § 1395nn(e)(8) and 42 C.F.R. § 411.357(i); (iv) fair market value compensation, 42 C.F.R. § 411.357(l); (v) assistance to compensate a nonphysician practitioner, *id.* § 411.357(x); (vi) time-share arrangements, *id.* § 411.357(y); and (vii) the (new) exception for limited remuneration to a physician, *id.* § 411.357(z).

10 42 C.F.R. § 411.355(e).

11 *Id.* § 411.354(d)(2)-(3). As discussed in the third white paper, these were retired by the Final Rule, but continue to be relevant for analyzing compensation exchanged prior to January 19, 2021. 85 Fed. Reg. 77492, 77541 (Dec. 2, 2020).

12 42 C.F.R. § 411.354(d)(4).

13 *Id.* § 411.354(c)(2)(ii)(1).

B. Reorganization of Definitions

The Stark Law's statutory provisions define "fair market value," in general, as the "value in arm[']s length transactions, consistent with the general market value."[14] The statute adds that in the case of "rentals or leases," "fair market value" means the "value of rental property for general commercial purposes (not taking into account its intended use)" and "in the case of a lease of space, 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."[15]

In 1995, CMS's predecessor, the Health Care Finance Administration (HCFA), codified the statutory definition of fair market value in the Stark Law's regulations at 42 C.F.R. § 411.351.[16] In later rulemakings, HCFA (and CMS) expanded the regulatory FMV definition to clarify certain concepts. For example, in 2001, HCFA addressed what it means for compensation to be "consistent with the general market value" by embedding a definition of "general market value" in the regulatory FMV definition.[17]

The Final Rule reorganizes the regulatory FMV definition "for clarity,"[18] creating new subsections pertaining to (i) the "general" FMV definition, (ii) the FMV definition for the "rental of equipment," and (iii) the FMV definition for the "rental of office space."[19] The Final Rule also removes the definition of "general market value" from the definition of "fair market value,"[20] and creates separate definitions of the phrase "general market value" as it applies to (i) "asset acquisition," (ii) "compensation for services," and (iii) "rental of equipment or office space."[21] The current regulatory definitions of "fair market value" and "general market value" are now organized and read as follows:

Fair market value means—

1. *General*. The value in an arm's-length transaction, 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 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. *Rental of office space*. With respect to the rental of office space, the value in an arm's-length transaction 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.

General market value means—

1. *Assets*. With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.

14 42 U.S.C. § 1395nn(h)(3).

15 *Id.*

16 60 Fed. Reg. 41914, 41978 (Aug. 14, 1995).

17 66 Fed. Reg. 856, 953 (Jan. 4, 2001) ("'General market value' means 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.").

18 85 Fed. Reg. 77492, 77553 (Dec. 2, 2020).

19 *Id.* at 77658.

20 *Id.*

21 *Id.* at 77554.

2. *Compensation*. With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other.

3. *Rental of equipment or office space*. With respect to the rental of equipment or the rental of office space, the price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.[22]

C. Disentangling the FMV and Volume/Value Standards

As a matter of statutory construction, the FMV and Volume/Value Standards appear to be separate and distinct standards. They are uniformly enumerated as separate requirements in the various statutory exceptions in which they appear,[23] and the statutory definition of "fair market value" makes no reference to the Volume/Value Standard.[24] CMS, however, has conflated these standards on occasion, providing that under certain circumstances (i) whether compensation takes into account the volume or value of referrals (or other business generated) may depend on whether the compensation is consistent with fair market value, and (ii) whether compensation is consistent with fair market value may depend on whether it takes into account the volume or value of referrals.

In the 2001 Stark II Phase I rulemaking, for example, HCFA created a special rule to protect arrangements pursuant to which a physician is required to refer patients to a particular provider as a condition of payment, provided certain safeguards are implemented.[25] (We will refer to this as the "Required Referrals Special Rule.") HCFA made it clear that as long as the conditions of the Required Referrals Special Rule are met, the agency would not consider compensation conditioned on referrals to implicate the Volume/Value Standard.[26] One condition of the Special Rule is that the physician's compensation under the relevant arrangement must be consistent with the "fair market value" of the physician's services.[27] So satisfying the Volume/Value Standard under the Required Referrals Special Rule turns on FMV considerations. HCFA then (further) confused matters by describing the Special Rule's FMV Standard in terms of the volume or value of referrals. Specifically, the Special Rule required that the physician's compensation be "consistent with fair market value for services performed (that is, the payment does not *take into account the volume or value of anticipated or required referrals*)."[28]

CMS also linked the FMV and Volume/Value Standards in the regulatory FMV definition. In 2001, HCFA sought to clarify the FMV definition by adding a statement regarding what is "usually" the "fair market price" in the context of asset purchases and services arrangements,[29] and in 2004, CMS revised the FMV definition to specifically incorporate the Volume/Value Standard:

> 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

22 *Id.* at 77658.

23 For example, the statutory exception for rental of office space requires that the rental charges over the term of the lease are "consistent with fair market value" and "not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties." 42 U.S.C. § 1395nn(e)(1)(A).

24 *See id.* § 1395nn(h)(3).

25 66 Fed. Reg. 856, 877 (Jan. 4, 2001).

26 *Id.*

27 42 C.F.R. § 411.354(d)(4)(ii).

28 66 Fed. Reg. at 959 (emphasis added).

29 *Id.* at 953 ("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.").

> compensation has not been determined in any manner that *takes into account the volume or value of anticipated or actual referrals*.[30]

CMS also noted in preamble discussion that fixed flat fee compensation could trigger the Volume/Value Standard under certain circumstances, including, for example, when "the fixed compensation exceeds fair market value for the items or services provided or is inflated to reflect the volume or value of a physician's referrals or other business generated."[31]

Given the agency's persistent intermingling of the FMV and Volume/Value Standards, it is not surprising that courts have sometimes conflated them as well. A good illustration is the recent decision of the U.S. Court of Appeals for the Third Circuit in *United States ex rel. Bookwalter v. UPMC* ("*Bookwalter II*").[32] In *Bookwalter II*, the Third Circuit concluded that, as a matter of law, relators had plausibly alleged violations of the Stark Law as a predicate for alleged violations of the federal civil False Claims Act (FCA).[33] The complaint concerned the compensation paid to neurosurgeons employed by affiliates of the University of Pittsburgh Medical Center (UPMC).[34] The Third Circuit noted that, because UPMC did not directly employ the surgeons, the only financial relationship that could exist between UPMC and the physicians was an ICA, and that the complaint pleaded sufficient facts to satisfy each prong of the regulatory ICA definition found at 42 C.F.R. § 411.354(c)(2) (ICA Definition).[35]

At that time (i.e., pre-Final Rule), the second prong of the ICA Definition would be met if the "aggregate compensation" provided for under the arrangement closest to the referring physician (in this case, the employment compensation paid to the neurosurgeons) "varies with, or takes into account" the volume or value of the physician's referrals to, or other business generated for, the DHS Entity (in this case, UPMC).[36] (We refer to this second prong as the "ICA Volume/Value Standard.") Although the ICA Definition did *not* have an FMV Standard, the Third Circuit nevertheless concluded that the relators' complaint plausibly alleged that the ICA Volume/Value Standard was met because the relators had alleged that "the surgeons' pay far exceeded their *fair market value*," and "aggregate compensation that far exceeds fair market value . . . suggests that the compensation takes referrals into account."[37]

In the Final Rule, CMS seeks to distinguish and keep separate the FMV and Volume/Value Standards. According to the agency, "a careful reading of the [Stark] statute" shows that the FMV Standard is "separate and distinct" from the Volume/Value Standard. Accordingly, CMS revised the regulatory definitions of "fair market value" and "general market value" (set forth above) to remove any reference to the Volume/Value Standard.[38] Similarly, CMS removed the parenthetical language discussed above from the Required Referrals Special Rule, since that parenthetical "conflates the concept of fair market value and the volume or value standard."[39] Finally, the agency emphasized that the Volume/Value Standard will no longer be met *unless* the compensation at issue satisfies the criteria of the newly promulgated Volume/Value Special Rules, which are silent on the subject of

30 69 Fed. Reg. 16054, 16128 (Mar. 26, 2004) (emphasis added).

31 *Id.* at 16059.

32 *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162 (3d Cir. 2019) ("*Bookwalter II*").

33 *Id.* at 166.

34 *Id.* at 166-67.

35 *Id.* at 170-71.

36 42 C.F.R. § 411.354(c)(2) as set forth in 72 Fed Reg. 51012, 51087 (Sept. 5, 2007).

37 *Bookwalter II*, 946 F.3d at 172 (emphasis added).

38 85 Fed. Reg. 77492, 77552-53 (Dec. 2, 2020).

39 *Id.* at 77549.

fair market value.[40] Hopefully, these changes will help both industry stakeholders and courts more easily distinguish, and properly apply, each of these important Standards.

D. Clarifying the Role of Survey Data

Over the years, a certain mythology has developed around market survey data, such that the US Department of Justice (DOJ), relators and courts frequently have treated such data as a key indicator of whether physician compensation is consistent with FMV. Again, *Bookwalter II* is a good example. In that case, the Third Circuit concluded that the relators had alleged that the neurosurgeons' employment compensation "far exceeded" FMV because, among things, several of the physicians were paid above the 90th percentile as compared to neurosurgeons nationwide.[41] *Bookwalter II* is not an outlier. There are numerous high-profile FCA settlements in which the operative complaint alleges that the amount of physician compensation violated the FMV Standard because the compensation exceeded a certain percentile (typically the 90th) in a market survey.[42]

CMS contributed to this market data mythology, when (in 2004) the agency created a "safe harbor" provision in the regulatory FMV definition, pursuant to which two hourly payment methodologies for a physician's personally performed services would be deemed to be "fair market value."[43]

- Under one safe harbor, an hourly payment rate for physician services would be deemed FMV if it was "less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market."[44]
- Under the other safe harbor, an hourly payment rate for physician services would be deemed FMV if it was determined by (i) "averaging the 50th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice)" in at least four of six specified surveys, and (ii) dividing that average compensation amount by 2,000 hours.[45]

In response to criticism from industry stakeholders, CMS eliminated these safe harbors in 2007, though the agency continued to advise that "[r]eference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value."[46]

In the preamble to the Final Rule, CMS notes that, based on comments it received on the Proposed Rule, "stakeholders may have been under the impression that it is CMS policy that reliance on salary surveys will result, in all cases, in a determination of fair market value for a physician's professional services."[47] According to CMS, this impression is mistaken: "It is not CMS policy that salary surveys necessarily

40 *Id.* at 77538 ("If the methodology used to determine the . . . compensation [to or from the referring physician] does not fall squarely within the [universe of] circumstances [defined by the Special Rules], the compensation is not considered to take into account the volume or value of the physician's referrals or other business generated."). The Volume/Value Special Rules are discussed in White Paper No. 3.

41 *Bookwalter II*, 946 F.3d at 172.

42 *See, e.g.*, Third Amended Complaint at 35-38, 40-41, 50-51, 55-56, *United States ex rel. Reilly v. North Broward Hosp. Dist.*, Case No. 10-60590 (S.D. Fla. 2010). In September 2015, North Broward Hospital District agreed to pay the United States for $69.5 million to settle this FCA action. US Dep't of Justice, "Florida Hospital District Agrees to Pay United States $69.5 Million to Settle False Claims Act Allegations" (Sept. 15, 2015), https://www.justice.gov/usao-sdfl/pr/florida-hospital-district-agrees-pay-united-states-695-million-settle-false-claims-act. *See also, e.g.*, Amended Complaint at 48-50, Ex. 11, *United States ex rel. Dorsey v. Adventist Health Sys. Sunbelt Healthcare Corp.*, Case No. 3:13-cv-00217 (W.D.N.C. 2013). In September 2015, Adventist Health System settled this FCA action, as well as an additional FCA action, with the United States for a combined settlement amount of $115 million. US Dep't of Justice, "Adventist Health System Agrees to Pay $115 Million to Settle False Claims Act Allegations" (Sept. 21, 2015), https://www.justice.gov/opa/pr/adventist-health-system-agrees-pay-115-million-settle-false-claims-act-allegations.

43 69 Fed. Reg. 16054, 16092 (Mar. 26, 2004). In the Final Rule, CMS inaccurately describes these FMV safe harbors as proposed but never finalized. 85 Fed. Reg. at 77552.

44 69 Fed. Reg. at 16128.

45 *Id.*

46 72 Fed. Reg. 51012, 51015-16 (Sept. 5, 2007).

47 85 Fed. Reg. at 77557.

provide an accurate determination of fair market value in all cases."[48] For example—and perhaps most significantly—"[p]arties do not necessarily fail to satisfy the fair market value requirement simply because the compensation [at issue] exceeds a particular percentile in a salary schedule."[49] Nor, for that matter, "are parties required to pay a physician what is shown in a salary schedule if the specific circumstances do not warrant that level of compensation."[50]

CMS's rationale appears to be that while survey data may provide some insight into the appropriate level of compensation that might be paid to a *hypothetical* physician, it does not reflect information about the *actual* parties, which information is likely to be relevant to, and affect, the appropriate valuation of *their particular* arrangement. Simply put, "the rate of compensation set forth in a salary survey may not always be identical to the worth of a particular physician's services."[51] Indeed, CMS notes, the circumstances unique to a particular arrangement may "dictate" that the parties "to an arm's length transaction veer from values identified in salary surveys and other valuation data compilations that are not specific to the actual parties to the subject transaction."[52] One such factor may be the specific quality of the physician's services. To illustrate, CMS provides the following example:

> [A]ssume 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. In this example, compensation substantially above $450,000 per year may be fair market value.[53]

Similarly, CMS states that paying a physician above what is in a salary schedule may be consistent with FMV if there is a "compelling need for the physician's services."[54] CMS provides the following example:

> [I]n an area that has two interventional cardiologists but no cardiothoracic surgeon who could perform surgery in the event of an emergency during a catheterization, a hospital may need to pay above the amount indicated at a particular percentile in a salary schedule to attract and employ a cardiothoracic surgeon.[55]

48 *Id.*

49 *Id.*

50 *Id.*

51 *Id.* at 77554.

52 *Id.*

53 *Id.*

54 *Id.* at 77557.

55 *Id.* "On the other hand," CMS notes, "hypothetical data may result in hospitals and other entities paying more than they believe appropriate for physician services. Assume a hospital is engaged in negotiations to employ a family physician. Independent salary surveys indicate that compensation of $250,000 per year would be appropriate for a family physician nationally; no local salary surveys are available. However, the cost of living in the geographic location of the hospital is very low despite its proximity to good schools and desirable recreation opportunities, and, due to declining reimbursement rates and a somewhat poor payor mix, the hospital's economic position is tenuous. Although the physician may request the $250,000 that the salary survey indicates would be appropriate for a hypothetical (unidentified) physician to earn, and the hospital may believe that it is compelled to pay the physician this amount, the fair market value of the physician's compensation may be less than $250,000 per year." *Id.* at 77554.

Of course, this does not mean that survey data plays no role in FMV assessments. CMS reiterates that "[c]onsulting salary schedules or other hypothetical data is an appropriate starting point in the determination of fair market value, and in many cases, it may be all that is required."[56] Moreover, survey data certainly can serve as a compliance safeguard, in that compensation that is not particularly high as compared to the market is less likely to be scrutinized by the government or potential whistleblowers.

In all events, as made clear in the Final Rule, survey data cannot, in and of itself, serve as definitive proof that compensation exceeds fair market value; and that alone should make it more difficult for FCA actions like *Bookwalter II* to survive a motion to dismiss for failure to state a claim.

56 *Id.* at 77557.

II. Commercial Reasonableness Standard

A. Introduction

The Stark Law statute has 15 exceptions. Of these, four—covering (i) space rentals,[57] (ii) equipment rentals,[58] (iii) employment[59] and (iv) certain arrangements between hospitals and physician groups that have been in place since 1989[60]—include a Commercial Reasonableness Standard. The exception covering the rental of office space, for example, protects payments by a lessee to a lessor for the use of premises provided several conditions are met, including that the lease would be "commercially reasonable even if no referrals were made between the parties."[61] The statute does not define "commercially reasonable."

The Stark Law regulations have 40 exceptions (15 of which largely track their statutory counterparts). In addition to the four exceptions noted above, CMS has included a Commercial Reasonableness Standard in six exceptions; specifically, those covering (i) isolated transactions,[62] (ii) fair market value compensation,[63] (iii) indirect compensation arrangements,[64] (iv) timeshare arrangements,[65] (v) limited remuneration to a physician[66] and (vi) value-based arrangements.[67]

Prior to its promulgation of the Final Rule in 2020, CMS, like Congress, had not defined the term "commercially reasonable" in the Stark Law regulations. Indeed, prior to the Proposed Rule in 2019, CMS had addressed commercial reasonableness only once, in 1998, when its predecessor (HCFA) stated in the preamble to a proposed rulemaking that it interprets commercial reasonableness "to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals."[68]

Over the past 15 years in particular, the absence of a statutory or regulatory definition of "commercial reasonableness" has become a major source of conflict and confusion, most notably in the context of actual and threatened FCA litigation. Increasingly, FCA whistleblowers and DOJ have taken the position that where, for example, a hospital employs a physician and the hospital's salary, benefit, overhead and other costs associated with the arrangement are greater than the revenues generated by the hospital based on the physician's personally performed services, the employment arrangement is not, and cannot be, "commercially reasonable."[69] As discussed further

57 42 U.S.C. § 1395nn(e)(1)(A).

58 *Id.* § 1395nn(e)(1)(B).

59 *Id.* § 1395nn(e)(2).

60 *Id.* § 1395nn(e)(7).

61 *Id.* § 1395nn(e)(1)(A)(v).

62 42 C.F.R. § 411.357(f).

63 *Id.* § 411.357(l).

64 *Id.* § 411.357(p).

65 *Id.* § 411.357(y).

66 *Id.* § 411.357(z).

67 *Id.* § 411.357(aa).

68 63 Fed. Reg. 1659, 1700 (Jan. 9, 1998).

69 *See, e.g., United States ex rel. Barker v. Columbus Reg'l Healthcare Sys., Inc.*, Case No. 4:14-cv-00304 (M.D. Ga. 2014); *United States ex rel. Schaengold v. Mem'l Health Inc.*, Case No. 4:11-cv-00058 (S.D. Ga. 2011); *United States ex rel. Reilly v. North Broward Hosp. Dist.*, Case No. 10-60590 (S.D. Fla. 2010).

below, in what probably is the most significant development in the Final Rule relating to the Commercial Reasonableness Standard, CMS has squarely rejected this proposition, memorializing—for the first time, and in the text of the regulations themselves—that "[a]n arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."

B. Proposed Rule

In the 2019 Proposed Rule, CMS proposed including a definition of "commercially reasonable" in the Stark Law's regulations for the first time.[70] In explaining its proposed definition, CMS stated that the "key question" to ask "when determining whether an arrangement is commercially reasonable is simply whether the arrangement makes sense as a means to accomplish the parties' goals."[71] The agency emphasized that "this determination should be made from the perspective of the particular parties involved in the arrangement."[72] The agency further emphasized that the "determination of commercial reasonableness is not one of valuation. Nor does the determination that an arrangement is commercially reasonable turn on whether the arrangement is profitable."[73]

> It is apparent . . . that there is a widespread misconception about our position on the nexus between the commercial reasonableness of an arrangement and its profitability. 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*.[74]

CMS noted that stakeholders had provided numerous examples of compensation arrangements they believed were "commercially reasonable" notwithstanding the fact that (i) the party "paying the remuneration does not recognize an equivalent or greater financial benefit from the items or services purchased in the transaction" or (ii) the party "receiving the remuneration incurs costs in furnishing the items or services that are greater than the amount of the remuneration received."[75]

The reasons offered by stakeholders for entering into such (non-profitable) arrangements included "community need, timely access to health care services, 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."[76] Indeed, one commenter suggested that "entire hospital service lines" (such as psychiatric and burn units) that must be managed and otherwise serviced by physicians frequently operate at a loss.[77]

70 84 Fed. Reg. 55766, 55790 (Oct. 17, 2019).

71 *Id.*

72 *Id.*

73 *Id.*

74 *Id.* (emphasis added).

75 *Id.*

76 *Id.*

77 *Id.*

> According to this commenter, with changes in reimbursement, more service lines will operate at a loss in the future. The commenter urged that these services are of vital need to communities and, unless CMS addresses the definition of "commercial reasonableness," health care providers may be prohibited from providing these services to their communities [for] fear of violating the [C]ommercial [R]easonableness [S]tandard.[78]

CMS concluded that these comments and concerns were "compelling" and proposed two alternative definitions of the term "commercially reasonable." The first would define "commercially reasonable" to mean that the arrangement "furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements."[79] The second would define "commercially reasonable" to mean that 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."[80] Importantly, both definitions would make it clear "that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."[81]

Finally, CMS emphasized two points. First, the agency noted that "arrangements that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements."[82]

> For example, a hospital may enter into an arrangement for the personal services of a physician to oversee its oncology department. If the hospital needs only one medical director for the oncology department, but later enters into a second arrangement with another physician for oversight of the department, the second arrangement merely duplicates the already-obtained medical directorship services and may not be commercially reasonable.[83]

Second, CMS noted that most Stark Law exceptions that include a commercial reasonableness standard add language such as ". . . even if no referrals were made between the parties" or " . . . even if no referrals were made to the employer."[84] The agency made clear that it was not proposing to eliminate this requirement from the exceptions where it appears.[85]

C. Final Rule

Following consideration of the comments on the Proposed Rule, CMS settled on the following definition of "commercially reasonable":

> *Commercially reasonable* means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.[86]

78 *Id.*

79 *Id.*

80 *Id.*

81 *Id.*

82 *Id.*

83 *Id.*

84 *Id.* at 55791.

85 *Id.*

86 85 Fed. Reg. 77492, 77657 (Dec. 2, 2020).

In large measure, CMS's discussion of the Commercial Reasonableness Standard in the Final Rule tracks the agency's discussion in the Proposed Rule. For example:

- CMS reiterated that the "determination of commercial reasonableness is not one of valuation" and "does not turn on whether the arrangement is profitable."[87] (The agency also noted, however, that it is not convinced that an arrangement's profitability "is completely irrelevant" or "always unrelated" to "a determination of its commercial reasonableness, for instance, in a case where the parties enter into an arrangement aware of its certain unprofitability and there exists no identifiable need or justification—other than to capture the physician's referrals—for the arrangement."[88])
- The agency also reiterated that unprofitable but commercially reasonable arrangements might arise for any number of reasons, including community need, timely access to health care services, fulfillment of licensure or regulatory obligations, the provision of charity care and the improvement of quality and health outcomes.[89] (CMS emphasized that this list from the Proposed Rule is non-exclusive; that is, it does not represent "the entire universe of arrangements that," although unprofitable, "could be commercially reasonable."[90])
- CMS reemphasized that arrangements "that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements."[91]

Although the Proposed and Final Rules largely are in accord, CMS did make one unfortunate—and, hopefully, inadvertent and/or incomplete—statement in the preamble of the Final Rule. According to the agency, in response to the Proposed Rule, a commenter expressed concern that "unscrupulous parties" could attempt to satisfy the Commercial Reasonableness Standard by arguing that the "goal of attracting a physician's business" is a "legitimate business purpose" of a compensation arrangement between a physician and DHS Entity.[92]

In response, CMS stated that while it shares this concern, it did not include the phrase "even if no referrals were made" in the definition of "commercially reasonable" because "this qualifying phrase (or similar language)" already "appears in the . . . text of many exceptions that require an arrangement to be commercially reasonable."[93] Thus, the agency concluded, "it would be redundant to include the language in the definition of 'commercially reasonable' itself."[94] CMS made it clear, however, that it believes "this qualifying language provides critical protection against program or patient abuse."[95]

87 *Id.* at 77531.

88 *Id.* at 77534.

89 *Id.* at 77531.

90 *Id.* at 77532.

91 *Id.* at 77533.

92 *Id.*

93 *Id.*

94 *Id.*

95 *Id.* at 77533-34.

CMS then made the following, seemingly gratuitous, statement:

> An arrangement whose purpose is to attract a physician's business, even if the parties claim this purpose, would not be commercially reasonable in the absence of the physician's referrals and, thus, would not satisfy this important requirement of the exceptions generally applicable to compensation arrangements that call for items or services to be provided by a physician.[96]

Depending on precisely what CMS means by "[a]n arrangement whose purpose is to attract a physician's business," this statement is potentially problematic. The following hypothetical helps demonstrate why. Assume the following:

- Hospital has 200 physicians on its medical staff. Thirty of these physicians are employed by Hospital (Employed Physicians); the remaining 170 physicians are not employed by Hospital (Independent Physicians).
- Hospital enters into a written Physician Employment Agreement (PEA) with each of its Employed Physicians. As specifically permitted under the Stark Law's Required Referrals Special Rule, each PEA includes a provision that requires each Employed Physician to make all referrals to Hospital (Required Referrals Provision). Consistent with the Required Referrals Special Rule, the Required Referrals Provision makes it clear that the Provision does not apply if (i) the patient expresses a preference for a different provider, practitioner or supplier; (ii) the patient's insurer determines the provider, practitioner or supplier; or (iii) the referral is not in the patient's best medical interests in the Employed Physician's judgment.
- Hospital's operative agreements with its Independent Physicians do not include a Required Referrals Provision.
- On an annual basis, Hospital reviews both (i) the volume of referrals made to Hospital by the 200 physicians on its medical staff, and (ii) the value of those referrals to Hospital (in terms of both revenue and margin). (Hospital undertakes these reviews for a host of perfectly legitimate reasons. For example, to the extent Independent Physicians refer the majority of their patients elsewhere for certain procedures, Hospital may want to survey its medical staff to determine what, if anything, Hospital can do better in terms of scheduling, patient satisfaction, clinical improvements, etc.)

96 *Id.* at 77534.

- Consistent with prior reviews, the review covering calendar year 2020 indicates that, all other things being equal, the volume and value of referrals made by Employed Physicians (who, among other things, are subject to the Required Referrals Provision) are greater than the volume and value of referrals made by Independent Physicians (who, among other things, are not subject to the Required Referrals Provision).
- Based, in part, on these results—and, in part, on other considerations (e.g., physician experience, physician expertise, patient satisfaction surveys, etc.)—Hospital decides to extend an offer of employment to Dr. Jane Smith, who is a primary care physician in the community and one of the 170 Independent Physicians on Hospital's medical staff.
- The PEA offered by Hospital to Dr. Smith has a term of three years (commencing on July 1, 2021) and provides for annual compensation of $250,000 per year. The PEA does not provide for bonuses or incentives of any kind. Like all of Hospital's PEAs, Dr. Smith's PEA includes a Required Referrals Provision. Dr. Smith, who previously earned $225,000 per year, accepts Hospital's offer of employment.

Hospital and all of its Employed Physicians intend for their employment arrangements to qualify for protection under the Stark Law's Employment Exception.[97] Pertinent to our hypothetical arrangement between Hospital and Dr. Smith, the Employment Exception has six requirements.

- First, the physician must have a "bona fide employment relationship with the employer for the provision of services."[98] It is undisputed that Dr. Smith meets this requirement.
- Second, the employment must be "for identifiable services."[99] It is undisputed that this requirement also is met here.
- Third, the "amount of the remuneration" under the arrangement must be "[c]onsistent with the fair market value of the services."[100] It is undisputed that the compensation at issue here (i.e., $250,000 per year) is consistent with FMV.
- Fourth, the "amount of the remuneration" under the arrangement must not be "determined in any manner that takes into account the volume or value of referrals by the referring physician."[101] Once again, it is undisputed that the compensation at issue here—which does not and will not fluctuate in any manner over the term of the PEA—meets this requirement.[102]
- Fifth, "[i]f remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier," the arrangement must satisfy "the conditions of § 411.354(d)(4)" (i.e., the Required Referrals Special Rule).[103] Once again, it is undisputed that all of the conditions of the Required Referrals Special Rule are met.

The sixth (and final) requirement of the Employment Exception is this: "The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer."[104] As noted above, CMS suggests in the preamble to the Final Rule that an arrangement "whose purpose is to attract a physician's business" cannot satisfy the requirement that an arrangement is "commercially reasonable in the absence of the physician's referrals." But that simply isn't true, either as a matter of logic or law, and the statement improperly injects a normative, intent-based condition into an objective, strict liability statute.

In our hypothetical, Hospital may hope (and even expect) that Dr. Smith will refer patients requiring hospital inpatient and outpatient services to Hospital. (Indeed, it would be strange for Hospital *not* to harbor such hopes and expectations given that the Stark Law, through the operation of the Required Referrals Special Rule, specifically permits Hospital to *require*

97 42 C.F.R. § 411.357(c).

98 *Id.*

99 *Id.* § 411.357(c)(1).

100 *Id.* § 411.357(c)(2)(i).

101 *Id.* § 411.357(c)(2)(ii).

102 *Id.* § 411.354(d)(5)(i)-(ii). Under these provisions, which set out the new Volume/Value Special Rule, as defined in White Paper No. 3, fixed flat fee arrangements do not trigger the Volume/Value Standard.

103 *Id.* § 411.357(c)(5).

104 *Id.* § 411.357(c)(3).

Dr. Smith to refer patients requiring hospital inpatient or outpatient services to Hospital.) Further, as reflected in our hypothetical, these hopes and expectations—along with Dr. Smith's experience, expertise, patient satisfaction scores, etc.—did, in fact, combine to motivate Hospital to offer Dr. Smith employment.

In case law analyzing the federal health care program anti-kickback statute,[105] courts have recognized that a party may "hope" or even "expect" that a particular arrangement will result in referrals (in the broader sense of that term), but such hope or expectation is insufficient to prove that the "purpose" of the arrangement was to induce referrals.[106] Given this jurisprudence, it is possible that CMS's reference to an arrangement "whose purpose is to attract a physician's business" involves a greater showing than mere hope or expectation.

That said, even if CMS did intend to say that the mere hope or expectation of physician business would cause an arrangement to fail to be "commercially reasonable even if the physician made no referrals to the entity," such a statement is simply incorrect. The fact that Hospital harbors such hopes and expectations, or even enters into the arrangement with the explicit motivation of attracting physician business, does not mean the (actual) arrangement between Hospital and Dr. Smith cannot be "commercially reasonable" even if no referrals are (in fact) made by Dr. Smith to Hospital. Assume, for example, that prior to offering Dr. Smith employment, Hospital estimates (based on complete and accurate historical data) that during each year of her employment, Dr. Smith will generate (i) $600,000 in revenue from personally performed services and (ii) $300,000 in costs unrelated to her compensation. Thus, Hospital concludes, if it pays Dr. Smith $250,000 each year, Hospital will generate an annual net margin of $50,000.

Under these circumstances, the arrangement would certainly meet the definition of "commercial reasonableness" adopted by CMS in the Final Rule: that is, the arrangement (i) would further "a legitimate business purpose of" Hospital and Dr. Smith and (ii) be "sensible, considering the characteristics of the parties, including their size, type, scope, and specialty." Moreover, we know the arrangement would be commercially reasonable "even if no referrals were made to the employer" because *none of the calculations that Hospital used to establish its compensation offer assumed or otherwise took into account, directly or indirectly, in whole or in part, any such referrals*.

Hopefully, CMS, when it next has the opportunity, will confirm that simply because a DHS Entity reasonably hopes and/or expects that a physician, upon her employment by the DHS Entity, will refer to the DHS Entity patients requiring the type of services furnished by the DHS Entity, does not mean that any employment arrangement ultimately entered into by the parties cannot meet the Commercial Reasonableness Standard.

105 42 U.S.C. § 1320a-7b(b).

106 *Hanlester Network v. Shalala*, 51 F.3d 1390, 1397 (9th Cir. 1995); *U.S. v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000).

III. Indirect Compensation Arrangements

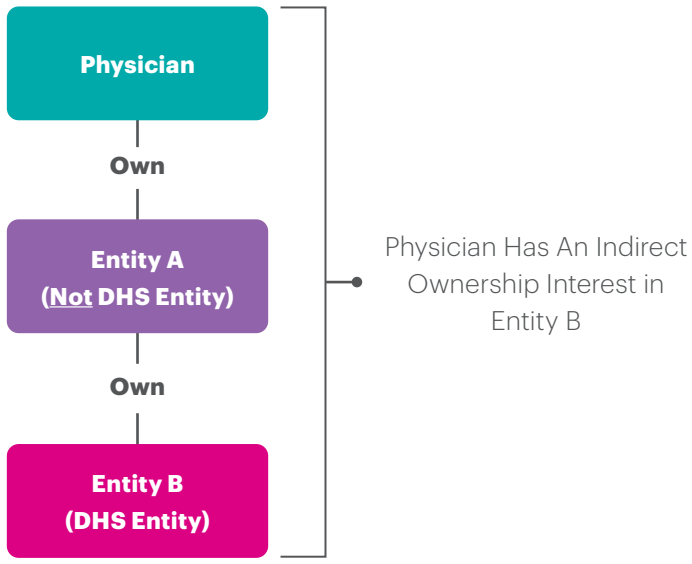
Historically, determining whether a physician has an indirect compensation arrangement with a DHS Entity has proven to be a complex, tricky and time-consuming undertaking. An ICA is the only type of financial relationship that (i) is not expressly addressed or defined in the Stark Law statute, and (ii) by regulation, requires application of a cumbersome three-part test to ascertain its existence. For these reasons, coupled with the dramatic definitional and directional change introduced in the Final Rule, we are devoting the balance of this white paper to the ICA Definition.

A. Stark Law Statute

A financial relationship is the *sine qua non* of a Stark Law cause of action. To implicate the Stark Law, there *must* be an underlying "financial relationship" between the referring physician or their immediate family member (IFM) and the DHS Entity.[107] (For ease of discussion, we omit the reference to IFMs for the remainder of this Section III, but remind the reader that all references to referring physicians also include their IFMs.)

By statute, a financial relationship may take one of two forms: (i) an ownership or investment interest held by the referring physician in the DHS Entity (ownership interest), or (ii) a compensation arrangement between the referring physician and the DHS Entity. When describing a financial relationship in the form of an ownership interest, the statute expressly provides that this "includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service."[108] In other words, the statute expressly provides than an ownership interest may be *indirect*. For example, assume Physician holds an ownership interest in Entity A; Entity A does not furnish DHS, but holds an ownership interest in Entity B, which does furnish DHS. Under the express terms of the Stark Law statute, Physician would be deemed to have an indirect ownership interest in Entity B. See *Diagram 1* below.

Diagram 1



107 42 U.S.C. § 1395nn(a)(1). The Stark Law statute provides that the statute's referral and billing prohibitions are predicated on the existence of a financial relationship. *Id.* at § 1395nn(a)(1)(A)-(B).

108 *Id.* § 1395nn(a)(2).

By contrast, when describing compensation arrangements (i.e., the second category of financial relationships), the statute does not use the term "indirect compensation arrangement" or—as under the definition of "ownership interest"—specify a chain of relationships that would be deemed to give rise to an indirect compensation arrangement.[109] Rather, it speaks only of a "compensation arrangement" and defines that, in pertinent part, as "any arrangement" involving the exchange of "remuneration" between a referring physician and DHS Entity.[110] The statute defines the term "remuneration," in turn, as "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind."[111]

These statutory provisions regarding compensation arrangements and remuneration are capable of at least two reasonable interpretations. The interpretation adopted by HCFA in 2001 is that the Stark Law applies to two types of compensation arrangements: (i) *direct* compensation arrangements, in which remuneration passes directly between the referring physician and DHS Entity without any intervening individuals or entities (collectively, "persons"); and (ii) *indirect* compensation arrangements, in which remuneration passes between a physician and DHS Entity through one or more intervening persons.[112] As detailed below, this interpretation permits completely separate financial relationships linking a physician and DHS Entity to give rise to an ICA between the referring physician and the DHS Entity, even though the referring physician and the DHS Entity are not, in fact, parties to any shared arrangement. For example, if (i) a physician owns a catering company, (ii) the catering company contracts with a bakery and (iii) the bakery has an agreement with a hospital, the physician may be deemed to have a financial "relationship" in the form of a compensation "arrangement" "with" the hospital.

The statutory language, however, lends itself to a second, narrower (and arguably more reasonable) reading, in which a compensation arrangement exists only if the physician and DHS Entity are *themselves* parties to a *single* "arrangement" pursuant to which the "remuneration" exchanged between the parties may flow either "directly" or "indirectly." Assume, for example, that Pharmacy engages Physician to staff its in-store urgent care clinic at a rate of $150 per hour. The *remuneration* that passes between them may be exchanged "directly" (e.g., Pharmacy writes a check to Physician A) or "indirectly" through an intermediary at the express direction of one of the principals (e.g., Pharmacy requests that its corporate parent send a check to Physician A on Pharmacy's behalf)—but, in either event, there is only a *single* "arrangement" and that *single* arrangement is "between" Pharmacy and Physician A.

As indicated above, HCFA and CMS have opted for the former, broader interpretation of the statutory term "compensation arrangement." Whether or not the agency's interpretation is correct, one thing is clear: HCFA and CMS have struggled mightily and from the beginning to manage the scope of the ICA construct.

B. 2001 Final Rule

HCFA first defined the term "indirect compensation arrangement" in the 2001 Phase I Regulations. It did so using a three-part test, which, despite multiple revisions over the years, has maintained this particular structure.[113] The 2001 version of the ICA Definition required three things:

- Prong One. The existence of an unbroken chain of at least two financial relationships between the referring physician and the DHS Entity.[114]
- Prong Two. The *aggregate* compensation received by the referring physician from the person in the chain with whom the physician has a "direct financial relationship" varies with or otherwise reflects the volume or value of the referring physician's referrals to or other business generated for the DHS Entity

109 *Id.*

110 *Id.* §§ 1395nn(a)(2), 1395nn(h)(1)(A).

111 *Id.* § 1395nn(h)(1)(B) (emphasis added).

112 42 C.F.R. § 411.354(a)(1)(ii) ("Financial Relationship means . . . [a] direct or indirect compensation arrangement"); *id.* § 411.354(a)(2)(i) ("A direct financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between [them]."); *id.* § 411.354(a)(2)(ii) (providing the conditions under which an indirect financial relationship exists).

113 66 Fed. Reg. 856, 958-59 (Jan. 4, 2001) (setting forth 42 C.F.R. § 411.354(c)(2)).

114 *Id.*

(2001 ICA Volume/Value Standard).[115] (As discussed below, while the regulation describes the aggregate compensation as being received by the referring physician, it also makes clear that if the referring physician is not a party to a compensation arrangement in the chain of financial relationships, the focus is on the aggregate compensation in the compensation arrangement closest to the referring physician.)

- Prong Three. The DHS Entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the aggregate compensation (in the compensation arrangement identified in Prong Two) triggers the 2001 ICA Volume/Value Standard (i.e., that the aggregate compensation varies with or otherwise reflects the volume or value of the referring physician's referrals to or other business generated for the DHS Entity).[116]

1. Prong One

To illustrate how these prongs operate in practice, we'll use a series of hypotheticals, and start with Prong One.

Hypothetical No. 1. An independent clinical diagnostic laboratory (Lab) (a DHS Entity by virtue of furnishing clinical diagnostic laboratory services, which are DHS) enters into a medical director agreement (MDA) with Physician A.[117] The MDA provides that Lab will pay Physician A $150 per hour, which will increase to $160 per hour in any month in which Physician A orders five or more diagnostic tests from Lab.

This MDA can be represented as follows: Lab → Physician A. There is only *one* financial relationship between the Lab and Physician A, taking the form of a direct compensation arrangement. This exchange of remuneration does not give rise to an ICA because Prong One, which requires at least two financial relationships, is not met.

Hypothetical No. 2. Physician A subsequently is employed by Medical Practice, a community-based physician organization. Lab and Physician terminate their MDA. Lab enters into an MDA with Medical Practice. Under the new MDA, Medical Practice agrees to make Physician A available to Lab for purposes of furnishing medical directorship services, and Lab agrees to pay Medical Practice under the same compensation terms that previously applied to Physician A.

115 *Id.* The original phrase, "varies with or otherwise reflects" was changed to "varies with or takes into account" in the 2007 Phase III Regulations. *See* 72 Fed. Reg. 51011, 51027 (Sept. 5, 2007).

116 66 Fed. Reg. at 958-59 (setting forth 42 C.F.R. § 411.354(c)(2)).

117 Clinical diagnostic laboratory services are DHS. *See* 42 U.S.C. § 1395nn(h)(6)(A); 42 C.F.R. § 411.351 (definition of "designated health services").

Under these circumstances, Prong One of the ICA Definition, as promulgated in 2001, is satisfied because there is an unbroken chain of two financial relationships between Physician A and Lab: (i) the MDA between Lab and Medical Practice and (ii) the employment arrangement between Medical Practice and Physician A. This unbroken chain of financial relationships can be represented schematically as follows: Lab → Medical Practice (Link 1) and Medical Practice → Physician A (Link 2).

Hypothetical No. 3. As in Hypothetical No. 2, Physician A is employed by Medical Practice. As in Hypothetical No. 1, however, the MDA is (directly) between Lab and Physician A. Because Medical Practice routinely sends a courier to Lab to deliver samples, Lab (with Physician A's knowledge and consent) sends her monthly compensation to the attention of the Medical Practice Administrator, who agrees to accept Lab's check on Physician A's behalf and deliver it to her.

If one were focusing exclusively on the physical flow of the "remuneration" at issue (i.e., payment for Physician A's services), the arrangement, like that in Hypothetical No. 2, appears to involve multiple "links"—Lab → Administrator (acting as Physician A's agent) (Link 1) and Administrator → Physician A (Link 2)—thereby satisfying Prong One of the ICA Definition.

This was not the case as of 2001, however. The 2001 rule made it clear that an "agent" does not qualify as an intervening person for purposes of applying Prong One of the ICA Definition. Thus, in Hypothetical No. 3, as in Hypothetical No. 1, there was a direct compensation arrangement between Lab and Physician A, with the Medical Practice Administrator, in accepting payment from Lab and transferring it to Physician A, simply serving as Physician A's agent.[118]

Put somewhat differently, by treating Physician A and her agent (Medical Practice Administrator) as one "person," what might otherwise have been an unbroken chain of two financial relationships (Lab → Administrator and Administrator → Physician A) collapsed into a single, direct compensation arrangement between Lab and Physician A.

2. Prong Two

Assuming the existence of an unbroken chain of two or more financial relationships, the analysis proceeds to Prong Two of the ICA Definition. Determining whether Prong Two of the ICA Definition is satisfied involves a two-step process. The first step is to identify the "direct financial relationship" (in the unbroken chain of financial relationships) that is closest to the referring physician. The second step is to ascertain whether the aggregate compensation in that financial relationship meets the 2001 ICA Volume/Value Standard.

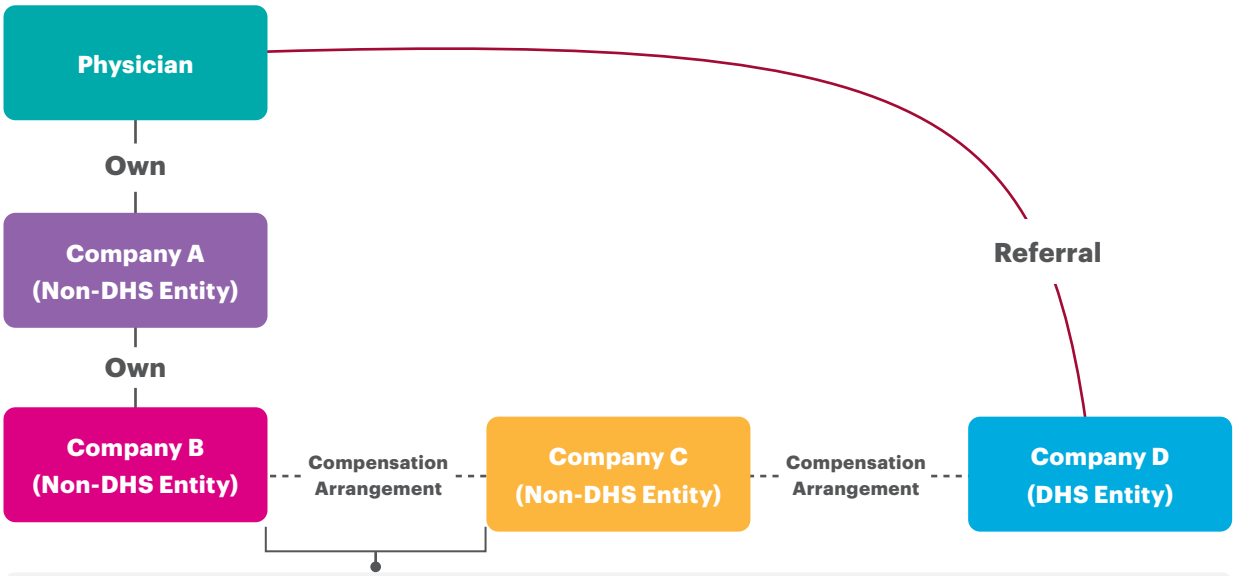
The regulations make it clear that the "direct financial relationship" that is the focus of the Prong Two inquiry *must* be a compensation arrangement.[119] (For ease of reference, we call this the "Prong Two Compensation Arrangement.") In the regulation, HCFA offers the following example: "if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C" for purposes of applying Prong Two.[120] See *Diagram* 2.

118 The rule in 2001 defined a "direct financial relationship" as involving the direct exchange of remuneration between physicians and DHS entities "without any intervening persons or entities *(not including an agent . . .)*)." 42 C.F.R. § 411.354(a)(2) as set forth in 66 Fed. Reg. at 958 (emphasis added).

119 42 C.F.R. § 411.354(c)(ii)(C) ("If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member).").

120 *Id.*

Diagram 2



This is the "Prong Two Compensation Arrangement" (i.e., it is the compensation arrangement closest to the referring physician in the unbroken chain of financial relationships between Physician and DHS Entity (i.e. Company D).

Recall that the unbroken chain of financial relationships between Lab A and Physician A in Hypothetical No. 2 is comprised of two compensation arrangements: Lab → Medical Practice (Link 1) and Medical Practice → Physician A (Link 2). Thus the Prong Two Compensation Arrangement—i.e., the compensation arrangement closest to Physician A—is the employment relationship between Medical Practice and Physician A (i.e., Link 2).

Hypothetical No. 4. Same facts as Hypothetical No. 2, except (i) Medical Practice has a physician-owner—Physician B—who also has occasion to refer patients to, and generate other business for, Lab; and (ii) the MDA provides that Lab will pay Medical Practice $150 per hour for Physician A's services, which rate will increase to $160 per hour in any month in which Physicians A and B, collectively, order five or more diagnostic tests from Lab.

The unbroken chain of financial relationships with respect to Physician B is captured schematically as follows: Lab → Medical Practice (Link 1) and Medical Practice → Physician B (Link 2). In contrast to Physician A, the closest *compensation* arrangement to Physician B is not her financial relationship with Medical Practice, because that's an *ownership* interest. Rather the closest *compensation* arrangement to Physician B is the MDA between Lab and Medical Practice. As such, the MDA is the Prong Two Compensation Arrangement for purposes of determining whether there is an ICA between Physician B and Lab, and the questions presented are these: (i) does the $150 per hour that Lab pays Medical Practice for Physician A's services, when considered in the aggregate, vary with or otherwise reflect Physician B's referrals to or other business generated for Lab; and (ii) does the Lab's agreement to pay Medical Practice an additional $10 per hour in any month in which Physicians A and B order more than five clinical lab tests from Lab alter the outcome? The answer to the first question is easy: There does not appear to be any relationship whatsoever between Physician B's referrals to Lab and Lab's payment to Medical Practice of $150 for each hour of medical director services Physician A furnishes. The answer to the second question, however, is more complicated.

As discussed at some length in White Paper No. 3, the Volume/Value Standard analysis is informed by several rules. Relevant here are the Unit-Based Special Rules, which provide that a unit-based payment methodology is deemed not to take into account the volume or value of a physician's referrals or other business generated if the unit of compensation (i) is consistent with fair market value for the service at issue, and (ii) does not change in any manner such that the unit takes into account the volume or value of the physician's referrals or other business generated. Here, even if we assume that paying either $150 or $160 per hour for Physician A's services would be consistent with FMV, because the additional amount will be paid only if Physicians A and B, collectively, order five or more clinical lab tests from Lab, the aggregate compensation under the MDA *does* take into account the volume of Physician B's referrals to Lab and, as such, with respect to the determination of whether Prong Two of the ICA Definition is met as to the putative ICA between Physician B and Lab, the answer (in 2001) was yes.

3. Prong Three

Assuming Prongs One and Two of the ICA Definition are met, the inquiry turns to the third and final prong. Prong Three of the ICA Definition is an outlier in Stark Law jurisprudence because, with perhaps one or two small exceptions, it is the only provision of the Stark Law that focuses on a party's state of mind. Specifically, Prong Three of the ICA Definition addresses the DHS Entity's state of mind as it relates to the ICA Volume/Value Standard (i.e., Prong Two of the ICA Definition). Specifically, for Prong Three of the ICA Definition to be met, the DHS Entity must have "actual knowledge" or act "in reckless disregard or deliberate ignorance of" the fact that the Prong Two Compensation Arrangement provides for "aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS."[121]

When promulgating the ICA Definition in 2001, CMS stated that the "knowledge" element of Prong Three of the ICA Definition essentially is "comparable to the *scienter* standard in the Civil Monetary Penalty Law."[122] Consistent with that standard, the third prong of the ICA Definition "generally imposes a duty of reasonable inquiry on providers."[123] CMS emphasized, however, that this duty does not impose an "affirmative obligation to inquire."[124] Rather, this duty requires that "providers in possession of facts that would lead a reasonable person to suspect the existence of an indirect financial relationship take reasonable steps to determine whether such a financial relationship exists."[125] CMS reiterated that, "absent information that would put a reasonable person on alert," a DHS Entity "has no affirmative duty to inquire or investigate" whether an ICA with a referring physician exists.[126]

In Hypothetical No. 4, then, the question would be whether Lab (the DHS Entity) knew or should have known that the compensation under the Prong Two Compensation Arrangement, when viewed in the aggregate, varies based on the volume of Physician B's referrals to Lab. The answer to this question, in turn, almost certainly is "yes" because (i) the Prong Two Compensation Arrangement in Hypothetical No. 4 is the MDA, (ii) Lab is a party to the MDA and (iii) the MDA specifically provides for Lab's compensation to increase from $150 to $160 per hour based on the volume of referrals by Physicians A and B, collectively.

121 42 C.F.R. § 411.354(c)(2)(iii).

122 66 Fed. Reg. at 865.

123 *Id.* While this guidance falls within the discussion of indirect ownership interests, CMS made it clear that the same standard applies to the ICA Definition. *Id.* at 866.

124 *Id.* at 865.

125 *Id.* In such a case, the DHS Entity must take "reasonable steps" to determine whether the physician's compensation varies with the volume or value of referrals or other business generated for the DHS Entity. According to CMS, "reasonable steps" may include obtaining a good faith, written assurance from the referring physician or entity that pays the physician that the physician's aggregate compensation falls within the ICA exception. *Id.* at 865, 866.

126 *Id.* at 866.

C. 2004 Final Rule

1. Agents as Intervening Persons

CMS changed the ICA Definition in the 2004 Stark II Phase II Regulations. First, CMS removed the carve-out for agents under Prong One of the ICA Definition.[127] Henceforth, even a party's agent *would* serve as an intervening person for purposes of determining whether there was an unbroken chain of at least two financial relationships between the referring physician and DHS Entity. The net effect of this change was to expand the universe of potential ICAs while causing a corresponding reduction in the overall number of direct compensation arrangements.

By way of example, in Hypothetical No. 3 above, we concluded that under the 2001 rule, Lab's payment—through the Medical Practice Administrator—to Physician A did not create a second financial relationship or, therefore, the prospect of an ICA between Lab and Physician A. Rather, as in Hypothetical No. 1, Lab and Physician A simply had a direct compensation arrangement. Under the 2004 rule, however, Lab and Physician A would no longer have a direct compensation arrangement. Rather, there would be an unbroken chain of two financial relationships between Lab and Physician A—made up of Lab → Administrator (Link 1) and Administrator → Physician A (Link 2)—and, as such, Lab and Physician A would have a potential ICA.

2. Prong Two: Applicability of Unit-Based Special Rules

Also of note in the Phase II Regulations is CMS's clarification that the Unit-Based Special Rules do not apply to the Volume/Value Standard in the ICA Definition.[128] In other words, the determination of whether the aggregate compensation at issue satisfies Prong Two of the ICA Definition must be performed without regard to the Unit-Based Special Rules. The net result of this clarification was to create multiple scenarios where the aggregate compensation was deemed (i) to trigger the Volume/Value Standard for purposes of the ICA Definition, where the Unit-Based Special Rules no longer applied, but (ii) not to violate the Volume/Value Standard in the potentially applicable Stark Law exception for indirect compensation arrangements (ICA Exception),[129] where the Unit-Based Special Rules continued to apply.

127 69 Fed. Reg. 16054, 16133 (Mar. 26, 2004).

128 *Id.* at 16058-59.

129 42 C.F.R. § 411.357(p).

The following hypothetical may prove instructive in demonstrating the interplay among (i) the Unit-Based Special Rules, (ii) the Volume/Value Standard in the ICA Definition, and (iii) the Volume/Value Standard in the ICA Exception.

Hypothetical No. 5. Hospital enters into a signed written agreement memorializing an under arrangement with community-based Medical Practice, which has a physician-owner (Physician A). Pursuant to the agreement, Hospital furnishes advanced imaging studies indirectly (i.e., through Medical Practice) to certain Hospital outpatients (Imaging Study Agreement). The imaging studies are performed by Medical Practice in its own premises, but are billed by Hospital. Hospital, in turn, pays Medical Practice $350 per imaging study.

Because the arrangement precedes the "stand in the shoes" provisions promulgated in 2007, Medical Practice's physician-owner (Physician A) does not stand in the shoes of Medical Practice. Thus, to the extent the arrangement creates a financial relationship between Physician A and Hospital, it takes the form of a potential ICA based on the following unbroken chain of financial relationships: Physician A → Medical Practice (Link 1) and Medical Practice → Hospital (Link 2). Because the financial relationship closest to Physician A (i.e., Link 1) is an ownership interest, the Prong Two inquiry focuses on the arrangement between Medical Practice and Hospital, and the question is whether the compensation provided for under that arrangement, when considered in the aggregate, varies with or otherwise reflects the volume or value of Physician A's referrals to Hospital.

The answer is "yes." That is, the more imaging studies Physician A orders for Hospital patients, the more Hospital pays Medical Practice. If Physician A orders one study, Hospital pays Medical Practice $350; if Physician A orders two studies, Hospital pays Medical Practice $700; and so on. Plainly then, the "aggregate" compensation paid by Hospital to Group will vary based on the volume of referrals by Physician A to Hospital. Indeed, assuming that such studies are ordered for Medicare and non-Medicare patients, the compensation methodology takes into account both (i) the volume of referrals and (ii) the volume of other business generated. Finally, assuming, as we must, that Hospital is aware that the Prong Two Compensation Arrangement—i.e., the Imaging Study Agreement to which Hospital is a party—triggers the ICA Volume/Value Standard, then Prong Three also is met, meaning the parties have an ICA.

As explained above, although CMS decided in 2004 that the Unit-Based Special Rules have no role to play under the ICA Definition, the same was not the case with respect to the ICA Exception. The ICA Exception requires, among other things, that the "compensation" (as opposed to the "aggregate compensation") under the Prong Two Compensation Arrangement not take into account the volume or value of the referrals of, or other business generated by, the physician for the DHS Entity. In Hypothetical No. 5, then, if (i) $350 per imaging study is within the range of fair market value for such studies and (ii) during the course of the parties' arrangement this per-unit amount does not vary in a manner that takes into account the volume or value of Physician A's referrals to or other business generated for Hospital, then, pursuant to the application of the Unit-Based Special Rules, the compensation at issue will not violate the Volume/Value Standard under the ICA Exception.

3. Prong Three: Knowledge Element

Finally, CMS used the 2004 rulemaking to reaffirm its interpretation of Prong Three of the ICA Definition, stating that the "knowledge" element in this prong "is the same as in the False Claims Act and the Civil Monetary Penalty Law."[130] CMS also rejected a commenter's suggestion that the third prong of the ICA Definition imposed "a simple negligence standard," emphasizing, once again, that "a DHS entity has no duty to inquire whether a referring physician receives aggregate compensation that varies with, or otherwise takes into account, referrals to, or other business generated for, the DHS entity unless facts or circumstances exist such that a failure to follow up with an inquiry would constitute deliberate ignorance or reckless disregard."[131]

D. 2007 Final Rule

In 2007, CMS made two changes to the ICA Definition, one largely semantic, the other much more substantive. The semantic change involved Prong Two of the ICA Definition. Specifically, CMS removed the phrase "or otherwise reflect" from Prong Two and inserted the phrase "or takes into account." Thus, effective December 4, 2007, the operative portion of Prong Two of the ICA Definition required that the "aggregate compensation" in the Prong Two Compensation Arrangement "varies with, *or takes into account*, the volume or value of the referring physician's referrals to or other business generated for the [DHS Entity]."[132]

The more substantive change was made to the Prong One analysis. As noted above, the 2004 rulemaking expanded the universe of potential ICAs by taking the position that that an agent of either the referring physician or the DHS Entity could act as an intervening person. As a result, a large number of what were previously considered direct compensation arrangements suddenly became potential indirect compensation arrangements. The pendulum swung back in 2007, however, due to the introduction of a new rule of regulatory construction known as the physician "stand in the shoes" (SITS) rule.[133]

Under the SITS rule, a physician's "physician organization" (e.g., their medical practice) would no longer be recognized as an intervening person. Rather, effective December 4, 2007, a physician would "stand in the shoes" of their medical practice and be deemed to have the same compensation arrangements as their medical practice.[134] The net effect of this change was to transform many potential ICAs into direct compensation arrangements.

Recall, for example, that in Hypothetical No. 4 above, Medical Practice (i) is owned by Physician B, (ii) employs Physician A and (iii) has a contractual arrangement with Lab to pursuant to which Physician A furnishes medical directorship services to Lab. Assume the arrangement has a three-year term running from January 1, 2007 through December 31, 2009. Between January 1 and December 3, 2007 (i.e., the day before the SITS rule took effect), neither Physician A nor Physician B would have a direct financial relationship with Lab.

- Between Physician A and Lab, there would be an unbroken chain of two financial relationships: (i) Physician A's compensation arrangement with Medical Practice (Link 1), and (ii) Medical Practice's compensation arrangement with Lab (Link 2). As such, the Prong Two Compensation Arrangement would be Physician A's employment arrangement with Medical Practice.
- Between Physician B and Lab there would be an unbroken chain of two financial relationships: (i) Physician B's ownership interest in Medical Practice (Link 1), and (ii) Medical Practice's compensation arrangement with Lab (Link 2). As such, the Prong Two Compensation Arrangement would be Medical Practice's compensation arrangement with Lab.

Starting on December 4, 2007, however, both Physician A and Physician B would "stand in the shoes" of Medical Practice and, as such, have a direct compensation arrangement with Lab. This direct compensation arrangement would take the form of the MDA between Medical Practice and Lab.

130 69 Fed. Reg. 16054, 16062 (Mar. 26, 2004).

131 *Id.*

132 72 Fed Reg. 51012, 51087 (Sept. 5, 2007).

133 *Id.* at 51028.

134 *Id.*

The SITS rule caused quite a stir, mobilizing the industry into coordinated action. In the face of industry pushback, CMS began to backtrack. On November 15, 2007, the agency postponed the provisions' effective date by one year with respect to financial relationships between and among persons and entities in academic medical centers and in "Section 501(c)(3) health care systems."[135] Approximately nine months later, the agency acted again, this time to reduce the scope of the SITS provisions in a more material fashion.

E. 2008 Final Rule

In a final rule issued on August 19, 2008, CMS promulgated a new and narrower SITS doctrine. Effective October 1, 2008, the SITS provisions would no longer apply to the physician employees and contractors of a physician organization.[136] Instead, the SITS rule would apply only to the physician-owners of a physician organization.[137] In our above hypothetical then, Physician A, who is employed by Medical Practice, would no longer stand in the shoes of Medical Practice as of October 1, 2008, and, as before December 4, 2007, could only have an indirect compensation arrangement with Lab. Physician B, on the other hand, who has an ownership interest in Medical Practice, would continue to stand in the shoes of Medical Practice and, therefore, continue to have a direct compensation arrangement with Lab.

CMS did "carve out" of the SITS rules certain arrangements pursuant to which a physician had an ownership interest in a physician organization. Recognizing that state corporate practice of medicine statutes have given rise to a variety of physician-ownership models whereby the physicians in question did not have the right or ability to participate in the financial outcomes of the organization, CMS drew a distinction between physicians whose ownership interest in a physician organization "is merely titular in nature"—i.e., "the physician is not able or entitled to receive any of the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment"—and traditional, non-titular owners.[138] A "titular owner" would not be required to stand in the shoes of the physician organization they "owned," but they could elect to do so.

Finally, in addition to excluding physician-employees, physician contractors, and "titular owners" from the purview of the SITS rule, the 2008 rulemaking addressed the so-called "corporate" stand in the shoes doctrine. In July 2007, CMS had proposed that a (parent) entity that owned or controlled a (subsidiary) DHS Entity would stand in the shoes of that (subsidiary) DHS Entity.[139] Consistent with its decision to restrict the scope of the *physician* SITS provisions, in the 2008 rulemaking, CMS took the occasion to explain (in preamble discussion) that it would not be adopting the *corporate* SITS provisions.[140]

F. 2019 Proposed Rule

The 2019 Proposed Rule did not purport to make any material changes to the ICA Definition, except to the extent that it interacted with certain proposed value-based exceptions (a topic that will be addressed in a later white paper). In an effort to increase uniformity in the terms and phrases that appear throughout the Stark Law, however, CMS did propose to remove the term "varies with" from the text of the second prong of the ICA Definition, leaving the inquiry to focus exclusively on whether the aggregate compensation (in the Prong Two Compensation Arrangement) *takes into account* the volume or value of referrals or other business generated by the referring physician for the DHS Entity.[141]

135 72 Fed. Reg. 64161, 64161-62 (Nov. 15, 2007).

136 73 Fed. Reg. 48433, 48752 (Aug. 19, 2008).

137 *Id.*

138 *Id.* at 48693-94.

139 72 Fed. Reg. 38122, 38184 (July 12, 2007).

140 73 Fed. Reg. at 48699.

141 84 Fed. Reg. 55766, 55841-42 (Oct. 17, 2019) (revising definition of indirect compensation arrangement under 42 C.F.R. § 411.354(c)(2)(ii)).

G. 2020 Final Rule

In contrast to the Proposed Rule, the Final Rule undertakes a major overhaul of the ICA Definition—specifically, Prong Two—and its interaction with the Unit-Based Special Rules. Prongs One and Three of the ICA Definition remain unchanged.

1. Retirement of Unit-Based Special Rules

As detailed in White Paper No. 3, in the Final Rule, effective January 19, 2021, without any advance notice to the public (in the 2019 Proposed Rule or otherwise), CMS largely retired the Unit-Based Special Rules. We say "largely" for two reasons. First, the Unit-Based Special Rules still apply (in their pre-Final Rule form) to arrangements as they existed prior to January 19, 2021.[142] Second, and critical to our discussion here, while the Unit-Based Special Rules are no longer applicable to the analysis of whether the Volume/Value Standard is violated with respect to those Stark Law *exceptions* in which the Volume/Value Standard appears, they have become—for the first time—relevant to determining whether an *ICA* exists.

Recall that since 2004, CMS's position has been as follows: (i) the Unit-Based Special Rules may *not* be used under Prong Two of the ICA Definition to determine whether the "aggregate compensation" in the relevant arrangement meets the Volume/Value Standard in the ICA *Definition*; (ii) the Unit Based Special Rules *may* be used, however, to determine whether the "compensation" in the relevant arrangement meets the Volume/Value Standard in the ICA *Exception*.[143] In the Final Rule, CMS reversed course and, as discussed in the next section, essentially embedded the Unit Based Special Rules into Prong Two of the ICA Definition.

2. New Prong Two Test

a. Overview

As has historically been the case, before the New Prong Two Test is applied, the Prong Two Compensation Arrangement—again, the compensation arrangement closest to the referring physician—must be identified.

The Final Rule then requires application and satisfaction of *both parts* of the New Prong Two Test in order for Prong Two of the ICA Definition to be met.

- The first part of the New Prong Two Test requires that the *aggregate* compensation (in the Prong Two Compensation Arrangement) *"varies with"* the volume or value of referrals or other business generated by the referring physician for the DHS Entity.[144] If this first part of the Test is not satisfied, then the inquiry ends, meaning that there is no ICA between the referring physician and the DHS Entity. If the first part of the new Test is satisfied, however, the inquiry proceeds to the second part of the Test.
- The second part of the Test essentially incorporates the various components of the historic Unit-Based Special Rules. Specifically, the second part of the New Prong Two Test is met if the "individual unit of compensation" (in the Prong Two Compensation Arrangement) meets any one of the following three criteria:
  - the individual unit of compensation is "not fair market value for items or services actually provided" (FMV Criterion); or
  - the individual unit of compensation is calculated using a formula that "includes the physician's referrals to the [DHS Entity] as a variable, resulting in an increase or decrease in the physician's [or IFM's] compensation that positively correlates with the number or value of the physician's referrals to the [DHS Entity]" (Referral Criterion); or
  - the individual unit of compensation is calculated using a formula that "includes the physician's other business generated to the [DHS Entity] as a variable, resulting in an increase or decrease in the physician's [or IFM's] compensation that positively correlates with the physician's generation of other business for the [DHS Entity]" (Other Business Generated Criterion).[145]

142 85 Fed. Reg. 77492, 77541 (Dec. 2, 2020).

143 69 Fed. Reg. 16054, 16058-59 (Mar. 26, 2004).

144 85 Fed. Reg. at 77665 (setting forth 42 C.F.R. § 411.354(c)(2)(A)).

145 *Id.* (setting forth a new provision at 42 C.F.R. § 411.354(c)(2)(A)(1)-(3)); *see also id.* at 77546.

b. New Prong Two Test: Part One

As noted above, the first part of the New Prong Two Test requires that the *aggregate* compensation (in the Prong Two Compensation Arrangement) "*varies with*" the volume or value of referrals or other business generated by the referring physician for the DHS Entity.[146] Thus, like the approach taken in the Volume/Value Special Rules (discussed in White Paper No. 3), the first part of the New Prong Two Test opts for an objective (i.e., bright line) mathematical inquiry that asks whether the compensation at issue, when considered in the *aggregate,* goes up or down if either the volume or value of referrals or other business generated increases or decreases.

Hypothetical No. 6. Health System is a nonprofit parent organization that is the sole member of two wholly-controlled, non-profit subsidiaries: a hospital (Hospital) and a physician organization (Physician Organization). Hospital transfers funds to Physician Organization in the ordinary course of business—both directly and through Health System—to help Physician Organization meet its financial obligations, including payroll. Physician Organization enters into an employment arrangement with Physician, pursuant to which Physician furnishes services at, and orders various diagnostic tests and other DHS from, Hospital. Physician Organization compensates Physician $240,000 per year in 24 equal biweekly installments of $10,000 each.

Hypothetical No. 6 gives rise to the following unbroken chain of financial relationships: Hospital → Physician Organization → Physician. For purposes of applying the New Prong Two Test, the Prong Two Compensation Arrangement is the direct compensation arrangement between Physician Organization and Physician in the form of their employment arrangement. The *aggregate* compensation in that compensation arrangement (i.e., $240,000 per year or $20,000 per month) does not satisfy the first part of the New Prong Two Test (and, as a result, Physician and Hospital do not have an ICA). Why? Because Physician's aggregate compensation (i.e., $240,000 per year) does *not* vary with Physician's referrals to or other business generated for Hospital. That is, regardless of whether Physician orders DHS for 150, 50, or no Hospital patients, she will be paid $240,000 each year, provided she remains an employee of Physician Organization.

Hypothetical No. 6 illustrates that a flat fee compensation methodology does not (and, we can safely assert, *cannot*) satisfy part one of the New Prong Two Test. Moreover, because the New Prong Two Test can be satisfied only if *both* parts of the Test are satisfied, the broader takeaway is that fixed, flat fee compensation will not satisfy the ICA Definition.

Hypothetical No. 7. The same facts as Hypothetical No. 6, but in addition to a base salary of $240,000 per year, Physician Organization agrees to pay Physician a bonus of $5 for each clinical diagnostic lab test Physician orders from Hospital's outpatient diagnostic laboratory.

146 *Id.* at 77665 (setting forth 42 C.F.R. § 411.354(c)(2)(A)). The first part of the New Prong Two Test reflects an "about face" on CMS's part with respect to the agency's ongoing efforts to use key terms and phrases throughout the Stark Law in a uniform and consistent manner. As part of that undertaking, the 2019 Proposed Rule called for the deletion of the words "varies with" from the 2001 ICA Volume/Value Standard, leaving the inquiry to focus exclusively on whether the aggregate compensation at issue "takes into account" the volume or value of referrals or other business generated. The Final Rule, however, takes the opposite tact: it deletes the phrase "takes into account" in favor of the phrase "varies with."

In contrast to Hypothetical No. 6, this compensation structure meets the first part of the New Prong Two Test. For the reasons discussed above, the base salary component ($240,000 per year) is not the issue. Here, however, Physician's *aggregate* compensation also includes a unit-based component (i.e., $5 per lab test) that *varies with* (i.e., is positively correlated to) the volume of Physician's referrals of DHS (i.e., the number of clinical lab tests ordered by Physician for Medicare patients) and the volume of other business generated by Physician (i.e., the number of clinical lab tests ordered by Physician for non-Medicare patients). Simply stated, every time Physician orders a clinical lab test from Hospital's outpatient laboratory, her aggregate compensation increases by $5.

c. New Prong Two Test: Part Two

Historically (meaning *before* January 19, 2021), the facts of Hypothetical No. 7 were sufficient to support the following conclusions:

- Prong Two of the ICA Definition was satisfied (i.e., the aggregate compensation in the parties' employment relationship "varies with or takes into account" the volume of Physician's referrals to and other business generated for Hospital).
- Prong Three of ICA Definition likely was satisfied (i.e., it would not be difficult to establish that Hospital knew, or should have known, that its affiliate (Physician Organization) was paying Physician aggregate compensation that "varies with or takes into account" the volume of Physician's referrals to and other business generated for Hospital.

Having determined the existence of an ICA between Physician and Hospital, the analysis would turn to whether the Unit-Based Special Rules[147] could be applied to determine whether the compensation exchanged under the Prong Two Compensation Arrangement satisfies the Volume/Value Standard in the ICA Exception.[148]

As noted above, although the Final Rule retires the Unit-Based Special Rules with respect to analyzing the Volume/Value Standard in Stark Law exceptions, it expressly (and for the first time) incorporates the elements of the Unit-Based Special Rules into the second part of the New Prong Two Test. CMS's stated objective for this is to exclude from the ICA Definition unit-based compensation arrangements that would have satisfied the Unit-Based Special Rules under the regulations that existed prior to January 19, 2021.

Specifically, part two of the New Prong Two Test requires that the "unit of compensation" (in the Prong Two Compensation Arrangement) meets at least one of the three criteria enumerated above.[149] Because the unit of compensation at issue in Hypothetical No. 7 ($5 per lab order) does not change during the course of the parties' arrangement—for example it does not decrease to $4 or increase to $6—pursuant to a formula that includes Physician's referrals to or other business generated for Hospital as a variable, the Referral Criterion and Other Business Generated Criterion of part two of the New Prong Two Test arguably are not met. Thus, the only remaining way to establish that the compensation arrangement meets the requirements of the New Prong Two Test is pursuant to the FMV Criterion, which will be met only if the "unit of compensation" at issue—again, $5 per lab test—"is not fair market value for items or services actually provided."[150]

As noted in White Paper No. 1, CMS has revised the definition of "referral" in the Final Rule to make it clear that a "referral" itself is not an "item or service" for Stark Law purposes.[151] When Physician in our hypothetical is paid $5, however, it is for ordering DHS from Hospital—i.e., "referring" a patient to the Hospital for DHS—and not for undertaking any *other* activities (or providing any other "items or services"). But because "referrals" are not "items or services," the unit of compensation at issue here ($5) cannot be "fair market value" for "items or services actually provided" and, as a result, the FMV Criterion of part two of the New Prong Two Test arguably is satisfied.

147 42 C.F.R. § 411.354(d)(2)-(3).

148 *Id.* § 411.357(p)(1)(i).

149 *Id.* § 411.354(c)(2)(ii)(A)(1)-(3).

150 *Id.* § 411.354(c)(2)(ii)(A)(1).

151 *Id.* § 411.351 (definition of "referral"). In the preamble to the 2019 Proposed Rule, CMS reiterated that "a physician's referrals are not items or services for which payment may be made under the physician self-referral law, and that neither the existing exceptions to the physician self-referral law nor the proposed exceptions in this proposed rule would protect such payments." 84 Fed. Reg. 55790, 55806 (Oct. 17, 2019).

Hypothetical No. 8. Same facts as Hypothetical No. 7, except that Physician Organization pays Physician a bonus of "$5 per lab test ordered from Hospital's outpatient diagnostic laboratory, provided that the lab test is not reimbursed, in whole or in part, by Medicare."

It is unclear whether the conclusion with respect to Hypothetical No. 7 would be the same if the terms of Physician's bonus were limited to $5 for each lab test ordered from Hospital's outpatient diagnostic laboratory that is not reimbursed, in whole or in part, by Medicare. Under these circumstances, Physician would be compensated solely for "other business generated," and CMS has not addressed whether "other business generated" qualifies as an "item or service" for Stark Law purposes. Presumably, CMS would take the position that the same principles apply[152]—and thus the arrangement satisfies the FMV Criterion of the second part of the New Prong Two Test, but whether a federal court would agree is less clear.

Hypothetical No. 9 below further highlights some of the confusion resulting from the agency's decision to (i) retire the Unit-Based Special Rules for purpose of the Stark Law's exceptions and (ii) embed the Unit-Based Special Rules in the ICA Definition—all in the absence of any public notice-and-comment period. CMS clearly believes that the latter change "will reduce the number of unbroken chains of financial relationships that fall within the ambit of the physician self-referral law."[153] According to the agency, "by analyzing unit-based compensation at the definitional stage"—i.e., when determining whether there is an ICA in the first instance—"many unbroken chains of financial relationships will no longer be required" to meet the requirements of the ICA Exception.[154] CMS's optimism may prove to be misplaced.

Hypothetical No. 9. Hospital enters into a services arrangement with Lithotripsy Company that is owned by Physician (a urologist). Physician is on Hospital's medical staff and routinely refers Medicare and other patients to Hospital for items and services (including but not limited to lithotripsy). The parties' arrangement is memorialized in a signed, written agreement. Under the agreement, Lithotripsy Company provides Hospital with a bundle of items and services (including access to and use of a lithotripsy machine and the services of a technician who operates the machine) in return for a per-use fee of $2,400. Hospital, in turn, schedules and registers patients, prepares them for the procedure, and bills payors, including Medicare, for the service. Hospital and Lithotripsy Company engage the services of an independent valuation consultant who confirms that the arrangement is commercially reasonable and the unit-based fee is consistent with fair market value.

152 85 Fed. Reg. 77492, 77573 (Dec. 2, 2020) (citing the Phase II Regulations for the proposition that "a [DHS Entity] is not permitted to pay a physician for the benefit of receiving the physician's referrals, [because] such payments are antithetical to the premise of the statute").

153 *Id.* at 77546.

154 *Id.*

Historically (i.e., prior to the Final Rule), the arrangement would give rise to an ICA between Physician (the owner of Lithotripsy Company) and Hospital. In a nutshell:

- Prong One. There is an unbroken chain of financial relationships between Physician and Hospital: Hospital → Lithotripsy Company (Link One) and Lithotripsy Company → Physician (Link Two). (Because Lithotripsy Company is not a physician organization, Physician does not stand in its shoes.)
- Prong Two. Because the financial relationship closest to Physician is her ownership interest in Lithotripsy Company, the services arrangement between Hospital and Lithotripsy Company is the Prong Two Compensation Arrangement. Under that arrangement, the aggregate compensation ($2,400 per procedure) varies with the volume of other business generated by Physician for Hospital. Why other business generated only? Because lithotripsy is not DHS, so Physician's orders for lithotripsy are not referrals. Such orders are other business generated, however, and each time Physician orders a lithotripsy procedure at Hospital, Lithotripsy Company receives $2,400.
- Prong Three. As a party to the lithotripsy services arrangement, Hospital likely knows or should know that the aggregate compensation under the Prong Two Compensation Arrangement varies with Physician's orders for lithotripsy procedures to be performed at Hospital.

Having established that Physician has an ICA with Hospital, the Stark Law's referral and billing prohibitions would attach unless an exception applies. The most obvious exception would be the ICA Exception.[155] The ICA Exception has multiple requirements, including that the compensation exchanged pursuant to the Prong Two Compensation Arrangement is (i) consistent with fair market value and (ii) not determined in a manner that takes into account the volume or value of Physician's referrals or other business generated to Hospital. The first requirement would be addressed through the independent fair market value study commissioned by the parties; the second requirement would be addressed by relying on the Unit-Based Special Rules. The latter would appear to apply because the unit-based compensation ($2,400 per procedure) is consistent with fair market value and does not vary during the term of the arrangement. Exercise over; problem solved: Physician and Hospital have an ICA, but that ICA meets the requirements of the ICA Exception.

But, how does this common contractual arrangement fare in the aftermath of the Final Rule? The Unit-Based Special Rules have been retired for purposes of the ICA Exception, so we know that if Physician and Hospital have an ICA, the Stark Law will be implicated whenever Physician refers a Medicare patient to Hospital for the furnishing of DHS. This brings us to the new ICA Definition. As a threshold matter, the analysis under Prongs One and Three of the ICA Definition remain unchanged; here (i) there is an unbroken chain of financial relationships between Physician and Hospital, and (ii) Hospital knows or should know that its compensation to Lithotripsy Company varies based on the volume of other business generated by Physician to Hospital. Accordingly, whether there is an ICA between Physician and Hospital depends entirely on the outcome of the New Prong Two Test.

Part one of the New Prong Two Test is satisfied because (as shown above) Lithotripsy Company's *aggregate* compensation *varies with* (i.e., positively correlates with) each order by Physician that a patient undergo a lithotripsy procedure at Hospital (which is other business generated). Part two of the New Prong Two Test focuses on the *unit of compensation*—i.e., $2,400 per procedure. Because this unit of compensation does not change during the course of the parties' arrangement—for example it does not decrease to $2,300 or increase to $2,500—pursuant to a formula that includes Physician's referrals or other business to Hospital as a variable, the Referral and Other Business Generated Criteria of part two of the New Prong Two Test arguably are not met. The only way that the second part of the Test can bet met, then, is if the "unit of compensation" ($2,400) is "not at fair market value for items and services actually provided."

On the one hand, the answer would appear to be that the unit of compensation *is* at FMV and, as such, that (i) part two of the New Prong Two Test is *not* met, and (ii) as a result, there is *not* an ICA between Physician and Hospital. As a threshold matter, in our hypothetical, an independent valuator concluded that

155 42 C.F.R. § 411.357(p).

$2,400 is FMV for the bundle of items and services furnished by Lithotripsy Company. Moreover, as a practical matter, lithotripsy arrangements of the type described in Hypothetical No. 9 are ubiquitous in the health care industry. As such, if CMS intended for such arrangements to create an ICA between Physician and Hospital (under the new ICA Definition), which ICA could no longer qualify for protection under the ICA Exception (in whole or in part because the Unit-Based Special Rules no longer apply), we would have expected the agency to clearly and pointedly announce this new position.

On the other hand, as noted above, CMS has taken the position that since "referrals" are not "items or services," no payment for "referrals" can—as the FMV Criterion of part two of the New Prong Two Test requires—be "fair market value for items or services actually provided." But if that's the case, and CMS ultimately takes the position that the same rule applies with respect to "other business generated," could it then be argued that the $2,400 per unit payment in Hypothetical No. 9 would not meet the FMV Criterion and as such would create an ICA between Physician and Hospital? Or is Hypothetical No. 9 distinguishable from, say Hypothetical No. 8 (involving $5 payments for each lab test ordered from Hospital's outpatient diagnostic laboratory, provided that the lab test is not reimbursed, in whole or in part, by Medicare), on the ground that the payment under Hypothetical No. 9 is being make in exchange for a bundle of items or services, whereas the payment under Hypothetical No. 8 is being made in exchange for nothing other than a "naked" order for DHS?

While we do not have any immediate answers or solutions to these genuinely hard questions, they do (once again) suggest that CMS's overhaul of the ICA Definition and the Unit-Based Special Rules without the benefit of a public notice-and-comment period may result in any number of unintended consequences.

d. Other Open Questions

As noted above, CMS touts its new approach to the Volume/Value Standard both in general and as it applies in the ICA context—for the "certainty" it affords the industry.[156] Such certainty, the agency states, "is critical to reduce the burden associated with compliance with the [Stark Law's] volume or value and other business generated standards."[157] To be fair, however, a good bit of uncertainty remains. In addition to the examples discussed above, we offer another example of such uncertainty.

156 85 Fed. Reg. at 77540.

157 *Id.*

Hypothetical No. 10. As under Hypothetical No. 6, Health System is a non-profit parent organization that is the sole member of two wholly-controlled, non-profit subsidiaries: a hospital (Hospital) and a physician organization (Physician Organization). Hospital transfers funds to Physician Organization in the ordinary course of business both directly and through Health System to help Physician Organization meet its financial obligations, including payroll. Physician Organization enters into an employment arrangement with Physician, pursuant to which Physician furnishes services at, and orders various diagnostic tests and other DHS from, Hospital. Physician Organization compensates Physician $240,000 per year in 24 equal bi-weekly installments of $10,000 each.

In an effort to enhance coordination of care (and hopefully profitability as well), Health System introduces a new annual bonus for all Health System employees, including Physician. Under the terms of the bonus, every employee will receive a bonus in an amount equal to (i) 2 percent of their annual base salary if Health System increases its year-over-year gross revenue by more than 5 percent, and (ii) 4 percent of their annual base salary if Health System increases its year-over-year gross revenue by more than 10 percent. Thus, Physician is certain to earn $240,000, but she may receive an additional bonus of $4,800 or $9,600 if Health System's gross revenue increases by the requisite percentages.

We assume that Prongs One and Three of the ICA Definition are satisfied under Hypothetical No. 10. With respect Prong Two, under part one of the New Prong Two Test, the question is whether, due to the existence of the system-wide bonus plan, Physician's aggregate compensation can be said to "vary with" the volume or value of Physician's referrals (or other business generated) to Hospital. This, in turn, requires us to determine whether the aggregate compensation includes Physician's referrals (or other business generated) to Hospital as a variable, resulting in an increase or decrease in Physician's compensation that positively correlates with the number or value of Physician's referrals (or other business generated) to Hospital.

On the one hand, it could be argued that the answer is "no." As a mathematical matter, it is possible that the gross revenue targets will be met and, as a result, Physician will paid aggregate compensation in the amount of $244,800 or $249,600 for the year in question *even if Physician does not make a single referral to (or generate any other business for) Hospital*. In other words, Physician's referrals/other business generated are *not* conditions precedent to receiving the bonus at issue. While there *may* be a positive correlation between the number or value of Physician's referrals or other business generated and her aggregate compensation, there will not *necessarily* be such a positive correlation.

On the other hand, it could be argued that the answer is "yes." If we set out Physician's opportunity to earn the system-wide bonus in mathematical terms, the volume or value of Physician's referrals to or other business generated for Hospital certainly are variables. The opportunity to earn the 2 percent bonus, for example, would be expressed mathematically as follows:

- $4,800 (.02 x $240,000) if the sum of A and B (A + B) is more than 5 percent greater than C, where the following is true:
    - A = the sum of all collections resulting from [Physician's personally performed services] + [Physician's referrals to Physician Organization and Hospital] + [Physician's other business generated for Physician Organization and Hospital].
    - B = the sum of all collections resulting from [the personally performed services of all of the other physicians and mid-level practitioners in Health System] + [the referrals to Physician Organization and Hospital by all of the other physicians and mid-level practitioners in Health System] + [the other business generated for Physician Organization and Hospital by all of the other physicians and mid-level practitioners in Health System].
    - C = the sum of [Physician Organization's gross revenue in the prior year] + [Hospital's gross revenue in the prior year].

(Of course, even assuming Physician's opportunity to earn the system-wide bonus did satisfy part one of the New Prong Two Test, the arrangement still might not give rise to an ICA following analysis of the arrangement under part two of that Test.)

In the preamble to the Final Rule, CMS, in response to a question regarding a hypothetical involving a similar incentive compensation structure—albeit in the context of direct compensation arrangements[158]—offers a perplexing answer. On the one hand, the agency agrees that it is "preferable" for the agency to identify for stakeholders "the universe of circumstances in which we believe compensation is determined in a manner that takes into account the volume or value of a physician's referrals or other business generated by the physician."[159] On the other hand, instead of analyzing the bonus plan raised by the commenter, CMS simply says that "outcomes based bonuses," such as that described by the commenter, "could" offend the Volume/Value Standard "depending on how they are structured."[160] In the end, the agency states, this is a determination that "must be made on a case-by-case basis."[161] That is certainly true, but why not analyze the commenter's hypothetical? Would that not have been *preferable*?

158 *Id.* at 77541.

159 *Id.* at 77542.

160 *Id.*

161 *Id.*

IV. Conclusion

As was the case in our earlier white papers, this white paper reflects a recurring theme. On the one hand, the Final Rule (i) unpacks and clarifies a number of the Stark Law's central components, making the analysis of arrangements under the Stark Law more straightforward, and (ii) generally speaking, CMS has made compliance with the Stark Law easier by shrinking the universe of arrangements that either don't result in a financial relationship in the first instance or that will qualify for protection under one or more Stark Law exceptions. On the other hand, the Final Rule—by moving so many pieces on the chess board at the same time and, in some cases, without sufficient vetting—has, at least in a few instances, simply replaced one conundrum with another. But that, of course, is precisely what future rulemakings are made for.

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April 15	12:30-1:45 pm ET	Key Standards (Part I): Distinguishing and Defining the 'Volume or Value' Requirement
April 29	12:30-1:45 pm ET	Key Standards (Part II): 'Fair Market Value' and 'Commercial Reasonableness' Standards, and Indirect Compensation Arrangements
May 13	12:30-1:45 pm ET	New Wine in Old Bottles: Providing Greater Flexibility Under Existing Exceptions
May 27	12:30-1:45 pm ET	What's Past is Prologue: Technology Subsidies Part Deux
June 10	12:30-1:45 pm ET	The Problem of the Square Peg and the Round Hole: When FFS and Managed Care Collide

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