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Stark Law Overhaul:
An In-Depth Review of CMS's New Final Rule

White Paper No. 3
Key Standards (Part I):
The "Volume or Value" Standard

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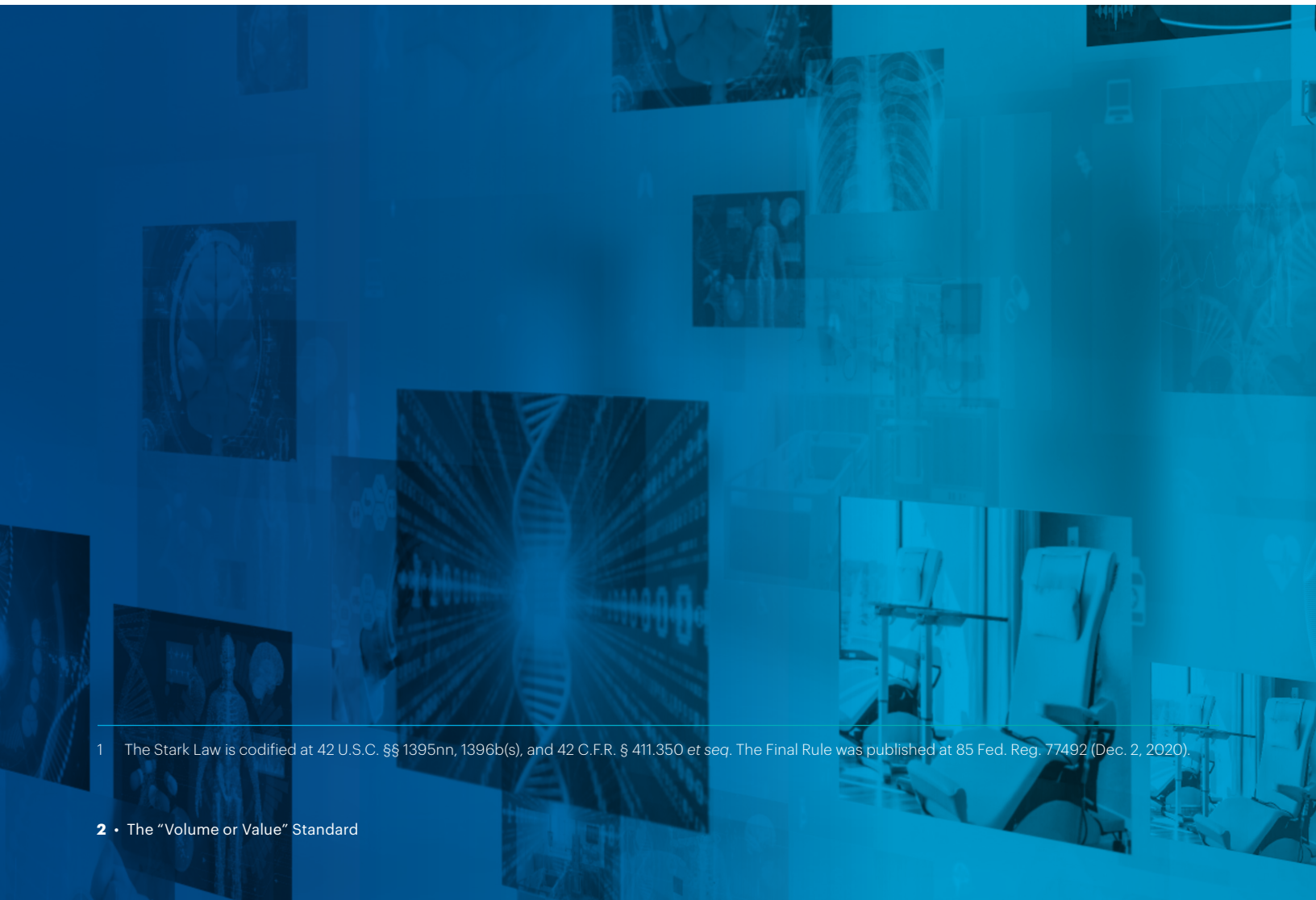
In December 2020, the Centers for Medicare & Medicaid Services (CMS) finalized its long-awaited changes to the agency's regulations governing the federal physician self-referral law, commonly known as the Stark Law (Final Rule).[1] The Final Rule represents the most significant Stark Law rulemaking in 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 third of these white papers, covering what is arguably the Stark Law's key substantive requirement, the so-called "volume or value" standard (Volume/Value Standard).



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. Introduction

The Volume/Value Standard is perhaps the most ubiquitous and challenging of the Stark Law's substantive requirements. Subject to a few important variations—discussed in detail below—the Volume/Value Standard generally asks the following question: Does the compensation provided for under the arrangement at issue take into account the volume or value of the physician's referrals to, or other business generated for, the entity that furnishes the designated health services (DHS Entity)?

In many cases, this question is easily answered. If, for example, an independent diagnostic testing facility (IDTF) offers a physician $25 for each Medicare beneficiary the physician refers to the IDTF for a diagnostic imaging study, this arrangement plainly provides for compensation that "takes into account" the "volume or value" of the physician's "referrals" to the IDTF.[2] However, in a surprising number of cases—many of which are discussed in this white paper—whether the arrangement at issue implicates the Volume/Value Standard is a more complicated question and a much closer call.

In the Final Rule, CMS discusses the Volume/Value Standard chronologically, tracing its evolution—including its multiple roles and formulations—over time. While Lewis Carroll is correct—the best way to tell a story is, in most cases, to start at the beginning—there are exceptions to every rule, and this is one of them. So while we offer a synopsis of the history of the Volume/Value Standard in Section III, we begin with what we believe is a more "user-friendly" organizational structure, which approaches the Volume/Value Standard in a conceptual (rather than chronological) fashion.

2 Radiology and certain other imaging services (e.g., magnetic resonance imaging) is a category of DHS. 42 U.S.C. § 1395nn(h)(6)(D), 42 C.F.R. § 411.351 (definition of "designated health services"). The Stark Law provides that, as a general rule, a "referral" occurs whenever a physician requests, orders, certifies (or recertifies) the need for, or establishes a plan of care involving, DHS. 42 U.S.C. § 1395nn(h)(5); 42 C.F.R. § 411.351 (definition of "referral").

II. Principal Functions

The Volume/Value Standard plays several different roles under the Stark Law, each of which is summarized below.

A. Indirect Compensation Arrangements

As an initial matter, the Volume/Value Standard is included in the definition of an "indirect compensation arrangement" (ICA), which is one of the four types of "financial relationships" under the Stark Law. Since 2001, the definition of an ICA (ICA Definition) has had three conditions or "prongs," each of which must be satisfied in order for a physician to have a financial relationship with a DHS Entity in the form of an ICA.[3] The first condition is straightforward: There must be an "unbroken chain" of two or more financial relationships between the physician and DHS Entity.[4] The second condition includes the Volume/Value Standard, although its wording has changed over time. Originally, the second prong of the ICA Definition would be met if the "aggregate compensation" provided for in the arrangement closest to the referring physician "varies with, or otherwise reflects" the volume or value of the physician's referrals to, or other business generated for, the DHS Entity. In 2007, CMS changed "otherwise reflects" to "takes into account."[5]

Thus, prior to the effective date of the Final Rule, the second prong of the ICA Definition would be met if the "aggregate compensation" in the relevant arrangement "varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS." For purposes of this white paper, we will refer to the formulation of the Volume/Value Standard set forth in prong two of the ICA Definition as the "ICA Volume/Value Standard."

B. Compensation Arrangement Exceptions

The Volume/Value Standard also features prominently in over 20 Stark Law exceptions for compensation arrangements, including the exceptions covering the rental of office space,[6] the rental of equipment,[7] bona fide employment relationships[8] and personal service arrangements.[9] The regulatory exception covering the rental of office space, for example, requires that "[t]he rental charges over the term of the lease arrangement are not determined . . . [i]n any manner that takes into account the volume or value of referrals or other business generated between the parties."[10]

3 66 Fed. Reg. 856, 958-959 (Jan. 4, 2001) (setting forth 42 C.F.R. § 411.354(c)(2)).

4 The first prong of the ICA Definition requires the following: "Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS *there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships . . . between them* (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link.)" 42 C.F.R. § 411.354(c)(2)(i) (emphasis added).

5 42 C.F.R. § 411.354(c)(2)(ii) as set forth in 72 Fed. Reg. 51012, 51027, 51087 (Sept. 5, 2007).

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

7 42 U.S.C. § 1395nn(e)(1)(B); 42 C.F.R. § 411.357(b).

8 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c).

9 42 U.S.C. § 1395nn(e)(3); 42 C.F.R. § 411.357(d). The Volume/Value Standard also can be found in the exceptions for (i) physician recruitment, 42 U.S.C. § 1395nn(e)(5) and 42 C.F.R. § 411.357(e); (ii) isolated transactions, 42 U.S.C. § 1395nn(e)(6) and 42 C.F.R. § 411.357(f); (iii) certain arrangements with hospitals that are unrelated to DHS, 42 U.S.C. § 1395nn(e)(4) and 42 C.F.R. § 411.357(g); (iv) 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); (v) charitable donations by a physician, 42 C.F.R. § 411.357(j); (vi) non-monetary compensation, *id.* § 411.357(k); (vii) fair market value compensation, *id.* § 411.357(l); (viii) medical staff incidental benefits, *id.* § 411.357(m); (ix) indirect compensation arrangements, *id.* § 411.357(p); (x) professional courtesies, *id.* § 411.357(s); (xi) retention payments in underserved areas, *id.* § 411.357(t); (xii) community-wide health information systems, *id.* § 411.357(u); (xiii) electronic prescribing items and services, *id.* § 411.357(v); (xiv) electronic health records items and services, *id.* § 411.357(w); (xv) assistance to compensate a nonphysician practitioner, *id.* § 411.357(x); (xvi) time-share arrangements, *id.* § 411.357(y); (vxii) the (new) exception for limited remuneration to a physician, *id.* § 411.357(z); and (xviii) the (new) exception for cybersecurity and related technology, *id.* § 411.357(bb).

10 42 C.F.R. § 411.357(a)(5).

While the various exceptions are fairly consistent in articulating the Volume/Value Standard, there are variations on the theme. In some instances, for example, the exception will use the term "anticipated referrals" instead of simply "referrals." Further, while some exceptions focus on referrals or other business generated "by the referring physician," others focus on referrals or other business generated "between the parties." Finally, one exception—for bona fide employment relationships—excludes the "other business generated" condition from its Volume/Value Standard.[11] For purposes of this white paper, and except as otherwise noted, we will refer to these various formulations of the Volume/Value Standard in the Stark Law's compensation arrangement exceptions, collectively, as the "Exception Volume/Value Standard."

C. Unit-Based Special Rules

In addition to being relevant for determining (i) whether a physician and DHS Entity have a financial relationship in the form of an ICA and (ii) whether the requirements of over 20 different compensation arrangement exceptions can be met, the Volume/Value Standard also has figured prominently in what commonly are known as the "unit-based special rules on compensation" (Unit-Based Special Rules). These Special Rules were introduced in 2001 to serve, in essence, as "safe harbors," protecting compensation methodologies that might otherwise be deemed to implicate or violate the Volume/Value Standard.

Specifically, the Unit-Based Special Rules—one for "referrals" and one for "other business generated"—provided that certain types of unit-based compensation (e.g., $150 per hour) would be deemed not to run afoul of the Exception Volume/Value Standard, provided certain conditions were met. The Special Rule covering referrals, for example, provided that "[u]nit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account the 'volume or value of referrals'" if the compensation (i) "is fair market value for items or services actually provided" and (ii) "does not vary during the course of the compensation arrangement in any manner that takes into account referrals of designated health services."[12] For purposes of this white paper, we will refer to this application of the Volume/Value Standard as the "Unit-Based Volume/Value Standard."

11 Unlike the Volume/Value Standard in other Stark Law exceptions, the statutory and regulatory exception for bona fide employment relationships is silent with respect to "other business generated." The regulatory exception, for example, requires that the amount of the employee's compensation "is not determined in any manner that takes into account the volume or value of [their] referrals." *Id.* § 411.357(c)(2)(ii).

12 42 C.F.R. § 411.354(d)(2) as set forth in 72 Fed. Reg. 51012, 51087-88 (Sept. 5, 2007).

D. Group Practices

Finally, a form of the Volume/Value Standard also appears in the statutory[13] and regulatory[14] provisions that govern how a "group practice" may compensate its physicians. Although group practices have more flexibility than most other DHS Entities when it comes to compensating their physician-members, they still are bound by yet another permutation of the Volume/Value Standard. Specifically, members of a group practice may receive a share of overall profits or a productivity bonus provided that they are not determined in a manner that is "directly" related to the volume or value of the member's referrals. Further, for all other forms of compensation, the member may not "directly or indirectly" receive compensation based on the volume or value of the member's referrals. For purposes of this white paper, we will refer to this final variation of the Volume/Value Standard as the "Group Practice Volume/Value Standard."

* * *

Given the various functions served by the Volume/Value Standard, it was perhaps inevitable that it would be subject to multiple, and at times conflicting, interpretations.[15] Several factors have exacerbated matters. First, as noted above, the statute itself can't decide whether the Volume/Value Standard should incorporate the terms "referrals," "anticipated referrals," "other business generated," "directly," "indirectly," and so on. Second, as explained in the chronology below, CMS has been unable to live with its own decisions regarding the Standard, leading to an inordinate number of additions, deletions, adjustments and revisions to the Standard over the past 25 years. Finally, the courts have been both subject to and the source of considerable confusion regarding the Volume/Value Standard. On occasion, the courts have been (i) confused as to which version of the regulations to apply,[16] and (ii) willing to disregard CMS's position with respect to the meaning and scope of the Volume/Value Standard[17]—and, as a result, the Standard has been at the epicenter of some of the most notorious federal civil False Claims Act cases predicated on alleged Stark Law violations.[18]

13 42 U.S.C. § 1395nn(h)(4).

14 42 C.F.R. § 411.352.

15 *See* 85 Fed. Reg. 77492, 77539 (Dec. 2, 2020).

16 *See, e.g., United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88 (3d Cir. 2009) (erroneously analyzing a services arrangement between a physician organization and a hospital from 2001 through 2006 as a direct compensation arrangement between the physician-owners of the physician organization and the hospital, even though the Stark Law "stand in the shoes" provisions were not effective until December 4, 2007, and had prospective application only).

17 *See United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 380 n.10 (4th Cir. 2015).

18 *See Tuomey*, 792 F.3d 364; *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No. 6:09-cv-1002, 2013 WL 6017329 (M.D. Fla. Nov. 13, 2013).

III. Chronology

In addition to appreciating the Volume/Value Standard's four principal functions, understanding the evolution of the Standard, and CMS's interpretation thereof, provides important context for the significant changes CMS has made to the Volume/Value Standard in the Final Rule. As reflected in the chronology below, CMS historically has focused principally on what *does not* (rather than on what *does*) take into account the volume or value or referrals or other business generated—e.g., personally performed services, unit-based compensation, required referrals. That, together with the other actions noted above, have sown considerable uncertainty among physicians and DHS Entities as to whether their compensation arrangements violate the Volume/Value Standard—and underscore why the changes made by the Final Rule to the Standard represent such a dramatic shift.

A. 1998: Stark II Proposed Regulations

In the preamble to the 1998 Stark II Proposed Regulations, CMS's predecessor, the Health Care Finance Administration (HCFA), addressed the Volume/Value Standard principally in its discussion of the definition of a "group practice" and, more specifically, the criteria physicians must meet to qualify as a "group practice."[19] The agency emphasized, however, that its analysis would apply to the Volume/Value Standard more generally (i.e., as it appeared throughout the proposed regulations).[20] According to HCFA, in order to qualify as a bona fide group practice, the physicians in the practice could not be paid for each referral they made or based on the volume or value of their referred services.[21] The easiest way for group practices to comply with this prohibition, the agency stated, is to "avoid a link between physician compensation and the volume or value of any referrals."[22]

B. 2001: Stark II Phase I Regulations

HCFA finalized its (initial) interpretation of the Volume/Value Standard in the 2001 Stark II Phase I Regulations, establishing several fundamental concepts in the process.

1. ICA Definition

HCFA finalized its formal, three-part ICA Definition, the second prong of which includes the ICA Volume/Value Standard. The Standard focused on whether the "aggregate compensation" received under the relevant arrangement (i.e., the compensation arrangement closest to the referring physician) "varies with or otherwise reflects" the volume or value of the physician's referrals to or other business generated for the DHS Entity at issue.[23] (As noted above, the wording of the ICA Volume/Value Standard was modified in 2007.)

2. Unit-Based Special Rules

The agency also introduced and codified the two Unit-Based Special Rules, which (as noted above) incorporate the Unit-Based Volume/Value Standard. As referenced above, these Special Rules were intended to serve as safe harbors, protecting unit-based compensation even where it was tied to the volume or value of a physician's referrals or other business generated, provided the *unit of compensation* was fair market value for the items or services actually provided and did not vary during the course of the compensation arrangement in any manner that took into account referrals of DHS or other business generated.[24]

19 63 Fed. Reg. 1659, 1690 (Jan. 9, 1998).

20 *Id.* at 1699-1700.

21 *Id.* at 1690.

22 *Id.*

23 66 Fed. Reg. 856, 958 (Jan. 4, 2001) (promulgating 42 C.F.R. § 411.354(c)(2)).

24 *Id.* at 876-877.

For example, assume a hospital entered into an agreement with a physician pursuant to which the hospital paid the physician $250 per hour for Service A. Even if that compensation might *otherwise* be said to take into account the volume or value of referrals or other business generated by the physician for the hospital, pursuant to the Unit-Based Special Rules, this would *not* be the case—that is, the Volume/Value Standard of the Stark Law exception at issue *would* be satisfied—if (i) $250 per hour was fair market value for Service A and (ii) the parties did not change the compensation rate during the course of the arrangement in any manner that took into account the physician's referrals of DHS to or other business generated for the hospital.

In sum, provided that the Unit-Based Special Rules were available and that the compensation at issue complied with those Special Rules, parties could be confident that their compensation arrangement did *not* violate the Volume/Value Standard. Of course, a key question was *when* parties could rely upon the Unit-Based Special Rules. Although HCFA discussed the Unit-Based Special Rules in the context of the Exception Volume/Value Standard,[25] the agency emphasized that its interpretation "applies to the [S]tandard *wherever* it appears in the statute and regulations."[26] (As discussed below, the agency walked back this position, at least in certain respects, just three years later.)

3. Required Referrals

Next, HCFA recognized that a common practice for employers and managed care organizations was (and remains) to require physicians to make referrals to specific providers. For example, a medical practice specializing in orthopedics might require its employed physicians to refer patients needing physical therapy services (a type of DHS) to the medical practice's physical therapy division. To accommodate this common practice, HCFA created a special rule to protect arrangements pursuant to which a physician was required to refer patients to a particular provider as a condition of payment, as long as certain safeguards were implemented. These safeguards prohibited application of the referral requirement if, for example, the patient expressed a preference for a different provider or the physician concluded that the referral would not be in the patient's best medical interests.[27] For purposes of this white paper, we will refer to this as the "Required Referrals Special Rule."

In the 2001 rulemaking, HCFA made it clear that as long as the requirements of the Required Referrals Special Rule were met, it would not consider compensation conditioned on referrals to implicate the Volume/Value Standard.[28] On the other hand, where compensation was conditioned on referrals and the requirements of the Special Rule were not met, the arrangement would (i) violate the Exception Volume/Value Standard and (ii) satisfy the second condition of the ICA Definition.[29]

25 *See id.* at 876-878.

26 *Id.* at 879. (emphasis added).

27 *Id.* at 877.

28 *Id.*

29 *Id.* at 866, 876.

4. Personally Performed Services Rule

As illustrated above, all versions of the Volume/Value Standard consider the relationship between the compensation at issue and the volume or value of "referrals." In 2001, HCFA defined the term "referral" in a manner that expressly carved out DHS that was "personally performed or provided by the referring physician."[30] Thus, where a physician's compensation was tied solely to their personally performed professional services—e.g., where a physician was paid a certain dollar amount for each worked relative value unit (wRVU) they generated—that arrangement would not be said to "vary with" or "take into account" the volume or value of "referrals." For purposes of this white paper, we will refer to this as the "Personally Performed Services Rule." (Although it would do so later, in 2001 HCFA neglected to address the relationship between personally performed services and "other business generated," which phrase is included in the ICA, Exception and Unit-Based Volume/Value Standards.)

5. Dual PC/TC Rule

In 2001, HCFA also tackled the fairly common scenario where there is a positive correlation between a physician's *personally* performed professional services and the ordering of DHS that will be performed by someone *other* than the physician, at least "in the context of inpatient and outpatient hospital services."[31] The agency confirmed that pursuant to the Personally Performed Services Rule, when a physician "initiates" and "personally performs" a professional service in a hospital setting (i.e., DHS), the physician will not be deemed to have made a "referral" with respect to the professional component (PC) of the service.[32]

The agency also acknowledged, however, that "there would still be a referral of any . . . technical component. . . or facility fee billed by the hospital in connection with the personally performed service" (and hence a referral of DHS).[33] Thus, for example, in the case of an inpatient surgery, there would be a referral of the technical component (TC) of the surgical service (i.e., DHS), even though the referring physician personally performs the surgery. For purposes of this white paper, we will refer to this as the "Dual PC/TC Rule." Due to the Dual PC/TC Rule, if the referring physician has a financial relationship with the hospital, that relationship must fit into a Stark Law exception;[34] otherwise, the physician's referral of the technical component of the service will give rise to a Stark Law violation.

6. Direct Correlation

Finally, in the preamble to the Phase I Regulations, HCFA expressed its belief that, at least with respect to the Group Practice Volume/Value Standard, "a compensation structure does not directly take into account the volume or value of referrals if there is no direct correlation between the total amount of a physician's compensation and the volume or value of the physician's DHS referrals."[35] The need for a *direct correlation* is important because it would be cited by CMS 20 years later when explaining (in the preamble to the Final Rule) its rationale for developing and codifying a new, objective definition of the Volume/Value Standard.[36]

C. 2004: Stark II Phase II Regulations

CMS revisited the Volume/Value Standard in the preamble to the 2004 Stark II Phase II Regulations, elaborating on and clarifying its still-evolving interpretation of the Standard.

30 42 C.F.R. § 411.351 (definition of "referral"). HCFA confirmed this elsewhere in the preamble to the Phase I Regulations. *See, e.g.*, 66 Fed. Reg. at 871 ("We are persuaded by the commenters that a physician does not make a 'request,' in the ordinary sense of that term, if he or she personally performs a designated health service. We agree it does not make sense to consider work that a referring physician initiates and personally performs as a referral to an entity. Thus, we are amending our definition of 'referral' to exclude services that are personally performed by the referring physician (that is, the referring physician physically performs the service)."); *id.* at 872 ("If the DHS are personally performed by the physician who established the plan of care, there would be no referral as to those personally performed services."); *id* at 879 ("[P]ersonally performed physician services fall outside the scope of section 1877 of the Act. For this and other reasons . . . we are defining a 'referral' for purposes of section 1877 of the Act to exclude referrals for work personally performed by the referring physician.").

31 66 Fed. Reg. at 941.

32 *Id.*

33 *Id.*

34 *Id.*

35 *Id.* at 908.

36 85 Fed. Reg. 77492, 77537 (Dec. 2, 2020).

1. ICA Definition and Unit-Based Special Rules

First, recognizing that the 2001 rulemaking may not have addressed the interplay between the ICA Volume/Value Standard and the Unit-Based Special Rules in sufficient detail or with sufficient clarity,[37] CMS took the position that the Unit-Based Special Rules do not apply in the context of the ICA Definition.[38] According to CMS, the Unit-Based Special Rules are simply unavailable at the financial relationship stage of a Stark Law analysis—i.e., when the parties are trying to determine whether an ICA exists by examining, in relevant part, whether the "aggregate compensation" received by the referring physician triggers the ICA Volume/Value Standard. Indeed, according to CMS, "time-based or unit-of-service based compensation will always vary with the volume or value of services when considered in the aggregate."[39] As a result, even if the Unit-Based Special Rules were available at the ICA Definition stage, they would not prevent prong two of the ICA Definition from being met. Unfortunately, and as discussed further below, this statement prompted some to believe (incorrectly) that CMS considered *all* unit-based compensation to implicate the ICA Volume/Value Standard.[40]

2. Flat Fee Compensation

Next, and seemingly at odds with the "direct correlation" position the agency took in 2001, CMS stated that "fixed, aggregate compensation" could trigger the ICA Volume/Value Standard under certain circumstances—e.g., 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."[41] Once again, although the agency's comments were made in a section of preamble discussing the ICA Volume/Value Standard, a careful reading suggests that CMS viewed fixed or flat fee arrangements as being able to violate the Volume/Value Standard more generally.[42]

3. Personally Performed Services Rule and "Other Business Generated"

The 2004 rulemaking clarified that the Personally Performed Services Rule applies to both "referrals" and "other business generated."[43] Thus, a physician could be compensated for their personally performed services without offending *any* version of the Volume/Value Standard. (It should be noted that neither HCFA in 2001 nor CMS in 2004 codified a definition of the term "other business generated." In preamble discussions, however, the agency has explained that the term covers two sets of services: DHS not covered by Medicare and non-DHS services, whether covered by Medicare or not.[44])

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37 In CMS's own words, "Many commenters expressed confusion at the interplay between (1) the definition of 'indirect compensation arrangement' at § 411.354(c)(2), which looks at whether the referring physician's aggregate compensation varies with, or otherwise takes into account 'the volume or value of referrals' generated by the referring physician, and (2) § 411.354(d)(2), which describes when certain compensation (such as time-based and unit-of-service based payments) will be deemed not to take into account 'the volume or value of referrals,' even though aggregate per unit compensation will always vary with the volume or value of referrals." 69 Fed. Reg. 16054, 16058 (Mar. 26, 2004). CMS received similar comments regarding "§ 411.354(d)(3) with respect to when compensation does not take into account 'other business generated between the parties.'" *Id.*

38 *Id.* at 16058-59.

39 *Id.*

40 This appears to have been an unfortunate (over)statement of the case, because the ICA Volume/Value Standard focuses on the volume or value of "referrals" or "other business generated," not on the volume or value of "items" or "services," many of which have nothing whatsoever to do with referrals or other business generated. For example, imagine a scenario in which the referring physician's husband is a landscaper who agrees to mow a hospital's lawn every two weeks in return for $150. There is no doubt that the $150 per service payment methodology is unit-based and will result in a higher aggregate dollar number the more services the landscaper-husband provides. Nevertheless, this arrangement cannot reasonably be said to implicate or violate the ICA Volume/Value Standard.

41 69 Fed. Reg. at 16059.

42 *Id.* ("It is important to bear in mind that, depending on the circumstances, fixed aggregate compensation can form the basis for a prohibited direct or indirect compensation arrangement.")

43 *See, e.g., id.* at 16067 ("Many commenters construed [the term 'other business generated'] to encompass personally performed services, including a physician's professional services. That was not our intent, nor do we believe it to have been the intent of the Congress. We have clarified the regulations . . . to reflect that 'other business generated' does not include personally performed services."); *id.* at 16068 ("Personally performed services are not considered 'other business generated' for purposes of these regulations. This interpretation is consistent with the exclusion of personally performed services from the definition of 'referral' . . . . The regulations have been revised to clarify that personally performed services do not count as other business generated for the DHS entity."); *id.* at 16068 ("[W]e have interpreted 'other business generated' to make clear that it excludes personally performed services"); *id.* at 16086 ("'[O]ther business generated between the parties' includes private pay health care business (but not personally performed services)."). *See also id.* at 16067 ("[W]e have modified the regulations to clarify that independent contractor and academic medical center physicians, like their group practice and employed counterparts . . . can receive productivity bonuses based on personally performed services . . . . The result of these interpretations is that all physicians . . . can be paid productivity bonuses based on work they personally perform").

44 *See, e.g., id.* at 16067 ("In Phase I, we interpreted 'other business generated' to include any health care business, including private pay business.").

4. Relationship Between Personally Performed Services Rule and Dual PC/TC Rule

As noted above, in 2001, HCFA established, through the Personally Performed Services Rule, that a DHS Entity could pay a physician for their personally performed services without triggering the Volume/Value Standard. The agency further noted that, pursuant to the Dual PC/TC Rule, under certain circumstances—e.g., a physician performing a procedure in a hospital's outpatient operating room—a physician's personally performed services may be inextricably linked to a referral of DHS. HCFA did not, however, attempt to reconcile these two rules. In other words, could a DHS Entity pay a physician for their personally performed services (e.g., $55 for each wRVU earned by the physician for their personally performed services) when some portion of their personally performed services would be directly correlated with a referral by the physician to the DHS Entity for the furnishing of DHS?

The agency answered this question in 2004, when a commenter—plainly wrestling with precisely this issue—presented the following scenario:

> A hospital employs a physician at an outpatient clinic and pays the physician for each patient seen at the clinic. The physician reassigns [their] right to payment to the hospital, and the hospital bills for the Part B physician service (with a site of service reduction). The hospital also bills for the hospital outpatient services, which may include some procedures furnished as 'incident to' services in a hospital setting. The commenter's concern is that the payment to the physician is inevitably linked to a facility fee, which is a designated health service (that is, a hospital service). Accordingly, the commenter wondered whether the payment to the physician would be considered an improper productivity bonus based on a DHS referral (that is, the facility fee).[45]

In response, CMS made it clear that the Personally Performed Services Rule, in effect, trumps the Dual PC/TC Rule: "The fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement)."[46] Elsewhere in the same section of the regulatory preamble, CMS repeated its conclusion: "[T]he statute contemplates that employed physicians can be paid in a manner that directly correlates to their own personal labor, including labor in the provision of DHS."[47]

5. Required Referrals

Finally, CMS revised the Required Referrals Special Rule to make clear that the Special Rule only applies to employment, personal services and managed care arrangements, and only if the required referrals related solely to the physician's services covered under the arrangement.[48]

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Over the next 15 years—i.e., between 2004 and 2019—CMS did not propose or issue any additional guidance regarding the Volume/Value Standard.

45 *Id.* at 16088-89 (emphasis added).

46 *Id.* at 16089.

47 *Id.* at 16087.

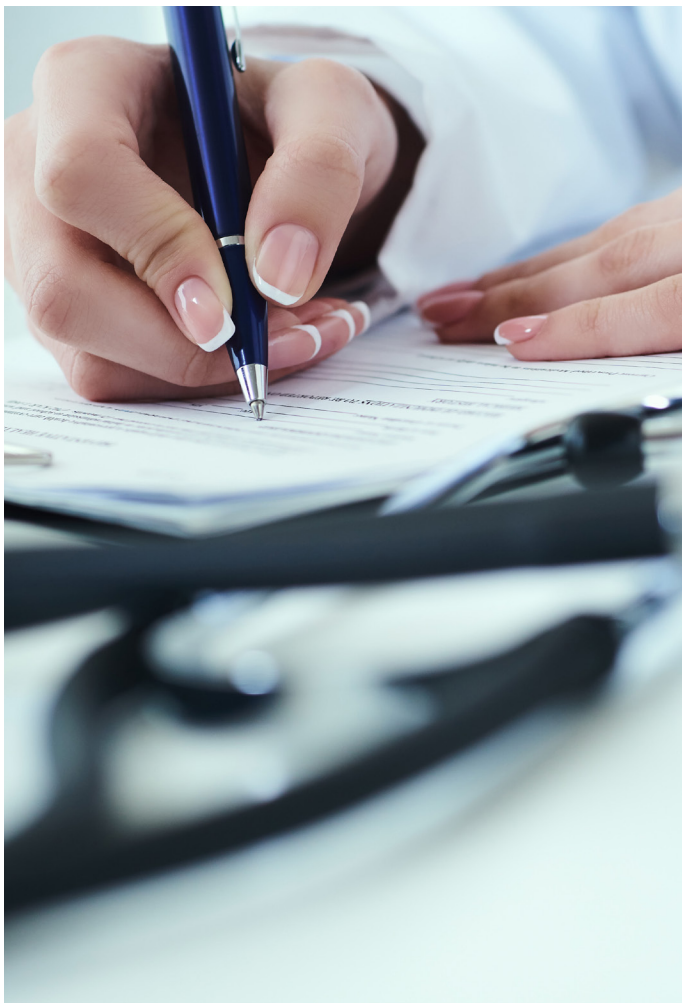
48 *Id.* at 16068-69. CMS also revised the Required Referrals Special Rule to clarify that the referral requirement must be reasonably necessary to effectuate the legitimate purposes of the compensation relationship. *Id.* at 16069.

IV. Proposed Rule

In the 2019 Proposed Rule, CMS proposed significant revisions to the Volume/Value Standard. According to the agency, these revisions were necessary because the Standard remained a source of substantial confusion. Specifically, CMS proposed creating two new special rules on compensation that would offer objective, "bright-line" tests for determining whether the compensation methodology at issue "takes into account" either (i) the volume or value of referrals or (ii) other business generated between the parties.[49] The first special rule would apply to compensation *from* a DHS Entity *to* a physician. The second special rule would apply to compensation *from* a physician *to* a DHS Entity.[50]

If the conditions of the proposed special rules were *not* met, then the parties would know with certainty that the compensation at issue did *not* take into account the volume or value of referrals or other business generated between the parties.[51] If the conditions of the proposed special rules were met *and* the compensation at issue did not qualify for protection under the Unit-Based Special Rules, the compensation would be deemed to take into account the volume or value of referrals or other business generated between the parties.[52]

The proposed special rules also included provisions outlining the "narrowly-defined circumstances" under which "fixed-rate compensation (for example, a fixed annual salary or an unvarying per-unit rate of compensation)" would be considered to be determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician for the DHS Entity.[53] Finally, the Proposed Rule contemplated that the proposed special rules for the Volume/Value Standard would apply to the ICA Definition.[54]



49 *See* 84 Fed. Reg. 55766, 55842-43 (Oct. 17, 2019) (setting forth proposed provisions to be codified at 42 C.F.R. § 411.354(d)(5)-(6)).

50 *Id.*

51 *Id.* at 55793.

52 *Id.* ("Unless the special rule at § 411.354(d)(2) for unit-based compensation applies and its conditions are met, the physician's (or immediate family member's) compensation would take into account the volume or value of referrals.").

53 *Id.* at 55794. *See also id.* at 55842-43 (setting forth proposed provisions to be codified at 42 C.F.R. § 411.354(d)(5)(i)(B), (ii)(B), and at §411.354(d)(6)(i)(B), (ii)(B)). ("There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.").

54 *Id.* at 55792 ("Our discussion in this section II.B.3. [The Volume or Value Standard and the Other Business Generated Standard (§ 411.354(d)(5) and (6))] of this proposed rule relates only to these standards as they apply … to the definition of remuneration at section 1877(h)(1)(C) of the Act and § 411.351 of our regulations [and] the definition of indirect compensation arrangement at § 411.354(c)(2) . . . .").

V. Final Rule

A. Volume/Value Special Rules

At the highest level, and consistent with the structure of the 2019 Proposed Rule, the Final Rule essentially abandons the pre-2019 Volume/Value Standard architecture. As discussed above, the Stark Regulations historically had two special rules on compensation, i.e., the Unit-Based Special Rules, that established safe harbors pursuant to which compensation would be deemed *not* to violate the Volume/Value Standard. The Stark Regulations were silent, however, with respect to what *does* "take into account" the volume or value of referrals or other business generated.[55]

The Final Rule answers this question by creating a "bright-line" test that establishes, for the first time, "exactly when compensation will be considered to take into account the volume or value of referrals or take into account other business generated between the parties."[56] The test is all-inclusive and exhaustive, establishing "the universe of circumstances under which compensation is considered to take into account the volume or value of referrals or other business generated."[57] Accordingly, "[i]f the methodology used to determine the . . . compensation [to or from the referring physician] does not fall squarely within the defined [universe of] circumstances, the compensation is not considered to take into account the volume or value of the physician's referrals or other business generated."[58] CMS cautioned, however, that its bright-line rules do not apply to the ICA Definition or the ICA Volume/Value Standard (which, as will be discussed in our next white paper, removes "takes into account" from the phrase "varies with or takes into account").[59]

The new "bright-line" test is set forth in two new special rules on compensation—the "Volume/Value Special Rules"—one of which addresses compensation flowing *to* the physician and the other compensation flowing *from* the physician. Each of the new Special Rules contains two subrules, one addressing *referrals* and the other addressing *other business generated*.

1. Compensation *to* Physician

With respect to referrals, under the new Volume/Value Special Rule covering compensation flowing from a DHS Entity *to* a physician, compensation will be considered to take into account the volume or value of referrals "only if":

> ...the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity.[60]

With respect to other business generated, the rule is identical except for the substitution of the phrase "other business generated for" for the phrase "referrals to."[61] Thus, if, as a matter of math (and as discussed further below), the compensation from the DHS Entity to the physician increases when the number of referrals or other business generated increases, the test is satisfied.

55 85 Fed. Reg. 77492, 77537 (Dec. 2, 2020).

56 *Id.*

57 *Id.* at 77538.

58 *Id.*

59 *Id.* at 77542.

60 *Id.* at 77667 (setting forth new provision to be codified at 42 C.F.R. § 411.354(d)(5)(i)).

61 *Id.* (setting forth new provision to be codified at 42 C.F.R. § 411.354(d)(5)(ii)).

2. Compensation *from* Physician

The new test for determining whether the Volume/Value Standard is met with respect to compensation flowing *from* a physician to a DHS Entity is similar, but depends on the existence of a *negative* correlation between the compensation and the number or value of referrals or other business generated (i.e., the compensation from the physician to the DHS Entity must decrease when the number of referrals or other business generated increases).[62]

3. Application of the Volume/Value Special Rules

The new Volume/Value Special Rules focus on whether a physician's referrals to, or other business generated for, the DHS Entity serve as a "variable" in the compensation formula. According to CMS, the word "variable" should be understood in terms of "general mathematical principles," where "x" is the variable in the equation, standing for an as-yet unknown number.[63] To illustrate, CMS posits a hypothetical in which a DHS Entity agrees to pay a physician incentive compensation equal to 20 percent of a bonus pool that is comprised of the DHS Entity's collections from a defined service line that includes DHS. According to CMS, the formula for calculating the physician's incentive compensation is represented by the following equation:

> (.20 x [the value of the physician's referrals of DHS]) + (.20 x [the value of the other business generated by the physician]) + (.20 x [the value of services furnished by the [E]ntity that were referred or generated by *other* physicians in the bonus pool]).[64]

The value of the physician's referrals to and other business generated for the Entity are each variables in this formula, meaning that the aggregate amount of the physician's 20 percent bonus will *necessarily* increase as the value of the physician's referrals or other business generated increase. Thus, the compensation formula meets the conditions of the new Volume/Value Special Rules (i.e., it does, in fact, take into account the value of the physicians referrals of DHS and other business generated for the DHS Entity).[65]

62 *Id.* (setting forth new provisions to be codified at 42 C.F.R. § 411.354(d)(6)(i) and (ii)).

63 *Id.* at 77540.

64 *Id.*

65 *Id.*

B. ICA Definition

Under the Final Rule, the Volume/Value Special Rules do not apply to the ICA Definition and therefore have no role in the determination of whether aggregate compensation triggers the ICA Volume/Value Standard.[66] (We will discuss this, along with CMS's other changes to the ICA Definition in the Final Rule, in our next white paper.)

C. Retirement of Unit-Based Special Rules

As noted above, since 2001, unit-based compensation methodologies (e.g., $350 per imaging study) have been protected under the Unit-Based Special Rules—and, therefore, satisfied the Exception Volume/Value Standard—provided two conditions were satisfied.

- First, the unit of unit of compensation (i.e., the $350 in our imaging study hypothetical) had to be consistent with fair market value.
- Second, the unit of compensation could not vary during the course of the compensation arrangement in any manner that took into account referrals or other business generated by the referring physician. (In our imaging study hypothetical, then, if an arrangement provided for a rate increase to $375 (from $350) for all imaging studies in excess of a threshold number (e.g., 100 studies per calendar quarter), the arrangement would not qualify for protection under the Unit-Based Special Rules, even if both rates were consistent with fair market value.)

The Unit-Based Special Rules had remained relatively untouched for 20 years, making them—along with the Personally Performed Services Rule—key pillars of the health care industry's approach to Stark Law compliance. Indeed, they continued to feature in their standard "safe harbor" role in the 2019 Proposed Rule. For example, with respect to our above hypothetical pursuant to which the DHS Entity would pay the physician 20 percent of the DHS Entity's collections from a defined service line that includes DHS, while the compensation formula may have met the conditions of the new Volume/Value Special Rules, it would *not* have violated the Exception Volume/Value Standard as long as it satisfied the two requirements of the Unit-Based Special Rules—i.e., the unit of compensation (i) was consistent with fair market value and (ii) did not vary during the course of the compensation arrangement in any manner that took into account referrals or other business generated by the physician.

However, in the Final Rule, CMS—in a completely unforeseen reversal of position, and without offering any opportunity for public comment—retired the Unit-Based Special Rules effective January 19, 2021 (i.e., just 47 days after the Final Rule's December 2, 2020 publication in the *Federal Register*).[67] In the agency's own words:

> If compensation takes into account the volume or value of referrals or the volume or value of other business generated under [the new Volume/Value Special Rules], that determination is final. The [Unit-Based Special Rules] may not be applied to then deem the compensation not to take into account the volume or value of referrals or other business generated.[68]

Importantly, the Unit-Based Special Rules are not being removed from the Stark Regulations altogether. For one thing, they remain part of the regulatory framework for the purpose of analyzing compensation provided in exchange for items and services furnished *prior* to January 19, 2021.[69] In addition, the Unit-Based Special Rules assume a brand new role in the analysis required under prong two of the ICA Definition, which (as noted above) will be addressed in our next white paper.

66 *Id.* at 77542.

67 This 47-day window is significant because, under the Congressional Review Act, "major rules" may not take effect prior to 60 days after the date on which the rule is published in the *Federal Register*. 5 U.S.C. § 801(a)(3).

68 85 Fed. Reg. at 77538. *See also id.* at 77540 ("[I]f compensation takes into account the volume or value of a physician's referrals to an entity or the volume or value of other business generated by a physician for an entity under final [Volume/Value Special Rules], no special rule, including [the Unit-Based Special Rules], may be applied to reverse that determination.").

69 *Id.* at 77541.

D. Flat Fee Compensation

As previously discussed, in the preamble of the 2004 rulemaking, CMS suggested that under certain circumstances, a flat fee payment could implicate the Volume/Value Standard if, for example, it was materially in excess of fair market value. In the Proposed Rule, CMS proposed defining the narrow circumstances under which fixed-rate compensation would, in fact, trigger the Volume/Value Standard.[70] The Final Rule does not adopt this proposal, however, and together with CMS's statements that only compensation methodologies that satisfy the new Volume/Value Standard Special Rules will be considered to take into account referrals or other business generated, this likely signals the agency's decision to abandon, once and for all, the theory that flat fee payments can trigger the Volume/Value Standard.[71]

E. Personally Performed Services

In the preambles of both the Proposed and Final Rules, CMS revisits the intersection of the Personally Performed Services Rule and the Dual PC/TC Rule. As discussed above, in 2004, CMS made it clear that the Personally Performed Services Rule trumps the Dual PC/TC Rule, stating "[the] fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement)."[72]

This proposition appeared to have been pretty much settled until 2015, when the US Court of Appeals for the Fourth Circuit issued an opinion in *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc. (Tuomey).*[73] In *Tuomey,* the legal effect of paying for self-performed services that have a nexus to DHS—such as an outpatient hospital facility fee for services personally performed by a physician in a hospital site of care—was front and center. The case involved potential indirect compensation arrangements between a hospital and various orthopedic surgeons in which the compensation arrangement in the unbroken chain of financial relationships closest to the referring surgeons was an employment arrangement between an affiliate of the hospital and each of the surgeons.[74]

When faced with the question of whether the aggregate compensation paid to each surgeon under their employment arrangement met the ICA Volume/Value Standard—which would mean the second prong of the ICA Definition was met—the Fourth Circuit reached two unsettling conclusions: (i) that it was not bound by CMS's regulatory interpretation in applying the Stark Law, and (ii) that compensation for an employed surgeon's self-performed services that were attached to a hospital facility fee (i.e., orthopedic surgery performed in the hospital's outpatient surgery operating rooms) did indeed meet the ICA Volume/Value Standard and, thus, the second prong of the ICA Definition.[75] The court summarized its reasoning as follows:

> In sum, the more procedures the physicians performed at the hospital, the more facility fees Tuomey [the hospital] collected, and the more compensation the physicians received in the form of increased base salaries and productivity bonuses.[76]

The court appeared particularly swayed by the testimony of the hospital's former Chief Financial Officer, who "admitted that every time one of the 19 physicians . . . 'did a legitimate procedure on a Medicare patient at the hospital pursuant to the part-time agreement[,] the doctor [got] more money,' and 'the hospital also got more money.'"[77] This prompted the court to conclude, "We thus think it plain that a reasonable jury could find that the physicians'

70 84 Fed. Reg. 55766, 55842-43 (Oct. 17, 2019) (setting forth proposed provisions to be codified at 42 C.F.R. § 411.354(d)(5)(i)(B) and (ii)(B), and at proposed § 411.354(d)(6)(i)(B) and (ii)(B)) ("There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.").

71 *See* 85 Fed. Reg. at 77538.

72 69 Fed. Reg. 16054, 16089 (Mar. 26, 2004).

73 *See United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 792 F.3d 364 (4th Cir. 2015).

74 *Id.* at 371.

75 *Id.* at 379.

76 *Id.*

77 *Id.*

compensation varied with the volume or value of actual referrals."[78] (We will tackle the *Tuomey* case and its implications in greater depth in our next white paper.)

Disappointingly, CMS made no real effort in the preambles of either the Proposed or Final Rule to contend with the *Tuomey* case in earnest. Instead, the agency simply doubled down on its 2004 position.

> [F]or clarity, we reaffirm[ ] the position we took in [2004]. We stated that, with respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service.[79]

Helpfully, CMS did make it clear that its position is not limited to employment relationships or employment bonuses, but extends to all direct and indirect compensation arrangements.[80]

> An association between personally performed physician services and designated health services furnished by an entity does not convert compensation tied solely to the physician's personal productivity into compensation that takes into account the volume or value of a physician's referrals to the entity or the volume or value of other business generated by the physician for the entity.[81]

Although CMS was asked by various commenters to codify this policy position in the Final Rule itself, the agency declined (on the ground that there was no need) to do so.[82]

F. Required Referrals

As discussed above, CMS historically has taken the position that if an employer or other principal directs the referrals of its physician-employee/agent, the physician's compensation necessarily triggers the ICA and Exception Volume/Value Standards unless the parties satisfy the requirements of the Required Referrals Special Rule. The Final Rule—which treats the Volume/Value Standard as separate and distinct from all other Stark Law provisions—eliminates the nexus between Volume/Value Standard and the Required Referrals Special Rule. That said, CMS has not abandoned the Required Referrals Special Rule; it simply has incorporated it in the relevant Stark Law exceptions, including those covering bona fide employment relationships, personal service arrangements and indirect compensation arrangements.[83] Now, each of those Stark Law exceptions explicitly states that if the compensation arrangement at issue is conditioned on referrals, the Required Referrals Special Rule must be satisfied for the arrangement to qualify for protection under that Stark Law exception.

78 *Id.* at 379-80. In making this determination, the court omitted the word "aggregate," which, at least in CMS's view, is a difference with quite a bit of meaning.

79 85 Fed. Reg. 77492, 77539 (Dec. 2, 2020).

80 *Id.* In explaining its decision to part ways with CMS guidance, the Fourth Circuit emphasized that the agency's 2004 guidance was focused on the ability to pay a physician-employee an employment bonus. *Tuomey,* 792 F.3d at 380 n.10.

81 85 Fed. Reg. at 77539.

82 *Id.*

83 *Id.* at 77547-48.

VI. Conclusion

Although more thought and analysis are warranted, two items relating to the treatment of the Volume/Value Standard under the Final Rule are particularly noteworthy. First, the precipitous elimination of the Unit-Based Special Rules is likely to result in a variety of unintended consequences. For example, although many DHS Entities and physicians (particularly those located in the Fourth Circuit) have been forced to contend with the *Tuomey* ruling for several years, some solace could be found in the Unit-Based Special Rules, which (in contrast to the agency's 2004 preamble statements) were codified in regulations. (Because the Fourth Circuit was dealing with the ICA Volume/Value Standard, it did not discuss the Unit-Based Special Rules or their impact on the *Tuomey* compensation arrangements under the Stark Law exception for indirect compensation arrangements.) Effective January 19, 2021, however, the Unit-Based Special Rules ceased to be available with respect to prospective financial relationships, substantially complicating the analysis.

Second, and relatedly, it is unfortunate that CMS decided to retire the Unit-Based Special Rules without offering the public (i) a meaningful opportunity to comment, (ii) a longer grace period in which to prepare for this material change, and/or (iii) a proper analysis of why, in the agency's view, *Tuomey* was wrongly decided or is distinguishable. These deficiencies may provide a basis for challenging, under the Administrative Procedure Act (APA),[84] CMS's elimination of the Unit-Based Special Rules. Potentially, such an APA challenge could be made both on procedural grounds (due to the lack of notice-and-comment) and substantive grounds (under a theory that CMS's failure to tackle the *Tuomey* decision rendered the agency's decision to retire the Unit-Based Special Rules "arbitrary and capricious"[85]).

84 5 U.S.C. § 500 *et seq.*

85 *Id.* §§ 553(b), 706(2)(A).

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April 1	12:30-1:45 pm ET	Separating the Wheat from the Chaff: Technical Requirements, Low-Dollar Violations, and Payment Discrepancies
April 15	12:30-1:45 pm ET	Key Standards (Part I): The 'Volume or Value' Standard
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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Key Contacts

The Dentons lawyers presenting this series, including Gadi Weinreich, Chris Janney and Ramy Fayed, are widely recognized as Stark Law thought leaders. They and other members of Dentons' US Health Care practice group have assisted countless clients in navigating this unforgiving law since its enactment in 1989, lectured extensively on its challenges and pitfalls, and authored multiple articles as well as two editions of *The Stark Law: A User's Guide to Achieving Compliance*.

Gadi Weinreich
Partner

Chris Janney
Partner

Samantha Groden
Senior Managing Associate

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Associate

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