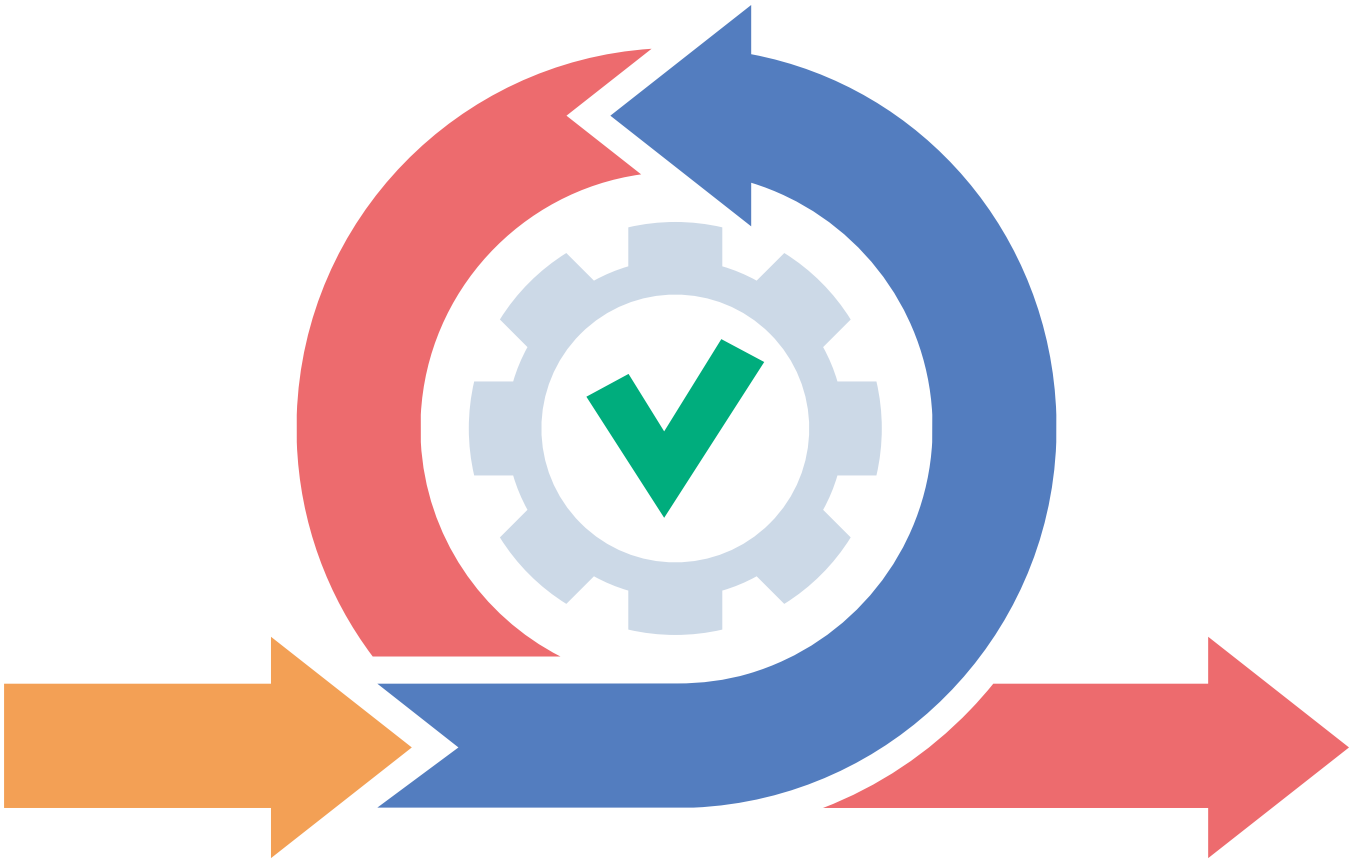

The Sprint to Modernize and Clarify the Stark Law—Part I

Troy A. Barsky, Crowell & Moring LLP, and Daniel H. Melvin, McDermott Will & Emery LLP

The Centers for Medicare & Medicaid Services (CMS) published its much-anticipated proposed Stark rule in the October 17, 2019 *Federal Register*, proposing the most substantive changes to the Stark regulations since the final Stark II rulemaking in the 2000s (Proposed Rule).[1] The comment period ends on December 31, 2019. Due to the length and detail of the Proposed Rule, this is a two-part series and, even then, does not discuss every proposal.[2] Part II will be published in the January issue *of AHLA Connections*. Part I focuses on CMS' proposals for:

- modifying the definition of "fair market value";
- new objective tests for when compensation "takes into account" the volume or value of referrals or other business generated;
- a new definition of "commercially reasonable"; and
- revisions to the "group practice" definition's special rules for profit shares and productivity bonuses.

The Proposed Rule attempts to provide relief for parties to value-based arrangements not currently protected by the regulatory waivers and makes significant strides in fulfilling CMS' long-standing goal of giving stakeholders "bright-line" rules. However, health lawyers and their clients should consider commenting on the Proposed Rule because in places it is very much a "first draft," breaks new ground having important implications for Stark/False Claims Act (FCA) litigation risk, and does not eliminate every ambiguity within the law. The Proposed Rule presents a valuable opportunity for stakeholders to make important and constructive contributions to CMS' modernization and clarification of Stark law policy and rules.

New and Clarified Definitions of Key Stark Terms

The nature and scope of the Stark law's "Big Three" terms—"fair market value," "volume or value," and "commercially reasonable"—dominate most debates over whether a particular type or amount of compensation to a physician satisfies an applicable Stark compensation exception. Unfortunately, CMS has seemingly had less to do with how these terms are construed than litigators and the courts in FCA cases. Based on the new proposals, CMS is reasserting itself as the arm of government primarily responsible for interpreting the Stark

law's "Big Three." This is a positive development and, given that the Proposed Rule may be the last time in years that CMS seriously reconsiders the nature and scope of the "Big Three," stakeholders will want to scrutinize CMS' proposals carefully.

"Fair Market Value"

The Stark statute defines "fair market value" as "the value in arms length [sic] transactions, consistent with the general market value, . . ."[3] The statute does not define "general market value." In prior rulemaking, CMS defined "fair market value" using the statutory language and issued a detailed definition of "general market value" that generally tracked an unrelated regulation defining "fair market value" for purposes of reasonable cost reimbursement for end-stage renal disease services. Concerned that its definition of "general market value" is inconsistent with "general valuation principles," CMS now wants "general market value" to mean the same as "market value," as CMS believes this term is used by the valuation industry. CMS' reconsideration of these definitions resulted in the following proposals:

- The "fair market value" definition is revised to read "The value in an arm's-length transaction, *with like parties and under like circumstances, of like assets or services*, consistent with the general market value of the subject transaction."[4]
- With respect to the rental of equipment or space, "fair market value" will mean the "value in an arm's-length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction."[5]
- "General market value" will mean "[t]he price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement."[6] CMS proposes an analogous definition for the "general market value" of rental property (including equipment).[7]

CMS' preamble discussion indicates that it conceives of "fair market value" *apart from* "general market value" as the value of the goods, services or rental property in a *hypothetical* arm's-length transaction between a *hypothetical* buyer and seller. In contrast, CMS conceives of "general market value" as the value the goods, services or rental property would bring as the result of bona fide bargaining between the *actual* buyer and seller *in the subject transaction* on the date of the arrangement.[8] Because "fair market value" must be consistent with the "general market value," "general market value" will ultimately control, and will, in CMS' view, now permit consideration of the particular characteristics of the buyer, seller, and the local market.

CMS indicates that it intends for "general market value" to be consistent with "market value" as used by the valuation community, seeing nothing in the legislative history or statutory definition that Congress intended for "general market value" to "deviate from general concepts and principles in the valuation community."[9] CMS seems to want to put to rest the notion that the Stark law's definition of "general market value" is distinguishable from the valuation industry's bedrock principles for determining "market value" and requires the valuation industry to depart from these principles. Further, CMS' proposed definition reflects a helpful recognition that physician compensation survey data is not the last or only word on the fair market value of physician compensation. However, the distinction CMS is drawing between the hypothetical nature of "fair market value" and the subject transactional nature of "general market value" is novel and likely to elicit comments from the valuation community.

> The Proposed Rule attempts to provide relief for parties to value-based arrangements not currently protected by the regulatory waivers and makes significant strides in fulfilling CMS' long-standing goal of giving stakeholders "bright-line" rules.

As noted above, the proposed regulatory definition of "general market value" is the price derived from "bona fide bargaining." CMS states in preamble discussion, "Market value is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another."[10] CMS' lone example is that determining the "general market value" of a physician's medical director services would not involve any consideration of the fact that the physician is in a position to make referrals to the hospital when not acting as medical director. CMS here might be alluding to the well-settled valuation principle that the fair market value of a service or good is what would be paid in an "arm's-length transaction," not one in which one of the parties has influence over the other party because of other valuable business he controls. However, CMS' statement that "market value" is limited to consideration of the "economics of the subject transaction" raises "elephant in the room" questions that need answers; the "economics" of physician employment arrangements and how such "economics" relate to "fair market value" is controversial. In the case of a health system-employed surgeon or proceduralist, is the hospital facility component of her professional services integral to the "economics" of the employment arrangement or "other business the parties may have with one another"? In the case of a health system-employed physician with predominantly an office-based practice, are the billed services and items

ancillary to the physician's services (e.g. lab and imaging) integral to the "economics" of the subject employment or "other business the parties may have with one another"? Finally, in the case of the "rock star" surgeon who is putting her professional clinical services out to bid, is her "general market value" consistent with the highest bids in the relevant market, even if it means the "economics" of the bargained for compensation can only be rationalized by reference to what the doctor will mean for the related surgical service line?

Expressed differently, does CMS' statement that the "general market value" of a physician's services is based solely on the "economics of the subject transaction" and not "other business the parties may have with one another" mean that the compensation must make "economic sense" solely on the basis of "physician clinical services" alone? Hospitals and health systems directly or indirectly employ more than one-third of all physicians in this country[11] and it is common knowledge that many of these physicians are paid clinical compensation that is more than what is supported by their professional services collections (even after accounting for "ramp-up" costs and community need considerations, and normalizing practice overhead expenses). Thus, the "economics" of these employment arrangements is apparently broader than just the "economics" of "physician clinical services" and involves the "economics" of health system service lines, programs, and enterprises within which the physicians work. Is CMS suggesting these hospital or health system "economics" are outside the "economics of the subject transaction" and, thus, irrelevant for the "general market value" of the physician's clinical services? What if a reputable valuator determines that consideration of such "economics" is consistent with "bona fide bargaining" and an "arm's-length transaction"?

CMS' proposed definitions of "fair market value" and "general market value" helpfully call into question the "survey says" approach to valuation that currently dominates valuation of physician clinical compensation. However, the proposed "fair market value" definition will not significantly lighten the regulatory burden of the standard for many employers of physicians. As illustrated by the recent decision in *United States ex rel. Bookwalter v. UPMC*,[12] allegations of above-fair market value compensation can be considered plausible because physicians were paid:

- compensation exceeding collections from their work, and
- rates per work Relative Value Unit (RVU) in excess of Medicare rates.

Consequently, it would be helpful if CMS clarified what it means by the "economics of the subject transaction" and "other business the parties may have with one another." If, notwithstanding CMS' express delinking of the "fair market value" and "volume or value" standards, there is still the trace of a "volume or value" standard in CMS' "fair market value" standard, it is important that the precise nature of it be understood.

> Because "fair market value" must be consistent with the "general market value," "general market value" will ultimately control, and will, in CMS' view, now permit consideration of the particular characteristics of the buyer, seller, and the local market.

"Volume or Value" Standard

Perhaps no key term of the Stark law has suffered more from ambiguity than the "volume or value" standard. This ambiguity is largely due to two developments. First, CMS construed the "volume or value" standard to be offended by even flat or fixed-amount compensation to a physician, such as $2,000 per month, that is "inflated to reflect" the volume or value of the physician's referrals.[13] Further, certain Stark compensation exceptions frame the "volume or value" standard as taking into account the volume or value of actual or "anticipated referrals."[14] These constructions of the "volume or value" standard meant that designated health services (DHS) entities had to be concerned about *how* and *why* their employees set the fixed-amount compensation at the amount that they did, including whether the value of a physician's past or anticipated referrals was a factor in the compensation-setting process. It was not enough to assure that, if the amount of the compensation to the physician was contingent, the contingency was not the volume or value of the physician's actual referrals—e.g., a physician employee paid a percentage of collections from his professional medical services and personally referred ancillary services, including Stark DHS. CMS has also stated that "a compensation arrangement does not take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary over the term of the arrangement in a manner that takes into account referrals or other business generated."[15] However, proof that compensation is fair market value and has not varied in a manner taking referrals into account has not always been a successful defense in Stark/FCA cases. Plaintiffs have successfully made the circular argument that compensation that takes into account the volume or value of referrals is, by definition, not fair market value and, thus, there is no fair market value defense.[16]

The second development contributing to the "volume or value" standard's ambiguity is the *Tuomey* case.[17] The central issue in *Tuomey* was the "volume or value" standard, and the

Fourth Circuit surprised many health lawyers and their clients by articulating in 2015 a correlation theory of the "volume or value" standard. Under this theory, compensation "varies with" or "takes into account" the volume or value of a surgeon's or proceduralist's referrals for hospital services if the compensation is based on the physician's personal productivity—e.g., a percentage of collections from personally performed physician services, or a dollar rate of compensation per work RVU generated from the physician's personally performed services. The rationale is that, because the surgeon or proceduralist orders operating/procedure rooms and other hospital services every time she performs a surgery or procedure, there will be a correlation between the physician's productivity compensation and the volume of the physician's referrals for hospital services. For many health lawyers and their clients, the idea that garden-variety productivity-based compensation to an employed proceduralist could offend the "volume or value" standard was completely novel, unwarranted, and had unintended negative consequences. So long as the requirement that an employed proceduralist perform her cases at the employer's affiliated hospital complies with the special "volume or value" safe harbor for such requirements (at 42 C.F.R. § 411.354(d)(4)), which Tuomey's referral requirement did not, there is nothing suspect or abusive about paying a proceduralist on the basis of her productivity.[18]

The correlation theory has now taken hold in the Third Circuit, but with a new twist that further muddies the water. In *UPMC*,[19] the majority of a three-judge panel expressly embraced *Tuomey's* correlation theory, concluding that the indirect compensation definition's "varies with" concept (but not its "takes into account" concept) only requires a *correlation*, not a *causal relationship*, between the physician's compensation and referrals.[20] The majority took the position that only when the "volume or value" standard is based solely on "takes into account" language, as in the Stark compensation exceptions, does the "volume or value" standard require a causal relationship between the physician's referrals and compensation. The concurring judge disagreed, arguing that "varies with" is merely a species of "takes into account" and both terms require a causal relationship. In the judge's opinion, permitting a plaintiff to make out an indirect compensation arrangement between a surgeon and a hospital by merely pleading that there is a correlation between the surgeon's referrals for hospital services and the surgeon's productivity compensation will open the floodgates to frivolous litigation. The Fourth Circuit's correlation theory and the Third Circuit's distinction between "varies with," which only requires correlation, and "takes into account," which requires a causal relationship, has made the "volume or value" standard even more ambiguous.

In the Proposed Rule, CMS effectively proposes a definition of the "volume or value" standard and certain modifications to existing regulations that have the potential of giving the industry "bright-line" clarity. However, whether the Proposed Rule has ruled out the correlation theory is not completely clear. *First*, CMS proposes to strike "varies with" from the second element of the "indirect compensation arrangement" definition. Importantly, this would effectively moot the Third Circuit's distinction in *UPMC* between the meaning of "varies with" and the meaning of "takes into account" (if such distinction survives an appeal). However, CMS forgot also to remove "varies with" from the third prong of the "indirect compensation definition," which was presumably an oversight that will be corrected in the final rule.

Second, CMS proposes amendments and makes explicit preamble statements clarifying that the "fair market value" and "volume or value" concepts are not causally linked. Compensation that is not fair market value does not necessarily take into account the volume or value of referrals, and compensation that takes into account the volume or value of referrals is not necessarily inconsistent with fair market value.[21] Further, under CMS' proposed "volume or value" definition (described below), fair market value is no longer relevant to whether the compensation "takes into account" the volume or value of referrals.

Third, CMS proposes adding a new provision to 42 C.F.R. § 411.354(d) that sets forth the *only two circumstances* when compensation *from a DHS entity to a physician* "takes into account" the volume or value of the physician's referrals or other business generated. The first circumstance is when the physician's compensation formula includes referrals as a variable and there is a "positive correlation" between the resulting compensation and the volume or value of the physician's referrals or other business generated for the DHS entity.[22] Although this provision uses the word, "correlation," it does not appear to mean a mere non-causal correspondence between the physician's referrals and compensation as in *Tuomey* and *UPMC*. Referrals must be a variable of the compensation formula, which was not the case in either *Tuomey* or *UPMC,* and, thus, requires a causal relationship between the compensation and the referrals. The one example CMS gives is when a physician is paid 50% of collections from her personally performed services and personally referred ancillaries, including DHS.[23] In such case, the compensation amount cannot be determined without reference to the physician's referrals for DHS, the two having a causal relationship.

Notably, this circumstance under which compensation to a physician will take into account the volume or value of the physician's referrals or other business generated will apply to a group practice's productivity bonuses based on the physician's referrals for DHS covered by Medicare's "incident to" benefit. In such case, the physician's referrals are an express variable in the compensation formula. Further, this circumstance will apply to conventional distributions by group practices of ancillary income pools (inclusive of DHS). Referrals are a variable in each physician's compensation formula insofar as the more referrals the physician makes to the group for DHS the greater the dollar value of the pool. The greater the dollar value of the pool, the greater the dollar value of the individual physician's distribution from the pool (even if the practice distributes the ancillary income pool on an equal per capita basis). Consequently, group practices will need to continue to satisfy the "group practice" definition's special rules or safe harbors for productivity bonuses and profit shares.

The second circumstance when compensation *from a DHS entity to a physician* "takes into account" the volume or

value of the physician's referrals or other business generated is when there is a "predetermined, direct correlation" between the physician's *prior* referrals to the DHS entity and the physician's "prospective rate of compensation" for a specified duration.[24] This definition applies to "fixed-rate compensation (for example, fixed annual salary or an unvarying per-unit rate of compensation) . . . ."[25] CMS gives one example: if the physician orders 300 or fewer diagnostic tests in the prior year, the physician will be paid $30 per work RVU in the next year by the DHS entity, but if the physician orders more than 300 diagnostic tests in the prior year, the physician will be paid $35 per work RVU.[26]

Based on this example, CMS clearly requires that the fixed-rate compensation have a causal relationship with the physician's referrals; it is not enough that there is a correspondence between the compensation amount and the volume or value of the physician's referrals.

> Fortunately, however, if CMS finalizes the rule substantially as proposed, hospitals and other DHS entities will not be as vulnerable to Stark/FCA complaints predicated on allegations of commercially unreasonable practice "losses."

Fourth, CMS proposes adding a new provision to 42 C.F.R. § 411.354(d) that sets forth the *only two circumstances* when compensation *from a physician to a DHS entity* "takes into account" the volume or value of the physician's referrals or other business generated. The first circumstance is when the compensation formula includes referrals as a variable and there is a "negative correlation" between the resulting compensation and the volume or value of the physician's referrals.[27] CMS gives the one example of a physician's office space rent to a hospital is $5,000 less $5 for each diagnostic test referred to the hospital.[28]

The second circumstance is when there is a "predetermined, direct correlation" between the physician's *prior* referrals to the DHS entity and the DHS entity's "prospective rate of compensation" for a specified duration.[29] CMS gives one example: the physician tenant's rent is $2,000/month if the physician is in the hospital's top 25% of admitting physicians [in the prior month or quarter], $2,500/month if the physician is in the second quartile [in the prior month or quarter], and $3,500/month if the physician is in the bottom half of admitting physicians [in the prior month or quarter].[30]

Finally, CMS recognized that these new "volume or value" tests could permit a DHS entity to require an employed or contracted physician to direct referrals to the DHS entity as a term of the arrangement without offending the "volume or value" standard of the applicable compensation exception. CMS proposes to add compliance with the special rule for directed referral requirements at 42 C.F.R. § 411.354(d)(4) as an element of the compensation exceptions for employment and personal services arrangements, including the academic medical centers, FMV arrangements, and indirect compensation arrangement exceptions.[31] CMS also proposes certain amendments to the special rule. Consistent with delinking "fair market value" and "volume or value," CMS proposes to strike from the "fair market value" standard of the special rule the parenthetical at the end: "(that is, the payment does not take into account the volume or value of anticipated or required referrals)." Note that, although the existing and proposed language of the special rule specifically refers to instances where the payer conditions "compensation" on referrals to a particular provider, etc., CMS clarifies in preamble discussion that "as proposed," the special rule applies to both (a) the compensation arrangement that includes a directed referral requirement, and (b) the compensation, itself.[32] If directed referrals is a term of the employment or personal services arrangement, DHS entities must satisfy the rule even if they do not condition the compensation, itself, or the dollar amount of the compensation, on referrals to a particular provider, practitioner, or supplier.

These limited circumstances where a physician's compensation will take into account the volume or value of referrals or other business generated reflect CMS' stated goal of making the "volume or value" standard an objective standard or test. Both the "positive correlation" and "predetermined direct correlation" approaches achieve CMS' goal, being approaches that avoid an inquiry into how or why fixed-rate compensation to or from a physician was set at a specified dollar amount. Further, notwithstanding CMS' use of the term "correlation" in its "volume or value" definitions, neither of these approaches accommodate *Tuomey's* correlation theory. Productivity compensation formulae for a surgeon or proceduralist do not include referrals as a variable; the only variables are the quantity of the physician's work or production and how the measure of that work or production will be converted to a dollar amount—e.g., percentage of collections from personally performed services or a dollar rate of compensation per work RVU. The correlation theory requires us to go outside the compensation formula and discern whether there is a correspondence between the resulting productivity compensation and the volume of the physician's referrals for hospitals. However, when CMS took up *Tuomey's* correlation theory in preamble discussion, CMS stated its position that a productivity bonus to an employed physician will not violate the "volume or value" standards, and unit-based compensation to non-employed physicians will not offend the "volume or value" standard if the compensation qualifies for the special "unit-based compensation" safe harbor at 42 C.F.R. § 411.354(d)(2).[33] It is unclear here whether (a) CMS is simply stating its position on productivity compensation under the *Tuomey* correlation

theory as it currently applies in the Fourth Circuit, or (b) CMS is suggesting that the correlation theory survives under its new special rules on "volume or value." We presume CMS' intent is the former because, as discussed above, under the Fourth Circuit's correlation theory productivity compensation to a surgeon or proceduralist offends the "volume or value" standard even though referrals are *not* a variable in the compensation methodology affecting how much the physician will be paid. CMS will presumably clarify the status of the *Tuomey* correlation theory in the final rule, but hospitals and health systems may want to specifically request clarification.

"Commercially Reasonable"

Several key Stark compensation exceptions, most notably the employment exception, require that the arrangement must be commercially reasonable even if the physician made no referrals to the DHS entity. CMS has never defined "commercially reasonable" by rule before, but now proposes consideration of two alternative definitions:

- "the particular arrangement furthers a legitimate purpose of the parties and is on similar terms and conditions as like arrangements," and
- "the arrangement makes commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty."[34]

Either approach will include, "An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."[35] This sentence makes clear CMS' intent that an arrangement may be commercially reasonable even if no party profits from the arrangement. Certain plaintiffs have made allegations in Stark/FCA cases that an employment arrangement that results in a practice "loss" is, *ipso facto*, commercially unreasonable. However, usually plaintiffs cite a practice "loss" as grounds for calling into question the commercial reasonableness of the employment arrangement, putting the defendant in a position of having to explain the practice "loss" to meet its burden of proof that the arrangement satisfies the employment exception. Consequently, the statement that an unprofitable arrangement may be commercially reasonable is probably not a "game changer." Moreover, these alternative definitions will not change the fact that the "commercially reasonable" element of the employment exception is coupled with the phrase, "even if no referrals were made to the employer."[36] If defendants in Stark/FCA cases continue to bear the burden of proof that a Stark exception applies, and the only applicable exceptions contain this form of commercial reasonableness standard, defendants will have to explain the "loss" without any reference to the physician's DHS referral value.

Fortunately, however, if CMS finalizes the rule substantially as proposed, hospitals and other DHS entities will not be as vulnerable to Stark/FCA complaints predicated on allegations of commercially unreasonable practice "losses." Consistent with the regulatory definition of "referrals," in the Proposed Rule CMS confirms that "referrals" means referrals for DHS, which, by definition, is limited to Medicare-covered DHS.[37] Thus, "commercially reasonable" should permit consideration of referrals for DHS not covered by Medicare. Further, the personal services and fair market value exceptions are still available for direct employment compensation arrangements between a physician and a DHS entity employer, and they do not have the "even if no referrals are made to . . . [the DHS entity]" language. Finally, CMS' proposed amendment to the "indirect compensation definition" and new rules on the "volume or value" standard raise the bar considerably for what passes as a plausible allegation of an indirect compensation arrangement. As it did in *UPMC*, a mere allegation of practice "losses" will not support a claim that the compensation satisfies the "volume or value" element of the indirect compensation definition. It appears that the issue of practice "losses" may as a practical matter be restricted in the future to the "fair market value" issue, not the "commercially reasonable" or "volume or value" issues.

> Although Stark law interpretation and analysis will always be plagued by the law's inherent complexity, CMS' attention to drafting errors and other fixable problems with the Proposed Rule will result in Stark regulations that are clearer than they have ever been.

"Volume or Value" Standard and the Special Rule for Group Practice Profit Shares

For a number of years health lawyers have debated the precise requirements of the "group practice" definition's special rule for profit shares. This rule permits a practice to pay a physician in the group practice a share of the *overall profits* of the group that is not directly related to the volume or value of the physician's referrals. The rule currently provides that "[o]verall profits means the group's entire profits derived from DHS payable by Medicare or Medicaid or any component of the group practice that consists of at least five physicians."[38] Some health lawyers have taken the position that this language requires a DHS pool to include the profits from all DHS generated by the participating physicians. Others have taken the position that a group practice can organize DHS profit pools by type of DHS, such that the group could have one DHS profit pool for laboratory tests in which one subset of physicians participate, and another DHS pool for imaging in which another, perhaps overlapping, subset of physicians participate. In preamble discussion, CMS indicates that it intended for "overall profits" to include *all* the DHS of the participating

physicians, either all the DHS profit of all the physicians in the group or all the DHS profit of a pod of at least five physicians.[39] Acknowledging that the current regulation text may not precisely evidence its intent, and "to provide a clear expression of our policy," CMS proposes to reword the rule to state

> Overall profits means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.[40]

Conclusion

CMS' amendments to and clarifications of the Stark law's "big three"—"fair market value," "commercially reasonable," and the "volume or value" standard, if finalized substantially as proposed, is a "game-changer." CMS should be commended for listening to the industry's concerns and proposing changes that go a long way towards achieving its goals of "bright-line" rules. Although Stark law interpretation and analysis will always be plagued by the law's inherent complexity, CMS' attention to drafting errors and other fixable problems with the Proposed Rule will result in Stark regulations that are clearer than they have ever been. C

Daniel H. Melvin is a partner at McDermott Will & Emery LLP and specializes in Stark, Anti-Kickback, and Medicare compliance matters. Daniel assists clients in investigating and addressing potential or alleged violations, including assistance with self-disclosures and defense of Stark- and Anti-Kickback-related qui tam actions. He is author of the book, "The Stark Law Explained: A Comprehensive Guide for the Health Care Industry, Attorneys and Compliance Professionals."

Troy A. Barsky is a partner in Crowell & Moring's Washington, DC office where he focuses on health care fraud and abuse, Medicare and Medicaid law and policy, and value-based care. He also defends clients seeking resolution of government health care program overpayment issues or fraud and abuse matters through self-disclosures and negotiated settlements with the United States. Troy has extensive prior government experience, serving at HHS for 11 years, most recently as the Director of the Division of Technical Payment Policy at CMS where he oversaw Stark Law policy.

Endnotes

1 84 Fed. Reg. 55766 (Oct. 17, 2019).
2 Views and opinions expressed in this article are those of the authors alone and not the law firms with which the authors are affiliated or AHLA.
3 42 U.S.C. § 1395nn(h)(3).
4 84 Fed. Reg. 55840 (to be codified at 42 C.F.R. § 411.351) (emphasis supplied).
5 *Id.*
6 *Id.*
7 *Id.*
8 84 Fed. Reg. 55766, 55798-99 (Oct. 17, 2019) (emphasis supplied).
9 *Id.* at 55798.
10 *Id.*
11 Carol K. Kane, Ph.D., *Updated Data on Physician Practice Arrangements: For the First Time, Fewer Physicians are Owners than Employees,* AMA Policy Research Perspectives (2019), https://www.ama-assn.org/system/files/2019-07/prp-fewer-owners-benchmark-survey-2018.pdf).
12 938 F.3d 397 (3d Cir. 2019).
13 63 Fed. Reg. 1659, 1700 (Jan. 9, 1998) (proposed Stark II rule); 66 Fed. Reg. at 877; 69 Fed. Reg. 16054, 16059, 16088 (Mar. 26, 2004) (final Stark II, Phase II rule); *see also* 72 Fed. Reg. 51012, 51029 (Sept. 5, 2007) (final Stark II, Phase III rule).
14 *See* 42 C.F.R. § 411.357(e)(1)(iii), (t)(1)(ii), and (r)(2)(iv).
15 66 Fed. Reg. 856, 877-78 (Jan. 4, 2001) (final Stark II, Phase I rule).
16 *See, e.g., United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602, 620-33 (W.D. Pa. 2010). *But see United States ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 693 (W.D. Ky. 2008).
17 *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364 (4th Cir. 2015).
18 In *Tuomey*, the part-time employed proceduralists were paid productivity compensation for personally performed procedures, but the compensation was contingent on the proceduralists referring their *private practice* patients *to* Tuomey for the compensated procedures. Consequently, there was a clearly impermissible causal relationship (not just a correlation) between each proceduralist's compensation and referrals to Tuomey.
19 938 F.3d 397 (3d Cir. 2019).
20 The Stark definition of "indirect compensation arrangement" currently requires that the relevant compensation link in the unbroken chain of financial relationships involves compensation that "varies with or takes into account" the volume or value of referrals or other business generated. 42 C.F.R. § 411.354(c)(2).
21 84 Fed. Reg. 55766, 55789, 55797 (Oct. 17, 2019).
22 *Id.* at 55842 (to be codified at 42 C.F.R. § 411.354(d)(5)(i)).
23 *Id.* at 55793.
24 *Id.* at 55842 (to be codified at 42 C.F.R. § 411.354(d)(5)(ii)).
25 84 Fed. Reg. 55766, 55794 (Oct. 17, 2019).
26 *Id.*
27 *Id.* at 55842-43 (to be codified at 42 C.F.R. § 411.354(d)(6)(i)).
28 *Id.* at 55793-94.
29 84 Fed. Reg. 55766, 55843 (Oct. 17, 2019) (to be codified at 42 C.F.R. § 411.354(d)(6)(ii)).
30 *Id.* at 55794.
31 *Id.* at 55795-96
32 *Id.* at 55796.
33 84 Fed. Reg. 55766, 55795 (Oct. 17, 2019).
34 *Id.* at 55790.
35 *Id.*
36 *Id.* at 55791.
37 84 Fed. Reg. 55766, 55791, 55802 (Oct. 17, 2019); 42 C.F.R. § 411.351 (defining "referrals" and "designated health services").
38 42 C.F.R. § 411.352(i)(2).
39 84 Fed. Reg. 55766, 55801 (Oct. 17, 2019); 84 Fed. Reg. at 55841 (to be codified at 42 C.F.R. § 411.352(i)).
40 84 Fed. Reg. at 55841 (to be codified at 42 C.F.R. § 411.352(i)).