Health Law Connections
January 2021

CMS Completes Sprint to Modernize the Stark Law—Part I

Daniel Melvin, McDermott Will & Emery LLP
Joan Polacheck, McDermott Will & Emery LLP
Troy A. Barsky, Crowell & Moring LLP

The Centers for Medicare & Medicaid Services (CMS) published its much-anticipated final Stark rule in the December 2, 2020 *Federal Register*, finalizing the most extensive changes to the Stark regulations since the final Stark II rulemaking in the 2000s (Final Rule).[1] The Final Rule is effective January 19, 2021, but it is possible that it could be stayed by the incoming Biden administration, along with other rules finalized by the Trump administration at the end of 2020.[2]

Due to the length of the Final Rule, this is a three-part series and, even then, will not discuss the entire rule. Parts II and III will be published in the February and March issues of *Health Law Connections*. Part I focuses on:

- New "definitions" for the volume or value of referrals and other business generated standards (the volume/value standards);
- The new and expanded "directed referral" *standard*; and
- The new "indirect compensation arrangement" definition.

Direct Compensation Arrangements and the New Volume/Value Standards

To provide the health care industry with "objective tests for determining whether compensation takes into account the volume or value of referrals or other business generated by the physician . . . ," CMS, in effect, "defines" these standards in the Final Rule. New 42 C.F.R. § 411.354(d)(5) and (6) specify when, *and only* when, compensation from or to a physician takes into account the volume or value of referrals or other business generated (OBG) by the physician.[3] While these new provisions are not, technically, definitions, for ease of communication we use "definitions" as a short-hand expression for them. CMS divides the "volume or value of referrals" (volume/value of referrals) and other business generated (volume/value of OBG) "definitions" into two contexts: (1) compensation received by a physician, and (2) compensation paid by a physician, each described below.

Compensation Received by a Physician. Compensation received by a physician takes into account the volume/value of referrals or OBG by the physician only if the formula used to calculate the physician's compensation includes the physician's referrals to or other business generated for the entity as a variable, resulting in an increase or decrease in the physician's compensation that *positively correlates* with the number or value of the physician's referrals to the entity.[4]

Compensation Paid by a Physician. Compensation paid by a physician takes into account the volume/value of referrals or OBG only if the formula used to calculate the entity's compensation includes the physician's referrals to or other business generated for the entity as a variable, resulting in an increase or decrease in the entity's compensation that *negatively correlates* with the number or value of the physician's referrals to or other business generated for the entity.[5]

Under these definitions, a hospital's payment of a fixed salary to a physician will never offend the volume/value standards, even if the compensation is above fair market value. This is consistent with CMS' policy that the volume/value of referrals and OBG standards are independent of the fair market value standard.

While the new "definitions" apply to the important exceptions for compensation to physicians for services, and to rent for space or equipment leases, the "definitions" do not apply to the following exceptions' volume/value standards:

- The medical staff incidental benefits exception at § 411.357(m);
- The professional courtesy exception at § 411.357(s);
- The community-wide health information systems exception at § 411.357(u);
- The electronic prescribing items and services exception at § 411.357(v);
- The electronic health records items and services exception at § 411.357(w); and
- The cybersecurity technology and related services exception at § 411.357 (bb).[6]

The new "definitions" for the volume/value standards are a real "game-changer." Key characteristics and implications of the new "definitions" are discussed below.

The New Volume/Value "Definitions" and the Special "Deeming" Rules or "Safe Harbors." Under the past volume/value of referrals and OBG standards, the special "deeming" rules or "safe harbors" for unit-based compensation at § 411.354(d)(2)-(3) were commonly key to complying with the standards. CMS acknowledges that the new volume/value "definitions" have made these "safe harbors" irrelevant but did not delete them. The reason the "safe harbors" are no longer relevant is that unit-based compensation based solely on a physician's personally performed services does not offend the new volume/value of referrals and OBG "definitions" at § 411.354(d)(5)(i)-(ii). CMS also acknowledges that the Stark employment exception's "productivity bonus safe harbor" (to the volume/value of referrals standard) is no longer relevant but has not deleted it because it is statutory.

Referrals and "Other Business Generated" as "Variables" in the Physician's Compensation Formula. CMS seems to think that if we paid attention in math class it will be easy to figure out when a physician's referrals/OBG are a "variable" in the physician's compensation formula (resulting in an increase or decrease to the compensation that positively correlates with number or value of the physician's referrals or OBG). In the context of compensation paid by a physician, CMS gives the example of

a physician leasing medical office space from a hospital. The rent is expressed as $5,000 per month less $5 for each diagnostic test the tenant refers to the hospital.[7] In this example, referrals are an explicit variable in the formula used to calculate the physician's rent, and it is certainly easy here to identify referrals as a variable in the hospital's compensation formula. Similarly, in the Proposed Rule's only example of when compensation received by a physician takes into account the volume or value of a physician's referrals or OBG, CMS hypothesized medical group compensation that pays 50% of a compensation pool composed of the practice's collections from the physician's personally performed services and collections from designated health services (DHS) and other services not personally performed by the physician but referred by the physician.[8] Here, again, the physician's referrals and OBG are an *explicit* variable in the physician's compensation formula, and it is easy to identify the physician's referrals and OBG as variables.

However, in the preamble to the Final Rule, CMS gives the example of an entity (but does not specify a group practice) paying a physician 20% of the entity's collections from a set of services furnished by the entity, telling us the collections will include collections from DHS referrals and OBG by the physician for the entity. CMS then reduces this compensation to the following mathematical formula: (.20 x value of the physician's referrals of DHS) + (.20 x the value of the OBG by the physician for the entity) + (.20 x the value of services furnished by the entity that were not referred or generated by the physician).[9] However, it is rare that a DHS entity expresses its physician compensation formula as 20% of the value of the physician's referrals of DHS plus 20% of the value of the other business generated by the physician for the entity plus 20% of the value of the services furnished by the entity not referred or generated by the physician. Instead, the DHS entity employer or purchaser of services would express the physician's compensation formula as "20% of the DHS entity's collections." Thus, the physician's compensation formula, expressed as a mathematical formula, will be .20 x DHS entity's collections; in this case the physician's referrals or OBG are not an express variable in the formula used to calculate the physician's compensation. Thus, it is apparent that CMS does not mean that referrals or OBG must be an explicit variable in the physician's compensation formula. However, CMS does not explain when referrals or OBG are an implicit variable in the physician's compensation formula.

For example, if a hospital hires an independent cardiologist to read all of the hospital's echocardiograms, and pays the cardiologist the rate of $20 per echocardiogram read, and the cardiologist refers her patients to the hospital for echocardiograms, are the cardiologist's referrals (all payors) to the hospital for echocardiograms an implicit variable in the formula used to calculate the physician's compensation? The more echocardiogram referrals the cardiologist makes, the more echocardiograms she can read and, thus, the more she is paid. Conversely, the fewer the echocardiogram referrals the cardiologist makes to the hospital, the fewer the echocardiograms the cardiologist can read and, thus, the less she is paid. In such case, the cardiologist's echocardiogram referrals to the hospital are not an express variable in the formula used to calculate her compensation. To calculate the cardiologist's compensation, we only

need to multiply the number of the physician's reads by $20, without any regard for the physician's referrals/OBG. However, are the cardiologist's referrals/OBG to the hospital for echocardiograms an implicit variable?

CMS' preamble commentary on productivity compensation, however, seems to provide the key to discerning when a physician's referrals/OBG are an *implicit* variable. CMS states that "[p]roductivity compensation based solely on a physician's personally performed services does not take into account the volume or value of the physician's referrals or other business generated standard, where it appears, in the exceptions . . . ."[10] CMS also states: "[U]nit-based compensation [e.g. $40 per work Relative Value Units (RVU)] based solely on personally performed services would not include the physician's referrals to or other business generated by the physician for the entity as a variable . . . ."[11] Further, discussing the categories of a DHS entity's collections that would be problematic to include in an individual physician compensation pool, the problematic categories of collections are those from services "furnished by the physician organization that the physician ordered but did not personally perform."[12] Consequently, we theorize that, if the *number* or *value* of the physician's referrals and OBG *for the DHS entity* are not an *explicit* variable in the formula used to calculate the physician's compensation, and the physician's compensation is not based in whole, or in part, on the services or items (or the collections therefrom) referred by the physician *but performed by the DHS entity*, the physician's referrals and OBG are *not* an implicit variable in the physician's compensation.

Applying this analytical approach (which is only theoretical at this stage of CMS' guidance on the new standards) to the echocardiography hypothetical above, we have already determined that the cardiologist's referrals to the hospital for echocardiograms are not an *explicit* variable in the cardiologist's compensation formula. The formula used to calculate the physicians' compensation is the number of reads times $20. The number or value of the cardiologist's own referrals to the hospital for echocardiograms are not an explicit variable in the physician's compensation formula. Thus, we next analyze whether the physician's compensation is based *solely* on the physician's personally performed services and conclude that it is. The cardiologist has to perform an echocardiogram read to be paid $20 and the hospital is clearly not furnishing this component of the echocardiogram. While the more referrals the cardiologist makes to the hospital for echocardiograms, the more echocardiograms the cardiologist will read, the $20 per read the physician receives is still solely a function of how many reads the cardiologist personally performs. There will be a meaningful degree of correlation between the number of echocardiogram referrals the cardiologist makes to the hospital and the amount of her compensation from the hospital, but she earns nothing from the technical component echocardiography services performed by the hospital pursuant to her referrals. Consequently, based on this approach, the cardiologist's referrals to the hospital for echocardiograms *furnished by the hospital* would *not* be a variable in the formula used to calculate the physician's compensation. Conversely, in the example above relating to a percentage of the DHS entity's collections, the physician's DHS referrals/OBG are an implicit variable in the physician's compensation formula that

affects the physician's compensation amount independently of personally performed services (i.e., the physician receives compensation based on services performed by the DHS entity for which the physician is only a source of referrals/OBG).

A Correlation Between Referrals/OBG and Compensation, and the New Volume/Value "Definitions." As noted above, the new "definitions" require that, for purposes of compensation received by a physician, the physician's referrals to or OGB for the entity must be a "variable" in the physician's compensation formula, resulting in an increase or decrease in the physician's compensation that "positively correlates" with the number or value of the physician's referrals or OBG for the entity.[13] The regulations provide that "a positive correlation between two variables exists when one variable increases as the other variable increases, and one variable decreases as the other variable decreases.[14] For purposes of compensation paid by a physician, referrals/OGB by the physician for the entity must be a "variable" in the physician's compensation formula, resulting in an increase or decrease in the physician's compensation that "negatively correlates" with the number or value of the physician's referrals or OBG for the entity.[15] The regulations provide that a "negative correlation" between two variables exists when one variable increases as the other variable decreases, or when a variable decreases as the other variable increases.[16]

The "correlation" of interest to many hospitals and health systems is the potentially "positive correlation" between a surgeon's (or proceduralist's) aggregate productivity compensation from a hospital employer (based solely on the physician's personally performed services) and the physician's admissions to the employer's hospital for surgeries or procedures that he will perform. In the final Stark II, Phase II rule, CMS stated that, notwithstanding a physician's concurrent orders for an outpatient hospital service whenever the physician has a patient encounter in the outpatient department, a physician may always be paid a "productivity bonus" for the physician's personally performed work.[17] By using the term, "productivity bonus," CMS seemed to be relying on the "productivity bonus" safe harbor to the volume/value standard of the employment exception, and CMS' preamble commentary in the Final Rule on productivity compensation seems to confirm this.[18] However, CMS was also persuaded by commenters on the Proposed Rule that, under its new volume/value "definitions," the volume/value safe harbors for unit-based compensation and the employment exception's productivity bonus safe harbor are no longer relevant.[19] Without any explanation for *why* the aggregate productivity compensation to a hospital-employed surgeon would *not* have a "positive correlation" with the number and value of the surgeon's concurrent admissions to the hospital for the surgery, CMS states that a physician may always be paid productivity compensation based *solely* on the physician's personally performed services.[20] This strongly suggests that CMS does not believe a hospital-employed surgeon's admissions are a variable in her compensation formula if her productivity compensation is based *solely* on her personally performed services; and, if the surgeon's admissions are not a variable in the physician's compensation, there cannot, in turn, be a "positive correlation" between the physician's admissions and the surgeon's compensation. Nevertheless, it would be helpful if CMS

affirmed that, in this context, only the physician's personally performed services are a "variable" in the productivity compensation formula.

The Expanded "Directed Referral" Standard

Recognizing that health systems, managed care organizations, and other entities employing or contracting for the personal services of physicians can have a legitimate business interest in steering patients to particular practitioners or facilities within the health system or managed care organization, CMS created a special "deeming" rule or "safe harbor" to the volume/value standard permitting hospitals and other DHS entities to require employed or contracted physicians to make referrals to particular providers, practitioners, and suppliers, if the following requirements are met.[21] (The track changes below show the substantive (but not literal) revisions CMS made to the special "safe harbor" for directed referrals, effective January 19, 2021.)

- The referral requirement is set out in writing and signed by the parties.
- The compensation arrangement otherwise complies with an applicable exception.
- The compensation, or the formula for determining the compensation:
  — is set in advance for the ~~term~~duration of the arrangement (even if the compensation arrangement is employment), meaning "[a]ny changes to the compensation (or the formula for determining the compensation) must be made prospectively. . . ;" and
  — is consistent with the fair market value of the physician's services ~~(that is, the payment does not take into account the volume or value of anticipated or required referrals).~~
- The referral requirement does not apply if:
  — the patient expresses a preference for a different provider, practitioner, or supplier;
  — the patient's insurer determines the provider, practitioner, or supplier; or
  — the referral is not in the patient's best medical interests in the physician's judgment.
- The required referrals relate *solely to* the physician's services covered by the scope of the employment, personal services arrangement or managed care contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement.

Under the Final Rule, however, requiring a physician to direct her referrals to a particular provider, practitioner, or supplier *is no longer a volume/value issue*.[22] *Instead*, CMS has converted the special "deeming" rule for directed referrals into an independent standard in the compensation exceptions for physician services arrangements, and modified the (now) independent standard to clarify its scope.[23] CMS also added the following requirement to those set out above:

(vi) . . . [N]either the existence of the compensation arrangement nor the amount of the compensation is contingent on the *number or value* of the physician's referrals to the particular provider, practitioner, or supplier. The requirement to make referrals to a particular provider, practitioner, or supplier *may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner or supplier.*[24]

Importantly, for the first time, CMS is expressly permitting DHS entities to make a bonus or "withhold" contingent on the physician achieving a percentage (but *not* a number or value) of "in-network" referrals, so long as the payment otherwise meets the volume/value standard of the applicable Stark exception (that includes a "directed referral" standard).[25] The DHS entity can also reduce the physician's fixed salary for the following year if the percentage target is not met in the current year, without offending the new volume/value and other business generated "definitions."[26] In the past, the consequences for a physician breaching a referral requirement was limited to termination of the physician. Health systems that employ physicians and struggle with so-called referral "leakage" will certainly be intrigued by the idea of tying compensation to achievement of "in-system" referral percentages.

Although CMS states that the compensation contingent on achieving an "in-network" percentage should not be evaluated for compliance with the volume/value standard, the volume/value and other business generated standards remain applicable to *all* compensation paid to a physician; and CMS cautions that the "directed referrals" standard cannot be used to pay compensation that would otherwise offend the volume/value and OBG standards. Given the example of a bonus pool funded to pay a physician differently stipulated percentages of the pool depending on the physician's "in-network" referral percentages, CMS cautions that, if the funding *formula* for the bonus pool offends the new volume/value and OBG "definitions" by, for example, including the number or value of the physician's referrals or OBG as a variable, the compensation would violate the volume/value and OBG standards.[27] Thus, the "directed referral," volume/value, and "other business generated" standards do not appear to be incompatible, that is, the "directed referral" standard does not permit an employer to do something the volume/value standards would not otherwise permit. In the case of compensation contingent on achieving an "in-network" referrals percentage, referrals might be a "variable" in the physician's compensation formula for purposes of the new volume/value of referrals "definition." However, the *number or value of* referrals in this case will not "result[] in an increase or decrease in the physician's . . . compensation that 'positively correlates' with the number or value of the physician's referrals to the entity."[28] A physician making nine out of a total of ten referrals "in-network" would have a higher percentage of "in-network" referrals than a physician making 80 out of a total of 100 referrals "in-network," and the percentage formula does not include the *value* of the referrals to the DHS entity as a variable. Thus, the "directed referral" percentage compensation will not "positively correlate" with the "number or value" of the physician's referrals and, thus, offend the new volume/value standards.

Notwithstanding the "directed referral" standard's greater flexibility and utility, the new standard raises questions and issues not yet addressed by CMS:

"In-Network" Referral Targets and the Three Directed Referral Exceptions. CMS does not indicate what happens if a physician does not hit the percentage target because of "outside" (DHS) referrals due to patient choice, insurer decisions, and the best medical interest of the patient in the physician's judgment. For example, if the physician has a 75% referral requirement, and the first ten referrals of the year include eight in-network and two out-of-network for an 80% "in-network" rate, but the physician's remaining five referrals for the year are "outside" referrals due to patient choice, the physician will fail the 75% target because she respected patient choice. CMS presumably intends for "outside" referrals due to one of the three exceptions to be excluded from the denominator used to calculate the percentage, but CMS has not explicitly said so.

Implied or Unexpressed Referral Conditions. CMS clearly states that the "directed referral" standard "is not limited to express or written requirements to refer patients to a particular provider, practitioner, or supplier selected by the entity paying the compensation."[29] Consequently, hospitals and health systems, in particular, will need to be sure to fully document in the physician's employment or services agreement both the financial and non-financial terms of the referral requirement *and* the potential consequences of the physician failing to comply. Note that the "directed referral" standard still applies to compensation *arrangements.* For example, if an employer puts a physician's compensation at risk for not hitting a 75% "in-network" target, the consequence of not hitting the target for the physician's compensation *amount* is clear. However, if the physician does not hit the target and the agreement is otherwise silent on the matter, the physician is not in breach of the employment agreement, subject to "for cause" termination. In this case, if the employer then decides to terminate or non-renew the physician's employment "without cause" because the physician failed to hit the stated target or the DHS entity's internal target, the physician could reasonably allege that the employer had conditioned the compensation *arrangement* on required referrals *without* setting this out in a signed writing.

Directed Referrals and Employed Surgeon Workplace Restrictions. In the preamble to the Final Rule, a few commenters asked whether employment terms prescribing *which* hospital or other facility a surgeon or proceduralist is to work at (usually accompanied by a restriction on the physician holding clinical privileges at other facilities) implicate the (now) "directed referral" standard of the employment exception. CMS agrees with the commenters that the standard is not intended to interfere with the employer's rights or infringe on the employer-employee relationship. However, by implication (only), CMS takes the position that such workplace restrictions *are* a form of directed referrals. While CMS does not plainly state this position, it concurs with the commenters' notion that, if the "directed referral" standard applies to workplace restrictions on surgeons and proceduralists, the employer can satisfy the exceptions by requiring and assisting the physician to find another "outside" physician to perform the surgery/procedure at the competing "outside" facility, so long as the referral to the "outside" physician is

"appropriate." CMS should explicitly confirm that its position is that such employee workplace restrictions implicate the "directed referral" standard because they are common in the industry and not always made subject to the "directed referral" standard's three required exceptions.[30]

The New Indirect Compensation Arrangement "Definition"

The test for when a chain of financial relationships creates an indirect compensation arrangement (the indirect compensation definition) has been critical to Stark Law analysis for a long time. The new indirect compensation definition at 42 C.F.R. § 411.354(c)(2), not even hinted at in the Proposed Rule, revolutionizes the indirect compensation definitional analysis.[31] While not eliminating the indirect compensation *exception* (42 C.F.R. § 411.357(p)), CMS has redesigned the indirect compensation *definition* so that few non-abusive unbroken chains of financial relationships will need the exception; and, in any event, it seems unlikely that any arrangement that satisfies the new indirect compensation definition would qualify for the exception.

Space does not permit a full description of the *current* indirect compensation definition, but it essentially has the following three elements. *All three elements must be present* for there to be an indirect compensation arrangement between a DHS entity and a referring physician:

- (a) There must be an unbroken chain of financial relationships (any kind) running between the referring physician and the DHS entity;
- (b) At least one link in the chain must be compensation running towards the physician (the Relevant Compensation) and, if there is more than one such link, the one closest to the physician is the Relevant Compensation; and
- (c) The DHS entity knows or should know that the aggregate Relevant Compensation varies with or takes into account the volume or value of the physician's referrals or other business generated for the DHS entity.[32]

The new indirect compensation definition retains certain of these elements, but adds new elements and modifies others, as follows, *all of which much exist*:

- (1) There must still be an unbroken chain of financial relationships, as described above.
- (2) There must still be Relevant Compensation, as described above;
- (3) The aggregate Relevant Compensation *varies with* the volume or value of referrals or other business generated for the DHS entity down the chain;
- (4) The Relevant Compensation's "*individual unit of compensation*" is:

(i)not fair market value; or
(ii)includes the physician's referrals to or other business generated for the DHS entity as a variable, resulting in an increase or decrease in the unit of compensation that positively correlates with the number or value of the physician's referrals to or other business generated for the DHS entity down the chain.

- (5) The DHS entity knows or should know that the aggregate Relevant Compensation[33] *varies with* the volume or value of referrals or other business generated for the DHS entity.[34]

Notwithstanding the fact that the new indirect compensation definition is novel and not even hinted at in the Proposed Rule, CMS does not provide an example illustrating how it works. However, CMS' intent seems fairly clear with one caveat. The elements ##1-3 and #5, above, essentially mirror the current definition. The "varies with" element (#3 above) still applies to the *aggregate* compensation. However, if the aggregate Relevant Compensation "varies with" the volume of the physician's referrals, if only because of a correlation between the two, and the DHS entity down the chain knows or should know this, instead of turning to the indirect compensation *exception* at this point and determining whether the unit-based compensation "safe harbors" at § 411.354(d)(2)-(3) apply, *CMS has included a unit-based compensation element into the definition, itself, at element # 4 above*. CMS only applies required element #4 to the "individual unit of compensation." Thus, if aggregate compensation to a physician only "varies with" the volume or value of the physician's referrals or OBG to the DHS entity down the chain because of a correlation between a physician's percentage of professional collections compensation and referrals/OBG for the DHS entity, it is unclear whether element #4 even comes into play because it is unclear whether percentage of professional collections compensation is unit-based compensation as contemplated by the definition. CMS has never made an explicit published statement that percentage of collections compensation (as compared to percentage of fee schedule) is a unit of or unit-based compensation. If the physician's aggregate compensation "varies with" the volume or value of the physician's referrals or OBG because of a correlation between the physician's *unit-based* compensation and referrals or OBG to the DHS entity, the definition's new fair market value (FMV) and volume/value elements at #4 above apply.

For example, the surgeon could be employed by the health system's affiliated medical group and admitting patients to the health system's affiliated hospitals. In such case, if the surgeon's *aggregate* compensation derived from a dollar rate per (personally performed) work RVU is deemed to "vary with" the volume or value of the surgeon's referrals or OBG to the down-the-chain hospital because of the correlation between the two, and the dollar rate per work RVU is *not* FMV, the surgeon's compensation would create an indirect compensation arrangement between the surgeon and the down-the-chain hospital. If the dollar rate per work RVU remains within the range of fair market value but is subject to an upward or downward adjustment tied to the number or value of the surgeon's admissions to the hospital, the surgeon's compensation would also

create an indirect compensation arrangement between the surgeon and the hospital because the dollar rate per work RVU compensation (the "individual unit of compensation") would now include the surgeon's referrals to the hospital *as a variable*. Only then would we turn to the exceptions for indirect compensation arrangements.

While we believe this hypothetical probably illustrates CMS' new indirect compensation definitional analysis, it would be helpful if CMS issued confirming guidance and clarify whether percentage of collections compensation is an "individual unit of compensation." Key implications of the new definition include the following:

- Relevant Compensation that is a fixed or flat aggregate amount, such as a guaranteed salary, will not create an indirect compensation arrangement, regardless of whether the Relevant Compensation is FMV or not.
- Unit-based compensation, such as a rate of compensation per work RVU, resulting in *aggregate* compensation that "varies with" the number or value of the physician's referrals or OBG for a down-the-chain DHS entity (because of the correlation between the two), will only create an indirect compensation arrangement with the DHS entity if the "individual unit of compensation" is not FMV *or* is subject to an adjustment (the unit rate) based on the *number* or *value* of the physician's referrals or OBG for the DHS entity.

Endnotes

1 85 Fed. Reg. 77492 (Dec. 2, 2020).
2 CMS' amendments to 42 C.F.R. § 411.352(i), the special rules for profit shares and productivity bonuses, is not effective until January 1, 2022, to give those group practices who need it time to restructure their compensation.
3 85 Fed. Reg at 77667, *codified at* 42 C.F.R. § 411.354(d)(5)-(6).
4 *Id., codified at* 42 C.F.R. § 411.354(d)(5). "Other business generated" means referrals for services or items that are not Stark designated health services (DHS). By definition, DHS is Medicare-covered.
5 *Id., codified at* 42 C.F.R. § 411.354(d)(6).
6 85 Fed. Reg at 77667, *codified at* 42 C.F.R. § 411.354(d)(5)(iv)-(6)(iv).
7 85 Fed. Reg. at 77538.
8 84 Fed. Reg. 55766, 55793 (Oct. 17, 2019).
9 85 Fed. Reg. at 77540.
10 85 Fed. Reg. at 77541.
11 *Id. at* 77542. *See also* 85 Fed. Reg. at 77540-41.
12 85 Fed. Reg. 77492, 77538.
13 85 Fed. Reg at 77667, *codified at* 42 C.F.R. § 411.354(d)(5).
14 *Id. codified at* 42 C.F.R. § 411.354(d)(5)(iii).
15 *Id. codified at* 42 C.F.R. § 411.354(d)(6).
16 85 Fed. Reg. 77492, *codified at* § 411.354(d)(6)(iii).
17 69 Fed. Reg. 16054, 16067, 16089 (Mar. 26, 2004).
18 85 Fed. Reg. at 77539.
19 85 Fed. Reg. at 77541.

20 *Id.*
21 66 Fed. Reg. 856, 877-78 (Jan. 4, 2001), *codified at* 42 C.F.R. § 411.354(d)(4).
22 85 Fed. Reg. 77492, 77550.
23 85 Fed. Reg. at 77666, *codified at* 42 C.F.R. § 411.354(d)(4).
24 *Id., codified at* 42 C.F.R. § 411.354(d)(4)(vi).
25 85 Fed. Reg. at 77549-550.
26 *Id.*
27 85 Fed. Reg. 77492, 77550.
28 85 Fed. Reg. at 77667, *codified at* 42 C.F.R. § 411.354(d)(5)(i).
29 85 Fed. Reg. at 77550.
30 Note that this issue is limited to employed surgeons, proceduralists, and, perhaps, employed radiation and medical oncologists assigned to supervise and manage plans of care at the employer's or its affiliates' radiation and chemotherapy facilities.
31 85 Fed. Reg. 77492, 77665, *codified at* 42 C.F.R. § 411.354(c)(2).
32 42 C.F.R. § 411.354(c)(2).
33 The regulatory text actually requires that the DHS entity know or should know that "the physician . . . receives aggregate compensation that varies with the volume or value of referrals or other business generated by the physician for the entity furnishing the DHS." However, based on the structure of the definition, CMS appears to mean the aggregate "Relevant Compensation," which might be down the chain from the physician.
34 85 Fed. Reg. at 77665, *codified at* 42 C.F.R. § 411.354(c)(2).

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."

Joan Polacheck is a Partner at McDermott Will & Emery LLP and advises clients on health care compliance and regulatory issues, including fraud and abuse, Stark Law, Anti-Kickback Law, and Medicare reimbursement issues. She represents a broad range of health care industry clients, including hospitals, physician groups, DME suppliers, IDTFs, and drug and device companies.

Troy 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.
