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Analyzing AMC Compensation Plans Under the New Stark Amendments: What's New and What's Really Not

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The culmination of the Trump administration's efforts to reform the Stark Law were published on December 2, 2020 in the form of amendments to the physician self-referral law regulations.[1] This effort, which first began two-and-a-half years prior with a solicitation of comments from the public on the Stark rule, produced another 150 pages of three-columned *Federal Register* commentary, countless amendments to the regulatory text, and three new exceptions. Much has been written about how these new regulations remove regulatory barriers and adopt objective tests for providers to determine compliance.

As explained below, while the new rules may change how academic medical centers (AMCs) analyze their faculty compensation plans for compliance with the Stark Law, they fall far short of providing a simple, objective test for ensuring compliance.

The Search for Certainty

A significant portion of the amendments focus on changes to the "special rules on compensation" and the determination of when compensation "takes into account" the volume or value of referrals or other business generated between the parties. These changes have a big impact on how AMCs analyze their faculty compensation plans under the Stark rule.

Most AMCs have employment relationships with their faculty physicians and the "takes into account" test has always been critical to protecting faculty physician referrals to various components of the AMC. The Centers for Medicare & Medicaid Services (CMS) discusses the "takes into account" test in a lengthy section of the commentary to the final rule entitled "Volume or Value Standard and the Other Business Generated Standard."[2] Evidencing some frustration with the provider community (or at least their attorneys), CMS writes "[d]espite our attempt at establishing clear guidance regarding the application of the volume or value standard and the other business generated standard, commenters to several requests for information . . . identified their lack of clear understanding as to whether compensation will be considered to *take into account* the volume or value of referrals or other business generated by the physician as one of the greatest risks they face."[3]

CMS concludes that "there is great value in having an objective test for determining whether the compensation is determined in a manner that takes into account the volume or value of referrals or takes into account the volume or value of other business generated between the parties."[4] It then states: "We are finalizing an approach that . . . defines *exactly* when compensation will be considered to take into account the volume or value of referrals or the volume or value of other business generated between the parties."[5]

But exactly how precise is this new approach? In reality, CMS has largely substituted one ambiguous standard for another. The lack of certainty that still pervades the "takes into account" determination is demonstrated by examining how a typical AMC faculty compensation plan would be analyzed under the new methodology.

The AMC Stark Analysis

Most AMCs include a teaching hospital and a separately organized Faculty Practice. There are many variations to this model, but typically the faculty practice includes one or more professional practice entities, sometimes organized by specialty but often integrated into a single, multi-specialty practice entity. (For simplicity, we refer to all these entities as the "Faculty Practice.") The teaching hospital typically provides financial assistance to the Faculty Practice to support their common educational, research, and patient care mission, and these funds are often used to support

recruitment and retention of highly trained faculty. The teaching physicians are dually employed by the practice entity for their clinical practice and the medical school for the academic component of their work. Typically, the faculty physicians are no more than nominal shareholders of the Faculty Practice and often do not own any equity interest in the Faculty Practice.

This structure creates both direct and indirect compensation arrangements for the teaching physicians, which need to be protected under the Stark law. The direct compensation arrangement runs from the physician to the Faculty Practice and the indirect compensation arrangement runs from the physician to the teaching hospital.

The Old Methodology

Under the old Stark rule methodology, we would first examine the direct compensation arrangement. This relationship is only problematic under the Stark rule if the Faculty Practice performs designated health services (DHS). If it does, then the teaching physician will be making referrals for DHS to the Faculty Practice and his or her direct compensation arrangement with the Faculty Practice needs to be protected. In many AMCs, the Faculty Practice does little or no DHS—the services are all performed by the teaching hospital—so the Stark Law is often not applicable to the direct relationship. But it is common for a few specialty groups within a Faculty Practice to provide some types of DHS.

Protection of the Direct Compensation Arrangement

There are two potential exceptions available under the Stark Law to protect the direct referral relationship between faculty physicians and their Faculty Practice. The first of these exceptions is the "in-office ancillary services" exception, which is available to Faculty Practices that qualify as a "group practice" under the Stark Law. While Faculty Practices typically will qualify as a group practice under Stark, determining how financial assistance from the affiliated teaching hospital to the Faculty Practice might be considered to affect its calculation of overall profits from DHS is uncertain.

Therefore, AMCs typically look to the "employment exception" to protect the direct referral relationship between a faculty physician and his or her Faculty Practice. Under this exception, referrals from a faculty physician are protected if, among other requirements, the compensation does not "take into account" the volume or value of referrals by the faculty physician to the Faculty Practice. This test is the same standard as applied to indirect compensation arrangements and is discussed below in that context.

Protection of the Indirect Compensation Arrangement

The more problematic relationship for AMCs has often been the indirect compensation arrangement between the faculty physicians and the teaching hospital. There are two Stark exceptions potentially available to protect this indirect arrangement: the "AMC exception" and the "indirect compensation arrangements exception." Typically, AMCs

have favored relying on the indirect compensation arrangements exception because the AMC exception includes a "set in advance" requirement not contained in the indirect compensation arrangements exception. The set in advance requirement in the AMC exception precludes the Faculty Practice from paying any year-end discretionary compensation unless it had established a "specific formula" that can be "objectively verified" prior to the start of the fiscal year for which the bonus is to be paid.[6] In practice, for timing or other reasons, AMCs sometimes have difficulty meeting the set in advance requirement.

In contrast, the indirect compensation arrangements exception has allowed year-end bonuses so long as the compensation received by the physician is fair market value for services actually provided and it does not take into account the volume or value of referrals or other business generated for the teaching hospital. This standard is more flexible; for example, by potentially allowing a discretionary bonus to be paid for academic recognition, citizenship and professional development, leadership role in a department, etc. Of course, the AMC will carry the burden of proof to demonstrate that a discretionary bonus is not a disguised form of a payment for referrals to the teaching hospital. In practice, it is often not difficult for an AMC to demonstrate that there is no association between the two.

Under the old methodology we would assume, for purposes of the analysis, that the physician's aggregate compensation from the Faculty Practice varied with his or her referrals to the teaching hospital, thereby creating an indirect compensation arrangement between the teaching physician and the teaching hospital. Typically, a teaching physician's services correlate with inpatient or outpatient hospital services at the teaching hospital, and under CMS' earlier guidance, this fact indicated the presence of an indirect compensation arrangement.[7] We then would apply the indirect compensation arrangement exception and rely upon the "special rules on compensation" to protect time-based or per-unit of service compensation (such as a per work Relative Value Unit (wRVU) payment) to protect the bulk of the teaching physician's compensation.

It is important to note that most faculty physician compensation is paid in the form of base salary (typically at least 50% and often as much as 90%), with the balance being in the form of incentive, per-unit of service compensation (often tied to individual wRVUs). This approach has always been the safest under the Stark Law. But it is common for Faculty Practice compensation plans to afford some latitude to department chairs to reward a faculty physician for exemplary service, and in these instances, the requirements of the special rules on compensation for protecting unit-based compensation cannot be met.

Under the old methodology, if there was any additional discretionary compensation—e.g., an award for academic achievement—the AMC could still argue that the award did not take into account the volume or value of referrals or other business generated by

the teaching physician for the teaching hospital. Any discretionary compensation that did not fit squarely within the deeming exception for unit-based compensation always presented some degree of risk because it would be analyzed under a facts and circumstances test to determine whether it took into account referrals to the teaching hospital, and the AMC would have the burden of proof.

Because any lack of certainty in a Stark Law analysis is a reason for concern, there have long been calls for CMS to provide an objective test for determining when compensation will be deemed to take into account referrals or other business generated. There is a crucial need for clarity on the "takes into account" analysis under Stark because it is a "strict liability" statute where the presence of good faith efforts to comply are irrelevant.[8]

The New Methodology

Under its new methodology, CMS drops the old, ambiguous "takes into account" test and substitutes an almost equally ambiguous "positively correlates" test. The new methodology makes this switch by adding Section 411.354(d)(5) to the special rules on compensation. This new section explains that compensation to a physician takes into account referrals (or other business generated) only if "*the formula used*" to calculate the physician's compensation includes the physician's referrals as a "*variable*" and the physician's compensation "*positively correlates*" with his or her referrals.[9]

A reading of only the regulatory text might lead to the conclusion that the new changes provide the long-sought-after certainty for avoiding risk under the "takes into account" test, but the reader would be making a potentially serious mistake in reaching that conclusion. The ambiguity arises in how CMS uses the italicized terms. CMS did not define these highlighted terms in any meaningful way in the regulation, and it is only through a very careful reading of the commentary that CMS' position becomes apparent.

First, in the commentary CMS indicates through several illustrations[10] that whether a compensation plan is expressed as a formula is irrelevant; CMS will convert the compensation plan to a mathematical formula even if it is expressed differently.

Second, CMS makes it clear that a Faculty Practice compensation plan cannot avoid risk simply by avoiding any reference to referrals as a "variable." CMS specifically rejected a recommendation that referrals be written or expressly articulated in the formula for them to be considered a variable.[11] Instead, CMS states that it will apply the same facts and circumstances test it previously applied using the "takes into account" test. In responding to comments, CMS uses a "system success" bonus as an example and states that "although bonus compensation based on 'system success' may not include referrals to or other business generated for the entity as a variable in many instances, the determination of whether the formula to determine the compensation includes such variables must be made on a *case-by-case basis*."[12] This case-by-case

review for determining when referrals will be considered present as a variable in a formula is no different than the previous test used for determining when compensation takes into account referrals.

The news is not all bad—CMS reiterates on several occasions in the commentary that per-unit of service payments that are fair market value for personally performed services will not be considered to take into account referrals, even when they are associated with DHS (as is often the case in the AMC setting), so long as they meet the requirements of the old deeming exceptions for per unit of service compensation at 42 C.F.R. § 411.354(d)(2) and (3). However, CMS refused a "large number of requests" to expressly permit compensation formulas based on personal productivity[13] and it confused matters further by stating that the old per-unit of service exceptions in the special rules on compensation remain "*only for historical purposes*" to assist parties in applying the historical policies in effect at the time of the existence of the compensation arrangement being analyzed for compliance with the Stark Law.[14]

Lastly, CMS made much of what it views as a streamlined analysis of indirect compensation arrangements. As noted above, under the old methodology, we would consider most faculty physicians to have an indirect compensation arrangement with their teaching hospital because of the association between their personal services and the teaching hospital's performance of inpatient or outpatient hospital services, which are both a form of DHS. The AMC would then have to show compliance with the per unit of service exceptions in the special rules on compensation at 42 C.F.R. § 411.354 (d)(2) and (3) and the indirect compensation arrangements exception at 42 C.F.R. § 411.357(p). Under the new methodology, the indirect compensation arrangements exception becomes largely irrelevant (much like the AMC exception is already) because the new "positively correlates" test is applied at an "earlier stage of analysis"; that is, when determining whether an indirect compensation arrangement exists at all. CMS explains that it revisited the "regulatory construct" and will apply a new approach where it analyzes unit-based compensation at the "definitional stage," which it views as less burdensome.

Impact of the New Stark Rules on the AMC Analysis

The new rules do little to provide greater certainty to AMCs in analyzing their faculty compensation plans. As before, compensation will not trigger Stark liability if the physician is paid at a fair market rate and on a per-unit of service basis even if the physician's professional services are closely associated with DHS performed by the teaching hospital. Additionally, as before, discretionary compensation that is not a per-unit of service payment will present risk under a facts and circumstances test. CMS continues to see physician compensation through a narrow construct of base salary and identifiable per-unit of service compensation. CMS' representation of having defined "*exactly"* when compensation will take into account referrals overstates what it accomplished with these amendments. The new "positively correlates" test seems no

more exact than the old "takes into account" test. Both depend upon the facts and circumstances of the particular arrangement.

The new analytical approach used by CMS to weed out indirect compensation arrangements at the definitional stage, rather than waiting to protect them under an analysis of the indirect compensation arrangements exception, also provides little practical benefit to AMCs. It may be a useful intellectual shortcut for health care lawyers, but it does not fundamentally change any of the results.

Finally, CMS has continued its practice of relying on commentary to fill in gaps in the regulatory text. A plain reading of the regulation, without consulting the commentary, might lead an AMC to reasonably conclude that it can avoid a determination that compensation paid to faculty physicians takes into account referrals under Stark simply by not using a mathematical formula that contains referrals as a variable. According to CMS' commentary, [15] this clearly is not the case, even though the regulation specifically lists the use of a "formula," and the use of referrals as a "variable" in that formula, as a predicate to finding that compensation takes into account referrals. CMS could have made its position clear in the regulatory text that neither an actual mathematical formula nor the identification of referrals as a variable is required to find a violation. Providers should not be expected to comb through hundreds of pages of CMS commentary to find the true meaning behind a provision of the Stark rule.

CMS' regulation and commentary regarding the "takes into account" test is a classic example of wanting to have it both ways—articulating what appears to be a straightforward, formulaic approach in the regulation, only to undermine it in the commentary. In the end, CMS may find that its reliance on commentary to impose standards not expressly stated in the Stark rule—a seemingly longstanding practice when it comes to the Stark regulations—may undermine its ability to enforce the law, as Department of Justice policy requires criminal and civil enforcement actions to be based on violations of applicable legal requirements, not mere noncompliance with guidance documents, such as commentary in the *Federal Register*.[16] AMCs will not want to test that hypothesis, however, so they will need to continue to be vigilant for Stark risk when developing faculty compensation plans.

About the Author

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[1] Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77492–77655 (Dec. 2, 2020).

[2] *Id.* at 77535.

[3] *Id*. at 77536.

[4] *Id.* at 77537.

[5] *Id.*

[6] 42 C.F.R. § 411.354 (d)(1).

[7] 69 Fed. Reg. 16059 (Mar. 26, 2004).

[8] 73 Fed. Reg. 48704 (Aug. 19, 2008) ("The physician self-referral statute is a strict liability statute, meaning that a financial relationship that does not meet a relevant exception because the compensation was above or below fair market value (or because of any other reason) is noncompliant, regardless of whether one or both parties to the arrangement were unaware of the defect.").

[9] 42 C.F.R. § 411.354(d)(5). There is also a corresponding "negatively correlates" test that is applicable where compensation is paid from a physician to a DHS entity, for example where the amount of rent paid by a referring physician to a teaching hospital goes down as his referrals go up. 42 C.F.R. § 411.354(d)(6). We focus on the "positively correlates" test because it will apply to AMC compensation paid to teaching physicians. The analysis is essentially the same under both tests, only in reverse, depending on whether the referring physician is paying or receiving compensation.

[10] 85 Fed. Reg. at 77538.

[11] *Id.* at 77542-43.

[12] *Id.* at 77542.

[13] *Id.* at 77540.

[14] *Id.* at 77544. The per unit of service exceptions are still contained in the rule at 42 C.F.R. § 411.354(d)(2) and (3).

[15] 85 Fed. Reg. 77543.

[16] Limitation on Use of Guidance Documents in Litigation, Department of Justice Manual, Section 1-20.000, https://www.justice.gov/jm/1-20000-limitation-use-guidance-documents-litigation (last visited Feb. 19, 2021).