The Stark Law is Never Easy: Attempts to Clarify May Fuel Confusion

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The Centers for Medicare & Medicaid Services (CMS) finalized its massive rulemaking, proposed in 2019, to modernize and clarify the Social Security Act's Physician Self-Referral Law ("the Stark Law" or "Stark").[i] The new rule, published on Dec. 2, 2020, has a number of benefits, including new exceptions for certain value-based payment arrangements and modest relaxation of certain terms that underlie the law's existing exceptions for compensation relationships between physicians and outside entities to which they refer their patients.

Decidedly not among the new rule's virtues, however, is simplicity. Like all of its predecessors, the new Stark rule is mind-numbingly complex. No physician or group practice executive could begin to understand the full length and breadth of it. Lawyers, accountants and other advisers will strive to decipher it. Certain questions may be answered more clearly than in prior rulemakings, whereas others will remain murky. The Stark Law is now over 30 years old and its implementing rules have been the subject of constant revisions. Will certainty ever be achieved? Based on MGMA's experience over the decades and its initial analysis of the new rule, it's highly unlikely.

Buried in the new final rule is one "clarification" that may complicate compensation planning for practice leaders, particularly large and mid-sized multispecialty groups using different compensation practices for different specialties or departments. Similarly, multi-site practices, whether single or multi-specialty, also may be affected if differing compensation plans are used for different locations. The balance of this article attempts to summarize the issue as concisely as possible, but with this caveat: Stark is never easy!

Almost all physician-owned practices rely on Stark's in-office ancillary services (IOAS) exception to protect referrals for designated health services ("DHS") (Stark parlance for clinical labs, most imaging and certain other ancillaries paid for by Medicare), provided **inside the group**. To use the IOAS exception, which has certain detailed requirements of its own not the subject of this article, the group first must qualify as a *bona fide* group practice as defined in the Stark Law and regulations. That qualification depends on a number of detailed requirements set forth in 42 CFR §411.352. Among those requirements are limitations on how group members are compensated in relation to their individual referrals of Medicare patients for DHS. Because the statute and regulations dictate permissible compensation structures within a group practice as a predicate requirement, groups must ensure compliance with the compensation provisions before an exception applicable to a group practice can be used. Notably, the changes discussed in this article around *bona fide* group practice compensation plans do not kick in until Jan. 1, 2022, as CMS recognizes groups may need time to make changes in order to comply with new standards.

This "compensation test," as it has come to be known, is relatively simple in theory. First, the statute and the rules prohibit a group member from receiving, **directly or indirectly**, compensation based on the volume or value of the physician's referrals for DHS. But then the statute and rules provide an exception to this prohibition for **profit sharing and productivity bonuses** if the share or bonus is not determined in a manner **directly** related to the volume or value of those referrals. Unfortunately, like seemingly everything else in Stark, complexity quickly arose. In permitting profit sharing not directly related to referrals, the statute uses the phrase "a share of overall profits of the group."[ii] Congress did not further elaborate on a how a "share" might be calculated, or what was intended by "overall" profits. CMS, in an interpretation that most thought helpful, long ago defined "overall" to mean the "**entire profits**" derived from the group's DHS payable by Medicare and Medicaid, or such profits derived from DHS "**of any component**" of the group consisting of **at least five** physicians.[iii] This interpretation became known as the "rule of five." Many commentators believed that this gave groups substantial flexibility in distributing profits to groups of five or more by department, specialty or location, as long as the grouping was reasonable and any linkage between profits distributed and referrals remained indirect. This view was buttressed by the language of §411.352(f)(2) of the old rule, which is part of what is known as the "unified business" test for groups. It read as follows, and has not been changed in the new rule:

> "(2) **Location and specialty-based compensation practices are permitted** with respect to revenues derived from services that are not DHS **and may be permitted with respect to revenues derived from DHS** under paragraph (i) of this section." (emphasis added)

Now CMS has muddied the waters considerably. In the preamble to the proposed rule in 2019, and again in the December 2020 final version, CMS articulates that "overall profits" means that DHS income pools must include the profits from **all the DHS** of the physician practice (or a component of at least five physicians in the practice). Under this interpretation, the final rule dictates that a group practice first must aggregate all DHS profits from the entire group or a component of five before distribution. The practical effect of this change is that group practices large enough to maintain separate components of five or more physicians will no longer be permitted to distribute profits from DHS on a "split pool" basis, in which one component receives profits from **one type of DHS** (e.g., laboratory) and another component receives profits from a different type of DHS (e.g., physical therapy). In other words, a group practice that furnishes both clinical laboratory and physical therapy services cannot distribute profits from laboratory services to one subset of physicians and profits from physical therapy to a different subset.

A group may continue to recognize separate components of at least five physicians for purposes of distributing profit shares and may establish components based on a range of criteria, such as similar practice patterns, years of experience, tenure with the group or location. The methodology used to distribute profit shares and eligibility to receive profits can vary by

component; however, CMS clarifies that the group must use one single methodology within a given component.

To illustrate, CMS provides an example:

- A group practice comprised of 15 physicians furnishes three types of DHS: clinical laboratory services, diagnostic imaging services, and radiation oncology services. The group divides its physicians into three components of five physicians (A, B, and C). To comply with the "revised" special rule on profit shares, the group practice must aggregate the profits from all of the DHS furnished by the group and referred by any of the five physicians in the component before distribution. The group may then distribute the overall profits from all DHS to: (i) Component A using one method (e.g., per-capita), (ii) Component B using a different method (e.g., personal productivity), and (iii) Component C using a third method (or the methodology used for A or B).

To reiterate, the final rule would not permit the group to distribute clinical laboratory services to Component A and imaging services to Component B. It would also not permit the group to use a per capita methodology for some physicians in Component A and personal productivity for other members of Component A.

CMS believes that Stark Law preamble guidance has **always** articulated this position; namely, that "overall profits" means the profits from **all** DHS, not profits from one individual category of DHS. To support this "longstanding" position, the agency cites previous preamble guidance dating as far back as 2001. Despite believing the preamble has been "clear" on this interpretation, CMS acknowledges that the regulatory text defining "overall profits" at 42 CFR §411.352(i) did "not accord precisely with" or "fully and exactly depict[]" preamble guidance. Therefore, the agency delayed implementation of the final rule's profit-sharing policies until Jan. 1, 2022. This is at least a moderate improvement from the proposed rule, which implied the prohibition around split pool distributions would be retroactive, raising concerns about groups that have understandably interpreted CMS policy differently.

It is worth noting that all this discussion and guidance is set forth in the preamble text, not the codified regulatory text. When agencies release proposed and final changes to regulations, the amended regulatory text is accompanied by "preamble" language — often the bulk of the Federal Register filing — that explains the rationale for the regulatory action of the federal agency. The preamble can contain history on rulemaking, responses to stakeholder comments, analysis and/or discussion on the agency's final decision.

Interestingly, the policy shift reflected in the preamble is not readily apparent from the change to the regulatory text itself. Therefore, ironically, CMS is perpetuating the same problem it sought to fix through the final rule. Subsection 352(i) of the old rule, still in effect through 2021, contains these provisions relevant to profit sharing.

(i) *"Special rule for productivity bonuses and profit shares*.

(1) A physician in the group practice may be paid **a share of overall profits of the group**, provided that the share is **not determined in any manner that is directly**

related to the volume or value of referrals of DHS by the physician." (emphasis added)

. . . . . .

"(2) **Overall profits** means the group's **entire profits derived from DHS** payable by Medicare or Medicaid **or the profits derived from DHS** payable by Medicare or Medicaid **of any component of the group practice that consists of at least five physicians.** Overall profits should be **divided in a reasonable and verifiable manner that is not directly related** to the volume or value of the physician's referrals of DHS. The share of overall profits **will be deemed not to relate directly**……." (emphasis added)

The three deeming provisions which follow in paragraph (2) of the old rule set out examples of how profit shares might be determined in a manner that does not relate directly to DHS referrals. But deeming provisions are not exclusive. The "reasonable and verifiable manner that is not directly related" language should protect a wide variety of formulae. Nowhere does the old rule state that different approaches may not be used for different specialties or locations.

Subsection 352(i) of the new rule is reorganized, renumbered and slightly reworded to read as follows:

(i) *"Special rules for profit shares and productivity bonuses*—(1) Overall profits.

(i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid **a share of overall profits that is not directly related** to the volume or value of the physician's referrals.

(ii) **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.

(iii) **Overall profits must be divided in a reasonable and verifiable manner**. The share of overall profits will be **deemed** not to directly relate to the volume or value of referrals if….(emphasis added)

The deeming provisions have been reworded slightly but, as with the old rule, they are not exclusive. And the "reasonable and verifiable" language survives as a general test.

As we compare the old and new rule language, we read the new (i)(1)(i) to be substantively the same as the old (i)(1). And the new language in (i)(1)(iii) seems substantively the same as the second and third sentences of the old (i) (2). So what is apparently intended to clarify policy in a

restrictive manner boils down to the difference between the first sentence of the old (i)(2) and the new (i)(1)(ii).

The old version divided the world of overall profits between a group's "**entire profits derived from DHS**," and the "**profits derived from DHS … of any component of the group**" having at least five physicians. The new version defines overall profits to be profits **derived from all** of the DHS of any component of at least five physicians, which can be the whole group. And if the group is less than five, then it is the same thing — "profits derived from all the DHS…" Parsing this down further, the real difference seems to be that in the old rule the word "**entire**" modified only the profits at the whole group level, whereas under the new rule, the word **"all**" modifies DHS from the whole group, a subgroup of at least five, or a group of fewer than five.

How does the average reader discern that this subtle change in terminology rules out different sharing methods for different ancillaries and/or different specialties and locations?

Conclusion

While CMS attempted to fix ambiguity around profit sharing and correct incongruity between prior preamble guidance and codified regulatory text, the final rule perpetuates the exact problems it sought to remedy by articulating guidance in the rule's preamble that is not clearly delineated in the regulation.

The Stark Law was intended to regulate referrals, not physician compensation, except as necessary to minimize financial incentives to refer DHS to entities a physician has a financial relationship with. Its original intent was to implement controls against overutilization and conflicts of interest. While laudable, the law has since snowballed into an abominable patchwork of codified regulatory text, preamble guidance, "deeming" provisions and special rules. To provide patients with swift access to necessary testing (such as imaging or laboratory work) within the practice, a group must meet eight separate tests to qualify as a *bona fide* group practice, then comply with three additional tests to satisfy the IOAS exception.

It has become undeniable after countless rulemakings that the Stark Law micromanages group practice operations and closely dictates how groups can compensate their physicians. The effect of running afoul of the compensation restrictions is not inconsequential: Failing to qualify as a *bona fide* group practice under Stark regulations limits the number of available exceptions for physicians and potentially exposes them to liability for referrals, even within the practice. Therefore, even minor changes to the group practice definition can have a significant impact. The time has come to evaluate whether the Stark Law's invasion into group practices drives quality and furthers patient protections, or whether it detracts from actual efforts to better patient outcomes and quality of care.

[i] "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations." 85 Fed. Reg. 77492-77682 (Dec. 2, 2020). Available from: bit.ly/3bcxtn1.
[ii] 42 USC 1395nn (h)(4)(B)(i).
[iii] 42 CFR 411.352(i)(2).

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