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CMS Corrects Inadvertent Omissions in Recent Stark Law Regulatory Amendments, Clarifies Reach of the Prohibition Related to Indirect Compensation Arrangements

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Earlier this month, the Centers for Medicare and Medicaid Services (CMS) released its final rules for the 2022 Medicare Physician Fee Schedule (PFS Final Rule) and 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System (OPPS Final Rule). Both rules take effect January 1, 2022. This post is the first in a series covering the myriad Medicare-related changes set forth in those rules. We turn first to an area addressed extensively in the PFS Final Rule—the amendments to the Physician Self-Referral Law (Stark Law) regulations.

Those amendments correct inadvertent omissions in a previous CMS rulemaking and clarify the reach of the prohibition related to “indirect compensation arrangements.” As the tale unfolded, within a matter of months of publishing its Modernizing and Clarifying the Physician Self-Referral Regulations Final Rule (MCR Final Rule), which went into effect January 19, 2021, and which made significant changes to the Stark Law, CMS identified certain crucial omissions related to the regulatory calculus for analyzing indirect compensation arrangements, and sought to correct those oversights through its 2022 Medicare Physician Fee Schedule Proposed Rule (PFS Proposed Rule). 85 Fed. Reg. 77492 (Dec. 2, 2020); 86 Fed. Reg. 39104 (July 23, 2021). After a short notice-and-comment period, on November 2, 2021, CMS announced that it had taken care of the issues through the PFS Final Rule, which is scheduled to be published in the Federal Register on November 19, 2021.

As explained in more detail below, the import of the PFS Final Rule for physicians, their immediate family members, and entities furnishing designated health services (DHS) is that, while indirect compensation arrangements still must satisfy the requirements of an applicable exception to avoid the Stark Law’s referral and billing prohibitions, the number of indirect compensation arrangements subject to those prohibitions, currently enforceable under the law set forth in the MCR Final Rule, is now reduced. More specifically, CMS’s corrections to that rule ultimately reduce the number of arrangements that satisfy the definition of “indirect compensation arrangement” and, thus, decrease the number of arrangements that fall within the prohibitions’ purview. To CMS’s credit, the changes appear to be consistent with its long-standing policy of ensuring program integrity against the risk of program or patient abuse. To better understand the significance of CMS’s clarifications, we provide a chronological-based history of the amendments to the definition of “indirect compensation arrangement.”

The Current Stark Law Prohibitions

As set forth at section 1877 of the Social Security Act (Act), the Stark Law prohibits (1) a physician from making referrals for certain DHS payable by Medicare to an entity with which he or she (or immediate family member) has a financial relationship, unless an exception applies, and (2) the entity from filing claims with Medicare (or billing another individual, entity, or third-party payer) for those referred services. 42 U.S.C. 1395nn. And section 1903(s) of the Act extends certain aspects of those prohibitions to Medicaid. Id. at 1396b(s). In addition to statutory exceptions, the Secretary of the Department of Health and Human Services has also created certain regulatory exceptions for those financial relationships that it believes do not pose a risk of program or patient abuse. 42 C.F.R. 411.350 et seq.

Since its passage, the Stark Law has been amended in a series of "significant and comprehensive rulemakings." PFS Final Rule at 1046. Not the least of which was the MCR Final Rule, which amended, in part, the definition of "indirect compensation arrangement." 85 Fed. Reg. 77492. Under that amendment, which remains the current, enforceable law, an indirect compensation arrangement exists if three conditions exist:

- An unbroken chain of financial relationships between the referring physician (or immediate family member)[1] and the entity furnishing the DHS;
- The referring physician receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS and the unit of that compensation either is not fair market value (FMV) for items or services actually provided, or includes the physician's referrals to or other business generated for the entity furnishing the DHS such that the physician's compensation positively correlates with those referrals or other business generated; and
- The entity furnishing DHS has actual knowledge, or acts in reckless disregard or deliberate ignorance, of the fact that the referring physician receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.[2]

Id. at 77665; 42 C.F.R. 411.354(c)(2)(i)–(iii). CMS clarified that whether the aggregate compensation varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the non-ownership or non-investment interest closest to the referring physician. 85 Fed. Reg. at 77665; 42 C.F.R. 411.354(c)(2)(ii)(C). Although the definition, as finalized through the MCR Final Rule, is the current law as of this post, its enforcement effect will be short-lived.

The PFS Proposed Rule

Shortly after publishing its MCR Final Rule, on July 23, 2021, CMS released the PFS Proposed Rule, which included revisions to the second condition of the definition of "indirect compensation arrangement." 86 Fed. Reg. at 39104. While the MCR Final Rule sought to more precisely identify arrangements that pose a "risk of overutilization, patient steering, and other abusive conduct at an earlier stage of the analysis," CMS explained that it "inadvertently omitted" from the definition a "subset of unbroken chains of compensation arrangements CMS has long identified as presenting significant program integrity concerns: Certain arrangements involving unit of service-based (*i.e.*, per-

click) payment for the rental of office space or equipment." Id. at 39322. This omission's significance is evident when "determining satisfaction of the requirements" of the regulatory exception at 42 C.F.R. 411.357(p) for indirect compensation arrangements. Id. at 39321–22; 85 Fed. Reg. at 77546.

Accordingly, CMS proposed to revise the second condition of the definition of "indirect compensation arrangement" to clarify that the individual unit of compensation received by the physician is either not FMV for items or services actually provided, calculated using a formula that includes the physician's referrals to or other business generated for the entity furnishing the DHS such that the physician's compensation positively correlates with those referrals or other business generated, or payment for anything other than services personally performed by the physician. 86 Fed. Reg. at 39576; 42 C.F.R. 411.354(c)(2)(ii)(A)(*1*)–(*4*) (as proposed). Apparent from this revision, CMS retained the first condition related to FMV from the MCR Final Rule but proposed to amend the second and third conditions and add an apparently sweeping, catch-all fourth condition.

CMS also proposed to define the term "individual unit" for the foregoing analysis as being either time or service. Specifically, the measure for a physician's compensation was proposed as being based either solely on time (during the period services are provided) or service (for the services provided themselves), or based on time (where neither time nor service are the sole determining factor). 86 Fed. Reg. at 39576; 42 C.F.R. 411.354(c)(2)(ii)(B)(*2*)(*i*)–(*iii*) (as proposed). CMS also proposed to add a qualifier related to services personally performed by a physician. 86 Fed. Reg. at 39576. That qualifier stated that personally performed services do not include services that are performed by any person other than the physician, including, but not limited to, the referring physician's employees, independent contractors, group practice members, or persons supervised by the physician. Id.; 42 C.F.R. 411.354(c)(2)(ii)(B)(*3*) (as proposed). After issuing the PFS Proposed Rule, CMS quickly sought industry comments.

Finalized Amendments to the Stark Law in the PFS Final Rule

Less than six months after announcing its proposals, on November 2, 2021, CMS issued the PFS Final Rule, within which CMS finalized its PFS Proposed Rule with nuanced clarifications related to the second condition of the definition of "indirect compensation arrangement" set forth at 42 C.F.R. 411.354(c)(2)(ii). CMS specifically revised that second condition as follows:

An indirect compensation arrangement exists if the conditions set forth at 42 C.F.R. 411.354(c)(2)(i) and (iii) exist and: The referring physician receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS and the unit of that compensation either is not FMV for items or services actually provided, could directly fluctuate as the number or value of the physician's referrals to or other business generated for the entity furnishing the DHS fluctuates, or is payment for the lease of office space or equipment or for the use of premises or equipment. PFS Final Rule at 1960; 42 C.F.R. 411.354(c)(2)(ii)(A)(*1*) and (*2*) (as finalized). And for purposes of this analysis, CMS also finalized and amended the term "individual unit," which measures the compensation paid to the physician as being based either on the item provided, solely on the service provided (including arrangements for items and services), or time (if neither based on item nor service). PFS Final Rule at 1960; 42 C.F.R. 411.354(c)(2)(ii)(B)(*1*)–(*3*) (as finalized).

Consistent with its revisions to include the term "individual unit" for purposes of defining an "indirect compensation arrangement," and similar to the MCFR Final Rule, CMS clarified that whether the aggregate compensation varies with the volume or value of referrals or other business generated by

the referring physician for the entity furnishing the DHS, as well as whether the amount of compensation that the physician receives per individual unit meets the conditions of 42 C.F.R. 411.354(c)(2)(ii)(A)(2), will still be measured by the non-ownership or non-investment interest closest to the referring physician. PFS Final Rule at 1961; 42 C.F.R. 411.354(c)(2)(ii)(C) (as finalized).[3]

Significance of the Finalized versus Non-Finalized Amendments

Services Not Personally Performed by the Physician

While CMS finalized most of the PFS Proposed Rule, CMS backpedaled from considering the individual unit of compensation received by the physician as including anything other than services personally performed by the physician at 42 C.F.R. 411. 354(c)(2)(ii)(A)(*4*) (as proposed)—apparently in response to industry pushback. While the PFS Proposed Rule was intended to further support policies finalized in the MCR Final Rule made in the context of assessing the risk of program and patient abuse associated with services personally performed by a physician, CMS agreed with commenters' concerns that 42 C.F.R. 411. 354(c)(2)(ii)(A)(*4*) (as proposed) "would have resulted in unintended limitations on unbroken chains of financial relationships that historically constituted indirect compensation arrangements but satisfied all requirements of an applicable exception and, therefore, were not considered to pose a risk of program or patient abuse." PFS Final Rule at 1067. For similar reasons, CMS also did not finalize 42 C.F.R. 411.354(c)(2)(ii)(B)(*3*) (as proposed)—namely, CMS's proposal to add a qualifier related to services personally performed by a physician. Id.

CMS also distinguished between "arrangements involving compensation to a physician for items or the services of others where the physician's referral of DHS to an entity or other business generated by the physician for the entity may contribute to the compensation received by the physician" and "arrangements that solely involve compensation for a physician's personally performed services." Id. at 1057. As explained by CMS: "Program integrity concerns arise when payment for items or services provided as the result of a physician's referrals or other business the physician generates, rather than the physician's own labor, is included in the calculation of compensation." Id. The prior definition of "indirect compensation arrangement" was not limited to those types of arrangements under which a physician was "paid solely for service that he or she personally performs." Id. If a physician's compensation is consistent with FMV for those services, then such arrangements do not raise program integrity or patient abuse concerns.

Unit of Service-Based Compensation for Lease Arrangements

CMS believes that all compensation is essentially unit-based compensation, and that arrangements involving unit of service-based compensation for the lease of office space or equipment or for the use of premises or equipment (whether direct or indirect) may pose a significant risk of program abuse. PFS Final Rule at 1056. Accordingly, CMS's proposed amendment, and the nuanced, more-targeted revision in the PFS Final Rule for 42 C.F.R. 411. 354(c)(2)(ii) (as finalized), specifically ensures that prohibitions on certain unit of service-based compensation formulas for the lease of office space or equipment, or for the use of premises or equipment, applies to all compensation arrangements that include them. Id. If the exception set forth at 42 C.F.R. 411.357(p) is used, the compensation for the lease of office space or equipment may not then be determined using a formula based on per-unit of service rental charges such that the charges reflect services provided to patients referred by the lessee to the lessor. Id.

As a consequence of the PFS Final Rule, as a whole, CMS expects that the number of affected

unbroken chains of financial relationships that involve arrangements for the use of premises or equipment that will implicate the Stark Law to be limited. As noted, the PFS Final Rule is set to take effect beginning January 1, 2022.

Stay tuned for additional posts in this blog series focusing on the PFS and OPPS Final Rules.

FOOTNOTES

[1] Hereafter, for purposes of the Stark Law's prohibition and statutory and regulatory exceptions, as well as this post, references to "physician" also include that physician's "immediate family member(s)."

[2] This condition appeared to incorporate a knowledge standard into a regulatory definition for a historically strict liability statute.

[3] Also similar to the MCR Final Rule, and for purposes of 42 C.F.R. 411.354(c)(2)(ii), CMS provided a helpful example: If a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, CMS would look to the aggregate compensation between company B and company C. PFS Final Rule at 1961; 42 C.F.R. 411.354(c)(2)(ii)(C).

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