CY 2022 MEDICARE PHYSICIAN FEE SCHEDULE FINAL RULE: CHANGES TO STARK LAW

December 6, 2021

On November 2, 2021, the Centers for Medicare & Medicaid Services ("CMS") issued the Calendar Year (CY) 2022 Medicare Physician Fee Schedule final rule ("2022 PFS Final Rule"), which addresses a number of topics, including important revisions to the Stark Law.

Specifically, the 2022 PFS Final Rule makes significant changes to the Stark Law with respect to:

- Indirect Compensation Arrangements (§ 411.354(c)(2));
- Exception for Preventative Screening Tests, Immunizations, and Vaccines (§ 411.355(h)); and
- List of CPT/HCPCS Codes (§ 411.351).

INDIRECT COMPENSATION ARRANGEMENTS

The Stark Law prohibits a physician from making referrals for certain Designated Health Services ("DHS") payable to Medicare or Medicaid to an entity with which the physician, or an immediate family member, has a financial relationship, unless an exception applies. Financial relationships include ownership, investment, or compensation. Compensation arrangements between a physician (or an immediate family member) and an entity can be either direct or indirect.

Over the years, CMS has published a number of regulations interpreting the Stark Law. In December 2020, CMS published a final rule entitled "Modernizing and Clarifying the Physician Self-Referral Regulations" (the "MCR Final Rule") (85 FR 77492) that revised the definition of an "indirect compensation arrangement." Under the regulation finalized in the MCR Final Rule and now in effect, an unbroken chain of financial relationships between a provider and an entity furnishing DHS is considered indirect compensation if the referring physician (or his or her immediate family member) receives aggregate compensation that varies with the volume or value of DHS referrals or other business generated by the referring physician, *and* the individual unit of compensation received by the physician: (1) is not fair market value for the items or services provided; or (2) includes the physician's DHS referrals to the entity as a variable, resulting in an increase or decrease in compensation that positively correlates with the number or value of the physician's DHS referrals to the entity; or (3) includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in compensation that positively correlates with the physician's generation of other business for the entity.

According to CMS, when simplifying the analysis in the MCR Final Rule, it inadvertently excluded certain arrangements involving unit of service-based payment for the rental or lease of office space or equipment from the definition of "indirect compensation arrangements." CMS has historically identified unit-based space and equipment leases as presenting significant program integrity concerns.

To rectify its omission, CMS modified the regulations such that, for an indirect compensation arrangement to exist, 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* (emphasis added).

Significantly, CMS notes that it will not be "grandfathering" arrangements regarding payments for the lease of office space or equipment or for the use of premises or equipment that were entered into after the effective date of the MCR Final Rule. CMS expects there to be a limited number of such leases. Additionally, CMS expects parties to be familiar with the requirements of 411.357(p)(1)(ii), which prohibits compensation for the rental of office space or equipment based on "[p]er-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee."

Under the current regulations finalized in the MCR Final Rule, determining whether an indirect compensation arrangement exists requires evaluating the individual unit of compensation received by the physician (or their immediate family member). The new rule seeks to clarify how to identify the unit to analyze, particularly in situations where compensation does not appear to be unit based or is calculated using more than one type of unit. As a preliminary matter, it is CMS's position that "all compensation essentially is unit-based compensation," whether that unit is "a discrete item, unit of service, unit of time, or a unit that results from combining different types of units into a single unit used to calculate the compensation."

Under the 2022 PFS Final Rule, an individual unit is:

- Item, if the physician (or immediate family member) is compensated solely per item provided.
- Service, if the physician (or immediate family member) is compensated solely per service provided, which includes arrangements where the "service" provided includes both items and services.
- Time, if the conditions of [these other units] are not met.

For compensation that is entirely paid per period of time, the individual unit of compensation is the *smallest* unit of time for which compensation is paid. In cases of "hybrid" compensation that include both a time-based unit component and a service-based unit component, the compensation should be converted into a unit of time for analysis. For example, if a physician is paid monthly and also receives a productivity bonus for each wRVU personally performed, the unit of compensation would be monthly—the monthly salary, plus the amount paid per wRVU times the number of wRVUs performed during the month. If, however, the productivity bonus was based on performing wRVUs above a predetermined target, then the unit of compensation would be the time period that the target applied (*e.g.*, a yearly

target). In cases where more than one unit of time is used to calculate physician compensation, each unit must be separately analyzed to determine whether an indirect compensation arrangement is present.

EXCEPTION FOR PREVENTATIVE SCREENING TESTS, IMMUNIZATIONS, AND VACCINES

Medicare is not currently making payments for COVID-19 vaccines, as the federal government purchased the initial supply of vaccines. But vaccines are considered DHS for the purposes of the Stark Law, as they fall within the definition of "outpatient prescription drugs." Thus, if COVID-19 vaccines become payable by Medicare, the prohibitions on physician self-referrals will apply to the referral and billing of COVID-19 vaccines unless an exception is applicable.

In order to avoid potential future problems, in the CY 2021 PFS Final Rule CMS added COVID-19 vaccines to the exception at § 411.355(h), which exempts preventative screening tests, immunizations, and vaccines if they are (1) subject to CMS-mandated frequency limits and (2) covered by Medicare and listed as eligible for this exception on the List of CPT/HCPCS Codes.

CMS also noted that it has not mandated frequency limits (limits on the number of times that Medicare will pay for a service for a beneficiary during an established period, which is often a calendar year or 12-month period) for COVID-19 vaccines and is uncertain if frequency mandates will be imposed. Because of this lack of frequency limits, COVID-19 vaccines do not meet the requirements of § 411.355(h). The 2022 PFS Final Rule therefore modifies § 411.355(h) to include COVID-19 vaccines despite the fact that they are not subject to a frequency limit. The same is true of monoclonal antibody products used to treat COVID-19, so long as these products continue to be paid for under the COVID-19 vaccine benefit.

Further, for clarity and consistency, CMS is removing the term "immunization" from § 411.355(h) and the headers used in the Code List (described below).

LIST OF CPT/HCPCS CODES

CMS maintains a List of Current Procedural Terminology ("CPT")/Healthcare Common Procedure Coding System ("HCPCS") Codes, which identify the items and services included in certain DHS categories (defined at § 411.351). This Code List is historically published in the Federal Register as an addendum to the annual Physician Fee Schedule final rule.

Following the publication of the January 1, 2022, Code List in the 2022 PFS Final Rule, CMS will publish the Code List solely on the CMS website (at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes). The Code List will continue to be updated annually. CMS will provide 30 days advance notice of such updates on the CMS website, as well as provide for a 30-day public comment period for each update using www.regulations.gov.

Correspondingly, CMS has finalized the definition of "List of CPT/HCPCS Codes" at § 411.351 to read:

> List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually and posted on the CMS website at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.

CONCLUSION

In sum, we recommend that providers carefully review CMS's 2022 PFS Final Rule, as it relates to the Stark Law. In particular, providers should be aware that arrangements regarding payments for the lease of office space or equipment or for the use of premises or equipment may be considered an indirect compensation arrangement under the 2022 PFS Final Rule.