Medicare Physician Fee Schedule Brings Sweeping Changes

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On November 2, 2021, the Centers for Medicaid & Medicaid Services (CMS) issued the Physician Fee Schedule final rule for calendar year 2022 ("2022 PFS Final Rule"), which addresses a range of topics, including revisions to the physician self-referral law regulations (the "Stark law"), so-called "split (or shared)" claim billing, telehealth, and more. Highlights are summarized below.

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Changes to the Stark Law Regulations – Indirect Compensation Arrangements

Unless an exception applies, the Stark law prohibits physicians from referring Medicare patients for certain "designated health services" to an entity with whom the physician has a financial relationship, which includes direct and indirect ownership interests and compensation arrangements. Over the years, however, much confusion has arisen regarding when an "indirect compensation arrangement" triggers the Stark Law, which has led to frustration, especially for attenuated, innocuous physician relationships. CMS acknowledged this in the December 2, 2020 final rule that implemented significant Stark law regulatory changes, stating that the prior regulatory scheme "cast a wide net to include the vast majority of unbroken chains of financial relationships between an entity and a physician," which then had to be "weeded out" through applicability of a Stark Law exception, noting this process was "unnecessarily burdensome." Accordingly, in that final rule, CMS changed when an indirect compensation arrangement is deemed to exist by significantly narrowing the scope of its application. That was welcome news to many providers, as it reduced the number of financial relationships subject to the Stark Law.

Unfortunately, the saga continues, as CMS has now revised the applicable regulation, 42 C.F.R. 411.354(c)(2), in the 2022 PFS Final Rule to broaden the scope of indirect compensation arrangements. Under the new rule, many indirect arrangements will now be "indirect compensation arrangements" and thus need to satisfy a Stark law exception, rather than being excluded from the definition altogether and not needing any exception because they are not deemed to create a financial relationship.

Under the revised regulation, when assessing the compensation arrangement closest to the physician that is in the chain of financial relationships between the physician and the entity to which the physician refers, there are two distinct prongs to consider:

- Aggregate compensation (§ 411.354(c)(2)(ii)(A)(1)): Does the aggregate compensation vary with the volume or value of referrals or other

business generated?

- Individual unit of compensation received (§ 411.354(c)(2)(ii)(A)(2)): Whether the unit of compensation: (i) is not fair market value; (ii) "could increase" as the number or value of the physician's referrals to, or other business generated for, the entity increases (or decrease as referrals or business generated decreases); or (iii) is payment for the lease of office space or equipment or use of premises or equipment.

CMS also explains the meaning of "individual unit," noting that essentially all compensation is unit-based compensation. For example, if a physician is paid a fixed annual salary of $350,000, the unit is a time-based unit of 1 year, and the individual unit of compensation is $350,000.

CMS comments that areas of particular risk include space and/or equipment leases, as well as "tiered" compensation where the individual unit may increase or decrease at certain levels of referrals or other business generated.

Compliance tip: Given the back and forth revisions to the Stark regulation over the past two years, it's possible that, without changing any details, a particular financial relationship may (1) have had an indirect compensation arrangement before January 19, 2021 (the effective date of the prior final rule), then (2) not had an indirect compensation arrangement for the remainder of 2021, and (3) will now have an indirect compensation arrangement again starting in 2022. Thus, providers and physicians should consider reviewing financial relationships that appeared compliant in 2021 for conformity with the revised regulation.

New Regulation With Revised Split (or Shared) Billing Policy

CMS finalized the agency's proposed regulation changing how and when practitioners may bill Medicare for evaluation and management ("E/M") services in the institutional setting that are "split (or shared)" by a physician and a nonphysician practitioner ("NPP") in the same group. Physicians may bill these services at the higher 100% PFS rate if certain criteria are met (an NPP is paid at 85% of the PFS rate). This regulation replaces CMS's recently withdrawn longstanding guidance on this topic from the Medicare Claims Processing Manual ("MCPM"). CMS received a flood of comments on the proposed regulation but made a just a few small changes in the final rule.

The new regulation defines split (or shared) E/M visits as E/M visits provided in the facility setting by a physician and an NPP in the same group, which may be billed by the practitioner who provides the "substantive portion" of the visit. In particular, the new regulation:

- Changes how to determine who performed the "substantive portion" of the visit, which sets the reimbursement rate, from a standard that was task-based to one based on which practitioner spent more time.
    - The substantive portion is "more than half" of the total time spent by the physician and the NPP. If the physician does anything less, payment is made at the 85% NPP rate. This definition will govern starting in 2023.
    - But in 2022, during a transition period to allow practitioners to adapt EHR functionality to track time, CMS is also allowing the substantive portion to be satisfied if the physician performs one of the three key components of an E/M service (history, exam, or medical decision making), as its historical policy allowed.
    - The activities that count as time spent are those listed in the CPT E/M guidelines. CMS also listed these activities in the preamble to the final rule, which specifies that not all require direct patient contact.
    - Further, clarifying ambiguity in its prior policy, CMS stated that "the substantive portion could be entirely with or without direct patient contact …."
    - For calculating the time for the "substantive portion," as required starting in 2023, only one practitioner's time counts when the two meet jointly with or discuss the patient. *g.*, if the NPP sees the patient for 10 minutes, the physician sees the patient for another 15, and then they meet together for another 5 minutes to discuss the patient, then the total time is 30 minutes, and the physician may bill for the service.
- Leaves undefined what is the "same group" within which split (or shared) claim are permitted.

    - This concept has been an area of some confusion and is important because CMS will not pay for partial E/M visits performed by practitioners that are not in the same group.
    - CMS considered several options for defining "group," including the same clinical specialty; the definition of "physician organization" under the self-referral laws; and tax identification number. CMS declined to adopt any definition, but it said it will continue to monitor claims to see if a definition becomes necessary.
- Expands the institutional settings for split (or shared) services to include critical care services and skilled nursing facilities (SNFs), each of which has special rules.
- Clarifies that split (or shared) billing applies both to new and to subsequent patient visits and for prolonged services.
- Specifies, as required documentation, that the medical record identify the practitioners involved and be signed and dated by the billing practitioner.
    - CMS noted that "it may be helpful for each practitioner … to directly document and time their activities in the medical record … in order to determine who performed the substantive portion …." But CMS is leaving this to the discretion of providers and practitioners to decide how time will be tracked.
    - To minimize the risk of challenges to claims, providers and practitioners should strive to develop a process that documents the activities and time spent by each practitioner for split (or shared) E/M services.
- Adds a claims modifier to indicate a split (or shared) service, so that CMS may more closely monitor these types of claims
- Codifies the new policy at 42 C.F.R. § 415.140, to be effective January 1, 2022

Compliance tip: CMS can be expected to scrutinize split (or shared) claims starting in 2022, when the new regulation takes effect. There are several ways to minimize the risk of claims denial, including training practitioners on the new split (or shared) service requirements and how best to document their tasks for billing these services.

Telehealth

CMS also finalizes policies in the 2022 PFS Final Rule for services added to the Medicare telehealth list during the COVID-19 PHE and policies for telehealth services used for the diagnosis, evaluation, or treatment of a mental health disorder. For example, the final rule extends Medicare reimbursement to physicians for certain telehealth services through the end of 2023, such as cardiological services and radiation oncology codes, to allow additional time for CMS to evaluate whether it should permanently add such services to the Medicare telehealth services list. Additionally, the final rule implements provisions of the Consolidated Appropriations Act of 2021, by adding the home of the beneficiary as a permissible originating site for telehealth services furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. CMS also finalized the requirement that an in-person, non-telehealth visit must be furnished at least every 12 months for these services (rather than the proposed 6-month timeframe), though exceptions to the in-person requirement may be made depending on the beneficiary's circumstances. Finally, CMS amended the current definition of interactive telecommunications system for telehealth services, but for mental health services only, to include two-way, real-time audio-only communications technology where the beneficiary is not capable of, or does not consent to, the use of video.

Clinical Labor Practice Expense Values

In the 2022 PFS Final Rule, CMS finalizes its proposed changes to the Practice Expense (PE) methodology, in particular, the clinical labor pricing component. CMS last updated the clinical labor component (e.g. nurses) almost twenty years ago when it used 2002 Bureau of Labor Statistics (BLS) data, with some supplementation from other sources. CMS followed the same basic approach in the proposed 2022 rule, using 2019 BLS data, again with some supplementation. This results in significant increases in clinical labor PE "values" across the board. *However*, because of the requirement to apply a "budget neutrality" adjustment, this creates "winners and losers" with some specialties—particularly those with high equipment and supply costs—seeing significant reductions in payment. CMS recognized this in the proposed rule and "smoothed" the implementation of the new values with a four-year transition, which they adopted in the final rule.

Other Significant Topics

The 2022 PFS Final Rule addresses a wide range of other material topics, beyond those listed here, including the office/outpatient E/M coding framework in the context of teaching physician services, billing for physician assistant services, vaccine administrative services, electronic prescribing of controlled substances, chronic care management, direct supervision flexibility during and after the public health emergency, and Medicare provider enrollment (including expansion of authority to deny or revoke a provider's or supplier's Medicare enrollment), to name a few.

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