2020 Medicare Physician Fee Schedule – Reimbursement and Payment Policy Proposals

August 2019

On July 29, 2019, the Centers for Medicare & Medicaid Services (CMS) released the FY 2020 Medicare Physician Fee Schedule (MPFS) proposed rule [CMS-1715-P] (Proposed Rule). A link to the full rule is available here. Stakeholder comments on the rule are due no later than 5:00 pm ET on Friday, September 27, 2019. Because CMS released the proposed 2020 MPFS Proposed Rule later than in prior years and must publish a final rule by early November 2019, many stakeholders plan to submit prior to the deadline in order to give the Agency time to duly consider their suggestions and concerns.

This year's rule outlines proposals related to a highly anticipated Evaluation and Management (E/M) reimbursement policy, modifications to physician supervision standards and other issues. This summary reviews CMS proposals on the following topics:

Changes in Fee Schedule Inputs:

- Practice Expense RVUs
- Malpractice Expense RVUs
- Geographic Practice Cost Indices (GPCIs)

Non-Physician Practitioner (NPP) Practice Authority & Reimbursement:

- Physician Assistant Supervision Standards
- Deferring to State Scope of Practice Requirements for NPPs
- Review & Verification of Medical Record Documentation

Payment Policy Changes:

- Valuation of Specific Codes
- Potentially Misvalued Services Under the MPFS
- Payment for E/M Services
- Intensive Cardiac Rehabilitation Services
- Therapy Services
- Coinsurance for Colorectal Cancer Screening Tests

Other Program/Policy Changes:

- Open Payments
- Home Infusion Therapy Benefit
- Ambulance Coverage Services
- Ambulance Fee Schedule-Medicare Ground Ambulance Data Collection System
- Advisory Opinion on the Application of Physician Self-Referral Law

Separate e-alerts will be forthcoming addressing other key aspects of the Proposed Rule dealing with behavioral health topics addressed in the Proposed Rule, and proposals relating to the Quality Payment Program (QPP) and value based care (including the Medicare Shared Savings Program, bundles and other arrangements).

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I. CHANGES IN FEE SCHEDULE INPUTS

Practice Expense RVUs

The Medicare Physician Fee Schedule assigns reimbursement rates for services based on three components: (i) work RVUs; (ii) practice expense RVUs; and (iii) malpractice RVUs. Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office, rent and personnel wages. CMS develops PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies and medical equipment. CMS determines the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies and medical equipment) typically involved with furnishing that service. Indirect expenses include administrative labor, office expense, and all other expenses. CMS uses survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs.

With respect to determining indirect PE per hour data, CMS, in the Proposed Rule, is proposing to incorporate two new specialties which became recognized by Medicare in 2018: Medical Toxicology and Hematopoietic Cell Transplantation and Cellular Therapy. Since the Physician Practice Expense Information Survey does not include data for the two aforementioned specialties, CMS is proposing to use proxy PE/HR values from similar specialties: medical toxicology from emergency medicine and hematopoietic cell transplantation and cellular therapy from hematology/oncology

Additionally, CMS is proposing to clarify the expected specialty assignment for a series of cardiothoracic services. In creating the low volume specialty list for CY 2018, CMS previously finalized through rulemaking a crosswalk to the thoracic surgery specialty for a series of cardiothoracic services that typically had fewer than 100 services reported each year. However, the expected specialty list for low volume services incorrectly listed a crosswalk to the cardiac surgery specialty instead of the thoracic surgery specialty. CMS is looking to correct this matter by updating the expected specialty list for the affected codes as shown on page 26 of the prepublication copy of the Proposed Rule (linked here). CMS does not anticipate this proposal having a discernible effect on the valuation of the affected codes.

CMS is also proposing to establish 23 new scope equipment codes for CY 2020 as shown on page 45 of the prepublication copy of the Proposed Rule (linked here). These scope proposals are based upon recommendations from the Scope Equipment Reorganization Workgroup. The purpose of the establishment of these new codes is to address the inconsistencies involving the use of scopes and video systems and the impact of such inconsistencies on CMS' review of direct PE input recommendations for pricing of the same.

CMS is proposing the following technical corrections to the direct PE input database to correct certain inconsistencies:

- Deletion of non-facility inputs for CPT codes 43231 (Esophagoscopy, flexible, transoral; with endoscopic ultrasound examination) and 43232 (Esophagoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)) since these services are never performed in a non-facility setting.
- Establishing CPT code 31231 (Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)) as the base procedure for nasal sinus endoscopies. The codes to be affected by this proposal are as shown on page 54 of the prepublication copy of the Proposed Rule (linked here).

As part of CMS' authority, CMS engaged StategyGen to conduct an in-depth and robust market research study to update the direct PE inputs for supply and equipment pricing. Based upon this study and other invoices reviewed by StategyGen, CMS is proposing to update the prices of supplies and equipment items as shown on page 63 of the prepublication copy of the Proposed Rule (linked here).

Malpractice RVUs

In the Proposed Rule, CMS is seeking comments on three proposed changes to the Malpractice RVU (MP RVU) component to fee schedule rates.

First, CMS is proposing to change its schedule for updating its malpractice premium data (used in calculating MP RVUs) from every five years to every three years. CMS is statutorily required to *annually* review and update the MP RVU value to reflect changes in: (i) Medicare's practitioner mix; and (ii) the intensity and complexity of services rendered by them. However, every five years CMS also pulls updated malpractice insurance premium data from private insurers to adjust the specialty level risk factors used to calculate MP RVUs. CMS is proposing to switch the MP RVU update schedule to every three years to align it with CMS' current schedule for updating MP GPCIs. If the updates were aligned, CMS would next review and update MP RVUs in 2020 and, thereafter, review and update both the GPCI and MP RVU in CY 2023.

Second, CMS is proposing to refine the methodology and malpractice premium datasets used to calculate MP RVUs in three ways. Specifically, it is proposing to:

- Pull malpractice insurance premium and claims data for more than just those listed as 'physicians' or 'surgeons' in order to create a larger dataset for calculating MP RVUs. (CMS does not identify the other types of providers for which it would pull data, so if non-physician data is used, this may misrepresent actual malpractice costs downward.)
- Combine 'minor surgery' and 'major surgery' malpractice insurance premiums to create a single surgery service risk group for calculating MP RVUs. (Currently, CMS only uses 'major surgery' data to calculate MP RVUs).
- Substitute malpractice premiums data (in all or part) from other physician specialties to replace or fill-in data when a private insurer does not capture data for a particular physician specialty. For example, if a certain insurer does not have insurance, premium rates and claims data for a certain specialty (such as Sleep Medicine), CMS is proposing to substitute the data of what CMS considers to be a similar specialty (like General Practitioner) for the specialists' data to complete the specialist data dataset rather than discard the data from that insurer. CMS provides no guidance on the criteria it will use to determine similar specialties.

Third, CMS is proposing to assign the default risk factor (1.00) to all technical-component only services for calculating MP RVUs for such services. CMS notes that this value matches the lowest physician specialty-level risk factor and is a necessary proxy because private insurers do not have sufficient professional liability premium data on the full range of clinicians who provide technical-component only services. CMS is seeking proposals for alternative proxies.

Geographic Practice Cost Indices (GPCIs)

CMS develops GPCIs to measure relative cost differences among payment localities compared to the national average for each of the three fee schedule components (work, practice expense and malpractice). GPCIs are updated every three years, and 2020 is an update year. The GPCIs proposed by CMS for CY 2020 are accessible here.

CMS uses the Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) wage and employment data to calculate work and practice expense GPCIs because of its reliability, public availability, level of detail and national scope. Therefore, for CY 2020, CMS is proposing to use the updated BLS OES data from 2014 through 2017 to compute the work and practice expense GPCIs. Additionally, in regards to the office rent index component of the practice expense GPCI, CMS is proposing to use the most recently available American Community Survey five-year estimates (from years 2013 through 2017).

In calculating GPCIs for the Proposed Rule, CMS identified two technical refinements to the methodology that could yield improvements over the current methodology. These refinements are applicable to the work GPCI and the employee wage index and purchased services index components of the practice expense GPCI. CMS is proposing to weight by total employment when computing county median wages for each occupation code (to address the fact that occupation wages can vary by industry within a county) and to use a weighted average when calculating the final county-level wage index. These proposed methodological refinements could yield improved mathematical precision.

II. PAYMENT POLICY CHANGES

Valuation of Specific Codes

Establishing valuations for newly created and revised CPT codes is a routine part of CMS' duty to maintain the MPFS. Since the MPFS' inception, CMS has also made it a priority to revalue services regularly to ensure its payment rates reflect changing trends in medical practice and current prices for inputs used in PE calculations.

To set RVUs for the MPFS, CMS thoroughly reviews and considers information and recommendations from the RVU Update Committee, Healthcare Professionals Advisory Committee, public commenters, medical literature, Medicare claims data, comparative databases and other codes within the MPFS, and consults with other physicians and health care professionals within CMS and the federal government.

In the Proposed Rule, CMS provides a list of HCPCS/CPT codes that are new, revised or potentially misvalued. CMS' proposed valuations for these codes are listed in the prepublication copy of the Proposed Rule (linked here) on the page numbers listed below:

- Proposed CY 2020 Work RVUs for New, Revised, and Potentially Misvalued Codes (pages 424 – 441)
- Proposed CY 2020 Direct Practice Expense Refinements (pages 442 – 485)
- Proposed CY 2020 Invoices Received for Existing Direct Practice Expense Inputs (page 486)
- Proposed CY 2020 New Invoices (page 486)
- Proposed CY 2020 Proposed No Practice Expense Refinements (pages 487 – 488)

For more information regarding the valuation of specific codes, consult the Proposed Rule available here.

Potentially Misvalued Services Under the MPFS

CMS is statutorily directed to conduct a periodic review, not less often than every five years, of the RVUs established under the MPFS, which includes identifying potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. CMS is currently welcoming comments on the HCPS and CPT codes, listed below, that it proposes as potentially misvalued.

- 10005 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion)
- 10021 (Fine needle aspiration biopsy, without imaging guidance; first lesion)
- 76377 (3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation)
- G0166 (External counterpulsation, per treatment session)

Payment for Evaluation and Management (E/M) Services

In July of 2018, CMS announced plans to provide a single payment level for all level 2 through 4 E/M visits in addition to various other significant coding policy changes for E/M visits. Various physician organizations, medical societies and state medical associations responded with concern that physicians would be undercompensated for services actually performed and physicians treating the sickest patients would be especially penalized. Thereafter, the American Medical Association (AMA)/ Specialty Society RVS Update Committee (RUC) and CPT Editorial Panel convened the AMA/CPT Workgroup on E/M (AMA/ CPT Workgroup) to propose further revisions to the E/M office visits coding and payment policies for CMS' consideration. In this Proposed Rule, CMS is proposing to adopt many changes to the E/M billing framework based on this Workgroup's suggestions. The following changes, if finalized, would be effective for services furnished on or after January 1, 2021.

First, CMS is proposing to adopt the new coding, prefatory language, and interpretive guidance framework issued for E/M visits by the AMA/CPT Workgroup in place of last year's finalized policies. In doing so, CMS would delete CPT code 99201 (level 1 office/outpatient visit for new patients) for CY 2021 onward. Beginning in CY 2021, level 1 visits would only be used for visits performed by clinical staff for established patients.

Second, CMS is proposing to replace the history and physical exam criteria for selecting the appropriate code level for office/outpatient E/M Code levels 2 through 5 with a time and effort-based criteria. Beginning in CY 2021, the details of the history and physical exam would no longer control the code level to be selected for office/outpatient E/M visits. Instead, practitioners would select the code level based on either: (i) the level of medical decision-making involved (as redefined in the new AMA/CPT guidance framework) or (ii) the total time personally spent by the reporting practitioner on the day of the visit (including face-to-face and non face-to-face time). If time is used as the criteria, Practitioners would have to meet the minimum time thresholds set by the CPT Editorial Panel to qualify for each code level. These changes would require more robust medical record entries than under the formerly proposed method.

Third, CMS is proposing to eliminate the uniform payment rate it established for levels 2-4 E/M office/outpatient visits established last year. Instead, CMS would provide different payment rates for each level and establish separate values for new and established patients within each code level.

Fourth, CMS is proposing to create a new CPT Code 99XXX to give practitioners credit for prolonged office/outpatient E/M Visits and delete the add-on code proposed last year (GPR01). Specifically, when an office/outpatient E/M visit code is selected based on time and the time threshold for a level 5 visit is exceeded by fifteen minutes or more, practitioners would be directed to apply the add-on CPT Code 99XXX to report the visit as prolonged. Yet, CMS is proposing to only count time spent on the date of service to determine the E/M code level.

If the proposal is finalized when time is used to select the office/outpatient E/M code level, any additional time spent by the reporting practitioner on a date before or after the date of service (e.g. reviewing medical records or test results) would not count toward meeting the time thresholds for CPT Codes 99202-99215 or 99XXX and could not be reported using CPT Codes 99358 or 99359 (which are intended to report time spent beyond 'usual' time). Consequently, if the proposal is adopted, CPT Codes 99358 and 99359 (for Prolonged E/M Visit Without Direct Patient Contact) could no longer be reported with office/outpatient E/M visits to capture services rendered on days other than the E/M visit day. Additionally, CMS would delete HCPCS Code GPR01 (Extended Office/Outpatient E/M Time) starting in CY 2021; instead, prolonged level 3, 4 or 5 office/outpatient E/M visits could be captured only by applying CPT Code 99XXX to the base code for the office/outpatient E/M visit.

CMS is requesting further public comment on how to code for prolonged E/M visits. Specifically, CMS believes the currently proposed add-on codes (CPT Codes 99358 and 99359 (for Prolonged E/M Visit Without Direct Patient Contact)) may need to be redefined, resurveyed, or revalued. CMS is asking for input on its proposal to adopt a single add-on code (CPT Code 99XXX) to report prolonged office/outpatient E/M visits when time is used as the criteria to select the E/M Code level, instead of using multiple add-on codes to track additional time. CMS notes this would be administratively simpler and align with policy objectives to only count additional time spent by the reporting practitioner on the date of service toward meeting the time threshold for selecting the E/M code level.

Fifth, CMS is proposing to adopt RUC's recommendations for coding and valuing the revised office/outpatient E/M Code set and new fifteen minute prolonged service code (CPT Code 99XXX), but CMS has concerns with, and seeks public comment on, this decision. Specifically, CMS is concerned with the integrity of the dataset and consequences for other code values. Over last year, the RUC collected data on the total time spent on an E/M visit date and any pre- and post-service time (capturing a period three days before and seven days after the E/M visit). Thereafter, each component time and the total times were separately averaged for survey purposes, causing the RUC to generate conflicting datasets. For some codes, the total E/M service time did not match the sum of the three component times measured. Given these discrepancies, CMS is seeking comment on which times it should use for valuing E/M Codes: total times or component (intra-service) times. CMS notes that both intra-service times and total times are important reference points for valuing many other services under the MPFS beyond valuing the E/M Code set, so the choice will impact other code values. Given this, CMS seeks comments on which times would be preferential for valuing E/M Codes.

Sixth, CMS seeks comments on (i) valuing the new prolonged service code (CPT 99XXX) at fifteen minutes of physician time and a 0.61 wRVU and (ii) removing equipment item ED021 (computer, desktop, with monitor) from the PE input for determining E/M codes' wRVUs. CMS believes this expense is more appropriately categorized as an overhead cost than practice expense.

Seventh, CMS is seeking a solution to compensate for resource-intensive visits. CMS is proposing to create a single add-on code for office/outpatient E/M visits to capture the higher resource costs typical to three common types of office/outpatient E/M visits: (i) separately identifiable office/outpatient E/M visits furnished in conjunction with a global procedure; (ii) primary care office/outpatient E/M visits for continuous patient care; and (iii) certain types of specialist office/outpatient E/M visits. To account for the higher resource costs of these E/M services, CMS previously proposed using two add-on G-code descriptors (assigned based on visit details): HCPCS Code GCG0X and HCPCS Code GPC1X. CMS is now proposing, and seeking comments on, whether using one code (GPC1X) is adequate and preferred over the two-code method. CMS is also seeking comments on its proposal to: (i) make this G-code add-on available for *all* levels of office/outpatient E/M visits (level 1 through 5); (ii) value GPC1X at one hundred percent of the work and time values for CPT Code 90785; (iii) assign a work RVU of 0.33 to the code; and (iv) assign physician time of eleven minutes to the code.

Finally, CMS is seeking public comment on whether it should adjust fee schedule rates for other MPFS services to account for any changes made to the office/outpatient E/M services values. CMS noted that many fee schedule services (such as global surgical services) incorporate the office/outpatient E/M service's assigned value into its valuation (as a service offered as part of the bundle). Additionally, other services have values that are closely tied to the values of the office/outpatient E/M visit codes *(e.g.transitional care management services, ESRD monthly services, annual wellness visit, etc.)*. CMS is seeking comments on whether it should: (i) individually adjust these codes' values proportionate to any changes to the E/M visit codes' values; (ii) universally apply a proportionate adjustment to all MPFS rates to preserve current proportionate differences in values between the codes; or (iii) make no changes.

CMS's proposed changes have sparked concerns with surgeons for two reasons. First, CMS is currently proposing to not apply the E/M code value increases to any office visits considered bundled into a global surgery package. Therefore, surgeons who are obligated to perform a full office/outpatient E/M visit pre-surgery or post-surgery may not be fully compensated for the E/M visit according to its complexity and time-intensive nature. Reimbursement for such will be incorporated into the pre-set global surgical service rate, which, as proposed, would not increase to align with the increased E/M visit rates. Second, surgeons are concerned that post-surgical work may not be separately billable or fully reimbursed. Previously, clinical and/or administrative work leading up to an E/M visit but occurring on a separate day of service could sometimes be included in calculating the E/M visit level 1 through 5 when such E/M visit was billable outside the surgical bundle. As currently proposed, physician work on dates other than the E/M visit date would not count towards calculating the E/M code level 1 through 5, resulting in reduced reimbursement.

Expanded Access to Intensive Cardiac Rehabilitation (ICR) Services

CMS is proposing to amend 42 C.F.R. §410.49(b) to expand the list of conditions for which Medicare Part B will cover intensive cardiac rehabilitation services (ICR Services), per the directive of Section 51004 of the BBA of 2018. Medicare Part B currently covers ICR Services and cardiac rehabilitation services (CR Services) for six qualifying conditions:

- Acute myocardial infarction within the preceding 12 months;
- Coronary artery bypass surgery;
- Current stable angina pectoris;
- Heart valve repair or replacement;
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or
- A heart or heart-lung transplant.

The BBA of 2018 amended 42 C.F.R. §410.49(b) to require Medicare Part B to cover CR Services and ICR Services for those patients with stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least six weeks. The law also granted the CMS Secretary discretion to grant coverage for CR Services and ICR Services for any additional condition for which the CMS Secretary has determined that a cardiac rehabilitation program shall be covered.

Accordingly, CMS is proposing to revise 42 C.F.R. §410.49(b)(vii) to add coverage for CR Services and ICR Services for any other cardiac conditions specified in a National Coverage Determination (NCD), unless coverage is not supported by clinical evidence. Thus, going forward, NCDs could expand CR Services and ICR Services to other covered conditions.

Finally, CMS is proposing regulations to clarify that CR Services are have been covered under Medicare Part B since February 18, 2014 under the NCD for Cardiac Rehabilitation for Chronic Heart Failure (Pub. 100-03 20.10.1) and that ICR Services have been covered under Medicare Part B since February 9, 2018, the effective date of the BBA of 2018. If passed, this would create retrospective coverage for such services back to these dates.

Revisions to Therapy Services Reimbursement Policies

CMS is proposing to codify prior changes to regulations governing billing for outpatient occupational therapy, physical therapy and speech-language pathology services (collectively Therapy Services) made by the Bipartisan Budget Act of 2018, Pub. L. 115-123, Feb. 9, 2018 (BBA of 2018). The BBA of 2018 repealed the Medicare outpatient therapy caps and replaced them with limits. Specifically, before the BBA of 2018, once a Medicare beneficiary's total outpatient therapy expenses for the year hit the therapy cap, Medicare ceased paying for any future therapy services provided to the beneficiary for the remainder of the calendar year. The BBA of 2018 revised regulations so that once the beneficiary's total therapy expenses hit the cap (renamed, the 'limit'), Medicare will pay for future therapy services only if they are billed with both the KX modifier and documentation of medical necessity. Once the limit is hit, Medicare denies claims billed without both. CMS may also perform targeted medical review of any claims submitted above the medical review threshold amount (MR Threshold) to verify medical necessity. For each year until 2028, the MR Threshold for all physical therapy and speech-language pathology services combined will be $3,000 and $3,000 for all occupational therapy services. In this Proposed Rule, CMS is proposing to revise current regulations at 42 C.F.R. §410.59 and 42 C.F.R. §410.60 to codify these changes.

Additionally, the Proposed Rule provides clarifying guidance on appropriate use of coding modifiers for therapy assistant services. On or after January 2, 2022, CMS will require outpatient physical therapy and occupational therapy services furnished in whole or part by a therapy assistant (whether a physical therapy assistant (PTA) or occupational therapy assistant (OTA)) to be paid at 85% of the fee schedule amount. For dates of service on or after January 1, 2020, claims for therapy assistant services must be submitted with a modifier indicating they were provided by a therapy assistant (PTA/OTA). Last year's CY2019 MPFS Final Rule created two modifiers for this purpose: (i) the CQ Modifier for services furnished in all or part by a PTA and (ii) the CO Modifier for services billed in all or part by an OTA. Such claims must also include the GP or GO therapy modifier, when applicable, to indicate the services were billed under a PT/OT plan of care or the GN modifier for a speech-language pathology plan of care.

In the Proposed Rule, CMS is also proposing clarifications for how to calculate the 10% De Minimis Standard—the standard used to determine when therapy services are considered to have been billed in all or part by a PTA/OTA and, thus, must be billed with the therapy assistant modifier (CQ/CO Modifier). CMS proposes that a service will be considered to have been 'furnished in all or part by a PTA or OTA' when more than 10% of the total service time *(defined as the sum of therapist's time in treating the patient and the assistant's time in treating the patient)* is furnished in whole or part by the assistant (PTA/OTA). When the assistant provides services concurrently with the therapist, CMS proposes that the CQ/CO Modifier must be applied when the assistant's service time is 10% or more of the total time the therapist delivers services. However, if *the therapist* and assistant separately furnish portions of the same service to a patient, the CQ/CO Modifier will be triggered if the minutes furnished by the assistant are greater than 10% of the total minutes of *both parties*. Additionally, CMS proposes that the CQ/CO Modifier policies should apply to all services billed with the GP or GO therapy modifier. Finally, CMS clarifies that if a PTA/OTA furnishes services without the therapist that are described by a procedure code, the PTA/OTA may bill directly for those services under that code without the modifier; the modifier is not required.

CMS is also proposing the following PT/OTA billing guidelines:

- **Evaluation/Re-Evaluation Services (CPT Codes 97161-97163, 97164, 97165-07167, 97168):** When a PTA/OTA furnishes a portion of a PT/OT evaluation or re-evaluation that exceeds the 10% De Minimis Standard, the CQ/CO modifier must be used on the claim, even though a PTA/OTA cannot furnish and bill for evaluations and re-evaluations solo. CMS also states the PTA/OTA can furnish part of the services either concurrently with or separate from the therapists' services.

- **Group Therapy Services (CPT Code 97150):** CMS proposes the CQ/CO Modifier should be applied when the total minutes of service furnished by the PTA/OTA, whether concurrently with or separately from the therapist, exceed 10% of the total time of group therapy service (defined as the therapist's total service minutes plus any PTA/OTA service minutes separate from the therapist).
- **Supervised Modalities (CPT Codes 97010-97028, HCPCS Code G0281,G0183, G0329):** CMS also proposes that the CQ/CO Modifier must be applied to a supervised modality when the PTA/OTA fully furnishes all service minutes or the minutes provided by the PTA/OTA exceed 10% of the total service minutes. Time is calculated for this purpose even though the service is not billed by time increments.
- **Services Defined by 15 Minute Increments/Units (CPT Codes 97032-97542, 97032-97036, 97110-97542, 97750-97755, 97760-97763):** Certain services are billable only with one-on-one patient contact. For dates of service on or after January 1, 2020, CMS is proposing to require a treatment note that explains the application/non-application of the CQ/CO modifier for each service furnished that day, including for untimed services. If no PTA/OTA is involved, the therapist can document such as "CQ/CO Modifier N/A."

Beneficiary Coinsurance Payment Obligations for Colorectal Cancer Screening Tests

Colorectal cancer screening tests are considered by CMS to be preventative tests, and provided to patients in the absence of signs or symptoms of illness or injury. When a Colorectal Cancer Screening Test is provided to a Medicare Part B beneficiary, the beneficiary is not obligated to pay the coinsurance for the procedure because Medicare covers 100% of the costs of such recommended preventative services. However, if during the procedure a polyp or growth is found and removed, the procedure is no longer considered to be a screening and becomes classified as a colonoscopy with biopsy and removal (a diagnostic procedure). As a result, the beneficiary becomes responsible for the entirety of their cost-sharing obligations (deductible and coinsurance).

Beneficiaries have continued to contact CMS noting their surprise that a coinsurance fee (20% or 25% depending on the setting) applies when they expected to receive a colorectal screening procedure fully covered by Medicare. Similarly, physicians have expressed concerns about beneficiaries' reactions upon being informed of their responsibility for coinsurance when polyps are discovered and removed.

CMS specifically invites comments on whether it should require physicians or their staff to provide a verbal notice with notation in the medical record of such possibility, or whether CMS should consider a different approach to informing patients of the potential copay implications, such as requiring physicians and/or their staff to provide written notice with standard language to patients prior to any colorectal cancer screening.

III. NON-PHYSICIAN PRACTITIONER (NPP) PRACTICE AUTHORITY & REIMBURSEMENT CHANGES

Adjustments to Physician Supervision Standards for Physician Assistant Services

In the Proposed Rule, CMS is considering deferring to state law to set more relaxed Medicare Physician Assistant (PA) supervision standards. Specifically, CMS is proposing to revise current regulations at 42 C.F.R. §410.72, which require all PA services be rendered under a physician's general supervision, to allow PA services to be provided under whatever supervisory level applicable state law mandates. Where state laws do not govern PA supervision, Medicare is proposing that the supervisory requirement could be met through detailed medical record documentation of his/her collaboration with a physician.

CMS cited two reasons for relaxing Medicare's PA supervision standard. First, CMS noted that many states have recently changed their laws to allow PAs to practice more autonomously, akin to nurse practitioners and clinical nurse specialists, as members of medical teams composed of physicians, nonphysician practitioners and other allied health practitioners. CMS recognized that some states are doing away with the general supervision requirement which requires PA services to be furnished under a physician's overall direction and control, but not necessarily in the physician's presence. Accordingly, CMS noted its current rule may restrict a PA's practice more than state laws require and create undue tension. Second, CMS noted that the general supervision requirement is often misinterpreted to inappropriately restrict a PA's scope of practice to less than that permitted by their education and expertise. The proposed changes would grant states the flexibility to develop requirements for PA services that are unique and appropriate for their state without conflicting with Medicare's standards.

For exploring and potentially finalizing such changes, CMS is requesting specific examples of state laws and state scope of practice rules that enable PAs to practice more broadly and examples of the tensions these laws create with Medicare's general supervision requirement.

Deferring to State Scope of Practice Requirements for NPPs in Facilities

CMS often defers to state scope of practice laws/regulations to define the parameters within which non-physician practitioners (NPPs) may practice, generally and within facilities. In addition to relaxing Medicare's general PA supervision standard, CMS is also considering adopting various changes to its ambulatory surgery center (ASC) and hospice regulations to enable NPPs to fully operate within their recently expanded state scope of practice authorities in many states. Specifically, CMS is proposing the following key changes.

ASCs: CMS is proposing to amend the ASC conditions for coverage at 42 C.F.R. §416.42(a) to allow either a physician or an anesthetist (defined at 42 C.F.R. §410.69(b) to include an anesthesiologist's assistant or certified registered nurse anesthetist (CRNA)) to examine the patient immediately before surgery in an ASC and evaluate the patient's risk of anesthesia and risk for the planned procedure. Currently, only physicians may perform pre-procedure evaluations in ASCs. This proposed change would allow the same clinician to complete the pre- and post-procedure anesthesia evaluation, even when that clinician is an anesthetist (defined as an anesthesiologist's assistant or CRNA). CMS is seeking comments on this proposed change and suggestions for revising any other ASC requirements to enable greater NPP utilization in ASCs while preserving quality of care.

Hospice: To further facilitate use of NPPs in hospice care, CMS is proposing to revise 42 C.F.R. §418.106(b)(1) to permit hospices to accept drug orders from either a physician, nurse practitioner or PA, when such individuals are authorized to prescribe drugs under applicable state law and hospice policies. When the prescribing party is a PA, CMS is further proposing to restrict prescribing to only those PAs who are: (i) designated as the patient's attending physician; and (ii) not employed or otherwise engaged by the hospice. Additionally, CMS is requesting public comment on appropriate use of NPPs, including:

- Defining the appropriate roles/duties of NPPs in a hospice;
- Defining the NPP's distinct role within the hospice interdisciplinary group;
- Whether NPP services should be considered core services on par with nursing services;
- Defining adequate supervision for NPPs providing hospice care given the vast variation in state laws;
- Defining time frames for physician co-signatures on NPP orders; and
- Defining essential personnel requirements for PAs and other NPPs.

Review and Verification of Supervisee Medical Record Documentation

CMS is also proposing more relaxed medical records documentation rules for supervisees. Specifically, CMS is proposing to allow all physicians, PAs and APRNs, who furnish and bill for professional services, to review and verify information inserted in the medical record by individuals they supervise (whether a physician, resident, nurse, student, medical student or other member of the medical team) instead of requiring them to re-document the information already entered by their supervisee. This rule would apply to all services paid under the MPFS. If adopted, CMS would amend current regulations governing teaching physicians, PAs and APRNs to add this flexibility to all medical record documentation processes.

IV. OTHER PROPOSED PROGRAM & POLICY CHANGES

Open Payments

The Open Payments Program is a national disclosure program established under Section 1128G of the Social Security Act (Act), which requires 'manufacturers of covered drugs, devices, biologicals or medical supplies to annually submit information about certain payments and other transfers of value they made in the preceding calendar year to individuals classified as 'covered recipients' (currently defined to include physicians and teaching hospitals). Specifically, when a manufacturer makes payments or transfers of value to a 'covered recipient' that, either individually or in the aggregate, exceed the minimum dollar thresholds set by CMS, the manufacturer must report such payment or transfer of value to the Open Payments System. For CY 2019, the annual reporting thresholds for individual payments or transfers of value a $10.79 and the aggregate annual reporting threshold is $107.91.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. 115-270, enacted on October 24, 2018 (SUPPORT Act) amended the definition of covered recipient for Open Payments reporting occurring on or after January 1, 2022, to include various new practitioners. Specifically, it added physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives to the existing list of physicians and teaching hospitals. In the Proposed Rule, CMS is: (i) proposing to codify these changes from the SUPPORT Act; (ii) proposing to address public comments received from the CY 2017 MPFS proposed rule, by simplifying the process for reporting data by adjusting the nature of payment categories; and (iii) proposing changes to standardize data on reported covered drugs, devices, biologicals or medical supplies.

Home Infusion Therapy Benefit Notifications

The 21st Centuries Cures Act, Pub. L. 114-255, enacted December 13, 2016 (Cures Act) creates a Medicare Part B benefit to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously via a pump or item of durable medical equipment. The Cures Act also requires the physician who establishes the plan of care for infusion therapy to provide notification (in a form, manner and frequency determined appropriate by the CMS Secretary) of the options available for the furnishing of infusion therapy (*e.g. in home, physician's office, hospital outpatient department, etc.*). In the Proposed Rule, CMS is seeking public comment on the form, manner and frequency that physicians should be required to adhere to in notifying patients of their treatment options when receiving infusion therapy under Medicare Part B.

Ambulance Coverage Services – Physician Certification Statement

CMS has received feedback from ambulance providers, suppliers, and their industry representatives that various situations exist where the need for a physician certification statement or non-physician certification is excessive, or at least redundant of existing documentation requirements. Two of the most prominent circumstances identified by the stakeholders include interfacility transports, commonly referred to as hospital to hospital transports, and specialty care transports.

Upon reviewing the need for physician and non-physician certification statements, stakeholders' concerns and CMS' commitment to reducing the burden placed on providers and suppliers, CMS has determined that instead of incorporating additional exceptions, its efforts would be better served by merely altering the structure of the existing regulatory framework. These changes are intended to maximize flexibility for ambulance providers and suppliers to obtain the requisite certification statements and maintain the focus on the determination that other means of transportation are contraindicated and that the transport is medically necessary.

To accomplish this, CMS is proposing to define Physician Certification Statements and Non-Physician Certification Statements in 42 C.F.R. §410.40 to clarify that: (i) the focus is on the certification of the medical necessity provisions; and (ii) the form of the certification statement is not prescribed, thus affording maximum flexibility to ambulance providers and suppliers. Furthermore, CMS is proposing, as part of the new, proposed definition of non-physician certification statement, to add licensed practical nurses, social workers and case managers to the list of staff who may sign a certification statement where the ambulance provider or supplier is unable to obtain a signed physician certification statement from the attending physician.

Ambulance Fee Schedule – Medicare Ground Ambulance Services Data Collection System

Section 1661(s)(7) of the Social Security Act establishes ambulance services as a Medicare Part B service where methods of transportation are contraindicated by the individual's condition. Ambulance services are paid for at the lesser of the actual billed amount or the ambulance fee schedule (AFS) amount—which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor and other applicable adjustment factors. AFS rates are adjusted annually based on an inflation factor. CMS is also tasked with developing a data collection system (which may include use of cost surveys) to collect cost, revenue, utilization and other information from providers and suppliers of ground ambulance services.

In the Proposed Rule, CMS is proposing to require providers and suppliers of ground ambulance services report the following data via its data collection instrument:

- Total costs related to ground ambulance services;
- Total revenue from ground ambulance services; and
- Total ground ambulance utilization.

This approach would consider all ground ambulance costs, revenue and utilization, regardless of whether the service was billable to Medicare or related to a Medicare beneficiary to collect total cost, total revenue and total utilization data. An overview of the elements of the data collection instrument proposed by CMS is as shown on page 549 of the Proposed Rule (linked here).

Additionally, CMS is required to collect data from ambulance providers and suppliers in different geographic locations, including rural areas and low population density areas. Thus, CMS is proposing to require ambulance provides and suppliers to identify their primary service by either providing a list of zip codes that constitute their primary service area or selecting a primary service area using pre-populated drop-down menus. The proposal expands to include secondary service areas, as well.

Furthermore, because CMS is authorized to exempt a ground ambulance provider or supplier from the 10% payment reduction for an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy or other similar situations, CMS is proposing that ground ambulance organizations in these or other similar situations could request that CMS grant a hardship exemption, and CMS could consider granting an exemption if the ground ambulance organization could demonstrate that the significant hardship interfered with its ability to submit the required data under the data collection system.

Finally, CMS is proposing changes to the informal review process in the event a ground ambulance provider or supplier is subject to the 10% payment reduction.

Advisory Opinions on the Application of the Physician Self-Referral Law

Section 1877(g)(6) of the Social Security Act requires CMS to issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) would be considered as prohibited. In the June 25, 2018 Federal Register, CMS published a *Request for Information Regarding the Physician Self-Referral Law* that sought recommendations from the public on how to address any undue impact and burden of the physician self-referral statute and regulations. Although CMS did not specifically request comments on the CMS advisory opinion regulations, it received a number of comments urging that CMS reconsider its approach to advisory opinions and transform the process such that the regulated industry may obtain expeditious guidance on whether a physician's referrals to an entity with which he or she has a financial relationship would be prohibited.

Based on these comments, CMS is proposing to clarify that the request for an advisory opinion must 'relate to' (rather than 'involve') an existing arrangement or one into which a requestor, in good faith, specifically plans to enter. This proposal potentially expands the scope of arrangements that CMS may issue advisory opinions on.

Additionally, CMS is proposing the following changes to allow it more discretion to make determinations in selecting requests for advisory opinions:

- Reject advisory opinion requests or not issue advisory opinions with respect to requests that do not describe the arrangement at issue with a level of detail sufficient for CMS to issue an opinion, and the requestor does not timely respond to CMS requests for additional information; and
- To ease the restriction that prohibits the acceptance of an advisory opinion request or issuance of an advisory opinion if CMS is aware of pending or past investigations or proceedings involving a course of action that is "substantially the same" as the arrangement or proposed arrangement between or among the parties requesting an advisory opinion, and instead allow CMS more discretion to determine, in consultation with OIG and DOJ, whether acceptance of the advisory opinion request or issuance of the advisory opinion is appropriate.

Finally, to promote the use of the advisory opinion process, CMS is proposing to:

1. Modify the time period for issuing advisory opinions from 90 days to 60 days;
2. Adopt an hourly fee of $220 for preparation of an advisory opinion and a hourly fee of $440 for an expedited review;
3. Not pursue sanctions against any individuals or entities that are parties to an arrangement that CMS determines is indistinguishable in all material aspects from an arrangement that was the subject of the favorable advisory opinion; and
4. Recognize that individuals and entities may reasonably rely on an advisory opinion as non binding guidance that illustrates the application of the self-referral law and regulations to specific facts and circumstances.

V. CONCLUSIONS

The Proposed Rule contains numerous proposals intended to help promote the Administration's objectives of reducing regulatory burden as consistent with CMS' "patients over paper-work" initiative.

Many proposals, if adopted in a final rule, are likely to shift financial resources under the Medicare program and MPFS from specialist services to primary care, and further encourage the use of advanced practice clinicians (including nurse practitioners, physician assistants and others). Certain of the proposals also appear to promote greater flexibility and clarity for the industry, including the aforementioned proposals related to the Stark advisory opinion process.

Stakeholder comments on the rule are due no later than 5:00 pm ET on Friday, September 27, 2019. Because CMS released the proposed 2020 MPFS later than in prior years and must publish a final rule by early November 2019, many stakeholders plan to submit prior to the deadline in order to give the Agency time to duly consider their suggestions and concerns. If you need assistance with drafting a response to CMS or understanding how the proposed MPFS may impact your business, please feel contact the authors. The Polsinelli Health Law and Public Policy Groups are available to help you navigate the complexity of the Proposed Rule and other related proposals.

Separate e-alert summaries of other portions of the MPFS Proposed Rule, including those related to behavioral health and those governing the value-based payment including the Quality Payment Program, Medicare Shared Savings Program, bundled payment arrangements and others will be published in the near future.