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Calendar Year (CY) 2022 Medicare Physician Fee Schedule Proposed Rule

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On July 13, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that announces and solicits public comments on proposed policy changes for Medicare payments under the Physician Fee Schedule (PFS), and other Medicare Part B issues, on or after January 1, 2022.

The calendar year (CY) 2022 PFS proposed rule is one of several proposed rules that reflect a broader Administration-wide strategy to create a health care system that results in better accessibility, quality, affordability, empowerment, and innovation.

Background on the Physician Fee Schedule

Since 1992, Medicare payment has been made under the PFS for the services of physicians and other billing professionals. Physicians' services paid under the PFS are furnished in a variety of settings, including physician offices, hospitals, ambulatory surgical centers (ASCs), skilled nursing facilities and other post-acute care settings, hospices, outpatient dialysis facilities, clinical laboratories, and beneficiaries' homes. Payment is also made to several types of suppliers for technical services, most often in settings for which no institutional payment is made.

For most services furnished in a physician's office, Medicare makes payment to physicians and other professionals at a single rate based on the full range of resources involved in furnishing the service. In contrast, PFS rates paid to physicians and other billing practitioners in facility settings, such as a hospital outpatient department (HOPD) or an ASC, reflect only the portion of the resources typically incurred by the practitioner in the course of furnishing the service.

For many diagnostic tests and a limited number of other services under the PFS, separate payment may be made for the professional and technical components of services. The technical component is frequently billed by suppliers, like independent diagnostic testing facilities and radiation treatment centers, while the professional component is billed by the physician or practitioner.

Payments are based on the relative resources typically used to furnish the service. Relative value units (RVUs) are applied to each service for work, practice expense, and malpractice expense. These RVUs become payment rates through the application of a conversion factor. Geographic adjusters (geographic practice cost index) are also applied to the total RVUs to account for variation in practice costs by geographic area. Payment rates are calculated to include an overall payment update specified by statute.

PAYMENT PROVISIONS

CY 2022 PFS Ratesetting and Conversion Factor

CMS is proposing a series of standard technical proposals involving practice expense, including the implementation of the fourth year of the market-based supply and equipment pricing update, changes to the practice expense for many services associated with the proposed update to clinical labor pricing, and standard rate-setting refinements.

With the proposed budget neutrality adjustment to account for changes in RVUs (required by law), and expiration of the 3.75 percent payment increase provided for CY 2021 by the Consolidated Appropriations Act, 2021 (CAA), the proposed CY 2022 PFS conversion factor is $33.58, a decrease of $1.31 from the CY 2021 PFS conversion factor of $34.89. The PFS conversion factor reflects the statutory update of 0.00 percent and the adjustment necessary to account for changes in relative value units and expenditures that would result from our proposed policies.

Evaluation and Management (E/M) Visits

CMS is engaged in an ongoing review of payment for E/M visit code sets. For CY 2022, we are making several proposals that take into account the recent changes to E/M visit codes, as explained in the AMA CPT Codebook, which took effect January 1, 2021. We are also proposing to clarify and refine policies that were reflected in certain manual provisions that were recently withdrawn. Specifically, we are proposing a number of refinements to our current policies for split (or shared) E/M visits, critical care services, and services furnished by teaching physicians involving residents.

Split (or shared) E/M visits

We are proposing to refine our longstanding policies for split (or shared) E/M visits to better reflect the current practice of medicine, the evolving role of non-physician practitioners (NPPs) as members of the medical team, and to clarify conditions of payment that must be met to bill Medicare for these services. In the CY 2022 PFS proposed rule, we are proposing the following:

- Definition of split (or shared) E/M visits as evaluation and management (E/M) visits provided in the facility setting by a physician and an NPP in the same group.
- The practitioner who provides the substantive portion of the visit (more than half of the total time spent) would bill for the visit.
- Split (or shared) visits could be reported for new as well as established patients, and initial and subsequent visits, as well as prolonged services.
- Requiring reporting of a modifier on the claim to help ensure program integrity.
- Documentation in the medical record that would identify the two individuals who performed the visit. The individual providing the substantive portion must sign and date the medical record.

- Codifying these proposals and revised policies in new regulations at 42 CFR 415.140.

Critical Care Services

Similarly, we are proposing to refine our longstanding policies for critical care services. In the CY 2022 PFS proposed rule we are proposing:

- To use American Medical Association (AMA) Current Procedural Terminology (CPT) prefatory language as the definition of critical care visits, including bundled services.
- To allow critical care services to be furnished concurrently to the same patient on the same day by more than one practitioner representing more than one specialty, and that critical care services can be furnished as split (or shared) visits.
- That no other E/M visit can be billed for the same patient on the same date as a critical care service when the services are furnished by the same practitioner, or by practitioners in the same specialty and same group to account for overlapping resource costs.
- That critical care visits cannot be reported during the same time period as a procedure with a global surgical period.

Teaching Physician Services

The AMA CPT office/outpatient E/M visit coding framework that CMS finalized for CY 2021, under which practitioners can select the office/outpatient E/M visit level to bill, was based either on use of the total time personally spent by the reporting practitioner or medical decision making (MDM). Under our existing regulations, if a resident participates in a service furnished in a teaching setting, a teaching physician can bill for the service only if they are present for the key or critical portion of the service. Under the so-called "primary care exception," Medicare makes PFS payment in certain teaching hospital primary care centers for certain services furnished by a resident without the physical presence of a teaching physician.

CMS is proposing to clarify that the time when the teaching physician was present can be included when determining E/M visit level. Under the primary care exception specifically, only MDM would be used to select the visit level to guard against the possibility of inappropriate coding that reflects residents' inefficiencies rather than a measure of the time required to furnish the services.

Telehealth Services under the PFS

As CMS continues to evaluate the temporary expansion of telehealth services that were added to the telehealth list during the COVID-19 PHE, CMS is proposing to allow certain services added to the Medicare telehealth list to remain on the list to the end of December 31, 2023, so that there is a glide path to evaluate whether the services should be permanently added to the telehealth list following the COVID-19 PHE.

Section 123 of the CAA removed the geographic restrictions and added the home of the beneficiary as a permissible originating site for telehealth services when used for the purposes of diagnosis, evaluation, or treatment of a mental health disorder, and requires

that there be an in-person, non-telehealth service with the physician or practitioner within six months prior to the initial telehealth service, and thereafter, at intervals as specified by the Secretary.

CMS is proposing to require an in-person, non-telehealth service be provided by the physician or practitioner furnishing mental health telehealth services within six months prior to the initial telehealth service, and at least once every six months thereafter. We are seeking comment on whether a different interval may be necessary or appropriate for mental health services furnished through audio-only communication technology. We are also seeking comment on how to address scenarios where a physician or practitioner of the same specialty/subspecialty in the same group may need to furnish a mental health service due to unavailability of the beneficiary's regular practitioner.

CMS is proposing to amend the current regulatory requirement for interactive telecommunications systems – which is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner – to include audio-only communication technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients in their homes.

CMS is proposing to limit the use of an audio-only interactive telecommunications system to mental health services furnished by practitioners who have the capability to furnish two-way, audio/video communications, but where the beneficiary is not capable of using, or does not consent to, the use of two-way, audio/video technology. CMS is also proposing to require use of a new modifier for services furnished using audio-only communications, which would serve to certify that the practitioner had the capability to provide two-way, audio/video technology, but instead, used audio-only technology due to beneficiary choice or limitations.

CMS is also soliciting comment on: (1) whether additional documentation should be required in the patient's medical record to support the clinical appropriateness of audio-only telehealth; (2) whether or not we should preclude audio-only telehealth for some high-level services, such as level 4 or 5 E/M visit codes or psychotherapy with crisis; and (3) any additional guardrails we should consider putting in place in order to minimize program integrity and patient safety concerns.

Therapy Services

CMS is implementing the final part of section 53107 of the Bipartisan Budget Act of 2018, which requires CMS, through the use of new modifiers (CQ and CO), to identify and make payment at 85% of the otherwise applicable Part B payment amount for physical therapy and occupational therapy services furnished in whole or in part by physical therapist

assistants (PTAs) and occupational therapy assistants (OTAs), for dates of service on and after January 1, 2022.

For CY 2022, in response to numerous stakeholder questions and to promote proper therapy care, CMS is proposing to revise the *de minimis* standard established to determine whether services are provided "in whole or in part" by PTAs or OTAs. Specifically, CMS is proposing to revise the *de minimis* policy to allow a timed service to be billed without the CQ/CO modifier in cases when a PTA/OTA participates in providing care to a patient with a physical therapist or occupational therapist (PT/OT), but the PT/OT meets the Medicare billing requirements for the timed service without the minutes furnished by the PTA/OTA by providing more than the 15-minute midpoint (also known as the 8-minute rule).

Under this proposal, any minutes that the PTA/OTA furnishes in the scenarios described above would not matter for purposes of billing Medicare. In addition to cases where one remaining unit of a multi-unit therapy service to be billed, this revision to the policy would apply in a limited number of cases where more than one unit of therapy, with a total time of 24-28 minutes is being furnished. For these limited cases, CMS is proposing to allow one 15-minute unit to be billed with the CQ/CO assistant modifier and one 15-minute unit to be billed without the CQ/CO modifier in billing scenarios where there are two 15-minute units left to bill when the PT/OT and the PTA/OTA each provide between 9 and 14 minutes of the same service.

Overall, the *de minimis* standard would continue to be applicable in the following scenarios:

- When the PTA/OTA independently furnishes a service, or a 15-minute unit of a service "in whole" without the PT/OT furnishing any part of the same service.
- In instances where the service is not defined in 15-minute increments including: supervised modalities, evaluations/reevaluations, and group therapy.

- When the PTA/OTA furnishes eight minutes or more of the final unit of a billing scenario in which the PT/OT furnishes less than eight minutes of the same service.
- When both the PTA/OTA and the PT/OT each furnish less than eight minutes for the final 15-minute unit of a billing scenario.

Physician Assistant (PA) Services

CMS is proposing to implement section 403 of Division CC of the CAA that authorizes Medicare to make direct payment to PAs for professional services they furnish under Part B beginning January 1, 2022. Medicare currently can only make payment to the employer or independent contractor of a PA. Consequently, PAs could not bill and be paid by the Medicare program directly for their professional services; they also did not have the option to reassign payment for their services or to incorporate with other PAs to bill the program for PA services. Beginning January 1, 2022, PAs would be able to bill Medicare directly for their services and reassign payment for their services.

Vaccine Administration Services Comment Solicitation

The pandemic has highlighted the importance of access to COVID-19 vaccines, as well as access to other preventive vaccines. Over the last several years, Medicare payment rates for physicians and mass immunizers for administering certain preventive vaccines (flu, pneumonia and hepatitis B vaccines) have decreased by roughly 30%. Given the ongoing stakeholder interest in this issue, the proposed rule includes a comment solicitation to obtain information on the costs involved in furnishing preventive vaccines, with the goal to inform the development of more accurate rates for these services. More specifically CMS is seeking information on:

- The different types of health care providers who furnish vaccines and how have those providers changed since the start of the pandemic.
- How the costs of furnishing flu, pneumococcal, and hepatitis B vaccines compare to the costs of furnishing COVID-19 vaccines, and how costs may vary for different types of health care providers.
- How the COVID-19 PHE may have impacted costs, and whether health care providers envision these costs to continue.

CMS is also seeking stakeholder input on two other issues. First, we are seeking input on our preliminary policy to pay $35 add-on for certain vulnerable beneficiaries when they receive a COVID-19 vaccine at home. CMS is interested in stakeholder input on what qualifies as the "home" and how we can balance ensuring program integrity with beneficiary access.

Second, as the market for COVID-19 monoclonal antibody products matures, CMS is also seeking comments on whether we should treat these products the same way we treat other physician-administered drugs and biologicals under Medicare Part B.

Payment for Medical Nutrition Therapy (MNT) Services and Related Services

The statute provides coverage of MNT services by registered dietitians and nutrition professionals when referred by a physician (an M.D. or D.O.) and also establishes the professional qualifications for these practitioners. Since January 1, 2002, registered dietitians and nutrition professionals have been recognized to provide and bill for MNT services, meaning nutritional diagnostic, therapeutic, and counseling services. For CY 2022, in response to stakeholder concerns about parity with other types of NPPs, we are proposing to establish regulations at §410.72 for their services since they are the only NPP type listed at section 1842(b)(18)(C) of the Act without a regulatory provision in this section of 42 CFR subpart B.

We are also proposing to update the payment regulation for MNT services at §414.64 to clarify that MNT services are, and have been, paid at 100% (instead of 80%) of 85% of the PFS amount, without any cost-sharing, since CY 2011. While we implemented this change through our usual change request process, we neglected to update this regulation when the Affordable Care Act (ACA) of 2010 amended the statute to except the coinsurance and

deductible for preventive services defined under section 1861(ddd)(3) of the Act that have a grade of A or B from the United States Preventive Services Task Force and MNT services received a grade of B.

Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as a Colorectal Cancer Screening

CMS is proposing to implement Section 122 of the CAA, which amends the statute by providing a special coinsurance rule for procedures that are planned as colorectal cancer screening tests but become diagnostic tests when the practitioner identifies the need for additional services (e.g., removal of polyps). At present, the addition of any procedure beyond the planned colorectal screening (for which there is no coinsurance) results in a beneficiary's having to pay coinsurance.

Section 122 of the CAA reduces, over time, the amount of coinsurance a beneficiary will pay for such services. That is, for services furnished on or after January 1, 2022, the coinsurance amount paid for planned colorectal cancer screening tests that require additional related procedures shall be equal to a specified percent (i.e., 20% for CY 2022, 15% for CYs 2023 through 2026, 10% for CYs 2027 through 2029, and zero percent beginning CY 2030) of the lesser of the actual charge for the service or the amount determined under the fee schedule that applies to the test.

The reduction over time of the coinsurance percentage holds true regardless of the code that is billed for establishment of a diagnosis, for removal of tissue or other matter, or for another procedure that is furnished in connection with and in the same clinical encounter as the screening. Thus, beginning CY 2022, the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter will be gradually reduced, and beginning January 1, 2030, will be zero percent.

Opioid Treatment Program (OTP) Payment Policy

CMS is proposing to allow OTPs to furnish counseling and therapy services via audio-only interaction (such as telephone calls) after the conclusion of the COVID-19 PHE in cases where audio/video communication is not available to the beneficiary, including circumstances in which the beneficiary is not capable of or does not consent to the use of devices that permit a two-way audio/video interaction, provided all other applicable requirements are met. CMS is proposing to require that OTPs use a service-level modifier for audio-only services billed using the counseling and therapy add-on code and document in the medical record the rationale for a service being furnished using audio-only services, in order to facilitate program integrity activities.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

There are several provisions that CMS is proposing that are aimed at bolstering the abilities of RHCs and FQHCs to furnish care to underserved Medicare beneficiaries. The following provisions demonstrate CMS's commitment to addressing health equities in rural and vulnerable populations.

Mental Health Services furnished via Telecommunications Technologies for RHCs and FQHCs

CMS is proposing to revise the current regulatory language for RHC or FQHC mental health visits to include visits furnished using interactive, real-time telecommunications technology. RHCs and FQHCs are not authorized to serve as distant site practitioners for Medicare telehealth services after the end of the COVID-19 public health emergency. However, this proposed change would allow RHCs and FQHCs to report and receive payment for mental health visits furnished via real-time telecommunication technology in the same way they currently do when visits take place in-person, including audio-only visits when the beneficiary is not capable of, or does not consent to, the use of video technology.

Rural Health Clinic (RHC) Payment Limit Per-Visit

Section 130 of the CAA as amended by section 2 of P.L. 117-7, requires that, beginning April 1, 2021, independent RHCs and provider-based RHCs in a hospital with 50 or more beds receive an increase in their payment limit per visit over an 8-year period, with a prescribed amount for each year from 2021 through 2028. Then, in subsequent years, the limit is updated by the percentage increase in Medicare Economic Index (MEI). Also beginning April 1, 2021, section 130 as amended requires that a payment limit per-visit be established for smaller provider-based RHCs enrolled before January 1, 2021. Lastly, section 130 of the CAA subjects all newly enrolled RHCs (as of January 1, 2021, and after), both independent and provider-based, to a national payment limit per-visit.

Payment for Attending Physician Services Furnished by RHCs or FQHCs to Hospice Patients

CMS is proposing to implement section 132 of the CAA, which makes FQHCs and RHCs eligible to receive payment for hospice attending physician services when provided by a FQHC/RHC physician, nurse practitioner, or physician assistant who is employed or working under contract for an FQHC or RHC, but is not employed by a hospice program, starting January 1, 2022.

Concurrent Billing for Chronic Care Management Services (CCM) and Transitional Care Management (TCM) Services for RHCs and FQHCs

CMS is proposing to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary during the same service period, provided all requirements for billing each code are met.

COVID-19 Vaccines Furnished in RHCs and FQHCs (Technical Updates)

Section 3713 of the CARES Act established Medicare Part B coverage and payment for a COVID-19 vaccine and its administration. CMS is proposing to make conforming technical changes to the regulatory text related to COVID-19 vaccines for RHCs and FQHCs.

Tribal FQHC Payments – Comment Solicitation

Outpatient clinics operated by a tribal organization under the Indian Self-Determination Education and Assistance Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act are eligible to become FQHCs. FQHCs are paid under the FQHC Prospective Payment System (PPS) under Medicare Part B based on the lesser of the FQHC PPS rate or their actual charges. There is an exception for payment under the FQHC PPS for certain tribal FQHCs in operation on or before April 7, 2000. Under the exception, grandfathered tribal FQHCs bill as if it were provider-based to an Indian Health Service (IHS) hospital and are paid the Medicare outpatient per visit rate, also referred to as the IHS all-inclusive rate (AIR).

CMS has received a request from the American Indian and Alaska Native community to amend its Medicare regulations to make all IHS- and tribally-operated outpatient facilities/clinics eligible for payment at the Medicare outpatient per visit/AIR, regardless of whether they were owned, operated, or leased by IHS. In addition, we have been asked to consider certain flexibilities regarding the cost reporting requirement for these types of facilities. Therefore, we are soliciting comment on these topics that could be used to inform future payment policy decisions.

<u>Electronic Prescribing of Controlled Substances-- Section 2003 of the SUPPORT Act</u>

Section 2003 of the SUPPORT Act requires electronic prescribing of controlled substances (EPCS) for schedule II, III, IV, and V controlled substances covered through Medicare Part D. The statute provides the Secretary with discretion on whether to grant waivers or exceptions to the EPCS requirement and specifies several types of exceptions that may be considered. It also gives the Secretary authority to enforce non-compliance with the requirement and to specify appropriate penalties for non-compliance through rulemaking. In December 2020, CMS implemented the first phase of this mandate by naming the standard that prescribers must use for EPCS transmissions and delaying compliance actions until January 1, 2022.

In the PFS proposed rule, we are proposing to implement the second phase of this mandate by proposing certain exceptions to the EPCS requirement. The proposed exceptions would apply:

- Where the prescriber and dispensing pharmacy are the same entity;
- For prescribers who issue 100 or fewer controlled substance prescriptions for Part D drugs per calendar year; and

- For prescribers who are in the geographic area of a natural disaster, or who are granted a waiver based on extraordinary circumstances, such as an influx of patients due to a pandemic.

We are proposing that prescribers be able to request a waiver where circumstances beyond the prescriber's control prevent the prescriber from being able to electronically prescribe controlled substances covered by Part D. We are proposing to initially enforce compliance by sending compliance letters to prescribers violating the EPCS mandate. In addition, we are seeking comment on different types of compliance actions, so that we may ensure prescribers electronically prescribe controlled substances covered under Part D without overly burdening them.

CMS is also proposing to extend the start date for compliance actions to January 1, 2023, in response to stakeholder feedback. However, we are soliciting comment on whether the original date of January 1, 2022, should remain, in light of the proposed exceptions to the mandate. We are also proposing to extend the compliance deadline for Part D prescriptions written for beneficiaries in long-term care facilities to January 1, 2025.

Requiring Certain Manufacturers to Report Drug Pricing Information for Part B

Drug manufacturers with Medicaid Drug Rebate Agreements are required to submit Average Sales Price (ASP) data for their Part B products in order for their covered outpatient drugs to be payable under Part B. Manufacturers without such agreements have the option to voluntarily submit ASP data. For calendar quarters beginning January 1, 2022, the CAA requires manufacturers of drugs or biologicals payable under Part B without a Medicaid Drug Rebate Agreement to report ASP data. CMS is proposing to make regulatory changes to implement the new reporting requirements.

Determination of ASP for Certain Self-administered Drug Products

Section 405 of the CAA requires the Office of Inspector General (OIG) to conduct periodic studies on non-covered, self-administered versions of drugs or biologicals that are included in the calculation of payment under section 1847A of the Social Security Act. This provision permits CMS to apply a payment limit calculation methodology (the "lesser of" methodology) to applicable billing codes, if deemed appropriate. That is, the Medicare payment limit for the drug or biological billing code would be the lesser of: (1) the payment limit determined using the current methodology (where the calculation includes the ASPs of the self-administered versions), or (2) the payment limit calculated after excluding the non-covered, self-administered versions. CMS is proposing the "lesser of" methodology for drug and biological products that may be identified by future OIG reports.

Section 405 of the CAA also requires that beginning July 1, 2021, the ASP-based payment limit for billing codes representing Cimzia® (certolizumab pegol) and Orencia® (abatacept) as identified in a July 2020 OIG report adhere to the "lesser of" methodology. CMS has applied this methodology for these billing codes in the July 2021 ASP Drug Pricing files.

Part B Drug Payment for Section 505(b)(2) Drugs

Some drugs approved through the pathway established under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act share similar labeling and uses with generic drugs that are assigned to multiple source drug codes. CMS is soliciting comment on a decision framework under which certain section 505(b)(2) drug products could be assigned to existing multiple source drug codes. This approach would be applied to section 505(b)(2) drug products where a billing code descriptor for an existing multiple source code describes the product and other factors, such as the product's labeling and uses, are similar to products already assigned to the code.

The framework approach is consistent with the concept of paying similar amounts for similar services and with efforts to curb drug prices.

Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance

The Clinical Laboratory Fee Schedule (CLFS) provides for a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses (generally referred to as a travel allowance) for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital). The travel allowance is paid only when the nominal specimen collection fee is also payable.

In an effort to be as expansive as possible within the current authorities to have diagnostic testing available to Medicare beneficiaries who need it during the COVID-19 PHE, we changed the Medicare payment rules to provide payment to independent laboratories for specimen collection from beneficiaries who are homebound or inpatients not in a hospital for COVID-19 testing under certain circumstances and increased payments from $3-5 to $23-25. Although we expect the increased specimen collection fees for COVID-19 clinical diagnostic laboratory tests will end at the termination of the COVID-19 PHE, we are seeking comments on our policies for specimen collection fees and the travel allowance as we consider updating these policies in the future through notice and comment rulemaking. Specifically, we are requesting comments regarding the nominal specimen collection fees for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital). We are also seeking comments related to the calculation of costs for transportation and personnel expenses for trained personnel to collect specimens from such patients. CMS is also announcing that we are making permanent the option for laboratories to maintain electronic logs of miles traveled for the purposes of covering the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a specimen sample.

Medical Nutrition Therapy Coverage and Payment Issues

We are proposing to remove the requirement that the medical nutrition therapy referral be made by the "treating physician" and update the glomerular filtration rate (GFR) to reflect

current medical practice. The statute provides coverage of MNT services that may only be provided by registered dietitians and nutrition professionals when referred by a physician (an M.D. or D.O.) and also establishes the professional qualifications for these practitioners. For CY 2022, we are proposing to establish regulations at §410.72 for registered dietitians and nutrition professionals, similar to established regulations for other non-physician practitioners. We are also proposing to update the payment regulation for MNT services at §414.64 to clarify that MNT services are, and have been, paid at 100% (instead of 80%) of 85% of the PFS amount, without any cost-sharing, since CY 2011.

Appropriate Use Criteria (AUC) Program

CMS is proposing to begin the payment penalty phase of the AUC program on the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID-19. This flexible effective date is intended to take into account the impact that the PHE for COVID-19 has had and may continue to have on practitioners, providers and beneficiaries. Currently, the payment penalty phase of the AUC program is set to begin January 1, 2022.

Pulmonary Rehabilitation

We are proposing to expand coverage of outpatient pulmonary rehabilitation services, paid under Medicare Part B, to beneficiaries who were hospitalized with COVID-19 and experience persistent symptoms, including respiratory dysfunction, for at least four weeks after hospitalization.

Medicare Shared Savings Program

CMS is proposing a longer transition for Accountable Care Organizations (ACOs) reporting electronic clinical quality measure/Merit-based Incentive Payment System clinical quality measure (eCQM/MIPS CQM) all-payer quality measures under the Alternative Payment Model (APM) Performance Pathway (APP), by extending the availability of the CMS Web Interface collection type for two years, through performance year (PY) 2023. This proposal responds to ACOs' concerns about the transition to all-payer eCQM/MIPS CQM measures, including with respect to aggregating all-payer data across multiple electronic health record (EHR) systems and multiple health care practices that participate in ACOs.

We are also proposing to freeze the quality performance standard for PY 2023, by providing an additional one-year before increasing the quality performance standard ACOs must meet to be eligible to share in savings, and additional revisions to the quality performance standard to encourage ACOs to report all-payer measures. These proposals, in addition to existing policies, provide three years for ACOs to transition to reporting the three eCQM/MIPS CQM all-payer measures under the APP. For more details on Shared Savings Program quality proposals, please refer to the Quality Payment Program PFS proposed rule fact sheet: https://qpp-cm-prod-

content.s3.amazonaws.com/uploads/1517/2022%20QPP%20Proposed%20Rule%20Overview%20Fact%20Sheet.pdf

CMS is proposing to revise the methodology for calculating repayment mechanism amounts for risk-based ACOs to reduce the percentage used in the existing amount by 50%. ACOs accepting performance-based risk must establish a repayment mechanism (i.e, escrow, line of credit, surety bond) to assure CMS that they can repay losses for which they may be liable upon reconciliation. We are also proposing to modify the threshold for determining whether an ACO is required to increase its repayment mechanism amount during its agreement period. These proposals would result in lower required initial repayment mechanism amounts, and less frequent repayment mechanism amount increases during an ACO's agreement period, thereby lowering potential barriers for ACOs' participation in two-sided models and increasing available resources for investment in care coordination and quality improve activities. We are also proposing to allow a one-time opportunity for certain ACOs that established a repayment mechanism to support their participation in a two-sided model beginning on July 1, 2019; January 1, 2020; or January 1, 2021; to elect to decrease the amount of their existing repayment mechanisms.

CMS is committed to ensuring that ACOs establishing a repayment mechanism to support their participation in a two-sided model beginning with PY 2022 do not overfund their repayment mechanism arrangements according to the existing methodology if we finalize the proposed revisions to reduce repayment mechanism amounts.

CMS is proposing to reduce burden and streamline the Shared Savings Program application process by modifying the prior participation disclosure requirement, so that the disclosure is required only at the request of CMS during the application process, and by reducing the frequency and circumstances under which ACOs submit sample ACO participant agreements and executed ACO participant agreements to CMS. We are proposing to amend the beneficiary notification requirement to set forth different notification obligations for ACOs depending on the assignment methodology selected by the ACO to help avoid unnecessary confusion for beneficiaries.

CMS is proposing revisions to the definition of primary care services that are used for purposes of beneficiary assignment. We are proposing that the changes would be applicable for determining beneficiary assignment beginning with PY 2022. We are also seeking comment on whether stakeholders believe there are other codes that should be included in this definition to inform future rulemaking.

We also seek comments from stakeholders on the Shared Savings Program's calculation of the regional adjustment, and blended national-regional growth rates for trending and updating the benchmark, as well as comments on the risk adjustment methodology. We are exploring how these policies interact with the Shared Savings Program's other benchmarking policies. If we determine changes to our existing policies are needed, we would propose modifications in subsequent rulemaking.

Updates to the Open Payments Financial Transparency Program

Open Payments is a national transparency program that requires drug and device manufacturers and group purchasing organizations (known as “reporting entities”) to report payments or transfers of value to physicians, teaching hospitals, and other providers (known as “covered recipients”) to CMS. The changes proposed for Open Payments in the proposed rule are intended to support the usability and integrity of the data for the public, researchers and CMS.

Under Open Payments, there are three kinds of records reported: (1) general (with categories like food and travel), (2) research, and (3) ownership interest. Several thousand payments in the general payments category are flagged by reporting entities for publication delay in each program year. The purpose of this delay is to keep a record from being publicly available because it contains sensitive information for research and development. Only payments that are associated with research should be delayed for publication. To address this, CMS is proposing language that will clarify the impermissibility of delaying general payments, and that research-related payments do not need to have been specifically outlined in the original research agreement to be reported as research payments. The research payment format allows CMS to verify that the payment is being delayed correctly.

Under Open Payments, reporting entities are required to report payments to teaching hospitals. Over the course of the program, CMS has heard from stakeholders that there is often not enough information included in teaching hospital records for verification that the record was correctly reported. This often leads to disputes, a process by which the covered recipient initiates a conversation with the reporting entity to get more information, creating work for both parties. CMS is proposing to add a required field to teaching hospital records to address this issue. The field would only be visible to the teaching hospital disputing the information.

Physician-owned distributorships (PODs) are a subset of group purchasing organizations, but are not specifically defined in the Open Payments regulation. Accordingly, CMS is proposing to include a specific definition for PODs, as well as make explicit the requirement for PODs to report and self-identify. The potential conflict of interest between providers and reporting entities is the heart of the Open Payments program, so quick and clear identification of physician-owned businesses would be beneficial.

CMS is also proposing changes to address an overlap between general and ownership payments. Currently, there is a nature of payment category for ownership. This general record for ownership is separate from ownership and investment interest, which is its own type of record. An entity may submit one or both types of record for ownership. CMS’s proposal would eliminate the confusion that the two types of ownership records may create and facilitate easier understanding and analysis of the data by having only one type of ownership record.

Recertification is part of the annual process that reporting entities undertake when they submit records, primarily allowing for the companies to update their system information. However, this process is not available for companies that do not have any records to report. CMS is proposing to give companies the option to recertify and attest to the fact that they do not have any records to submit for a reporting year. This proposal will simplify communication about compliance between reporting entities and CMS.

Medicare Provider Enrollment

CMS is proposing several provider enrollment regulatory revisions that will strengthen program integrity while assisting Medicare beneficiaries. These include:

- Exempting certain types of independent diagnostic testing facilities (IDTF) from several of our IDTF supplier standards in 42 CFR § 410.33.
- Expanding our authority to deny or revoke a provider's or supplier's Medicare enrollment in order to protect the Medicare program and its beneficiaries.
- Establishing specific rebuttal procedures in regulation for providers and suppliers whose Medicare billing privileges have been deactivated.

Medicare Ground Ambulance Data Collection System

CMS is proposing a series of changes to the Medicare Ground Ambulance Data Collection System including:

- Proposed changes to the data collection period and data reporting period for selected ground ambulance organizations in year three;
- Proposed revisions to the timeline for when the payment reduction for failure to report will begin and when the data will be publicly available; and
- Proposed revisions to the Medicare Ground Ambulance Data Collection Instrument. Through review of questions and feedback that we received, we have identified some instances where changes and clarifications to the instrument could improve clarity and be less burdensome to respondents.

For more information, please visit: https://www.federalregister.gov/public-inspection/current