Fact sheet

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

Nov 02, 2021 Medicare Parts A & B

On November 2, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that includes updates on 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 final rule is one of several 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, generally 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 fixed-dollar conversion factor. Geographic adjustments (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 finalized a series of standard technical proposals involving practice expense, including standard rate-setting refinements, the implementation of the fourth year of the market-based supply and equipment pricing update, and changes to the practice expense for many services associated with the update to clinical labor pricing. We are finalizing our proposal to update the clinical labor rates for CY 2022 through the addition of a four-year transition period as requested by public commenters. We have used a four-year transition to incorporate new pricing data in the past, such as for the previous supply and equipment pricing update, and we believe that it will help provide payment stability and maintain beneficiary access to care.

With the budget neutrality adjustment to account for changes in RVUs (required by law), and expiration of the 3.75 percent temporary CY 2021 payment increase provided by the Consolidated Appropriations Act, 2021 (CAA), the CY 2022 PFS conversion factor is $33.59, a decrease of $1.30 from the CY 2021 PFS conversion factor of $34.89. The PFS conversion factor reflects the statutory update of zero percent and the adjustment necessary to account for changes in relative value units and expenditures that would result from our finalized 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 finalized several policies 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 clarifying and refining policies that were reflected in certain manual provisions that were recently withdrawn. Specifically, we are making 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 refining 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 final rule, we are establishing the following:

- Definition of split (or shared) E/M visits as E/M visits provided in the facility setting by a physician and an NPP in the same group. The visit is billed by the physician or practitioner who provides the substantive portion of the visit.
- By 2023, the substantive portion of the visit will be defined as more than half of the total time spent. For 2022, the substantive portion can be history, physical exam, medical

decision-making, or more than half of the total time (except for critical care, which can only be more than half of the total time).
- Split (or shared) visits can be reported for new as well as established patients, and initial and subsequent visits, as well as prolonged services.
- A modifier is required on the claim to identify these services to inform policy and help ensure program integrity.
- Documentation in the medical record must identify the two individuals who performed the visit. The individual providing the substantive portion must sign and date the medical record.
- Codifying these revised policies in a new regulation at 42 CFR 415.140.

Critical Care Services

For critical care services, we are refining our longstanding policies, establishing that:

- Critical care services are defined in the CPT Codebook prefatory language for the code set.
- The CPT Codebook listing of bundled services are not separately payable.
- When medically necessary, critical care services can be furnished concurrently to the same patient on the same day by more than one practitioner representing more than one specialty, and critical care services can be furnished as split (or shared) visits.
- Critical care services may be paid on the same day as other E/M visits by the same practitioner or another practitioner in the same group of the same specialty, if the practitioner documents that the E/M visit was provided prior to the critical care service at a time when the patient did not require critical care, the visit was medically necessary, and the services are separate and distinct, with no duplicative elements from the critical care service provided later in the day. Practitioners must report modifier -25 on the claim when reporting these critical care services.
- Critical care services may be paid separately in addition to a procedure with a global surgical period if the critical care is unrelated to the surgical procedure. Preoperative

and/or postoperative critical care may be paid in addition to the procedure if the patient is critically ill (meets the definition of critical care) and requires the full attention of the physician, and the critical care is above and beyond and unrelated to the specific anatomic injury or general surgical procedure performed (e.g., trauma, burn cases). We are creating a new modifier for use on such claims to identify that the critical care is unrelated to the procedure. If care is fully transferred from the surgeon to an intensivist (and the critical care is unrelated), the appropriate modifiers must also be reported to indicate the transfer of care. Medical record documentation must support the claims.

Teaching Physician Services

The AMA CPT office/outpatient E/M visit coding framework that CMS finalized for CY 2021 provides that practitioners can select the office/outpatient E/M visit level to bill based either on either 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," in certain teaching hospital primary care centers, the teaching physician can bill for certain services furnished independently by a resident without the physical presence of a teaching physician, but with the teaching physician's review.

CMS finalized and clarified that when time is used to select the office/outpatient E/M visit level, only the time spent by the teaching physician in qualifying activities, including time that the teaching physician was present with the resident performing those activities, can be included for purposes of visit level selection. Under the primary care exception, time cannot be used to select visit level. Only MDM may be used to select the E/M visit level, to guard against the possibility of inappropriate coding that reflects residents' inefficiencies rather than a measure of the total medically necessary time required to furnish the E/M services.

Telehealth Services under the PFS

As CMS continues to evaluate the inclusion of telehealth services that were temporarily added to the Medicare telehealth services list during the COVID-19 PHE, we finalized that certain services added to the Medicare telehealth services list will remain on the list through December 31, 2023, allowing additional time for us to evaluate whether the services should be permanently added to the Medicare telehealth services list.

We finalized that we will extend, through the end of CY 2023, the inclusion on the Medicare telehealth services list of certain services added temporarily to the telehealth services list that would otherwise have been removed from the list as of the later of the end of the COVID-19 PHE or December 31, 2021. We also have extended inclusion of certain cardiac and intensive cardiac rehabilitation codes through the end of CY 2023. This will allow for more time for CMS and stakeholders to gather data, for stakeholders to submit support for requesting that services(s) be permanently added to the Medicare telehealth services list, and to reduce uncertainty regarding the timing of our processes with regard to the end of the PHE. Additionally, we are adopting coding and payment for a longer virtual check-in service on a permanent basis.

Section 123 of the CAA removed the geographic restrictions and added the home of the beneficiary as a permissible originating site for telehealth services furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. Section 123 requires for these services that there must be an in-person, non-telehealth service with the physician or practitioner within six months prior to the initial telehealth service and requires the Secretary to establish a frequency for subsequent in-person visits. We are implementing these statutory amendments, and finalizing that an in-person, non-telehealth visit must be furnished at least every 12 months for these services, that exceptions to the in-person visit requirement may be made based on beneficiary circumstances (with the reason documented in the patient's medical record), and that more frequent visits are also allowed under our policy, as driven by clinical needs on a case-by-case basis.

CMS is amending the current definition of interactive telecommunications system for

telehealth services – 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 communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients in their homes under certain circumstances.

CMS is limiting 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, or does not consent to, the use of two-way, audio/video technology. CMS also finalized a requirement for the use of a new modifier for services furnished using audio-only communications, which would serve to verify 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. We are also clarifying that mental health services can include services for treatment of substance use disorders (SUDs).

Therapy Services

CMS is completing implementation 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 percent 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) — when they are appropriately supervised by a physical therapist (PT) or occupational therapist (OT), respectively — for dates of service on and after January 1, 2022.

CMS defines services furnished in whole or in part by PTAs or OTAs as those for which the PTA or OTA time exceeds a *de minimis* threshold. For CY 2022, in response to numerous stakeholder questions and to promote proper therapy care, CMS is revising the policy for the *de minimis* standard. Specifically, CMS' revised policy would allow a 15-minute timed

service to be billed without the CQ/CO modifier in cases when a PTA/OTA participates in

providing care to a patient, independent from the PT/OT, but the PT/OT meets the Medicare billing requirements for the timed service on their own, without the minutes furnished by the PTA/OTA, by providing more than the 15-minute midpoint (that is, 8 minutes or more — also known as the 8-minute rule). Under this finalized policy, any minutes that the PTA/OTA furnishes in these scenarios would not matter for purposes of billing Medicare.

In addition to cases where one unit of a multi-unit therapy service remains to be billed, we revised the *de minimis* policy that would apply in a limited number of cases where there are two 15-minute units of therapy remaining to be billed. For these limited cases, CMS is allowing one 15-minute unit to be billed with the CQ/CO 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 when the total time is at least 23 minutes and no more than 28 minutes.

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 8 minutes or more of the final 15-minute 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 8 minutes for the final 15-minute unit of a billing scenario (the 10 percent standard applies).

Billing for Physician Assistant (PA) Services

CMS is implementing section 403 of the CAA, which authorizes Medicare to make direct

payment to PAs for professional services that they furnish under Part B beginning January

1, 2022. Medicare currently can only make payment to the employer or independent contractor of a PA. Beginning January 1, 2022, PAs may bill Medicare directly for their professional services, reassign payment for their professional services, and incorporate with other PAs and bill Medicare for PA services. _

Vaccine Administration Services

Administration of Preventive Vaccines

Effective January 1, 2022, CMS will pay $30 per dose for the administration of the influenza, pneumococcal and hepatitis B virus vaccines. In addition, CMS will maintain the current payment rate of $40 per dose for the administration of the COVID-19 vaccines through the end of the calendar year in which the ongoing PHE ends. Effective January 1 of the year following the year in which the PHE ends, the payment rate for COVID-19 vaccine administration will be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines.

In-Home Administration of COVID-19 Vaccines

CMS will continue the additional payment of $35.50 for COVID-19 vaccine administration in the home under certain circumstances through the end of the calendar year in which the PHE ends.

COVID-19 Monoclonal Antibody Products

CMS will continue to pay for COVID-19 monoclonal antibodies under the Medicare Part B vaccine benefit through the end of the calendar year in which the PHE ends. During this interim time, we will maintain the $450 payment rate for administering a COVID-19 monoclonal antibody in a health care setting, as well as the payment rate of $750 for administering a COVID-19 monoclonal antibody therapy in the home.

Effective January 1 of the year following the year in which the PHE ends, CMS will pay physicians and other suppliers for COVID-19 monoclonal antibody products as biological products paid under section 1847A of the Act; health care providers and practitioners will be paid under the applicable payment system, and using the appropriate coding and payment rates, for administering COVID-19 monoclonal antibodies similar to the way they are paid for administering other complex biological products.

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

The statute provides coverage of MNT services furnished by registered dietitians and nutrition professionals when the patient is 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 of registered dietitians and nutrition professionals with other types of NPPs, we established regulations at § 410.72 to describe their services. The addition of this regulation parallels the regulations in place for other types of NPPs listed at section 1842(b)(18)(C) of the Act. We also finalized regulatory text at § 410.72(f) to state the requirements for these NPPs to bill on an assignment-related basis by cross-reference to our general assignment regulation at § 424.55. For consistency in our regulations, we made conforming amendments to our regulations regarding assignment requirements for PAs, nurse practitioners, clinical nurse specialists, and certified nurse mid-wives at §§ 410.74(d)(2), 410.75(e)(2), 410.76(e)(2) and 410.77(d)(2), respectively.

We also updated the payment regulation for MNT services at § 414.64 to clarify that MNT services are, and have been, paid at 100 percent (instead of 80 percent) of 85 percent 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 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. We also finalized removing the requirement that the medical nutrition therapy referral be made by the "treating" physician which allows for additional physicians to make a referral to MNT services. Finally, we updated the glomerular filtration rate (GFR) to reflect current medical practice and align with accepted chronic kidney disease staging which slightly moved the upper GFR range to 59 mL/min/1.72m² from 50 mL/min/1.72m².

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

CMS finalized implementation of Section 122 of the CAA, which provides 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 percent for CY 2022, 15 percent for CYs 2023 through 2026, 10 percent 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 finalized its proposal 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 also finalized a requirement that OTPs use a service-level modifier for audio-only services billed using the counseling and therapy add-on code in order to facilitate program integrity activities.

Additionally, in order to avoid a significant decrease in the payment amount for methadone that could negatively affect access to methadone for beneficiaries receiving services at OTPs, CMS is issuing an interim final rule with comment to maintain the payment amount for methadone at the CY 2021 rate for the duration of CY 2022. CMS is also seeking comment on OTP utilization patterns for methadone, particularly, the frequency with which methadone oral concentrate is used compared to methadone tablets in the OTP setting, including any applicable data on this topic.

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

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

Mental Health Services Furnished via Telecommunications Technologies for RHCs and FQHCs

CMS finalized its proposal to revise the current regulatory language for RHC or FQHC mental health visits to include visits furnished using interactive, real-time telecommunications technology. This change will 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. CMS also finalized that an in-person, non-telehealth visit must be furnished at least every 12 months for these services; however, exceptions to the in-person visit requirement may be made based on beneficiary circumstances (with the reason documented in the patient's medical record) and more frequent visits are also allowed under our policy, as driven by clinical needs on a case-by-case basis.

Rural Health Clinic (RHC) Payment Limit Per-Visit

Section 130 of the CAA as amended by section 2 of Pub. Law 117-7, requires that, beginning April 1, 2021, already-enrolled independent RHCs and provider-based RHCs in larger hospitals 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 most provider-based RHCs in a hospital with fewer than 50 beds enrolled before January 1, 2021 be subject to a payment limit based on their 2020 per-visit rate, updated annually by the percentage increase in MEI. 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 finalized its proposal 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 finalized its proposal 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 finalized its proposal 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 they 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 received a request from American Indian and Alaska Native communities to amend its

CMS received a request from American Indian and Alaska Native communities 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, if 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 solicited comment on these topics. We plan to further review the comments received and may consider them for potential future payment policy decisions.

Electronic Prescribing of Controlled Substances-Section 2003 of the SUPPORT Act

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 final rule, we are implementing the second phase of this mandate by finalizing in regulation certain exceptions to the EPCS requirement. An exception will apply if a prescriber meets any of the following:

- the prescriber and dispensing pharmacy are the same entity;
- the prescriber issues 100 or fewer controlled substance prescriptions for Part D drugs per calendar year; and
- the prescriber is in the geographic area of an emergency or disaster declared by a federal, state or local government entity, or
- the prescriber has been granted a CMS-approved waiver based on extraordinary circumstances, such as technological failures or cybersecurity attacks or other emergency.

We are allowing prescribers 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.

CMS is also delaying the start date for compliance actions to January 1, 2023, in response to stakeholder feedback. We are also delaying the start date for compliance actions for Part D prescriptions written for beneficiaries in long-term care facilities to January 1, 2025. We will initially enforce compliance by sending compliance letters to prescribers violating the EPCS mandate.

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. To date, manufacturers without such agreements have had the option to voluntarily submit ASP data. For calendar quarters beginning January 1, 2022, section 401 of the CAA requires manufacturers of drugs or biologicals payable under Part B without a Medicaid Drug Rebate Agreement to report ASP data. CMS is making regulatory changes to implement this new reporting requirement.

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 finalized 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 beginning 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. In the CY 2022 PFS proposed rule, CMS solicited 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. CMS received feedback from stakeholders in response to the comment solicitation and will continue to evaluate this approach.

Clinical Laboratory Fee Schedule: Laboratory Specimen Collection Fee 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 the travel allowance) for trained personnel to collect specimens from homebound patients and inpatients (except hospital inpatients). 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 make diagnostic testing available to Medicare beneficiaries 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 clinical diagnostic laboratory tests (CDLTs) under certain circumstances and increased payments from $3-5 to $23-25. Although the increased specimen collection fees for COVID-19 CDLTs will end at the termination of the COVID-19 PHE, in the CY 2022 PFS proposed rule, we sought 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 requested comments regarding the nominal specimen collection fees related to the calculation of costs for transportation and personnel expenses for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital), how specimen collection practices may have changed because of the PHE, and what additional resources might be needed for specimen collection for COVID-19 CDLTs and other tests after the PHE ends.

We received feedback from stakeholders in response to the comment solicitation, which we plan to take into consideration for possible future rulemaking for the CLFS laboratory specimen collection fee and travel allowance.

CMS also clarified 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.

Appropriate Use Criteria (AUC) Program

CMS finalized our proposal 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. Previously, the payment penalty phase of the AUC program was set to begin January 1, 2022.

Pulmonary Rehabilitation

CMS proposed 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. We finalized coverage for outpatient pulmonary rehabilitation services, paid under Medicare Part B, to beneficiaries who have had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks.

Medicare Shared Savings Program

CMS finalized a longer transition for Accountable Care Organizations (ACOs) to prepare for reporting electronic clinical quality measures/Merit-based Incentive Payment System clinical quality measures (eCQM/MIPS CQM) under the Alternative Payment Model (APM) Performance Pathway (APP), by extending the availability of the CMS Web Interface collection type for an additional three years, through performance year (PY) 2024. This policy responds to ACOs' concerns about the transition to all-payer eCQM/MIPS CQMs, including aggregating all-payer data across multiple health care practices that participate in the same ACO and across multiple electronic health record (EHR) systems.

We are also finalizing delaying the increase in the quality performance standard ACOs must meet to be eligible to share in savings until PY 2024, by maintaining the 30th percentile of the MIPS quality performance category score for PY 2023, and additional revisions to the quality performance standard to encourage ACOs to report all-payer measures. These changes, in addition to existing policies, provide four years for ACOs to transition to reporting the three eCQM/MIPS CQMs under the APP. For more details on

Shared Savings Program quality policies, please refer to the Quality Payment Program PFS

final rule fact sheet: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1654/2022%20Quality%20Payment%20Program%20Final%20Rule%20Resources.zip

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. CMS finalized revisions to the repayment mechanism arrangement policy to reduce by 50 percent the percentage used in the existing methodology for determining the repayment mechanism amount. We also specified how we identify the number of assigned beneficiaries used in the repayment mechanism amount calculation and the annual repayment mechanism amount recalculation. We also finalized modifications to the threshold for determining whether an ACO is required to increase its repayment mechanism amount during its agreement period. These changes will 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 improvement activities. We also finalized 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 finalized policies that 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 also finalized the proposal 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

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CMS finalized revisions to the definition of primary care services that are used for purposes of beneficiary assignment. The updated definition will be applicable for determining beneficiary assignment beginning with PY 2022.

In this final rule we also provide a summary of public comments on the Shared Savings Program's benchmarking methodology received in response to the comment solicitations in the CY 2022 PFS proposed rule on calculation of the regional adjustment, and blended national-regional growth rates for trending and updating the benchmark, as well as on the risk adjustment methodology. We appreciate the ongoing dialogue between CMS, ACOs, and other program stakeholders on considerations for improving the Shared Savings Program's benchmarking policies. We will take these comments into consideration as we contemplate additional refinements to the Shared Savings Program's benchmarking methodologies and will propose any specific policy changes, as appropriate, in future notice and comment 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. CMS finalized as proposed several changes to the Open Payments program to support the usability and integrity of the data for the public, researchers, and CMS, including the following:

- Adding a mandatory payment context field for records to teaching hospitals;
- Adding the option to recertify annually even when no records are being reported;
- Disallowing record deletions without a substantiated reason;
- Adding a definition for a physician-owned distributorship as a subset of applicable manufacturers and group purchasing organizations and updating the definition of ownership interest;

- Requiring reporting entities to update their contact information;
- Disallowing publication delays for general payment records;
- Clarifying the exception for short-term loans; and
- Removing the option to submit and attest to general payment records with an "Ownership" Nature of Payment category.

Medicare Provider Enrollment

CMS finalized all of its proposed provider enrollment regulatory provisions. These involve:

- Exempting independent diagnostic testing facilities (IDTF) that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing 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 finalized our proposed changes to the Medicare Ground Ambulance Data Collection System including:

- Finalizing our proposal for a new data collection period beginning between January 1, 2023, and December 31, 2023, and a new data reporting period beginning between January 1, 2024, and December 31, 2024, for selected ground ambulance organizations in year 3;
- Revisions to the timeline for when the payment reduction for failure to report will begin aligning the timelines for the application of penalties for not reporting data with our new timelines for data collection and reporting and when the data will be publicly available beginning in 2024; and

- Revisions to the Medicare Ground Ambulance Data Collection Instrument. These changes and clarifications to the instrument will improve its clarity and make the instrument less burdensome for respondents to complete.

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

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