

Final Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2019

On November 1, 2018, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that includes updates to payment policies, payment rates, and quality provisions for services furnished under the Medicare Physician Fee Schedule (PFS) on or after January 1, 2019.

The calendar year (CY) 2019 PFS final rule is one of several final rules that reflect a broader Administration-wide strategy to create a healthcare system that results in better accessibility, quality, affordability, empowerment, and innovation.

Background on the Physician Fee Schedule

Payment is made under the PFS for services furnished by physicians and other practitioners in all sites of service. These services include, but are not limited to, visits, surgical procedures, diagnostic tests, therapy services, and specified preventive services.

In addition to physicians, payment is made under the PFS to a variety of practitioners and entities, including nurse practitioners, physician assistants, and physical therapists, as well as radiation therapy centers and independent diagnostic testing facilities.

Payments are based on the relative resources typically used to furnish the service. Relative Value Units (RVUs) are applied to each service for physician work, practice expense, and malpractice. These RVUs become payment rates through the application of a conversion factor. Payment rates are calculated to include an overall payment update specified by statute

PAYMENT PROVISIONS

Streamlining Evaluation and Management Payment and Reducing Clinician Burden

CMS is finalizing a number of documentation, coding, and payment changes to reduce administrative burden and improve payment accuracy for office/outpatient evaluation and management (E/M) visits over several years. For CYs 2019 and 2020, we are implementing several documentation policies to provide immediate burden reduction, while other changes to documentation, coding, and payment would be implemented in CY 2021.

For CY 2019 and CY 2020, CMS will continue the current coding and payment structure for E/M office/outpatient visits and practitioners should continue to use either the 1995 or 1997 E/M documentation guidelines to document E/M office/outpatient visits billed to Medicare. For CY 2019 and beyond, CMS is finalizing the following policies:

- Elimination of the requirement to document the medical necessity of a home visit in lieu of an office visit;
- For established patient office/outpatient visits, when relevant information is already contained in the medical record, practitioners may choose to focus their documentation on what has changed since the last visit, or on pertinent items that have not changed, and need not re-record the defined list of required elements if there is evidence that the practitioner reviewed the previous information and updated it as needed. Practitioners

should still review prior data, update as necessary, and indicate in the medical record that they have done so;

- Additionally, we are clarifying that for E/M office/outpatient visits, for new and established patients for visits, practitioners need not re-enter in the medical record information on the patient's chief complaint and history that has already been entered by ancillary staff or the beneficiary. The practitioner may simply indicate in the medical record that he or she reviewed and verified this information; and
- Removal of potentially duplicative requirements for notations in medical records that may have previously been included in the medical records by residents or other members of the medical team for E/M visits furnished by teaching physicians.

Beginning in CY 2021, CMS will further reduce burden with the implementation of payment, coding, and other documentation changes. Payment for E/M office/outpatient visits will be simplified and payment would vary primarily based on attributes that do not require separate, complex documentation. Specifically for CY 2021, CMS is finalizing the following policies:

- Reduction in the payment variation for E/M office/outpatient visit levels by paying a single rate for E/M office/outpatient visit levels 2 through 4 for established and new patients while maintaining the payment rate for E/M office/outpatient visit level 5 in order to better account for the care and needs of complex patients;
- Permitting practitioners to choose to document E/M office/outpatient level 2 through 5 visits using medical decision-making or time instead of applying the current 1995 or 1997 E/M documentation guidelines, or alternatively practitioners could continue using the current framework;
- Beginning in CY 2021, for E/M office/outpatient levels 2 through 5 visits, we will allow for flexibility in how visit levels are documented— specifically a choice to use the current framework, MDM, or time. For E/M office/outpatient level 2 through 4 visits, when using MDM or current framework to document the visit, we will also apply a minimum supporting documentation standard associated with level 2 visits. For these cases, Medicare would require information to support a level 2 E/M office/outpatient visit code for history, exam and/or medical decision-making;
- When time is used to document, practitioners will document the medical necessity of the visit and that the billing practitioner personally spent the required amount of time face-to-face with the beneficiary;
- Implementation of add-on codes that describe the additional resources inherent in visits for primary care and particular kinds of non-procedural specialized medical care, though they would not be restricted by physician specialty. These codes would only be reportable with E/M office/outpatient level 2 through 4 visits, and their use generally would not impose new per-visit documentation requirements; and
- Adoption of a new “extended visit” add-on code for use only with E/M office/outpatient level 2 through 4 visits to account for the additional resources required when practitioners need to spend extended time with the patient.

CMS believes these policies will allow practitioners greater flexibility to exercise clinical judgment in documentation, so they can focus on what is clinically relevant and medically necessary for the beneficiary. CMS intends to engage in further discussions with the public to potentially further refine the policies for CY 2021.

After consideration of concerns raised by commenters in response to the proposed rule, CMS is not finalizing aspects of the proposal that would have: (1) reduced payment when E/M office/outpatient visits are furnished on the same day as procedures, (2) established separate coding and payment for podiatric E/M visits, or (3) standardized the allocation of practice expense RVUs for the codes that describe these services.

Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

CMS is finalizing our proposals to pay separately for two newly defined physicians' services furnished using communication technology:

- Brief communication technology-based service, e.g. virtual check-in (HCPCS code G2012) and
- Remote evaluation of recorded video and/or images submitted by an established patient (HCPCS code G2010)

Practitioners could be separately paid for the brief communication technology-based service when the patient checks in with the practitioner via telephone or other telecommunications device to decide whether an office visit or other service is needed. This would increase efficiency for practitioners and convenience for beneficiaries. Similarly, the service of remote evaluation of recorded video and/or images submitted by an established patient would allow practitioners to be separately paid for reviewing patient-transmitted photo or video information conducted via pre-recorded "store and forward" video or image technology to assess whether a visit is needed.

CMS is also finalizing policies to pay separately for new coding describing chronic care remote physiologic monitoring (CPT codes 99453, 99454, and 99457) and interprofessional internet consultation (CPT codes 99451, 99452, 99446, 99447, 99448, and 99449).

Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders

In the CY 2019 PFS proposed rule, CMS sought comment on creating a bundled episode of care for management and counseling treatment for substance use disorders. Comment was also sought for regulatory and subregulatory changes to help prevent opioid use disorder and improve access to treatment under the Medicare program. CMS sought comment on methods for identifying non-opioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these non-opioid alternatives including barriers related to payment or coverage. CMS received many comments on these solicitations with detailed information to help inform future rulemaking.

Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder and Other Substance Use Disorders

Through an interim final rule with comment period, CMS is implementing a provision from the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act that removes the originating site geographic requirements and adds the home of an individual as a permissible originating site for telehealth

services furnished for purposes of treatment of a substance use disorder or a co-occurring mental health disorder for services furnished on or after July 1, 2019.

Additionally, the SUPPORT for Patients and Communities Act establishes a new Medicare benefit category for opioid use disorder treatment services furnished by opioid treatment programs (OTP) under Medicare Part B, beginning on or after January 1, 2020. We note that there is a 60-day period to comment on the provisions of the interim final rule discussed earlier, during which we are requesting information regarding services furnished by OTPs, payments for these services, and additional conditions for Medicare participation for OTPs that stakeholders believe may be useful for CMS to consider for future rulemaking to implement this new Medicare benefit category.

Providing Practice Flexibility for Radiologist Assistants

CMS is revising the physician supervision requirements so that diagnostic tests performed by a Radiologist Assistant (RA) that meets certain requirements, that would otherwise require a personal level of physician supervision as specified in our regulations, may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations. This is in response to stakeholder comments that the current requirement of personal supervision that applies to some diagnostic tests is overly restrictive when the test is performed by an RA, and does not allow for radiologists to make full use of RAs, and that reducing the required level of supervision will improve efficiency of care.

Discontinue Functional Status Reporting Requirements for Outpatient Therapy

Since January 1, 2013 as required by the Middle Class Tax Relief and Jobs Creation Act of 2012, all providers of outpatient therapy services have been required to include functional status information on claims for therapy services. CMS implemented a system that collects data using non-payable HCPCS G-codes and modifiers to describe a patient's functional limitation and severity at periodic intervals during outpatient therapy services. In response to the Request for Information on CMS Flexibilities and Efficiencies that was issued in the CY 2018 PFS proposed rule, CMS received comments requesting burden reduction related to the functional status reporting requirements.

The data from the functional reporting system was to be used to aid CMS in recommending changes and reforming of Medicare payment for outpatient therapy services that were subject to the statutory therapy caps. Going forward, the functional status reporting data that would be collected may be even less purposeful because the Bipartisan Budget Act of 2018 repealed the therapy caps while imposing protections to ensure therapy services are furnished when appropriate. As a result, CMS is finalizing our proposal to discontinue the functional status reporting requirements for services furnished on or after January 1, 2019.

Outpatient Physical Therapy and Occupational Therapy Services Furnished by Therapy Assistants

The Bipartisan Budget Act of 2018 requires payment for services furnished in whole or in part by a therapy assistant at 85 percent of the applicable Part B payment amount for the service effective January 1, 2022. In order to implement this payment reduction, the law requires us to establish a new modifier by January 1, 2019 and CMS details our plans to accomplish this in the final rule.

CMS is finalizing our proposal to establish two new modifiers – one for Physical Therapy Assistants (PTA) and another for Occupational Therapy Assistants (OTA) – when services are furnished in whole, or in part by a PTA or OTA. However, CMS is finalizing the new modifiers as “payment” rather than as “therapy” modifiers, based on comments from stakeholders. These will be used alongside of the current PT and OT modifiers, instead of replacing them, which retains the use of the three existing therapy modifiers to report all PT, OT, and Speech Language Pathology services, that have been used since 1998 to track outpatient therapy services that were subject to the therapy caps. CMS is also finalizing a de minimis standard under which a service is furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA, instead of the proposed definition that applied when a PTA or OTA furnished any minute of a therapeutic service. The new therapy modifiers for services furnished by PTAs and OTAs are not required on claims until January 1, 2020.

Conversion Factor

With the budget neutrality adjustment to account for changes in RVUs, all required by law, the final 2019 PFS conversion factor is \$36.04, a slight increase above the 2018 PFS conversion factor of \$35.99.

Practice Expense (PE): Market-Based Supply and Equipment Pricing Update

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, but excluding malpractice (MP) expenses. CMS develops PE RVUs for each physician’s service by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses.

CMS worked with a contractor to conduct an in-depth and robust market research study to update the PFS direct PE inputs for supply and equipment pricing for CY 2019. These supply and equipment prices were last systematically developed in 2004-2005. A report from the contractor with updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs is available as a public use file displayed on the CMS website under downloads for the CY 2019 PFS final rule.

CMS is finalizing the proposal to adopt updated direct PE input prices for supplies and equipment. While CMS is adopting most of the prices for supplies and equipment as recommended by the contractor and included in the proposed rule, in the case of particular items, CMS is finalizing refinements to the proposed prices based on feedback from commenters. CMS is also finalizing our proposal to phase-in use of these new prices over a 4-year period beginning in CY 2019 to ensure a smooth transition.

Payment Rates for Non-excepted Off-campus Provider-Based Hospital Departments Paid Under the PFS

Section 603 of the Bipartisan Budget Act of 2015 requires that certain items and services furnished by certain off-campus hospital outpatient provider-based departments are no longer paid under the Hospital Outpatient Prospective Payment System (OPPS) and are instead paid under the applicable payment system. In CY 2017, CMS finalized the PFS as the applicable payment system for most of these items and services.

Since CY 2017, payment for these items and services furnished in non-excepted off-campus provider-based departments has been made under the PFS using a PFS Relativity Adjuster based on a percentage of the OPPS payment rate. The PFS Relativity Adjuster in CY 2018 is 40 percent, meaning that non-excepted items and services are paid 40 percent of the amount that would have been paid for those services under the OPPS. CMS is finalizing that the PFS Relativity Adjuster remain at 40 percent for CY 2019. CMS believes that this PFS Relativity Adjuster encourages fairer competition between hospitals and physician practices by promoting greater payment alignment between outpatient care settings.

Medicare Telehealth Services

For CY 2019, CMS is finalizing our proposals to add the following codes to the list of telehealth services:

- HCPCS codes G0513 and G0514 (Prolonged preventive service(s))

CMS is also finalizing policies to implement the requirements of the Bipartisan Budget Act of 2018 for telehealth services related to beneficiaries with end-stage renal disease (ESRD) receiving home dialysis and beneficiaries with acute stroke effective January 1, 2019. CMS is finalizing the addition of renal dialysis facilities and the homes of ESRD beneficiaries receiving home dialysis as originating sites, and to not apply originating site geographic requirements for hospital-based or critical access hospital-based renal dialysis centers, renal dialysis facilities, and beneficiary homes, for purposes of furnishing the home dialysis monthly ESRD-related clinical assessments. CMS is also finalizing policies to add mobile stroke units as originating sites and not to apply originating site type or geographic requirements for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

Clinical Laboratory Fee Schedule

The Clinical Laboratory Fee Schedule (CLFS) final rule entitled “Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System” implemented Section 1834A of the Social Security Act (the Act), which required extensive revisions to the Medicare payment, coding, and coverage for clinical diagnostic laboratory tests (CDLTs) paid under the CLFS. Beginning January 1, 2018, the payment amount for a test on the CLFS is generally equal to the weighted median of private payer rates determined for the test, based on the data of “applicable laboratories” that is collected during a specified data collection period and reported to CMS during a specified data reporting period. The first data collection period was from January 1 through June 30, 2016, and the first data reporting period was from January 1, 2017, through March 31, 2017, including an additional 60-day enforcement discretion period.

In determining payment rates under the private payer rate-based CLFS, one of our goals is to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment amounts without imposing undue burden on those entities. In the interest of facilitating this goal, CMS proposed a change to the way Medicare Advantage payments are treated in our definition of “applicable laboratory.” CMS is finalizing this proposal, which we believe may result in additional laboratories of all types that serve a significant population of beneficiaries enrolled in Medicare Part C in meeting the majority of Medicare revenues threshold and potentially qualifying as an applicable laboratory and report data to CMS.

In addition, CMS sought public comments on alternative approaches for defining an applicable laboratory, for example, using the Form CMS 1450 14X Type of Bill (TOB) or CLIA certificate number to define an applicable laboratory. Based on comments we received and further analysis of the various options, we are amending the applicable laboratory definition to include hospital laboratories that bill for their non-patient laboratory services on the CMS 1450 14X TOB bill. CMS also sought public comments on potential changes to the low expenditure threshold component of the definition of an applicable laboratory, and will consider those comments as we continue to evaluate and refine Medicare CLFS payment policy in the future.

Ambulance Fee Schedule Payments

The Bipartisan Budget Act of 2018 extended the temporary add-on payments for ground ambulance services for 5 years. The three temporary add-on payments include: (1) a 3 percent increase to the base and mileage rate for ground ambulance transports that originate in rural areas; (2) a 2 percent increase to the base and mileage rate for ground ambulance transports that originate in urban areas; and (3) a 22.6 percent increase in the base rate for ground ambulance transports that originate in super rural areas. These provisions were set to expire on December 31, 2017, but have been extended through December 31, 2022. The Bipartisan Budget Act also increased the payment reduction from 10 percent to 23 percent for non-emergency basic life support transports of beneficiaries with end-stage renal disease for renal dialysis services furnished other than on an emergency basis by a provider of services or a renal dialysis facility. This provision is effective with ambulance services furnished on or after October 1, 2018. CMS has revised the applicable regulations to conform with these requirements.

Recognizing Communication Technology-Based and Remote Evaluation Services for Rural Health Clinics and Federally Qualified Health Centers

For CY 2019, CMS finalized payment for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) for communication technology-based services and remote evaluation services that are furnished by an RHC or FQHC practitioner when there is no associated billable visit. These services will be payable for medical discussions or remote evaluations of conditions not related to an RHC or FQHC service provided within the previous 7 days or within the next 24 hours or at the soonest available appointment. RHCs and FQHCs will be able to bill for these services using a newly created RHC/FQHC Virtual Communication Service HCPCS code, G0071, with payment set at the average of the PFS national non-facility payment rates for communication technology-based services and remote evaluation services.

Wholesale Acquisition Cost-Based Payment for Part B Drugs: Finalizing a Reduction of the Add-on Amount

Most Part B drug payments are based on Average Sales Price (ASP) methodology and, by statute, include an add-on payment of 6 percent of the ASP amount. Some Part B drug payments, are based on the wholesale acquisition cost (WAC). WAC-based payment amounts typically exceed amounts based on ASP.

CMS has finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs determined under section 1847A of the Social Security Act, during the first quarter of sales when ASP is unavailable, will be subject to a 3 percent add-on in place of the 6 percent add-on that is currently being used. This change in policy will help curb excessive spending, especially for new drugs with high launch prices, and will also decrease beneficiary cost sharing. The reduction of the add-on percentage for certain WAC-based payments for new Part B drugs is consistent with the Fiscal Year 2019 President's Budget Proposal and MedPAC's June 2017 Report to the Congress. In addition, CMS will also update manual provisions to permit Medicare Administrative Contractors to use an add-on percentage of up to 3 percent, rather than 6 percent, when utilizing WAC for pricing new drugs. We would also like to reiterate that these changes only apply to WAC-based payment for new Part B drugs.

Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs)

This final rule also addresses a subset of changes to the Medicare Shared Savings Program for ACOs proposed in the August 2018 proposed rule "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations Pathways to Success" and other revisions designed to update program policies under the Shared Savings Program. In order to ensure continuity of participation, finalize time-sensitive program policy changes for currently participating ACOs, and streamline the ACO core quality measure set to reduce burden and encourage better outcomes, CMS is finalizing the following policies.

- A voluntary 6-month extension for existing ACOs whose participation agreements expire on December 31, 2018, and the methodology for determining financial and quality performance for this 6-month performance year from January 1, 2019, through June 30, 2019.
- Allowing beneficiaries who voluntarily align to a Nurse Practitioner, Physician Assistant, Certified Nurse Specialist, or a physician with a specialty not used in assignment to be prospectively assigned to an ACO if the clinician they align with is participating in an ACO, as provided for in the Bipartisan Budget Act of 2018.
- Revising the definition of primary care services used in beneficiary assignment.
- Providing relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in 2018 and subsequent years.

Reducing the Shared Savings Program core quality measure set by eight measures; and promoting interoperability among ACO providers and suppliers by adding a new CEHRT threshold criterion to determine ACOs' eligibility for program participation and retiring the current Shared Savings Program quality measure on the percentage of eligible clinicians using CEHRT.

Request for Information on Price Transparency

Under current law, hospitals are required to establish and make public a list of their standard charges. In an effort to encourage price transparency by improving the public accessibility of price information, CMS included a Request for Information related to price transparency and improving beneficiary access to provider and supplier charge information in the CY 2019 PFS proposed rule. CMS appreciates the input provided by commenters.

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging

For CY 2019, CMS is finalizing the revision of the significant hardship criteria in the AUC program to include: 1) insufficient internet access; 2) electronic health record (EHR) or clinical decision support mechanism (CDSM) vendor issues; or 3) extreme and uncontrollable circumstances. CMS is also finalizing allowing ordering professionals experiencing a significant hardship to self-attest their hardship status. In addition, CMS is adding independent diagnostic testing facilities (IDTFs) to the definition of applicable setting under this program. This will allow the AUC program to be more consistently applied to outpatient settings. CMS is also allowing AUC consultations, when not personally performed by the ordering professional, to be performed by clinical staff under the direction of ordering professional. This will allow the ordering professional to exercise their discretion to delegate the performance of this consultation.

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