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Date	2018-07-12
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On July 12, 2018, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that includes proposals to update 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 proposed rule is one of several proposed 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 (E/M) Payment and Reducing Clinician Burden

CMS is proposing a number of coding and payment changes to reduce administrative burden and improve payment accuracy for E/M visits. We propose:

- to allow practitioners to choose to document office/outpatient E/M 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;
- to expand current options by allowing practitioners to use time as the governing factor in selecting visit level and documenting the E/M visit, regardless of whether counseling or care coordination dominate the visit;
- to expand current options regarding the documentation of history and exam, to allow practitioners to focus their documentation on what has changed since the last visit or on pertinent items that have not changed, rather than re-documenting information, provided they review and update the previous information; and
- to allow practitioners to simply review and verify certain information in the medical record that is entered by ancillary staff or the beneficiary, rather than re-entering it.

We are also soliciting comment on how documentation guidelines for medical decision-making might be changed in subsequent years.

To improve payment accuracy and simplify documentation, we propose new, single blended payment rates for new and established patients for office/outpatient E/M level 2 through 5 visits and a series of add-on codes to reflect resources involved in furnishing primary care and non-procedural specialty generally recognized services. As a corollary to this proposal, we propose to apply a minimum documentation standard where Medicare would require information to support a level 2 CPT visit code for history, exam and/or medical decision-making in cases where practitioners choose

to use the current framework, or, as proposed, medical decision-making to document E/M level 2 through 5 visits. In cases where practitioners choose to use time to document E/M visits, we propose to require practitioners to document the medical necessity of the visit and show the total amount of time spent by the billing practitioner face-to-face with the patient. Practitioners could choose to document additional information for clinical, legal, operational or other purposes, and we anticipate that for those reasons, they would continue generally to document medical record information consistent with the level of care furnished. However, we would only require documentation to support the medical necessity of the visit and associated with the current level 2 CPT visit code.

To recognize efficiencies that are realized when E/M visits are furnished in conjunction with other procedures, we propose a multiple procedure payment adjustment that would apply in those circumstances. We also propose new coding to recognize podiatry E/M visits that would more specifically identify and value these services. We propose a new prolonged face-to-face E/M code, as well as a technical modification to the practice expense methodology.

We propose to eliminate the requirement to justify the medical necessity of a home visit in lieu of an office visit, and solicit public comment on potentially eliminating a policy that prevents payment for same-day E/M visits by multiple practitioners in the same specialty within a group practice. For E/M visits furnished by teaching physicians, we also propose to eliminate 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.

We are soliciting public comment on the implementation timeframe of these proposals, as well as how we might update E/M visit coding and documentation in other care settings in future years. CMS believes these proposals would 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.

Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

We are proposing 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 GVCI1)**
- Remote Evaluation of Recorded Video and/or Images Submitted by the Patient (HCPCS code GRAS1)

Practitioners could be separately paid for the Brief Communication Technology-based Service when they check in with beneficiaries 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 Remote Evaluation of Recorded Video and/or Images Submitted by the 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.

We are also proposing to pay separately for new coding describing Chronic Care Remote Physiologic Monitoring (CPT codes 990X0, 990X1, and 994X9) and Interprofessional

Internet Consultation (CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99449).

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

We are seeking comment on creating a bundled episode of care for management and counseling treatment for substance use disorders. We are also seeking comment for regulatory and subregulatory changes to help prevent opioid use disorder and improve access to treatment under the Medicare program. We seek 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.

Providing Practice Flexibility for Radiologist Assistants

CMS is proposing to revise the physician supervision requirements so that any diagnostic test performed by a Radiologist Assistant (RA) may be furnished under, at most, a direct level of physician supervision, when performed by an RA in accordance with state law and state scope of practice rules. 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, we 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 to, and reforming Medicare payment for outpatient therapy services that were subject to the statutory therapy caps. Going forward, the

functional status reporting data we would collect 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, we are proposing to discontinue the functional status reporting requirements for services furnished on or after January 1, 2019.

Outpatient PT and OT 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 we detail our plans to accomplish this in the proposed rule.

We are proposing to establish two new therapy modifiers – one for PT Assistants (PTA) and another for OT Assistant (OTA) – when services are furnished in whole or in part by a PTA or OTA. These are to be used in conjunction with the three existing therapy modifiers that have been used since 1998 to track outpatient therapy services that were subject to the therapy caps. 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 proposed 2019 PFS conversion factor is $36.05, 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. We develop PE RVUs for each physicians' 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.

We 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 proposed rule.

We are proposing to adopt the updated direct PE input prices for supplies and equipment. We are proposing to phase in our use of the new direct PE input pricing over a 4-year period beginning in 2019 to ensure a smooth transition from the prices we currently include and the payments for the services that include them to the final updated prices and payments in CY 2022.

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 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 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. For CY 2019, CMS is proposing to maintain the current PFS relativity adjuster Relatively Adjuster at 40 percent. CMS believes that this PFS Relatively Adjuster encourages fairer competition between hospitals and physician practices by promoting greater payment alignment between outpatient care settings.

Medicare Telehealth Services

For CY 2019, we are proposing to add the following codes to the list of telehealth services:

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

We are also proposing 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. We propose to add 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. We propose 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.

In determining payment rates under the private payer rate-based CLFS, one of our objectives 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 our goal, we proposed a change to the way Medicare Advantage payments are treated in our definition of "applicable laboratory." If we were to finalize the proposed change, additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C could meet the majority of Medicare revenues threshold and potentially qualify as an applicable laboratory and report data to CMS.

In addition, CMS is seeking public comments on alternative approaches for defining an applicable laboratory, for example, using the Form CMS 1450 14x bill type or CLIA certificate number to define an applicable laboratory. We are also seeking public comments on potential changes to the low expenditure threshold component of the definition of an applicable laboratory. We are particularly interested in receiving comments from the physician community and small independent laboratories as to the administrative burden and relief associated with revisions to the low expenditure threshold.

Ambulance Fee Schedule (AFS) Payments

The Bipartisan Budget Act of 2018 extended the temporary add-on payments for ground ambulance services for 5 years. The 3 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 reduction from 10 percent to 23 percent in payments for non-emergency basic life support transports of beneficiaries with end-stage renal disease for renal dialysis services. This provision is effective with services on or after October 1, 2018. CMS is proposing to revise regulations to conform with these requirements.

Recognizing Communication Technology-Based Services for RHCs & FQHCs

For CY 2019, CMS is proposing 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 would 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 would be able to bill a newly created RHC/FQHC Virtual Communications G-code, with payment set at the average of the PFS national non-facility payment rates for communication technology-based services and remote evaluation services.

WAC-Based Payment for Part B Drugs: Proposal to Alter Add-on Amount

Many art 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 wholesale acquisition cost (WAC) such as single-source drugs without ASP data. WAC-based payment rates typically exceed rates based on ASP amounts.

CMS believes that reducing the 6 percent add-on for WAC-based Part B drug payments would help curb excessive spending by better aligning payments and drug acquisition costs, especially for drugs with high launch prices. The payment reductions would also decrease beneficiary cost sharing. A reduction of the add-on percentage for these WAC-based payments for Part B drugs is consistent with Fiscal Year 2019 President's Budget Proposal and MedPAC's June 2017 Report to the Congress.

Thus, the rule is proposing that, effective January 1, 2019, WAC-based payments for new Part B drugs during the period first quarter of sales when ASP is unavailable, the drug payment add-on would be 3 percent in place of the 6 percent add-on that is currently being used. If this proposal is finalized, we would also update Manual provisions in order 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.

Aligning the Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organization (ACO) with the Meaningful Measures Initiative

Recently, 98 percent of Medicare Shared Savings Program ACOs successfully reported quality measures for the 2017 performance period. We are proposing to reduce the total number of measures in the Shared Savings Program quality measure set from 31 to 24 and focus the measure set on more outcome based measures including patient experience of care. Reducing the number of measures on which ACOs are evaluated decreases the number of performance

metrics to which they are required to track and eliminates redundancies between measures that target similar populations. This enables ACOs to better utilize their resources toward improving patient care. These proposals further reduce burden by aligning the proposed changes to Merit-based Incentive Payment System (MIPS). At the same time, the addition of two new patient experience of care measures and one new measure to the CMS Web Interface measures that are reported under MIPS makes the Shared Savings Program measure set more outcomes oriented.

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 public accessibility of charge information, in the fiscal year (FY) 2019 Hospital Inpatient Prospective Payment System (IPPS) proposed rule, CMS announced it is updating its guidelines to specifically require hospitals to make public a list of their standard charges via the Internet. However, CMS is concerned that challenges continue to exist for patients due to insufficient price transparency. We are seeking information from the public regarding barriers preventing providers and suppliers from informing patients of their out-of-pocket costs; what changes are needed to support greater transparency around patient obligations for their out of pocket costs; what can be done to better inform patients of these obligations; and what role providers of health care services and suppliers should play in this initiative.

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging

For CY 2019, CMS proposes to revise 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. In addition, we are proposing to add 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. We are also proposing to allow AUC consultations, when not personally performed by the ordering professional, to be performed by auxiliary personnel. This will allow the ordering professional to exercise their discretion to delegate the performance of this consultation.

Quality Payment Program

To implement the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), CMS established the Quality Payment Program (QPP), which consists of two participation pathways for doctors and other clinicians – the Merit-based Incentive Payment System (MIPS), which measures performance in four categories to determine an adjustment to Medicare payment, and Advanced Alternative Payment Models (Advanced APMs), in which clinicians may earn an incentive payment through sufficient participation and are excluded from MIPS reporting requirements.

The proposed changes to QPP aim to reduce clinician burden, focus on outcomes, and promote interoperability of electronic health records (EHRs), including by:

- Removing MIPS process-based quality measures that clinicians have said are low-value or low-priority, in order to focus on meaningful measures that have a greater impact on health outcomes; and
- Overhauling the MIPS “Promoting Interoperability” performance category to support greater EHR interoperability and patient access to their health information, as well as align this performance category for clinicians with the proposed new Promoting Interoperability Program for hospitals.

Under the requirements of the Bipartisan Budget Act of 2018, CMS is continuing the gradual implementation of certain MIPS requirements to ease administrative burden on clinicians. The proposed changes to the QPP reflect feedback and input from clinician partners and stakeholders and will continue to incorporate that feedback. Also, free and customized support for clinicians from CMS technical assistance networks will continue in 2019.

Aligning with the agency’s goals of improving quality of care, CMS also proposes waivers of MIPS requirements as part of testing a demonstration called the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) demonstration. The MAQI demonstration would test waiving MIPS reporting and payment adjustments for clinicians who participate sufficiently in Medicare Advantage (MA) arrangements that are similar to Advanced APMs. The demonstration will look at whether waiving MIPS requirements would increase levels of participation in such MA payment arrangements and whether it would change how clinicians deliver care.

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