Proposed Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2018

On July 13, 2017, 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, 2018.

The calendar year (CY) 2018 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.

Request for Information

In addition to the payment and policy proposals, CMS is releasing a Request for Information (RFI) to welcome feedback on positive solutions to better achieve transparency, flexibility, program simplification, and innovation. This will inform the discussion on future regulatory action related to the PFS.

We would like to start a national conversation about improving the healthcare delivery system; how Medicare can contribute to making the delivery system less bureaucratic and complex; and how we can reduce burden for clinicians, providers, and patients in a way that increases quality of care and decreases costs, thereby making the healthcare system more effective, simple, and accessible while maintaining program integrity and preventing fraud.

CMS is soliciting ideas for regulatory, sub-regulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include recommendations regarding payment system re-design; elimination or streamlining of reporting; monitoring and documentation requirements; operational flexibility; and feedback mechanisms and data sharing that would enhance patient care, support the doctor-patient relationship in care delivery, and facilitate patient-centered care. Ideas could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, providers, and suppliers.

In responding to the RFI, CMS should be provided with clear and concise proposals that include data and specific examples. If the proposals involve novel legal questions, analysis regarding CMS' authority is welcome. CMS will not respond to RFI comment submissions in the final rule, but rather will actively consider all input in developing future regulatory proposals or future sub-regulatory guidance.

PAYMENT PROVISIONS

Changes in Valuation for Specific Services

CMS reviews the resource inputs for several hundred codes under the annual process referred to as the potentially misvalued code initiative. Recommendations from the American Medical Association- Relative Value Scale Update Committee (RUC) are critically important to this work. For CY 2018, CMS is proposing the values for individual services that generally reflect the expert recommendations from the RUC without as many refinements as CMS has proposed in recent years.

Overall Payment Update and Misvalued Code Target

The overall update to payments under the PFS based on the proposed CY 2018 rates would be +0.31 percent. This update reflects the +0.50 percent update established under the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, reduced by 0.19 percent, due to the misvalued code target recapture amount, required under the Achieving a Better Life Experience (ABLE) Act of 2014.

Section 1848 of the Social Security Act requires the Secretary to periodically identify potentially misvalued services and to review and make appropriate adjustments to the relative values for those services. Through the ABLE Act, Congress set a target for adjustments to misvalued codes in the fee schedule for 2016, 2017, and 2018. **The target is 0.50 percent for 2018.**

If the net reductions in misvalued codes in 2018 are less than 0.50 percent of the total revenue under the fee schedule, a reduction equal to the percentage difference between 0.50 percent and the percent of expenditures represented by misvalued codes reductions must be made to payments for all PFS services.

In this proposed rule, CMS has proposed misvalued code changes that would achieve 0.31 percent in net expenditure reductions. If finalized, these changes would not meet the misvalued code target of 0.50 percent, therefore requiring the -0.19 percent overall reduction to payments for PFS services.

After applying these adjustments, and the budget neutrality adjustment to account for changes in RVUs, all required by law, the proposed 2018 PFS conversion factor is \$35.99, an increase to the 2017 PFS conversion factor of \$35.89.

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

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 no longer paid under the OPPS beginning January 1, 2017. For CY 2017, CMS finalized the PFS as the applicable payment system for most of these items and services.

For CY 2018, CMS is proposing to reduce current PFS payment rates for these items and services by 50 percent. CMS currently pays for these services under the PFS based on a percentage of the OPPS payment rate. The proposal would change the PFS payment rates for these services from 50 percent of the OPPS payment rate to 25 percent of the OPPS rate. CMS believes that this adjustment will encourage fairer competition between hospitals and physician practices by promoting greater payment alignment.

Medicare Telehealth Services

For CY 2018, we are proposing to add several codes to the list of telehealth services, including:

- HCPCS code G0296 (visit to determine low dose computed tomography (LDCT) eligibility);
- CPT code 90785 (Interactive Complexity);
- CPT codes 96160 and 96161 (Health Risk Assessment);
- HCPCS code G0506 (Care Planning for Chronic Care Management); and
- CPT codes 90839 and 90840 (Psychotherapy for Crisis).

Additionally, in this proposed rule, we are proposing to eliminate the required reporting of the telehealth modifier for professional claims in an effort to reduce administrative burden for practitioners. We are also seeking comment on ways to further expand access to telehealth services within our current statutory authority.

Malpractice Relative Value Units (RVUs)

For CY 2017, we collected updated professional liability insurance data for the purposes of updating the malpractice geographic practice cost indices, but we did not propose to use the data to update the specialty risk factors used in the calculation of malpractice RVUs at that time. Rather, we solicited comment on whether we should consider updating the malpractice RVUs based on the updated professional liability insurance data prior to the next expected 5-year update (CY 2020).

For CY 2018, CMS is proposing malpractice RVUs developed using the most recent data available. We are also proposing to align future updates with the geographic practice cost index updates, which has been done once every three years. Additionally, we are seeking comments regarding the availability of supplemental data sources for future updates.

Care Management Services

CMS is continuing efforts to improve payment within traditional fee-for-service Medicare for chronic care management and similar care management services to accommodate the changing needs of the Medicare patient population. CMS is proposing to adopt Current Procedural Terminology (CPT) codes for CY 2018 for reporting several care management services currently reported using Medicare G-codes. Also we are seeking public comment on ways we might further reduce burden on reporting practitioners for chronic care management and similar services, for example, through stronger alignment between CMS requirements and CPT guidance for existing and potential new codes.

Improvement of Payment Rates for Office-based Behavioral Health Services

CMS is proposing an improvement in the way rates are set that will positively impact office-based behavioral health services with a patient. The proposed change would increase payment for these services by better recognizing overhead expenses for office-based face-to-face services with a patient.

Evaluation and Management Comment Solicitation

Most physicians and other practitioners bill patient visits to the PFS under a relatively generic set of codes that distinguish level of complexity, site of care, and in some cases whether or not the patient is new or established. These codes are called Evaluation and Management (E/M) visit codes. Billing practitioners must maintain information in the medical record that documents that they have reported the appropriate level of E/M visit code. CMS maintains guidelines that specify the kind of information that is required to

support Medicare payment for each level. There are three key components to selecting the appropriate level:

- History of Present Illness (History);
- Physical Examination (Exam); and
- Medical Decision Making (MDM).

We agree with continued feedback from stakeholders that these guidelines are potentially outdated and need to be revised, especially the history and exam components.

CMS is seeking comment from stakeholders on specific changes we should undertake to update the guidelines, to reduce the associated burden, and to better align E/M coding and documentation with the current practice of medicine. We are especially seeking comment on how we might focus on initial changes to the guidelines for history and exam, because we believe documentation for these elements may be more significantly outdated.

Emergency Department Visits Comment Solicitation

CMS is seeking comment from stakeholders on whether emergency department visits are undervalued due to increasing heterogeneity of the settings under which emergency department visits are furnished and changes to the patient population.

Solicitation of Public Comments on Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule

The Clinical Laboratory Fee Schedule (CLFS) final rule entitled "Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System" implements Section 1834A of the Social Security Act (the Act), which requires extensive revisions to the Medicare payment, coding, and coverage for Clinical Diagnostic Laboratory Tests (CDLTs) paid under the CLFS. Under the final rule, the payment amount for a test on the CLFS furnished on or after January 1, 2018, generally will be 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.

Laboratory industry feedback suggested that many reporting entities would not be able to submit a complete set of applicable information to CMS by the March 31, 2017 deadline. As a result, on March 30, 2017, we announced a 60-day period of enforcement discretion until May 30, 2017, with respect to the data reporting period for reporting applicable information under the Medicare CLFS and the application of the Secretary's potential assessment of civil monetary penalties (CMPs) for failure to report applicable information.

CMS is seeking comments from applicable laboratories and reporting entities regarding their experience with the first data collection and reporting periods under the new private payer rate-based CLFS. Comments received will be used to inform CMS regarding potential refinement to the CLFS for future data collection and reporting periods.

Part B Drugs: Payment for Biosimilar Biological Products - Comment Solicitation

In the CY 2016 PFS final rule with comment period, CMS finalized a proposal to make clear that average sales price (ASP) for all national drug codes (biosimilar products) assigned to the same reference biological product would be included in the same billing and payment code. This means that biosimilar products that rely on a common reference product's biologics license application are grouped into the same payment calculation for determining a single average sales price payment limit, and that a single Healthcare

Common Procedure Coding System (HCPCS) code is used for such biosimilar products. CMS is soliciting comments on the effects of its payment policy based on experience with the United States' biosimilar product marketplace since the regulations went into effect on January 1, 2016. CMS is particularly interested in new or updated material, such as market analyses or research articles that provide evidence which supports positions expressed in comments.

<u>Part B Drug Payment: Infusion Drugs Furnished through an Item of Durable Medical Equipment</u> (DME)

The 21st Century Cures Act changed the payment methodology for infusion drugs or biologicals furnished through a covered item of DME from being based on average wholesale price to the methodology average sales price (ASP). This change was modified by the Social Security Average Sales Price and was effective January 1, 2017. CMS is proposing to revise 42 CFR §414.904(e)(2) to conform regulations with the new payment requirements in section 5004(a) of the 21st Century Cures Act.

New Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

Under this proposal, RHCs and FQHCs would receive payment for regular and complex chronic care management services, general behavioral health integration services, and psychiatric collaborative care model services using two new billing codes created exclusively for RHC and FQHC payment. This payment would be in addition to the payment for an RHC or FQHC visit.

Appropriate Use Criteria for Advanced Diagnostic Imaging

CMS is proposing to implement the Medicare Appropriate Use Criteria (AUC) Program for Advanced Diagnostic Imaging in a manner that allows practitioners more time to focus on and adjust to the Quality Payment Program. The Medicare AUC program is proposed to begin with an educational and operations testing year in 2019, which means physicians would be required to start using AUCs and reporting this information on their claims. During this first year, CMS is proposing to pay claims for advanced diagnostic imaging services regardless of whether they contain information on the required AUC consultation. This allows both clinicians and the agency to prepare for this new program.

In conjunction with the proposed rule, CMS is posting newly qualified provider-led entities and clinical decision support mechanisms. Qualified provider-led entities are permitted to develop AUC, and qualified clinical decision support mechanisms are the tools through which physicians use to access the AUC. Physicians may begin exploring these mechanisms well in advance of the start of the Medicare AUC program. In addition, by having qualified clinical decision support mechanisms available (some of which are free of charge) clinicians may use one of these mechanisms to earn credit under the Merit-Based Incentive Payment System as an improvement activity. This improvement activity was included in the Quality Payment Program proposed rule that was released on June 20, 2017.

It is important to receive comments that help us understand the current readiness of stakeholders. Therefore, we specifically seek comment related to whether the program should be delayed beyond the proposed start date of January 1, 2019, and are interested in comments regarding how long, if longer that one year, such a period of educational and operations testing should be available.

Medicare Diabetes Prevention Program Expanded Model

The proposed rule also makes additional proposals to implement the Medicare Diabetes Prevention Program (MDPP) expanded model starting in 2018. The MDPP expanded model was announced in early 2016, when it was determined that the Diabetes Prevention Program (DPP) model test through the Center for Medicare and Medicaid Innovation's Health Care Innovation Awards met the statutory criteria for

expansion. The proposed rule proposes additional policies necessary for suppliers to begin furnishing MDPP services nationally in 2018, including the MDPP payment structure, as well as additional supplier enrollment requirements and supplier compliance standards aimed to ensure program integrity. Please see MDPP the fact sheet on the expanded model for more information: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-13-3.html.

Physician Quality Reporting System (PQRS)

Under the PQRS, individual eligible professionals and group practices who did not satisfactorily report data on quality measures in 2016 are subject to a downward payment adjustment of 2.0 percent in 2018 to their PFS services. 2016 was the last reporting period for PQRS. The final data submission timeframe for reporting 2016 PQRS quality data to avoid the 2018 PQRS downward payment adjustment was January through March 2017. PQRS is being replaced by the Merit-based Incentive Payment System (MIPS) under the Quality Payment Program (QPP). The first MIPS performance period is January through December 2017.

CMS is proposing to change the current PQRS program policy that requires reporting of 9 measures across 3 National Quality Strategy domains to only require reporting of 6 measures for the PQRS. We are also proposing similar changes to the clinical reporting requirements under the Medicare Electronic Health Record Incentive Program for eligible professionals.

We are proposing these changes based on stakeholder feedback and to better align with the MIPS data submission requirements for the quality performance category. For MIPS, eligible clinicians need only report 6 quality measures for the quality performance category, except those reporting via the Web Interface with no requirement to ensure that the measures span across 3 National Quality Strategy domains.

Patient Relationship Codes

In May 2017, CMS posted the operational list of patient relationship categories that are required under MACRA. In this rule, we are proposing the use of Level II HCPCS modifiers on claims to indicate these patient relationship categories. Further, we are proposing that the HCPCS modifiers may be voluntarily reported by clinicians beginning January 1, 2018. We anticipate that there will be a learning curve with respect to the use of these modifiers, and we will work with clinicians to ensure their proper use.

Medicare Shared Savings Program Rules

CMS is proposing several modifications to the rules for accountable care organizations (ACOs) participating in the Medicare Shared Savings Program. These proposed modifications are designed to reduce burden and streamline program operations. The proposals include the following:

- Revisions to the assignment methodology to reflect the requirement under section 17007 of the 21st
 Century Cures Act (Pub. L. 114-255, December 13, 2016), that for performance years beginning on or
 after January 1, 2019, the Secretary determine an appropriate method to assign Medicare FFS
 beneficiaries to an ACO based on their utilization of services furnished by rural health clinics (RHCs)
 or federally qualified health centers (FQHCs);
- The addition of three new chronic care management codes (CCM) and behavioral health integration (BHI) codes to the definition of primary care services used in the ACO assignment methodology; and
- Reduction of burden for stakeholders submitting an initial Shared Savings Program application and the application for use of the skilled nursing facility (SNF) 3-Day Rule Waiver.

2018 Value Modifier

In order to better align incentives and provide a smoother transition to the new Merit-based Incentive Payment System under the Quality Payment Program, we are proposing the following changes to previously-finalized policies for the 2018 Value Modifier:

- Reducing the automatic downward payment adjustment for not meeting minimum quality reporting requirements from negative four percent to negative two percent (-2.0 percent) for groups of ten or more clinicians; and from negative two percent to negative one percent (-1.0 percent) for physician and non-physician solo practitioners and groups of two to nine clinicians;
- Holding harmless all physician groups and solo practitioners who met minimum quality reporting requirements from downward payment adjustments for performance under quality-tiering for the last year of the program; and
- Aligning the maximum upward adjustment amount to 2 times the adjustment factor for all physician groups and solo practitioners.