Small Entity Compliance Guide

Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule

Federal Register, Vol. 84, No. 221, Pages 62568-63563, Friday, November 15, 2019

42 CFR parts 403, 409, 410, 411, 414, 415, 416, 418, 424, 425, 489, and 498

CMS–1715–F & IFC

RIN 0938-AT72

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, Pub. L. 104-121, as amended by Pub. L. 110-28, May 25, 2007) contains requirements for issuance of "small entity compliance guides." Guides are to explain what actions affected entities must take to comply with agency rules. Such guides must be prepared when agencies issue final rules for which agencies were required to prepare a Final Regulatory Flexibility Analysis under the Regulatory Flexibility Act.

The complete text of this final rule can be found on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F.html.

Summary

This major final rule revises payment polices under the Medicare PFS and makes other policy changes, including provisions to implement certain provisions of the Bipartisan Budget Act of 2018 (Pub. L. 115-123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115-271, October 24, 2018), related to Medicare Part B payment, applicable to services furnished in CY 2020 and thereafter. In addition, this final rule includes provisions related to other payment policy changes as addressed in section III. of this final rule. To facilitate beneficiary access to treatment for treatment-resistant depression (TRD) as using esketamine, we are creating two new HCPCS G codes, G2082 and G2083, effective January 1, 2020 on an interim final basis.

Background

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. Per the statute, RVUs must be established for three categories of resources (work, practice expense (PE); and malpractice expense) and we must establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

Provisions of the Final Rule

CY 2020 PFS Ratesetting:
We are finalizing work RVUs that differ from the American Medical Association Relative Value Scale Update Committee's (AMA RUC) recommendations for about a quarter of the 270 codes reviewed this year; different PE RVUs from the RUC-recommended PE RVUs; a series of standard technical provisions involving PE, including the implementation of the second year of the market-based supply and equipment pricing update; and standard ratesetting refinements to update premium data involving malpractice expense and geographic practice cost indices (GPCIs). There is no overall cost impact of the PE, malpractice, and GPCI provisions since the updates will be implemented budget neutrally through the ratesetting methodology.

Establishment of the PFS New Opioid Treatment Program Benefit Mandated by Section 2005 of the SUPPORT Act and Provider Enrollment Provisions:
We are implementing a newly authorized opioid treatment program (OTP) benefit by the creation of the OTP provider type and separate OTP specific bundled payment rates for the treatment of opioid use disorder (OUD). We are also finalizing no beneficiary copayments in the initial years of implementation.

Coinsurance for Colorectal Cancer Screening Tests:
In this final rule, we are signaling our intention to review beneficiary communication strategies and materials to ensure beneficiaries have the necessary information to understand this Medicare benefit.

Evaluation and Management (E/M) Services:
● *Adoption of New Coding for CY 2021*: We are adopting most of the new coding, prefatory language, and interpretive guidance that has been laid out by the AMA's Common Procedural Terminology CPT Editorial Panel because their changes are consistent with our goals of burden reduction and align with the policies we finalized in the CY 2019 PFS final rule.
● *Office/Outpatient E/M Visit Valuation for CY 2021:* We are accepting the RUC-recommended work values for the Office/Outpatient E/M Visit codes for CY 2021. We note that we did not make any proposals to accept the RUC recommendations to increase the value of the 10- and 90-day global periods based on the revalued office/outpatient E/M.
● *Add-on HCPCS G Code for Primary Care and Ongoing Care Related to a Single, Serious, or Complex Chronic Condition for CY 2021:* We are finalizing valuation for an additional, consolidated payment for visit complexity for primary care and/or ongoing care related to a single, serious, or complex chronic condition.

Care Management Services:
● *Transitional Care Management (TCM)*: We are finalizing both increased valuation of TCM services and revised billing requirements that allow currently restricted care management codes to be billed concurrently with TCM when medically appropriate.
● *Chronic Care Management (CCM)*: We are maintaining existing CPT coding, but finalizing a Medicare-specific HCPCS add-on G-code to allow separate payment for finer time increments of non-complex chronic care management by clinical staff.
● *Principal Care Management (PCM)*: We are finalizing payment for Medicare-specific HCPCS G-codes for practitioners performing care management for patients with a single high-risk complex chronic condition.

***Response to the CY 2018 Request for Information (RFI) on Burden Reduction: Review and Verification of Medical Record Documentation*:**
We are finalizing changes to our regulations so that physicians, teaching physicians, physician assistants (PAs), and advanced practice registered nurses (APRNs), that specifically include nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs) and certified registered nurse anesthetists (CRNAs), can review and verify (sign and date) rather than re-documenting notes made in the medical record by other physicians, residents, nurses, medical; PA; and APRN students, and other members of the medical team.

Deferring to State Scope of Practice Requirements:
We are revising the health and safety regulations for ambulatory surgical centers (ASC) and hospices to allow certified registered nurse anesthetists (CRNA) to evaluate the risk of anesthesia prior to surgery (currently limited to physicians), and retaining the requirement that a physician must evaluate the risks of the procedure to be performed on the patient. We are also allowing hospices to accept drug orders from PAs (currently limited to physician and nurse practitioners) who are: (1) acting as the attending physician; (2) operating within state scope of practice requirements and hospice policy; and (3) not employed by, or under contract with the hospice.

***Response to the CY 2018 RFI on Burden Reduction--Physician Supervision Requirement for Physician Assistants (PAs)*:**
For States with applicable law and scope of practice rules regarding physician supervision of PAs, we are clarifying that any state laws and scope of practice rules that describe the required practice relationship between physicians and PAs, including explicit supervisory or collaborative practice requirements, describe a form of supervision for purposes of section 1861(s)(2)(K)(i) of the Medicare law.

Stark Law Advisory Opinion Regulations:
CMS has the authority to issue written advisory opinions concerning whether a referral relating to designated health services is prohibited under section 1877 of the Act (the Stark Law). ln response to the burden reduction RFI published last year, several commenters urged CMS to revamp its advisory opinion process so that more hospitals and physicians can benefit from the certainty that only an advisory opinion can provide, and therefore, we are addressing some of industry's concerns.

Updates to the Quality Payment Program:
● *Merit-based Incentive Payment System (MIPS)*:
We are finalizing the MIPS Value Pathways (MVP), the CYs 2020 and 2021 MIPS Performance Thresholds, and modifications to the requirements of MIPS Third Party Intermediaries to meet the same measure standards that is required of the MIPS quality measures.
● *Alternative Payment Models (APM)*: We are finalizing policies concerning the APM Scoring Standard, the CMS Multi-Payer Medical Home Models and the modifying definition of Marginal Risk.

***Open Payments*:**
We are expanding the definition of “covered recipient” to include the additional provider types contained in the SUPPORT Act, adjusting the nature of payment categories in response to stakeholder feedback, and standardizing the data for reported products.

***Changes to the Ambulance Physician Certification Statement (PCS) Requirement**:*
We are finalizing provisions clarifying the requirements for Certification Statements, and adding licensed practical nurses (LPN), social workers and case managers as staff members who may sign the PCS if the provider/supplier is unable to obtain the attending physician's signature within 48 hours of the transport to reduce the amount of documentation required while also giving greater flexibility in who can sign the PCSs.

Other Changes to Part B Services:
The final also includes policies concerning the Telehealth Services, Therapy Services, Intensive Cardiac Rehabilitation, Medicaid Promoting Interoperability Requirement for Eligible Professionals, Medicare Shared Savings Program, and the Home Infusion Therapy Benefit.

Small Entities Affected

For purposes of the RFA, physicians, nonphysician practitioners (NPPs), and suppliers including independent diagnostic testing facilities (IDTFs) are considered small businesses if they generate revenues of $10 million or less, according to the Small Business Administration size schedule. We estimate that approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in section VII. of the final rule (Regulatory Impact Analysis), as well as elsewhere in the final rule are intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities. (See Table 119 (CY 2020 PFS Estimated Impact on Total Allowed Charges by Specialty) of the final rule, which show the payment impact on PFS services of the policies contained in this final rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 119.)

For the Quality Payment Program, we estimate that between 210,000 and 270,000 clinicians will become Qualifying APM Participants (QPs) and the total lump sum APM Incentive Payments will be approximately $535-685 million in the 2022 Quality Payment Program payment year. We estimate that approximately 880,000 clinicians will be MIPS eligible clinicians for the 2020 MIPS performance period. We estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments and positive MIPS payment adjustments ($433 million redistributed) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality. Up to an additional $500 million is also available for the 2022 MIPS payment year for additional positive MIPS payment adjustments for exceptional performance.

Section 101(a) of the Medicare Access and CHIP Reauthorization Act of 2015 repealed the previous statutory update formula (known as the Sustainable Growth Rate) and specified the PFS update for CY 2015 and beyond. The PFS update for CY 2020 is 0.00 percent, which is reflected in the overall update. After applying the required budget neutrality adjustment, the conversion factor for January 1, 2020 through December 31, 2020 will be $36.09. Please refer to section VII. of the final rule for the full regulatory impact analysis.

This rule imposes no direct federal compliance requirements with significant economic impacts on small entities. In order to assist physicians, NPPs, and suppliers including IDTFs in understanding and adapting to changes in Medicare billing and payment procedures, we have developed webpages that include additional material on the PFS at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html and https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.