Small Entity Compliance Guide

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program--Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program--Accountable Care Organizations--Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act; Final Rules and Interim Final Rule

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42 CFR Parts 405, 410, 411, 414, 415, 425, and 495

CMS–1693–F, CMS–1693–IFC, CMS–5522–F3, and CMS–1701–F

RIN 0938–AT31, 0938–AT13, & 0938–AT45

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-1693-F.html.

This final rule implements changes to the physician fee schedule (PFS) and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services. It finalizes the calendar year (CY) 2019 proposed relative value units (RVUs) for new, revised and misvalued procedure codes. The final rule also:

- Announces, in accordance with the statute, that for January 1, 2019, through December 31, 2019, the PFS update will be 0.25 percent. After applying the required budget neutrality adjustment, the conversion factor for January 1, 2019 through December 31, 2019 will be $36.04.
- Addresses, implements or discusses changes to several of the quality reporting initiatives that are associated with PFS payments – Quality Payment Program--Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year, which addresses the extreme and uncontrollable circumstances MIPS eligible clinicians faced as a result of widespread catastrophic events, as well as a

subset of the changes to the Medicare Shared Savings Program for Accountable Care Organizations (ACOs).

- Addresses certain other revisions designed to update program policies under the Shared Savings Program.
- Addresses changes to other programs and includes discussions regarding:
  - Potentially Misvalued Codes.
  - Communication Technology-Based Services.
  - Provisions Expanding Telehealth Services for the Treatment of Opioid Use Disorder and Other Substance Use Disorders under the SUPPORT Act.
  - Valuation of New, Revised, and Misvalued Codes.
  - Payment Rates under the PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital.
  - Evaluation & Management (E/M) Visits.
  - Therapy Services.
  - Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-based Payments.
  - Potential Model for Radiation Therapy.
  - Clinical Laboratory Fee Schedule.
  - Ambulance Fee Schedule – Provisions in the Bipartisan Budget Act of 2018.
  - Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).
  - Appropriate Use Criteria for Advanced Diagnostic Imaging Services.
  - Medicaid Promoting Interoperability Program Requirements for Eligible Professionals.
  - Physician Self-Referral Law.
  - Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes.

Finally, this rule also implements, as an interim final rule, the amendments made by the SUPPORT for Patients and Communities Act to the Medicare telehealth provisions in the Social Security Act and regarding permissible telehealth originating sites for purposes of treatment of a substance use disorder or a co-occurring mental health disorder for telehealth services furnished on or after July 1, 2019 to an individual with a substance use disorder diagnosis.

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. Approximately 95 percent of physicians are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS.

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.