#### **Small Entity Compliance Guide**

Medicare Program; CY 2022 Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements.

Federal Register, Vol. 86, No. 221, Pages 64996-66031, Friday, November 19, 2021

42 CFR parts 403, 405, 410, 411, 414, 415, 423, 424, and 425

CMS-1751-F

RIN 0938-AU42

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 (RFA).

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-1751-F.html.

#### **Summary**

This major final rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare provider enrollment policies; requirements for prepayment and post-payment medical review activities; requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan, or a Medicare Advantage Prescription Drug (MA-PD) plan; changes to the Medicare Diabetes Prevention Program (MDPP) expanded model; updates to Prepayment and Postpayment Review; updates to the Open Payments program; and amendments to the physician self- referral law regulations.

## **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 2022 PFS Ratesetting:

We are establishing work relative value units (RVUs) (based on the recommendations from the AMA's Relative Value Scale Update Committee) with refinements to approximately 30 percent of the 117 codes reviewed this year. We are addressing several issues related to how practice expenses are considered in setting rates, including the implementation of the fourth and final year of the market-based supply and equipment pricing update, and similarly implementing a new update to clinical labor pricing to match the supply and equipment update. Clinical labor rates were last updated for CY 2002 and stakeholders have raised concerns that the long delay since clinical labor pricing was last updated has created a significant disparity between CMS' clinical wage data and the market average for clinical labor rates. We believe periodic updates to clinical labor rates based on current data are important to maintain relativity with the supply and equipment pricing updates.

We are finalizing a four-year transition to update the clinical labor pricing. Using a transition will help to maintain payment stability and mitigate potential negative effects on healthcare providers by gradually phasing in the changes over a period of time. We note that services typically furnished by family practice and internal medicine professionals would be positively affected by the pricing update, which will positively impact access to care for disadvantaged and underserved groups. We also note that payment was reduced for many of these services that involve proportionally more clinical labor as a result of the prior market-based supply and equipment pricing update. These same services will now be helped by the clinical labor pricing update.

Conversely, services that proportionally use more supplies and equipment will see a payment decline that will be mitigated by the four-year transition. We believe that the ongoing trend of market consolidation and site of service differentials highlight the need to update the overall PFS practice expense input data comprehensively, including a full accounting of indirect/overhead costs, to account for current trends in the delivery of health care, especially with regards to independent versus facility-based practices. We believe that CMS efforts to improve pricing accuracy will improve the sustainability of the PFS and the broader health system, improve access to care, and reduce inequitable disparities.

#### Medicare Telehealth and Other Services involving Communications Technology:

We are finalizing provisions in this year's rule, including:

- Implementation of section 123 of the Consolidated Appropriations Act, 2021 (CAA), removing the geographic and site of service restrictions for telehealth when used for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. A non-telehealth in-person visit is required between the provider and the beneficiary within the 6 months of the initial telehealth services, with subsequent in person follow-ups every 12 months after, between telehealth mental health services, with the possibility for exceptions to be documented in the medical record. We are also implementing section 125 of the CAA by adding the newly created rural emergency hospital Medicare provider type to the list of eligible telehealth originating sites, effective in 2023.
- Amending the regulatory requirement for interactive telecommunications systems to allow audioonly communication technology for mental health services furnished to established patients in their homes that are paid under the PFS. The revised regulation similarly applies to counseling and

therapy services provided under the Opioid Treatment Program (OTP) benefit in cases where the beneficiary does not have access to audio and video communication technology, or prefers audio-only interaction. These telehealth mental health services adjustments are in effect now and will continue after the conclusion of the PHE.

- Revising the timeframe for which certain services added to the Medicare telehealth list on a temporary basis will continue to be on the list until December 31, 2023 or after the conclusion of the PHE, whichever is later.
- Reviewing and recommending action on stakeholder requests for adding services to the Medicare telehealth list. This process is part of the annual PFS rulemaking process.

## Evaluation and Management (E/M) Services:

We are engaged in an ongoing review of several E/M visit code sets and longstanding policies that exist in CMS' manual instructions. This year we finalized updates and refinements, for split (or shared) E/M visits, critical care services, and teaching physician services.

#### PFS Conversion Factor:

We finalized coding and payment policies for office/outpatient E/M visits and several analogous services for CY 2021 that resulted in historic increases in payment for these services. Collectively, these policies resulted in a 9 percent decrease to the conversion factor due to the statutory requirement that the PFS maintain budget neutrality. Subsequently, Congress passed the CAA of 2021, which mandated a 3.75 percent increase in PFS payments for CY 2021, in part offsetting the overall reduction to the conversion factor due to the increased valuation of the office/outpatient E/M visits. Congress also prohibited CMS from implementing use of an add-on code describing the inherent complexity associated with primary care and non-procedural specialty care visits that also reduced the overall budget neutrality reduction. We note that the 3.75 percent adjustment only applies to payments in CY 2021 and is set to expire at the end of this payment year. The PFS conversion factor in this final rule will reflect this reduction, required under current statute. We are projecting the conversion factor to decrease by approximately 3.72 percent from \$34.89 in CY 2021 to approximately \$33.60 in CY 2022. Stakeholders have continued to express concern to CMS about the potential cut to payment in CY 2022.

#### Vaccine Administration Services:

We are finalizing provisions in this year's rule, including:

- Effective January 1, 2022, CMS will pay \$30 per dose for the administration of the influenza, pneumococcal and hepatitis B virus vaccines. In addition, CMS will maintain the current payment rate of \$40 per dose for the administration of the COVID-19 vaccines through the end of the calendar year in which the PHE ends. Effective January 1 of the year following the year in which the PHE ends, the payment rate for COVID-19 vaccine administration will be set at a rate to alignwith payment rate for the administration of other Part B preventive vaccines.
- CMS will continue the additional payment of \$35.50 for COVID-19 vaccine administration in the home under certain circumstances through the end of the calendar year in which the PHE ends.

• CMS will continue to pay for COVID-19 monoclonal antibodies under the Medicare Part B vaccine benefit through the end of the calendar year in which the PHE ends. Effective January 1 of the year following the year in which the PHE ends, CMS will pay for COVID-19 monoclonal antibody products as biological products paid under section 1847A of the Act. We note healthcare providers will be paid under the applicable payment system, and using the appropriate coding and payment rates, for administering COVID-19 monoclonal antibodies similar to the way they are paid for administering other complex biological products.

### Drugs and Biological Products Paid Under Medicare Part B:

- Requiring Certain Manufacturers to Report Drug Pricing Information for Part B Drug manufacturers with Medicaid Drug Rebate Agreements are required to submit Average Sales Price (ASP) data for their Part B products in order for their covered outpatient drugs to be payable under Part B. To date, manufacturers without such agreements have had the option to voluntarily submit ASP data. For calendar quarters beginning January 1, 2022, section 401 of the CAA requires manufacturers of drugs or biologicals payable under Part B without a Medicaid Drug Rebate Agreement to report ASP data. CMS is making regulatory changes to implement this new reporting requirement.
- Determination of ASP for Certain Self-administered Drug Products Section 405 of the CAA requires the Office of Inspector General (OIG) to conduct periodic studies on non-covered, self-administered versions of drugs or biologicals that are included in the calculation of payment under section 1847A of the Social Security Act. This provision permits CMS to apply a payment limit calculation methodology (the "lesser of" methodology) to applicable billing codes, if deemed appropriate. That is, the Medicare payment limit for the drug or biological billing code would be the lesser of: (1) the payment limit determined using the current methodology (where the calculation includes the ASPs of the self-administered versions), or (2) the payment limit calculated after excluding the non-covered, self-administered versions. CMS finalized the "lesser of" methodology for drug and biological products that may be identified by future OIG reports.

Section 405 of the CAA also requires that beginning July 1, 2021, the ASP-based payment limit for billing codes representing Cimzia® (certolizumab pegol) and Orencia® (abatacept) as identified in a July 2020 OIG report adhere to the "lesser of" methodology. CMS has applied this methodology for these billing codes beginning in the July 2021 ASP Drug Pricing files.

## Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs):

• Revising the current regulatory language for RHC or FQHC mental health visits to include visits furnished using interactive, real-time telecommunications technology. This change will allow RHCs and FQHCs to report and receive payment for mental health visits furnished via real-time telecommunication technology in the same way they currently do when visits take place in-person, including audio-only visits when the beneficiary is not capable of, or does not consent to, the use of video technology. CMS also finalized that an in-person, non-telehealth visit must be furnished at least every 12 months for these services; however, exceptions to the in-person visit requirement may be made based on beneficiary circumstances (with the reason documented in the patient's medical record) and more frequent visits are also allowed under our policy, as driven by clinical needs on a case-by-case basis.

- Implementing section 130 of the CAA as amended by section 2 of Pub. Law 117-7, requiring that, beginning April 1, 2021, already-enrolled independent RHCs and provider-based RHCs in larger hospitals receive an increase in their payment limit per visit over an 8-year period, with a prescribed amount for each year from 2021 through 2028. Then, in subsequent years, the limit is updated by the percentage increase in Medicare Economic Index (MEI). Also beginning April 1, 2021, section 130 as amended requires that a payment limit per-visit be established for most provider-based RHCs in a hospital with fewer than 50 beds enrolled before January 1, 2021 be subject to a payment limit based on their 2020 per-visit rate, updated annually by the percentage increase in MEI. Lastly, section 130 of the CAA subjects all newly enrolled RHCs (as of January 1, 2021, and after), both independent and provider-based, to a national payment limit per-visit.
- Implementing section 132 of the CAA, which makes FQHCs and RHCs eligible to receive payment for hospice attending physician services when provided by a FQHC/RHC physician, nurse practitioner, or physician assistant who is employed or working under contract for an FQHC or RHC, but is not employed by a hospice program, starting January 1, 2022.
- Allowing RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary during the same service period, provided all requirements for billing each code are met.
- Made conforming technical changes to the regulatory text related to COVID-19 vaccines for RHCs and FQHCs.

# Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs):

CMS finalized its proposal to allow OTPs to furnish counseling and therapy services via audio-only interaction (such as telephone calls) after the conclusion of the COVID-19 PHE in cases where audio/video communication is not available to the beneficiary, including circumstances in which the beneficiary is not capable of or does not consent to the use of devices that permit a two-way audio/video interaction, provided all other applicable requirements are met. CMS also finalized a requirement that OTPs use a service-level modifier for audio-only services billed using the counseling and therapy add-on code in order to facilitate program integrity activities.

Additionally, in order to avoid a significant decrease in the payment amount for methadone that could negatively affect access to methadone for beneficiaries receiving services at OTPs, CMS is issuing an interim final rule with comment to maintain the payment amount for methadone at the CY 2021 rate for the duration of CY 2022. CMS is also seeking comment on OTP utilization patterns for methadone, particularly, the frequency with which methadone oral concentrate is used compared to methadone tablets in the OTP setting, including any applicable data on this topic.

#### Medicare Shared Savings Program:

Accountable Care Organizations (ACOs) have raised concerns about the transition to electronic clinical quality measures (eCQMs/ MIPS CQMs) all-payer quality measure reporting, which are measures that are reported using data from electronic health records (EHRs) and/ or health information technology systems and are submitted for all ACO clinicians' patients regardless of payer under the new Alternative Payment Model (APM) Performance Pathway (APP) due to

concerns over aggregating all-payer data across multiple EHR systems and multiple health care practices.

We are finalizing a longer transition to ACO all-payer quality measure reporting by extending the CMS Web Interface for performance years 2022, 2023, and 2024 for Shared Savings Program ACOs, providing an incentive for ACOs to report eCQMs/MIPS CQMs in performance year 2022 and 2023, and finalizing policies to freeze the quality performance standard used to determine ACO shared savings at the 30th percentile across all MIPS Quality performance category scores for performance year 2023.

We are also finalizing proposed changes to other Shared Savings Program policies, including: updates to the beneficiary assignment algorithm to reflect FFS coding updates; reducing ACO burden by reducing repayment mechanism amounts ACOs must reserve in order to transition to performance-based risk; and reducing burden and streamlining the Shared Savings Program application and beneficiary notification processes.

## Medicare Diabetes Prevention Program (MDPP):

We are amending our regulations to:

- Shorten the MDPP services period to 1 year by removing the Ongoing Maintenance phase (months 13-24) of the MDPP set of services. We anticipate removing the Ongoing Maintenance sessions phase will improve the uptake of organizations enrolling in Medicare to become MDPP suppliers, thus enabling more beneficiaries to access the MDPP set of services. In addition, we believe that shortening the length of the program will make the program more manageable for MDPP beneficiaries because it reduces their commitment to MDPP to one year as opposed to twoyears.
- Update the amount of the performance payments for the Core Sessions and Core Maintenance Sessions, and remove reference to, and requirements of, the Ongoing Maintenance phase.
- Add a provision to waive the provider enrollment application fee for all organizations enrolling in Medicare as MDPP suppliers that submit an application on or after January 1, 2022 and remove reference to CMS-20134.

#### Quality Payment Program:

We are finalizing several policies to further realize our vision for MIPS Value Pathways (a subset of measures and activities focused on meaningful participation for a specialty or clinical episode) and begin implementation of MVPs in 2023. The following are the key provisions:

- Allow voluntary MVP reporting for individuals, groups, subgroups, and APM entities beginning with the 2023 performance period and signal mandatory subgroup reporting formultispecialty groups beginning with the 2026 performance period.
- Reduce the number of quality and cost measures and improvement activities required for MVP participants.
- Implement seven MVPs for the 2023 performance period: Advancing Rheumatology Patient

Care, Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes, Advancing Care for Ischemic Heart Disease, Optimizing Chronic Disease Management, Emergency Medicine Undifferentiated High-Risk Conditions, Improving Care for Lower ExtremityJoint Repair, and Patient Safety and Support of Positive Experiences with Anesthesia.

- Create a new MIPS reporting option, subgroups, in which a subset of clinicians in a larger group can separately elect to report MVPs or the APP beginning in CY 2023. We finalized the requirement for multi-specialty groups to form subgroups by CY2026.
- Add scoring policies for MVPs that are similar to traditional MIPS with limited exceptions. We are finalizing the following changes:
- *Eligibility*: Revise the current MIPS eligible clinician definition to include Clinical Social Workers and certified nurse-midwives.
- Quality Performance Category: Add 4 new MIPS quality measures and remove 13 MIPS quality measures. MIPS will only retain the Web Interface for non-SSP participants through CY2022; SSP Participants will have the Web Interface through CY2024.
- Cost Performance Category: Add 5 cost measures for implementation into MIPS, filling some measurement gaps and moving towards the statutory requirement of 50 percent of expenditures under parts A and B coverage requirement.
- Promoting Interoperability Performance Category: Modify our current policy to require eligible clinicians to report two of the measures associated with the Public Health and Clinical Data Exchange objective. Require eligible clinicians attest to conducting an annual assessment of the High Priority Guide in the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides).
- Improvement Activities Performance Category: Updates to the improvement activities inventory, including modifying 6 previously adopted improvement activities to fill gaps and standardize/update language related to health equity across the improvement activities inventory.
- MIPS Final Score Methodology: Beginning with 2023, remove transition policies such as the scoring floors (3 out of 10 points) for quality measures and removal of bonus points (for reportingadditional high priority quality measures and end-to-end electronic quality measures). Establish a 7-point minimum score for new quality measures for their first 2 years in the program and a 5-pointfloor in their second year. Use historic benchmarks based on the 2020 baseline period for the 2022 performance period. Update the complex patient bonus formula to better target clinicians who care for higher percentages of medically and socially complex patients. Create a new redistribution policy for small practices that are not measured on certain performance categories and automatically reweight small practices under the Promoting Interoperability category.
- MIPS Payment Adjustments: Establish the performance threshold using the mean of the 2017 performance period data (75 points) and an additional performance threshold of 89. This will be the last year the additional performance threshold for exceptional performance will be available.

Quality Payment Program: Advanced APM updates: Codify statutory changes to the QP thresholds for performance years 2021 through 2023, freezing them at the levels set for PY 2020.

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW:

### Appropriate Use Criteria (AUC):

We are beginning the AUC claims processing systems edits and payment penalty phase of the program on the later of January 1, 2023, or the January 1 of the year after the year in which the PHE for COVID-19 ends. This will be a delay from the current date of January 1, 2022.

# Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR):

We are updating regulatory text to improve consistency, accuracy and clarity in terminology, definitions and requirements, as appropriate, across the conditions of coverage for these programs. We are also expanding coverage of PR to patients who have had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction forat least 4 weeks.

#### Removal of Two National Coverage Determinations (NCDs):

We are removing two outdated NCDs: Enteral and Parenteral Nutritional Therapy (effective since 7/11/1984) and Positron Emission Tomography (PET) Scans (effective since 9/03/2013). Removing an NCD means that the local Medicare Administrative Contractors (MACs) will make the coverage determinations forthose items or services either on a claim-by-claim basis or through the Local Coverage Determination (LCD) process.

# Electronic Prescribing for Controlled Substances (EPCS) under Section 2003 of the Support Act:

We are extending the date of compliance actions to January 2023 to be responsive to stakeholder feedback. We are also extending the compliance deadline for long term care facilities to January 1, 2025 primarily because of implementation barriers and a lack of infrastructure for electronic prescribing associated with the setting, and also because of their high priority role during the pandemic. We are finalizing exceptions for where the practitioner and dispensing pharmacy are thesame entity, for small prescribers, and for cases of extraordinary circumstances, such as natural disasters or an influx of patients due to a pandemic. Prescribers will also be able to request a waiver for cases where circumstances beyond their control prevent them from electronically prescribing. In the first year of implementation, actions against prescribers who do not comply with this mandate will be limited to a letter notifying prescribers that they are out of compliance, in order to avoid overly burdening prescribers while they work to mitigate the effects of the pandemic.

## Medicare Provider and Supplier Enrollment Changes:

To help strengthen Medicare program integrity while simultaneously recognizing emerging and innovative medical technologies, we are:

• Expanding the types of parties within the purview of these denial and revocation authorities to include excluded individuals in an administrative or management services role who furnish services payable by a federal health care program.

- Expanding our authority to include situations where the physician or other eligible professional surrenders his or her DEA certificate in response to a show cause order.
- Establishing specific rebuttal rights for deactivated providers/suppliers.
- Eliminating or revising some of these factors to better enable CMS to target shorter (but no less concerning) periods of non-compliant billing

#### Provider/Supplier Medical Review Requirements:

We are finalizing regulations that add several provisions related to the management of prepayment and post-payment medical reviews.

### Open Payments Program:

To both clarify and strengthen the Open Payments program, we are finalizing a provision to disallow publication delays of certain payments, clarify requirements for reporting, and define Physician-Owned Distributorships (PODs).

## **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 VI. 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 149 (CY 2022 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 149.)

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 810,000 clinicians will be MIPS eligible clinicians for the 2022 MIPS performance period. We estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments and positive MIPS payment adjustments (\$603 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 performance period 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 2021 is 0.00 percent, which is reflected in INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW:

This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

the overall update. In addition, the Consolidated Appropriations Act, 2021 (CAA) provided a 3.75 percent increase in PFS payments for CY 2021 which is due to expire for CY 2022. After applying the required budget neutrality adjustment, the conversion factor for January 1, 2022 through December 31, 2022 will be \$33.60. Please refer to section VI. 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 <a href="http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html">http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html</a> and <a href="https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html">https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html</a>.