DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS–1751–F]

RIN 0938–AU42

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; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Final rule.

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; updates to the Medicare Ground Ambulance Data Collection System; changes to the Medicare Diabetes Prevention Program (MDPP) expanded model; and amendments to the physician self-referral law regulations.

DATES: These regulations are effective on January 1, 2022.

FOR FURTHER INFORMATION CONTACT: *DivisionofPractitionerServices@cms.hhs.gov,* for any issues not identified below.

Michael Soracoe, (410) 786–6312, or *DivisionofPractitionerServices@cms.hhs.gov,* for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Larry Chan, (410) 786–6864, for issues related to potentially misvalued services under the PFS.

Patrick Sartini, (410) 786–9252, and Larry Chan, (410) 786–6864, for issues related to telehealth services and other services involving communications technology.

Julie Adams, (410) 786–8932, for issues related to payment for anesthesia services.

Sarah Leipnik, (410) 786–3933, or *DivisionofPractitionerServices@cms.hhs.gov,* for issues related to split (or shared) services.

Michelle Cruse, (410) 786–7540, and Michael Konieczny, (410) 786–0825, for issues related to payment for vaccine administration services.

Regina Walker-Wren, (410) 786–9160, for issues related to billing for services of physician assistants and PFS payment for teaching physician services.

Pamela West, (410) 786–2302, for issues related to PFS payment for therapy services, medical nutrition therapy services, and services of registered dietitians and nutrition professionals.

Liane Grayson, (410) 786–6583, for issues related to coinsurance for certain colorectal cancer screening services and PFS payment for critical care services.

Lisa Parker, (410) 786–4949, and Michele Franklin, (410) 786–9226, for issues related to RHCs and FQHCs.

Laura Kennedy, (410) 786–3377, for issues related to drugs payable under Part B.

Heather Hostetler, (410) 786–4515, and Elizabeth Truong, 410–786–6005, for issues related to removal of selected national coverage determinations.

Sarah Fulton, (410) 786–2749, for issues related to Appropriate Use Criteria for Advanced Diagnostic Imaging (AUC); and Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation.

Rachel Katonak, (410) 786–8564, for issues related to Medical Nutrition Therapy.

Sabrina Ahmed, (410) 786–7499, for issues related to the Medicare Shared Savings Program (Shared Savings Program) quality reporting requirements and quality performance standard.

Janae James, (410) 786–0801, Elizabeth November, (410) 786–4518, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to Shared Savings Program beneficiary assignment, repayment mechanism requirements, and benchmarking methodology.

Naseem Tarmohamed, (410) 786–0814, or *SharedSavingsProgram@cms.hhs.gov,* for inquiries related to Shared Savings Program application, compliance and beneficiary notification requirements.

Amy Gruber, *AmbulanceDataCollection@cms.hhs.gov,* for issues related to the Medicare Ground Ambulance Data Collection System.

Juliana Tiongson, (410) 786–0342, for issues related to the Medicare Diabetes Prevention Program (MDPP).

Laura Ashbaugh, (410) 786–1113, for issues related to Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance and Use of Electronic Travel Logs.

Frank Whelan, (410) 786–1302, for issues related to Medicare provider enrollment regulation updates.

Katie Mucklow, (410) 786–0537, for issues related to provider and supplier prepayment and post-payment medical review requirements.

Lindsey Baldwin, (410) 786–1694, and Michele Franklin, (410) 786–9226, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Lisa O. Wilson, (410) 786–8852, or Meredith Larson, (410) 786–7923, for inquiries related to the physician self-referral law.

Joella Roland, (410) 786–7638, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan.

Kathleen Ott, (410) 786–4246, for issues related to open payments.

Molly MacHarris, (410) 786–4461, for inquiries related to Merit-based Incentive Payment System (MIPS).

Brittany LaCouture, (410) 786–0481, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Addenda Available Only Through the Internet on the CMS Website: The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysisianFeeSched/index.html.* Click on the link on the left side of the screen titled, "PFS Federal Regulations Notices" for a chronological list of PFS **Federal Register** and other related documents. For the CY 2022 PFS final rule, refer to item CMS–1751–F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this final rule and posted on the CMS website identified above should contact *DivisionofPractitionerServices@cms.hhs.gov.*

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Table A: New Improvement Activities for the CY 2022 Performance Period/2024 MIPS Payment Year and Future Years

New Improvement Activity	
Proposed Activity ID:	**IA_AHE_8**
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Create and Implement an Anti-Racism Plan
Proposed Activity Description:	Create and implement an anti-racism plan using the CMS Disparities Impact Statement or other anti-racism planning tools.[1] The plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism and an understanding of race as a political and social construct, not a physiological one. The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps. This may also include an assessment and drafting of an organization's plan to prevent and address racism and/or improve language access and accessibility to ensure services are accessible and understandable for those seeking care. The MIPS eligible clinician or practice can also consider including in their plan ongoing training on anti-racism and/or other processes to support identifying explicit and implicit biases in patient care and addressing historic health inequities experienced by people of color. More information about elements of the CMS Disparities Impact Statement is detailed in the template and action plan document at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.
Proposed Weighting:	High
Rationale:	The proposed activity aimed to address systemic inequities, including systemic racism, as called for in Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, published January 20, 2021.[2] This activity began with the premise that it is important to acknowledge systemic racism as a root cause for differences in health outcomes between socially-defined racial groups.[3] [4] We believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, per the improvement activity definition at § 414.1305, because it supports MIPS eligible clinicians in identifying health disparities and implementing processes to reduce racism and provide equitable quality health care. This activity is intended to help MIPS eligible clinicians move beyond analyzing data to taking real steps to naming and eliminating the causes of the disparities identified. We also proposed making this activity high-weighted because MIPS eligible clinicians will need considerable time and resources to develop a thorough anti-racism plan that is informed by data, and to implement it throughout the practice or system. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Comments:	Several commenters expressed support for the proposal to adopt this improvement activity, and for the high weight that we assigned to it. One commenter stated that this activity would be easier for larger, more established practices than smaller or solo practices to adopt. Another commenter stated that CMS should encourage MIPS eligible clinicians to implement this and other new equity-related activities for longer than 90 days to track and impact real improvement.
Response:	We appreciate the commenters' support. We disagree that this activity would be more appropriate for larger, more established practices to adopt. A small or new practice could tailor the activity to their context, fulfilling the requirements within their constraints in the same way as a larger, more established practice. MIPS eligible clinicians will be encouraged to fit these requirements to their specific context. We currently require a minimum of 90 days for the implementation period of this activity, but we support MIPS eligible clinicians who wish to implement this activity for longer periods of time. MIPS eligible clinicians could also attest to this activity in multiple years as they make steady progress towards intended outcomes. As mentioned in the Disparities Impact Statement, CMS offers technical assistance on health equity which a MIPS-eligible clinician can access by emailing healthequityTA@cms.hhs.gov.
Final Action:	After consideration of the public comments we received, we are finalizing this activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_AHE_8**
Subcategory:	Achieving Health Equity

Activity Title:	Create and Implement an Anti-Racism Plan
Activity Description:	Create and implement an anti-racism plan using the CMS Disparities Impact Statement or other anti-racism planning tools.[1] The plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism and an understanding of race as a political and social construct, not a physiological one. The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps. This may also include an assessment and drafting of an organization's plan to prevent and address racism and/or improve language access and accessibility to ensure services are accessible and understandable for those seeking care. The MIPS eligible clinician or practice can also consider including in their plan ongoing training on anti-racism and/or other processes to support identifying explicit and implicit biases in patient care and addressing historic health inequities experienced by people of color. More information about elements of the CMS Disparities Impact Statement is detailed in the template and action plan document at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.
Weighting:	High
New Improvement Activity	
Proposed Activity ID:	**IA_AHE_9**
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
Proposed Activity Description:	Create or improve, and then implement, protocols for identifying and providing appropriate support to: a) patients with or at risk for food insecurity, and b) patients with or at risk for poor nutritional status. (Poor nutritional status is sometimes referred to as clinical malnutrition or undernutrition and applies to people who are overweight and underweight.) Actions to implement this improvement activity may include, but are not limited to, the following: • Use Malnutrition Quality Improvement Initiative (MQii) or other quality improvement resources and standardized screening tools to assess and improve current food insecurity and nutritional screening and care practices. • Update and use clinical decision support tools within the MIPS eligible clinician's electronic medical record to align with the new food insecurity and nutrition risk protocols. • Update and apply requirements for staff training on food security and nutrition. • Update and provide resources and referral lists, and/or engage with community partners to facilitate referrals for patients who are identified as at risk for food insecurity or poor nutritional status during screening. Activities must be focused on patients at greatest risk for food insecurity and/or malnutrition—for example patients with low income who live in areas with limited access to affordable fresh food, or who are isolated or have limited mobility.
Proposed Weighting:	Medium
Rationale:	Food insecurity is a widespread and worsening issue in the United States. Estimates indicate that the number of food insecure people in the United States increased from 35.2 million people (1 in 9 people) in 2019 to 45 million people (1 in 7 people) in 2020.[5] Older adults are particularly at risk because of low income, mobility issues, dementia, and other factors such as social isolation. Food insecurity also disproportionately affects Black and Latinx households.[6] Malnutrition is also widespread in the United States.[7] Both food insecurity and malnutrition are associated with worse health outcomes and higher spending on healthcare.[Error! Bookmark not defined.] For example, adults who are malnourished at the time of hospitalization or surgery are more likely to have worse hospitalization, surgical, and recovery outcomes.[8] The improvement activity would fill a gap in the inventory, which does not currently include an improvement activity related to food insecurity or malnutrition. We believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, because ameliorating food insecurity and malnutrition leads to better health outcomes.[9] [10] This activity would create an opportunity for MIPS eligible clinicians to help address food insecurity and malnutrition, and provide the Malnutrition Quality Improvement Initiative as a resource.[11] Evidence indicates that they can help patients by increasing enrollment in the Supplemental Nutrition Assistance Program (SNAP) (https://www.fns.usda.gov/snap/supplemental-nutrition-assistance-program), which is associated with reduced food insecurity[12] or connecting their patients to other community resources. This activity also created an opportunity for MIPS eligible clinicians to help address malnutrition by ensuring patients in need receive a detailed nutritional assessment and appropriate nutritional care.