



September 10, 2021

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: CMS-1751-P; 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.**

Dear Administrator Brooks-LaSure:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 133,500 family physicians and medical students across the country, I write in response to the Calendar Year (CY) 2022 Medicare Physician Fee Schedule (MPFS) and Quality Payment Program (QPP) [proposed rule](#) as published in the *Federal Register* on July 23, 2021.

### General Comments

The AAFP commends the Centers for Medicare & Medicaid Services' (CMS') leadership and commitment to improving the Medicare program for all beneficiaries and improving access to high-quality, comprehensive, and coordinated care. We appreciate the agency's efforts to support primary care during the COVID-19 pandemic and long term. We look forward to working with CMS on designing and implementing policies that support these shared goals through both the MPFS and the QPP.

Our members are on the frontline of medicine, caring for patients of all ages with diverse needs – and they practice in all settings. More than 90% of family physicians accept Medicare – making them the foundation of care delivery for our health system. The recommendations we offer in this letter reflect our members' experiences caring for patients across the country and our goal to build a health system founded in family medicine and primary care that advances health equity, improves health, and reduces system costs.

In this letter, we provide detailed comments on the following high-priority areas, in addition to several other issues:

1. **The estimated CY 2022 conversion factor** – The AAFP is deeply concerned with the projected reduction in the CY 2022 conversion factor and its estimated impact on family medicine. We urge CMS to use its authorities to ensure the financial stability of family

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medicine practices, which will, in turn, ensure access to high-quality, comprehensive primary care for Medicare beneficiaries across the country.

2. **Telehealth** – We strongly recommend CMS add the telephone evaluation and management (E/M) codes to the Medicare telehealth services list on a Category 3 basis. The AAFP supports CMS' proposals to permanently cover audio/video and audio-only mental health telehealth visits for all Medicare beneficiaries.
3. **Employed physicians' experiences with the 2021 office/outpatient evaluation and management changes** – Employed family physicians report that their employers are not incorporating the 2021 office/outpatient E/M changes into their contracts, undermining the intended investment in primary care.
4. **Vaccine administration payment** – The AAFP recommends implementing the spring 2021 Relative Value Scale Update Committee's (RUC's) recommendations for vaccine administration payment codes in CY 2022. We recommend that CMS consider whether a more innovative payment methodology would more effectively capture the value of vaccinations and optimize vaccination rates for Medicare beneficiaries compared to the traditional cost-based payment methodology.
5. **Automatic application of the extreme and uncontrollable circumstances policy for the Merit-based Incentive Payment System (MIPS) 2021 performance period** – Given the recent surge in COVID-19 cases, the AAFP strongly urges CMS to apply the extreme and uncontrollable circumstances policy for the 2021 performance period. It is vital that family medicine and other physician practices focus on providing patient care during this time and not be required to comply with a burdensome MIPS reporting process.
6. **MIPS Value Pathways (MVPs)** – The AAFP is hopeful that MVPs can help physician practices transition out of fee-for-service (FFS) and reduce the administrative burden of MIPS reporting if they are designed and implemented appropriately. We recommend that CMS continue to work with physician groups to increase alternative payment model (APM) options for primary care practices and focus on reducing the burden of reporting within MVPs.

#### Changes in Relative Value Unit (RVU) Impacts

CMS notes that statutory budget neutrality requirements require them to make adjustments to preserve budget neutrality if the proposed changes result in the estimated amount of expenditures for the year to differ by more than \$20 million from what expenditures would have been absent these changes. Due to statutory requirements, there is no MPFS update adjustment factor for CY 2022. As a result, the estimated CY 2022 conversion factor is 33.5848, which is 3.75 percent lower than the CY 2021 conversion factor of 34.8931. The estimated reduction is attributable to congressional action, which applied a 3.75 percent increase in the CY 2021 conversion factor to address Medicare cuts amid the COVID-19 pandemic.

#### *AAFP Response*

The AAFP recognizes that the estimated reduction in the conversion factor and resulting payment reductions for CY 2022 are due to statutory requirements. Nonetheless, we are deeply concerned

that family medicine will face an estimated 1.6 percent reduction in allowed charges in CY 2022 due to the lower conversion factor. Family physicians have been serving on the frontline of a national pandemic and public health emergency (PHE) for a year and a half, and recent trends indicate the pandemic will continue. As a result, family medicine practices are facing ongoing financial strain as they absorb growing costs associated with personal protective equipment (PPE), as well as worsening staff shortages and physician burnout. The same practices are also implementing innovative workflows to catch patients up on routine immunizations, screenings, and other preventive services that were delayed during the pandemic. **Family medicine practices are a cornerstone of many communities, particularly those that are rural and underserved. Therefore, it is vital that these practices are adequately supported and can keep their doors open. We urge CMS to use its existing authorities to ensure the financial stability of family medicine practices, which, in turn, will provide access to high-quality, comprehensive primary care for Medicare beneficiaries across the country.**

CMS has several opportunities in the CY 2022 MPFS final rule to ensure primary care services are fairly valued under the MPFS and to help ensure the financial stability of primary care practices. For example, CMS should immediately implement the practice expense labor pricing updates; improve vaccine administration payments; accept the RUC recommendations for chronic care management (CCM) services; and take steps to ensure permanent coverage and payment of audio/video and audio-only telehealth services after the PHE. CMS should automatically apply the extreme and uncontrollable circumstances exception for the 2021 MIPS performance year; use its emergency authority to lower the performance threshold in future performance years; and make every effort to reduce the administrative burden under the MPFS and QPP.

Over the long term, the AAFP is concerned that the MPFS has failed to keep up with the pace of inflation. At the same time, Medicare payments for hospitals, skilled nursing facilities, hospital outpatient departments, and ambulatory surgery centers continue to benefit from annual updates. We are staunch supporters of transitioning to a value-based health care system and are concerned that the lack of positive updates to the MPFS, coupled with budget neutrality requirements, produce widespread underinvestment in high-quality primary care services and negatively impact APMs built on a FFS chassis. A lack of positive updates could also negatively impact access to high-quality care in FFS. Primary care practices, which operate on a thin financial margin, find Medicare an increasingly unviable financial model. Further, a lack of existing APMs is hampering physician practices from moving away from FFS, particularly for those primary care practices with limited experience in value-based payment models. Cutting primary care physicians' FFS payments under the MPFS when many lack appropriate APMs for them to move into threatens beneficiaries' access to care and undermines the intent of the Medicare Access and CHIP Reauthorization Act (MACRA).

#### Practice Expense RVUs (section II.B.)

CMS proposes a series of technical updates and changes to its practice expense RVU methodology and its data. Potentially most significant is CMS' proposal to update the clinical labor pricing for 2022 in conjunction with the final year of the supply and equipment pricing update. Clinical labor rates were last updated for 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources. CMS proposes to use the most current BLS survey data (i.e., 2019) as the main source of wage data for this proposal. CMS is considering the use of a four-year transition to implement the clinical labor pricing update. CMS notes that a multi-year transition could stabilize the fluctuations in payments caused by the pricing update for affected stakeholders and promote payment stability. However, CMS

also recognizes that a phased transition would delay the full implementation of updated pricing and continue to rely on, in part, outdated data for clinical labor pricing.

In this section, CMS solicits public comment to help it better understand the resource costs for services involving the use of innovative technologies, including, but not limited to, software algorithms and artificial intelligence (AI). In its solicitation, CMS asks the following questions:

- To what extent are services involving innovative technologies, such as software algorithms, AI substitutes, and/or supplements for physician work? To what extent do these services involving innovative technology inform, augment, or replace physician work?
- How has innovative technology, such as software algorithms and/or AI, affected physician work time and intensity of furnishing services involving the use of such technology to Medicare beneficiaries?
- How is innovative technology, such as software algorithms and/or AI, changing cost structures in the physician office setting? Do costs for innovative technology, such as software algorithms and/or AI, to furnish services to patients involve a one-time investment and/or recurring costs? How should CMS consider costs for software algorithms and/or AI that use patient data that were previously collected as part of another service? As technology adoption grows, do these costs decrease over time?
- How is innovative technology affecting beneficiary access to Medicare-covered services?
- Compared to other services paid under the MPFS, are services driven by or supported by innovative technology, such as software algorithms and/or AI, at greater risk of overutilization or more subject to fraud, waste, and abuse? To what extent do services involving innovative technology require mechanisms, such as appropriate use criteria to guard against overutilization, fraud, waste, or abuse?
- Compared to other services paid under the MPFS, are services driven by or supported by innovative technology, such as software algorithms and/or AI, associated with improved quality of care or improvements in health equity? Are there guardrails, such as removing the source of bias in a software algorithm and/or AI, that Medicare should require as part of considering payment amounts for services enabled by software algorithm and/or AI?

#### *AAFP Response*

The AAFP supports CMS' proposal to update the clinical labor pricing for 2022 using the most recent BLS data as the primary source. For all the reasons given by CMS in the proposed rule, we support this update and believe, after almost 20 years, that it's long overdue. This update will help ensure that CMS' practice expense RVU methodology better approximates the most current practice expenses incurred by family physicians.

**We encourage CMS to fully implement the update in the pricing of clinical labor in 2022 and not phase in the changes over four years.** As noted, clinical labor pricing is more than two decades old. The reality is that clinical labor is just a fraction of the direct practice inputs, which, in turn, are a fraction of total practice expenses, and practice expense RVUs are only a fraction of the total RVUs for most services. Further prolonging the necessary improvement in CMS' practice expense RVU methodology will result in additional, unnecessary delays for an already overdue pricing update. While the AAFP recognizes this update may negatively impact certain specialties and procedures, we note that the lack of pricing updates has likely disadvantaged family medicine for several years. Thus, CMS should implement the pricing update in CY 2022 to address the long-term negative impact on family medicine and other specialties. We strongly recommend CMS update clinical labor pricing more often to avoid these drastic impacts in the future.

Regarding the resource costs for services involving innovative technologies, including but not limited to software algorithms and AI, we would first observe that current levels of adoption of artificial intelligence/machine learning (AI/ML) solutions are minimal. AI/ML solutions deployed in the clinical domain function are very similar to current clinical decision support software. They may decrease the effort of collecting needed data for medical decision making or alert the clinician to a clinical situation. Still, they do not substantially change the level of clinical effort by the clinician. This is particularly true for primary care, which is largely made up of E/M services and includes cognitive work by the physician that will still need to occur even when an AI/ML solution is being utilized. We urge CMS to ensure that future efforts to pay for AI/ML solutions do not result in the devaluation of primary care. For those AI/ML solutions that provide a diagnosis, the clinician is still the liable party to ensure the accuracy of the diagnosis. Therefore, while the specific task (i.e., making the diagnosis) may change (i.e., verifying the accuracy of the AI/ML diagnosis prediction), the level of effort is likely not substantially changed. In the future, this may change as the AI/ML solutions improve and liability reform occurs.

AI/ML solutions are either vended solutions with associated fees or homegrown solutions that require significant capital and ongoing investment. In addition, some AI/ML solutions, namely computer vision or audio solutions, require specific hardware to be deployed. There are likely significant costs around interoperability and data quality. With either vended or homegrown solutions, there are ongoing costs in either fees or maintenance costs.

AI/ML solutions can increase either the capacity or capability in health care. Increasing capacity can allow for more services for beneficiaries and improved access by decreasing wait times. By increasing capabilities, it will enable beneficiaries to receive care at more locations.

The risk of overutilization and increased fraud, waste, and abuse can be lessened by focusing payment on AI/ML solutions offered by a patient's usual source of care. When an AI/ML solution is integrated into traditional practice, CMS has more options to combat fraud, waste, and abuse.

We agree with CMS' interpretation of the value of providing more capabilities to primary care through AI/ML. It will lead to improved patient access, higher quality, and lower total costs. We also agree with CMS' concern with the potential equity and fairness issues around AI/ML. As the health care system develops and adopts AI/ML solutions, work must be done to identify and limit bias and inequity in AI/ML. Eliminating bias and inequity requires resources. Therefore, CMS should consider how physicians and other clinicians will need to be reimbursed for activities that reduce bias and inequity when using AI/ML and work with other agencies to fund needed investments in representative data samples.

#### Telehealth and Other Services Involving Communications Technology (section II.D.)

CMS proposes to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. The purpose of this proposal is to allow for more time for evidence to be collected and submitted for permanent inclusion on the Medicare telehealth services list.

There were a number of services CMS added to the Medicare telehealth services list on an interim basis in response to the COVID-19 pandemic but have not been added to the Medicare telehealth services list on a Category 3 basis. As a result, coverage for these services, when provided via

telehealth, will end when the PHE ends. CMS solicits comments on whether any of the services added to the Medicare telehealth services list for the duration of the PHE should now be added to the Medicare telehealth list on a Category 3 basis to allow for additional data collection.

CMS proposes implementing telehealth mental health provisions enacted by the Consolidated Appropriations Act of 2021 (CAA). This includes removing geographic restrictions under section 1834(m) and adding the patient's home as an eligible originating site for telehealth services furnished for diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on, or after, the PHE for COVID-19.

The CAA prohibits payment for telehealth services furnished in the patient's home unless the physician or other practitioner furnishes an item or service in person within the six months before the first time they provide a telehealth service to the beneficiary. CMS proposes to make an ongoing requirement that the physician or practitioner must furnish an in-person service to the beneficiary within the six-month period before the date of any telehealth service to diagnose, evaluate, or treat a mental health disorder. The agency seeks comment on whether a different interval for in-person services may be appropriate. CMS seeks comment on whether the required in-person service could also be furnished by another practitioner of the same specialty and subspecialty within the same group as the practitioner who furnishes the telehealth service. CMS also seeks comment regarding the extent to which a patient routinely receiving mental health services from one practitioner in a group might have occasion to see a different practitioner of the same specialty for treatment of the same condition. Finally, CMS seeks comments on an alternative policy to allow the required in-person service to be furnished by a practitioner in the same specialty in the same group when the practitioner furnishing the telehealth service is unavailable, or the two professionals are practicing as a team.

CMS notes that telehealth services furnished for a diagnosed substance use disorder (SUD) or co-occurring mental health disorder – which also do not have geographic restrictions and for which the patient's home is an eligible originating site – do not have the same in-person requirements. CMS seeks comments on a claims-based mechanism to distinguish between these services and those permitted by the CAA, which have an in-person requirement.

CMS also proposes revising the regulatory definition of 'interactive telecommunications system' to permit the use of audio-only communications technology for tele-mental health services under certain conditions when provided to beneficiaries in their home. CMS also proposes to adopt an ongoing requirement that an in-person service must be furnished within six months of an audio-only mental health service. Payment would be limited to physicians or practitioners who have the capacity to furnish two-way audio-video telehealth services but provide the service via audio-only because the beneficiary is unable to use, does not wish to use, or does not have access to two-way audio-video technology. CMS proposes to create a service-level modifier to identify that these services were furnished to a beneficiary in their home using audio-only technology. CMS seeks comment on whether it should exclude certain higher-level services, such as level 4 or 5 E/M visit codes, from audio-only.

CMS seeks comment on whether the direct supervision flexibilities allowed under the COVID-19 PHE should be continued beyond the COVID-19 PHE or for CY 2021. The flexibility will enable physicians to meet the requirements for direct supervision (required for certain diagnostic tests and services furnished incident to physician services and other services) by being immediately available through a virtual presence using real-time audio/video technology instead of their physical presence. The

agency seeks comments on whether this flexibility should be made permanent for all or some subset of services.

Finally, CMS proposes to permanently adopt coding and payment for Healthcare Common Procedure Coding System (HCPCS) code G2252 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion*).

### *AAFP Response*

The AAFP supports the proposal to retain services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. We agree this extension will allow more time for CMS and stakeholders to collect information regarding the utilization of these services during the COVID-19 pandemic and collate evidence and other supporting documentation to apply for permanent addition to the Medicare telehealth services list.

**We strongly recommend CMS add the telephone E/M codes (CPT 99441-99443) to the Medicare telehealth services list on a Category 3 basis.** Audio-only telehealth services have been crucial to improving equitable access to care during the PHE and warrant inclusion on a Category 3 basis. In September 2020, after using telehealth for several months due to the pandemic, more than 80% of family physicians responded to an AAFP survey indicating they were using phone calls to provide telehealth services. Together with ongoing reports from physicians that phone calls are vital to ensuring access for many patients, this survey data indicates that phone calls are more accessible for many patients compared to video visits. This may be particularly true for Medicare beneficiaries. According to the Pew Research Center, only about 61 percent of patients over 65 years own smartphones, while 92 percent own any type of cell phone.<sup>1</sup> As CMS notes in the proposals for tele-mental health services, many beneficiaries may prefer audio-only services, while others may lack the necessary broadband connectivity needed for video visits. Abruptly ending payment for audio-only telephone services at the end of the PHE will exacerbate access disparities for Medicare beneficiaries without smartphones and poor broadband connectivity. Similar to other services added via Category 3, stakeholders will need more time to collect data and evidence on the importance and quality of audio-only telehealth visits after the PHE. Thus, the AAFP strongly opposes the proposal to end payment for the telephone E/M codes at the end of the PHE.

We note that adding services to the Medicare telehealth services list on a Category 3 basis is only an interim solution and encourage CMS to consider how to permanently ensure coverage of, and payment for, audio-only services. The AAFP is pleased that CMS proposed to change the definition of 'interactive telecommunications system' for audio-only mental health services. We strongly agree that CMS has the authority to change the definition and encourage CMS to modify the definition to allow for audio-only interactions for other types of audio-only services. The term 'interactive telecommunications system' is not defined under section 1834(m) of the Social Security Act as requiring both audio and visual capabilities, but rather it is defined at 42 CFR 410.78 as "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner." The AAFP requests that CMS promulgate an interim final rule with comment to amend the definition of 'telecommunications system' in 42 CFR 410.78 to allow for audio-only services. Even

if CMS moves to waive the video component of a telehealth visit, without Congressional action amending the originating and geographic site restrictions under section 1834(m) of the Social Security Act, Medicare beneficiaries in non-rural areas will not be able to access these visits once the COVID-19 PHE ends.

The AAFP supports proposals to remove geographic restrictions and add home as an originating site for tele-mental health services. We believe the permanent expansion of tele-mental health services will improve access to mental and behavioral health care for beneficiaries, many of whom may struggle to access these services easily in their community.

We do not support the proposal to require an in-person service to be provided within six months of a telehealth mental health service. While we recognize the CAA requires an in-person service to be provided before a physician or other practitioner can furnish the *first* mental health telehealth visit, Congress did not make this an ongoing requirement, and existing evidence does not support the need for such an ongoing requirement for mental health services. We oppose arbitrary in-person service requirements for mental health services.

If CMS chooses to institute an ongoing in-person service requirement to safeguard program integrity, we recommend that another practitioner of the same specialty within the same group should be able to furnish the required in-person service. This would be consistent with Medicare's existing policy for an established patient relationship. The proposed six-month requirement for in-person services would create unnecessary barriers to accessing vital mental health services since access to mental health practitioners in beneficiaries' communities is disparate. Therefore, should CMS insist upon implementing an ongoing in-person requirement, we recommend lengthening the interval for the required in-person service. Since the Medicare definition for an established patient involves a three-year period, we recommend adopting the same time period for this in-person service requirement. The AAFP recommends against an arbitrary six-month, in-person service requirement for mental health services and urges CMS to defer to individual clinicians' judgment on how often in-person services are needed.

**The AAFP strongly supports the proposal to change the definition of 'interactive telecommunications system' and allow audio-only technology for tele-mental health services.**

We agree that maintaining Medicare coverage of audio-only telehealth services is essential to ensuring equitable access to mental health care after the PHE. Many Medicare beneficiaries do not have access to broadband or video technology in their homes, while others prefer audio-only services for various reasons. As stated above, the AAFP does not support arbitrary in-person visit requirements for mental health services provided via telehealth, including audio-only technology.

The AAFP supports requiring most physicians or practitioners providing the audio-only service to have the capability to offer it via synchronous audio/video technology, though exceptions may be needed due to issues with broadband connectivity. We believe physicians should be able to attest to meeting this requirement using a basic electronic health record (EHR) check-box functionality. We recommend against requiring additional documentation beyond this type of check-box attestation to minimize additional administrative burdens for physicians.

While the AAFP agrees the physician or practitioner should be able to provide the service via synchronous audio/video technology, an exception to this requirement may be needed when



physicians experience broadband connectivity issues. Many family physicians practice in rural and remote areas and may experience somewhat regular interruptions in their broadband connection. CMS should include an exception to this requirement to ensure that broadband interruptions do not continually result in postponed visits. Specifically, the exception would apply to instances when a physician cannot offer a video visit due to a connectivity issue *as long as the physician serves as the patient's usual source of care*. We believe that limiting this connectivity exception to a patient's usual source of care provides adequate safeguards for program integrity and quality of care.

We recommend against excluding higher-level services, such as level 4 or 5 E/M services. Diagnosing, evaluating, and treating patients experiencing a mental health crisis or those with multiple mental health conditions may require significant time and/or a high level of medical decision making. These patients may also benefit most from being able to access an audio-only service. Excluding higher-level services will result in unnecessary barriers to care.

The AAFP recommends that CMS permanently allow physicians to meet the requirements for direct supervision by being immediately available through a virtual presence using real-time audio/video technology instead of their physical presence. We believe this flexibility has improved access to care during the COVID-19 PHE, particularly in rural areas, and would continue to do so after the PHE ends. The AAFP previously wrote to CMS requesting that the agency modify direct supervision requirements for certain services to ensure access to care in rural areas.

While CMS did not include a proposal related to virtual supervision for a teaching physician, the AAFP again recommends payment for the teaching physician's virtual presence through audio/video real-time technology for telehealth services is made permanent policy. We are pleased that CMS finalized regulations in the CY 2021 MPFS to allow teaching physicians to meet the requirements to bill for teaching services through a virtual presence when supervising residents furnishing services in rural areas. This also applies to the provision of Medicare telehealth services. The AAFP recommends applying this policy for all teaching physicians, regardless of geographic location. We believe this flexibility will help ensure access to comprehensive mental health care should tele-mental health services be covered for all beneficiaries after the PHE.

We appreciate CMS' efforts to continue promoting access to telehealth services. As stated above and shared [previously](#), family physicians report that continued coverage of audio-only telehealth services is critical to ensuring equitable access to care. However, code G2252 does not adequately capture the physician work performed during audio-only visits. Family physicians report that audio-only visits require the same level of medical decision making as an audio/video or in-person service. We are further concerned that CMS opted to create a new, largely duplicative code that will increase confusion and administrative burden for family physicians. The AAFP continues to have these concerns about permanently adopting coding and payment for G2252. We want to emphasize that **permanently adopting this code should not be considered a permanent solution to covering audio-only services.**

Valuation of Specific Codes (section II.E.)

CMS proposes the valuation of multiple new or revised Current Procedural Terminology (CPT) and HCPCS codes for 2022. Of most interest to family physicians are CMS' proposals related to CCM and principal care management (PCM) codes. Specifically, CMS proposes to accept the work RVUs and direct practice expense inputs recommended by the RUC for all these codes.

In addition to the proposals on the values for CCM codes, CMS is interested in understanding more about the standard practice used to obtain beneficiary consent for these services and how different levels of supervision impact this activity. During the COVID-19 PHE, CMS has allowed clinicians to obtain beneficiary consent for certain services under general supervision. Before the COVID-19 PHE, CMS required beneficiary consent to be obtained either by, or under the direct supervision of, the primary care practitioner – consistent with CMS' conditions of payment for this service under the MPFS. CMS is interested in understanding how billing practitioners furnishing CCM at different service sites (e.g., physician office settings, Rural Health Centers [RHCs], Federally Qualified Health Centers [FQHCs]) have been obtaining beneficiary consent during the past year and how different levels of supervision impact this activity. CMS seeks comment on levels of supervision necessary to obtain beneficiary consent when furnishing CCM services.

CMS also solicits comments on the impact of infectious diseases on codes and rate setting. This includes the types of resource costs that may not be fully reflected in payment rates for existing services and additional strategies to account for PHE-related costs, including feedback on the specific types of services and costs that may benefit from further reviews, such as infectious disease control measures, research-related activities and services, or PHE-related preventive or therapeutic counseling services. CMS is interested in detailed feedback from stakeholders to inform them whether they should consider changing payments for services or developing separate payments for such services in future rulemaking.

CMS solicits comments on whether it should consider creating separate coding and payment for medically necessary activities involved with chronic pain management and achieving safe and effective dose reduction of opioid medications when appropriate, or whether the resources involved in furnishing these services are appropriately recognized in current coding and payment. Specifically, CMS is interested in feedback regarding whether the resource costs involved in furnishing the following activities would be best captured through an add-on code to be billed with an E/M visit or a stand-alone code:

- Diagnosis
- Assessment and monitoring
- Administration of a validated rating scale(s)
- Development and maintenance of a person-centered care plan
- Overall treatment management
- Facilitation and coordination of any needed behavioral health treatment
- Medication management
- Patient education and self-management
- Crisis care
- Specialty care coordination, such as complementary and integrative pain care and SUD care
- Other aspects of pain and/or behavioral health services, including care rendered through telehealth modalities

To price such a code, CMS might consider using a crosswalk to the valuation and inputs for reference codes such as:

- CPT code 99483 (Assessment of and care planning for a patient with cognitive impairment)
- HCPCS code G2064 (Comprehensive care management services for a single high-risk disease, e.g., principal care management, at least 30 minutes of physician or other qualified health care professional time per calendar month)
- HCPCS code G0108 (Diabetes outpatient self-management training services, individual, per 30 minutes)

CMS also seeks comment on whether any components of the service could be provided 'incident to' the services of the billing physician who is managing the beneficiary's overall care, like the structure of the Behavioral Health Integration (BHI) codes. BHI codes can include services that are not delivered personally by the billing practitioner and delivered by other members of the care team (except the beneficiary), under the direction of the billing practitioner on an incident to basis, subject to applicable state law, licensure, and scope of practice.

CMS also seeks information on which health care settings and stages in treatment transitions from opioid dependence are occurring, as well as what types of practitioners furnish these services.

#### *AAFP Response*

The AAFP appreciates and supports CMS' proposal to accept the work RVUs and direct practice expense inputs recommended by the RUC for all the CCM and PCM codes. We agree with CMS that accepting these updated values is consistent with their goals of ensuring continued and consistent access to these crucial care management services and further addresses CMS' longstanding concern about the undervaluation of care management under the MPFS.

In the context of CCM, we note that CMS proposes to maintain code G0506 (Comprehensive assessment of and care planning for patients requiring chronic care management services (list separately in addition to primary monthly care management service)). CMS created this code as part of the 2017 MPFS to describe the work of initiating CCM services at a comprehensive E/M visit, an Annual Wellness Visit (AWV), or an Initial Preventive Physical Exam (IPPE) (i.e., "Welcome to Medicare" visit). Since the finalization of G0506 for the 2017 payment year, there have been subsequent changes to the CCM code family, such as the establishment of code 99491 (Chronic care management services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored). The physician work described by code G0506 may also be described by code 99491. Given this possibility and the current revaluation of the CCM codes, we question whether there is an ongoing need for code G0506 and suggest CMS consider deleting it.

**We would observe that CCM is best provided in a team-based approach. Therefore, the process of obtaining consent for CCM should reflect that.** How this looks and works will vary, depending on the size and sophistication of the practice or larger organization to which the practice belongs. For instance, in an independent primary care medical home, patients are identified as candidates for CCM through a team-based risk stratification process. While the physician, patient,

and care management team within the practice collaborate to create a plan of care with patient-directed goals and tasks for both patient and practice, the initial consent for this program is just as well explained and obtained by team members under *general* supervision as it is by the physician or under the physician's *direct* supervision.

In a large, urban medical center, physicians refer patients to social work for CCM enrollment and consent consideration. A referral would include reasons substantiating the need for services. A social worker would then conduct a phone call regarding CCM enrollment and eligibility, explaining that social work support is still available without CCM. If the patient consents to CCM, an order is made, and details are shared with the primary care physician, who must cosign. As in the independent practice described above, all work is coordinated and under the general supervision of the primary care physician with further reinforcement by the primary care physician at subsequent visits with the patient. The result of this workflow is that the physician is still very involved, but a face-to-face or even direct/prolonged conversation is not required to enroll and effectively coordinate CCM services.

As such, the AAFP does not believe that consent for team-based CCM service should only be obtained by the physician or under the physician's direct supervision. Trying to force the team-based approach of CCM into a FFS model has contributed to the inefficiency and administrative burden of the current CCM program. Instead, we recommend CMS allow practices to enroll patients with consent obtained by the care coordinator, the physician, or any other member of the care team under general supervision.

In our comments on the CY 2021 MPFS [proposed](#) and [interim final](#) rules, the AAFP strongly recommended that CMS recognize the additional costs physician practices incur to protect their staff and patients from COVID-19. **A year later, as family medicine practices confront a significant surge in COVID-19 cases and an even more transmissible variant, the costs associated with PPE, social distancing, and proper cleaning of equipment and patient rooms are only increasing.** For example, the Occupational Safety and Health Administration (OSHA) recently finalized additional safety [requirements](#) for physician practices to protect health care workers against COVID-19. **Compensating physician practices for these costs is essential to ensuring they can remain open and care for patients during this national emergency, particularly as practices face reductions in Medicare payment rates in CY 2022.**

In September 2020, the CPT Editorial Panel created code 99072 (Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease.) Also, in September 2020, the RUC made recommendations to CMS on the direct practice expense inputs for this new code.

The code and its recommended inputs were intended to address the issues CMS is now soliciting input. Instead of paying for 99072 and the PHE-related costs it represented, CMS chose to designate the code as 'bundled' on the premise that payment was already included in other services paid under the MPFS.

We remain disappointed CMS effectively declined to compensate physician practices for the additional clinical staff time and supplies they used to keep their patients and themselves safe during the PHE. The AAFP is still concerned about the ramifications of this decision as physician practices

continue to report significant financial strains, as well as the added threat of COVID-19 variants that are more readily transmissible and currently causing a dramatic surge in cases.

Comparing the practice expense inputs recommended for code 99072 and those already included in other services illustrate why CMS' decision to bundle code 99072 was inappropriate. For instance, consider code 99072 in comparison to code 99213, a common office visit:

- Code 99072 includes a three-minute, pre-visit phone call by clinical staff to screen the patient (symptoms check) and provide instructions on social distancing during the visit. Code 99213 does not; the only pre-visit clinical staff time is four minutes to identify the need for imaging, lab, other test result(s), and ensure the information has been obtained.
- Code 99072 includes one minute of clinical staff time to do a temperature check when the patient arrives (often in the parking lot), which was not anticipated when CMS allocated five minutes of clinical staff time to code 99213 to obtain vital signs in the exam room.
- Code 99072 includes two minutes for clinical staff to don PPE, which was again not anticipated when CMS allocated two minutes for 99213 to prepare the room, equipment, and supplies. Saying the two minutes allocated to 99213 covers the two minutes needed to don PPE means CMS is no longer compensating practices for the other time needed to prepare the room, equipment, and supplies for the visit.
- Code 99072 includes five minutes of clinical staff time for cleaning the room and equipment, while code 99213 only includes three minutes for that function. How payment for three minutes compensates for five minutes (which is really five additional minutes reflecting the extra time needed to disinfect under the PHE) is unclear.
- Code 99072 includes three surgical masks, reflecting the fact the physician/qualified health professional, patient, and clinical staff person all need one during the encounter; code 99213 includes none.
- Code 99213 includes one sanitizing cloth wipe for purposes of cleaning surfaces, instruments, and equipment in the exam room. Recognizing one cloth wipe is insufficient to clean and disinfect an entire exam room, code 99072 includes additional cleaning supplies.

CMS has taken many positive steps to support practices in this regard over the past year and a half. **We urge CMS to continue these efforts by making code 99072 an active code (Status A) under the MPFS and paying appropriately for it, based on the recommendations of the RUC and others.**

Lastly, we are overall supportive of the concept of separate coding and payment for CCM to demonstrate complexity of care. Patients with chronic pain and an opioid use disorder (OUD) are complex cases requiring a lot of time for correct dosing and counseling. That time is currently not captured effectively using existing E/M codes, even when it is time-based. Separate coding and payment for chronic pain management would potentially:

- Encourage comprehensive pain management among primary care physicians
- Help with stratifying utilization and demonstrating the need for this service via data that is lost if the service is reported with existing visit codes
- Allow for independent valuation of the resources involved, which enhances the likelihood of appropriate payment for non-face-to-face time involved with this work
- Allow for different parameters than standard visits in terms of incident-to billing and treatment locations

- Allow for reporting of a substance use intervention, in addition to a standard E/M, since the reality is that they are separate services often carried out in one prolonged visit (including home or virtual settings)

As CMS contemplates aligning coding and payment for CCM with better value, we would encourage them to think beyond traditional FFS models. Instead, consider a mechanism that might offer a bundled per patient, per month payment, utilizing the code or another value-based payment that aligns with a patient-centered process. There are a variety of state-level mandates for managing and monitoring controlled substances. Often, these requirements include work between visits not captured in existing E/M codes (e.g., checking of prescribing databases). A bundled payment may better capture this work between visits. There are also varying requirements among states for who performs all the work and how it is performed. The physician should be involved closely but not necessarily required to do every task. Pursuing CCM using a team-based approach supported by a bundled payment makes more sense and still allows compliance with state requirements.

The AAFP appreciates CMS taking steps to ensure that CCM services are adequately valued under the MPFS. We agree that primary care physicians may not be appropriately paid for this important but complex service they provide regularly. **We encourage CMS to continue taking steps to ensure that advanced primary care services, like this one, are fairly valued under the MPFS and, therefore, are more accessible to Medicare beneficiaries.** While establishing payment for CCM is an important first step, it will also be vital for CMS to implement an [add-on code](#) to account for complex E/M visits as finalized in the CY 2021 MPFS final rule.

Regarding 'incident-to' billing, it can ease the burden on the physician and is consistent with team-based care provided in most primary care practices. AAFP policy on [Payment, Non-Physician Providers](#) states, "Services delegated to, and provided by, non-physician providers under physician supervision must be provided with the same quality and should be reimbursed at the same level as services directly provided by a physician." Accordingly, the AAFP supports 'incident-to' billing under Medicare and believes components of CCM could be provided 'incident to' the services of the billing physician who is directly supervising the clinical staff and managing the beneficiary's overall care.

We have a concern with linking separate coding and payment for CCM to safe and effective dose reduction. We fear that, if not done right, it may lead to a 'one-size fits all' mentality and unintended consequences to patient care, which we saw with the Centers for Disease Control and Prevention's (CDC's) Guideline for Prescribing Opioids for Chronic Pain (although we understand CDC is updating this guideline to undo some of that damage).

As CMS contemplates whether to create separate coding and payment for CCM, we offer the following additional thoughts for its consideration:

- Be cautious about standardizing diagnosis coding associated with any new service codes. For instance, a specific requirement to list diagnosis code G89.4 (Chronic pain syndrome) could be inadvertently triggering or traumatizing to the patient by affecting the bias of people they interact within the health care system as compared to providing physicians with directions to simply use a better or more accurate description of their pain or a cause, if known.
- Administering a validated rating scale(s) is often already done in practices. It would probably be best for CMS not to specify the scale(s) that must be used in this regard.
- Developing and maintaining a person-centered care plan is a worthwhile idea that contributes to health equity and potentially removes the risk of forced tapering. If CMS pursues this, we

recommend they clearly outline the associated documentation requirements and ensure they are not so onerous as to disincentivize the use of these new codes.

- Facilitating and coordinating needed behavioral health treatment is critically important. CMS needs to recognize that counseling services delivered by family physicians should be part of this and not just referral to behavioral health facilities, particularly in rural settings where access is limited.
- It's important to include telehealth modalities and encompass telehealth communication and activities between visits. However, CMS must carefully consider the implications of any required patient cost sharing for services between visits, making CCM less palatable for practices caring for communities affected by lower socioeconomic status.
- Allow for submission of a code for CCM on the same date as an E/M service. Otherwise, comprehensive care is discouraged. If a patient is seen for a multi-problem encounter (not related to pain syndrome or an OUD), separately capturing the additional physician and team resources is important. While a separate encounter may seem logical, it isn't patient centered (e.g., because it requires more missed work) nor efficient in utilization of resources (e.g., redundant check in, insurance verification, scheduling, and appointment confirmation).

We appreciate that CMS is considering separate coding and payment for CCM and support the concept in general. We look forward to working with CMS to make it a reality through future rulemaking.

#### Evaluation and Management Visits (section II.F.)

CMS proposes policy changes related to split (or shared) visits by a physician and a non-physician provider (NPP) in the same group. CMS proposes:

- To define a split (or shared) visit as an E/M visit in the facility setting (i.e., an institutional setting in which payment for services and supplies furnished incident to a physician's or practitioner's professional services is prohibited by regulation) that is performed in part by both a physician and an NPP who are in the same group
- To require a split (or shared) visit be furnished in accordance with applicable law and regulations, including conditions of coverage and payment, such that the E/M visit could be billed by either the physician or the NPP if it were furnished independently by only one of them in the facility setting
- To allow split (or shared) visits to be reported for new and established patients (as well as initial and subsequent visits) and for critical care and certain skilled nursing facility/nursing facility (SNF/NF) E/M visits (i.e., those not required to be performed in their entirety by a physician)
- To allow only the physician or NPP who performs the substantive portion of the split (or shared) visit to bill for the visit
- To define 'substantive portion' as more than half of the total time spent by the physician and NPP performing the visit
- That the distinct time of service spent by each physician or NPP furnishing a split (or shared) visit would be summed to determine the total time and who provided the substantive portion (and therefore bills for the visit), consistent with the CPT E/M guidelines
- That the same listing of activities in the CPT E/M guidelines will define what can count toward total time for purposes of determining the substantive portion for visits that are not critical care services; CMS proposes a different listing of qualifying activities for split (or shared) critical

care services and seeks public comment on whether there should be yet a different listing of qualifying activities for purposes of determining the total time and substantive portion of split (or shared) emergency department visits

- To allow a practitioner to bill for a prolonged E/M visit as a split (or shared) visit
- That documentation in the medical record must identify the two individual practitioners who performed the visit and that the individual who performed the substantive portion (and therefore bills the visit) would be required to sign and date the medical record
- To create a modifier to describe split (or shared) visits and to require the modifier be appended to claims for split (or shared) visits, whether the physician or NPP bills for the visit

CMS does not propose to define 'group' for purposes of split (or shared) visit billing in this rule but does note that it considered several options, such as:

- Requiring that the physician and NPP must be in the same clinical specialty
- Aligning the definition of 'group' with the definition of 'physician organization' at 42 CFR 411.351 (related to the physician self-referral law)
- Considering physicians and NPPs with the same billing tax identification number (TIN) as being in the same group, although this approach may be too broad in multi-specialty groups or health care systems that include many physicians and NPPs who do not typically work together to furnish care to patients in the facility setting

CMS also proposes policy changes that would impact payment for teaching physicians' services. Specifically, CMS proposes that:

- When total time determines the office/outpatient E/M visit level, only the time that the teaching physician was present can be included.
- Under the primary care exception, only medical decision making can be used to select office/outpatient E/M visit level.

#### *AAFP Response*

Before addressing what CMS proposes related to E/M visits, we want to alert CMS to a situation that is otherwise thwarting changes CMS made to the RVUs of E/M office/outpatient visits in the 2021 MPFS. Specifically, in the 2021 fee schedule, CMS adopted increased RVUs for office/outpatient E/M visit codes 99202-99215. The AAFP and others anticipated this increase in value would benefit primary care physicians and the patients they serve, since codes 99202-99215 often comprise the most common services provided by such physicians.

Unfortunately, we increasingly hear this is not the case. **Most family physicians are employed physicians<sup>a</sup>, and many of their employers are not reflecting the increased RVUs or Medicare payment allowances in their employment contracts.** Instead, the employers keep their employed physicians' contracts at 2020 levels and pocket the increased Medicare payments for codes 99202-99215 or using those payment increases to offset decreases elsewhere in the fee schedule. On top of that, many private payers are taking advantage of multi-year contracts with physician practices to delay or avoid increasing the value of codes 99202-99215 until current contracts come up for renewal. **Consequently, the increased investment in primary care expected from the 2021 E/M code revaluation has not materialized in many cases.**

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<sup>a</sup> According to the AMA Physician Practice Benchmark Survey found that family physicians are more likely to be employed than any other specialty, with 58.3 percent of family physicians being employed. See page 13 of [the report](#) to compare the rates of employment across specialties.



We understand physicians' contracts with private payers and the organizations that employ physicians are outside of CMS' purview. However, we believe it's important for CMS to know what is happening in this regard as it considers additional efforts to support primary care. **The AAFP urges CMS to use the tools at its disposal, including rulemaking and sub-regulatory guidance, to help ensure the 2021 E/M RVU increases are passed down to primary care physicians.**

The AAFP generally supports the CMS proposal regarding split (or shared) visits in the facility setting. We appreciate that CMS is broadening its perspective regarding such visits (e.g., by allowing them for new and established patients). We also appreciate that CMS' proposals otherwise leave its current policies related to 'incident-to' billing intact. The [AAFP's policy](#) states that services delegated to, and provided by, NPPs under physician supervision must be provided with the same quality and should be paid at the same level as services directly provided by a physician. What CMS proposes with respect to split (or shared) visits seems consistent with this policy (e.g., by requiring the physician and NPP to be part of the same group).

We also appreciate that CMS proposes to use the same listing of activities in the CPT E/M guidelines to define what can count toward total time to determine the substantive portion for visits that are not critical care services. The AAFP [agrees](#) that CPT describes the services that physicians provide and that inclusion of a service in CPT reflects contemporary medical practice. CMS policy consistent with CPT E/M guidelines avoids unnecessary administrative complexity and burden, of which there is already plenty under the MPFS. As to whether there should be a different listing of qualifying activities for purposes of determining the total time and substantive portion of split (or shared) emergency department visits, we think the CPT list looks good and the exceptions are reasonable, understanding time is not a component in the emergency department setting. We endorse the application of the list given for emergency department visits.

Like CMS, we do not believe the lack of a definition for 'group' in this context is problematic. To the extent CMS is considering possible definitions, we would encourage it not to adopt one requiring that the physician and NPP be in the same clinical specialty. Such a definition could be problematic in primary care groups where physicians and NPPs in multiple clinical specialties (e.g., family medicine, general internal medicine, general pediatrics) work together to deliver primary care services to Medicare beneficiaries and other patients.

The definition of 'physician organization' at 42 CFR 411.351 is also problematic. That definition is "a physician, a physician practice, or a group practice that complies with the requirements of § 411.352." Those requirements are extensive. While they may be pertinent for implementing the physician self-referral law, they are overly prescriptive and burdensome when implementing policy on split (or shared) visits. The requirements at 42 CFR 411.352 also have the disadvantage of requiring a group practice to have at least two physicians who are members of the group (whether employees or direct or indirect owners), which would prohibit groups with a solo physician from taking advantage of split (or shared) visits. Many rural practices involve a solo physician with one or more NPPs who provide care in institutional settings, such as the local hospital or nursing facility, as well as the office. Defining a 'group' in the same manner as a 'physician organization' at 42 CFR 411.351 would effectively prohibit such practices from leveraging split (or shared) visits to care for their patients, thereby creating another barrier to care for rural and other patients served by solo practices. The AAFP recommends against adopting this definition for a group.

Of the possible definitions referenced in the proposed rule, the one equating a 'group' with a single TIN is the most appealing in its clarity and simplicity. As CMS notes, a TIN may represent multi-specialty groups or even health care systems that employ physicians and NPPs who do not typically work together. However, we doubt the typical physician in any group is likely to split (or share) a visit with an NPP in which the physician does not have clinical confidence, especially where the physician has assumed responsibility for the visit by billing it under their billing number. A broad definition of 'group' would give practices that needed flexibility to implement the type of team-based care that is otherwise the impetus for what CMS is proposing related to split (or shared) visits.

The last point on which we wish to comment regarding split (or shared) visits is the proposal to create a modifier to describe split (or shared) visits and to require the modifier be appended to claims for such visits, whether the physician or NPP bills for the visit. As noted in the proposed rule, CMS cannot currently identify through claims that a visit was performed as a split (or shared) visit, which means CMS could know a visit was performed as a split (or shared) visit only through medical record review. CMS believes it is important for program integrity and quality considerations to have a way to identify who is providing which E/M services and how often Medicare is paying at the physician rate for services provided in part by NPPs. If finalized, CMS argues the proposed modifier would give them insight – directly through its claims data instead of only through medical record review – into the specific circumstances under which these split (or shared) visits are furnished. CMS claims that such information would be helpful to them in considering whether it needs to offer additional clarification to the public or further revise the policy for these E/M visits in future rulemaking.

**We strongly disagree with this proposal.** The arguments CMS uses in support of this proposal could also be applied to E/M services provided in the global period of procedural services, but CMS has not proposed to require a similar modifier to identify who is providing those E/M visits. CMS references program integrity concerns but does not cite any Office of Inspector General, Government Accountability Office, or other reports that reference split (or shared) visits as a program integrity concern, nor are we aware of any such reports. Likewise, CMS references an interest in quality considerations but does not describe those considerations or how collecting this data via claims will address them. In short, CMS' proposal to create a modifier to describe split (or shared) visits and to require the modifier be appended to claims for such visits (whether the physician or NPP bills for the visit) amounts to another unnecessary administrative requirement for physician practices that the new E/M coding guidelines were designed to alleviate. We urge CMS not to finalize this proposal.

Regarding the proposals related to teaching physicians' services, we agree that both proposals are reasonable. More specifically, to the proposal that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included. We observe that the proposal is consistent with the fact that resident time is generally considered to be paid through Medicare's graduate medical education (GME) funding. We appreciate there is an opportunity for the teaching physician to bill for time. Sometimes, that is significant, so it's an important option for teaching physicians. To the proposal that, under the primary care exception, only medical decision making can be used to select the office/outpatient E/M visit level, this makes sense to us, too, in that the medical decision making should drive the visit level selection in such situations.

The AAFP continues to support CMS' decision to refrain from applying the CY 2021 E/M RVU increases to the global surgical packages. Based upon analyses from RAND and the Medicare Payment Advisory Commission, as well as ongoing concerns from the Health and Human Services

(HHS) Office of Inspector General, we do not believe it would be appropriate to adjust the E/M components of the global surgical packages until ongoing questions about the global periods are addressed. For instance, RAND's analysis of post-operative visit data collected through claims found that most procedures with 10-day global periods did not have an associated post-operative visit. For procedures with 90-day global periods, RAND found the ratio of observed-to-expected post-operative visits provided was only 0.39. Until verifiable, third-party data provides a clear justification for including E/M codes in the global period. We strongly support CMS' decision not to apply the E/M increases to the global packages.

#### Billing for Physician Assistant Services (section II.G.)

CMS proposes to implement a provision in the CAA that removes the requirement to make payment for physician assistant (PA) services only to the employer of the PA, effective January 1, 2022. This will allow PAs to bill the Medicare program and be paid directly for their services in the same way nurse practitioners (NPs) and clinical nurse specialists (CNSs) do. PAs will also be able to reassign their rights to payment and may choose to incorporate as a group and bill the Medicare program. This proposal does not change the PA benefit category, Medicare payment percentage, or the requirement for PA services to be performed under physician supervision.

#### *AAFP Response*

The AAFP opposes this proposal. We believe that PAs and other NPPs are an integral part of a physician-led care team. The AAFP [supports](#) third-party payment for services of a PA, in which PAs and physicians deliver care in integrated practice arrangements with payment for the PA's services being provided to the employer of the PA. While we recognize this proposal does not modify the requirement for PA services to be performed under physician supervision, we are concerned that allowing direct payment and permitting PAs to incorporate as a group could undermine the quality of care for Medicare beneficiaries.

#### Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests (section II.I.)

Currently, beneficiaries are not required to pay Part B coinsurance for planned colorectal cancer screening tests recommended by the U.S. Preventive Services Task Force with a grade of A or B. However, any additional diagnostic procedures performed that day, like removing tissue if polyps are found, are billed to the beneficiary at 20 or 25 percent of the cost, depending on the setting. In accordance with the CAA, CMS is proposing phase beneficiary coinsurance requirements when a planned colorectal cancer screening test requires a related procedure, including the removal of tissue or other matter, furnished in connection with, as a result of, and in the same clinical encounter as the screening test. Beginning on January 1, 2022, CMS will pay 80 percent for these services, with the percentage increasing over several years until Medicare pays 100 percent in 2030 and thereafter.

#### *AAFP Response*

The AAFP [strongly supports](#) minimizing cost sharing for patients, especially when costs may be unknown before a procedure. Cost-sharing requirements create barriers to care for many patients and may cause them to forgo needed services. The AAFP is pleased CMS is implementing this

change to phase out cost sharing for same-visit colorectal screening and associated procedures. We recommend CMS finalize this proposal.

#### Vaccine Administration Services (section II.J.)

In the proposed rule's preamble, CMS notes that vaccine administration services are not technically valued or paid under the MPFS since they are not included within the statutory definition of physicians' services. CMS has historically based payment rates for the administration of preventive vaccines by suppliers based on an evaluation of the resource costs involved in furnishing the service, similar to the methodology CMS uses to establish payment rates under the MPFS.

CMS has historically established payment rates for vaccine administration services under the MPFS based on a direct crosswalk to CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular). Because CMS finalized reductions in the valuation for that code in 2018 and because the reductions in overall valuation have been subject to the multi-year phase in of significant reductions in practice expense (PE) RVUs, the payment rate for the vaccine administration codes has been concurrently reduced. Payment for vaccine administration has decreased by more than 30 percent since 2015. In 2015, the national payment rate for these services was \$25.51, while in 2021, the national payment rate is \$16.94.

To support the development of an accurate and stable payment rate for preventive vaccines, CMS seeks comment on several questions related to the cost of routine and COVID-19 vaccine administration in various settings.

#### *AAFP Response*

The AAFP appreciates CMS continuing to acknowledge that payment for vaccine administration services has decreased substantially in recent years and is no longer adequate. Adequate payment rates are an important strategy for improving access to, and utilization of, recommended immunizations. In a July 2021 AAFP survey, family physicians reported that vaccine payment rates impact their ability to offer vaccinations in their practice. Survey respondents indicated that counseling time for routine immunizations has increased in recent years, further increasing routine immunization costs.

Primary care practices continue to provide the majority of vaccinations to Medicare beneficiaries and, therefore, are essential to improving access to, and utilization of, recommended vaccines. A recent study reviewed 2017 Medicare Part B FFS data and the Medical Expenditure Survey.<sup>2</sup> The authors found that primary care physicians provided the largest share of services for vaccinations.<sup>3</sup> Primary care physicians provided 54 percent of visits for vaccination.<sup>4</sup> It is vital that Medicare payment policies support primary care physicians' ability to offer recommended immunizations in their practices, as they continue to be the primary setting beneficiaries get their vaccines.

The AAFP strongly supports CMS' intent to restore vaccine administration payment rates to a more adequate level, given the recent reductions in payment. **However, we strongly urge CMS to consider how payment rates, and perhaps a new payment methodology, could help boost Medicare beneficiaries' uptake of recommended vaccinations.** The Medicare Payment Advisory Commission's (MedPAC's) 2021 report to Congress outlined current vaccination rates for Medicare

beneficiaries.<sup>5</sup> MedPAC reported that vaccination rates among Medicare beneficiaries have increased in recent years but are still not meeting objectives set by the CDC. Further, there are racial and ethnic disparities in vaccination rates among Medicare beneficiaries. Vaccination rates for Black and Hispanic beneficiaries are consistently lower than white beneficiaries.<sup>6</sup> Evidence suggests that immunization rates dropped significantly during the COVID-19 pandemic and have not rebounded to pre-pandemic levels.<sup>7</sup> These low rates come at a cost to the Medicare program. A recent analysis found Medicare incurred \$106.4 billion in 2016-2018, treating diseases potentially preventable with in-line vaccines and select pipeline vaccine candidates, highlighting the ongoing economic burden of vaccine-preventable diseases in the US.<sup>8</sup> Increasing beneficiary vaccination rates would improve beneficiary outcomes, reduce Medicare spending, and help prevent the depletion of the Medicare Trust Funds.<sup>9,10</sup>

We also note that improving vaccination rates among Medicare's more than 62 million beneficiaries is essential to safeguarding national and global public health. The importance of vaccination to achieving herd immunity and ending the spread of vaccine-preventable disease could not be more evident than it is right now. Given the major role Medicare plays in insuring millions of Americans and setting payment policies adopted across our health care system, it is vital that CMS leverage Medicare vaccine administration payments to ensure the public's health and prevent future outbreaks of vaccine-preventable disease.

Studies show that higher vaccine administration payment rates are associated with higher rates of utilization.<sup>11</sup> In a recent survey of physician practices, 80 percent of respondents indicated increasing vaccine administration payment rates would help overcome vaccination barriers and costs created by the pandemic.<sup>12</sup> These barriers and costs are often disproportionately felt by practices caring for medically underserved communities and could be exacerbating disparities in vaccination rates. Coupled with low vaccination rates among beneficiaries, these results suggest that updated Medicare payment rates for routine and seasonal vaccinations are urgently needed.

**The AAFP strongly recommends CMS implement the Spring 2021 RUC recommendations for vaccine administration services for CY 2022.** The values recommended by the RUC more accurately estimate and pay for the costs required to administer vaccines, which is essential to ensuring access to recommended vaccines from beneficiaries' usual source of care.

While we believe that implementing the RUC recommendations is the most appropriate interim solution, the AAFP also believes **CMS should consider whether it would be more effective and sustainable to develop a payment methodology for vaccine administration that considers the value of preventive vaccinations instead of only considering the cost of furnishing these services.** Vaccines are considered a high-value service because they are low-cost and very clinically effective. Given the significant benefits of vaccination, paying for vaccine administration services using a cost-based methodology may not adequately support physician practices and other immunizers, leading to suboptimal vaccination rates and vaccine-preventable disease. Moving away from a cost-based methodology could provide physicians with more flexibility to provide extensive counseling services or implement innovative clinical workflows to optimize vaccination among their patients.

We believe CMS has the authority and flexibility to implement a more innovative payment methodology for vaccine services to improve adult immunization rates and reduce the incidence of vaccine-preventable illness among Medicare beneficiaries. **We recommend that CMS work closely with the AAFP and other stakeholders on a long-term solution that appropriately values the impact immunizations have on beneficiary outcomes and costs.**

Regarding COVID-19 vaccines, the AAFP supports the \$40 per dose payment rate and believes Medicare should continue to pay for COVID-19 vaccine administration at this rate for the foreseeable future. The \$40 per dose payment rate more accurately covers the costs that many practices incur by offering the COVID-19 vaccine. According to an internal survey, family medicine practices offering COVID-19 vaccines incur several unique costs. These include ultra-cold storage requirements, longer counseling time, the use of clinic space for the 15-minute observation time, and additional reporting requirements.

Some practices also incur significant additional costs when trying to obtain the vaccine for their practices or prevent waste. One family physician reported they had to travel 40 minutes each way to get the COVID-19 vaccine and bring it back to their practice. We recommend CMS work with the CDC and other partners within HHS to reduce the barriers that primary care practices continue to face when offering the COVID-19 vaccine. Similar to our recommendations for routine and seasonal vaccines, we recommend CMS consider whether an alternative payment methodology could facilitate greater utilization of COVID-19 vaccines in the future.

The AAFP supports CMS continuing to provide an add-on payment for physicians to provide COVID-19 vaccines to patients in their homes. We believe this payment is essential in supporting family physicians who practice home-based primary care and are going to great lengths to vaccinate hard-to-reach populations.

#### Payment for Medical Nutrition Therapy (MNT) Services and Related Services (section II.K.)

CMS makes several proposals to improve access to, and utilization of, medical nutrition therapy (MNT) and diabetes self-management training (DSMT) services. CMS proposes to create a new section of regulatory text to outline specific payment policies for registered dietitians and other nutrition professionals who can currently bill Medicare directly for the services they provide. CMS proposes to clarify that MNT and DSMT services cannot be provided incident to the services of a billing physician or other practitioner. If a physician bills for MNT or DSMT services, they would have to personally perform those services and be certified or approved for MNT and DSMT, respectively. As such, registered dietitians and other nutrition professionals can only be paid for their professional services only if they have personally performed those services. CMS also proposes to clarify that dietitians and other nutrition professionals cannot charge beneficiaries any amount for MNT services.

#### *AAFP Response*

The AAFP supports these proposals and CMS' goal of improving Medicare beneficiaries' utilization of evidence-based nutrition services.

#### Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (sections III.A., III.B., and III.C.)

Currently, RHCs and FQHCs may not bill for transitional care management (TCM) services for a beneficiary if another practitioner or facility has already billed for CCM services for the same beneficiary during the same period. CMS proposes to allow 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 each billing code are met. This would include the services described by HCPCS codes G0511 (General Care Management for RHCs and FQHCs only) and G0512 (Psychiatric Collaborative Care Model (CoCM) code for RHCs and FQHCs only), which both describe a service period of one calendar month. This is called concurrent billing.

CMS proposes to revise the requirement that an RHC or FQHC mental health visit must be an in-person encounter to permanently allow FQHCs and RHCs to provide visits for the diagnosis, evaluation, and treatment of a mental health disorder through interactive, real-time communications technology. To align with proposals made under the MPFS, CMS proposes to allow RHCs and FQHCs to furnish mental health visits using audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction. This proposed change would allow RHCs and FQHCs to report and be paid for telehealth mental health visits the same way they currently do when the services are in person. To track utilization, CMS proposes to require RHCs and FQHCs to append the modifier -95 when the service is furnished via audio/video or audio-only telehealth.

CMS seeks comments on whether they should require an in-person service within six months before furnishing a telehealth service and whether they should create a similar ongoing in-person requirement. CMS asks for input on whether this could be particularly burdensome for RHC and FQHC patients and whether the agency should defer to the clinical judgment of the practitioner on how often an in-person visit would be appropriate.

#### *AAFP Response*

**The AAFP strongly supports the proposal to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary during the same service period, provided that all requirements for billing each code are met.** We agree with CMS' conclusion that a patient may benefit from each of these services provided within the same time period (e.g., a calendar month). Patients receiving TCM services after discharge would likely still benefit from the more comprehensive care management plan developed under CCM, as well as the behavioral health-specific care management included in the Psychiatric Collaborative Care Management (CoCM). Allowing RHCs and FQHCs to bill TCM and other care management services will facilitate the utilization of high-value care management services, which can decrease avoidable admissions and help address social determinants of health (SDoH) and mitigate health disparities.

The AAFP strongly supports the proposal to revise the requirement that RHC and FQHC mental health visits must be in person. We also support the proposal to allow mental health services to be furnished using audio/video or audio-only technology. We believe these proposals will improve access to mental health services for RHC and FQHC patients who are disproportionately low income and likely face additional barriers to mental health services. As stated previously, the AAFP recommends against imposing an in-person service requirement for telehealth mental health visits. Existing evidence does not support the need for such a requirement, which could negatively impact

access to care for beneficiaries. **We recommend CMS defer to the clinical judgment of the practitioner on how often an in-person visit would be appropriate.** Existing studies suggest low-income patients and those living in rural communities face more transportation barriers compared to other patients.<sup>13</sup> As such, it is likely that in-person requirements would more profoundly impede access to care for the populations that RHCs and FQHCs serve.

#### Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging (section III.F.)

CMS proposes to delay full implementation of the Appropriate Use Criteria (AUC) program until the later of January 1, 2023, or January 1 of the year after the year in which the COVID-19 PHE ends. CMS cites a variety of barriers to fully implementing the program.

#### *AAFP Response*

**The AAFP strongly supports the proposal to delay the full implementation of the AUC program.** The AUC program is overly burdensome, complex, and does not reflect the high level of family physicians' participation in APMs. The AAFP has [advocated](#) for CMS to continue delaying full implementation of the AUC program and publicly report the obstacles to implementation. We thank CMS for being responsive to our recommendations. The AUC program does not consider quality, patient outcomes, or other important factors, which are more appropriately addressed in APMs. According to an AAFP survey, more than half of our members report participating in an APM. These physicians are already accountable for the quality and cost of their care, including strong incentives to reduce unnecessary utilization of costly imaging services, rendering the AUC program unnecessary. Thus, we strongly agree with the proposal to delay its implementation and urge CMS to finalize this proposal.

#### Pulmonary Rehabilitation, Cardiac Rehabilitation, and Intensive Cardiac Rehabilitation (section III.H.)

CMS proposes to cover pulmonary rehabilitation for Medicare beneficiaries who have been diagnosed with severe manifestations of COVID-19, defined as requiring hospitalization in the intensive care unit (ICU) or otherwise, and who experience continuing symptoms, including respiratory dysfunction for at least four weeks post-discharge. CMS seeks comments regarding the appropriateness of the coverage criteria for pulmonary rehabilitation for beneficiaries diagnosed with COVID-19, including the characteristics of the patients for whom pulmonary rehabilitation is covered and the timing of their symptoms as presented above.

CMS proposes to modify regulations for pulmonary rehabilitation to encourage the utilization and reduce the burden on pulmonary rehabilitation programs while also creating greater consistency with cardiac rehabilitation and intensive cardiac rehabilitation services.

#### *AAFP Response*

The AAFP supports the proposal to cover pulmonary rehabilitation for Medicare beneficiaries who have been diagnosed with severe COVID-19 and are experiencing post-COVID syndrome. We agree that existing evidence indicates patients with severe COVID-19 can benefit from pulmonary rehabilitation. The AAFP recommends that CMS expand pulmonary rehabilitation coverage to all



beneficiaries with post-COVID syndrome. Further, coverage should evolve and change as the definition and understanding of post-COVID syndrome improve.

The AAFP appreciates CMS reducing the regulatory burden on pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation programs to increase utilization. We previously [wrote](#) to CMS regarding ongoing barriers to cardiac rehabilitation in rural areas. Evidence indicates that patients living in rural areas are less likely to participate in cardiac rehabilitation, citing distance from the home as the most common reason for not completing the program.<sup>14</sup> Specifically, family physicians report the requirement for a physician to be immediately available and accessible is an insurmountable obstacle for increasing rural access to cardiac rehabilitation. To ensure rural beneficiaries can access this evidence-based care, we recommended CMS revise the National Coverage Determination (NCD) for cardiac rehabilitation programs to allow them to operate under the general supervision of a physician when an automated external defibrillator (AED) is immediately available and when the patient is attended to by nursing staff currently trained in Basic Life Support and AED use.

CMS could alternatively (or in conjunction with the above recommendation) permit the supervising physician of a cardiac rehabilitation program to be immediately available and accessible through a virtual presence, particularly in rural areas. This would provide cardiac rehabilitation programs with more flexibility and could facilitate new cardiac rehabilitation programs in rural areas, ultimately improving access to care. The AAFP previously recommended that CMS allow physicians to supervise other services under the MPFS through virtual, two-way, audio/video synchronous technology. In the CY 2021 MPFS, CMS also finalized regulations to permanently allow teaching physicians to supervise residents via a virtual presence when the resident was providing services in a rural area. As such, we believe CMS has the authority to provide rural cardiac rehabilitation programs with this flexibility.

#### Medical Nutrition Therapy (MNT) (section III.I.)

Medical nutrition therapy (MNT) is covered for Medicare beneficiaries with diabetes or renal disease when they meet the criteria for chronic renal insufficiency and are referred to MNT by a treating physician. CMS proposes to remove the requirement for the referral for MNT to be made by the treating physician and instead allow for referral by any physician. CMS notes that care coordination between the hospital or post-acute care professionals and the primary care physician is the goal and a standard of care in today's medical environment. Therefore, CMS is confident beneficiaries will continue to receive high-quality, coordinated care. CMS also notes that less than one percent of the estimated 14 million eligible Medicare beneficiaries have accessed MNT. CMS attributes part of the underutilization to the current requirement for referral by a treating physician. This proposal aims to improve access to, and utilization of, MNT services, which most eligible beneficiaries do not currently receive.

CMS further proposes updating the glomerular filtration rate (GFR) eligibility criteria to align with up-to-date standards for chronic kidney disease stages III-V.

#### *AAFP Response*

The AAFP supports CMS' goal of improving access to, and utilization of, MNT services. Accordingly, we support the proposal to remove the requirement for the referral for MNT services to be made by

the treating physician and instead allow any physician to refer a patient to MNT. This proposal is consistent with the statutory language that requires referral by a physician but does not specify that it must be the treating physician. Also, as CMS notes, this change will increase the capacity and availability of physicians who can refer beneficiaries to MNT, which should alleviate some of the demand on primary care physicians as the usual source to perform this function.

While we agree that care coordination within a patient's care team is a common goal and should be considered the standard of care, family physicians often report challenges communicating with other clinicians caring for their patients. Family physicians often shoulder the burden of contacting other clinicians to ensure care is well coordinated across the care team. The AAFP commends CMS for working to advance interoperability and otherwise improve communication tools that clinicians use to coordinate care. We urge CMS to continue these efforts to minimize the burdens on primary care physicians and subsequently improve quality of care.

The AAFP supports the proposal to update the GFR eligibility criteria to align with up-to-date clinical standards.

#### Medicare Diabetes Prevention Program (MDPP) (section III.L.)

CMS proposes to amend its regulations to preclude the provision of ongoing maintenance sessions unless a Medicare Diabetes Prevention Program (MDPP) beneficiary has started the first core session on, or before, December 31, 2021. This change would effectively relieve MDPP suppliers of the requirement to provide ongoing maintenance sessions and make the MDPP timeframe consistent with the national DPP for MDPP service periods that begin on or after January 1, 2022. If finalized, this policy would reduce the administrative burden and costs associated with the ongoing maintenance sessions phase to MDPP suppliers with minimal impact to beneficiaries who have historically low participation rates in the second year of MDPP.

CMS also proposes to update the amount of the performance payments for the core sessions, core maintenance sessions, and ongoing maintenance sessions (where applicable). This change would apply to all MDPP beneficiaries starting the MDPP set of services on, or after January 1, 2022. As shown in Table 28 of the proposed rule, this change would increase Medicare payments for each session except the first and last (which would remain at the current payment level) during the first year of the MDPP, boosting MDPP supplier revenue during that period.

Lastly, CMS proposes to add a provision to its regulations to waive the provider enrollment Medicare application fee for all organizations enrolling in Medicare as MDPP suppliers on, or after January 1, 2022, and make a conforming amendment to remove a reference that links MDPP suppliers to the definition of 'institutional provider.'

#### *AAFP Response*

The AAFP supports CMS' proposals related to the MDPP. As CMS notes, all of them are designed to reduce burden and better support suppliers in a program that shows promise in reducing costs and improving quality of treating individuals with diabetes. The waiver of provider enrollment fees and the increased payments for MDPP beneficiary achievement is particularly helpful, shortening the program's duration to one year, aligning the program with the national DPP. We encourage CMS to finalize these proposals for 2022.

There remain other areas for improvement. For instance, there needs to be more alignment of MDPP with the national DPP, such as eliminating the once per lifetime limitation in MDPP, which is a barrier to access the program. CMS should also consider allowing suppliers to offer MDPP virtually, which would address equity issues and is currently allowed in the national DPP – provided there is an initial in-person encounter or established patient relationship with the MDPP provider, and there is ongoing coordination with the patient’s primary care medical home.

#### Medicare Provider and Supplier Enrollment Changes (section III.N.1.)

CMS proposes to modify several regulations to enhance its authority to terminate, revoke, or deactivate a provider’s or supplier’s enrollment in Medicare.

CMS proposes revisions to the regulations regarding its ability to revoke enrollment if the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. These proposals would reduce the number of factors CMS considers when determining whether to revoke enrollment. It would allow CMS to consider a shorter time period during which a significant number of claims were denied.

#### *AAFP Response*

While we agree that protecting the Medicare program and the Trust Funds from fraud and abuse is essential, the AAFP is concerned that these proposals could create significant administrative burdens for physicians.

We are particularly concerned with the proposals that remove and modify the factors CMS will consider when determining whether to revoke a physician’s enrollment. CMS proposes to remove the length of the physician’s enrollment in the Medicare program as a factor and reduce the time period CMS is required to examine. CMS also proposes to remove the reason for claim denials as a factor under consideration. CMS even notes in the proposal that “even if a period of erroneous claim submissions reflected no nefarious intent,” they would revoke a physician’s enrollment for a short period for erroneous claim submissions. These proposals give CMS wide-ranging authority to revoke a physician’s enrollment without providing adequate notice or allowing the physician to address issues that may be leading to claim denials. We can think of several scenarios where these proposed changes would result in CMS unfairly revoking a physician’s enrollment, even when they have demonstrated no nefarious intent.

For example, a series of claim denials could occur if CMS or a Medicare Administrative Contractor (MAC) changes Medicare coverage policies or documentation requirements for services commonly provided in a physician’s practice. There are many reasons why a physician practice may not be immediately aware of such a change, including responding to a surging national pandemic and submitting claims incorrectly for a short period of time. A physician could also move to another state with different MAC and local coverage determinations (LCDs) and, for certain services, be unaware of the difference and continue to bill as they previously did under a different MAC’s LCDs. In another scenario, the American Medical Association (AMA) CPT group could change codes commonly used by physicians without their knowledge. This could cause the physician to bill a code erroneously early in the year before the physician becomes aware of, and familiar with, the revised CPT codes. Finally,

a MAC could erroneously deny claims for a particular service even though the physician is billing it appropriately.

In these situations, there could be a series of claim denials within a short period of time that occur without nefarious or fraudulent intent. However, CMS would not consider the reason for the claim denials and would have the authority to revoke the physician or practice's Medicare enrollment. The physician practice will then have to go through a costly, burdensome appeals process. During the process, the practice's Medicare patients will be unable to receive care from their primary care physician and may not be able to access care elsewhere. We are deeply concerned these proposals will disproportionately disadvantage small, solo, rural, and other practices in underserved communities. **The AAFP urges CMS not to finalize these proposals and, at a minimum, outline a notification and waiting period before CMS revokes Medicare enrollment in situations where there is no nefarious intent.**

Provider/Supplier Medical Review Requirements: Addition of Provider/Supplier Requirements Related to Pre-payment and Post-payment Reviews (section III.N.2.)

CMS currently contracts with entities to conduct pre-and post-payment reviews to prevent improper Medicare payments from being made. However, current procedures and authorities for conducting these reviews are not codified in regulation. CMS proposes to codify definitions and procedures for pre-and post-payment reviews.

*AAFP Response*

The AAFP recognizes the importance of conducting oversight activities to protect the Medicare program from fraudulent or incorrect payments. We do not have any concerns with CMS codifying various procedures and authorities for conducting these reviews. However, we recommend CMS direct its various contractors to minimize the burden these reviews place on physician practices, particularly when there is no history of improper conduct or nefarious intent.

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.O.)

CMS proposes to permanently allow opioid treatment programs (OTPs) to provide OUD therapy and counseling services using audio-only technology when or if a two-way video is not available to the beneficiary, including if the beneficiary has not consented to using a two-way audio/visual technology. CMS is also proposing that, during and after the PHE, OTPs will be required to indicate in a patient's medical record when and why a visit for substance use counseling or therapy was audio-only.

*AAFP Response*

The AAFP appreciates CMS' efforts to align payment policy for OUD treatment to support patients' and clinicians' ability to choose the most appropriate modality of care (i.e., audio-video, audio-only, in person) for treatment. Access to audio-only OUD treatment services [has been shown](#) to improve equity and reduce barriers to care, especially surrounding stigmas of drug use.

Requesting documentation for when and why the visit was audio-only is acceptable so long as there are not duplicative reporting requirements for OTPs. As discussed previously, the AAFP believes that

physicians should be able to attest to having the capacity to furnish two-way audio/video visits using a check box functionality in their EHR. We encourage CMS to accept this as sufficient documentation. In reviewing additional considerations to preserve program integrity and minimize patient safety concerns, the AAFP urges CMS to avoid administrative requirements that are financially burdensome and time consuming, thereby hindering physicians' ability to administer evidence-based OUD treatment services.

#### Updates to the Physician Self-referral Regulations (section III.P.)

CMS proposes to revise the regulation that sets forth the conditions for an indirect compensation arrangement. Specifically, CMS proposes to revise the regulation to include as a potential indirect compensation arrangement any unbroken chain of financial relationships in which the compensation arrangement closest to the physician (or immediate family member of the physician) involves compensation for anything other than services that the physician personally performs. This includes certain arrangements involving the unit of service-based payment for the rental of office space or equipment. Thus, CMS proposes revisions to its regulations that would ensure the prohibition on certain units of service-based compensation formulas for the rental of office space or equipment, and they apply to all compensation arrangements that include them, including indirect compensation arrangements. CMS proposes to consider an unbroken chain of financial relationships between a physician and an entity that meets the other conditions of § 411.354(c)(2)(i) through (iii) to be an indirect compensation arrangement for purposes of the physician self-referral law if the unit of compensation received by the physician (or immediate family member) is payment for anything other than services personally performed by the physician (or immediate family member). For these purposes, CMS considers services performed by any person other than the physician (or immediate family member), including, but not limited to, the referring physician's (or immediate family member's) employees, independent contractors, group practice members, or persons supervised by the physician (or the immediate family member) not to be personally performed by the physician. For these purposes, CMS proposes to define the individual unit as:

- Time – where the compensation paid to the physician (or immediate family member) is based solely on the period of time during which the service are provided;
- Service – where the compensation paid to the physician (or immediate family member) is based solely on the service provided; and
- Time – where the compensation paid to the physician (or immediate family member) is not based solely on the period of time during which a service is provided or based solely on the service provided.

CMS proposes a change to the exception for preventive screening tests, immunizations, and vaccines, which would address the fact that there is currently no frequency limit on the administration of COVID-19 vaccines. CMS proposes to permit the use of the exception at § 411.355(h) for COVID-19 vaccines even when they are not subject to CMS-mandated frequency limits, provided that all other requirements of the exception are satisfied. CMS seeks comment on its proposed approach and whether it should limit this regulatory relief to the period during which the current PHE is in effect, until such time as CMS mandated frequency limits apply for COVID-19 vaccines or some other period of time.

In the alternative, CMS proposes removing the CMS-mandated frequency limit requirement for all vaccines and seeks comment on whether it would be necessary to include alternative program integrity requirements in the exception at § 411.355(h). CMS seeks comments regarding whether

physicians are likely to order vaccines more frequently than recommended by HHS and any other organization they identify as an authority on this matter. CMS is not proposing to remove the CMS-mandated frequency limit requirement concerning preventive screening tests.

Lastly, CMS proposes using the word ‘vaccine’ rather than ‘immunization’ in the self-referral exception at § 411.355(h) and more frequently updating the lists of CPT and HCPCS codes that define certain designated health services, while publishing those lists only on the CMS website. Specifically, CMS proposes to update the relevant code lists each calendar quarter and provide public notification in advance of updates. CMS would post an advance notification on its website on March 1, June 1, September 1, and December 1, each year, with corresponding code list updates effective April 1, July 1, October 1, and January 1, respectively. CMS proposes a 30-day public comment period following each advance notification posting of the upcoming quarterly code list update. This new process and schedule would begin with the update effective April 1, 2022.

#### *AAFP Response*

In general, CMS’ proposal to revise its regulations that set forth the conditions for the existence of an indirect compensation arrangement under the physician self-referral rules seems reasonable. It is otherwise consistent with CMS’ application of the self-referral prohibitions and exceptions to other compensation arrangements. The one portion of the proposal we take issue with is CMS’ definition of ‘services personally performed’ by the physician (or immediate family member).

CMS proposes to consider any services performed by any person other than the physician (or immediate family member), including, but not limited to, the referring physician’s (or immediate family member’s) employees, independent contractors, group practice members, or persons supervised by the physician (or the immediate family member), not to be personally performed by the physician. This definition seems contrary to how CMS views physician services elsewhere under the Medicare program. For instance, under Medicare’s ‘incident-to’ rules, a physician may bill and be paid by Medicare as if the physician personally performed the service or the services were performed by employees under the physician’s direct supervision. Similarly, Medicare regularly treats group practice members as more or less interchangeable for billing and payment purposes without regard to who performed the services.

Having different definitions of ‘services personally performed’ under different parts of the Medicare program adds to the administrative complexity and burden of the program. The added complexity and burden make it more difficult for physicians to comply with Medicare’s rules and regulations. We believe CMS should take a more consistent approach to define ‘services personally performed’ and revise its proposed definition for purposes of indirect compensation arrangements as follows:

*‘Services personally performed’ by the physician excludes any services performed by any person other than the physician (or immediate family member), including, but not limited to, the referring physician’s (or immediate family member’s) employees, independent contractors, group practice members, or persons supervised by the physician (or the immediate family member), for which the physician may not otherwise bill Medicare under the physician’s own provider number.*

Such a definition or one similar would better align the proposed regulations with other Medicare regulations that govern physician billing.

The AAFP supports CMS' proposal to permit the exception at § 411.355(h) for COVID-19 vaccines even when they are not subject to CMS-mandated frequency limits, provided that all other requirements of the exception are satisfied. We encourage CMS to maintain this regulatory relief until CMS otherwise applies frequency limits to COVID-19 vaccines. We also support CMS' consideration of removing existing frequency limits from all Medicare-covered vaccines. Physicians are unlikely to order vaccines more frequently than recommended by the CDC's Advisory Committee on Immunization Practices (ACIP). Alternative program integrity requirements would seem unnecessary, especially given Medicare's current payment rates for non-COVID-19 vaccines and their administration – a point we addressed elsewhere in this letter.

Finally, the AAFP is comfortable with CMS' proposals to use the word 'vaccine' rather than 'immunization' in the self-referral exception at § 411.355(h) and to more frequently update the lists of CPT and HCPCS codes that define certain designated health services while publishing those lists only on the CMS website. We think updating those lists quarterly with a 30-day advance notice and comment period is sufficient.

Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan (section 2003 of the SUPPORT Act) (section III.Q.)

CMS notes that the electronic prescribing for controlled substances (EPCS) has increased during the PHE and continues to encourage all prescribers to adopt the EPCS as soon as feasible for them. CMS also notes that the Department of Justice (DOJ) promulgates regulations related to biometric data required for multifactor authentication and full implementation of EPCS. To ensure the compliance deadline for EPCS does not interfere with prescribers' ability to prescribe controlled substances for those who need pain treatment or have SUDs, CMS proposes delaying the EPCS compliance date from January 1, 2022, to January 1, 2023.

*AAFP Response*

The AAFP supports the proposal to delay the EPCS compliance date to January 1, 2023. As CMS notes in the proposed rule, implementing the required systems for EPCS is costly and requires time for physicians and other prescribers to learn new systems. As family medicine practices face another surge of the COVID-19 pandemic, flu season, and a new COVID-19 vaccine booster campaign, it's likely they may not have the time or resources to fully comply with EPCS. We thank CMS for acknowledging these challenges and modifying the compliance date accordingly.

Medicare Shared Savings Program (MSSP) (section III.J.)

**Amending the Reporting Requirements under the APM Performance Pathway (APP) for Performance Years 2022 and 2023**

For performance year 2022, CMS is proposing that Medicare Shared Savings Program (MSSP) accountable care organizations (ACOs) would be required to report the 10 CMS Web Interface measures and administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey. CMS would calculate the two administrative claims measures included under the APM Performance Pathway (APP). Alternatively, the ACO could report the three electronic clinical quality measures/MIPS clinical quality measures (eCQM/MIPS CQMs) and administer the CAHPS for

MIPS Survey. CMS would calculate the two administrative claims measures included under the APP. If the ACO selects the second option to report the three eCQM/MIPS CQMs and meets the data completeness and case minimum requirements for all three measures, and achieves a quality performance score equivalent to, or higher than, the 30<sup>th</sup> percentile of the performance benchmark on at least one measure in the APP set, the ACO would meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses for the performance year. If an ACO chooses this option, its performance on all three eCQM/MIPS CQMs would be used for MIPS scoring under the APP. If an ACO decides to report both the 10 CMS Web Interface measures and the three eCQM/MIPS CQMs, it would receive the higher of the two quality scores.

For performance year 2023, ACOs would be required to report either the 10 CMS Web Interface measures and at least one eCQM/MIPS CQM and administer the CAHPS for MIPS Survey. CMS would calculate the two claims-based measures included in the APP. Alternatively, the ACO could report the three eCQM/MIPS CQMs and administer the CAHPS for MIPS Survey. CMS would calculate the two claims-based measures included in the APP. If the ACO selects the second option to report the three eCQM/MIPS CQMs and meets the data completeness and case minimum requirements for all three measures, and achieves a quality performance score equivalent to or higher than the 30<sup>th</sup> percentile of the performance benchmark on at least one measure in the APP set, the ACO would meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses for the performance year. If an ACO chooses this option, its performance on all three eCQM/MIPS CQMs would be used for MIPS scoring under the APP. If an ACO decides to report both the 10 CMS Web Interface measures and the three eCQM/MIPS CQMs, it would receive the higher of the two quality scores.

Beginning with performance year 2024 and beyond, ACOs would be required to report the three eCQM/MIPS CQMs and administer the CAHPS for MIPS Survey. CMS would calculate the two claims-based measures included in the APP. If the ACO meets the MIPS data completeness and case minimum requirements and is in the first performance year of an ACO's first agreement period, CMS is proposing the ACO would meet the quality performance standard if it meets the MIPS data completeness and case minimum requirements and:

- For performance year 2022, reports the 10 CMS Web Interface measures or the three eCQM/MIPS CQMs and administers the CAHPS for MIPS Survey
- For performance year 2023, reports the 10 CMS Web Interface measures and at least one eCQM/MIPS CQM or reports the three eCQM/MIPS CQMs and administers the CAHPS for MIPS Survey
- For performance year 2024 and beyond, reports the three eCQM/MIPS CQMs and administers the CAHPS for MIPS Survey

CMS seeks comments on these proposed updates and whether CMS should extend the CMS Web Interface collection type for more than the two years they propose.

#### *AAFP Response*

The AAFP appreciates CMS' delay in sunsetting the CMS Web Interface. However, we are concerned that the updated timeline remains a significant issue for ACOs and their participants. ACOs will still need to ensure their entire system can report an eCQM/MIPS CQM – regardless of whether an ACO reports one or all eCQM/MIPS CQMs. Thus, the work and resources required to report one are the same as reporting all. Since ACOs will be required to report at least one eCQM/MIPS CQM beginning in 2023, they essentially have a year to update their systems and



workflows. The changes ACOs will need to make to be ready to report the APP eCQM/MIPS CQM set are extensive, burdensome, and costly. We strongly urge CMS to work with the Office of the National Coordinator for Health Information Technology (ONC) to address issues with vendors. This can be particularly difficult for small and rural ACOs. There are longstanding problems and barriers with updating EHR systems when regulations and reporting requirements change. Independent physician practices will have to pay for very costly EHR updates to report successfully. As a result, the changes CMS proposes are burdensome, difficult to implement in the real world, and place a significant financial strain on practices that successfully improve quality and reduce costs. The scale of the MSSP magnifies the difficulties in transitioning to eCQM/MIPS CQMs, but they span across all APMs. We encourage CMS to continue engaging with ACOs and stakeholder groups to develop a workable timeline for ACOs to transition to the APP measure set. An adequate timeline will support the continued success of the MSSP and assure MIPS eligible clinicians (ECs) considering joining an ACO that the MSSP is a predictable and stable option.

### **Solicitation of Comments on Addressing Health Disparities and Promoting Health Equity**

CMS believes that assessing ACOs' quality performance on a broader population can positively impact the quality of care for all groups. They expect the transition to eCQM/MIPS CQMs will help address health disparities and promote health equity by promoting a single standard of care across all patients receiving care from practices participating in MSSP ACOs.

CMS is seeking comments and recommendations about how ACOs can utilize their resources to ensure that patients – regardless of racial/ethnic group, geographic location, and/or income status – have access to equal care and how ACOs can improve the quality of care provided to certain communities while addressing the disparities that currently exist in health care. CMS also seeks comments and recommendations about encouraging health care providers serving vulnerable populations to participate in ACOs and other value-based care initiatives. This includes soliciting comments about whether adjustments to quality measure benchmarks should be made to consider ACOs serving vulnerable populations.

#### *AAFP Response*

The AAFP appreciates CMS' commitment to advancing health equity through its programs and seeking comments on addressing health disparities within these programs most effectively. The AAFP shares this commitment. Our position paper on the [SDoH](#) outlines how family physicians are uniquely qualified to identify social needs and connect patients to third-party services and public programs in their community to address those needs. This is an important step to mitigate health disparities. Still, most payment methodologies and models do not sufficiently account for patients' social risk factors which can disadvantage the physicians caring for the most vulnerable, high-risk patients.

Risk-based payment adjustments will be vital to encourage physician practices serving vulnerable populations to participate in ACOs and other value-based care initiatives. FFS structures typically do not pay for, or support, robust care coordination activities to address social needs within a patient's community. Existing risk-adjustment models often do not sufficiently quantify patients' social risk factors, leading to additional challenges for physician practices, such as inadequate payment and inaccurate quality and cost performance scores.

Payment adjustments need to provide additional resources to provide practices with the support they need to address social needs within their patient population. One approach, outlined in a recent [Health Affairs blog](#) and proposed by the AAFP in the Advanced Primary Care Alternative Payment Model (APC-APM), is to use geographic indices of social risk, such as the Robert Graham Center's (RGC) [social deprivation index](#) (SDI) to adjust payment. The RGC SDI is a composite measure of area-level deprivation based on seven demographic characteristics collected in the American Community Survey and used to quantify the socioeconomic variation in health outcomes. While there are mechanisms to adjust payments, the larger outstanding question of what it costs to manage populations with increased social risks remains.

### **Seeking Comment on Considerations Related to the Use of Regional FFS Expenditures in Establishing, Adjusting, Updating, and Resetting the ACO's Historical Benchmark**

CMS has received extensive feedback expressing concerns with the MSSP's regional benchmarking methodology. CMS has analyzed the concerns and is interested in considerations and approaches to modify the program's benchmarking methodology.

#### *AAFP Response*

The AAFP, along with others, supports the [Value in Health Care Act of 2021](#). We strongly believe that the long-term success of the MSSP and APMs depends on accurate and reliable benchmarking methodologies. Including an ACO's own beneficiaries in the regional calculation puts ACOs at a disadvantage, with a significant impact on rural ACOs where the ACO often covers a larger percentage of the region's FFS beneficiaries. The issues with the current benchmarking methodology jeopardize an ACO's ability to generate shared savings and could negatively impact participation in the MSSP. Participants who do not feel they can be appropriately assessed or have equal opportunities for incentives will lose confidence in the program. CMS could rectify this flaw by removing an ACO's beneficiaries from the regional benchmark. Updating the methodology would level the playing field and ensure all ACOs have an equal opportunity to succeed in the program. While we believe it is important for CMS to address this issue within the MSSP, we also urge CMS and CMMI to review methodologies of existing and developing models to ensure they appropriately account for an APM participant's regional presence.

#### Updates to the Quality Payment Program (QPP) (section IV.)

##### **General Comments**

The AAFP has supported MACRA's intent to move physicians and practices out of FFS and into APMs. We firmly believe that primary care services are most appropriately paid for using a value-based methodology that captures the benefits of preventive and primary care and emphasizes the quality of care over the volume of services provided. However, the QPP is falling short of its goal of facilitating movement into these more advanced models. We appreciate CMS recognizing that significant changes are needed to reduce the burden on physicians, prepare them for value-based payment, and make reporting more meaningful to practices and patients. The AAFP is hopeful that MVPs, if designed and implemented appropriately, can provide an on-ramp to APMs. In our comments, we offer a number of suggestions for how CMS should implement MVPs to more effectively reduce the reporting burden and align with existing APMs, including by offering cross-category credit.

Still, we remain concerned that the MIPS positive payment adjustments meant to incentivize physicians have been so small that they do not cover the cost for practices to administer this resource-intensive

program, let alone invest in enhancing their capacity to participate in APMs. Further, the negative payment adjustments for failing to participate in MIPS or meet the performance threshold have significant financial consequences. Significant negative consequences could be an incentive to move out of MIPS, but the financial harm they cause forces practices to find ways to make up the lost revenue. By doing so, practices must continue to focus on the volume of services provided rather than developing the skill sets they need to advance to APMs. Given the potential for negative payment adjustments and the cost and time required for reporting, **the AAFP urges CMS to automatically apply the extreme and uncontrollable circumstances policy for the 2021 performance year.** The negative payment adjustment would punish practices for circumstances beyond their control, and the financial impact would be a substantial setback to their ability to prepare for and move to APMs.

Finally, there are not enough APMs available for practices – making MVPs an on-ramp to nowhere. The Center for Medicare and Center for Medicare & Medicaid Innovation (CMMI) need to coordinate efforts to develop a clear pathway out of FFS. The AAFP stands ready to work with QPP staff and CMMI to develop a suite of stable and predictable primary care models that facilitate the transition out of FFS.

The role of primary care is foundational in the transition to value-based care, and a lack of models is hampering practices' ability to move out of FFS. Models need to offer varying levels of risk, with opportunities to assume more advanced risk over time. The AAFP supports payment models that provide prospective payment for advanced primary care services and recognizes the need for a continuum of models to meet the needs of diverse practice settings. A continuum of models across payers is necessary to create model stability. Models must also be consistent and reliable from the model announcement, request for applications, and throughout the duration of the model implementation period, to foster trust and encourage further participation in APMs.

The AAFP is committed to working with CMS to address ongoing issues within the QPP and ensure primary care practices can successfully transition into APMs. With these goals in mind, we offer the following comments on CMS' proposals for calendar year (CY) 2022.

### **APM Performance Pathway**

CMS proposes to extend the CMS Web Interface as a reporting option under the APP for MSSP ACOs for performance years 2022 and 2023. For 2022, ACOs would have the option to report either the CMS Web Interface, the APP eCQM/MIPS CQM set, or both. For the 2023 performance year, CMS would only score Web Interface submissions for ACOs that submitted at least one eCQM/MIPS CQM from the APP measure set. For the 2022 and 2023 performance years, the ACO would have the opportunity to report on the eCQM/MIPS CQM set and the CMS Web Interface measures and have their MIPS quality score based on the higher submission. CMS seeks comment on this proposal.

CMS proposes adding the All-cause Unplanned Admissions for Multiple Chronic Conditions (MCC) for MIPS measure into the MIPS quality measure set beginning with the 2022 MIPS performance period. CMS also proposes to replace the MCC for ACOs measure with the MCC for MIPS measure within the APP beginning in the 2022 performance year.

CMS seeks comments on its proposal to include the following measures in the APP for the 2022 performance period:

- Quality ID 321: CAHPS for MIPS
- Measure 479: Hospital-wide, 30-day All-cause Unplanned Readmission Rate for MIPS EC Groups
- Measure TBD: Risk-standardized, All-cause Unplanned Admissions for Multiple Chronic Conditions for MIPS
- Quality ID 001: Diabetes Hemoglobin A1c Poor Control
- Quality ID 134: Preventive Care and Screening: Screening for Depression and Follow-up Plan
- Quality ID 236: Controlling High Blood Pressure
- Quality ID 318: Falls: Screening for Future Fall Risk
- Quality ID 110: Preventive Care and Screening: Influenza Immunization
- Quality ID 226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
- Quality ID 113: Colorectal Cancer Screening
- Quality ID 112: Breast Cancer Screening
- Quality ID 438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease
- Quality ID 370: Depression Remission at 12 Months

#### *AAFP Response*

The AAFP continues to have concerns with CMS' elimination of the APM Scoring Standard. As discussed in our [comments](#) last year, the APP is a one-size-fits-all approach that does not consider the differences between APMs. The APP requirements align with the MSSP but not with other APMs, such as Comprehensive Primary Care Plus and Primary Care First. We ask that CMS reinstate the APM Scoring Standard.

#### **Quality Performance Category**

For the 2022 MIPS performance period, CMS proposes to allow the administrative claims measure Risk-standardized Acute Unplanned Cardiovascular-related Admission Rates for Patients with Heart Failure to fulfill the outcome measure quality reporting requirement.

CMS seeks comment on how it can allow outcome-based administrative claims measures (not applicable to administrative claims measures that are population health measures) to be applied to fulfill the outcome measure requirement within traditional MIPS. CMS is considering three options. For the first option, CMS would utilize a registration process similar to the proposal for MVPs. The MIPS EC, group, or virtual group would elect to have an outcomes-based administrative claims measure be calculated and scored to fulfill the outcome measure requirement of the quality category. The EC, group, or virtual group would only be able to register if they are eligible for a measure to be calculated and scored (i.e., meets the case minimum requirement). CMS does not believe it would be technically possible to develop a registration system for this option because they would not have sufficient data from the performance period at the time of registration to determine if an EC is eligible to report the measure.

For the second option, CMS assessed the potential for automatically calculating an outcome-based administrative claims measure. ECs would still be required to submit six measures. CMS would calculate a score for seven measures, and performance for the quality category would be based on the six measures with the highest score. However, CMS would not be able to objectively decipher the

intent of the EC as to whether they would want to have an outcome-based administrative claim measure automatically calculated and applied to their quality score.

For the third option, CMS considered using historical data as the means for determining eligibility to register to have an outcome-based administrative claims-based measure calculated.

#### *AAFP Response*

The AAFP supports CMS' proposal to allow ECs to use outcome-based administrative claims to count toward the outcome measure requirement of the quality category. We agree there may be challenges in implementing such a policy, but a combination of CMS options could address some of these issues. The third option would be appropriate for most ECs as it would allow ECs to make a better-informed decision as to whether they would likely meet the case minimum to be scored on the measure.

The AAFP recommends that CMS implement a modified version of the first and second option for ECs for which CMS does not have adequate historical data and for ECs that have not historically met the case minimum. These ECs would still submit six measures, and CMS would automatically calculate their score on an outcome-based administrative claims measure. CMS would compare the EC's performance on the outcome quality measure they submitted to the administrative claims measure and use the higher of the two scores to calculate the quality performance category score. ECs would need to register to indicate to CMS that they wish to be scored using such an option. This option would not reduce administrative burden but would allow ECs to see how they would score on an outcome-based administrative claims measure to inform their decision for the following years. ECs in these categories could also register to be scored on the outcome-based administrative claims measure and submit five measures. During registration, they would attest to understanding that they would receive zero points for the administrative claims measure if they do not meet the case minimum. It is important to give ECs a choice so they can gain experience with an outcome-based administrative claims measure before transitioning to an APM or MVP.

#### **Data Completeness Criteria**

The existing regulatory text outlining the data completeness criteria erroneously reflected that the criteria are only applicable to Qualified Clinical Data Registry (QCDR) measures, MIPS CQMs, and eCQMs. The policy requires reporting on 70 percent of a measure's denominator-eligible patients, regardless of payer. This policy does not apply to those reporting via Medicare Part B claims, as they cannot report data for all payers. CMS is proposing to modify the policy to state, "MIPS eligible clinicians and groups submitting quality measures data on Medicare Part B claims measures must submit data on at least 70 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment year 2022."

CMS also omitted a proposal that would have extended the existing policy to determine the data completeness criteria for the 2021 MIPS performance period. CMS proposes to retroactively establish the data completeness criteria for the 2021 MIPS performance period, effective January 1, 2021. For the 2021 performance period, in addition to the proposal regarding Medicare Part B claims, CMS proposes to update the existing regulations to maintain the data completeness criteria threshold of at least 70 percent, in which MIPS ECs and groups submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs would need to submit data on at least 70 percent of the MIPS EC or group's patients that meet the measure's denominator criteria, regardless of payer.

CMS is proposing to maintain the data completeness threshold of 70 percent for the 2022 MIPS performance period. CMS is proposing to increase the data completeness threshold to 80 percent for the 2023 MIPS performance period.

#### *AAFP Response*

The AAFP [opposed](#) CMS' decision to increase the data completeness threshold to 70 percent for the 2021 MIPS performance period, as we felt it was inappropriate to increase the threshold unless real-time (or near real-time) feedback is provided to physicians to alert them when a patient is eligible for a quality measure. Since physicians still do not have sufficient data, we remain opposed to the proposed 2022 threshold of 70 percent and oppose CMS' proposal to increase it to 80 percent for the 2023 MIPS performance period. We urge CMS not to finalize this proposal and to decrease the data completeness threshold to 60 percent.

#### **Groups and Virtual Groups Reporting via the CMS Web Interface**

CMS is proposing to extend the Web Interface reporting option for an additional year. CMS will sunset the CMS Web Interface measures as a collection type/submission type starting with the 2023 performance period. CMS is proposing to modify the definitions of 'collection type' and 'submission type' to reflect the sunsetting of the Web Interface.

CMS is proposing substantive changes to the CMS Web Interface measures.

#### *AAFP Response*

The AAFP appreciates CMS' delay in sunsetting the CMS Web Interface. However, we are concerned that the updated timeline remains a significant issue for practices. The changes practices will need to make to report using a different method are extensive, burdensome, and costly. We strongly urge CMS to work with ONC to address issues with vendors. There are longstanding problems and barriers with updating EHR systems when regulations and reporting requirements change. Independent physician practices will have to pay for very costly EHR updates to report successfully. As a result, the changes CMS proposes are burdensome, difficult to implement in the real world, and place a significant financial strain on practices that successfully improve quality and reduce costs.

#### **Request for Information (RFI) Regarding the COVID-19 Vaccination by Clinicians Measure**

CMS began developing a COVID-19 Vaccination by Clinician measure for MIPS, which would assess the percentage of patients 18 and older seen for a visit during the measurement period who have ever completed or reported having ever completed a COVID-19 vaccination series. The measure would be reported as a MIPS CQM. The measure allows for an exception if the COVID-19 vaccination series was not administered, as documented by a MIPS EC, due to patient contraindication or vaccine availability.

The Measure Applications Partnership (MAP) expressed concerns regarding the patient population that would be assessed (i.e., including patients who received one dose versus only assessing patients who received a complete series) and a lack of available evidence and clinical guidance for vaccine administration. The feasibility of implementing the measure would be challenging given the limited supply, availability, and potential inconsistencies and discrepancies from collecting and reporting data for COVID-19 vaccinations. CMS seeks feedback about a potential COVID-19 vaccination measure.

*AAFP Response*

The AAFP has officially supported the existing ACIP recommendations for COVID-19 vaccination for all eligible populations and is committed to improving COVID-19 vaccination rates across the country. We know that COVID-19 vaccines provide strong protection against severe disease and death and are the most effective tool to end the COVID-19 pandemic. As mentioned previously, family physicians play an integral role in vaccine counseling and administration. They have implemented innovative workflows and taken on significant costs to offer the COVID-19 vaccine to their patients. We strongly agree with CMS' efforts to improve access to, and utilization of, COVID-19 vaccines. **However, we are deeply concerned that the measure CMS is developing will unfairly penalize family physicians and other clinicians for widespread vaccine hesitancy and patients' decision to refuse vaccination. Physicians cannot be held accountable for political and cultural forces that act against science.**

We appreciate that a measure similar to this could inform efforts to help reduce transmission, morbidity, mortality, and associated costs of treating COVID-19 infections during an evolving national pandemic. Such a measure would add value by increasing available data on vaccination and providing visibility into an important intervention to limit COVID-19 infections. However, it is premature for CMS to implement the measure as currently outlined, and several improvements and modifications are needed before this measure is ready for testing. The incomplete specifications require immediate mitigation and further development, and testing should continue. CMS should align this measure with the COVID-19 vaccination for health care workers measure to include only those who receive the full course of the vaccine as meeting the measure. Since the frequency of COVID-19 vaccination to maintain immunity is currently unknown, we anticipate the measure will continue to evolve to include the most effective ongoing strategies. We anticipate the measure could be readily modified to cover similar vaccination needs for any future infectious pandemics that may occur. **The AAFP is concerned the measure does not currently include an exclusion for patient refusal. Given our country's divided views regarding the COVID-19 vaccine, patient refusal must be a part of the measure exclusion criteria.**

The federal COVID-19 vaccination distribution plan focused heavily on mass vaccination sites and retail pharmacies and later included an additional focus on community health centers and, to some degree, physician practices. Since many COVID-19 vaccines are not administered in a physician's office, physicians can recommend that their patients receive the vaccination but cannot enforce or follow up on this recommendation to determine if the patient complied without considerable burden on practice staff since practices aren't notified when patients receive a vaccine. This puts physicians at a disadvantage to meet the measure and risks inaccurate and unreliable performance rates. The lack of interoperability among data systems (i.e., pharmacy, public vaccination efforts, other routes vaccines are administered) and state immunization information systems that lack the bidirectional capability and are not integrated with a practice's EHR will add burden to tracking and reporting of this measure for all settings.

In a July 2021 AAFP survey, some family physicians indicated that additional reporting and administrative requirements for the COVID-19 vaccines were a primary reason they chose not to offer the vaccine in their practices. The practices offering the vaccine cited these reporting requirements as additional, unique costs of administering the COVID-19 vaccine. We are concerned that implementing this measure could increase administrative burdens associated with COVID-19 vaccination and lead more physician practices to conclude they cannot afford to offer it, ultimately worsening access to the vaccine for beneficiaries. **For all these reasons, we oppose tying physician payment to**

**performance on this measure in the forthcoming MIPS performance periods.** We would recommend CMS instead measure physician and other clinician counseling about the vaccine rather than the individual clinician giving the vaccine.

The AAFP opposes mandating the use of this measure in the forthcoming MIPS performance periods, as we believe it will be administratively burdensome for physicians to report and premature given the current state of COVID-19 vaccinations across the country. If CMS decides to include this measure in the 2023 performance period, it should be optional, and physician practices should be able to choose whether or not to report it. The QPP currently allows clinicians to choose quality measures considered in their score, and that approach should not change. We note that when CMS implements a measure in MIPS, even on a voluntary or pay for reporting basis, private payers often adopt the measure and tie physicians' payment to that measure. As such, we caution against finalizing a measure for the MIPS program that has not been thoroughly tested and endorsed.

A PHE requires a fresh approach to the information collected and quick action to address the emergency, none of which should be tied to payment. CMS should work with EHR vendors to improve ease of data collection and payers to improve patient outreach and share all-payer information with physicians. **If CMS wants to collect additional data on COVID-19 vaccination, we recommend against using the QPP and instead consider a new approach altogether.**

After the COVID-19 PHE, and once the COVID-19 vaccine measure has been thoroughly tested and endorsed, the measure can be handled similarly to routine and seasonal vaccines. The National Quality Forum (NQF) endorsement process considers feasibility and barriers and should be relied upon to determine when the measure is ready for implementation. Specifications should include all vaccine-eligible patients, regardless of age, and an exception must be allowed if an age-appropriate, fully licensed vaccine is not available for administration. The measures must also allow an exception for patients that refuse vaccination.

#### **Quality Data Submission Criteria**

Beginning in 2022, CMS proposes adding the 'last primary care visit rule' as an additional exclusion for the CAHPS for MIPS Survey. This rule would exclude patients from the survey sampling frame if the patient's last primary care visit during the sampling period were associated with an institutional setting. CMS also proposes removing patients sampled for the Spring In-Center Hemodialysis (ICH) CAHPS survey from the sampling frames for CAHPS for MIPS.

CMS proposes adding an Asian language survey adjustor to the list of case-mix adjusters used for CAHPS for MIPS. The current list includes age, education, self-reported general health status, self-reported mental health status, proxy response, Medicaid dual eligibility, and eligibility for Medicare's low-income subsidy. This adjustor was previously used in the CAHPS for ACOs survey.

In 2018, CMS changed the Access to Specialists measure to 'unscored' because of low reliability and response rates. However, CMS implemented a shorter, streamlined version of the CAHPS for MIPS Survey, improving response rates and reliability of the Access to Specialists Summary Survey Measure (SSM). As such, CMS no longer has analytic concerns with scoring the measure. CMS is proposing to benchmark and score the Access to Specialists measure. This would mean there are nine SSMs included in the CAHPS for MIPS scoring process, with one SSM remaining unscored.

CMS seeks comments on these proposals.



#### *AAFP Response*

The AAFP supports this proposal.

#### **Cost Performance Category**

CMS seeks comment on the following five proposed episode-based cost measures:

- Melanoma Resection (procedural)
- Colon and Rectal Resection (procedural)
- Sepsis (acute inpatient medical condition)
- Asthma/Chronic Obstructive Pulmonary Disease (chronic condition)
- Diabetes (chronic condition)

#### *AAFP Response*

The AAFP supports developing episode-based cost measures that can more accurately measure physicians on costs within their control. Physicians should only be assessed on the costs they can reasonably influence and control. Episode-based cost measures allow physicians to use MIPS and MVPs as a stepping-stone to APMs. Adequately preparing physicians to understand and improve performance on cost measures is vital to transitioning to APMs. Until practices feel they understand the measures and are confident in their ability to influence cost measure performance, they will be reluctant to move to models with higher levels of financial risk. We are cautiously optimistic about new asthma/chronic obstructive pulmonary disease (COPD) and diabetes episode-based cost measures and look forward to their review and potential endorsement by NQF. The AAFP continues to urge CMS to identify ways to provide timely and relevant cost and utilization information to practices that will enable them to better manage costs for their patients.

The AAFP believes episode-based cost measures are more appropriate for the MIPS program than the total per capita cost (TPCC) and Medicare Spending per Beneficiary (MSPB) measures. As discussed in previous [letters](#) and this letter, we remain opposed to using the TPCC measure. TPCC is difficult to influence outside of a total cost of care APM, where there is shared interest and accountability in improving performance. Since there is no such shared accountability in MIPS, it seems likely primary care physicians will be penalized for decisions made by other members of a patient's care team. **For these reasons, the AAFP does not support using the TPCC measure in MIPS or MVPs.** In addition to episode-based cost measures, we encourage CMS to explore alternative ways to assess primary care on cost that recognize the long-term benefits of primary care may not be appropriately reflected in short-term cost measures. We welcome further discussions on the cost category for MIPS and MVPs.

#### **Proposed Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes**

CMS proposes revising the operational list of care episode and patient condition groups and codes beginning with the 2022 calendar year to include the five new care episode and patient condition groups. The care episode and patient condition groups are the basis for the five new episode-based measures proposed for the cost performance category. CMS seeks comments on this proposal.

#### *AAFP Response*

The AAFP supports this proposal.

#### **Proposed Process for Cost Measure Development by Stakeholders**

CMS proposes to conduct an environmental scan using the existing criteria for measure prioritization. The scan would identify a list of priority areas and suggested measures for development to be used by stakeholders wishing to develop cost measures. The criteria include:

- Clinical coherence of measure concept (to ensure valid comparisons across clinicians)
- Impact and importance to MIPS (including cost coverage, clinician coverage, and patient coverage)
- Opportunity for performance improvement
- Alignment with quality measures and improvement activities to ensure meaningful assessments of value

#### *AAFP Response*

The AAFP supports this proposal. As discussed earlier in this letter, we believe it is important for CMS to transition away from using TPCC in MIPS. Allowing stakeholders to develop new cost measures will help expedite that process.

Primary care physicians provide continuous, longitudinal care, which includes focusing on prevention and wellness. Expecting primary care physicians to reduce the total cost of care based on preventive services is not an appropriate measurement of the value of these services. Preventive measures have long-term benefits to both patients and the health care system, but they may increase short-term spending. However, investing in preventive services is a critical element of the transformation to value-based health care spending. While higher utilization of preventive care may reduce costs in the long term, the TPCC measure and MIPS are not designed to capture those savings and do not account for the value of such services. In addition to developing episode-based cost measures, we encourage CMS to review more appropriate ways to measure cost and believe CMS should explore using non-preventive utilization measures as a proxy for cost.

#### **Standards for Measure Construction**

CMS proposes using the same standards for cost measure construction used by the technical expert panels, clinical subcommittees, and clinician expert workgroups as they consider cost measures. The standards include:

- Measures must assign services that accurately capture the role of attributed clinicians
- Measures must have clear, ex-ante attribution to clinicians
- Measures must be based on episode definitions that have clinical face validity and are consistent with practice standards
- Measures' construction methodology must be readily understandable to clinicians
- Measures must hold clinicians accountable for only the costs they can reasonably influence
- Measures must convey clear information about how clinicians can alter their practice to improve performance
- Measures must demonstrate variation to help distinguish quality of care across individual clinicians
- Measure specifications must allow for consistent calculation and reproducibility using Medicare claims data

Additionally, cost measures must be based on a standard set of measure components to include episode definitions based on trigger codes that determine the patient cohort, attribution, service assignment, exclusions, and risk adjustment.

CMS seeks comment on these proposed standards and measure components. CMS also seeks feedback on the challenges stakeholders may encounter in developing cost measures and resources to assist their development.

CMS proposes that cost measures developed by stakeholders for potential use in MIPS would undergo the pre-rulemaking process described in section 1890A(a) of the Act. The submission process would begin with a call for cost measures. At the end of the period, stakeholders would submit their candidate measures for review by completing the required data fields to submit to the measures under consideration (MUC) list. If approved, the measures would be placed on the final MUC list. Measures submitted to the MUC list must be fully specified and tested for reliability and validity.

Submissions to the MUC list would be reviewed against a set of criteria. CMS proposes that stakeholders who wish to submit measures must submit measure specification information, test results, and related research to address the specified inclusion criteria (applicable, feasible, scientifically acceptable, not duplicative of existing measures, fully developed, consistent, fulfill a clinical performance gap).

#### *AAFP Response*

The AAFP supports this proposal. Cost measures must be designed to ensure they appropriately capture costs that physicians can reasonably influence. Further, cost measures must have meaningful alignment with quality measures and must be actionable. Physicians must have confidence in the accuracy and validity of the measures before they will be comfortable transitioning to APMs, where they may have more accountability for the total cost of care.

Regarding risk adjustment, the AAFP encourages CMS to explore alternative methodologies that do not rely on hierarchical condition category (HCC) scores and incorporate SDoH.

The AAFP supports holding cost measures to the same review and submission process as quality measures.

#### **Improvement Activities Performance Category**

CMS proposes to revise its policy regarding the percentage of national provider identifiers (NPIs) within a taxpayer identification number (TIN) or virtual group that must perform the same activity for the group to receive credit. To account for the new subgroup reporting option available for MVPs, CMS proposes to revise existing regulations to state, “beginning with the 2022 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs that are billing under the group’s TIN or virtual group’s TINs or that are part of the subgroup, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance year.” CMS requests comments on this proposal.

#### *AAFP Response*

The AAFP supports this proposal and believes it is important to hold subgroups to the same standard as ECs in traditional MIPS. Aligning requirements for subgroups and other types of participants helps ensure that those reporting through a subgroup are meaningfully contributing to an improvement activity rather than relying on others in the group to receive credit.

### **Promoting Interoperability (PI) Performance Category**

CMS proposes maintaining the Prescription Drug Monitoring Program (PDMP) measure as optional for an additional year. It would be worth 10 bonus points. CMS also requests comments on the future direction of the measure.

#### *AAFP Response*

We agree with maintaining this measure as optional for an additional year. We also agree that PDMP data can improve patient care and is valuable in addressing the opioid crisis. We have concerns with measuring physician adoption of the PDMP query. We believe the issues hindering wide-scale adoption is not physicians' unwillingness to use this function but the poor interoperability and user experience of Certified EHR Technology (CEHRT) and PDMP software. If PDMP queries were integrated into a clinician's workflow in a user-friendly way, we believe we would see rapid, wide-scale adoption. We strongly recommend that CMS work with ONC to establish measures for CEHRT to provide integrated, user-centered PDMP query that is more easily adopted. **CMS should not include [health information technology \(IT\) utilization measures](#) in the MIPS (or other) payment programs.**

CMS is proposing to modify the Provide Patients Electronic Access to their Health Information measure to require MIPS ECs to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely and use any application configured to meet the technical specifications of the application programming interface (API) in the MIPS EC's CEHRT.

CMS wants to align the date for this proposal for making information about encounters available with the date of service start date (January 1, 2016) as finalized in the Patient Access and Interoperability final rule (85 FR 25528), and as proposed for the Promoting Interoperability Program for eligible hospitals and critical access hospitals (CAHs) in the fiscal year (FY) 2022 Inpatient Prospective Payment System (IPPS) proposed rule (86 FR 25631). CMS considered an alternative for on or after January 1, 2012, or on or after January 1, 2019.

#### *AAFP Response*

While we support patients' having ready access to their data and agree the information should not only be available for a short, arbitrary duration, we strongly oppose the use of the term 'indefinitely' in the measure. Record retention laws and regulations govern the timeframes physicians are required to retain a patient's health information. We recommend using those timelines for when ECs must make patient health information available to reduce regulatory burden and confusion. This measure should also be limited to only information that is readily available within the EHR. A practice may switch between CEHRTs. Due to a lack of robust interoperability, some may encounter information not available in the new EHR. Therefore, only information readily available within the EHR should be used for this measure.

### **Proposed Scoring of the Public Health and Clinical Data Exchange Objective**

Beginning with the 2022 MIPS performance year, CMS proposes that an EC receive 10 points for the Public Health and Clinical Data Exchange objective if they attest 'yes' for the Immunization Registry and Electronic Case Reporting measures. If an EC claims an exclusion for one or more measures, they receive 10 points for the objective if they report a 'yes' for one measure and claim an exclusion for the remaining measure. If an EC fails to report on any one of the two measures or reports a 'no,'

they will receive zero points for the objective and a total score of zero points for the promoting interoperability category. If an EC claims exclusions for both measures, CMS will redistribute the points for the objective to the Provider to Patient Exchange objective.

CMS proposes to retain the Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting measures and make them optional and available for bonus points beginning with the performance period in CY 2022.

#### *AAFP Response*

We agree with the value of, and need for, public health data exchanges. Public health registries and other mechanisms for data exchange have not been universally adopted because they are not integrated into physicians' clinical workflow, and CEHRT does not have a user-centered experience for data submission and the use of these registries. Again, the problem is not that physicians are unwilling to report to public health registries, but rather that the current process for doing so is overly burdensome and, in some cases, prohibitively expensive. We again oppose the use of health IT utilization measures in MIPS (or other payment programs). We support exclusions for MIPS measures when achieving the measure is not feasible due to circumstances outside the physician's control, such as lack of access to broadband or the availability of registries. We strongly disagree with bypassing these exclusions and redistributing the points to other measures. We strongly oppose CMS' continued 'all-or-nothing' approach to scoring the promoting interoperability category. The promoting interoperability category is burdensome and complex. Penalizing a physician for failing to meet one measure can substantially impact the physician's final score and subsequent payment adjustments. CMS' scoring approach is counterproductive and not conducive to preparing practices for an APM.

CMS proposes to add a new measure to the Protect Patient Health Information objective. Beginning with the 2022 performance period, CMS proposes that an EC must attest to having conducted an annual self-assessment using the SAFER High Priority Practices Guide at any point during the calendar year in which the performance period occurs. ECs would attest 'yes' or 'no.' CMS proposes requiring this measure, but it would not be scored and would not affect the total number of points earned for the promoting interoperability category.

#### *AAFP Response*

We strongly agree with the need to protect patient health information, particularly since it is essential to protecting the patient-physician relationship. We have [advocated](#) for these protections to be fortified as interoperability advances and information becomes more readily accessible. There are many laws in place to require the protection of such data. Adding a MIPS measure adds administrative burdens associated with reporting and understanding the potential nuances between the measure definition and the requirements under the law (i.e., HIPAA, information blocking). The AAFP has previously [recommended](#) that CMS, ONC, and other agencies harmonize the requirements across regulations to address confusion and compliance burden for physician practices. For these reasons, we do not support the reporting of measures on protecting health information.

Beginning with the performance period in CY 2022, CMS proposes to no longer require ECs to attest to statements B and C of the information blocking statements. ECs would only be required to attest to statement C, which states, "Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor."

#### *AAFP Response*

The AAFP supports this proposal and appreciates CMS' effort to reduce clinician burden by updating its policy.

Beginning with the CY 2022 performance period, CMS proposes no longer requiring an application for clinicians and small practices seeking to qualify for the small practice hardship exception and reweighting. CMS would instead automatically assign a weight of zero percent to the promoting interoperability performance category and redistribute its weight to another performance category or categories (according to their policies) in the event no data is submitted for any of the measures by, or on behalf of, an EC in a small practice. If data is submitted for an EC in a small practice, they would be scored on the promoting interoperability category like all other ECs. The small practice significant hardship exception still would be subject to annual renewal. CMS would verify whether a practice meets the definition of a small practice on an annual basis.

CMS seeks comments on potential options to increase small practice participation in the future.

#### *AAFP Response*

**The AAFP strongly supports the automatic application of the hardship exception to small practices.** We believe small practices have not applied for the exception for various reasons, including lack of awareness, fear of being audited, and the burden of applying. Similarly, there are many reasons that physicians have not adopted CEHRT. Small practices often lack the resources necessary to build an IT infrastructure and implement CEHRT. The time and burden of implementing an EHR are significant barriers to a practice that does not have the resources to outsource such a project. We also know that lack of access to reliable broadband internet poses a barrier to many practices in rural areas. In addition to financial support, CMS needs to invest in technical assistance for small practices to help them implement and maintain an EHR. While implementation may be the initial barrier, small practices also face challenges in the ongoing maintenance of an EHR, including data management, upgrades, and training. Further, reporting to the promoting interoperability performance category is overly burdensome, particularly for small practices.

As CMS implements MVPs, it will be imperative that they support small practices in maintaining and optimizing the use of their CEHRT. We support CMS' efforts to move to more electronic data collection methods to reduce reporting burden, but we are concerned that this may leave some small practices behind. To fully realize the potential of MVPs and ultimately support clinicians' transition to APMs, it will be vital to ensure these practices can access and utilize CEHRT.

#### **MIPS Final Score Methodology Quality Performance Category**

CMS proposes revising its policy related to changes that impact quality measures during the performance period. CMS proposes changing the language from 'significant changes' to 'significant changes or errors' and omitting certain codes or including inactive or inaccurate codes. This will provide that for each measure submitted and impacted by significant changes or errors before the applicable data submission deadline, performance would be based on data for nine consecutive months of the applicable CY performance period. If such data are not available or CMS determines that they may result in patient harm or misleading results, the measure is excluded from a MIPS EC's

total measure achievement points and total available measure achievement points. CMS requests comments on this proposal.

#### *AAFP Response*

The AAFP is supportive of this proposal. For each circumstance, we encourage CMS to work with stakeholders to assess whether it would be appropriate to measure a practice on nine months of data, particularly for quality measures with a 12-month performance period.

#### **Quality Measure Benchmarks**

CMS is considering two benchmarking options for the 2022 MIPS performance period. They propose to use performance period benchmarks for the CY 2022 performance period. CMS seeks comments on potential alternatives that may be more appropriate, including historical benchmarks. CMS is considering using historic benchmarks from the 2021 MIPS payment year for the 2022 performance period. CMS is concerned that utilizing outdated data could result in distributions of scores used for benchmarks that no longer reflect the standard of care, especially as care changes in response to the PHE.

CMS proposes to expand the definition of the baseline period. For instances in which a measure is suppressed two performance periods before the standard baseline period and cannot be used to calculate a benchmark, CMS proposes using the data from three performance periods prior to calculate benchmarks if a performance period benchmark cannot be calculated. If a measure had undergone a substantive change or was suppressed in the baseline period three performance periods prior, CMS would not use it to calculate benchmarks. The measure would be subject to the scoring policies for Class 2 measures. CMS would not use benchmarks calculated from performance periods that are older than three performance periods prior.

#### *AAFP Response*

The AAFP supports the proposal to use performance period benchmarks. While this is not ideal, we feel it would be more appropriate than using historical benchmarks. Performance period benchmarks will be more representative of the care provided during the COVID-19 pandemic. We strongly encourage CMS to release the 2021 performance year benchmarks as soon as possible in 2022.

#### **Scoring Measures Based on Achievement**

For the 2022 performance period, CMS proposes removing the three-point floor for each measure that can be reliably scored against the benchmark. Measures would receive 1-10 points. CMS invites comments on this proposal.

#### *AAFP Response*

The AAFP believes CMS should assess the full impact of this policy before removing the three-point floor. We encourage CMS to review how frequently ECs have performance rates that place them below the three-point floor – particularly ECs in small and rural practices.

#### **Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements**

For the 2022 performance period, CMS proposes to remove special scoring policies for Class 2 measures that meet the data completeness requirement but do not have a benchmark due to fewer than 20 individual clinicians or groups adequately reporting the measure or meeting the case

minimum requirement. CMS proposes to retain the 3-point floor for Class 2 measures for small practices.

CMS is proposing a new Class 4 measure classification for new measures in the program's first two years. Measures that can be reliably scored against a benchmark because they meet data completeness requirements, have a performance period benchmark calculated, and meet case minimum requirements will be considered Class 4a and receive 5-10 points. A measure that cannot be reliably scored against a benchmark because it lacks a benchmark or does not meet case minimum requirements but meets the data completeness requirement will be considered Class 4b and receive 5 points. Measures that cannot be scored because they do not meet the data completeness requirement will remain subject to the Class 3 measure policy and receive a score of zero for clinicians other than small practices. Small practices will continue to receive 3 points.

#### *AAFP Response*

The AAFP supports these proposals. We appreciate CMS' new policy for a 5-point floor for new measures in their first two years of the program. We encourage CMS to indicate which measures will be considered Class 4 measures. It will be important for CMS to communicate whether a measure is in its first or second year as a Class 4 measure so physicians can plan appropriately.

CMS should also consider implementing a similar scoring floor policy for new cost measures. Physicians being measured on new cost measures will not have data for the patients being attributed to them for the measures. The new cost measures have a different structure (episode versus total cost), and varying attribution methodologies than what physicians may be familiar with from previous measures. Providing a scoring floor will allow physicians to adjust and understand the new measures without fearing their performance will significantly harm their MIPS scores. After two years, physicians will have more experience with the measures and better understand the data and identify ways to improve their performance.

#### **Minimum Case Requirements**

CMS proposes to modify their minimum case requirements policy to broaden the type of measures that have an exception to the 20-case minimum and provide for a measure-specific minimum requirement determined on a case-by-case basis. Measures with a measure-specific case minimum will be specified in the annual list of MIPS measures.

#### *AAFP Response*

The AAFP supports CMS' efforts to ensure physicians are assessed on measures that are reliable and valid. However, we caution CMS that introducing too many case minimum requirements will add complexity and burden to the program. It is already difficult for physicians to track which requirements apply to which measures. Varying case minimum thresholds will add a new level of burden and further complicate a physician's ability to identify measures that would be appropriate for them to report.

We ask CMS to monitor whether there are increasing numbers of measures requiring measure-specific case minimums and the impact on burden. In addition, we ask CMS to review the existing measures and ensure they meet at least a 0.70 reliability. CMS should determine whether they need to adjust to existing measures based on their updated case minimum policy.



CMS notes that their bonus point policies introduced at the beginning of the program were intended to be temporary. As such, CMS proposes that beginning with the 2022 performance period, they will no longer provide bonus points for reporting high-priority measures and for reporting measures submitted using end-to-end electronic reporting. CMS seeks comments on this proposal.

#### *AAFP Response*

The AAFP encourages CMS to continue offering bonus points for reporting outcome measures and for electronic end-to-end reporting. Both outcome measures and electronic reporting remain priorities for CMS, and they should continue to recognize practices for their efforts to meet these priorities.

#### **Cost Performance Category**

##### **Scoring Flexibility for Changes that Impact Cost Measures During the Performance Period**

Beginning with the 2024 MIPS payment year, CMS proposes to exclude a cost measure from an EC's score if the data used to calculate the measure are impacted by significant changes during the performance period. Calculating the cost measure score under such a circumstance could lead to misleading or inaccurate results. For purposes of this policy, 'significant changes' are external to the care provided, and CMS determinations may lead to misleading or inaccurate results. A significant change could include rapid or unprecedented changes to service utilization. CMS will empirically assess this to determine the extent changes impact the calculation of a cost measure score that reflects clinician performance.

#### *AAFP Response*

The AAFP supports this policy. As the COVID-19 pandemic continues to surge, CMS must assess whether it can reasonably score physicians on the cost category. The unpredictability of the COVID-19 pandemic makes it difficult for CMS and practices to understand the impact on cost. Practices have experienced various changes in utilization, including increased use of telehealth services and a rebound in in-person services in 2020 after an initial drop in utilization. Research suggests that missed preventive care services and CCM could lead to additional illness and cost, some of which family medicine practices may already be seeing.<sup>15</sup> Physicians should not be unfairly penalized for these variations in utilization or their impact on costs. Researchers and physicians are still learning new things about the long-term effects of COVID-19, but early evidence shows that many people experience long-term symptoms that interfere with their ability to complete daily tasks and may drive additional utilization of services.<sup>16</sup>

**We strongly urge CMS to automatically apply the extreme and uncontrollable circumstances policy for the 2021 performance period.** COVID-19 cases are steadily increasing, with little sign of waning in the near term. Physician practices report that they are overwhelmed with caring for patients with COVID-19 (including long COVID), providing COVID-19 vaccines, and providing regular primary care services. It is not reasonable to expect practices to report data for a year that has been and continues to be severely impacted by the COVID-19 pandemic. Family physicians and other clinicians must focus on caring for patients during this challenging time, not completing a burdensome reporting process.

The data will not be reliable or indicative of a practice's true quality and cost performance. Practices should not have to submit a reweighting application when it's clear the COVID-19 pandemic has had a national impact. Instead, CMS should automatically apply the extreme and uncontrollable circumstances policy in a timely manner.

### **Calculating the Final Score Performance Category Weights**

The performance category weights for the 2022 performance year will be as follows:

- Quality – 30 percent
- Cost – 30 percent
- Improvement activities (IA) – 15 percent
- Promoting interoperability – 25 percent

#### *AAFP Response*

The AAFP strongly urges CMS to explore ways to use its authority to maintain a cost category weight of 20 percent for the 2022 performance period. It would be unfair to increase the category's weight when we do not have a way to account for the significant impact the COVID-19 pandemic has had on cost performance. As stated elsewhere in this letter, the AAFP does not believe CMS should expect practices to continue or exceed their performance level they achieved before the COVID-19 pandemic.

### **Complex Patient Bonus**

Due to the concerns of the direct and indirect effects of the COVID-19 PHE, CMS proposes to continue doubling the complex patient bonus for the CY 2023 MIPS payment year. The doubled numerical value (subject to the 10-point cap) would be added to the final score.

CMS also proposes to revise the complex patient bonus by limiting the bonus to clinicians who have a median or higher value for at least one of the two risk indicators (HCC and dual proportion); standardizing the distribution of the two risk indicators so that the policy can target clinicians who have a higher share of socially and/or medically complex patients; and providing one overall complex patient bonus cap at 10 bonus points.

#### *AAFP Response*

The AAFP supports CMS' intent to ensure the complex patient bonus targets practices caring for high-risk and complex patients. However, we are concerned that CMS' proposed methodology could disadvantage rural practices. We ask CMS to delay implementation of the updated methodology until after the COVID-19 pandemic has ended. The long-term effects of COVID-19 will likely need to be accounted for in risk-adjustment calculations. CMS proposes limiting the complex patient bonus to ECs, groups, subgroups, APM entities, and virtual groups with a risk indicator at or above the calculated median. As CMS notes, beneficiaries in rural areas have lower HCC scores compared to beneficiaries in urban locations despite previous research showing that rural populations are sicker than urban populations.<sup>17</sup> As a result, practices in rural areas may be inadvertently deemed ineligible for the complex patient bonus. To address this, we recommend CMS calculate the median HCC risk indicator at both the national and regional levels and determine eligibility using the lower of the two scores. A regional median would account for the historically low HCC scores in rural areas. Additionally, we believe using the lower of the two scores would compensate for instances in which an ACO may have a large market share, which would skew the regional median higher.

### **Final Score Performance Category Weights Redistributing Performance Category Weights**

CMS seeks comment on whether external factors, such as national shortages or rapid or unprecedented changes in health care personnel, medical supplies, diagnostic tools, or materials; or patient case volumes and patient case mixes should inform CMS' future decision making about whether to reweight the cost performance category. CMS also seeks comment on whether there are

other external factors they should consider or other circumstances that could affect their ability to reliably calculate a score for the cost performance category.

#### *AAFP Response*

The AAFP strongly believes the external factors outlined by CMS should inform their decision making on whether to reweight the cost category. It would be unreasonable to assess a physician on costs that were, by definition, beyond their control. We encourage CMS to consider significant changes in guidelines and whether the external factors will impact beyond the applicable performance period. This is particularly true for events, such as the COVID-19 PHE. For example, the COVID-19 pandemic has required unprecedented increases in testing to diagnose the virus – including tests to rule out COVID-19 in addition to the COVID-19 test itself. The PHE has necessitated the rapid development and widespread distribution of a new vaccine. In addition, the recommended vaccine schedule is rapidly evolving. The effect COVID-19 will have on cost is unknown and unpredictable, but we know it will be long term. Existing risk-adjustment methodologies may not appropriately account for the impact of COVID-19. These are current examples of unforeseen changes in guidelines and utilization that will affect cost due to their magnitude. Future instances could result in significant and rapid changes that CMS will need to consider as it decides whether to reweight the cost category.

**We strongly urge CMS to automatically apply the extreme and uncontrollable circumstances policy for the 2021 performance period.** COVID-19 cases are steadily increasing, with little sign of waning in the near term. It is unreasonable to expect practices to report data for a year that continues to be severely impacted by the COVID-19 pandemic. The data will not be reliable or indicative of a practice's true quality and cost performance. Practices should not have to submit a reweighting application when it's clear the pandemic has had a national impact.

#### **Redistributing Performance Category Weight for Small Practices**

CMS proposes a separate reweighting policy for ECs in small practices. Specifically, CMS proposes that when the promoting interoperability category is reweighted, CMS will transfer that category's weight to the quality performance category, so the quality category will be weighted at 40 percent. The cost performance category will be weighted at 30 percent, and the improvement activities performance category will be 30 percent. When the cost and promoting interoperability performance categories are reweighted, the quality performance category will be 50 percent, and the improvement activities performance category will be 50 percent. CMS seeks comments on this proposal.

#### *AAFP Response*

The AAFP supports this policy and appreciates CMS' recognition that small practices often face unique challenges requiring alternative policies.

#### **MIPS Payment Adjustments**

CMS proposes using the mean of the final score for all MIPS ECs from a prior period to set the performance threshold for the 2024, 2025, and 2026 MIPS payment years. CMS will reassess the methodology for MIPS payment years 2027-29.

For the 2022 performance period, CMS proposes to use the rounded mean 2019 MIPS payment year data to establish the performance threshold. The 2022 performance period threshold will be 75 points.

CMS proposes establishing the additional performance threshold using the 25<sup>th</sup> percentile of the final scores for the 2019 MIPS payment year. For the 2022 performance period, the additional performance threshold will be 89 points.

#### *AAFP Response*

**The AAFP encourages CMS to explore ways to use its authority, including emergency authorities under the PHE, to adjust the performance threshold beginning with the 2022 performance period.** Continuing to increase the performance threshold fails to recognize the significant and long-term impact of the COVID-19 pandemic on physician practices. Setting the performance threshold at 75 for the 2022 performance period will represent a 30-point increase since the 2020 performance period. Practices will have been grappling with the COVID-19 pandemic for a full two years by the time the 2022 performance period begins. The steep increase from 45 to 75 points assumes that practices will not only perform as well as they did before COVID-19 but that they will be able to perform better than before. Failure to exceed the performance threshold will result in a negative payment adjustment, including a potential nine percent negative adjustment. This effectively punishes practices for focusing on patients rather than submitting data. Continuing to increase the performance threshold could also negatively impact practices' ability to make the necessary investments in APMs. Therefore, we believe it is reasonable for CMS to use its authority to delay the increase of the performance threshold due to the impacts of the COVID-19 pandemic.

**The AAFP again urges CMS to automatically apply the extreme and uncontrollable circumstances policy for the 2021 performance period.** Family physicians and other clinicians must be able to focus on caring for patients during this challenging time, not completing a burdensome and costly reporting process. Further, the data will not be reliable or indicative of a practice's true quality and cost performance. Practices should not have to submit a reweighting application when it's clear the COVID-19 pandemic has had a national impact. Instead, CMS should automatically apply the extreme and uncontrollable circumstances policy in a timely manner.

#### **Public Reporting on the Compare Tools**

CMS proposes a one-year delay in publicly reporting new improvement activities and promoting interoperability measures for individuals, groups, and subgroups reporting via MVPs. CMS believes this will encourage participation in MVPs as new activities and promoting interoperability measures would be available for public reporting in traditional MIPS the first year they are used. Existing improvement activities and promoting interoperability measures that become newly available as part of an MVP would be available for public reporting in the first year the MVP is in the program. CMS requests comments on this proposal and any feedback on alternate approaches they should consider.

CMS proposes creating a subgroup public reporting workflow. The subgroup would indicate on an individual profile page or a group profile page that the group has subgroups and provide a link to the subgroup's performance information.

CMS proposes a one-time, one-year delay in public reporting of subgroup information. For CY 2023, CMS would not report any subgroup-level performance information, but the information would be available for public reporting beginning with the CY 2024 performance period. Beginning with performance year (PY) 2024, CMS would publicly report subgroup performance information.

CMS also considered a one-year public reporting delay for all new subgroups each performance year. Additionally, CMS considered publicly reporting subgroup information without delay but providing new subgroups the opportunity to opt out of public reporting of their performance information for their first year.

CMS plans to continue its approach regarding whether a group participates in an ACO. CMS would indicate data that comes in via the APP as technically feasible. CMS seeks comment on alternative ways to publicly report performance information via APPs and additional considerations to publicly report this information.

CMS proposes to add affiliations to clinician profile pages for the following types of facilities: inpatient rehabilitation facilities, long-term care hospitals, skilled nursing facilities, inpatient psychiatric facilities, home health agencies, hospices, and dialysis facilities. CMS would determine affiliations with these facilities using claims data the same way they do to determine hospital affiliations. CMS seeks comment on this proposal and whether they should consider a limit on the number of procedures done or conditions treated at a given facility to determine clinician-facility affiliations.

#### *AAFP Response*

The AAFP believes it may be confusing for patients if CMS delays reporting new measures for clinicians reporting through MVPs but not those who continue to report through traditional MIPS. Without the information, patients will have an incomplete picture of MVP participants, which would be counterproductive to the intent of the Compare Tools. We encourage CMS to implement an option to allow MVP participants to opt out of having their data displayed for their first year. Alternatively, if CMS moves forward with a blanket delay, the AAFP recommends including a note on the clinician's page so that beneficiaries are not confused by the lack of information for certain clinicians and not others.

We understand the intent behind delaying the reporting of subgroup data, but we have the same concerns with delaying reporting measures for MVP participants but not traditional MIPS.

The AAFP supports the addition of facility affiliations if CMS can reliably determine a relationship between the physician and the facility. We support setting a threshold to determine an affiliation. A threshold needs to demonstrate a meaningful and consistent relationship between the physician and the facility.

#### **Utilization Data Request for Information**

CMS believes adding utilization data to profile pages on Care Compare will provide patients and caregivers with meaningful information to inform their health care decisions. CMS is considering displaying the number of times a clinician performed a procedure or treated a condition within a certain time period on their profile page on the Care Compare website. However, CMS believes they need to apply a minimum experience level before annotating a profile to indicate experience with the condition or procedure. CMS is considering setting a threshold based on the number of times a clinician performed a procedure or treated a condition within a certain timeframe, or the proportion of the clinician's practice represented by the procedure or condition. Alternatively, CMS could rank clinicians compared to their peers (specialty and geography may be considered when defining peers) in the volume of procedures performed or the frequency with which they treat each condition.

CMS seeks comments on these approaches and whether there are alternatives they should consider. CMS also seeks comments on whether national or local thresholds may be appropriate, potential types of utilization data that could help Medicare patients, whether caregivers make informed decisions, and technical considerations for presenting a specific affiliation among clinicians, diagnoses, and procedures.

#### *AAFP Response*

We understand that utilization data may be beneficial for finding specialist physicians for certain procedures or conditions. The AAFP is concerned that, given the breadth of services furnished by primary care physicians, displaying utilization data could be confusing for patients. For instance, it could lead patients to believe that family physicians only practice a narrow set of services and cannot address an acute problem. We are also concerned that patients may equate volume with quality. While the utilization and quality information may be presented simultaneously, it may be difficult for patients to distinguish them – particularly since the Compare Tools only include Medicare data. As such, we do not think CMS should include utilization data in the Compare Tools.

#### **APM Incentive Payment Recipient**

CMS makes two proposals to improve the timeliness of APM incentive payments. CMS proposes to clarify that, when they divide the APM incentive payment between two or more TINs, they apportion the payment among TINs based on the share of total payments for covered professional services made to each TIN in the same base year. This is used to calculate the incentive payment. CMS also proposes to revise the existing methodology to identify TINs to distribute payments. Under this proposal, CMS would add a step to identify TINs associated with the qualified participant (QP) during the payment year if they cannot find an associated TIN during the performance year. This would allow CMS to make payments earlier in the calendar year and reduce reliance on the public notice process to make payments.

#### *AAFP Response*

The AAFP supports this proposal and appreciate CMS' efforts to make payments earlier in the year. Shortening the timeframe between performance and payment and reducing the barriers practices face to receiving incentive payments will further encourage participation in APMs.

#### **Newly Proposed Quality Measures**

The AAFP strongly supports the addition of the Person-Centered Primary Care Measure (PCPCM) to MIPS. This measure addresses the core elements of primary care in the form of a patient-reported outcome measure. Primary care requires a whole-person approach, prioritization of needs, sophisticated primary care team, and consideration of the patient's goals within the context of their social system. The PCPCM assesses whether the patient's needs, goals, and social systems – the whole person – are being considered when providing care. While many aspects of quality primary care are challenging to capture using standard data from EHRs, patients are well equipped to report them.

The PCPCM aligns with the AAFP's [Vision and Principles of a Quality Measurement Strategy for Primary Care](#). The AAFP supports measures that focus on the unique features of primary care that are most responsible for better outcomes and lower costs and are under the reasonable control of the primary care physician. The PCPCM focuses on many elements that are known to add value to the health care system. Additionally, this measure is well aligned with CMS' [Meaningful Measures](#)

initiative. The structure of the PCPCM allows it to be reported annually and with a lower burden and cost compared to CAHPS.

#### Request for Information on Patient Access Outcomes Measures

*What do stakeholders believe would be useful ways to measure patients' access to their electronic health information using health IT methods, such as patient portals and/or third-party applications? What actionable figures related to users' medical record behavior, including but not limited to, the frequency of logins, number of messages sent, or lab results viewed could be captured?*

Patients and physicians must be able to access a patient's complete health information from one source, rather than logging in to many portals and chasing down information from pharmacies (e.g., immunization records) and other data sources. Measuring this ability to access all this information from one source could facilitate greater access and patient engagement, as well as create accountability for health IT and EHR vendors to implement the necessary data standards and applications to ensure one source access.

*How effectively is the promoting interoperability performance category at measuring the use of health IT-enabled processes to improve patient outcomes? What measures in the current performance category are most relevant to patient outcomes?*

The promoting interoperability performance category does not effectively measure health IT-enabled processes that improve patient outcomes. The AAFP has long opposed the use of health IT utilization measures, as they do not measure meaningful use of technology or its impact on patients' health. Instead, this category adds an unnecessary burden to physicians and other clinicians. As we mentioned previously, these measures are not the best way to improve the adoption of certified health IT. Instead, CMS should work with ONC to improve the usability of CEHRT and public health reporting systems.

*Should we require health care providers to maintain a record of third-party applications which patients use to access their patient health information through APIs incorporated within certified technology so this information could be used to assess patient usage of the applications?*

No, this requirement would be extremely burdensome for physician practices. The burden and cost of tracking and measuring patients' access to their health information should not be placed on physicians and other clinicians. Rather, such measures should not be implemented until they can be tracked automatically by the third party and/or EHR vendor. ONC is already examining how these measures could be conducted at the CEHRT level, which is much more appropriate than reporting by physician practices.

*What are specific technologies, capabilities, or system features (beyond those currently addressed in the promoting interoperability performance category) that can increase patient utilization of tools to access their health information? How do these technologies and features support improved access or usability within EHR systems and other applications (for instance, alternate authentication technologies that can simplify consumer logon)? How could CMS reward health care providers for higher adoption rates and use of these available technologies?*

Health IT vendors must make use of this technology seamless to physicians and other clinicians. The entire promoting interoperability performance category should measure health IT usability rather than a measure of physician action. Physicians are limited by the inefficiencies in technology rather than by what they are committed to accomplishing for the patient in terms of access to integrated and complete health care information.

Further, assuming all patients want or will use patient portals and other tools is a one-size-fits-all approach that ignores patient preferences and systemic barriers. Some patients may not want or feel comfortable using these tools to access their health information. As we discussed with respect to telehealth, access to a stable broadband connection can be challenging for many beneficiaries and hamper patients' use of portals and other tools. Physicians cannot control patients' preferences for using technology nor their ability to properly connect with them. Therefore, the AAFP recommends against measuring physicians on their patients' use of portals or other tools.

*What are key administrative processes that could benefit from more efficient electronic workflows? How could CMS measure and reward participating MIPS ECs for greater uptake of patient portal access or subsequent health outcomes?*

Physicians should not be measured on patients' use of patient portal access and the resulting outcomes. The lack of uptake of patient portals is a failure of health IT vendors, not physician practices. The current system is not user-friendly, and therefore, patients aren't interested in using these tools. Patients are required to log into multiple portals to see their information. Some information, such as vaccinations, is not accessible to patients at all. This process is burdensome and creates barriers to accessing health information. Instead, patients need access to user-friendly apps that compile their health care information from all sources into one easily accessible location.

#### Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs – Request for Information

CMS plans to transition to full digital quality measurement by 2025 and believes data standardization and interoperability enabled by APIs will support this transition. CMS seeks feedback on the proposed definition of Digital Quality Measures (dQMs), a software that processes digital data to produce a measure score(s).

#### *AAFP Response*

The AAFP supports CMS' goal of transitioning to full digital quality measurement by 2025 and agrees that standardization and interoperability enabled by APIs are essential to this transition. Performance measure data should be extracted from multiple data sources and should not rely on physicians and their teams to self-report data. This leads to less accurate and reliable data and financial penalties for non-reporting that disproportionately impact small practices. Moving to dQMs that extract data will reduce administrative burden and help resolve comparability problems with performance data submitted through various mechanisms. We urge CMS to ensure that physician practices do not bear the brunt of the costs when transitioning to dQMs. Health IT updates are extremely costly, particularly for smaller practices and those that care for a high proportion of underserved patients. CMS should not impose a huge cost on these practices as a prerequisite for successful performance in quality programs. Instead, we urge CMS to work with ONC to ensure standardization and other regulatory



mechanisms are used to minimize the cost on physician practices and hold health IT vendors accountable for making the necessary updates.

CMS is also seeking feedback on the use of Fast Healthcare Interoperability Resources (FHIR) for current eCQMs, specifically:

- Do you agree that a transition to FHIR-based quality reporting can reduce the burden on health IT vendors and providers?
- Would access to near real-time quality measure scores benefit your practice? How so?

#### *AAFP Response*

The AAFP agrees that the transition to FHIR can reduce reporting burden, even though we believe this could take time. During the transition to the use of FHIR, CMS should make every effort to mitigate any additional burden on physicians. CMS may need to relax reporting requirements and emphasize existing measure initiatives to support an 'all-hands-on-deck' transition. Transitions normally require running parallel systems for a specified period of time, which is burdensome and costly. Relaxing requirements for using the 'old' system would help address this burden. Requirements for using new technologies must provide adequate flexibility for small, rural, and underserved practices that may not have resources or access to the latest technologies for reporting.

The AAFP has been calling for near real-time feedback for some time. Feedback would be beneficial if delivered in a push and pull environment for maximum flexibility. Practices should be able to query the data and drill down into all feedback to continually identify and address care gaps. Improving quality at the point of care is the desired goal, rather than analyzing the past.

CMS seeks comments on several questions on four proposed areas of action in transition to dQMs by 2025.

*Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements? What are the strengths and limitations of this approach? Are there specific FHIR implementation guides suggested for consideration?*

We agree with the move from eCQMs to dQMs and the alignment of quality measurement and interoperability requirements. These have the potential to reduce the burden on physicians and practices to report quality and increase the types of quality measures that can be adopted.

*How important is a data standardization approach that supports patient-generated health data (PGHD) and other currently non-standardized data?*

The AAFP supports a data standardization approach to include PGHD and other non-standardized data. However, there will be a learning curve and a transition period to move existing patient-reported outcomes (PRO) and PGHD data to this standard. Prioritization should be given to data that will have the greatest impact on quality and the shortest timeline to adopt.

*What functionalities, described in Section (4)(b) or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (e.g., standardized EHR data available via FHIR-based APIs)?*

We would like to see the functionalities identified in this section, as well as the following additional functionalities in quality measure tools: flexible queries, push and pull real-time feedback, graphing abilities (e.g., run charts) to support QI, ability to drill down to the patient level to identify quality gaps, and aggregating data at multiple levels (geographic) for public health and research. Physician practices should be able to use the same calculation and data sources as payers and thus calculate real-time scores and identify gaps with identical results as payers. This would improve practices' ability to address performance concerns in real time instead of being surprised at the end of the performance year and determining where a problem score came from.

*How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes, such as public health or research?*

Standardized data would allow for improved data aggregation for all purposes. It would also facilitate the development of innovative applications to help improve patients' and physicians' use of data to improve the quality of care. The end-to-end calculation would also allow unlimited analyses and comparisons to be performed without burdening physicians and other clinicians.

*What role can or should data aggregators play in CMS quality measure reporting in collaboration with providers? How can CMS best facilitate and enable aggregation?*

Aggregators should perform uniform, standard, and scheduled aggregations at levels based on payment decisions and provide interpreted feedback to users. Applications should also be available to allow users to aggregate data at any level desired at any point in time. Real-time dashboards should aggregate data using dQM software to make payment determinations, so progress and gaps are monitored in real time.

#### Closing the Health Equity Gap in CMS Clinician Quality Programs – Request for Information (RFI)

CMS seeks comment on potentially stratifying quality measure results by race and ethnicity and improving demographic data collection in hospitals.

CMS requests information on revising CMS programs to report health disparities based on social risk factors, race, and ethnicity more comprehensively and actionable for hospitals, providers, and patients. Feedback will inform a future, comprehensive RFI focused on closing the health equity gap in CMS programs and policies. CMS is interested in feedback about the potential benefits and challenges of measuring hospital equity using an imputation algorithm to enhance existing administrative data for race and ethnicity until self-reported information is sufficiently available. CMS is interested in current data collection practices by hospitals to capture demographic data elements

(i.e., race, ethnicity, sex, sexual orientation and gender identity [SOGI], language preferences, tribal membership, disability status). CMS is interested in the potential challenges with collecting a minimum set of demographic data elements in alignment with national data collection standards and standards for interoperable exchange. CMS seeks comments on other efforts within the MIPS program to bridge the equity gap.

#### *AAFP Response*

The AAFP appreciates and strongly supports CMS' commitment to addressing health disparities and closing the health equity gap across programs. We share the agency's commitment to advancing health equity and look forward to partnering to achieve this shared goal.

The AAFP supports efforts to stratify quality measure results by race and ethnicity. The AAFP agrees this is necessary to identify and ultimately mitigate racial and ethnic health disparities. Due to concerns that CMS has noted about the accuracy of race and ethnicity data, we do not believe it would be appropriate to tie overall program performance and payment to stratifications results at this time. However, we urge CMS to quickly make data available to physician practices to facilitate quality improvement at the point of care. We recommend CMS ultimately expand to stratifying quality measures by a broader set of characteristics, including primary language, geographic location, income, gender identity, sexual orientation, age, and ability status. Self-reported data should be used for those characteristics for which it is considered the gold standard.

The AAFP does not support the use of an imputation algorithm to enhance race and ethnicity data. We are concerned this approach would further exacerbate existing disparities and result in less accurate and reliable data sets. This could inhibit the identification of disparities and hamper quality improvement efforts by physician practices and health systems.

While we agree that self-reported race and ethnicity data is the gold standard, we are also concerned that mandating this data collection could be burdensome and erode patients' trust in physicians and other health professionals. Physicians are not professionals in data collection, use, or privacy. CMS should not require them or other clinicians to explain to patients why they are collecting self-reported data and how CMS would use it in quality reporting programs. This type of data collection should be done separately from direct patient care discussions.

#### MIPS Value Pathways

##### **MVP Transition**

CMS notes there are statutory requirements in section 1848 of the Act that may constrain their ability to adopt certain changes to MVPs that stakeholders have suggested. Requirements include four MIPS performance categories, setting the performance threshold, calling for measures and annual quality measure selection process, and prescribed category weights. The statute does provide limited flexibilities in other areas, and CMS is interested in exploring any existing flexibilities that will assist them in implementing MVPs. CMS requests public comment on innovative ideas that help achieve their desired MVP results – improve value, reduce burden, help patients compare clinician performance to inform choice, and reduce barriers to movement into APMs.

CMS envisions that the future goal of the QPP is to ensure there is more granular data available for patients, clinicians, and other stakeholders. This includes an end state where technology will allow for the submission of discrete data elements, which would allow CMS to calculate measure performance

for clinicians, groups, and subgroups rather than having data aggregated and calculated before reporting.

CMS envisions that some MVPs would be primarily reported by a single specialty, and other MVPs would include measures and activities relevant to a range of clinicians. CMS is interested in MVPs that target a focused episode of care and MVPs that measure the patient journey and care experience longitudinally. CMS would like to explore how MVPs could best measure the value of multi-disciplinary, team-based care. CMS seeks comments on the concepts outlined above.

#### *AAFP Response*

The AAFP continues to support CMS' efforts to advance physicians to APMs. We are hopeful that MVPs can serve as a path to prepare practices to transition out of FFS if designed and implemented appropriately. However, we remain concerned that the transition away from FFS will be hampered by the shortage of APMs available for practices – particularly small and independent practices. The AAFP was a strong supporter of the Comprehensive Primary Care (CPC) and CPC+ models, and we believe there is potential in the Primary Care First (PCF) model. Unfortunately, practices can no longer apply to participate in PCF, and the PCF model is only available in limited geographic areas. This means the primary APM option for our members is MSSP. There are no APM options for practices that do not have an ACO available or wish to remain independent.

**We strongly urge CM to work with CMMI to develop a clearer path out of FFS for all practices, including developing options that span the risk spectrum.** We are encouraged by the vision for CMMI discussed in a recent [Health Affairs blog](#). The agencies should ensure MVPs include the measures and activities that will adequately prepare participants for an APM. Increasing alignment between MIPS and APMs will create a clearer on-ramp for practices to move into APMs. Further, models need to be able to accommodate physicians across the financial risk spectrum. Physicians will be reluctant to transition to APMs if the only models available require a jump to significant downside risk.

The AAFP also urges CMS to ensure MVPs will meaningfully reduce the burden of reporting to MIPS by finding ways to offer cross-category credit within MVPs. Cross-category credit would also incentivize participation in MVPs and more clearly differentiate them from traditional MIPS. Absent a reduction in burden and complexity, there will be little incentive to report an MVP.

#### **MVP Guiding Principles**

CMS requests comments on innovative approaches to measuring the value that might include APM performance measurement approaches and using a single-patient population for MVP cost and quality measures in the future.

#### *AAFP Response*

The AAFP strongly encourages CM and CMMI to work together to identify ways to align measures and measurements across MVPs and APMs. Meaningful coordination between MVPs and APMs will be critical to the success of MVPs. Unless MVPs are aligned with APMs, they will not serve as a transition to APMs – they will merely be a different reporting structure within MIPS. For example, MVPs designed around primary and preventive care should use some of the same measures used in primary care APMs.

#### **MVP Participant Definition**

CMS proposes defining an MVP participant as an individual MIPS EC, multi-specialty group, single-specialty group, subgroup, or APM entity. They are assessed on an MVP for all MIPS performance categories. Beginning with performance period 2025, an MVP participant includes an individual EC, single-specialty group, subgroup, or an APM entity. CMS requests comments on this proposal.

CMS requests comments on whether opt-in participants, voluntary participants, and virtual groups should be allowed to report MVPs as MVP participants in the future.

#### *AAFP Response*

**The AAFP strongly urges CMS to assess the implementation of subgroup reporting before requiring multi-specialty groups to split into subgroups.** Many policy decisions still need to be resolved before CMS proposes to require subgroup reporting. CMS needs to work with stakeholders to understand the issues and barriers to subgroup reporting before making them mandatory. We also don't believe there will be sufficient MVPs available by 2025 to accommodate multi-specialty groups. Requiring these groups to report by subgroups will increase the burden and diminish the effectiveness of subgroup reporting.

The AAFP believes opt-in participants, voluntary participants, and virtual groups should participate in an MVP. This will help them prepare for a potential sunset of traditional MIPS.

#### **MVP and Subgroup Implementation Timeline**

Beginning with the 2023 performance period and future years, CMS proposes to use the MVPs included in the MIPS final inventory of MVPs established by CMS through rulemaking. CMS requests comments on how long MVP reporting should be voluntary, the transition to mandatory MVP reporting, and the timing for when they should sunset traditional MIPS. CMS does not believe it is feasible to maintain both traditional MIPS and MVPs long term.

CMS is considering sunsetting traditional MIPS by the end of the 2027 MIPS performance period. CMS notes they are not making any proposals at this time. Any proposal to sunset traditional MIPS would be included in future rulemaking. CMS requests comments on their incremental timeline for mandatory MVP reporting, including the timing of sunsetting traditional MIPS. CMS also requests comments on what should happen when highly specialized clinicians cannot identify an applicable and relevant MVP.

CMS proposes to no longer allow multi-specialty groups to report MVPs beginning with the 2025 MIPS performance period. Instead, if a multi-specialty group would like to report MVPs, they would need to form subgroups. CMS will use Participation Lists to identify MIPS ECs within a group TIN that should be included in the subgroup of APM participants to report the APP.

#### *AAFP Response*

The AAFP strongly believes MVPs should remain optional. CMS should focus on implementing, evaluating, and improving MVPs to make them an efficient and attractive reporting option for MIPS participants. CMS needs to fully assess the implementation of MVPs before determining a timeline to sunset traditional MIPS. In addition to developing APMs, CMS needs to assess the number of MVPs available, address barriers to participation, and monitor the performance of MVP participants. The AAFP also asks that CMS assess its progress toward digital measurement and provide enhanced feedback to MVP participants before setting the timeline to sunset traditional MIPS. Prematurely

setting an end date to traditional MIPS could damage progress toward meaningful MVPs. There would need to be a focus on the quantity of MVPs available rather than the quality of MVPs.

The AAFP opposes CMS' proposal to require subgroup reporting beginning in 2025. There are still many policy decisions and logistical details that need to be resolved before groups can split into subgroups. CMS needs to work with stakeholders to understand the issues and barriers to subgroup reporting and adjust its policies accordingly. We also don't believe there will be sufficient MVPs available by 2025 to accommodate multi-specialty groups. Requiring these groups to report by subgroups will increase the burden and diminish the effectiveness of subgroup reporting and MVPs.

### **Subgroup Composition**

CMS proposes to add definitions for single-specialty and multi-specialty groups. Specifically, CMS proposes to define a single-specialty group as a group that consists of one specialty type as identified by ECs in the Provider, Enrollment, Chain, and Ownership System (PECOS). CMS proposes that a multi-specialty group is a group that consists of two or more specialty types as identified by ECs in PECOS. CMS requests comments on these proposals.

CMS proposes to define a subgroup as a subset of a group that contains at least one MIPS EC as identified by a combination of the group TIN, the subgroup identifier, and each EC's NPI. Except where otherwise specified, each MIPS EC in the subgroup receives a final score based on the subgroup's combined performance assessment. Each MIPS EC in the group will receive a final score based on the group's combined performance assessment.

MIPS ECs in groups who do not have an MVP available and applicable to their practice would continue to participate in MIPS through group reporting or individually. If their group reports through traditional MIPS or an MVP, the clinicians will receive their group's score if they submit data. If the group chooses not to report, the EC can report as an individual. Groups will continue to report for ECs in their TIN, including clinicians reporting through subgroups. CMS seeks comment on this proposal.

CMS has finalized definitions for special status determination but has not formally defined what special status means. CMS proposes to formally define special status as a MIPS EC that meets the definition of an ambulatory surgical center (ASC)-based MIPS EC, facility-based MIPS EC, hospital-based MIPS EC, non-patient-facing MIPS EC, or a small practice; or is located in a Health Professional Shortage Area (HPSA) or rural area. CMS requests comments on this proposal.

CMS proposes that determinations for meeting the low-volume threshold criteria and special status for subgroups are determined at the group level. CMS seeks comment on this proposal and requests feedback on whether they should reevaluate the future of MIPS eligibility for clinician participation in subgroups at the subgroup level.

CMS is not proposing to require any criteria for the composition of subgroups at this time. However, CMS requests comments on the options for multi-specialty groups to participate as subgroups for reporting MVPs for the first year of voluntary subgroup reporting. They also request feedback on whether restrictions should be applied in the future for the composition of subgroups and any associated criteria that need to be established. CMS requests comments on the criteria which should be used to define what types of groups are required to report more than one MVP.

CMS does not believe an APM entity should be eligible to form subgroups for reporting MVPs or the APP because APM entities are often composed of multiple TINs. The proposed definition of subgroup would not include APM entities comprised of more than one TIN, which would result in the exclusion of APM entities from forming subgroups. APM entities comprised of multiple TINs could choose to form subgroups through their affiliated TIN.

CMS proposes that an individual EC or group electing to participate in MIPS is not eligible to participate as a subgroup. CMS seeks comment on whether clinicians in these categories (opt in, voluntary reporters, virtual groups) should be allowed to form subgroups in future years and what additional criteria would need to be established.

#### *AAFP Response*

The AAFP encourages CMS to allow for multi-specialty participation within a subgroup. Like CMS, we believe there are instances where relying on PECOS specialty designations may not accurately represent a physician's practice. Additionally, primary care encompasses several specialties, including family medicine, general internal medicine, and general pediatrics. As noted by the AAFP's policy on Primary Care, non-primary care physicians and clinicians often work as part of the care team to meet the needs of specific patients. We caution CMS against restricting subgroup participation to a single specialty as this may disrupt the team-based nature of primary care.

CMS could address its concern that subgroups will report on MVPs that are not relevant to their clinicians by requiring the specialties within a subgroup to align with the applicable specialties identified for a specific MVP. As CMS develops its MVP inventory, it should solicit feedback on which specialties anticipate reporting a proposed MVP. CMS could cross-reference this with historical data to verify that a meaningful number of physicians within those specialties have previously reported the quality measures within the proposed MVP. The resulting list would support team-based care and alleviate the need to restrict subgroup reporting to a single specialty while also ensuring subgroups report relevant MVPs. A group would be required to report on more than one MVP if no MVPs are available that encompass all specialties within the practice.

We ask CMS to clarify what it means that groups will continue to report MIPS for the ECs in their TIN, including the ECs reporting through subgroups.

The AAFP encourages CMS to develop its criteria for subgroup reporting as soon as feasible to allow practices time to adjust to any new or changed requirements. We urge CMS to ensure its criteria have addressed issues and barriers to subgroup reporting before requiring subgroup reporting. We caution CMS that changing the criteria and requirements frequently or without allowing practices time to adjust to any changes could jeopardize a practice's ability to comply.

The AAFP supports CMS' proposal to apply a group's low-volume threshold determination and special status assignment to subgroups.

#### **Future Vision of Subgroups**

CMS envisions that a future goal of the QPP is to ensure there is more granular data available for patients, clinicians, and other stakeholders. They anticipate this can be accomplished using a three-pronged approach of mandatory subgroup reporting, broad use of standards-based APIs that leverage the FHIR standard within EHRs, and the creation and use of dQMs. CMS requests information on the vision for data granularity.

CMS is considering limiting clinicians in multi-specialty groups to participate through a single-specialty subgroup. They could establish a threshold that must be met for a subgroup to be considered a single-specialty subgroup, such as requiring 75 percent of the clinicians in a subgroup to have the same PECOS primary specialty designation or specialty codes on Medicare Part B claims. However, CMS has concerns about some of the limitations of PECOS, especially for clinician types such as NPs and PAs, whose specialty in PECOS is not related to the scope of care they provide but rather the degree received. CMS seeks comment on setting a threshold for single-specialty subgroups and ways to overcome their concerns. They would like to consider potential approaches to validating and auditing specialty information.

CMS is also considering whether a different data source could determine subgroup composition. CMS is interested in ways they could provide guardrails for subgroups that do not use PECOS or use PECOS information to categorize specialties into specialty families or teams of clinicians who practice in relevant specialties for a given MVP. During the MVP registration period, the subgroup would attest that the clinicians in a subgroup practice similar scopes of care. CMS welcomes feedback on how specialty families could be identified and what criteria would need to be established for CMS to set requirements on subgroup information.

A third option would be to analyze claims data to identify the primary clinician specialty based on their billing patterns. CMS requests comments on these approaches.

As an alternative to limiting how subgroups can be formed, CMS is considering adding an approved list of specialties and clinician types allowed to report each MVP. CMS requests comments on this alternative approach.

#### *AAFP Response*

The AAFP supports CMS' future vision for increased data granularity. We applaud CMS for its efforts to move toward increased electronic quality measurement. Improved data collection methods can reduce the burden on practices and provide physicians and other clinicians with timely and relevant information to improve patient outcomes.

As noted above, the AAFP cautions CMS against restricting subgroup reporting to a single specialty. The AAFP believes CMS' alternative option of assigning which specialties can report an MVP may be more appropriate than determining subgroup composition using PECOS data. We encourage CMS to use taxonomy codes rather than PECOS specialties to identify the specialties that may report an MVP. Taxonomy codes offer a deeper level of specificity than the PECOS specialty codes and would make it clearer which specialties may want to report an MVP. The AAFP reiterates that it strongly encourages CMS to solicit stakeholder feedback when determining whether an MVP may apply to a specific specialty. While we support identifying which specialties may report an MVP, we would not support CMS assigning MVPs to subgroups.

We do not believe subgroups would need to attest to their specialty composition when registering. CMS should verify this information using claims data and the taxonomy code associated with each NPI within the subgroup.

#### **MVP Requirements**



CMS proposes that MVPs must include at least one outcome measure that is relevant to the MVP topic. Additionally, each MVP that applies to more than one clinician specialty should include at least one outcome measure relevant to each clinician specialty included. CMS proposes to allow the inclusion of outcomes-based administrative claims measures. CMS would allow such measures to meet the outcome measure requirement. CMS requests comments on this proposal.

If an outcome measure is not available, CMS proposes that an MVP must include at least one high-priority measure that is relevant to the MVP topic. Each MVP must include at least one high-priority measure that is relevant to each clinician specialty included. CMS requests comments on this proposal.

CMS believes it is important to rely on a consistent understanding of patient-centered measures. For example, *Health Affairs* states, “Measures should be patient-centered and incorporate new approaches to assessing patient health status and patient experience. Such measures include assessment of clinical outcomes, patient-reported outcome measures, as well as new approaches to evaluation of patient experience.”

CMS requests comments on whether other aspects of patient measurement should be considered part of the patient-centered measures definition.

CMS proposes to codify that population health measure means, “A quality measure that indicates the quality of a population or cohort’s overall health and well-being, such as, access to care, clinical outcomes, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services.” CMS seeks comments on this proposal.

CMS envisions that health equity measures would be included in all MVPs. CMS requests information on the following:

- Should health equity measures be developed to broadly apply to the various specialties and subspecialties participating in MIPS?
- Is there value in the development of more specialty-specific health equity measures?
- Considering MIPS and MVPs include several specialties and subspecialties, what factors should be considered when developing a health equity measure?
- In the future, should CMS include a health equity measure in the foundational layer of all MVPs as a required measure? If not, why not?

#### *AAFP Response*

The definition of population health measure proposed by CMS seems reasonable. However, the definition of population and/or cohort could become problematic. The AAFP is concerned about the size of a ‘population’ or ‘cohort’ for which an individual physician would be responsible. Population health measures would be better applied at the system level.

The AAFP believes health equity measures can be developed to be broadly applicable to all MIPS participants once all stakeholders understand the root causes of inequities and have tools available to address equity. Health equity is everyone’s job, and measuring health equity at the physician and group level is premature. The factors that lead to health inequity are broad, complex, and historical. They involve wealth, employment insurance, culture, racism, personal choice, and trust. Assigning responsibility for health inequities to the health care community alone and financially penalizing those

that serve a community where health inequities exist is not prudent at this time. This multi-factorial problem needs to be addressed at a societal level, without blame at this point.

CMS (or other government agencies) should already have data that could be analyzed at the population level using geographic algorithms, billing data, HCC scores, and other data elements to determine where potential health inequities exist. This information should be shared with physicians and hospitals to help them target improvement efforts. Targeting would be much more efficient than attempting to collect specialty-specific, self-reported data from physicians and hospitals. Without ongoing access to data that helps identify health inequities, physician practices will not have enough information to address them.

Any measures should be population-based and widely applicable to a geographic region. Any rates that might be indicative of disparities (e.g., rates of various procedures, visits per capita by zip code, ER visits by zip code, rates of uncontrolled diabetes per capita, denials by payer per capita) should be analyzed at a geographic level and used to inform physicians and hospitals that care for patients in that geographic area. As stated in this letter, potential areas of inequity need to be addressed at a societal level, not merely at the clinician/hospital level. For example, it is difficult for physicians to manage and be held accountable for patients with chronic conditions who do not seek care. Disparities can be exacerbated by relying on the analysis of visits and encounters since those suffering from inequities are the least likely to seek care.

We would not recommend including a measure in the foundational layer until we better grasp the root causes of health inequities. Once the health care community, government, payers, and other stakeholders have tools at their disposal to address health inequities, then it may be appropriate to measure their performance if it's the right measure. A great deal of testing will be needed. CMS may find that physicians, other clinicians, and hospitals are more responsive to information without a financial penalty.

CMS proposes an annual solicitation process to solicit stakeholder recommendations for potential updates to established MVPs. Beginning in January of the year before the performance period, stakeholders could submit their recommendations to revise established MVPs. CMS would accept stakeholder input on a rolling basis. Any changes to MVPs would be addressed in future notice and comment rulemaking. Changes to existing measures and activities would be made under the traditional MIPS performance category policies, and those changes would be reflected in the MVP. CMS would consult with the stakeholders who originally nominated the MVP about any publicly recommended changes. However, they would be unable to communicate with the stakeholder about whether their recommendations would be accepted ahead of rulemaking, and CMS would ultimately decide whether updates should be made. CMS seeks comments on this proposal.

#### *AAFP Response*

The AAFP supports requiring MVPs to include at least one outcome measure or a high-priority measure relevant to the MVP topic if an outcome measure is not available. The AAFP supports CMS' proposal to allow outcome-based administrative claims measures to count toward the outcome measure requirement. Regarding the outcome measure requirement, we ask CMS to clarify how this applies when the only outcome measure in the MVP is CAHPS. We are not clear if the MVP participant would be required to report CAHPS or if they could report a high-priority measure instead, even though an outcome measure is technically available in the MVP. We are concerned that an MVP participant may be forced to report CAHPS, which is not financially feasible for some practices.

In general, the AAFP supports the proposal to annually solicit recommendations for updates to MVPs. However, we are concerned with CMS' process to only consult with the stakeholders who submitted the MVP about publicly recommended changes. We understand that all stakeholders will have an opportunity to provide feedback through the rulemaking process, but we feel it would be beneficial to consult with all the applicable specialties within the MVP before rulemaking. If CMS consults with only the stakeholders that submitted the MVP, it creates an environment where a few specialties influence an MVP compared to the other relevant specialties. We think it would generate more buy in and foster collaboration if CMS consulted with all specialties that report the MVP.

We also encourage CMS to provide greater transparency in the development of MVPs, including proactively involving all relevant specialties for an MVP candidate. CMS should publish the list of MVP candidates as they are submitted to allow interested stakeholders to coordinate with the MVP's developer and provide feedback throughout the review process. Including relevant stakeholders at the beginning and during the process offers interested parties the opportunity to hear first-hand CMS feedback on the proposal and better understand the intent of the MVP. Early collaboration would allow for a smoother and comprehensive review process and ultimately improve participation in MVPs.

#### **Proposed MVP Reporting Requirements**

CMS proposes that an MVP participant must select and report, if applicable, four quality measures, including one outcome measure, or, if an outcome measure is not available, one high-priority measure included in the MVP, excluding the population health measure.

CMS proposes that paragraph §414.1365(c)(1) does not apply to a small practice that reports on an MVP that includes fewer than four Medicare Part B claims measures, provided that the small practice reports each such measure that is applicable.

CMS proposes that MVP participants be scored on the cost measures included in the MVP they are reporting.

CMS proposes that MVP participants must report on two medium-weighted improvement activities; one high-weighted improvement activity; or attest to participation in a certified patient-centered medical home (PCMH) or comparable specialty practice.

CMS is not establishing different reporting requirements for promoting interoperability for MVPs from what is established under traditional MIPS.

For CY 2023 and 2025, CMS proposes requiring subgroups to submit their affiliated group's data for the promoting interoperability performance category. CMS seeks comment on whether they should allow or require subgroups to report subgroup-level performance data for the promoting interoperability category.

CMS requests comments on technical challenges clinicians may encounter reporting promoting interoperability at the subgroup level. CMS seeks comments on these issues to better understand whether they should reconsider subgroup reporting in the future.

CMS requests comments on how the promoting interoperability category could lead to greater cohesion among MIPS performance categories.

CMS proposes that an MVP participant will be scored on one population health measure. Participants would identify which MVP and population health measure they intend to report during the election period.

CMS proposes that individual ECs that elect to participate in MIPS as a subgroup will have their performance assessed at the subgroup level across all MIPS categories based on the MVP and the APP.

CMS proposes a registration period that begins on April 1 and ends on November 30 of the applicable CY performance period or a later date specified by CMS. To report CAHPS for MIPS, a group, subgroup, or APM entity must complete their registration by June 30 of the performance period or a later date specified by CMS. Clinicians participating in subgroups or groups reporting on the CAHPS for MIPS Survey within an MVP would not be able to change their participation in the CAHPS for MIPS Survey beginning July 1 of the applicable performance period.

MVP participants must submit the following at the time of registration: select an MVP, one population health measure, and any outcomes-based administrative claims measure on which the participant intends to be scored; and subgroups must submit a list of each TIN/NPI associated with the subgroup which identifies each individual EC NPI in the subgroup for the group TIN and a plain language name for the subgroup. MVP participants would not be able to submit or make changes to the MVPs they select after the close of the registration period.

CMS requests comments on these proposals. CMS also requests comments on whether participants would be interested in the ability to select multiple MVPs at the time of registration. CMS would also like to know if MVP participants believe they would report on multiple MVPs and want to submit data on multiple MVPs.

#### *AAFP Response*

The AAFP continues to believe CMS should move beyond health IT utilization measures. CMS could incentivize participation in MVPs by allowing practices that attest to using 2015 Edition CEHRT or having PCMH recognition to automatically receive full credit in the promoting interoperability performance category. This approach would align with APMs and allow MVP participants to build other competencies required for successful participation in value-based payment models. Practices would also have more flexibility to use their CEHRT in new and innovative ways to improve patient outcomes, naturally creating more cohesion across the performance categories.

If CMS continues to require reporting on health IT measures, we agree that allowing subgroups to report their affiliated group's data is appropriate. Practices may find it difficult or burdensome to extract data and report the promoting interoperability measures by subgroup. There are no certification criteria for CEHRT that cover extracting such data and reporting by subgroup.

The AAFP encourages CMS to open the registration period at the beginning of the calendar year rather than waiting until April 30. We think it would be beneficial to allow MVP participants to register for more than one MVP. This gives them the ability to assess which MVP may be most appropriate without forcing them to make a final decision before they are ready.

While the AAFP supports measuring MVP participants on the cost measures in the MVP, we have concerns with some of the cost measures themselves. The AAFP has significant concerns with using the TPCC measure. Primary care provides continuous, longitudinal care, which includes focusing on prevention and wellness. Expecting primary care physicians to reduce the total cost of care based on preventive services is not an appropriate measurement of the value of these services. Preventive measures have long-term benefits to both patients and the health care system, but they may increase short-term spending. However, investing in preventive services is a critical element of the transformation to value-based health care spending. We believe physicians could be unfairly penalized for successfully improving the utilization of recommended preventive services if total per capita costs (TPCC) are measured in the same year as those services are provided. While higher utilization of preventive care may reduce costs in the long term, this measure and MIPS itself are not designed to capture those savings and do not account for the value of such services.

The AAFP has previously expressed opposition to the TPCC measure and remains opposed to measuring TPCC at the individual clinician or practice level. This measure is difficult to influence outside of a total cost of care APM, where there is shared interest and accountability in improving performance by the larger health care system. Since there is no such shared accountability in MIPS, it seems likely primary care physicians will be penalized for decisions made by other members of a patient's care team. The AAFP does not support using the TPCC measure in MIPS or MVPs for the reasons listed above. We continue to encourage CMS to explore alternative ways to assess primary care costs that recognize the long-term benefits of primary care may not be appropriately reflected in short-term cost measures. We welcome further discussions on the cost category for MIPS and MVPs.

The AAFP is encouraged by the development of the two new chronic condition episode measures. We look forward to their submission for National Quality Forum (NQF) endorsement.

### **Scoring MVP Performance**

CMS proposes that an MVP participant that is not an APM entity be scored on measures and activities included in the MVP in accordance with §414.1365(d)(1) through (3). An MVP participant that is an APM entity is scored on measures and activities included in the MVP in accordance with §414.1317(b). Unless otherwise indicated, the performance standards at §414.1380(a)(1)(i) through (iv) apply to the measures and activities in the MVP. Finally, CMS proposes that an MVP participant be scored under MIPS in four performance categories.

CMS would exclude a population health measure from the total achievement points and the total available points if the administrative claims measure does not have a benchmark or meet the case minimum requirement. CMS would score a subgroup on each selected population health measure that does not have a benchmark or meet the case minimum criteria based on their affiliated group's score, if available. CMS would exclude the measure from the subgroup's total measure achievement points and total available measure achievement points if the affiliated group's score is unavailable.

A solo practitioner or an individual EC that is part of a group that chooses to be scored as an individual would not be scored on population health measures. CMS requests comments on approaches to scoring individual ECs on population health measures.

CMS proposes that MVP participants would receive zero measure achievement points for each selected outcomes-based administrative claims measure that does not have a benchmark or meet the case minimum. CMS requests comments on these proposals.

#### *AAFP Response*

We are concerned that CMS intends to use the same benchmarks from traditional MIPS for MVPs. We believe this is contrary to CMS' goal to make more meaningful comparisons between participants. We also encourage CMS to explore the idea of developing regional benchmarks for cost and/or utilization measures in MVPs as the benchmarks for these measures vary regionally. This would more closely align with APMs and provide participants an opportunity to better understand how they would be assessed in an APM.

The AAFP encourages CMS to continue identifying areas where they can align and streamline MIPS reporting through MVPs. One potential option would be to provide multi-category credit. For example, IA\_AHE\_3 promotes the use of patient-reported outcomes tools such as the PHQ-9. Practices that choose to report Screening for Depression and Follow-up Plan (Quality ID 134) must use a standardized screening tool. By electing to report this quality measure, they have demonstrated their commitment to improvement, as practices are assessed on their performance and improvement on quality measures, and therefore, should also receive credit for the improvement activities category.

Additionally, we reiterate our suggestion that CMS provide automatic full credit to the promoting interoperability category for practices that attest to using 2015 Edition CEHRT or PCMH recognition.

We recommend against scoring individual ECs on population health. It is not appropriate to score individual ECs on population health measures, given that individual ECs may not have the financial support and resources required to positively influence population health measure outcomes. There is often a lack of funding, data, or infrastructure support for small and independent practices that may impact their ability to influence such measures.

#### **Calculating the Final Score in MVPs**

CMS proposes that the final score for MVP participants would be calculated using the same scoring methodology as traditional MIPS.

CMS proposes to use the category weights established for traditional MIPS for MVP participants that are not an APM entity. CMS proposes to use the category weights for APM entities at §414.1317(b) to calculate a final score for an MVP participant that is an APM entity.

In general, CMS proposes the same reweighting policies for MVPs as for traditional MIPS. However, CMS does not believe there will be cases where no quality measures apply to the MVP participant and do not believe the traditional MIPS policy for reweighting the quality category should apply to MVP participants.

CMS proposes that any reweighting applied to an affiliated group would apply to the subgroup(s). If reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the event of an extreme and uncontrollable circumstance or the data for the subgroup are inaccurate, unusable, or otherwise compromised due to circumstances outside of the control of the subgroup.

CMS proposes redistributing category weights according to the same policies as traditional MIPS.

#### *AAFP Response*

The AAFP supports this proposal. We agree that CMS should not implement an MVP that does not have applicable quality measures, and therefore, the policy for reweighting the quality category would not be applicable.

#### **Enhanced Performance Feedback**

Beginning with the 2023 performance period, CMS proposes to include comparative performance feedback within the annual performance feedback provided to MVP participants, comparing the performance of similar clinicians who report the same MVP.

CMS also requests comments on what stakeholders consider 'actionable feedback.'

#### *AAFP Response*

The AAFP is pleased CMS intends to provide comparative feedback to MVP participants. We are strong supporters of providing timely and actionable feedback to physicians. CMS requests feedback on what would be considered actionable feedback. The AAFP offers the following suggestions:

- Gaps in care for quality measures within the MVP, including flagging which patients are eligible for which measures
- High-cost areas that have been attributed to the EC or EC's TIN
- High-cost areas from specialists (including the specialist's name)
- Emergency department and hospital utilization
- Leakage
- Most recent HCC score for individual patients and average HCC score for TIN

We also suggest CMS provide claims-line feed data to interested practices. We strongly encourage CMS to do thorough user testing to ensure the reports are accurate and user-friendly. While the previous supplemental Quality and Resource Use Reports (QRUR) provided detailed information, it was often outdated, overwhelming, and difficult to analyze. Unless feedback is timely and accurate, it will only add burden, and practices will not use the information.

#### **Optimizing Chronic Disease Management MVP**

The AAFP appreciates CMS prioritizing an MVP focused on CCM, a core tenant of primary care. We are hopeful that reporting to MIPS through this MVP will provide family physicians with a more meaningful and less burdensome reporting experience. In general, we are supportive of the quality measures selected. As we mentioned previously, we are strong supporters of the PCPCM and are pleased that it's included in this MVP.

We urge CMS to identify opportunities in this (and other) MVPs to provide cross-category credit. For example, practices electing to report the PCPCM could receive automatic credit for the improvement activity 'Promote use of Patient-reported Outcome Tools.' By electing to report this quality measure, they have demonstrated their commitment to improvement, as practices are assessed on their performance and improvement on quality measures, and therefore, should also receive credit for the improvement activities category. We also believe that practices that attest to having PCMH certification or recognition have sufficiently demonstrated meaningful use of CEHRT and should automatically receive full credit in the promoting interoperability category, in addition to the full credit they already receive for the improvement activities category.

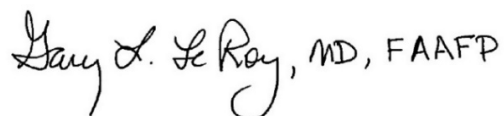
We encourage CMS to use the asthma/COPD and diabetes episode-based cost measures instead of TPCC once the NQF endorses them. CMS should incorporate additional relevant episode-based cost measures as they are developed and endorsed.

The AAFP asks CMS to continue to engage with stakeholders as it refines its proposed MVPs. Since MVPs will be implemented in 2023, we do not believe CMS needs to finalize its proposal until next year. We stand ready to work with CMS to refine the Optimizing Chronic Conditions MVP and other primary care MVPs.

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Thank you for the opportunity to provide comments on the proposed rule. Should you have any questions or wish to discuss our comments further, please contact Meredith Yinger, Senior Regulatory Strategist, at [myinger@aafp.org](mailto:myinger@aafp.org) or 202-235-5126.

Sincerely,



Gary LeRoy, MD, FAAFP  
Board Chair  
American Academy of Family Physicians

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<sup>3</sup> Ibid.

<sup>4</sup> Ibid.

<sup>5</sup> Medicare Payment Advisory Commission. (2021). *Report to the Congress: Medicare and the Health Care Delivery System*. Chapter 7: Medicare vaccine coverage and payment. [http://www.medpac.gov/docs/default-source/default-document-library/jun21\\_ch7\\_medpac\\_report\\_to\\_congress\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/default-document-library/jun21_ch7_medpac_report_to_congress_sec.pdf?sfvrsn=0)

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