AMERICAN ACADEMY OF FAMILY PHYSICIANS

September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8016
Baltimore, MD 21244

Re: CMS-1784-P; Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 130,000 family physicians and medical students across the country, I write to provide comprehensive comments on the calendar year (CY) 2025 Payment Policies Under the Physician Fee Schedule (PFS) and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program (MSSP) Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments proposed rule as published in the July 31, 2024, *Federal Register.*

The AAFP thanks the Centers for Medicare & Medicaid Services (CMS) for its commitment to an "administration-wide strategy to create a more equitable health care system that results in better accessibility, quality, affordability, empowerment, and innovation for all Medicare beneficiaries." CMS, working through the Center for Medicare and Medicaid Innovation (CMMI), has a stated aim to "increase the number of people in a care relationship with accountability for quality and total cost of care by 2030." CMMI is emphasizing the importance of primary care in achieving these goals, stating that "advanced primary care and accountable care models are central to driving growth in the number of beneficiaries in accountable care relationships. Family physicians account for nearly 40 percent of the primary care physician workforce with more than 90 percent caring for Medicare patients.[i] Family physicians are the cornerstone of primary care delivery for our health system and central to the achievement of these CMS/CMMI strategic goals. AAFP and its members are committed to these goals and are grateful for the opportunity to submit comments on this year's proposed rule.

The comments in this letter provide our best thinking on the specific proposals CMS has included in this year's rule; **however, we would not be fully representing our members and their patients if we did not also address our concerns for the long-term sustainability of Medicare and the physicians who make the program possible**. As we have expressed in the past, both to the agency[ii,iii] and to Congress,[iv,v] there are fundamental flaws within the PFS that, absent broader legislative reform, limit CMS' ability to have meaningful impacts on patients and their physicians. The statutory guidelines CMS is working within limit its ability to adequately address these growing concerns, including the ability to support its strategic goals for accountable care with a commensurate

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investment in primary care. We urge the agency to recognize these limitations and work with Congress to implement long term solutions.

Most importantly, the PFS is underfunded, physicians are underpaid, and family physicians continue to be one of the lowest paid specialties in the United States. The number of factors and the resulting impact on physician payment grows every year through:

- Annual reductions to the conversion factor due to budget neutrality or expiration of congressional funding meant to offset budget neutrality reductions;
- The statutory freeze on annual payment updates;
- The lack of any mechanism to account for inflation;
- Sequestration, which is now not set to expire until 2031;
- The expiration of the Advanced Alternative Payment Model (AAPM) bonus, which will undermine progress toward value-based payment models that provide clinicians with the financial support and flexibility they need to deliver better care at lower costs; and
- Statutory requirements that force CMS to increase the Merit-based Incentive Payment System (MIPS) performance threshold, which CMS estimates will result in a negative payment adjustment for most clinicians in small and medium sized practices, for whom patients in rural and other underserved areas rely on for their care.

AAFP is deeply concerned that these factors stand in stark contrast to other areas of Medicare spending that continue to increase at substantially higher rates. This imbalance has and will continue to destabilize physician practices, accelerate consolidation, worsen access to care for beneficiaries, and contribute to increased health care spending.[vi,vii] While this imbalance is experienced across all medical specialties, the impact on primary care is striking and at odds with CMS/CMMI stated goals. The number of primary care physicians declined from 68.4 to 67.2 per 100,000 people between 2012 and 2021, and family physicians are reporting a 25 percent reduction in patient panel size over the last 10 years. The 2024 Primary Care Scorecard report titled *No One Can See You Now,* cites chronic underinvestment in primary care as one of the driving forces behind this decline – attracting fewer medical students and residents, causing physicians to limit their clinical practice hours or stop seeing patients altogether by choosing an administrative or other role over clinical practice or leaving the profession entirely.

While CMS promotes the rule as "support[ing] physicians and other practitioners in delivering care that meets the needs of people with Medicare," the AAFP questions how long the PFS can meet the needs of people with Medicare if physicians cannot afford to stay in business with continuing payment reductions that do not keep pace with inflation or the growing demands placed on physicians, especially primary care physicians. We recognize CMS' limitations under the Social Security Act, and we urge the agency to publicly identify the statutory shortcomings that hinder its ability to implement policies that will lead to meaningfully systemic improvements in access, quality, affordability, and equity. The AAFP has put forth potential solutions[viii,ix,x] including redefining the PFS' budget neutrality standards, implementing an annual inflation adjustment, and taking a more holistic approach to budget neutrality that would account for costs and savings across all Medicare parts and settings.

CMS serves the public as a trusted partner and steward, dedicated to advancing health equity, expanding coverage, and improving health outcomes. Accordingly, **we believe the agency has a responsibility, and is best positioned, to provide the public with information on the current state of the program as well as threats to its sustainability.** For example, the current $20 million

threshold for budget neutrality imposed on the PFS has not been updated since it was implemented in 1992. Budget neutrality is also a standard not applied to other parts or settings under Medicare, which has resulted in a significant imbalance in Medicare spending growth. The trajectory of Medicare spending over time is misaligned with their stated goals of supporting equitable access to accountable care relationships, which predominantly relies on primary care physicians. Physician payment has increased just 11 percent while hospital and skilled nursing facility payment has increased by roughly 60 percent over two decades between 2001 and 2021. Given this stark imbalance, it is not surprising that physicians are disillusioned and increasingly employed by hospitals and others who benefit from increased payment. Meanwhile, access to high quality primary care—including a focus on prevention—suffers as investments and innovations in rescue care are seemingly thriving.

Another factor meriting attention is that beneficiary cost sharing is a significant and growing barrier to the kind of comprehensive primary care CMS is seeking to enable. Our members are unified in their view that a major barrier to physicians' ability to bill for the kind of comprehensive primary care they want to deliver, and CMS has expressed its support for, is the requirement that patients must share in the cost of most services received. For example, billing for chronic care management (CCM) services continues to happen at less than ideal rates. However, it is important to note that the degree to which this service is billed should not be interpreted solely as a sign those services are not being delivered in many primary care practices. Rather, it is often the case that the service threshold for billing this service is being met but practices cannot bill consistently for these services because beneficiaries are unwilling to consent to it based on the additional cost-sharing they experience under the current rules. We note this challenge as especially germane given the discussion above on payment challenges and barriers in the current PFS, as any increase in physician payment will also increase beneficiaries' financial obligations, thus requiring the two be addressed together.

Inadequate data and information flow across care settings continues to hamper family physicians' ability to deliver high quality, comprehensive, and coordinated care to patients. The ongoing lack of interoperability is the underlying theme of these challenges and highlighted throughout our comments. The AAFP's Information Sharing in Value-based Payment Models for Primary Care Position Paper outlines several key calls to action to improve electronic exchange of information. **The AAFP calls on CMS to prioritize strategies designed to improve interoperability.** We are encouraged by CMMI's recent Data-Sharing Strategy Initiative and appreciate the vision outlined in the 2023 HHS Data Strategy. The AAFP believes stronger efforts should be undertaken to improve data-sharing for all physicians serving Medicare beneficiaries, not just those participating in CMMI models.

Similarly, the issues of administrative burden associated with quality measurement have become increasingly intertwined. The AAFP supports CMS' efforts to improve outcomes, increase efficiency, and lower costs. However, the ever-increasing number of measures to which payment is tied under different models, exacerbated by the inefficient payer-specific approaches to measurement, takes the focus away from real innovation and places it on performance tracking and measurement. Because there is insufficient primary care payment in PFS and minimal, if any, investment for practices to update their infrastructure in many innovation models, they are struggling to meet quality reporting requirements to maintain current PFS payment levels and do not experience commensurate increases in payment in many innovation models.

The AAFP recognizes CMS is limited in its current statutory authority to address many of these concerns, and we urge the agency to take a more holistic, creative, and bold approach to addressing

systemic issues under the PFS while also managing its obligations to implement the necessary annual updates. We are grateful for the work the agency has undertaken to use what tools it has to improve the system for patients. Unfortunately, unless the fundamental flaws noted above are addressed, they will continue to undermine the well-intentioned attempts CMS makes to improve physician payment in ways that will secure a primary care physician workforce for the future and contribute to overall, systemic improvements.

One of CMS' most notable items of interest to primary care champions in this year's rule is the introduction of Advanced Primary Care Management (APCM) codes. We are pleased to see CMS understands that "a strong foundational primary care system is fundamental to improving health outcomes, lowering mortality, and reducing health disparities" and that the Department of Health and Human Services (HHS) has recognized the need to strengthen primary care as well. To be clear, we are grateful for the work CMS has done to introduce this new primary care payment opportunity and view the new APCM code set as a step in the right direction. Unfortunately, our ability to celebrate the implementation of these new codes is stifled by the foundational issues inherent in the PFS noted above and additional implementation concerns, including beneficiary cost-sharing, that may hinder successful widespread adoption in practice.

In response to the specific proposals CMS presents in the 2025 proposed rule, we provide our thoughts and detailed recommendations throughout the balance of this letter. For CMS proposals of particular significance to family physicians and primary care, our high-level recommendations are noted here:

- Finalize the APCM codes with modifications that mitigate lack of uptake due to beneficiary cost-sharing impediments, appropriate valuation, and potential operational challenges to ensure achievement of CMS' goals;
- Allow payment for G2211 when modifier 25 is appended to the accompanying office/outpatient (O/O) evaluation and management (E/M) to facilitate reporting of a Medicare Annual Wellness Visit, vaccine administration, or Medicare Part B preventive services;
- Finalize the prepaid shared savings program for ACOs with enough flexibility to allow ACOs to allocate those prepaid funds towards the specific needs of their patient populations;
- Expand the array of services included in the primary care exception (PCE); and
- Work to reduce administrative and regulatory burdens imposed on physicians in the MPFS, MSSP, and QPP.

Determination of Practice Expense (PE) Relative Value Units (RVUs) (section II.B.)

CMS proposes multiple technical refinements to its PE RVU methodology and the pricing of specific supply and equipment items and supply packs. CY 2025 is the final year of CMS' four-year transition to updated clinical labor pricing. CMS did not receive new wage data or other additional information for use in clinical labor pricing from interested parties before the publication of this proposed rule. Therefore, CMS' proposed clinical labor pricing for CY 2025 is based on the clinical labor pricing CMS finalized in the CY 2024 PFS final rule, incremented an additional step for the final Year 4 of the update.

CMS is not proposing to incorporate the 2017-based Medicare Economic Index (MEI) in PFS rate setting for CY 2025. As it did for 2024, CMS is delaying any application of the rebased and revised

MEI pending the results of the AMA's practice cost data collection efforts and other sources of data CMS could consider for updating the MEI. CMS invites comments on this approach.
CMS also solicits comments on:

- The general topic of more comprehensive updates to supply and equipment pricing.
- Ways CMS may continue work to improve the stability and predictability of any future updates, particularly regarding scheduled, recurring updates to PE inputs for supply and equipment costs.

CMS believes establishing a cycle of timing to update supply and equipment cost inputs every four years may be one means of advancing shared goals of stability and predictability. Under this approach, CMS would collect available data, including submissions and independent third-party data sources, and propose a phase-in period over the next four years.

Further, CMS seeks feedback on possible mechanisms to establish a balance whereby its methodology would account for inflation and deflation in supply and equipment costs and how economies of scale should or should not factor into future adjustments to CMS' methodology. CMS seeks information about specific mechanisms that may be appropriate and approaches that would leverage verifiable and independent, third-party data that is not managed or controlled by active market participants.

AAFP Comments

The AAFP supports CMS' proposal to base clinical labor pricing for CY 2025 on the clinical labor pricing CMS finalized in the CY 2024 PFS final rule, incremented an additional step for the final Year 4 of the update. We continue to appreciate that CMS repriced the clinical labor inputs in its direct practice expense methodology and support the final transition to more current pricing in that regard. Updating clinical labor pricing is essential to more accurately capturing the cost of hiring and retaining medical assistants, nurses, and other essential clinical practice staff. As we recommended in previous comments and reiterate below, the AAFP encourages CMS to update these data more regularly to ensure payment rates enable practices to employ essential clinical staff and avoid significant redistributive impacts on others.

The AAFP also supports CMS' proposal to not incorporate the 2017-based MEI in PFS rate setting for CY 2025, pending the results of the AMA's practice cost data collection efforts. We urge CMS to collaborate with the AMA on the AMA's current data collection effort to ensure consistency and reliability in physician payment. Updates to MEI weights should be postponed until new AMA survey data are available.

In regards to more regularly scheduled, recurring, and comprehensive updates to the PE inputs, the AAFP supports practice expense RVUs based on the actual resources, both direct and indirect, physicians use to provide services. As such, the AAFP supports the concept of regularly scheduled, recurring updates to the PE inputs, including pricing of clinical labor, supplies, and equipment. As CMS notes, such updates would allow the agency to account for inflation and deflation in supply and equipment costs as well as the costs of clinical labor. Such updates would also allow the agency to appropriately factor economies of scale into future adjustments to CMS' methodology.

Comprehensive updates every four years would be consistent with this concept. However, if CMS chooses to pursue such an update schedule, we encourage the agency to implement the changes in one year and leave the PE RVUs stable for the remaining three rather than using a four-year phase-

in period as suggested in the proposed rule. Using a phased approach in conjunction with comprehensive updates every four years would mean the PE RVUs would always be in a state of flux, which is contrary to CMS' stated desire to continue work to improve the stability and predictability of any future updates.

The AAFP does not have recommendations regarding specific mechanisms that may be appropriate and approaches that would leverage verifiable and independent, third-party data not managed or controlled by active market participants for purposes of updating PE input prices on a regular basis. However, the AAFP is happy to work with CMS and others to identify relevant mechanisms and approaches moving forward.

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (section II.D.)

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

d. Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

CMS is proposing to remove the frequency limitations for Subsequent Inpatient Visits (Current Procedural Terminology (CPT) codes 99231-99233), Subsequent Nursing Facility Visits (CPT codes 99307-99310), and Critical Care Consultation Services (Healthcare Common Procedure Coding System (HCPCS) codes G0508 and G0509) for CY 2025. CMS will gather additional data to determine how practice patterns are evolving and what permanent changes, if any, should be made to frequency limitations.

AAFP Comments

The AAFP supports CMS' proposal to remove the telehealth frequency limits for Subsequent Inpatient Visits, Subsequent Nursing Facility Visits, and Critical Care Consultation Services for CY 2025. We urge CMS to permanently remove these limitations.

e. Audio-only Communication Technology to Meet the Definition of "Telecommunications System"

An "interactive telecommunications system" is currently defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and the distant site physician or practitioner. In the CY 2022 PFS final rule, CMS removed the geographic restrictions for Medicare telehealth services for the diagnosis, evaluation, or treatment of a mental health disorder and added the patient's home as a permissible originating site. CMS also finalized a policy to allow audio-only services for telehealth services furnished to established patients in their homes for the purposes of diagnosis, evaluation, or treatment of a mental health disorder (including SUD) if the distant site physician is technically capable of using an interactive telecommunications system, but the patient is not able or does not consent to the use of video technology.

Given the statutory extensions of telehealth flexibilities and their adoption of other extensions, CMS now believes it would be appropriate to expand the audio-only flexibility to any telehealth service furnished to a beneficiary in their home (when the patient's home is a permissible originating site). The current statutory Public Health Emergency (PHE)-related telehealth flexibilities will expire on December 31, 2024, and beyond that date, the patient's home is a permissible originating site only for

services for the diagnosis, evaluation, or treatment of a mental health or SUD, and for the monthly end-stage renal disease (ESRD)-related clinical assessments described in section 1881(b)(3)(B).

Physicians must append CPT modifier “93” for audio-only services. Rural health clinics (RHCs) and federally qualified health centers (FQHCs) must append Medicare modifier “FQ.” Practitioners have the option to use both “FQ” or the “93” modifiers or both when appropriate and true, since they are identical in meaning.

AAFP Comments

As noted in our comments on prior years’ proposals, the AAFP strongly supports audio-only services as they are clinically effective, valuable for patients, and vital for ensuring equitable access to essential care for a range of patient populations. Audio-only access can be an effective and appropriate means of providing care as a supplement to in-person care with the patient’s established primary care physician, particularly for patients who face barriers accessing video telehealth visits.

Audio-only services continue to play an important role in primary care, particularly among practices caring for underserved or vulnerable populations. Coverage of, and fair payment for, audio-only services is essential to facilitating equitable access to care. The AAFP looks forward to working with policymakers to support legislative changes that will ensure access to this valuable modality. In the meantime, we support CMS' proposal to expand the audio-only flexibility to any telehealth service furnished to a beneficiary in their home (when the patient’s home is a permissible originating site).

f. Distant Site Requirements

CMS continues to hear safety and privacy concerns from stakeholders related to requiring practitioners to use their home address when providing telehealth services from their homes. While they consider proposals that may better protect the safety and privacy of practitioners, CMS proposes to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home through CY 2025.

AAFP Comments

The AAFP supports CMS’ proposal to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home through CY 2025 and urge CMS to make this change permanent.

The digitization of health data has produced many benefits, including easing patients’ access to their own health information. The ubiquity of health data has also elevated the risk of misuse, including cyberattacks against all health care organizations. Additionally, as state legislatures across the country attempt to criminalize aspects of health care for patients and physicians alike, it is important to minimize situations in which individuals’ personal identifiable information could be inappropriately accessed and used in ways that could be harmful to them. The AAFP stands with family physicians and their patients in support of the confidential patient-physician relationship, and we urge CMS to not require physicians include their home address on Medicare enrollment paperwork related to rendering telehealth or any other service in 2025 and beyond.

2. Other Non-face-to-face Services Involving Communications Technology Under the PFS

Proposal to Extend Definition of "Direct Supervision" to Include Audio-Video Communications Technology through 2025 and Proposal to Permanently Define "Direct Supervision" to Include Audio-Video Communications Technology for a Subset of Services

Throughout the COVID-19 PHE, CMS amended the definition of "direct supervision" to permit the virtual presence of the physician through audio/video real-time communications technology. CMS extended this flexibility through December 31, 2024. CMS continues to have concerns about potential safety and quality of care implications. They are proposing to temporarily extend this flexibility through December 31, 2025.

CMS is also proposing to adopt a definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only) for the subset of services described under §410.26: (1) services provided incident-to a physician or other practitioner's service when provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision, and for which the code has been assigned a PC/TC indicator of '5', and (2) services described by CPT code 99211.

AAFP Comments

The AAFP supports CMS' proposal to allow direct supervision using real-time audio/video telecommunications technology through December 31, 2025, for all services and permanently for the subset of services described under §410.26. The AAFP recommends CMS allow direct supervision of non-physician clinicians by physicians using real-time audio/video technology on a permanent basis for all services. The AAFP strongly believes in the value of physician-led team-based care and that health professionals should work collaboratively as clinically integrated teams in the best interest of patients, which can be accomplished via real-time audio/video technology. This virtual capability continues to promote patient access, continuity, convenience, and choice, decreasing the spread of communicable diseases and providing critical support to patients and physicians in rural and other areas dealing with health professional shortages.

Teaching Physician Billing for Services Involving Residents with Virtual Presence

In the 2021 PFS final rule, CMS established a policy allowing teaching physicians to meet the requirements to be present for the key or critical portions via audio/video real-time communications technology for services furnished by residents when the services are furnished in residency training sites located outside of an OMB-defined MSA. In response to feedback, CMS modified its policy to allow teaching physicians to have a virtual presence in all teaching settings in clinical instances when the service is furnished virtually (e.g., a 3-way telehealth visit, with all parties in separate locations). The policy applies to all residency training locations through December 31, 2024.

CMS is proposing to extend this policy through December 31, 2025. The teaching physician's virtual presence requires real-time observation (not just availability) and excludes audio-only technology.

AAFP Comments

The AAFP continues to strongly encourage CMS to allow a teaching physician to have a virtual presence, regardless of whether the service is provided in-person or via telehealth. The virtual

presence promotes patient access, continuity, convenience, and choice, and it decreases the spread of communicable diseases. A virtual presence does not preclude a teaching physician from providing a greater degree of involvement in services furnished with the resident. The teaching physician would still have discretion to determine the appropriateness of a virtual presence rather than in-person, depending on the services furnished and the resident's experience. The teaching physician can also review the service with the resident during or immediately after the visit to exercise full and personal control over the service. However, surgical, high-risk, interventional, endoscopic, or other complex procedures under anesthesia should remain excluded from this policy.

(a) Request for Information (RFI) for Teaching Physician Services Furnished Under the Primary Care Exception

CMS is seeking information to help them consider whether and how best to expand the array of services included in the primary care exception (PCE) under future rulemaking. CMS seeks information about the following:

- the types of services that could be allowed under the PCE, specifically preventive services, and whether the currently required six months of training in an approved program is sufficient for residents to furnish these types of services without the presence of a teaching physician;
- whether the inclusion of specific higher-level or preventive services would hinder the teaching physician from maintaining sufficient personal involvement in the care and impede the teaching physician's ability to remain immediately available for up to four residents at any given time, while directing and managing the care furnished by these residents.

AAFP Comments

The AAFP greatly appreciates CMS' consideration of and request for information on expanding the services allowed under the PCE. The PCE traditionally permits a teaching physician to bill for certain lower and mid-level evaluation and management (E/M) services furnished by residents in certain types of residency training settings, even when the teaching physician is not present with the resident, if certain conditions are met. The PCE provides invaluable experience for applicable medical residents, expands patient access to primary care, and improves relational continuity of the patient and primary care physician in teaching centers.

In the proposed rule, CMS states the PCE "broadens opportunities for teaching physicians to involve residents in furnishing services … and promote safe, high-quality patient care." We agree: the PCE is an integral element that allows teaching physicians to provide the experiences necessary for residents to become autonomous family physicians who provide safe, comprehensive, quality care. Practice patterns imprinted during residency training persist beyond graduate training.[xi]

Historically, our members have reported that the absence of many high-value services on the PCE list discourages the integration of those services in residency training, which has a negative impact on physician training, patient access, and longer-term outcomes. Adding preventive services to the list of services allowed under the PCE may improve utilization of several under-utilized but high-value services, which is particularly important as HHS advances towards its goal of "a health care system that not only treats those who are sick but also keeps people well."

Expanding E/M services allowed under the PCE would support patient access and primary care workforce development by directing necessary resources to family medicine residency programs. In

previous recommendations, we noted comments in the final CY1996 MPFS rule that suggest the PCE was established out of concern that physical presence requirements for Part B payment would "unfairly deny reimbursement for the activities of teaching physicians in these programs and endanger the financial viability of these programs."[xii] Expanding services allowed under the PCE would help family medicine resident training programs remain financially stable—which ultimately supports primary care workforce development.

Expanding the services allowed under the PCE would not compromise patient safety or reduce teaching physician involvement in directing care. **Existing Accreditation Council for Graduate Medical Education (ACGME) requirements which set resident supervision levels based on individual assessments of a resident's competencies are sufficient to ensure safe and effective care, even if the list of services allowed under the PCE is expanded to include higher-level E/M services.** While the six-month standard established in the PCE is an appropriate federal minimum to ensure residents across the country have sufficient experience to begin providing direct care to patients, we reiterate that residency programs impose much more rigorous standards and more personalized oversight of a resident's needed level of supervision than the six-month standard as needed to ensure residents are prepared to practice without direct supervision in a wide range of clinical competencies.

Residency programs regularly evaluate resident physicians to determine the level of supervision required by teaching physicians. In 2023, the ACGME updated core residency program requirements. The updated requirements state every residency curriculum must include "competency-based goals and objectives for each educational experience designed to promote progress on a trajectory toward autonomous practice."[xiii] The emphasis on competency-based assessments enables residency programs to adjust resident supervision based on an individual's progression and needs. ACGME core requirements state, "The trajectory to autonomous practice is documented by Milestones evaluations…" Residents must demonstrate their competency against a set of requisite goals and objectives to decrease their level of supervision. Residency programs, through their ACGME-required Clinical Competency Committee process, must assess and determine when and under what circumstances (considering level of complexity, acuity, urgency, etc.) each resident has the appropriate competency to provide care without direct supervision. **This requirement ensures residency programs have proper guardrails in place to ensure patient safety, while allowing the resident the autonomous experience necessary to practice independently once the program is complete**.

In addition to the core program requirements, the AGCME program requirements for Family Medicine note, "The program must demonstrate that the appropriate level of supervision in place for all residents is based on each resident's level of training and ability, as well as patient complexity and acuity." The requirements further state, "Appropriate supervision is essential for patient safety and high-quality teaching. Supervision is also contextual. The level of supervision for each resident is commensurate with that resident's level of independence in practice; this level of supervision may be enhanced based on factors such as patient safety, complexity, acuity, urgency, risk of serious safety events, or other pertinent variables."[xiv]

Teaching physicians would also have more availability to residents who need their assistance if their physical presence is no longer required for additional services and more complex E/M visits the resident physician is able to furnish. While residency requirements provide additional guardrails to maintain patient safety, many of the services we propose for inclusion under the PCE are often furnished by non-physician clinicians or auxiliary staff with less training and clinical experience than residents with six months of residency training. Although the physician's physical presence in the

exam room is not required for "incident-to" billing of these services, the physician remains sufficiently involved as to merit PFS payment. **If this level of supervision is safe for non-physician clinicians and sufficient for payment by CMS, we believe residents who meet the relevant competency requirements could also provide additional services without a teaching physician being physically present in the exam room when the resident provides the service to the patient.**

While we make the comparison to non-physician providers to emphasize the potential inconsistency in the approach to payment for supervision of physician residents, it is important to recognize that residents' education and training better prepares them to work under general supervision without the physical presence of the teaching physician than nurse practitioners. Residents have completed a four-year education program compared to the two-year education most nurse practitioners complete. Residents also have more clinical training than the minimum 500 hours required for nurse practitioners to seek certification.[xv] There are no standardized residency training or post-graduate requirements for nurse practitioners.[xvi] However, residents who furnish services under the PCE must also have at least six months of clinical program training experience. Even though licensed nurse practitioners have less education, training, and experience than family medicine residents, they may furnish more complex E/M services and bill either under their own provider number or incident to physicians without the presence of the teaching physician.

Including additional services under the PCE would not impede the teaching physician's ability to remain available for up to four residents and direct care. If a resident reviews the patient's visit with the teaching physician before, during, or after a visit, it does not reduce the availability of the teaching physician or impose additional time burdens. Without the requirement to be physically present during a visit, the teaching physician has more time available to other residents. This level of involvement allows teaching physicians to focus with residents on medical decision-making without the necessity of direct supervision, assuring appropriate care.

Accordingly, we urge CMS to expand the list of services available under the PCE to include (1) additional preventive services, (2) all levels of office/outpatient E/M services, and (3) additional codes related to patient continuity and integration of care. Our detailed recommendations and response to CMS' request for information follow.

(1) Additional preventive services to allow under the PCE

We request CMS to include the following preventive services under the PCE:

- **G0442** – Alcohol misuse screening
- **G0443** – Brief face-to-face behavioral counseling for alcohol misuse
- **G0444** – Annual depression screening
- **G0446** – Annual, face-to-face intensive behavioral therapy for cardiovascular disease
- **G0447** – Face-to-face behavioral counseling for obesity
- **99406** – Smoking and tobacco use cessation counseling visit; intermediate
- **99407** – Smoking and tobacco use cessation counseling visit; intensive

We recommend CMS continue to encourage the integration of all high-value services, including these preventive services, in resident training. CMS has previously recognized the need to expand the PCE to include additional preventive services to further integrate them into residency training. For example, the PCE allows teaching physicians to bill for Medicare wellness

visits (G0402, G0438, G0439) furnished by a resident without a teaching physician present during the service. Additional opportunities for teaching physicians to integrate these preventive services into training are needed to ensure residents include these services in their day-to-day practice after program completion.

Alcohol screening and behavioral counseling services are underutilized.[xvii] Research suggests insufficient training and a lack confidence in their ability to furnish services are primary barriers to residents incorporating alcohol misuse screening and intervention into regular practice.[xviii] Additionally, approximately half of US adults over age 35 are not screened for depression.[xix] Expanding the PCE to include these services will increase utilization during residency and post-residency.

Screening and interventions for tobacco use have increased over time yet there is still an opportunity to increase the use of screening and interventions in the primary care setting.[xx] Research indicates physicians who used best practices for tobacco use screening and cessation during residency training were twice as likely to continue to furnish tobacco-related screening and interventions upon program completion, compared to physicians who only received training during residency.[xxi] We believe allowing these services to be furnished by residents under the primary care exception would allow teaching physicians to increase opportunities for residents to practice these services during residency.

The AAFP believes the existing requirements related to resident training are sufficient to ensure safe and effective care for these additional preventive services. While the six-month standard is an appropriate federal minimum to ensure residents across the country have sufficient experience to begin providing direct care to patients, we wish to stress that residency programs impose much more rigorous standards and more personalized oversight of a resident's needed level of supervision than the six-month standard. As discussed above, the ACGME competency-based program requirements ensure all resident physicians demonstrate the competencies required to furnish a particular service without a teaching physician's physical presence.

Further, the preventive services listed above would be furnished in an ambulatory setting where patients are typically not acute. Compared to surgical, high-risk, interventional and other complex procedures, we believe the risk of patient harm is low for these preventive services, making the physical presence of a teaching physician unnecessary for patient safety. Existing PCE requirements ensure residents would still have immediate access to the teaching physician, allowing the resident to seek immediate feedback if needed. Allowing these preventive services under the PCE would not compromise patient safety.

Non-physician clinical staff often furnish these preventive services under the direct supervision of the physician, with the physician receiving full PFS payment under "incident to" billing despite the lack of their personal presence during the service. Standardized screening instruments are frequently used for alcohol misuse and depression screening, and they are often administered by nurses or other auxiliary staff under the direct supervision of a physician. Additionally, tobacco cessation counseling may be provided by non-physician clinicians with less clinical training and experience than a resident with six months of training experience. Allowing these additional preventive services under the PCE would not hinder the teaching physician from maintaining sufficient involvement to warrant payment, as the level of physician involvement required to merit billing would be the same or more when furnished under the PCE.

Adding these preventive services to the PCE would not preclude a teaching physician from providing a greater degree of involvement in services furnished by a resident if the teaching physician deemed it necessary. The teaching physician would still have the discretion to determine the level of personal involvement they felt was appropriate in relation to the services being furnished, as well as the experience and demonstrated competency of the resident. Teaching physicians are still required to be on site for resident supervision, and residents must review all encounters with the teaching physician—even if the teaching physician does not directly see the patient. All documentation must be reviewed and countersigned by the teaching physician. Thus, teaching physicians would remain highly involved with resident delivery of these services if allowed as services under the PCE.

(2) Higher-level office/outpatient E/M services to allow under the PCE

We recommend CMS allow all levels of office/outpatient E/M visits (99202-99205, 99212-99215) under the PCE to provide residency programs with the resources needed to support workforce development and improve access and patient continuity of care—all without compromising patient safety or impeding the teaching physician's overall management of care.

With a shortage of primary care physicians, ensuring the sustainability of existing residency programs is crucial to maintaining primary care access. Many residency programs have expenses that exceed allocated resources and funding, and residency program directors are often pressured by their sponsoring organization to demonstrate a financial benefit (or at minimum, a break-even) to continue the program. An analysis of financial data from family medicine residency programs found increases in average expenses per resident outpaced growth in graduate medical education (GME) funding, forcing programs to rely on other sources of funding, including clinical revenue, to remain solvent.[xxii] Family medicine residency clinics must also remain financially viable to cover the salary and benefits of a sufficient number of trained teaching physicians.

Because of the tight financial margins in most family medicine residency programs, accurate coding and billing patterns are critical to program sustainability. Research suggests residency clinics may be using lower-complexity codes when a higher-level code is more accurate.[xxiii,xxiv] This coding pattern results in decreased resources for family medicine programs at a time when CMS is otherwise investing more in primary care (e.g., by implementing and expanding code G2211). Over time, the potential revenue loss from inaccurate coding may reduce access by reducing the number of primary care residency training programs, which ultimately reduces the number of new family medicine physicians.

Coding is difficult in residency clinics because it is not always clear when a visit will meet the medical decision-making (MDM) criteria for a level 4 or 5 visit. As a result, some experienced residents may furnish a visit that meets the MDM criteria of a level 4 or 5 E/M visit, but unless they stop the visit to call in the teaching physician, they are unable to accurately code the visit based on the actual MDM level involved. These visits do not surpass the resident's capabilities or supervision requirements but require a teaching physician's presence to code accurately because the PCE policy does not encompass higher-complexity codes.

This assertion is supported by studies seeking to understand the effects of the temporary expansion of the PCE during the COVID-19 PHE. During the PHE, CMS allowed office/outpatient E/M visits at any level to be furnished under the PCE.[xxv] A recent analysis of billing data from one residency program during the COVID-19 PHE found that the use of higher-complexity visit codes increased for patients seen by residents, while coding patterns generally remained the same for attending

physicians (patients seen without the presence of a resident).[xxvi] This suggests the overall frequency of higher-complexity visits did not change and lifting the restriction for residents allowed for more accurate coding based on MDM.

When the temporary PCE expansion expired, it restored limitations on the types of visits residents can furnish—even those residents determined by faculty to have the necessary clinical competencies—which added administrative barriers that ultimately reduce access. As described above, the exclusion of more complex E/M codes may also prevent the clinic from being reimbursed for services furnished under the direction of the teaching physician. Over time, this weakens clinic finances and makes recruiting and retaining teaching physicians challenging. Allowing higher-level E/M codes under the PCE would therefore improve patient access and strengthen family medicine residency programs — a critical pipeline for primary care physicians.

As noted, existing ACGME requirements which set resident supervision levels based on individual assessments of a resident's competencies are sufficient to ensure safe and effective care, even if the list of services allowed under the PCE is expanded to include higher-level E/M services. These requirements ensure residency programs have proper guardrails in place to ensure patient safety, while allowing the resident the autonomous experience necessary to practice independently once the program is complete.

Accordingly, CMS does not need to impose additional safeguards regarding the resident's experience (such as additional training time requirements) to ensure they are qualified to provide care. **Residency programs are not only obligated to continuously determine the appropriate level of supervision a resident requires but are also in the best position to do so. The list of services furnished under the PCE could be expanded to include all levels of office/outpatient E/M services without compromising patient safety.**

CMS also seeks information on whether adding all levels of E/M services would reduce teaching physician involvement in care to the point PFS payment is no longer warranted. **Teaching physicians would be able to remain sufficiently involved in directing these services to warrant PFS payment for directing and managing additional E/M services furnished by qualified residents.** Currently, non-physician practitioners (such as nurse practitioners) may furnish level 4 and 5 visits and bill "incident to" a supervising physician without the physician being present during the service. Expanding the PCE to include all levels of E/M service is therefore compatible with existing CMS policy because it is the amount of physician involvement (not the physician's physical presence during the service) which justifies payment. Resident physicians would still review patient care with the teaching physician just as non-physician clinicians do when billing a service "incident to" a supervising physician.

Again, while we make the comparison to non-physician providers to emphasize the potential inconsistency in the approach to payment for supervision of physician residents, it is important to recognize that residents' education and training better prepared to work under general supervision without the physical presence of the teaching physician than nurse practitioners. Residents have completed a four-year education program compared to the two-year education most nurse practitioners complete. Residents also have more clinical training than the minimum 500 hours required for nurse practitioners to seek certification.[xxvii] There are no standardized residency training or post-graduate requirements for nurse practitioners.[xxviii] However, residents who furnish services under the PCE must also have at least six months of clinical program training experience. Even though licensed nurse practitioners have less education, training, and experience than family

medicine residents, they may furnish more complex E/M services and bill either under their own provider number or incident to physicians without the presence of the teaching physician.

Including additional services under the PCE would not impede the teaching physician's ability to remain available for up to four residents and direct care. If a resident reviews the patient's visit with the teaching physician before, during, or after a visit, it does not reduce the availability of the teaching physician or impose additional time burdens. Without the requirement to be physically present during a visit, the teaching physician has more time available to other residents. This level of involvement allows teaching physicians to focus with residents on medical decision-making without the necessity of direct supervision, assuring appropriate care.

(3) Additional patient continuity and integration of care codes to include under the PCE

In addition to the preventive services and E/M services discussed above, we ask CMS to consider allowing the following codes under the PCE:

- **99421-99423** – Online digital E/M service for an established patient
- **99495** – Transitional care management
- **99497** – Advance Care Planning, including explanation and discussion of advance directives
- **99498** – Add-on code for CPT 99497 (Advance Care Planning, each additional 30 minutes)
- **99490** – Chronic Care Management services, first 20 minutes of clinical staff time directed by a physician or other qualified health care professional
- **99439** – Add-on code for CPT 99490 for each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional

Residency programs must provide the experiences necessary to develop primary care physicians who can integrate care across settings and serve as a longitudinal source of care. A**dding codes related to patient continuity and integration of care under the PCE will improve utilization and encourage residents to provide these high-value services after graduation.** It will also expand access by allowing qualified residents to provide these services to their patient panel without the face-to-face presence of a teaching physician.

We also note that many of these codes help to provide the resources needed to employ appropriate staff for team-based care. Residency programs often have very limited financial resources and may be unable to employ a full team without the additional financial support these codes offer. Adding these services to the PCE would help to ensure residency programs have the resources to hire sufficient medical assistants, nurses, and other staff, which is critical to teaching resident physicians how to successfully lead an engaged and impactful multidisciplinary care team.

These services may be provided without the teaching physician physically present without compromising patent safety. Advance Care Planning and Chronic Care Management services are often provided by other less qualified staff under general or direct supervision by the patient's physician. Allowing eligible resident physicians to direct these services would provide teaching physicians with an opportunity to train residents in the skills needed to be an effective physician leader of a multidisciplinary care team. **Residents would still review care with the teaching physician for these services, allowing the physician to effectively manage patient care and remain sufficiently involved as to warrant PFS payment.**

AAFP asserts that adding the aforementioned codes to the list of services available under the PCE would improve the ability of the teaching physician to remain immediately available for up to four residents at a time. As previously expressed, many residents are perfectly capable of furnishing the recommended additions to the PCE list without the physical presence of the teaching physician. However, because those codes are not included as part of the PCE, regardless of the resident's competence, they must request the presence of the teaching physician. This means the teaching physician is not available to assist the other three residents. Additions to the PCE list would expand teaching physician availability rather than harm it in any way.

Future Rulemaking

To further increase the number of teaching physicians who are able to use the PCE to offer their residents opportunities to develop needed skills for a successful career in family medicine, the AAFP recommends CMS consider expanding the PCE regulations to include Teaching Health Centers (THCs) in future rulemaking. Currently, a technical problem within the regulation prevents THCs from using the Teaching Physician Primary Care Exception modifier. The AAFP encourages CMS to apply the PCE rules for payments for services furnished by residents in patient care activities, when determining payments made under Section 340H of the Public Health Service Act. This would allow THCs to utilize the PCE, offering teaching physicians more flexibility and residents more expansive patient care experiences, and it would align payments for services provided at THCs with those furnished by residents under Medicare GME.

Valuation of Specific Codes (section II.E.)

Therapeutic Apheresis and Photopheresis (CPT codes 36514, 36516, and 36522)

In the CY 2024 PFS final rule, CMS finalized CPT codes 36514 (Therapeutic apheresis; for plasma pheresis), 36516 (Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion), and 36522 (Photopheresis, extracorporeal) as potentially misvalued, as CMS believed there may have been a possible disparity with the clinical labor type. As a result, the PE clinical labor type was reviewed for these three codes at the January 2024 Relative Value Scale Update Committee (RUC) meeting, with no work review. The PE Subcommittee and the RUC agreed that clinical staff code L042A (RN/LPN) did not appropriately represent the work of an Apheresis Nurse Specialist. Since there is not a clinical staff code for an Apheresis Nurse Specialist; the RUC agreed with the specialty societies' recommendation that the training and experience of an oncology nurse (clinical staff code L056A, RN/OCN) would more accurately reflect the work of an apheresis nurse for these CPT codes. CMS proposes the RUC-recommended direct PE inputs for CPT codes 36514, 36516, and 36522 without refinement. The RUC did not make recommendations, and CMS is not proposing any changes to the work RVU for CPT codes 36514, 36516, and 36522.

AAFP Comments

The AAFP participated in the presentation of these codes to the RUC and its PE Subcommittee. We were among the specialties recommending that the clinical staff code be changed from L042A (RN/LPN) to L056A (RN/OCN). Accordingly, we appreciate and support CMS' proposal to accept the RUC-recommended direct PE inputs for these three codes without refinement.

Telemedicine Evaluation and Management (E/M) Services (CPT codes 9X075, 9X076, 9X077, 9X078, 9X079, 9X080, 9X081, 9X082, 9X083, 9X084, 9X085, 9X086, 9X087, 9X088, 9X089, 9X090, and 9X091)

In 2023, the CPT Editorial Panel agreed to add a new evaluation and management (E/M) subsection for telemedicine services effective with the 2025 CPT code set. The 17 new codes (CPT codes 9X075-9X091) describe services that would otherwise be furnished in-person and therefore are subject to section 1834(m). Eight codes describe synchronous audio-video services (CPT codes 9X075-9X082), eight codes describe synchronous audio-only services (CPT codes 9X083-9X890), and one code describes an asynchronous service (CPT code 9X091). The Panel also agreed to delete three codes (CPT codes 99441-99443), which describe telephone E/M services.

CMS' long-standing interpretation of section 1834(m) allows Medicare to pay for services that would otherwise be furnished in person but instead are furnished via telecommunications technology. The Act expressly requires payment to the distant site physician or practitioner of an amount equal to the amount they would have been paid had the service been provided without the use of a telecommunications system. Services that are not ordinarily furnished in person, such as remote patient monitoring and communication technology-based services, are not considered Medicare telehealth services and not subject to geographic, site of service, and practitioner restrictions.

The RUC information provided to CMS describes the new codes as services that would have otherwise been provided in person, which makes them subject to section 1834(m). The codes are patterned after the in-person office visit codes. The RUC-recommended work RVUs (wRVUs) for the audio-video codes are nearly identical to the parallel O/O E/M codes. The RUC-recommended wRVUs for the audio-only codes are slightly lower than the corresponding O/O E/M codes. According to the RUC, this is because their survey data showed that "the audio-video and in-person office visits require more physician work than the audio-only office visits."

CMS notes that, except for the modality, the service elements of the new telemedicine CPT E/M codes are no different than the O/O E/M codes. CMS further points out that there are existing CPT codes on the Telehealth Services list – the O/O E/M code set – that can be provided via two-way audio/video generally and via audio-only in certain circumstances. CMS would need to establish RVUs for the telemedicine E/M codes equal to the corresponding non-telehealth services to satisfy the requirements under section 1834(m)(2)(A).

CMS does not believe there is a programmatic need to recognize the audio/video and audio-only telemedicine E/M codes under Medicare. They propose to assign CPT codes 9X075-9X090 a Procedure Status indicator of "I," meaning there is a more specific code that should be used.

Under current statute, beginning January 1, 2025, the geographic and site of service restrictions for Medicare telehealth services will return, except for certain circumstances. The new CPT codes do not change Medicare's authority to pay for visits provided via interactive telecommunications technology in accordance with section 1834(m).

CMS seeks comment on their understanding of the applicability of section 1834(m) to the new telemedicine E/M codes and how they might potentially mitigate the negative impact from the expiring telehealth flexibilities, preserve some access, and assess the magnitude of potential reductions in access and utilization. CMS developed proposed CY 2025 payment rates based on the presumption that changes in telehealth utilization will not affect overall service utilization. They have not historically considered changes in Medicare telehealth policies to result in significant impact on utilization such

that a budget neutrality adjustment would be warranted. They are unsure of the continued validity of that premise under current policies where patients have grown accustomed to broad access to services via telehealth. CMS is seeking comment on what impact the expiration of the current flexibilities would have on overall service utilization for CY 2025.

CMS is proposing to accept the RUC-recommended values for CPT code 9X091 and to delete HCPCS code G2012. For 9X091, they propose to accept the RUC-recommended work RVU of 0.30 and the RUC-recommended direct PE inputs. CMS notes that, like their current policy, CPT code 9X091 would be considered a communication technology-based service that is not subject to the requirements of 1834(m).

AAFP Comments

First, the AAFP supports the CMS proposal to accept the RUC-recommended work value of 0.30 and the RUC-recommended direct PE inputs for CPT code 9X091 and to delete HCPCS code G2012. We agree with CMS that, like G2012, CPT code 9X091 should be considered a communication technology-based service that is not subject to the requirements of 1834(m).

Regarding the remaining 16 new telemedicine E/M CPT codes that will be effective with the 2025 CPT code set, we believe CMS has fairly and reasonably interpreted both the way the new codes are presented by CPT and the applicability of section 1834(m) of the Social Security Act. Accordingly, we support the CMS proposal to assign CPT codes 9X075-9X090 a Procedure Status indicator of "I", meaning that there is a more specific code that should be used for purposes of Medicare. As CMS notes, in this case, the more specific code(s) are the existing office/outpatient E/M codes currently on the Medicare Telehealth Services list when billed with the appropriate place of service (POS) code to identify the location of the beneficiary and, when applicable, the appropriate modifier to identify the service as being furnished via audio-only communication technology.

Per the AAFP's "Telehealth and Telemedicine" policy, we believe payment models, including the Medicare physician fee schedule, should support the physician's ability to direct the patient toward the appropriate service modality (i.e., provide adequate reimbursement) in accordance with the current standard of care. In general, telemedicine visits require the same level of work by the physician and incur the same level of liability as in-person visits; therefore, those telemedicine services should be reimbursed at parity with the corresponding in-person visit, consistent with CMS' interpretation of section 1834(m).

For administrative simplicity and other reasons, the AAFP has historically encouraged physicians and health plans to abide by the principles of CPT, especially in a fee-for-service payment system like the Medicare physician fee schedule. In this case, the current CPT principles and code structures are working. The greater good of administrative simplicity supports maintaining the existing CPT principles, as CMS proposes, rather than requiring physicians to use 16 new codes for services already adequately captured by existing office/outpatient E/M codes in combination with POS codes and modifiers (where applicable).

The AAFP believes current telemedicine payment policies warrant increased standardization among payers. Unnecessary variability in policies among payers leads to administrative complexity and burden for physicians and patients. Thus, if CMS finalizes its proposals for these codes, we hope it will use whatever influence it has to encourage Medicare Advantage plans and Medicaid programs to do the same.

Regrettably, whether CMS finalizes its proposal or not is unlikely to mitigate the negative impact from the expiring telehealth flexibilities related to geographic location or site of service restrictions. Regarding what impact the expiration of the current flexibilities would have on overall service utilization for CY 2025, we are inclined to agree with CMS' presumption that changes in telehealth utilization will not affect overall service utilization. Like CMS, we do not think changes in Medicare telehealth policies will have significant impact on utilization such that a budget neutrality adjustment would be warranted.

There is evidence to support those presumptions. For instance, decreases in primary care visit volume were only partially offset by increasing telehealth use for all patients during the COVID-19 pandemic, and it's estimated the percentage of pre-pandemic visit volume that was converted to telehealth during the pandemic was only 10 percent for primary care. Telehealth utilization among Medicare patients has been relatively stable at 13-15 percent since Q2 of 2022, while commercial utilization has generally remained at 4-5 percent and is primarily for mental health issues.

Finally, we wish to address CMS' ongoing policy of paying differentially between POS 02 (Telehealth Provided Other than in Patient's Home) and POS 10 (Telehealth Provided in Patient's Home). The AAFP supports CMS' policy to pay telehealth services billed with POS 10 at the non-facility rate. We agree with CMS that many physician practices continue to offer both in-person and telehealth appointments, and thus, physicians offering telehealth services to patients in their homes still have to pay for the practice expense of having a physical practice. We also agree that paying at the non-facility rate will enable more physicians to continue offering telehealth services, improving equitable access to care for patients. While absent congressional action, only behavioral health services can be billed with a POS 10 code after 2024, the AAFP notes that practice costs and downstream implications on patients' access to care apply more broadly, including to family medicine practices.

We remain concerned that services billed with POS 02 continue to be paid by Medicare at the facility rate. During and throughout the PHE, many practices invested in new technologies to shift to a predominantly virtual environment. While practices have transitioned back to offering in-person care, some patients still prefer the telehealth option for a variety of reasons. As a result, primary care practices are maintaining their office presence while also offering telehealth services to meet their patients' needs. Regardless of the patient's location, the practice expenses remain the same. Furthermore, by providing hybrid options (i.e., telehealth and in-person), the physician and patient may determine which modality is most appropriate for the service being delivered. This provides convenient options for patients while also increasing their access to the comprehensive and patient-centered care provided by their primary care physician. Coverage and payment policies should support patients' and clinicians' ability to choose the most appropriate modality of care (i.e., audio-video, audio-only, or in-person) and ensure appropriate payment for care provided. The longitudinal and comprehensive relationships between family physicians and their patients mean they are in the best position to decide what type of modality is appropriate for their care.

Paying telehealth services at the facility rate creates a disincentive for office-based practices that do not receive a facility fee to provide telehealth services, further disadvantaging them in an already uneven playing field. In addition to appropriately accounting for practice expenses, payment rates must also appropriately and fairly value physician work. The cognitive work of a physician does not differ based on the modality of care. When provided by a patient's usual source of care, telehealth (including audio-only) is another tool for practices that can provide increased access to a trusted member of the medical team. Policies should be designed to equip all primary care practices with more tools, not less, to facilitate the delivery of high quality, longitudinal primary care.

COVID-19 Immunization Administration (CPT code 90480)

On August 14, 2023, new CPT codes were created to consolidate over 50 previously implemented codes and streamline the reporting of immunizations for the novel coronavirus (SARS-CoV-2, also known as COVID-19). The CPT Editorial Panel approved the addition of a single administration code (CPT code 90480) for administration of new and existing COVID-19 vaccine products. The RUC reviewed the specialty societies' recommendations for this code at the September 2023 RUC meeting. CMS proposes the RUC-recommended work RVU of 0.25 for CPT code 90480 (Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, single dose). CMS also proposes the RUC-recommended direct PE inputs for CPT code 90480 without refinement.

AAFP Comments

The AAFP supports CMS' recommendation of 0.25 wRVUs for code 90480. This value is supported by a time and intensity comparison with the key reference service, 90460 (Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered) and fits nicely with the established wRVUs for other codes with similar time. We likewise support the recommended direct practice expense inputs for code 90480. We note they are the same inputs currently assigned to code 90460, which was recently reviewed in 2021.

Acupuncture - Electroacupuncture (CPT codes 97810, 97811, 97813, and 97814)

Following review of these codes by the RUC in April 2023, CMS proposes the RUC-recommended wRVUs for all four CPT codes for CY 2025. Specifically, CMS proposes a wRVU of:

- 0.61 for CPT code 97810 (Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient),
- 0.46 for CPT code 97811 (Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)),
- 0.74 for CPT Code 97813 (Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient), and
- 0.47 for CPT code 97814 (Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with reinsertion of needle(s) (List separately in addition to code for primary procedure)).

CMS also proposes the RUC-recommended direct PE inputs for CPT codes 97810, 97811, 97813, and 97814 without refinement.

AAFP Comments

Low back pain, whether acute, subacute or chronic, is among the most common reasons patients see family physicians. Acupuncture, a covered service for Medicare beneficiaries, is an evidence-based treatment included in the clinical guidelines for *Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain* developed by the American College of Physicians and endorsed by the AAFP. Given Medicare recognizes the therapeutic benefit of acupuncture, as evidenced by its

decision to cover and pay for it beginning in 2020, we are disappointed CMS recommends decreasing the work and practice expense RVUs of both add-on codes, 97811 and 97814.

Evidence-based guidelines list acupuncture as a first-line therapy for low back pain, which is the most common condition for which opioids are prescribed. Successful treatment of low back pain, whether acute or chronic in nature, with medical acupuncture can help patients avoid use of opioids and other high cost and potentially harmful services, including surgery. Reducing the relative value of codes 97811 and 97814 could have the unintended consequence of discouraging the delivery of this important clinical intervention. As organizations, both large and small, consider payment implications as indicators of where to place their priorities in patient care, the proposed payment decrease could result in physician acupuncturists being discouraged from providing medical acupuncture to Medicare patients. The typical Medicare patient receiving acupuncture receives one unit of the base code (either 97810 or 97813) plus one unit of the corresponding add-on code.

Family physicians are the largest group of primary care clinicians trained in medical acupuncture. Family physicians also deliver the majority of primary care in the U.S. As noted throughout our comments, persistent underfunding of primary care puts that workforce, and access to equitable care for patients, at risk. Decreased funding for this high-value, low cost, evidence-based treatment, frequently delivered by family physicians, is inconsistent with CMS' broader strategic aims to strengthen primary care.

We hope that CMS will consider these potential harmful impacts on patients and prioritize seniors' access to medical acupuncture by maintaining current payment levels for this evidence-based, low-cost treatment for low back pain, especially considering the costs of alternatives, such as prescription medication, including opioids, steroid epidurals, and surgery.

Accordingly, the AAFP respectfully recommends CMS maintain the current work and practice expense RVUs for codes 97811 and 97814.

<u>Annual Alcohol Screening (HCPCS codes G0442 and G0443)</u>

After review by the RUC in April 2023, CMS proposes the RUC-recommended work RVU of 0.18 for HCPCS code G0442 (Annual alcohol misuse screening, 5 to 15 minutes) and the RUC-recommended work RVU of 0.60 for HCPCS code G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes). CMS proposes the RUC-recommended direct PE inputs for HCPCS code G0443 without refinement.

For code G0442, CMS proposes to maintain the current 15 minutes of clinical labor time for the CA021 "Perform procedure/service----NOT directly related to physician work time" activity. This clinical labor activity is specifically noted as not corresponding to the surveyed work time of 5 minutes, and CMS does not believe it would be typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the RUC-recommended 5 minutes. CMS believes the current 15 minutes of clinical labor time would be more typical to ensure the accuracy of this screening procedure. CMS also proposes to maintain 15 minutes of corresponding equipment time for the EF023 exam table because of its proposed clinical labor time refinement.

AAFP Comments

The AAFP participated in the presentation of these codes to the RUC and its PE Subcommittee. Accordingly, we appreciate and support CMS' proposal to accept the RUC-recommended work RVUs for both codes and the direct PE inputs for code G0443 without refinement.

Regarding the clinical staff time for G0442, in retrospect, we agree with CMS that the RUC-recommended clinical labor time of 5 minutes for the CA021 "Perform procedure/service---NOT directly related to physician work time" activity is insufficient. We agree with CMS that it would not be typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the RUC-recommended 5 minutes. We initially recommended more time than that to the RUC. Thus, we support the CMS proposal to maintain the current 15 minutes of clinical labor time for the CA021 "Perform procedure/service---NOT directly related to physician work time" activity and for the corresponding equipment time for the EF023 exam table.

Annual Depression Screening (HCPCS code G0444)

After review by the RUC in April 2023, CMS proposes the RUC-recommended work RVU of 0.18 for HCPCS code G0444. CMS proposes to maintain the current 15 minutes of clinical labor time for the CA021 "Perform procedure/service---NOT directly related to physician work time" activity for code G0444. This clinical labor activity is specifically noted as not corresponding to the surveyed work time of 5 minutes, and CMS does not believe it would be typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the RUC- recommended 5 minutes. CMS believes the current 15 minutes of clinical labor time would be more typical to ensure the accuracy of this screening procedure. CMS also proposes to maintain 15 minutes of corresponding equipment time for the EF023 exam table because of its proposed clinical labor time refinement.

AAFP Comments

The AAFP participated in the presentation of this code to the RUC and its PE Subcommittee. Accordingly, we appreciate and support CMS' proposal to accept the RUC-recommended work RVUs for the code.

Regarding the clinical staff time for G0444, in retrospect, we agree with CMS that the RUC-recommended clinical labor time of 5 minutes for the CA021 "Perform procedure/service---NOT directly related to physician work time" activity is insufficient. We agree with CMS that it would not be typical for the clinical staff to administer the questionnaire, clarify questions as needed, and record the answers in the patient's electronic medical record in the RUC-recommended 5 minutes. We initially recommended more time than that to the RUC. Thus, we support the CMS proposal to maintain the current 15 minutes of clinical labor time for the CA021 "Perform procedure/service---NOT directly related to physician work time" activity and for the corresponding equipment time for the EF023 exam table.

Behavioral Counseling & Therapy (HCPCS codes G0445, G0446, and G0447)

After review by the RUC in September 2023, CMS proposes the RUC-recommended work RVU of 0.45 for each of these three codes, G0445-G0447. However, CMS is not proposing the RUC-

recommended direct PE inputs for these codes. Instead, CMS proposes to maintain the patient education booklet (supply code SK062), which the RUC had recommended eliminating in favor of 10 sheets of laser printing paper (supply code SK057). Likewise, CMS is proposing not to modify the equipment minutes to equal the sum of clinical staff time plus the physician/QHP time as reflected by the RUC survey median.

CMS is proposing the RUC recommended refinements to clinical staff time for code G0445. Specifically, CMS proposes to move two minutes from CA021 Perform procedure/service--not directly related to physician work time to CA035 Review home care instructions, coordinate visits/prescriptions. CMS agrees with the RUC that this more accurately reflects the clinical work involved in arranging follow-up and/or referrals with clinical and community resources and providing educational materials.

Lastly, for code G0445, CMS proposes to accept the RUC recommendations to eliminate a whip mixer (EP086) and biohazard hood (EP016) among the equipment assigned to the code.

AAFP Comments

The AAFP participated in the presentation of these codes to the RUC and its practice expense Subcommittee. Accordingly, we appreciate and support CMS' proposal to accept the RUC-recommended work RVUs for these codes, especially given the insufficient number of survey responses in each case. For similar reasons, we support CMS' proposal to not modify the equipment minutes to equal the sum of clinical staff time plus the physician/QHP time as reflected by the RUC survey median.

We appreciate and support CMS' proposal to accept most of the rest of the RUC's recommended refinement to the PE inputs for these codes. We also support CMS' proposal to maintain the patient education booklet (supply code SK062), which the RUC had recommended eliminating in favor of 10 sheets of laser printing paper (supply code SK057). Our original recommendation to the RUC included maintenance of the patient education booklet.

<u>Preexposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)</u>

For 2025, CMS proposes national rates for three HCPCS codes established in 2024 that reflect the relative resource costs associated with the counseling and drug administration portions of PrEP of HIV, pending finalization of a National Coverage Determination (NCD) for such services. CMS' proposals are as follows:

- For HCPCS code G0011 ((Individual counseling for pre-exposure prophylaxis (PrEP) by physician or QHP to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15-30 minutes), CMS proposes a work RVU of 0.45 based off work and direct PE inputs cross walked from HCPCS code G0445 (High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes: education, skills training and guidance on how to change sexual behavior; performed semiannually, 30 minutes).
- For HCPCS code G0012 (Injection of pre-exposure prophylaxis (PrEP) drug for HIV prevention, under skin or into muscle), CMS proposes a work RVU of 0.17 based on the work

and direct PE cross walked from CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular).

- For HCPCS code G0013 (Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence), CMS proposes a work RVU of 0.18 based on the work and direct PE inputs cross walked from CPT code 99211 (Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional).

AAFP Comments

The AAFP believes the proposed cross walk for work RVU and PE inputs in each case is reasonable as an initial valuation, pending finalization of the related NCD. Because these are new codes and the NCD is not yet finalized, we encourage CMS to review and, as needed, revise the valuation of these codes in three years to ensure the initial valuations and cross walks still make sense in the light of clinicians experience with the services.

Request for Information (RFI) for Services Addressing Health-Related Social Needs (Community Health Integration (G0019, G0022), Principal Illness Navigation (G0023, G0024), Principal Illness Navigation-Peer Support (G0140, G0146), and Social Determinants of Health Risk Assessment (G0136))

CMS is issuing a broad RFI on the newly implemented Community Health Integration (CHI) (G0019, G0022), Principal Illness Navigation (PIN) (G0023, G0024), Principal Illness Navigation- Peer Support (PIN-PS) (G0140, G0146), and Social Determinants of Health Risk Assessment (SDOH RA) (G0136) services. Specifically, CMS seeks comments on:

- related services that may not be described by the current coding and barriers to furnishing the services addressing health-related social needs.
- auxiliary personnel (beyond clinical social workers) furnishing these services, certifications, and/or training requirements that are not adequately captured in current coding and payment for these services.
- community-based organizations (CBOs) and their collaborative relationships with billing practitioners, including CBOs' roles, the extent to which practitioners are contracting with CBOs, incident to billing, and auxiliary personnel employed by CBOs under general supervision of practitioners.
- coding Z codes on claims associated with billing for CHI, PIN, and SDOH risk assessment codes and whether practitioners are capturing unmet social needs on claims using Z codes for social risk factors or in some other way,
- ways to identify specific services (e.g., fractures) and to recognize possible barriers to improved access to these kinds of high-value, potentially underutilized services,
- anything else CMS should consider in the context of these codes and what else CMS could consider to be included in this newly established code set.

AAFP Comments

The AAFP appreciates CMS' ongoing efforts to identify and value the growing number of services primary care physicians deliver to patients, including efforts that offer appropriate payment to identify,

monitor, and address patient-level health-related social needs (HRSN) in the context of providing person-centered care. SDOH have a substantial impact on the health of many Americans and are a key driver of health inequities. We believe family physicians play an important role in identifying both upstream SDOH and downstream HRSN and connecting their patients to available resources in their community. The AAFP provides resources to assist physicians and their health care teams in this effort and advocates for the development of community-based infrastructure, such as the community care hub, to support efficient and impactful connections between health care delivery organizations and social care community based organizations in a community and person-centered manner.

However, it is equally important to note that family and other primary care physicians cannot be held accountable for addressing individual level social needs when the resources to do so do not exist at the community level. In other words, it is incumbent upon communities and its key stakeholders to ensure that sufficient resources are available to address SDOH needs. As pointed out in our introductory comments, hospitals have been the beneficiaries of increased Medicare spending over the last twenty years. Hospitals are also frequently one of, if not the largest employer in their respective communities. Their role in developing community infrastructure to support addressing social needs is incumbent upon all hospital organizations – especially those benefitting from not-for-profit tax status and thus not otherwise contributing financially to the support of community infrastructure.

In previous comments, we've noted that family physicians cite the need to expand their capabilities to identify and address a patient's SDOH needs as reason to transition to alternative payment models (APMs) that include prospective population-based payments that are sufficiently funded to resource the necessary staff and other resources. Even with the new CHI and PIN codes CMS created in 2024, current FFS payment structures do not offer sufficient or stable funding necessary for primary care practices to effectively identify and address individual health-related social needs without strong community support. The AAFP believes these new codes represent another example of how well-intended actions, taken within the context of a flawed PFS, have marginal impact at best, and at worst, harms family physicians and care teams by over-burdening them with expectations that cannot be met. The AAFP urges CMS to push forward toward new payment strategies to more comprehensively and sustainably finance primary care which will allow family physicians to do what they most want – deliver comprehensive, continuous, coordinated care that considers the needs of the whole person, including SDOH factors, in the context of their community and family setting.

While we hope for more and commit to actively working with CMS to identify ways to achieve this goal, we continue to be most appreciative of CMS' efforts to incorporate payment for CHI, PIN, and CHW services, as well as SDOH screening, within the current payment structures that exist today.

Unfortunately, we are less than a year into implementation of these services as part of the Medicare physician fee schedule. Consequently, we do not have any data on many of the questions CMS asks in this RFI (e.g., what types of auxiliary personnel are typically furnishing these services, family physicians' use of Z codes on claims to capture unmet social needs).

Regarding barriers to furnishing the services addressing HRSN, we note, as we have before, that cost sharing requirements create barriers for patients that are likely to reduce utilization. Not only will patients with limited financial resources be reluctant to receive such services, but we remain concerned that, given the likelihood these services will be provided to patients with limited financial resources, practices are likely to forego billing for the service out of concern for the patient's out of

pocket cost, further limiting the positive impact of these new codes. We recognize CMS does not have the authority to waive cost sharing for CHI services, however, the AAFP encourages CMS to work with Congress to identify solutions to this systemic barrier to care.

Another barrier remains the time specified in some of the code descriptors. For instance, the AAFP urges CMS to modify the descriptor for code G0019 to read "20 minutes" instead of "60 minutes." The time duration of CHI services may vary significantly each month. For example, in the initial months, CHWs and auxiliary staff will likely spend significant time understanding the patient's specific needs and goals, but once this information is established, interventions are likely to be less time intensive. We are concerned that the 60-minute time requirement is too high and creates a barrier to integrating CHI services. Therefore, we strongly recommend that CHI services follow a similar format to chronic care management (CCM) codes, which allow for services to be delivered in 20-minute increments.

Likewise, the AAFP urges CMS to modify the descriptor for code G0023 to read "20 minutes" instead of "60 minutes." As with CHI, the time duration of PIN services may vary significantly each month; for example, we expect that services might be more time-intensive in the first month compared to others. We strongly recommend that PIN services follow a similar format to CCM codes, allowing for services to be delivered in 20-minute increments. Following a similar format may also reduce confusion and help to facilitate adoption.

Regarding types of auxiliary personnel and certifications and/or training requirements to provide these services, we encourage CMS to continue to ensure that certification and/or training requirements do not inadvertently create barriers that block qualified individuals with valuable lived experience from providing CHI services. The AAFP recognizes the importance of training and certification standards for individuals who provide medical care. However, CHI services are not medical services per se; rather, they are services to address HRSNs that impact a practitioner's ability to treat a diagnosed problem. We also note that research on the impact of community health worker certification programs is limited and inconclusive. Until more is known regarding the benefits and drawbacks of community health worker certification, we believe that allowing for flexibility in training and certification requirements is appropriate to support the development of a diverse CHI services workforce.

Finally, we want to affirm our support for SDOH risk assessment and other related changes by CMS that strengthen the ability to identify and address patient-level HRSN that interfere with the primary care physician's ability to support the patient's achievement of their best health. CMS' efforts in this regard must be part of a broader multiagency strategy to support the development of community-based infrastructure such as community care hubs (CCHs) or other payer and provider agnostic systems to ease the burden on all parties, including the community-based organizations best equipped to address patients' social needs.

Evaluation and Management (E/M) Visits (section II.F.)

CMS proposes to allow payment for G2211 even when modifier 25 is appended to the accompanying office/outpatient E/M) in certain instances. Specifically, beginning in 2025, on claims where modifier 25 is used to facilitate reporting a Medicare Annual Wellness Visit (AWV), vaccine administration, or Medicare Part B preventive services at the same encounter as the E/M service, G2211 will also be paid, if CMS finalizes its proposal.

AAFP Comments

The AAFP strongly supports this proposal. As detailed in a February 7, 2024, letter to CMS leadership, the current restriction that prohibits use of G2211 with any service requiring a modifier 25 means there are many primary care visits that reflect the complexity and ongoing relationship that G2211 is otherwise intended to address but do not benefit from it. Allowing payment of code G2211 when the office/outpatient E/M base code is reported by the same practitioner on the same day as an AWV, vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient setting will add appropriate nuance to CMS' policy in this regard. As CMS hopefully finalizes this policy later this year, we encourage it to include the code for an Initial Preventive Physical Exam (also known as the "Welcome to Medicare" visit), G0402, along with the two codes for Annual Wellness Visits (G0438, G0439) in its definition of "AWV" for purposes of this policy.

Enhanced Care Management (section II.G.)

Advanced Primary Care Management (APCM) Services (HCPCS codes GPCM1, GPCM2, and GPCM3)

CMS is proposing to incorporate key payment and service delivery elements from CMMI models to create permanent coding and payment under the PFS for advanced primary care. CMS proposes to define advanced primary care using the 2021 NASEM report on Implementing High-Quality Care as: "whole-person, integrated, accessible, and equitable health care by interprofessional teams that are accountable for addressing the majority of an individual's health and wellness needs across settings and through sustained relationships with patients, families, and communities."

CMS is proposing to adopt coding and payment policies that recognize APCM services. APCM services incorporate elements of several specific, existing care management and communication-technology based services (CTBS) into a bundle of services that reflects the essential elements of the delivery of advanced primary care for payment under the PFS starting in 2025.

AAFP Comments

The AAFP is grateful for CMS' consistently strong expressions of support for primary care as noted in its Innovation Center 2021 Strategy Refresh and by CMMI's ongoing commitment to test new primary care payment models. The AAFP is pleased that CMS is proposing to incorporate learnings from CMMI models into an advanced primary care payment opportunity under the PFS through the introduction of APCM codes. We appreciate CMS taking this important step toward better recognizing the importance of comprehensive primary care and improving payment to support it.

The AAFP appreciates that CMS has tried to make APCM billing more broadly applicable and easier to implement than some of the existing codes it's intended to replace.

Sharing CMS' goals to maximize adoption and use of these new codes, we believe the proposal would be significantly strengthened by additional refinements in these areas:

- Addressing beneficiary cost sharing barriers
- More appropriately valuing the services
- Clarifying implementation requirements to address potential operational challenges.

We will reiterate some of these concerns in response to specific elements of CMS' proposal later in this letter. We note our more general concerns in these three areas as follows.

Addressing Beneficiary Cost Sharing Barriers

AAFP policy supports a primary care coverage for all approach that ensures the availability of primary care to all patients regardless of their income, location or socioeconomic status, and that these essential services are provided by the patient's primary care medical home or usual source of primary care. We have urged Congress to waive cost sharing for chronic care management and transitional care management services for all Medicare beneficiaries who have identified a usual source of primary care and who receive those services from their usual source of primary care, regardless of the payment model through which the patient is attributed. Unfortunately, patient cost-sharing requirements persist and are limiting uptake of many services included in the new APCM codes.

A 2022 study found that MPFS billing codes for preventive services, such as providing counseling for smoking cessation or weight loss and care management services including CCM and TCM were underutilized even though primary care physicians were providing code-appropriate services to many patients. The median use of the preventive and care coordination billing codes was 2.3 percent among eligible patients.[xxix] Many family physicians report that patients decline CCM services because they are reluctant to agree to the monthly cost-sharing requirement. This is similar to concerns expressed about other new codes Medicare has implemented, including G2211, SDOH risk assessments, and community health integration services. Patients are hesitant to pay for these services as "add-ons" when they are not new services in many cases, but the introduction of new codes for specific activities, or even groups of activities as the APCM codes represent. These well-intended code introductions are problematic when implementation of the codes introduces patient cost-sharing. If CMS wants to ensure successful widespread adoption of the new APCM codes, addressing patient cost-sharing requirements is an important barrier that must be addressed.

More Appropriate Valuation of the APCM Services

We encourage CMS to reconsider its approach to assessing the work and practice expenses associated with APCM required capabilities as we are concerned the proposed valuations may not cover the costs of furnishing these services. For example, the AAFP notes services included in the APCM codes have higher payment rates when billed individually, and practices may be compelled to evaluate whether they want to continue billing for services separately or to report APCM services which is likely not the scenario CMS is hoping for.

The AAFP recognizes that appropriate valuation of comprehensive primary care is challenging given the history of incomplete and under-valued primary care payment in the MPFS. Attempting to rectify these issues with new comprehensive codes valued on the flawed history of MPFS primary care payment will inevitably perpetuate these flaws. **Instead of relying on the incomplete and undervalued historical payment under the MPFS, the AAFP encourages CMS to work with CMMI to better understand the ongoing operational costs associated with advanced primary care capabilities and make appropriate adjustments to the APCM values.**

As noted in our specific comments related to valuation in the next section of this letter, CMMI has developed meaningful insights into the operational requirements and costs associated with fulfilling service delivery expectations under its many primary care focused models from Comprehensive

Primary Care, Comprehensive Primary Care Plus to Primary Care First, and the newly introduced Making Care Primary model. These insights provide a far more relevant and accurate view of the real costs associated with delivering APCM services. The AAFP is eager to work with CMS to explore this as a way of arriving at a more accurate valuation of the new APCM codes that will increase the likelihood of successful adoption and achievement of CMS' overall aims to strengthen primary care on behalf of its beneficiaries.

Clarifying implementation requirements to address potential operational challenges

The AAFP applauds CMS for the creativity demonstrated by the introduction of the APCM codes within the inherent limitations of the MPFS. As CMS is well aware, administrative burden is often cited as a challenge with the adoption of new codes such as CCM and TCM. As noted above, the AAFP recognizes the efforts CMS has taken to make the APCM codes more broadly applicable and easier to implement. We note that, unlike CCM, APCM codes are applicable to all Medicare beneficiaries, not just those with two or more chronic conditions. Likewise, we note that APCM codes do not have the same time constraints inherent in CCM or TCM, which lessens the time-tracking burden on practices. This small shift is aligned with the view of most family physicians that focusing attention on patients and their needs is preferable to tracking time.

The list below captures the high-level overarching concerns that we encourage CMS to address in 2025 final rule. More specific recommendations follow in the subsequent sections.

- Eligibility to bill APCM codes requires practices to have a specific set of service elements and practice-level capabilities. **How and when will CMS provide more specific criteria by which practices can self-assess the degree to which they meet CMS' expectations for the service elements and practice capabilities? What level of attestation and/or documentation of required service capabilities will be required for CMS to consider a practice eligible to bill APCM?**

- Physicians and non-physician practitioners (NPPs) who use an advanced primary care model of care delivery can bill for APCM services when they are the continuing focal point for all needed health care services and responsible for all the patient's primary care services, as described in the proposed service elements of the codes. **How does CMS intend to monitor and ensure that the billing physician is delivering comprehensive primary care - not just providing a primary care service as an adjunct to other specialty care being delivered to the patient?**

- CMS has clearly stated that billing physicians must have the ability to furnish every service element but are not required to deliver those services within a given month to be able to bill the APCM codes for eligible patients. Given that billing infrastructures are typically built around patient encounters, this introduces a degree of complexity and potential burden to practices. **How will CMS direct practices to initiate billing for the APCM codes to minimize the potential operational challenges?**

- CMS has established consent is required for practices to bill APCM services for all patients, including both new and established patients. Additionally, an initiating visit is required for new patients but not established patients, which the AAFP fully supports. **While it is clear consent**

can be obtained for new patients at the initiating visit, the AAFP seeks additional clarity from CMS on how practices can gain consent from established patients through multiple modalities including face-to-face encounters, telephone conversations, and written consent.

- Primary care practices rely on many other stakeholders to successfully deliver on many of the required service capabilities, particularly those involving access to patient data from outside their practice setting and the ability to easily ingest and use these data for clinical decision-making. **What plans does CMS have to ensure that patient information flow and technology requirements support the expectations of CMS for primary care practices of all sizes and in all locations?**

The AAFP is concerned these potential complexities and burdens could deter practices from reporting APCM services. By clearly articulating its plans for implementation, CMS can best position this opportunity for success with otherwise hesitant primary care physicians and practices. It is also worthwhile to note reluctance to change practice workflows or strategies is greater when it is required of only one payer. **We urge CMS to consider requiring Medicare Advantage plans and state Medicaid programs to also implement coverage and payment for APCM services as a strong expression of its support for widespread adoption of APCM services on behalf of Medicare and Medicaid enrollees.**

We offer the follow comments in response to CMS' specific questions related to the APCM codes in addition to the above general comments:

Attribution

CMS expects that the practitioner who bills for APCM services intends to be responsible for the patient's primary care and serves as the continuing focal point for all needed health care services. CMS anticipates that most practitioners providing APCM services will manage all the patient's health care services over the month and have either already been providing ongoing care for the beneficiary or have the intention of being responsible for the patient's primary care. CMS anticipates the codes will mostly be used by primary care specialties, such as general medicine, geriatric medicine, family medicine, internal medicine, and pediatrics. CMS also acknowledges that, in some instances, certain specialists function as primary care practitioners (e.g., OB/GYN or a cardiologist). CMS notes that HCPCS code G2211 can also be billed when medical services are "part of ongoing care related to a patient's single, serious condition, or complex condition," but this is different from the APCM requirement. A specialist's management of one or more serious conditions alone does not mean that practitioner is responsible for the patient's primary care and the focal point for all needed care, and thus would not necessarily mean the practitioner could bill for APCM.

CMS proposes that APCM services may only be reported once per service period and only by the single practitioner who assumes the care management role with a particular beneficiary for the service period. CMS does not see the need or value of proposing restrictions or complex operational mechanisms to identify a single physician or NPP who may bill for APCM services for a specific beneficiary. CMS seeks comment on methodologies that could allow for identification of the beneficiary's primary care practitioner. They are also seeking comment on whether there should be additional requirements to prevent potential care fragmentation or service duplication.

AAFP Comments

The AAFP supports CMS' desire to avoid imposing complex requirements to identify who can bill for APCM services. However, we believe this is one of the key challenges of implementing a code that requires assuming full responsibility for a patient's care within the FFS structure. The AAFP agrees that the individual reporting APCM services should be responsible for a patient's primary care. Given the comprehensiveness and continuity required to provide advanced primary care, it would be inappropriate for non-primary care specialties to report APCM services.

For example, many third-party vendors provide the annual wellness visit to beneficiaries without coordinating or communicating with the beneficiary's established PCP. Not only does this result in fragmented care, but it also precludes the beneficiary's PCP from reporting and receiving payment for the AWV. The AAFP receives member reports of the same issues with CCM and TCM.

While there may not be an easy solution, we offer some suggestions for CMS' consideration. The AAFP also encourages CMS to conduct an analysis and examine lessons learned from similar services (e.g., AWV, CCM, TCM) for other potential solutions.

The AAFP agrees with CMS' proposal against requiring a visit to confirm an established patient's relationship with the physician. Since an initiating visit will not be required for patients with an established relationship with a physician or practice, CMS could review utilization history to confirm the ongoing relationship with a primary care physician.

Another option would be to pilot the patient relationship codes created under MACRA. To date, they have been voluntary, and uptake has been minimal. The HCPCS modifier X1 (Continuous/Broad Services) is intended to indicate the physician provides "principal care for a patient, with no planned endpoint of the relationship." For example, APCM services could be reported with the HCPCS X1 modifier. By reporting this modifier, the physician is signaling to CMS that they are responsible for the patient's longitudinal care and thus the most appropriate physician to report APCM services. Should CMS use the patient relationship codes, we urge CMS to consider the impact of any potential new or additional documentation burden. We believe it would be best to pilot use of the modifiers to allow CMS to monitor its uptake as well as verify they are appropriately reported.

Fundamentally, the delivery of a primary care service and the provision of comprehensive primary care are not the same thing. The AAFP defines comprehensive primary care as "the concurrent prevention and management of multiple physical and emotional health problems of a patient over a period of time in relationship to family, life events and environment." As discussed in the AAFP's policy on Primary Care,

> *Physicians without training in the primary care specialties of family medicine, general internal medicine, or general pediatrics may sometimes provide patient care services that primary care physicians usually deliver. These physicians may focus on specific patient care needs related to prevention, health maintenance, acute care, chronic care or rehabilitation. These physicians, however, do not offer these services within the context of comprehensive, first contact and continuing care.*

As such, we strongly encourage CMS to closely monitor APCM services provided by non-primary care specialties. The AAFP also urges CMS to develop ways that more appropriately identify non-physician clinicians working as part of a physician-led primary care team and those providing specialist care.

Service Descriptions

CMS proposes that APCM services are "designated care management services" that could be provided by auxiliary personnel under the general supervision of the billing practitioner.

CMS is not proposing to include time thresholds in the code descriptors for APCM services. CMS is also proposing that the APCM code descriptors would not include the timeframe restrictions for billing certain CTBS (e.g., that there is not a related E/M service provided within the previous 7 days or an E/M service or procedure within the next 24 hours or the soonest available appointment).

CMS is proposing that not all elements included in the APCM code descriptors must be furnished during any given calendar month for which the service is billed and anticipates there will be some months where it may be appropriate for some service elements to be performed more than once during the month for the patient. Even if not all elements are provided each month, CMS proposes that billing practitioners and auxiliary personnel must have the ability to furnish every service element and furnish these elements as is appropriate.

CMS is not requiring that specific minutes spent furnishing APCM services be documented but actions or communications that fall within the APCM elements of the service would be described in the medical record.

CMS seeks feedback on the service descriptions and whether there are elements of other care management services that should be removed or altered for purposes of delivering APCM services.

AAFP Comments

The AAFP is generally supportive of the service descriptions included in APCM services. We support CMS' efforts to simplify the coding requirements by eliminating the time thresholds and broadening applicability to all patients.

The AAFP appreciates CMS' recognition that not all patients will need all APCM service elements on a monthly basis. **We interpret the proposed rule to indicate a billing physician can report APCM services for a beneficiary even if the beneficiary has no interaction with that physician or their auxiliary personnel during the month (as long as the practice can provide all APCM elements).** We strongly support allowing practices to report APCM services for all beneficiaries for whom they have assumed responsibility of care. Longitudinal and comprehensive care is a trademark of primary care, and it is a benefit to patients, regardless of the timing or frequency with which they interact with their physician or care team. Further, reliable payment better supports the ongoing resources needed to provide quality primary care. We believe this is CMS' intent but ask CMS to provide more explicit guidance as it will help practices better understand the impact of APCM service requirements. We also ask CMS to clarify documentation expectations for months when APCM services are reported but the patient has not had any interaction with the physician or care team.

As noted in our introductory comments on the APCM codes, there are potential challenges associated with operationalizing the APCM codes, including timing for reporting the services, potential requirements associated with attesting to or otherwise demonstrating that a practice can perform all service elements, and obtaining patient consent in light of anticipated cost sharing. **We encourage CMS to be as descriptive and specific as possible when addressing the service delivery elements and practice capabilities in the final rule to mitigate these concerns.**

Stratification

CMS proposes that APCM services would be stratified into three levels based on certain patient characteristics that are indicative of patient complexity and the consequent resource intensity involved in the provision of APCM services:

- Level 1 [GPCM1]: Patients with one or fewer chronic conditions
- Level 2 [GPCM2]: Patients with two or more chronic conditions
- Level 3 [GPCM3]: Patients with two or more chronic conditions and who are Qualified Medicare Beneficiaries

CMS seeks feedback on the use of QMB status and multiple chronic conditions as the basis to bill for APCM Level 3, whether QMB status is an appropriate indicator to identify beneficiaries with added social risk, and whether there is an equivalent marker of social deprivation for use in commercial markets that might be a possible alternative identifier.

AAFP Comments

The AAFP does not object to CMS' proposal to use QMB status as a proxy indicator for patients with added social risk. To ease operational burden, we ask CMS to make it easy for practices to identify when a patient is a QMB. The AAFP has concerns, however, that relying on QMB status to stratify payment based on level of social risk recognizes only a fraction of Americans experiencing health-related social needs. It is likely that there are many beneficiaries with two or fewer chronic conditions that have social risk factors that may impact their care.

While there is no widely adopted or universal approach to social risk adjustment, there are validated social risk indices that the AAFP supports for risk adjustment purposes. The Area Deprivation Index and the Social Deprivation Index are two such models that the AAFP references in its value-based payment policy. We encourage CMS to review findings of methodologies tested in CMMI models as well as to engage with payers and policymakers to align on a common framework that incorporates a broader understanding of social risk using validated data and methodologies. CMS should incorporate their learnings into the APCM framework. In the interim, we ask CMS to consider creating an add-on code for QMBs that could be reported with any of the APCM levels.

In terms of overall patient risk and level of complexity, the AAFP believes the proposed tiers overlook a subset of the Medicare population that may require additional support than what is accounted for in Level 3. As proposed, stratification is heavily weighted toward uncomplicated, lower-risk patients. Practices will be paid the same for patients with high complexity (e.g., patients with six or more

chronic conditions) as for patients with as few as two uncomplicated chronic conditions. We recommend CMS create two additional tiers to target seriously ill beneficiaries. The codes would be structured similarly to GPCM2 and GPCM3 but would reflect beneficiaries with six or more chronic conditions and beneficiaries with six or more chronic conditions and QMB status.

The primary reason for creating a new, higher-risk tier is to ensure that it is valued appropriately to account for the higher resource costs of delivering advanced primary care to patients with complex illness. Given that the CCM code construct and valuation fail to recognize the differences in resource inputs that are needed for more complex patients, we recommend CMS establish payment rates in line with those used in CMMI models for similar patient populations. The high complexity payment rates used in past and present Innovation Center primary care models fall roughly in the $200-$250 range.

In alignment with the CMMI models, we strongly encourage CMS to adopt a valuation of $200-$250 for the new tiers, which will more accurately reflect the resource costs associated with furnishing APCM services for seriously ill Medicare beneficiaries with many chronic conditions. **If CMS wants to incorporate payment policy from Innovation Center primary care models, as it states in the proposed rule, it should also incorporate the concept of higher risk tiers valued in the $200 to $250 range.**

Beneficiary Consent

CMS proposes to require beneficiary consent to receive APCM services. Consent must be documented in the medical record. CMS seeks feedback on the proposed beneficiary consent requirements, including how best to effectively educate both practitioners and beneficiaries on the benefits of APCM, especially as it reflects a new bundle of services that may have previously been separately billed, and whether a CMS-provided template to facilitate patient consent would be helpful. They also seek feedback on whether they should require practitioners to revisit consent on an ongoing basis with patients.

AAFP Comments

The AAFP understands the importance of patient consent. Since one aim of consent is to inform beneficiaries about cost-sharing, we reiterate our concern that cost-sharing presents a significant barrier to enrolling patients. **The AAFP believes formal beneficiary consent is not necessary if cost-sharing is eliminated. Until then, we think it would be reasonable and appropriate to obtain consent annually and encourage CMS to develop a template.** Our members have expressed challenges in obtaining consent at a face-to-face visit due to time constraints that prohibit discussion of a care management program. Physician visits are often constrained to 15 to 20-minute increments. During that time, they must address a broad range of issues - the patient's chief complaint, any additional concerns the patient may bring up during the encounter, ensure the patient is up to date on all preventive care, capture quality metrics, etc. **The AAFP recommends CMS allow practices to obtain consent independent of a face-to-face encounter, including through phone conversations with patients.** If CMS wishes to tie consent to an encounter, we believe CMS could still provide flexibility by establishing a timeframe around an encounter. For example, CMS could allow practices to obtain consent via phone or electronic communications if it occurs within a certain period following an encounter. Beneficiaries would receive the same information and provide consent,

which would be documented in their medical record. Beneficiaries who have received a care management service would not need an initiating visit. The AAFP seeks clarification as to whether the beneficiary would need a new, separate consent for APCM services. Since many beneficiaries will be eligible for both CCM and APCM and practices may continue billing both services, separate consents would be difficult for practices to maintain and confusing for beneficiaries. **We encourage CMS to simplify and streamline the consent policies.**

Initiating Visit CMS proposes to require an initiating visit for APCM services only for new patients. CMS would align the definition of "new patient" with the definition in the CPT Professional Code Book. CMS proposes that the same services that can serve as an initiating visit for CCM services could serve as an initiating visit for APCM services. The initiating visit could be provided in person or as a telehealth service. CMS is not proposing to require an initiating visit for established patients and for beneficiaries that received another care management service (CCM or PCM). CMS states that an initiating visit may be needed, even when not required. A billing practitioner may furnish and bill for medically necessary visits, including before initiating APCM services. a**AAFP Comments**

The AAFP supports this proposal and appreciates CMS aligning its definition of new patient with the CPT definition.

24/7 Access and Continuity of Care

CMS proposes to include for APCM services the same scope of service elements established for CCM and PCM services for 24/7 access and Continuity of Care, with some modifications. Those providing APCM services would need to provide 24/7 access for urgent needs to the care team/practitioner with real-time access to the patient's medical records, including providing patients/caregivers with a way to contact health care professionals in the practice to discuss urgent care needs, regardless of the time of day or day of week.

CMS notes that true access is fully informed by knowledge about the patient and their care, which is only possible through real-time access to the patient's electronic health information. Practices can achieve 24/7 access informed by health IT through call coverage by a practitioner from the practice or a covering practitioner with health IT system access.

CMS proposes to specify for the 24/7 Access to Care element that the practice would maintain the capability to provide care in alternative ways to traditional office visits to best meet the patient population's needs, such as e-visits, phone visits, home visits, and/or expanded hours. CMS is not proposing that a practice would need to regularly deliver care in all these alternative ways. CMS seeks comment on this requirement.

AAFP Comments

The AAFP is supportive of this requirement and encourages CMS to maintain flexibility in how practices can satisfy the requirement to provide alternative visits. While we support the intent of CMS' proposal to add "real-time" access to a patient's medical record, we believe this could be challenging for practices that rely on a third party to provide afterhours call coverage. Improvements in data sharing infrastructures, such as HIEs, may help alleviate some of these barriers.

Comprehensive Care Management

CMS proposes the same "Comprehensive Care Management" service element as established for CCM and PCM services with some modifications. For APCM services, the element would be "overall comprehensive care management" rather than specific to chronic conditions. It may include "systematic assessment of the patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications." CMS seeks comment on these requirements.

AAFP Comments

The AAFP supports this proposal. FFS undervalues many component parts of primary care, including care management, and therefore fails to account for the complexity of primary care. The Medicare Payment Advisory Commission (MedPAC) has long advised policymakers to address the underpricing of primary care services in FFS and the NASEM consensus report confirmed that FFS does not adequately value or support the longitudinal, person-centered care that is the hallmark of primary care. For example, many patients benefit from regular care management and coordination services that are not billable under FFS. The introduction of CCM and TCM provided new pathways for physicians to receive payment for this time and resource intensive work when provided to specific patients. However, care management provided to their overall patient panel has thus far been uncompensated care. Expanding the scope and payment for care management provided by primary care teams is an important step in recognizing these vital services that have been taken for granted for far too long.

Patient-centered Comprehensive Care Plan

CMS proposes the same "Comprehensive Electronic Care Plan" service element as established for CCM and PCM services with some modifications. CMS proposes that the plan must be "patient-centered" and "is available timely within and outside the billing practice," as appropriate to individuals involved in the beneficiary's care, can be routinely accessed and updated by care team/practitioner, and a copy provided to the patient/caregiver.

The care plan should be patient-friendly, accessible to the patient, and should limit the use of unfamiliar medical jargon and acronyms. It should be structured and standardized, documented in health IT to enable sharing among patients, caregivers, and care team members. The care plan should be updated at regularly defined intervals, and when the patient's health status, preferences, goals, and values change.

The comprehensive care plan for all health issues typically includes, but is not limited to, the following elements: problem list; expected outcome and prognosis; measurable treatment goals; cognitive and functional assessment; symptom management; planned interventions; medical management; environmental evaluation; caregiver assessment; interaction and coordination with outside resources and practitioners and providers; requirements for periodic review; and when applicable, revision of the care plan. CMS seeks feedback on these proposed requirements.

AAFP Comments

The AAFP supports this proposal. We ask that CMS issue additional guidance to clearly define the expectations regarding updating the care plan at "regularly defined intervals."

Care plans are often developed as part of the annual wellness visit. The AAFP encourages CMS to provide flexibility regarding the care plan requirement and allow care plans developed as part of the AWV to satisfy the APCM care plan requirement, when deemed appropriate by the patient and their primary care physician.

The AAFP has heard from members that many EHRs are lacking in their care plan features making creating and maintaining care plans a clunky and glitchy process. Given that EHR features can vary greatly by vendor and even practice, the AAFP encourages CMS to work with other agencies, stakeholders, and physicians to establish clear, minimum requirements for EHR vendors that improve the process to create, share, reconcile, and integrate multiple plans of care into a comprehensive care plan.

Management of Care Transitions

CMS proposes the same "Management of Care Transitions" service element as established for CCM and PCM services with some modifications. CMS is proposing to require the billing practitioner to "ensure timely exchange of electronic health information" with other practitioners and providers. CMS also proposes that the care team/practitioner would follow up with the patient and/or caregiver within seven days after each ED visit and hospital discharge. CMS seeks comment on these proposed requirements.

AAFP Comments

While the AAFP shares CMS' interest in ensuring successful transitions in care settings for its beneficiaries, we also note that accomplishing this is fraught with challenges – most of which are relate to inadequate data and information flow across care settings. CMS states that "[k]ey aspects of follow-up after ED visits and hospitalizations include identifying and partnering with target hospitals and EDs where the majority of a practice's patients receive services to achieve timely notification and transfer of information following hospital discharge and ED visits." Although this is accurate, the AAFP points out that this is often easier said than done. Partnering with hospitals and other health care settings is one of the major barriers to primary care physicians implementing transitional care management. Establishing consistent and proactive communication channels from hospitals, EDs, and other health care settings varies widely – even in areas with robust health information exchanges. We often hear from members that they are only able to connect with one hospital in their area, despite multiple hospitals using the same EHR. Small and independent practices face steeper challenges as they have fewer resources and less leverage to establish information exchanges with their local hospitals.

The ongoing lack of interoperability is the underlying theme of these challenges and highlighted throughout our comments. The AAFP's Information Sharing in Value-based Payment Models for Primary Care Position Paper outlines several key calls to action to improve electronic exchange of information. **The AAFP calls on CMS to prioritize strategies designed to improve interoperability.** We are encouraged by CMMI's recent Data-Sharing Strategy Initiative and appreciate the vision outlined in the 2023 HHS Data Strategy. **The AAFP believes stronger efforts should be undertaken to improve data-sharing for all physicians serving Medicare beneficiaries, not just those participating in CMMI models.**

Practitioner, Home-, and Community-based Care Coordination

CMS proposes the same "Home- and Community-based Care Coordination" service element as established for CCM and PCM services with some modifications. CMS proposes to specify that the "ongoing communication and coordinating receipt of needed services" is not only with home- and community-based service providers but also with "practitioners," "community-based social service providers, hospitals, and skilled nursing facilities (or other health care facilities), as applicable." They also propose that documentation would include "the patient's psychosocial strengths and needs, and functional deficits, goals, preferences, and desired outcomes, including cultural and linguistic factors." CMS seeks comment on these proposed requirements.

AAFP Comments

The AAFP is supportive of this requirement but encourages CMS to make community-based social service providers optional until there are better systems in place to support coordination. There have been significant efforts to establish stronger collaboration between community-based social service providers and the health care system. We are encouraged by HHS' commitment to prioritizing addressing social determinants of health and their support of community care hubs. HHS funding has helped several states bolster the partnership between community-based organizations (CBOs) and physician practices.

Despite progress, widespread collaboration and communication is far from the norm. The information exchange infrastructures between these historically siloed support systems are still in their infancy. Interviews with early adopters of technology used to coordinate community-based social services indicate that even when these platforms are provided at no cost to community organizations, their uptake is limited due to the community organizations' limited resources to train staff and update workflows. There are often privacy and security concerns related to information sharing. Additionally, technology platforms used by CBOs were not necessarily designed to securely transmit information to outside systems.

Enhanced Communications Opportunities

CMS proposes the same "Enhanced Communications Opportunities" service element as established for CCM and PCM services with some modifications. CMS proposes to add "internet and patient portal" as examples of asynchronous non-face-to-face consultation methods and to specify that the practitioner would provide "other communication technology-based services, including remote evaluation of pre-recorded patient information and interprofessional telephone/internet/EHR referral service(s), to maintain ongoing communication with patients, as appropriate." CMS also proposes to include "access to longitudinal patient-initiated digital communications that require a clinical decision, such as virtual check-ins and digital online assessment and management and E/M visits (or e-visits)."

CMS is not proposing timeframe restrictions for this element. CMS seeks feedback on these proposed requirements.

AAFP Comments

The AAFP recommends CMS remove "interprofessional telephone/internet/EHR referral service(s)" from this service element. Aside from interprofessional referral services, all other services in this element are focused enhanced communication opportunities between patients and

their care teams. Additionally, interprofessional referrals (CPT codes 99446-99449) are largely reported by specialties other than primary care.

The AAFP appreciates that CMS is not proposing the timeframe restrictions for certain CTBS. We ask CMS to clarify whether virtual check-ins and e-visits are an explicit requirement of this service element. CMS states practices should provide, "access to longitudinal patient-initiated digital communications that require a clinical decision, *such as* [emphasis added] virtual check-ins and digital online assessment and management and E/M visits (or e-visits)."

Our understanding is that CMS lists virtual check-ins and e-visits as examples rather than as a requirement. Physicians are in best position to determine how their patients interact with the practice. Requiring specific types of encounters when a practice's patient population is not likely to use would add unnecessary compliance costs that do not improve patient access. The AAFP also asks CMS to clarify the documentation requirements for such interactions, including the degree to which a physician or QHP needs to be involved.

Patient Population-Level Management

CMS is proposing that all practices would use data to develop clear improvement strategies and analytic processes to proactively manage population health, including analyzing patient population data to identify gaps in care and risk-stratifying the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients and offer additional interventions, as appropriate.

CMS notes that this requirement would be met for practitioners billing for APCM services through a TIN that is participating in an ACO in the MSSP, ACO REACH, MCP, and PCF. CMS seeks feedback on these proposed requirements.

AAFP Comments

The AAFP supports this element but asks CMS to clarify the documentation requirements. We also urge CMS to provide flexibility for how practices meet this service element.

While supportive of this element, the AAFP reiterates our concerns regarding the challenges to building robust data infrastructures. The AAFP strongly urges CMS to apply its learnings from CMMI models and other initiatives to provide timely, actionable data to all physicians. CMS notes that the proposed patient population-level management standards are similar to those tested in several CMMI models. Participants in MSSP and REACH ACOs, PCF, and MCP meet this requirement. Since this element is aligned with the requirements of those models, it would be reasonable to expect practices would be provided with the same access to data, regardless of whether they participate in an ACO or other CMMI model.

Practices must invest in multiple tools, each operating with its own data environment and interoperability challenges. In addition to the EHR, physician practices will often pay separately for an enterprise data warehouse, analytics platform, care management solutions, and even separate tools for data visualizations. These disparate solutions to support population health management are in addition to other traditional solutions required to run a practice. The cost of implementing and maintaining these disparate solutions is a barrier – particularly for small, independent practices – and a burden to the overall system. **For these reasons, implementation and support for community-centric, industry agnostic approaches, such as the health data utility model, is essential and**

we encourage CMS to work with stakeholders to develop affordable and practical solutions for practices.

Performance Measurement

CMS proposes a practice-level requirement of performance measurement of primary care quality, total cost of care, and meaningful use of CEHRT. CMS proposes that this element can be met in several ways. MIPS ECs may meet the requirement by registering for and reporting the "Value in Primary Care" MVP. Practitioners part of a TIN that is an MSSP ACO or REACH ACO, or a PCF or MCP practice would meet the requirement by virtue of their participation in those programs. MSSP participants would be required to report the APM Performance Pathway (APP) Plus quality measure set.

CMS believes the Value in Primary Care MVP is well-suited to reflect the care delivered using the advanced primary care model as it was developed to include quality metrics that reflect clinical actions that should be considered the foundations of primary care. By virtue of their participation in MIPS and reporting the MVP, practitioners would also be required to report the promoting interoperability performance category. CMS notes that requiring practices to perform the measures and attestations to the meaningful use of CEHRT is similar to requirements tested in CMMI models (e.g., PCF and MCP). MSSP participants will be required to demonstrate meaningful use of CEHRT by reporting the PI category beginning in 2025.

CMS is seeking feedback on ways to align the APCM services with other Medicare programs and initiatives. CMS seeks feedback on whether there are areas of duplication within the APCM service elements and practice capabilities. They also seek comment on how to appropriately align the time period for which the practitioner bills the monthly APCM code with the calendar year reporting period covered by the MVP, and how they would verify and enforce the performance measurement requirement of the APCM services.

AAFP Comments

The AAFP appreciates that CMS is proposing to use performance measurement as a mechanism to ensure practices are delivering the service elements required to report APCM in an effort to avoid more burdensome reporting or documentation requirements. We agree with CMS that the measures reflected in the Value in Primary Care MVP are consistent with the focus of the APCM service requirements and practice capabilities for advanced primary care. We are hopeful that using the Value in Primary Care MVP in this manner will better support the original intent of MVPs to serve as a transition to alternative payment models.

We thank CMS for their work in the 2024 MPFS to improve alignment of the performance measures used in the Value in Primary Care MVP with alternative payment models. However, we also note there continue to be a number of quality measures in the MVP the AAFP is aligned with in principle but cannot support in practice due to systemic limitations, most notably the persistence of health data silos that makes successful reporting on important measures such as Adult Immunization Status an extreme and unnecessary burden on family physicians and primary care practices.

While we agree the Value in Primary Care MVP is well-suited to reflect high quality care delivered using advanced primary care, we urge CMS to exercise caution when establishing policy that ties a practice's ability to bill specific services to performance measures. We are concerned this could lead

to a slippery slope that creates an uneven playing field where payment for certain services is restricted based on reporting requirements.

Finally, the AAFP reiterates our overall concerns regarding MIPS and MVPs, including the unfair and uneven application of the performance threshold that has a disproportionately negative impact on small to medium practices who are often the main source of care for rural and underserved areas, and the lack of equity in accountability across medical specialties, especially within the MVPs.

Duplicative Services and Concurrent Billing Restrictions

CMS is proposing that APCM services could not be billed by the same practitioner or another practitioner within the same practice for the same patient concurrent with: CCM, PCM, TCM, interprofessional consultation, remote evaluation of patient video/images, virtual check-in, and e-visits.

CMS considered whether other care management services (e.g., BHI, CHI, PIN, RPM) would be duplicative of APCM services. However, they believe those services may complement APCM services.

CMS also seeks comment on potential overlap between APCM services and other services paid under the PFS, including but not limited to care management and care coordination and other CTBS. CMS seeks comment on whether the degree of overlap would warrant a policy to restrict the services from being billed concurrently with APCM services. They seek comment on whether any overlap would depend on whether the same or a different practitioner reports the services.

AAFP Comments

The AAFP believes APCM services are an important step in the transition to more comprehensive payment for primary care. We agree that additional services, such as behavioral health integration, are complementary to APCM. It may be appropriate to incorporate them into APCM services or a hybrid payment option in the future, but we recommend maintaining them as separate services until more is known about how APCM services are implemented.

As it relates to concurrent billing for CTBS, we believe this may be operationally difficult for large, multi-specialty practices. CMS may want to explore allowing concurrent billing of CTBS within the same practice when it is reported by a different specialty. We encourage CMS to work with the National Uniform Claim Committee to establish a more specific taxonomy to ensure concurrent nurse practitioners and physician assistants providing concurrent services are a different specialty than the physician who reported ACPM services.

Valuation of APCM Services – GPCM1, GPCM2, and GPCM3

CMS compared the service elements described by the proposed APCM codes to the values established for the specific care management and CTBS codes. In looking at historical data, Medicare non-complex CCM code is billed on average for five months and with three add-on codes for beneficiaries who receive care management services during a year. Information from interviews conducted as part of the CCM evaluation efforts indicates that practitioners overwhelmingly meet and exceed the 20-minute threshold for non-complex CCM. Practitioners reported spending between 45 minutes and an hour per month. CMS notes that this does not account for the care management

services provided beyond one time-based billing interval and without reaching the next; nor does it account for the resources involved in maintaining certain advanced primary care practice capabilities, continuous readiness, and monitoring activities to fully furnish and bill APCM services. It also does not account for the changes to utilization of APCM that may occur as a result of the billing and documentation requirements for APCM when compared to the current coding and payment for care management and CTBS services. CMS proposes to set baseline APCM code values based on historical utilization of the care management services used in designing APCM services. Utilization of care management services has been significantly higher than CTBS, and CMS found that CTBS are not typically billed for a patient in the same month as care management services.

CMS will continue to seek information to help them identify the best approach for reflecting the proposed CTBS elements incorporated into APCM services. They are particularly interested in data that could illuminate differences between what services are furnished and what is being reported separately.

CMS assumed the typical case for APCM Level 1 would require fewer resources than the current care management services. CMS concluded that APCM Level 1 services would be similar in work to that of billing two units of non-complex CCM (CPT code 99490) over the course of a year. They based the proposed inputs for APCM Level 1 on CPT code 99490 multiplied by 1/6. Specifically, they proposed a work RVU for GPCM1 of 0.17. The resulting PE and MP RVUs are proportionally similar to those for CPT code 99490. eCMS assumed APCM Level 2 services would require higher intensity work associated with managing a patient with multiple chronic conditions and would require more, and more frequent, APCM service elements. They concluded that APCM Level 2 would be similar to utilization assumptions of providing five units of non-complex CCM (CPT code 99490) and three units of add-on codes annually. CMS is also accounting for continued underutilization of CCM services by adding one unit of complex CCM (CPT code 99487) annually. CMS proposed inputs are based on CPT code 99490 multiplied by 5/12, CPT add-on code 99439 multiplied by 1/6, CPT add-on code 99489 multiplied by 1/12, and CPT code 99487 multiplied by 1/12. The proposed wRVUs for GPCM2 are 0.77. The resulting PE and MP RVUs are proportionally similar.

CMS is proposing to value APCM Level 3 services as a relative increase to the valuation of APCM Level 2 based on recent Medicare expenditure data for dually eligible Medicare beneficiaries. Per person per year spending on dually eligible beneficiaries in 2021 was 218 percent higher than spending for non-dually eligible beneficiaries. CMS based the proposed inputs for APCM Level 3 on the APCM Level 2 inputs multiplied by 218 percent. Specifically, CMS proposes a wRVU for GPCM3 of 1.67. The resulting proposed PE and MP RVUs are proportionally similar.

The approximate national payment rates based on the CY 2024 conversion factor are as follows:

- GPCM1 - $10
- GPCM2 - $50
- GPCM3 - $110

CMS seeks feedback on whether the proposed values appropriately reflect the resource costs associated in furnishing these services, or whether adjustments to the proposed values or additional coding may be needed. They are broadly interested in input on potential refinements in code and service definitions, including how they might refine their utilization assumptions for these codes, and other important information involving coding and payment for APCM services. They are interested in

developing a better understanding of the resource costs involved in furnishing comprehensive care management as part of advanced primary care to various patient populations, including specifically QMBs.

AAFP Comments

The AAFP is concerned the proposed values may be too low to support the ongoing resources associated with advanced primary care as well as increased operational costs to report APCM services. Unlike other fee-for-service codes that are valued to support the resources and costs associated with an encounter or specific threshold of patient care (e.g., 20 minutes of CCM), ACPM services are meant to support a broad range of practice capabilities. As such, the logic and applicability of current valuation methods are unlikely to appropriately account for the resources to provide APCM services. **Given the close alignment with CMMI models, we recommend CMS examine the costs and resources associated with the care delivery requirements of those models and adjust the valuations accordingly.**

The overhead for maintaining advanced primary care can be substantial. Practices provide varying degrees of advanced primary care that may or may not align with CMS' requirements to report APCM services. A 2018 RAND study examined the financial costs associated with comprehensive primary care capabilities. The functions assessed in the study closely mirror the requirements of the APCM services. The study found annual costs of advanced primary care functions ranged from $10,561-$275,500, with median estimated annual costs of $113,171 per primary care physician FTE. [xiii] Costs for smaller practices are often on the higher end of the estimated ranges as they tend to have fewer resources to hire additional staff and may rely on higher cost staff to perform care management tasks that can be performed by auxiliary staff (e.g., a physician performing medication reconciliation).

We are concerned that using CCM as the crosswalk codes does not fully account for the increased resources necessary to furnish APCM services to a broader range of patients. Not only is CCM more limited in its applicability, but it has also been historically underutilized. CMS took efforts to account for the underutilization but those adjustments still only account for the resources associated with CCM. It does not account for the increased work or practice expenses incurred with maintaining practice-level advanced primary care capabilities or providing APCM services to more beneficiaries. Additionally, CMS did not include the CTBS codes in their valuation as they are not typically billed for a patient in the same month as care management services. Given the challenges with tracking time for CCM services combined ensuring time is tracked separately for CTBS, we believe it is likely practices are providing CTBS during the same month as CCM but not billing for it. AAFP members report that it has been challenging to bill CTBS because patients are often upset that they must pay cost-sharing for services they are used to receiving for free. As a result, our members continue to provide these services as uncompensated care.

In addition to our other concerns about the valuation of these services, we would observe that there seems to be an inconsistency between the assumptions underlying valuation and those underlying CMS' utilization estimates for the services. As we understand it, for purposes of estimating utilization, CMS assumes that beneficiaries who receive APCM services will do so for 12 months each year. However, the valuation methodology assumes beneficiaries receive only a fraction of that. For instance, CMS' proposed inputs for the Level 2 APCM code are based on CPT code 99490 multiplied by 5/12, CPT add-on code 99439 multiplied by 1/6, CPT add-on code 99489 multiplied by 1/12, and CPT code 99487 multiplied by 1/12. From our perspective, it seems unreasonable to expect practices

to maintain APCM capabilities and provide APCM services for 12 months while setting the value of those capabilities and services at a fraction of that time.

CMS' overreliance on CCM combined with the failure to account for the increased resources needed to provide advanced primary care have resulted in artificially low values. Ensuring appropriate valuation of APCM services is a vital step toward correcting the historic undervaluation of primary care and providing adequate financial support to practices to sustain high-quality advanced primary care. **We reiterate our recommendation that CMS to take a broader view when valuing ACPM services and leverage the learnings gained through the CMMI primary care payment models to more appropriately account for the cost of delivering the required APCM services.**

Request for Information: Advanced Primary Care Hybrid Payment

CMS is seeking feedback on how to better support advanced primary care through changes in billing and coding within the PFS as the agency seeks to create sustainable pathways for primary care practices to deliver high-quality care and transition towards value-based care. The focus is on creating new billing and coding for advanced primary care services, which should reflect the complexity and resources involved in providing longitudinal care. CMS is specifically interested in feedback on value-based care opportunities, billing requirements, person-centered care, health equity, and quality improvement.

AAFP Comments

The AAFP is appreciative of CMS' request for further information related to hybrid payment for primary care in the PFS. This is consistent with the AAFP's long-held position that fee-for-service is incompatible with the comprehensive, continuous, and relationship-based nature of primary care. This structural mismatch, which is administratively burdensome, combined with an approach that has systematically undervalued primary care payment for decades, contributes to the level of primary care workforce dissatisfaction and dissipation we are currently witnessing.[xxx] Due to the limited 60-day comment period, we are not able to address all the questions posed by CMS in the RFI, many of which require additional modelling and engagement with AAFP members. However, we express our support for the direction CMS is exploring to ensure well-designed primary care payment is widely available and accessible - not limited to demonstrations or models.

For the purpose of our responses to this RFI, we use the following terminology for clarity:

- Fee-for-Service (FFS) = health care reimbursements made retrospectively after delivery of a covered service to an eligible beneficiary.
- Population Based Payment (PBP) = Per-beneficiary per month payment amount intended to replace some or all of the FFS payments with prospective monthly payment.
- Hybrid payment = A combination of FFS + PBP
- Bundle = the services identified for prospective payment using a PBP.

The AAFP supports primary care hybrid payment that moves away from sole reliance on FFS and shifts more primary care payment into population-based payments or primary care "bundles", such as the proposed APCM codes. To be successful, hybrid payments must also increase overall payment to a level that allows primary care clinicians to innovate and more easily integrate diverse care activities to meet their patients' unique needs, improve care quality and reduce costs. However, as we

expressed in the introduction to this letter, implementing a truly effective and impactful hybrid payment within the context of the MPFS requires additional reforms to the underlying FFS payment structures to happen first.

In order to more accurately value the work of primary care CMS must increase investments. We agree the payment mechanism (i.e., prospective PBP or retrospective FFS) is important. This was evident, for example during the pandemic when primary care practices were doing everything they could to continue to support patients even though in-person encounters had dropped precipitously. Practices receiving prospective PBP payments had an ongoing revenue source and could continue to pay staff, versus practices receiving only retrospective FFS payments that were paid retrospectively only after a service was delivered leading to practice closures and patients being left with nowhere to turn but hospital emergency room.

As noted above, this structural shift in payment is not sufficient on its own to address the degree to which primary care has been harmed by years of underinvestment. Regardless of the form of payment, the actual payment amount is most important. Therefore, absent broader reforms, including addressing a very outdated approach to budget neutrality, we believe introduction of hybrid payment (new population-based payments) for primary care must be done outside of current budget neutrality constraints.

The AAFP also strongly urges any patient cost sharing responsibilities associated with high-value primary care services, whether FFS or PBP, be fully waived while ensuring physician practices are "made whole," meaning they are paid the full allowed amount they would otherwise receive if patient cost sharing were applied. This would increase Medicare's payment responsibility, thus likely triggering a budget neutrality adjustment. This is an additional reason the AAFP firmly believes implementation of hybrid payment for primary care cannot be subject to existing budget neutrality requirements. We recognize this would require Congressional action and encourages CMS to work with Congress to facilitate the necessary changes.

These comprehensive, foundational reforms to the PFS are needed for primary care payment payments to be properly optimized and scaled.

<u>Streamlined Value-Based Care Opportunities</u>

CMS is seeking to creating pathways for primary care physicians and clinicians, including those new to value-based care, to move away from the current dominant discrete and disjointed FFS payment mechanism for primary care towards a prospective, population-based approach better suited for the delivery of comprehensive, longitudinal, team-based care.

When considering the evolution of a hybrid payment system within the PFS, CMS seeks input on the following questions:

AAFP Comments

> *How can CMS better support primary care clinicians and practices who may be new to population-based and longitudinal care management?*

The AAFP appreciates CMS' attention and desire to support primary care practices new to population-based care delivery and recommends three steps CMS can take to support the care teams and infrastructure necessary to make this transition:

1. **Provide upfront infrastructure payments** which offer necessary capital investments to primary care practices to invest in the infrastructure, technology, and staff required to support coordinated, team-based care. Practices often need to invest in implementing or upgrading their electronic health record, hire care coordinators/managers, and invest in population health management tools.
2. **Increase the overall investment in primary care**, as described throughout this letter, is paramount to improving population health outcomes and reducing overall health care costs. When practices new to these arrangements are supported by both upfront and increased investments in primary care, they can make critical investments in practice capabilities to better meet their patients' needs.
3. **Address the lack of effective and inefficient health IT infrastructure** (i.e. data silos, lack of interoperability, and reliance on organizational portals) which is one of the frequently cited administrative challenges and barriers to efficient and effective patient-centered care. Physicians and other clinicians report significant administrative challenges leading to feelings of hopelessness and burnout.[xxxi] Alleviating these challenges and allowing physicians to focus on patients, and not chasing or reporting information using inefficient and uncoordinated systems, will go a long way toward restoring the much needed professional identity of family and other physicians.

   How can CMS ensure that potential future advanced primary care payment will not induce clinicians to leave effective accountable care relationships and clinician networks that already produce positive results? Additionally, how can CMS support growth over time in existing effective accountable care relationships and clinician networks?

The AAFP believes primary care practices need a stable suite of multi-payer models, across the risk spectrum with predictable, prospective revenue streams adequate to meet patient and practice needs. A small amount of attrition may be a natural consequence of expanding the suite of payment options for primary care practices, however this is not necessarily a bad thing. Ensuring practices have options to choose what best meets their practice and patients' needs may result in a practice choosing a different option that was previously unavailable to them. The AAFP encourages CMS to work across agencies and programs to create a seamless participation experience for physicians and patients as they implement future advanced primary care payments and think about how these payments could supplement current programs, such as integrating hybrid advanced primary care payment into the PFS which is also the foundation of the SSP.

Should CMS evolve the proposed APCM services into an advanced primary care payment that includes E/M and other relevant services, or maintain a separate code set for APCM?

The AAFP believes the APCM codes can be the first step in a tiered approach to more advanced primary care bundled payment as described in more detail later in this RFI. However, we encourage CMS to further refine the APCM, gather data, and ensure its success before exploring expansion of the advanced primary care bundle concept.

If E/M services are bundled together for advanced primary care payments, how can CMS ensure that there is not a disincentive for primary care clinicians to continue to provide E/M visits, or increase accountability to E/M visits as warranted?

The purpose of hybrid primary care payments as stated in the PFS RFI is to provide primary care teams the resources and flexibility needed to deliver comprehensive, longitudinal, team-based care. The AAFP understands some stakeholders may have concerns about perceived stinting of care and the idea that receiving a PBP would incentivize clinicians to deliver fewer services. The individuals who choose family medicine are not in it for the money and this argument falls flat among those who regularly witness the passion and commitment family physicians have to their patients. However, if this argument is not compelling, physicians and other clinicians are always held accountable for the quality of care provided. This means primary care practices are incentivized to address all of a patient's health care needs effectively and early to avoid utilization of more expensive care later, which can negatively impact their performance as reflected in quality or cost performance measures. Additionally, because patients ideally choose their primary care physician (vs. being assigned) for purposes of receiving the PBP, physicians have added incentive to ensure patient satisfaction.

> *CMS has historically used information presented by the Relative Value Scale Update Committee to determine PFS payment rates. Are there other sources of data on the relative value of primary care services that CMS should consider when setting hybrid payment rates?*

Given the AAFP's concerns regarding foundational issues embedded in the current MPFS approach to primary care payment, using historical PFS payment rates to set hybrid payment rates will result in codifying the current inequities. Success of hybrid payment is contingent on not only changing the structure but on correcting for the long-term underinvestment in primary care. Considering historic primary care FFS payments as an actuarially equivalent reference point is a non-starter for a successful hybrid payment model.

To that end, we have encouraged Congress and CMS to invest resources in additional, supplemental sources of information, especially physician time, rather than relying almost exclusively on the RUC. However, we emphasize that existing budget neutrality constraints would make it challenging for *any* convening body, be it the RUC or another expert panel, to allocate and reallocate payment effectively. Making recommendations on how to redistribute resources within the fee schedule without the addition of new money perpetuates the unnecessary food fight among physician specialties.

The AAFP is an active participant in the RUC process and has been since its inception in 1991. The RUC and CMS have revalued E/M codes multiple times (1997, 2007, 2021) since the first Medicare physician fee schedule in 1992. We acknowledge that, each time, the work RVU has increased.

That said, it is important to continue evaluating whether the methods and data used by the RUC and CMS are accurately valuing all services under the fee schedule. The underlying methodology was developed by Harvard University and CMS (formerly, the Health Care Financing Administration) in the late 1980s. Much has changed in the world and in medicine since then. It's worth noting that what CMS and the RUC use now is not exactly what Dr. William Hsiao and his colleagues recommended to CMS. It may be worth exploring/identifying how the current system deviates from RBRVS as initially envisioned and whether returning to RBRVS' roots has any value.

We believe there is value in utilizing different data sources and modernizing data collection to allow other experts to make supplemental recommendations to CMS, particularly with regard to the valuation of primary care services. The RUC is currently challenged to capture the work of primary care in its current process of valuing E/M services. There are two ways in which this happens. First, the RUC survey process focuses on the "typical" patient and distributes surveys based on vignettes for E/M services that are much less specific, making it more difficult to quantify the physician work involved in more cognitive interactions than for more specific procedural service vignettes. It also

struggles to account for evolving clinical practice as new treatments and technologies become available, leading to the delivery of more complex E/M visits.

For example, the “typical” patient vignette for the most recent survey of code 99214 read, “Office visit for an established patient with a progressing illness or acute injury that requires medical management or potential surgical treatment.” Compare this with the vignette for 45379 (Colonoscopy, flexible; with removal of foreign body(s)): “A 50-year-old patient with abdominal pain and constipation swallowed a diagnostic capsule, which became lodged at the ileo-cecal valve. Colonoscopy with removal of the foreign body is performed.”

Second, this problem is compounded when these broad E/M vignettes are surveyed across more than 50 specialty societies, many of which do relatively few and much more straight-forward E/M visits than primary care. This approach undervalues the input of the primary care specialties that provide the most complex E/M services and do so most commonly. We also have concerns that the survey process is labor intensive for the clinicians taking it and therefore relatively few complete surveys, potentially worsening the reliability of the results. Additional data sources could therefore be warranted and result in more robust recommendations.

We note that more participation and input from primary care teams and beneficiaries may be helpful to CMS in advancing its goals of improving access to care, moving towards value-based payment, and improving health equity. However, providing access to helpful data and analyses will be key. Other organizations struggle with finding, analyzing, and presenting data to CMS that may provide a different perspective than that recommended by the RUC, which benefits from dedicated staff and other resources. Since CMS is charged with setting RVUs based on actual resource costs, we believe the lack of access to data and survey capabilities by others contributes to an overreliance on the RUC.

CMS may also improve their methodologies by improving access to Medicare and Medicaid data. Disseminating Medicare utilization data earlier would be particularly helpful to immediately understand if the utilization of this service is as anticipated. The first quarter of Medicare claims data should be available by July 1st of each year. A full year of claims data should be available by April each year (example, 2023 data should be publicly available by April 2024). Availability of Medicaid utilization data is also necessary to examine trends in services in the non-Medicare population. The absence of Medicare Advantage claims data is also problematic, since the number of patients in this program has increased. CMS should share recent Medicaid claims data and investigate mechanisms to collect and share Medicare Advantage encounter information.

Finally, as noted in our response to the proposed APCM codes, the AAFP recognizes that appropriate valuation of comprehensive primary care is challenging given the history of incomplete and under-valued primary care payment in the MPFS. Attempting to rectify these issues with new comprehensive codes valued on the flawed history of MPFS primary care payment will inevitably perpetuate these flaws. **Instead of relying on the incomplete and undervalued historical payment under the MPFS, the AAFP encourages CMS to work with CMMI to better understand the ongoing operational costs associated with advanced primary care capabilities and make appropriate adjustments to the APCM values.**

Billing Requirements

CMS is seeking to understand how advanced primary care hybrid payments can balance program integrity, high-quality care, payment stability, and clinician burden and looks for input on the following questions:

> *Are there particular types of items or services that should be excluded from the advanced primary care bundle?*

The AAFP believes any service delivered in high volume which benefits patients, such as preventive services and immunizations, should be excluded from the APC bundle. Additionally, discrete services like minor procedures (lacerations, ECGs, etc.), and medications should also be excluded from the bundle.

> *Are there particular services paid under the PFS today that should be included in the advanced primary care bundle?*

The AAFP believes the following services are appropriate to be paid through a PBP payment: (1) care management services, (2) communications such as emails, phone calls, and patient portals with patients and their caregivers, (3) behavioral health integration services, and (4) office-based evaluation and management visits, regardless of modality, for new and established patients. The AAFP supports taking a tiered approach to PBP that recognizes each practice's capabilities and the unique needs of their patient populations. The AAFP encourages CMS to meet practices where they are in terms of the services they can deliver to patients, while providing the necessary supports to enhance care delivery capabilities and move into a more sophisticated arrangement if desired and feasible. Consistent with the AAFP's comments on underlying MPFS reforms above, we strongly believe that PBPs need to continually be updated based upon inflation and reflect payment increases to the underlying FFS amounts for services captured in an APC hybrid payment.

To meet this goal, the AAFP recommends CMS first focus on refining the APCM to maximize its uptake and ensure primary care practices are able to operationalize the codes and overcome any unforeseen implementation challenges. The AAFP believes the APCM codes can be the first tier to provide an on ramp to more advanced primary care bundled payments. A tiered bundle approach could be structured as follows:

1. APCM services
2. APCM services + E/M
3. APCM services + E/M and BHI

This approach would allow primary care teams to build capacity and advanced practice capabilities over time while choosing which bundled service approach is right to meet their practice and patients' needs.

> *Care management coding and payment have historically required an initiating visit prior to starting monthly billing, to ensure that the services are medically reasonable and necessary and consistent with the plan of care. Are there other ways that CMS could ensure the clinician billing APCM is responsible for the primary care of the Medicare beneficiary?*

The AAFP recognizes the importance of consistent physician-patient relationships and the power of value-based payment to help codify and reward these relationships by establishing accountability for

patients at the physician level. AAFP policy on establishing physician accountability in VBP is aligned with the Health Care Payment Learning and Action Network resource on patient attribution which describes "patient self-selection" as the gold standard, the AAFP encourages payers to incentivize or require patients to identify their primary care physician as part of the insurance enrollment process.

> *Care management coding and payment require beneficiary cost sharing. Has beneficiary cost sharing been a barrier to practitioners providing such services?*

As noted in our APCM comments, AAFP policy supports a primary care coverage for all approach that ensures the availability of primary care to all patients regardless of their income, location or socioeconomic status. As such the AAFP supports the provision of primary care services to patients without financial barriers, such as deductibles and cost sharing. This is essential when services are provided by the patient's usual source of primary care and should apply regardless of the payment model through which the patient is attributed.

Family physicians often report that their patients decline important care due to cost sharing. Studies[xxxii] have backed up these anecdotes by showing that patient cost sharing requirements are associated with lower utilization of important primary care and preventive services and increased hospitalizations, thus increasing overall health care spending while disincentivizing high value care. Patient cost sharing requirements also hinder uptake of existing Medicare codes such as chronic care management. One study[xxxiii] found that MPFS billing codes for preventive medicine and care management services are being underutilized even though primary care physicians were providing code-appropriate services to many patients. The median use of the preventive and care coordination billing codes was 2.3 percent among eligible patients. One of the primary reasons family physicians report being unable to bill these codes is because patients don't consent to paying the associated cost sharing amount.

In order to incentivize uptake and have a meaningful impact on both primary care investment and patient care delivery, the AAFP strongly recommends 100 percent of patient cost sharing responsibilities be waived for the PBP component of hybrid payment, in addition to high-value preventive services paid under FFS. Patients are conditioned by the long-standing FFS approach to pay only when a direct service is rendered. They are, understandably, unlikely to do so for services that they are not receiving directly. What they cannot appreciate is that the PBP payment is made in lieu of FFS payments that will eliminate cost-sharing for other services. It is unreasonable to ask patient and their primary care physicians to engage in health care financing 101 to describe this important and necessary shift in payment The AAFP has and continues to advocate to Congress to waive cost sharing, and we urge CMS to work with Congress to facilitate the necessary changes to ensure the benefits of hybrid payments implemented in the PFS are realized.

> *Consistent with the initiating visit requirement in the APCM proposal, should CMS require the billing of specific qualifying services for billing of an advanced primary care bundle that is larger in scale and scope than APCM?*

The AAFP believes the scale and scope of the initiating visit requirement for the APCM is sufficient to also bill an advanced primary care bundle, however we reiterate the same concerns and recommendations related to the initiating visit for the APCM as mentioned above.

> *Are there Health IT functions beyond what is proposed for APCM services that clinicians should be required to have to bill for an advanced primary care bundle? What should CMS consider in the design of the advanced primary care bundle to effectively incorporate Health IT*

standards and functionality, to support interoperability and the aims of advanced primary care?

Given the broad, system level challenges related to HIT as outlined in the APCM section above, including inconsistent data and information sharing, slow progress towards meaningful interoperability, data quality and timeliness, data access challenges, lack of data standards, and the need for primary care practices to invest in multiple disparate population health management tools, the AAFP does not recommend CMS implement additional HIT functions beyond what is proposed for APCM services. The AAFP's Information Sharing in Value-based Payment Models for Primary Care Position Paper outlines several key calls to action to improve electronic exchange of information. The AAFP calls on CMS to prioritize strategies designed to improve interoperability. We are encouraged by CMMI's recent Data-Sharing Strategy Initiative and appreciate the vision outlined in the 2023 HHS Data Strategy. The AAFP believes stronger efforts should be undertaken to improve data-sharing for all physicians serving Medicare beneficiaries, not just those participating in CMMI models.

Person-Centered Care

CMS is seeking comment on how an advanced primary care code(s) could be structured to both increase efficiency and promote the use of high-value services and asks the following questions:

How can CMS structure advanced primary care hybrid payments to improve patient experience and outcomes?

Advanced primary care hybrid payments provide primary care teams the flexibility and innovation to deliver comprehensive, longitudinal, team-based care to their patients, improving quality and patient experience. Primary care practices with expanded capabilities are better able to meet their patients' medical, behavioral, and social needs by expanding access to high-touch primary care, longitudinal care management, and wraparound services to address health-related social needs. CMS can use specific measures to monitor these aspects of care, such as access, outcomes, and experience including the Person-Centered Primary Care Measure, a tested and validated patient-reported outcome performance measure (PRO-PM) that measures aspects of access and experience.

How can CMS facilitate coordination between primary care clinicians that bill for advanced primary care bundles and specialists to reduce costs and improve patient outcomes?

The AAFP believes data sharing between primary care and specialists is critical to reduce costs and improve patient outcomes. As previously stated, the AAFP is encouraged by CMMI's recent Data-Sharing Strategy Initiative and appreciate the vision outlined in the 2023 HHS Data Strategy. The AAFP believes stronger efforts should be undertaken to improve data-sharing for all physicians serving Medicare beneficiaries, not just those participating in CMMI models. Additionally, CMS should explore expanding incentives tested in CMMI models that better integrate primary and specialty care, such as the MCP eConsult and ambulatory co-management codes.

Health Equity, Clinical, and Social Risk

CMS seeks input on how advanced primary care billing and payment policy could be used to reduce health disparities and social risk. Furthermore, they are seeking to balance a simple payment structure that encourages the uptake of advanced primary care services, while ensuring that the risk adjustment method used to develop the payment rates incentivizes the appropriate coding of patient

conditions and needs, including those that have previously been under-documented, such as dementia and patient frailty. CMS seeks input on the following questions:

> *What risk factors, including clinical or social, should be considered in developing payment for advanced primary care services?*

The AAFP's policy on risk adjustment for primary care payment states risk adjustment methodologies should incorporate clinical diagnoses, demographic factors, and other relevant information such as social drivers of health without exacerbating health care disparities or expanding the administrative burden on primary care practices. Social drivers of health should be identified as risk factors and used for risk adjustment of populations.

> *What indicators are used to capture added social risk in commercial insurance? Should CMS consider using these?*

Based on conversations with commercial payers, we know they use indicators such as deprivation indices, social risk indices, z-codes, and other claims data to capture social risk and risk adjust their value-based contracts. The AAFP cautions against reliance on the use of SDOH screening data for this purpose as these data are too nascent and incomplete in their adoption to be reliable. Our policy recommends the use of validated indices that typically draw upon publicly available, geographic data on a wide range of evidence-based social needs indicators. However, we note that the national benchmarks for the Area Deprivation Index in particular, which is used by CMS and commercial payers alike, can mask regional variances so should be used with caution or weighted appropriately. We also encourage payers to ensure the ADI is standardized when used as recent research points to potential misallocation of resources based on risk adjustment without standardization of the ADI.

> *What metrics should be used or monitored to adjust payment to ensure that health disparities are not worsened as an unintended consequence?*

The AAFP suggests the CMS explore the following proposed metrics for adjusting payments to ensure that health disparities are not worsened include:

1. Social Needs: Screening, documenting, and reporting patients' social needs to incorporate them into risk adjustment methodologies will be an important contributor to understanding population level social risk. As noted above, the AAFP believes the adoption of new data standards is too nascent and incomplete to be reliable at a population level.
2. Patient Outcome Measures: Tracking health outcomes across different sociodemographic groups.
3. Access to Care: Monitoring access to various health care services such as primary care, specialist services, and mental health care, etc., can also reveal disparities.
4. Quality and Performance Measures: Assessing adherence to guidelines, patient safety, and patient-reported outcomes can help ensure all patients receive high-quality care.
5. Patient Experience: Collecting and analyzing patient experience data can provide insights into disparities in care delivery.
6. Stratification: CMS should also consider stratifying these measures according to available demographic data and/or by geography to ensure health disparities are not exacerbated and health care payments are equitable to meet patients' needs.

Quality Improvement and Accountability

CMS is interested in how advanced primary care payment bundles could encourage primary care physicians and clinicians to engage in accountable relationships with beneficiaries to manage costs and increase access to high-quality care for Medicare beneficiaries. They seek input on the following questions:

> *What are key patient-centered measures of quality, outcomes and experience that would help ensure that hybrid payment enhances outcome and experience for patients?*

The AAFP believes performance measures should focus on processes and outcomes that matter most to patients and have the greatest impact on overall health and unnecessary spending. VBP measures and the mechanisms of measurement should be aligned across payers to reduce unnecessary administrative burden. Measures of primary care should focus on the unique features most responsible for better outcomes and lower costs, and under the reasonable control of primary care physicians. The Center for Professionalism and Value in Health Care (CPVHC), through its Measures that Matter to Primary Care initiative, has developed a suite of performance measures that have been tested and validated for use at the individual clinician level and can be applied by different stakeholders, including primary care practices, employers, patients, insurers and health systems. These include the Person-Centered Primary Care Measure and the Continuity of Care Measure.

> *How could measures of quality, outcomes, and experience guard against and decrement in access or quality?*

The AAFP encourages CMS to prioritize actionable measures with a demonstrated need for improvement and to measure cost within the context of quality.

To guard against a decrement in access and/or quality, we encourage CMS to analyze performance data holistically so that quality measure data is analyzed alongside corresponding cost measure data. This could help ensure that efforts to decrease costs do not jeopardize quality (and vice versa). Additionally, CMS can use specific measures to monitor multiple aspects of care, such as access, outcomes, and experience. One such measure is the Person-Centered Primary Care Measure a tested and validated patient-reported outcome performance measure (PRO-PM) that measures aspects of access and experience.

> *As described in the APCM proposal, reporting of the "Value in Primary Care" MVP would be an APCM service element for MIPS eligible clinicians beginning in 2026. Since this MVP contains measures focused on both the total cost and quality of care, would its inclusion as an APCM service element be sufficient to count as "accountable care?" If not, what other service delivery or quality reporting would be expected in "accountable care?"*

As noted in our comments on the APCM codes, the AAFP agrees with CMS that the measures reflected in the Value in Primary Care MVP are consistent with the focus of the APCM service requirements and practice capabilities for advanced primary care. AAFP appreciates that CMS is proposing to use performance measurement as a mechanism to ensure practices are delivering the service elements required to report APCM in an effort to avoid more burdensome reporting or documentation requirements and are hopeful that using the Value in Primary Care MVP in this manner will better support the original intent of MVPs to serve as a transition to alternative payment models with continued evolution of the measures included in the MVP.

Should CMS consider flexibilities for smaller practices to bill the advanced primary care bundle? Should CMS consider flexibilities for entities exempt from MIPS to bill the advanced primary care bundle?

If practices are not required to report the MVP, those that are exempt from MIPS are either likely to be QPs or below the low-volume threshold (LVT). Practices below the LVT are less likely to bill this or any other bundled service since they, by definition, have a small Medicare population which also means they are less likely to be primary care practices.

However, the AAFP is supportive of CMS considering flexibilities for small practices to bill the APC bundle and encourages CMS to explore avenues to increase the capabilities of practices with limited resources. As previously mentioned, primary care practices benefit from upfront and increased investment when transitioning to value-based care delivery and this is especially true for small practices. CMS should build on lessons learned from CMMI models providing upfront infrastructure payments to smaller organizations such as the ACO Investment Model, Making Care Primary, and ACO Primary Care Flex.

Would clinicians be willing to take on more accountability to further reduce the frequency and/or administrative burden of billing?

Reducing the administrative burden associated with billing is a baseline step that should be taken to ensure all physicians and other clinicians can focus on taking care of patients – not getting paid for the essential work they do. The AAFP is strongly opposed to requiring physicians and their practices to assume increasing accountability for this to happen. The willingness of primary care practices to take on more accountability, however, should result in less frequent and less burdensome billing processes. This should be among the benefits of taking on more accountability but should not be seen as a prerequisite.

Supervision of Outpatient Therapy Services in Private Practices, Certification of Therapy Plans of Care with a Physician or NPP Order, and KX Modifier Thresholds (section II.H.)

2. Certification of Therapy Plans of Care with a Physician or NPP Order

Sections 1835(a)(2)(C) and 1835(a)(2)(D) of the Act require that payment for Medicare therapy services may be made for outpatient physical therapy, occupational therapy, and speech-language pathology services only if a physician certifies that: (a) the services are or were required because the patient needs or needed therapy services; (b) a plan for furnishing such services was established by a physician or qualified therapist providing such services, and is periodically reviewed by the physician; and (c) the services are or were furnished while the individual was under the care of a physician. The regulations at 42 CFR 424.24 require that a physician, nurse practitioner physician assistant, or clinical nurse specialist who has knowledge of the case sign the initial certification for the patient's plan of treatment and recertify that plan every 90 days.

To reduce administrative burden, CMS proposes to amend the process by which therapy plans of care are certified by creating an exception to the requirement that physician sign the plan of care in limited instances. CMS proposes to create an exception to the physician signature requirement for purposes of an initial certification in cases where a signed and dated order/referral from a physician, NP, PA, or CNS is on file and the therapist has documented evidence that the plan of treatment has been delivered to the physician, NP, PA, or CNS within 30 days of completion of the initial evaluation.

CMS also seeks comment on whether this exception should include a time limit on when a physician may modify the plan of care and how recent an order must be in order to qualify for the exception.

AAFP Comments

The AAFP appreciates CMS' efforts to reduce administrative burden for physicians, qualified health professionals, and therapists by allowing CMS and its contractors to treat the physician/NPP signature on the order or referral as equivalent to a signature on the plan of treatment for purposes of the initial certification if that physician/NPP has not signed and returned the patient's plan of treatment to the therapist within 30 days of the initial evaluation. We understand this exception would only apply in cases where the patient's physician/NPP has signed and dated the written order or referral and indicated the type of therapy needed, and that written order or referral is on file in the medical record along with evidence that the therapy plan of treatment was transmitted/submitted to the ordering/referring physician or NPP.

Administrative functions and regulatory compliance overburden family physicians at the point of care and after patient care hours, making them significant factors fueling health care consolidation and encouraging many independent practices to either sell or close their doors altogether. Studies have estimated that primary care physicians spend nearly 50 percent of their time on cumbersome administrative tasks.[xxxiv] Many practices have hired dedicated staff to address the ever-growing number of administrative tasks unrelated to direct patient care. Unfortunately, as administrative tasks are growing, physician payment has been failing to keep pace with inflation. The result is that physicians' practices are unable to sustain staffing levels necessary to keep pace with the growing administrative burdens. These trends underscore the strain on the primary care workforce that contributes to diminished primary care access that is not experienced equally or equitably and contributes to health disparities across populations.

Accordingly, AAFP supports CMS' proposal to permit its contractors to treat the physician/NPP signature on the order or referral as equivalent to a signature on the plan of treatment for purposes of the initial certification when the order is signed and dated, the type of therapy is identified and the written order or referral is on file in the medical record along with evidence the therapy plan of treatment was transmitted/submitted to the ordering/referring physician or NPP. This is a pragmatic update to the regulations otherwise designed to ensure 1) therapy services are medically necessary and 2) patients receiving such services are under the care of a physician/NPP.[xxxv] A physician's order provides evidence of both requirements, making the signature on the plan of care requirement an unnecessary, redundant safeguard.

AAFP supports CMS' limited application of this exception. We believe the existing signature requirements should remain for purposes of certification in cases where the patient does not have an order or referral as well as for the purposes of re-certification regardless of the presence of an order or referral. AAFP also supports the requirement that the exception only applies if the patient presents to the therapist within 90 days of the date documented on the order/referral. Failure to include a time limit on the order/referral could potentially result in patients presenting to therapists after their condition has changed, for which the referring physician may need to provide additional direction or information to the therapist. Accordingly, in cases where the order/referral is older than 90 days, the existing signature requirements should still apply.

AAFP strongly opposes any limitation on the physician's ability to modify the plan of care. Current regulations allow for changes to the treatment plan by the physician without time restriction and

require the physician's continued direct involvement through the requirement that the plan of care be recertified every 90 days.[xxxvi] Potentially implementing a time limit (e.g., 10 business days from the date of receipt of a plan of care) in which a physician/NPP may modify the plan of care (in the case of a patient with an order for the therapy services) would mean an order or referral for therapy equates to a physician relinquishing their ability to direct the care of their patient. At any time during the episode of care, a patient may present to a primary care physician exhibiting a change in condition that warrants a modification to the plan of care or even the cessation of therapy services. Physicians must retain the ability to direct the course of treatment in collaboration with the therapist to ensure the appropriate level of care is always being delivered.

Accordingly, AAFP supports this proposal insofar as it reduces administrative burden but opposes any change that would impede the physician's ability to meaningfully direct the patient's care.

Advancing Access to Behavioral Health Services (section II.I.)

In the CY 2024 PFS proposed rule, CMS sought comment on whether there is a need for potential separate coding and payment for interventions initiated or furnished in the emergency department (ED) or other crisis settings for patients with suicidality or at risk of suicide, such as safety planning interventions and/or telephonic post-discharge follow-up contacts after an emergency department visit or crisis encounter, or whether existing payment mechanisms are sufficient to support furnishing such interventions when indicated. In response to the comments submitted, CMS is making several proposals in this year's rule.

1. Safety Planning Interventions and Post-Discharge Telephonic Follow-up Contacts

b. Safety Planning Interventions (SPI)

CMS proposes to create an add-on G code that would be billed along with an E/M visit or psychotherapy when safety planning interventions are personally performed by the billing practitioner in a variety of settings.

- **GSPI1:** *Safety planning interventions, including assisting the patient in the identification of the following personalized elements of a safety plan: recognizing warning signs of an impending suicidal crisis; employing internal coping strategies; utilizing social contacts and social settings as a means of distraction from suicidal thoughts; utilizing family members, significant others, caregivers, and/or friends to help resolve the crisis; contacting mental health professionals or agencies; and making the environment safe; (List separately in addition to an E/M visit or psychotherapy).*

CMS is proposing to value HCPCS code GSPI1 based on the valuation for CPT code 90839 (Psychotherapy for crisis), which describes 60 minutes, and which CMS believes describes a similar level of intensity as HCPCS code GSPI1. For HCPCS code GSPI1, CMS is assuming a typical time of 20 minutes, resulting in a proposed work RVU of 1.09 (based on one third of the work value currently assigned to CPT code 90839, which is 3.28).

CMS seeks feedback on whether 20 minutes accurately captures the typical amount of time spent with a patient on safety planning interventions, including all six elements enumerated in this section. Additionally, CMS seeks comments on whether these interventions typically occur in the context of an encounter, such as an E/M visit or psychotherapy, or whether there may be times when they may be

furnished as a standalone service and whether CMS should consider allowing this code to be billed on its own.

Finally, CMS seeks comments regarding which clinician types might be most likely to bill such a code on its own. CMS notes that training and expertise are needed to perform these interventions safely and appropriately and seeks comment regarding whether clinical staff who meet the definition of auxiliary personnel defined at 42 CFR 410.26(a)(1) or who are employed by a hospital could participate in furnishing this service under the supervision of the billing practitioner in certain settings with the relevant training needed to perform the service as well as what sort of training would be needed.

AAFP Comments

AAFP supports CMS' proposal to establish separate coding and payment under the PFS describing safety planning interventions as there is increased attention required by the physician and care team to provide these services for patients with suicidality or at risk of suicide. We agree with CMS that there is a need for separate coding and payment for these interventions under the current task and activity focused nature of the PFS. While comprehensive payment for primary care is always preferable to one-off billing requirements for specific tasks, we welcome these additions to the PFS.

However, the AAFP disagrees with CMS' proposal to value HCPCS code GSPI1 partially based on the valuation for CPT code 90839 (Psychotherapy for crisis). CMS notes that for HCPCS code GSPI1, it is assuming a typical time of 20 minutes, and therefore proposes work RVU of 1.09 (based on one third of the work value currently assigned to CPT code 90839, which is 3.28).

The AAFP believes the amount of time necessary to deliver all six elements of the code is, *at a minimum* 20 minutes and more likely to average around 55 minutes and as much as 120 minutes for complex situations with families or others involved. Accordingly, *as the code is currently defined*, a more appropriate strategy would be to crosswalk the value to 90839 (60 minutes) at 3.28, rather than one third of the work value.

However, given the variability in time needed to furnish all six elements of the code, and the need to appropriately bill for complex cases, AAFP recommends CMS allow the service to be billed in multiple units of 20 minutes, for which the proposed value would be appropriate. AAFP also recommends that CMS allow GSPI1 to be furnished as a standalone service. We note that 90839, on which GSPI1 is based, is not an add-on code and can be billed independently of E/M services. We also recommend that CMS allow for maximum flexibility in the first year of implementation to ensure that these services are being delivered. After CMS has collected enough claims data, it may fine-tune the policy governing this code.

Finally, we appreciate CMS' request for input on which clinician types might be most likely to bill such a code on its own. As AAFP notes in its position paper on Mental and Behavioral Health Care Services by Family Physicians, most people with mental health conditions will be diagnosed and treated in the primary care setting.[18] Mental illness also complicates other medical conditions, making them more challenging and expensive to manage. Together, these factors make mental health an important issue for family medicine practices.

However, to require that these services be furnished directly by the treating professional, as proposed would create a barrier to care. Many family physician practices include non-physician clinicians (NPCs) including physician assistants, nurse practitioners and other clinicians. Family physicians

have been at the forefront of innovation in practicing with NPCs, especially in underserved communities.

Regarding GSPI1, we acknowledge the sensitive nature of these services and support CMS requiring appropriate training and supervision for NPCs before furnishing them. The AAFP believes NPCs should always function under the direction and responsible supervision of a practicing, licensed physician even in states where practitioners and physician assistants have independent practice authority. While NPCs cannot substitute for physicians, they are an integral part of physician-led health care teams. NPCs being able to practice at the top of their license and experience is crucially important to the success of a physician-led, team-based care model because it allows the physician to appropriately prioritize the highest-need, most complex patients in their care. Accordingly, we recommend CMS allow appropriately trained NPCs under the supervision of a physician furnish these services.

c. Post-Discharge Telephonic Follow-up Contacts Intervention (FCI)

CMS also proposes a monthly billing code to describe the specific protocols involved in furnishing post-discharge follow-up contacts that are performed in conjunction with a discharge from the emergency department for a crisis encounter, as a bundled service describing four calls in a month, each lasting between 10-20 minutes.

- ***GFCI1:*** *Post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter, per calendar month.*

CMS is proposing to price this service based on a direct crosswalk to CPT code 99426 (Principal care management; first 30 minutes of clinical staff time directed by a physician or other qualified healthcare professional), which is assigned a work value of 1.00 work RVUs.

Part B cost sharing would apply for HCPCS code GFCI1. The practitioner must obtain verbal or written consent in advance of furnishing the services described by GFCI1, which would be documented by the treating practitioner in the medical record, like the conditions of payment associated with care management and other non-face-to-face services paid under the PFS.

CMS notes that GFCI1 could be billed regardless of whether proposed HCPCS code GSPI1 was also furnished and billed for the same patient. However, the billing practitioner would need to meet a threshold of at least one real-time telephone interaction with the patient to bill HCPCS code GFCI1, and unsuccessful attempts to reach the patient would not qualify as a real-time telephone interaction.

CMS seeks comments on whether this threshold is appropriate as well as whether to finalize a specified duration that the code can be billed following discharge (for example, up to two months post-discharge) the number of calls per month, the billing structure (for example, four calls for each discharged patient), and any other relevant feedback.

AAFP Comments

AAFP again supports the creation of this code and its inclusion in the PFS. However, we believe CMS' proposal to price this service based on a direct crosswalk to CPT code 99426 (Principal care management; first 30 minutes of clinical staff time directed by a physician or other qualified healthcare professional) undervalues the service. Because the code represents a bundled service

describing 4 calls of 10-20 minutes, or a total time of 40-80 minutes, a better crosswalk would be to 99426 and 99427 (Principal care management; each additional 30 minutes of clinical staff time directed by a physician or other qualified healthcare professional) which would result in a work value of 1.71 work RVUs. These two codes together represent 60 minutes of clinical staff time, which is the mid-point of the range of 40-80 minutes.

AAFP supports CMS' proposal to allow CFCI1 to be billed regardless of whether proposed HCPCS code GSPI1 was also furnished and billed for the same patient. We also support the proposal that the billing practitioner would need to meet a threshold of at least one real-time telephone interaction with the patient to bill HCPCS code GFCI1, and unsuccessful attempts to reach the patient would not qualify as a real-time telephone interaction.

Finally, we have questions regarding CMS' requirement that the patient consent to the services. While we agree consent is a necessary component to the services, especially given the financial liability the patient will incur, we note that for family physicians, it may not be possible to obtain consent before performing the services. Accordingly, we urge CMS to allow consent to be obtained during the initial phone call.

4. Comment Solicitation on Payment for Services Furnished in Additional Settings, including Freestanding SUD Treatment Facilities, Crisis Stabilization Units, Urgent Care Centers, and Certified Community Behavioral Health Clinics (CCBHCs)

AAFP Comments

The AAFP appreciates CMS' questions regarding system capacity and workforce issues broadly, including how entities such as urgent care centers can play a role in addressing some of the capacity issues in emergency departments. This issue is particularly important in rural and underserved communities, as rural residents are more likely to be uninsured and are more likely to report difficulty obtaining needed health care than their urban counterparts, largely due to the limited number of clinicians and facilities in their area.[19,20] Rural hospitals have closed at an alarming rate over the last ten years, and many rural populations face long travel times for primary and emergency care. As a result, family physicians are an essential source of emergency services, maternity care, hospital outpatient services, and primary care in rural areas.

Family physicians are well-trained, versatile physicians who provide highly competent emergency and acute medical care for patients of all ages in emergency department and urgent care settings due to their broad scope of training, particularly in small and rural communities. Urgent care centers are increasingly staffed by mid-level NPPs who have a severely limited scope of practice as compared to family physicians. Patients are often referred to emergency departments for simple procedures routinely managed by family physicians in an outpatient setting. **In order to maximize effectiveness and safety, the AAFP strongly believes all urgent care centers should utilize a physician-led health care team**.

Beyond emergency departments and urgent care centers, the U.S. also faces a critical family physician workforce shortage, compounded by misalignment of resources in medical education, which has led to disparate care access for patients nationwide. **The AAFP encourages CMS to work with Congress to consider ways to reimagine our country's GME system so that it better supports and invests in primary care**. Though the current system excels at educating skilled physicians and physician researchers, the primary care physician shortage prevents the U.S. from

taking advantage of the better outcomes and lower per capita costs associated with robust primary care systems in other countries.[xxxvii]

Given the evidence that most physicians are trained at large academic medical centers in urban areas and that physicians tend to practice within 100 miles of their residency program,[21] the current distribution of trainees leads to physician shortages that are particularly dire in medically underserved and rural areas. While 20 percent of the U.S. population lives in rural communities, only 12 percent of primary care physicians and eight percent of subspecialists practice in these areas. **We support consistent funding for GME for family medicine to ensure that new residency slots are allocated to address rural and urban imbalances, reduce physician shortages, and focus on medically underserved areas, all of which will help prevent rural urgent care centers and emergency departments from being overburdened**.

Transparency and data are necessary to ensure that GME slots are being allocated appropriately and most effectively for the communities they serve. The AAFP supports policies that would provide authority to the Secretary of HHS to utilize existing data and to collect any additional data necessary to enable tracking, research, and analysis on the impact of federal GME funding on the geographic and specialty distribution of the physician workforce. Having this data will help address our nation's current maldistribution of physicians and allow us to target the allocation of GME slots toward hospitals and programs in areas and specialties of need, including by considering which ones have a proven track record of training physicians who ultimately practice in physician shortage areas.

Additionally, collecting more detailed, comprehensive data on the amounts of Direct Graduate Medical Education (DGME) vs. Indirect Medical Education (IME) payments would improve transparency and increase understanding of how these payments can be used most effectively. Further details about the utilization of IME should also be considered; transparency of how IME dollars are spent could illustrate the need for increased IME in some locations but may also show if these funds being used in unintended ways in other locations. If a program is not utilizing IME funds in the way they are intended, those funds could be shifted elsewhere to support the creation of additional GME slots.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)

CMS proposes requiring RHCs and FQHCs to bill the individual HCPCS codes that comprise general care management HCPCS code G0511 and to use the same codes as are billed under the PFS. Subsequently, the agency proposes removing the requirement for RHCs and FQHCs to report HCPCS code G0511. Payment rates would be updated annually based on total PFS amounts and would be paid at the national non-facility PFS payment rate. CMS proposes to continue permitting billing add-on codes related to these services and to adopt the coding and policies of APCM services.

CMS proposes to continue allowing payment for non-behavioral health care visits delivered via telecommunications technology through December 31, 2025. The agency proposes to continue delaying the in-person visit requirement for patients regarding mental health care services currently provided via telehealth by RHCs and FQHCs until January 1, 2026.

CMS proposes allowing RHCs and FQHCs to bill for Part B preventive vaccines at the time they are administered. This change would allow FQHCs to receive payment for immunizations much earlier, before annual cost reconciliation reports.

CMS proposes removing RHC productivity standards, given the restructured payment limits for RHCs that were passed in the Consolidated Appropriations Act, 2021 (CAA, 2021). For FQHCs, the agency proposes a rebased, productivity-adjusted market basket update of 3.5 percent.

AAFP Comments

A significant proportion of family physicians practice in FQHCs and RHCs, and millions of low-income patients and those living in rural communities rely on RHCs and FQHCs for primary care and other comprehensive services. The AAFP is strongly supportive of federal policies that bolster financial and workforce support for these essential care providers, including securing proper payment and adequate regulatory billing flexibility to help ensure equitable access. We applaud FQHCs and RHCs for their role in delivering high-quality, comprehensive primary care to communities and patients who most need it.

The AAFP appreciates CMS closely monitoring the outcomes of the billing changes made in last year's physician fee schedule for FQHCs and RHCs related to HCPCS code G0511, as we requested in our comments. We are particularly appreciative of CMS' proposal to remove the requirement for RHCs and FQHCs to report code G0511 and for the clinics to instead bill by individual HCPCS codes—including add-on codes for additional time spent related to these services—as we had expressed concern that last year's payment rate might not sufficiently account for the resources required to provide suitable care. The AAFP believes allowing clinics to bill individual HCPCS codes will support HHS' 2023 Data Strategy and will offer CMS, as well as clinics, the opportunity to measure and better understand the utilization of individual codes in different clinic types, geographic regions, and patient populations. While the AAFP strongly supports simplifying administrative processes and reducing burden, it is critically important that physicians and their care teams be paid in accordance with the level of expertise and care they provide, and we thank CMS for their efforts to ensure RHCs and FQHCs are appropriately compensated. Additionally, the AAFP would support RHCs being eligible for reimbursement under the G2211 code, as primary care clinicians in other settings are, which we believe would help both CMS and RHCs fully account for the additional time, intensity, and practice expense inherent to longitudinal care that G2211 was designed to capture.

As detailed earlier in this letter, the AAFP is broadly supportive of CMS taking a new approach in its pursuit of adequately valuing and paying for primary care services. We support the best practices and new tools found through CMMI models being integrated into larger CMS programs so the benefits can be experienced by more patients and physicians nationwide. The AAFP appreciates CMS' recognition that providing advanced primary care requires significant resources to maintain appropriate practice capabilities and support a team-based care approach, which are not currently fully recognized or paid for by the existing care management codes. We support CMS proposing to allow RHCs to bill APCM codes alongside clinicians who are paid under traditional fee-for-service. As currently written, the AAFP has concerns with how the APCM proposals would be operationalized and the level of burden that would be placed on small and mid-sized practices. We support CMS providing further guidance on documentation and other requirements before finalizing these proposals.

The AAFP supports CMS continuing through December 31, 2025, to define "immediate availability" in FQHCs and RHCs to include real-time, interactive audio/visual communications for the direct supervision of services provided incident to a physician's service. We strongly support CMS' proposal to continue allowing payment to RHCs and FQHCs for non-behavioral health care visits delivered via telecommunications technology through December 31, 2025, as well as the agency's proposal to

continue delaying the in-person visit requirement for patients regarding mental health care services currently provided via telehealth by RHCs and FQHCs until January 1, 2026. These provisions improve equitable access to care for low-income patients and those in rural communities,[4] which the AAFP has long supported, and it allows the agency to appropriately defer to a physician's clinical judgment regarding how often each patient needs to be seen in-person.

The AAFP is extremely supportive of CMS' proposal to allow RHCs and FQHCs to bill for Part B preventive vaccines (pneumococcal, influenza, hepatitis B, and COVID-19) at the time they are administered, beginning July 1, 2025. This change would allow these clinics to receive payment for immunizations sooner, providing increased financial stability and helping ensure broad vaccine access for patients. Every day, family physicians in FQHCs and RHCs provide routine and lifesaving preventive health measures and interventions, including immunizations. The AAFP has long been supportive of programs and initiatives that will ensure financial stability and delivery system support for physicians serving rural communities, and we welcome this proposal as a small but important step toward long-term financial stability for RHCs and FQHCs.

Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Conditions for Certification and Conditions for Coverage (CfCs) (section III.C.)

CMS proposes to amend the Provision of Services Conditions for Certification and Conditions of Coverage to add standards that would explicitly require RHCs and FQHCs to furnish primary care services, as well as explicitly prohibit RHCs from being a rehabilitation facility or a facility primarily dedicated to behavioral health care. Under this proposal, previous CMS interpretive guidance stating RHCs must be "primarily engaged in furnishing primary care services" – calculated by whether 50 percent of an RHC's hours are spent providing primary care services – would no longer be enforced. These proposed changes are meant to clarify the intent and requirements of the program governing RHCs and FQHCs and are designed to allow RHCs to provide more outpatient specialty services (as appropriate in a clinician's scope of practice) and better meet the needs of patient populations. CMS considers primary care practice "the entry point into the health care system" and quoted the AAFP's definition of primary care practice in this proposal. The agency seeks public comment on what types of behavioral health care RHCs offer, how often those services are being provided, and what barriers RHCs face in providing behavioral health care.

AAFP Comments

The AAFP supports CMS' proposed amendments to the *Provision of Services* CfCs, which would stop requiring RHCs spend more than 50 percent of their time "being primarily engaged in furnishing primary care services" and would instead trust RHC physicians and their care teams to provide the most appropriate care possible within their scope of practice for each individual patient. The AAFP appreciates CMS referencing our definition of primary care practice, which "serves as the patient's entry point into the health care system and as the continuing focal point for all needed health care services." We support physicians' clinical expertise being trusted to treat patients as they see fit, and we welcome RHCs being given this flexibility to allow family physicians to provide the full scope of care they're qualified to offer.

The AAFP appreciates CMS' clarification that RHCs cannot be a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases. We agree with CMS that the term "mental diseases" is outdated, though we understand it appears in statute and must be referenced accordingly. The AAFP does not support CMS' proposal to define "mental diseases"; instead, we encourage CMS to define the facilities primarily for the care and treatment of mental diseases. This

would be consistent with past CMS actions, given that "rehabilitation agency" has already been defined, and it would offer CMS the opportunity not to define an outdated term that's rarely used in health care today.

Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions (section III.D.)

In accordance with current law, CMS proposes to make conforming changes to the regulatory data reporting and payment requirements related to tests under Medicare's clinical laboratory fee schedule (CLFS). CMS proposes to revise the definitions of both the "data collection period" and "data reporting period" to specify that for the data reporting period of January 1, 2025, through March 31, 2025, the data collection period is January 1, 2019, through June 30, 2019. CMS also proposes to revise its regulations to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning January 2025.

In addition, CMS proposes to make conforming changes to its requirements for the phase-in of payment reductions to reflect current law. Specifically, CMS proposes to revise its regulations to indicate that for CY 2024, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2023, and for CYs 2025 through 2027, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

AAFP Comments

The AAFP appreciates CMS updating its regulations to conform with the current statutory provisions governing data reporting and payment requirements related to the CLFS. We remain hopeful Congress will provide a permanent solution that will set Medicare payment for lab services on a sustainable path forward. In 2014, Congress passed the Protecting Access to Medicare Act (PAMA/P.L. 113-93) to reform the Medicare CLFS to a single national fee schedule based on private market data from all types of laboratories that serve Medicare beneficiaries, including independent labs, hospital labs, and physician office labs (POLs). Unfortunately, the first round of data collection in 2017 failed to capture adequate and representative private market data, leaving out virtually all hospital labs and significantly under sampling POLs. The significant under sampling led to nearly $4 billion in cuts to those labs providing the most ordered test services for Medicare beneficiaries.

Congress has intervened on a bipartisan basis multiple times to delay the next CLFS reporting period and delay cuts to maintain access to lab services for patients. However, without a sustainable solution to this problem, labs face another round of cuts of up to 15 percent in January of 2025. The AAFP supports the Saving Access to Laboratory Services Act (SALSA) as a permanent solution that would set Medicare payment for lab services on a sustainable path forward. SALSA will give CMS new authority to collect private market data through statistically valid sampling from all laboratory segments for the widely available test services where previous data collection was inadequate. We are hopeful Congress will enact SALSA to protect patients and allow laboratories to focus on providing timely, high quality clinical laboratory services for patients, continuing to innovate, and building the infrastructure necessary to protect the public health.

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

CMS proposes to permanently extend policy allowing opioid treatment programs (OTPs) to offer audio-only visits for periodic assessments for patients receiving treatment via buprenorphine

(flexibilities initiated in response to the COVID-19 public health emergency). CMS also proposes to allow OTPs to initiate treatment with either buprenorphine or methadone via telehealth (if a practitioner or primary care provider determines an evaluation can be accomplished via audio-visual platform) in order to align payment policy with a recent rule from the Substance Abuse and Mental Health Services Administration (SAMHSA) finalizing standards related to OUD treatment. CMS further proposes to update the add-on code for OTP intake to include the addition of a SDOH risk assessment.

AAFP Comments

Family physicians provide comprehensive health care to patients of all ages and are tuned in to the needs of their community. As a result, they are often the first line of defense for primary care, chronic care management, and acute illness. Family physicians play a crucial role in safe pain management prescribing practices, screening patients for opioid use disorder (OUD), and prescribing and maintaining treatment of medications for OUD (MOUD).

The AAFP commented in support of the recent SAMHSA rule, and we encourage CMS to finalize this proposal, which we believe would improve access to lifesaving MOUD treatment. We also support CMS efforts to update Medicare payment policy to reflect the latest federal OUD treatment standards issued by SAMHSA.

The AAFP also supports the proposal to update G2076 to reflect the OTP furnishing an SDOH risk assessment to identify unmet health-related social needs. The AAFP believes SDOH have a substantial impact on the health of many Americans and are a key driver of health inequities, and AAFP policy supports partnering with community resources in the treatment of substance use disorder. Incorporating SDOH risk assessment into the OTP intake process will help to identify individual unmet health-related social needs that could have negative impacts on treatment outcomes. The ability for the treating physician to address unmet health-related social needs is dependent upon the degree to which the needed resources exist within the community.

Medicare Shared Savings Program (section III.G.)

Prepaid Shared Savings

CMS is proposing a new program called “prepaid shared savings” for Accountable Care Organizations (ACOs) that are part of the BASIC track’s Levels C-E or the ENHANCED track and have a proven track record of generating shared savings within the Medicare Shared Savings Program (MSSP). Qualifying ACOs will receive quarterly advanced payments based on their previously earned shared savings. These funds are intended to be invested in enhancing staffing levels, health care infrastructure, and offering additional services to beneficiaries. At least 50 percent of these prepaid shared savings must be allocated to direct beneficiary services that fall outside the scope of traditional Medicare coverage. This includes essential services such as meals, transportation, dental care, vision care, hearing aids, and reductions in Part B cost-sharing.

ACOs are obligated to repay the advanced payments from their future earned shared savings. Should the shared savings prove insufficient, the ACOs will be held accountable for reimbursing CMS directly. CMS has crafted this proposal with the intention of maintaining a budget-neutral framework. ACOs interested in participating in this program will need to submit supplemental information during the annual MSSP application cycle, with the program set to commence on January 1, 2026.

AAFP Comments

Overall, the AAFP is pleased to see this innovative proposal from CMS to provide advanced payments to high-performing ACOs. We believe this initiative has the potential to significantly enhance the capabilities of ACOs and improve patient outcomes.

Currently, many ACOs use their shared savings payments to fund physician and clinician incentives, in addition to providing beneficiary services. The mandated allocation of at least 50 percent of advanced payments to direct beneficiary services outside traditional Medicare coverage may limit the flexibility of ACOs to invest in areas they believe would have the greatest impact. We understand the intent behind this requirement; however, we believe it could hinder the ability of ACOs to tailor their investments to the unique characteristics of their patient populations and specific needs, including the essential physician and clinician workforce delivering services to beneficiaries.

We encourage CMS to consider providing more flexibility to allow ACOs the ability to allocate funds based on their own assessments of their priorities and the most effective ways to improve care. Additionally, we believe it would be valuable to gather data on how ACOs are currently spending their shared savings before imposing specific allocation requirements as this information could inform the development of more targeted and effective policies.

Health Equity Benchmark Adjustment

In an effort to promote equity in health care, CMS proposes a Health Equity Benchmark Adjustment (HEBA) for ACOs entering new agreement periods starting January 1, 2025. The proposed HEBA would be calculated based on the percentage of an ACO's assigned beneficiaries who are either enrolled in the Medicare Part D low-income subsidy (LIS) program or are dually eligible for both Medicare and Medicaid. By introducing HEBA, CMS is offering a new avenue for ACOs to receive an upward adjustment to their historical benchmarks. Under this proposal, an ACO's historical benchmark could be adjusted upwards using the highest value among three possible adjustments: a positive regional adjustment, a prior savings adjustment, or the HEBA.

This change is particularly aimed at benefiting ACOs that serve a larger portion of beneficiaries from underserved communities, especially those that may have received lower regional adjustments or prior savings adjustments in the past, or none at all.

CMS proposes that ACOs with less than 20 percent of their assigned beneficiaries enrolled in the Medicare Part D LIS or are dually eligible would not be eligible for this adjustment. According to CMS' projections, if this proposal were to be implemented, approximately 20 out of 456 ACOs in 2023 would qualify for a HEBA that exceeds any prior savings or regional adjustments. On average, these ACOs could expect an increase of $230 per capita, which translates to an average increase of 1.57 percent to their historical benchmarks.

AAFP Comments

The AAFP is pleased CMS proposed the Health Equity Benchmark Adjustment (HEBA) and believes it will be a valuable tool to address health disparities within the Medicare Shared Savings Program. The HEBA offers a promising avenue for ACOs providing care for underserved populations to receive a more equitable benchmark adjustment. It may also serve as an incentive to bring new entrants interested in meeting the needs of underserved populations to the program.

While the AAFP appreciates the HEBA's potential to provide an upward adjustment to ACOs serving these communities, we would like to express our support for increasing the maximum potential adjustment to 5 percent. Currently, it seems the HEBA may not be able to achieve the same level of adjustment as the other two adjustment mechanisms.

By allowing the HEBA to reach a maximum of 5 percent, CMS can ensure that ACOs caring for underserved populations can receive a truly equitable benchmark adjustment, commensurate with the needs of their patients.

Alternative Payment Model (APM) Performance Pathway (APP) Plus Quality Measure Set, Scoring Methodology, and Incentives to Report via electronic Clinical Quality Measures (eCQMs)

CMS proposes to implement a new Alternative Payment Pathway (APP) Plus quality measure set that would include the six measures currently in the set and incrementally incorporate the remaining five Adult Universal Foundation measures by the 2028 performance year. CMS proposes that MSSP ACOs would be required to report the APP Plus measure set as electronic clinical quality measures (eCQMs), Medicare CQMs, or a combination. ACOs would need to report all measures within the APP Plus measure set to satisfy the SSP quality reporting requirement. MIPS CQMs and the CMS Web Interface will no longer be available.

Beginning with the 2025 performance year, CMS proposes to use flat benchmarks for Medicare CQMs for the first two performance periods.

CMS proposes to extend the eCQM reporting incentive to performance year 2025 and subsequent performance years. The incentive would apply only to ACOs that report all eCQMs in the APP Plus measure set. It would not apply to ACOs that report a combination of eCQMs/Medicare CQMs or only Medicare CQMs.

AAFP Comments

The AAFP strongly urges CMS to maintain the MIPS CQM reporting option for ACOs for the foreseeable future. We also ask CMS to delay sunsetting the Web Interface option for an additional three years to align with the timeline required in the CMS Interoperability and Prior Authorization Final Rule.

The AAFP supports CMS' proposal to use flat benchmarks for Medicare CQMs for the first two years the measures are in the program. We also support CMS' proposal to extend the eCQM incentive. However, in line with our other comments, we believe it should be extended for those that report a combination of eCQM/Medicare CQMs or only Medicare CQMs.

The AAFP strongly opposes requiring MSSP ACOs to report the APP Plus measure set as well as the abrupt decision to sunset the MIPS CQM option. Since CMS announced the sunsetting of the CMS Web Interface option, ACOs have spent significant time, money, and resources to shift to reporting the eCQMs/MIPS CQMs. The unintended consequences of these policies have a direct impact on patients and practices. Forcing ACOs to divert shared savings into temporary technologies detracts resources from patient care. Additionally, ACOs are feeling forced to remove practices that may need more time to adopt new technologies. These practices tend to be smaller and independent, creating even more barriers for these types of practices to join.

MIPS CQMs and eCQMs expanded the population on which an ACO's quality is evaluated from a sample of Medicare beneficiaries to all payers. ACOs continue to face substantial challenges making this transition. These include aggregating data across all participating practices – often across multiple EHRs.

CMS recently recognized the need to assist ACOs in their efforts to aggregate data and complete patient matching and released an open source dedupliFHIR tool. While this is a promising step forward, as with any new technology or tool, its first iteration is not comprehensive and will require refinements. Specifically, testing with real world data needs to be completed to verify its degree of accuracy and ability to handle more complex but necessary tasks such as data normalizing, phonetic matching, and de-duplication/patient matching (i.e. rectifying multiple data elements for one patient), which continues to be a major issue. No other entity that participates in CMS quality programs is required to complete this level of aggregation and reporting and while a tool such as dedupliFHIR will assist in these efforts, it does not address all the concerns, nor it is prudent to rely on its use without understanding whether it works as intended and produces consistent and accurate results.

The AAFP applauded CMS' decision to establish the Medicare CQM option. However, since CMS has indicated Medicare CQMs are not a permanent option, ACOs and EHR vendors are reluctant to invest time and resources to transition to it. Many vendors have elected not to support Medicare CQMs, while others will not be ready to offer it until late 2025. ACOs and vendors are still trying to operationalize how to identify the Medicare CQM population as the first Medicare CQM patient lists were only shared with ACOs in May of this year.

CMS' sudden decision to eliminate the MIPS CQM option further complicates things for ACOs. ACOs and vendors have little time to accommodate such a significant change. The time and resources spent by those who already invested in the transition will be wasted. Abruptly removing the MIPS CQM reporting option in the same year CMS plans to retire the Web Interface will harm ACOs and the patients they serve and places vendors in an untenable position as most will not be able to support Medicare CQMs just two months following issuance of the final rule.

The AAFP continues to strongly oppose requiring MSSP ACOs to report the MIPS promoting interoperability category. The additional reporting requirements do not contribute to better patient care or improved outcomes and will serve as a disincentive for participation in advanced APMs (AAPMs). CMS should repeal the CEHRT requirements for ACOs, as well as the increased CEHRT requirements for AAPMs taking effect in 2025. Instead, CMS should institute a "yes/no" attestation to demonstrate CEHRT adoption and compliance with information blocking requirements, and leverage the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC) data already set to be collected directly from certified health IT developers under the new Insights Condition and Maintenance of Certification finalized in the Health Data, Technology, and Interoperability (HTI-1) Final Rule.

Under the new Insights Condition and Maintenance of Certification data finalized in the HTI-1 Final Rule, certified health IT developers will soon be required to report on use of their products across four areas related to interoperability, which will reflect real-world physician use of CEHRT in actual clinical settings, rendering this massive data reporting exercise largely obsolete.

Lastly, CMS has neglected to provide evidence explaining how the inclusion of promoting interoperability and increased CEHRT requirements will actually increase interoperability among health IT products used by ACOs. We expect the provider information blocking penalties to be a

powerful incentive without the need to burden physicians with duplicative and burdensome PI reporting requirements. Moreover, information blocking policies reach beyond CEHRT so they would be more effective at advancing information exchange across a range of emerging technologies than the proposed policies, which are limited strictly to CEHRT.

Eligibility Requirements and Application Procedures

Currently, ACOs are held to a standard of maintaining a minimum of 5,000 assigned beneficiaries throughout their agreement period in the Shared Savings Program. Failure to meet this threshold could lead to termination from the program. CMS is proposing a shift in policy to take effect on January 1, 2025. With this change, ACOs would still need to meet the 5,000-beneficiary requirement to initiate a new agreement period, but should they fall short during the agreement period they would be granted until the time of renewal to regain compliance. This offers a reprieve, allowing ACOs to remain in the program and work towards increasing their beneficiary count.

AAFP Comments

The AAFP supports CMS' proposal and is grateful for a more flexible approach to the eligibility requirements to address challenges related to beneficiary count and reduce the risk of involuntary termination in the SSP. The increased flexibility will be particularly beneficial for ACOs that may experience temporary fluctuations in their beneficiary populations. By allowing ACOs to remain in the program and work towards increasing their beneficiary count, CMS is providing a valuable opportunity for these organizations to continue their participation, maintain stability for practices, patients, and the SSP as a whole, and contribute to improving the quality of care for Medicare beneficiaries.

Beneficiary Assignment Methodology

Beginning January 1, 2025, CMS plans to redefine what constitutes "primary care services" for the purpose of assigning Medicare FFS beneficiaries to ACOs. This redefinition aims to align with the payment policy proposals under the Medicare Physician Fee Schedule (PFS). The proposed expansion includes a variety of services such as Safety Planning Interventions, Post-Discharge Telephonic Follow-up Contacts, Virtual Check-in Services, Advanced Primary Care Management Services, Cardiovascular Risk Assessment and Risk Management, Interprofessional Consultation, and Caregiver Training Services in both direct care and behavior management/modification.

CMS is also proposing an expansion of a previously established exception within the Shared Savings Program's voluntary alignment policy. This policy change is in response to the development of disease-specific models by the CMS Innovation Center, which utilizes claims for both primary care and other types of services to assign beneficiaries to participating entities. Under the proposed changes, beneficiaries would retain the freedom to voluntarily identify a primary clinician from a Shared Savings Program ACO as their main health care provider. However, this designation alone would not automatically result in their assignment to a Shared Savings Program ACO.

To put this into perspective, for Performance Year (PY) 2024, there are roughly 152,000 beneficiaries who have selected a primary clinician that is a Shared Savings Program ACO clinician. Out of these, approximately 83,000 beneficiaries are voluntarily aligned to a Shared Savings Program ACO, having met all the necessary assignment eligibility criteria. Yet, this number constitutes a relatively small fraction of the overall Shared Savings Program assigned beneficiary population, which stands at about 10.8 million beneficiaries. A simulation using PY 2024 data reveals that less than 1 percent

(703 beneficiaries) who are currently voluntarily aligned to a Shared Savings Program ACO would be reassigned based on claims to an entity participating in a CMS Innovation Center model.

AAFP Comments

The AAFP is supportive of CMS adding the following services to what constitutes “primary care services” for the purposes of assigning Medicare FFS beneficiaries to ACOs: Safety Planning Interventions, Post-Discharge Telephonic Follow-up Contacts, Virtual Check-in Services, Advanced Primary Care Management Services, Cardiovascular Risk Assessment and Risk Management, and only the Interprofessional Consultation Code 99452.

The AAFP does not support the inclusion of the other inter-professional consultation codes, as they are most commonly done by neurologists, cardiologists, internal medicine sub-specialties, and NPs/PAs (whose specialty affiliation is unknown). The one code in the family that may make sense for MSSP beneficiary assignment is 99452 (interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes). By definition, this service is "provided by a treating/requesting physician or other qualified health care professional," rather than a consultant.

The AAFP does not support the inclusion of caregiver training service codes (97550-97552) as 2024 is the first year they were in the CPT book and there are no claims data available on these codes. Further, when they went through the RUC process, they were surveyed by PT, OT, and speech-language pathology, and the proposed updates look similarly oriented. As such, they are not delivered by common members of a primary care team and should not be included in the SSP beneficiary assignment methodology.

The AAFP does not support the proposal to expand the previously established exception within the Shared Savings Program’s voluntary alignment policy. The HCP-LAN recommends patient choice, or voluntary alignment, as the gold standard for patient attribution or assignment and this aligns with AAFP policy. Fundamentally, the AAFP believes voluntary alignment should remain a fundamental principle of all value-based arrangements, as it is in the MSSP. In alignment with the LAN’s recommendations, we believe beneficiaries should have the autonomy to choose their primary care physician and be aligned with an ACO if they actively desire to do so. Overriding this choice undermines patient autonomy and could potentially lead to unintended consequences. We understand the need to reconcile competing incentives between overlapping models and encourage CMS and CMMI to work together to find solutions that prioritize the needs of patients and ensure continuity of care to enhance patient outcomes.

Beneficiary Notification Requirements

CMS is proposing changes to the Beneficiary Notification follow-up requirements within the Shared Savings Program to take effect January 1, 2025. Under the current system, ACOs must provide follow-up communication to beneficiaries no later than either their next primary care service visit or within 180 days of the initial written notice. However, ACOs have reported challenges with this requirement, particularly when the next primary care visit is scheduled shortly after the original notification, or when the timing of such visits is unpredictable. Responding to these concerns, CMS is proposing to eliminate the need for follow-up communication to coincide with the next primary care visit. Instead, ACOs would only be required to provide this follow-up within 180 days of the original notification.

Furthermore, for ACOs operating under preliminary prospective assignment with retrospective reconciliation, CMS is looking to narrow the scope of beneficiaries who must receive notifications. The proposal suggests focusing on those beneficiaries who are more likely to be assigned to the ACO, such as those who have received at least one primary care service from an ACO professional during the assignment window.

AAFP Comments

The AAFP supports the proposed changes to the beneficiary notification requirements. By eliminating the need for follow-up communication to coincide with the next primary care visit and narrowing the scope of beneficiaries who must receive notifications, CMS is reducing the administrative burden on ACOs and allows ACOs to focus more on providing high-quality care to patients.

RFI on Establishing Higher Risk and Potential Reward under the ENHANCED Track

CMS is proposing a new, higher risk track participation option for ACOs in the Shared Savings Program. To avoid self-selection bias, CMS plans to replace the existing ENHANCED track with this new option. CMS is seeking input on how to design this new option. The agency hopes to create a track that will encourage ACOs to participate actively while also generating savings for Medicare.

AAFP Comments

The AAFP appreciates CMS' efforts to explore new and innovative approaches to incentivize ACO participation. However, we do not support the proposal to replace the ENHANCED track with a higher risk option.

The AAFP believes a higher risk track, when offered alongside the ENHANCED track, can be a valuable tool for supporting ACOs as they gradually increase their risk-taking capabilities. Removing the ENHANCED track as a steppingstone to higher levels of risk could hinder the progress of ACOs and limit their ability to transition to more advanced models of care.
We encourage CMS to explore the development of a higher risk track that would offer significant rewards for ACOs that demonstrate exceptional performance and are willing to take on greater financial risk. However, it is crucial to ensure that this new option is designed in a way that supports ACOs at all stages of their development, provides adequate safeguards to protect against excessive financial losses, and includes guardrails to ensure incentives are shared with the physicians and care teams that contribute to their success.

Medicare Part B Payment for Preventive Services (§§ 410.10, 410.57, 410.64, 410.152) (section III.H.)

CMS proposes a physician’s order will no longer be required for beneficiaries seeking immunization against hepatitis B to align with proposals in section III.M. (Expand Hepatitis B Vaccine Coverage). CMS also proposes to establish a payment amount for drugs covered as additional preventive services (DCAPS), including drugs covered under the 2023 Proposed National Coverage Determination for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV), if finalized. CMS proposes that payment for DCAPS would follow similar Average Sales Price (ASP) methodology used for other Part B drugs (typically 106 percent of ASP). In the event ASP data is unavailable, CMS would use data from other sources such as the National Average Drug Acquisition Cost (NADAC) survey.

AAFP Comments

The AAFP recommends CMS finalize this proposal, which will expand Medicare beneficiary access to hepatitis B vaccination and allow more beneficiaries to be vaccinated by their family physician. Currently, hepatitis B vaccines are covered under Part B only when a beneficiary's medical history indicates that they are at intermediate or high risk of hepatitis B infection.

This proposal aligns with the AAFP's policy on immunizations which emphasizes that patients should receive vaccinations from their usual source of care. The AAFP's position is aligned with survey data that indicates a patient's own doctor is their most trusted source of information on vaccines.[xxxviii] However, new vaccines are only covered under Medicare Part D which creates unnecessary barriers for primary care physicians to administer shingles, respiratory syncytial virus (RSV), and other vaccines in their office. Family physicians are considered out-of-network by Part D plans and are therefore unable to submit vaccine claims to receive the established administration payment under Part B. In addition, the level of payment for vaccine product is unknown at the time of administration and Part D plans may require patient cost-sharing when vaccines are administered in an out-of-network setting, creating further disincentives for primary care administration of these important vaccines.[xxxix] While there are certain vendor services that facilitate billing Part D vaccines for physician practices, many practices are unable to invest in these services. These access barriers contribute to lower than optimal vaccination rates for Medicare beneficiaries.

Due to these challenges, the Medicare Payment Advisory Commission has repeatedly recommended covering all preventive vaccines under Medicare Part B.[xl] The AAFP recognizes that CMS may not have the authority to add new ACIP-recommended vaccines under Part B coverage, but we urge the agency to use its available authority to minimize these challenges for physicians and work with Congress to close this vaccine access gap for beneficiaries.

We also support CMS' proposed approach to use ASP methodology to set product payment for DCAPS, including PrEP for HIV. The AAFP supports proposed coverage for PrEP for HIV under Part B and appreciates the effort to simplify payment by applying payment methodologies used for other Part B drugs to DCAPS, as we believe this will help reduce administrative complexity in practices that use the same product when furnishing treatment or preventive services.

Request for Information: Building upon the MIPS Value Pathways (MVPs)Framework to Improve Ambulatory Specialty Care (section III.J.)

The CMS Innovation Center is considering a potential new model to increase the number of specialty care clinicians (specialists) participating in value-based payment and to encourage more coordination between specialty care and primary care physicians. CMS suggests potential benefits of building upon the current MVP framework would include the ability to use more narrow measure sets allowing for more meaningful comparisons of clinicians in the same specialty, and the ability to reach a broader range of specialty clinicians. CMS seeks comment on parameters of a potential model such as participation requirements, performance assessments, payment methodology, and incentives for integration with primary care and accountable care entities.

AAFP Comments

The AAFP is strongly supportive of efforts to transition away from fee-for-service to value-based payment (VBP) approaches, as described in the AAFP's Guiding Principles for VBP, and applauds the Innovation Center's commitment to expand accountable care participation to more specialists. We

appreciate the opportunity to provide comments on a potential ambulatory specialty model based on the MVP framework.

The AAFP has concerns about this proposal, including:

- MVPs do not provide a reporting structure akin to reporting in existing, population-based APMs, and we believe this model could further deter specialist participation in ACOs by incentivizing investments in infrastructures that do not improve coordination between primary care and specialist physicians;
- Exclusion from MIPS adjustment (as proposed in the RFI) would inadvertently harm remaining eligible clinicians due to the budget-neutral method used to calculate MIPS payment adjustments;
- A potential model based on the MVP framework would not address the existing barriers to primary care-specialist collaboration (e.g., lack of information and/or data-sharing capabilities), and many of the aims of the potential model could be addressed by overall modification of the MVP program, including a focus on addressing known issues related to interoperability, instead of a new APM model.

While the AAFP supports the Innovation Center's strategic aim to improve coordination and collaboration between primary care and specialty care, we do not believe the financial incentives inherent in the MVP approach are significant enough on their own to achieve this result. We note that despite the risk of a steep financial penalty of up to nine percent based on performance, clinicians in smaller practices are more often penalized. This disparity suggests that in addition to incentives, practices need the resources to invest in infrastructure needed to drive MIPS performance outcomes. As the AAFP has noted in prior comments, the MIPS program is using negative payment adjustments from the majority of clinicians in small practices to fund positive adjustments for clinicians working in large health systems. Although the financial incentives and penalties resulting from MACRA are intended to drive quality, they are also driving unintended consolidation instead as practices seek acquisition to gain the financial capital to fund practice investments. **The AAFP urges CMS and the Innovation Center to focus on addressing persistent and unresolved barriers to coordination between specialists and primary care, namely: interoperability of health IT systems and limited data sharing.** Medicare beneficiaries rarely see just one or two physicians, and they may not limit their physician choice to those practicing within the same "system or network" of the physician's choosing. Instead, one study found that beneficiaries saw a median of two primary care physicians and five specialists working in four different practices requiring care to be coordinated with the equivalent of an additional 99 physicians and 53 practices for every 100 Medicare beneficiaries they care for.[xli] The AAFP certainly supports beneficiaries' freedom to choose their physicians while acknowledging that this freedom creates the need to address a more efficient way of navigating a very complex web of data and information flow that has not yet been achieved.

We encourage these changes to be made in the current MIPS and MVP frameworks instead of testing another potential model. At this stage of MACRA implementation, it is clear that additional financial incentives are not the missing element needed to increase specialist participation in advanced payment models OR to level the playing field for smaller practices.

We are also concerned that a potential new model that fails to address the underlying problems with MIPS and MVPs further destabilizes the shift toward value-based care. Many of the goals outlined for this potential model are the same as those laid out when CMS introduced MVPs. Building on the existing MIPS and MVP foundation will only create an additional layer of administrative complexity to the QPP program that does not directly address known barriers to success, while failing to achieve

CMS' vision to increase APM participation. **We strongly urge CMS to focus efforts on reforming the current MIPS framework for all clinicians, not a subgroup of specialists, prioritizing program revisions that address barriers to increasing coordination and collaboration between primary care and specialist physicians – most notably doubling down to address the lack of incentives focused on changing the incomplete, inefficient and ineffective data and information sharing that persists across beneficiaries' physicians of choice.**

Participant Definition

CMS asks how participants in a potential mandatory model could be defined. As discussed above, **the AAFP does not support a potential new model that would only apply to a subset of specialists and allow exclusions from MIPS payment adjustments.** We are deeply concerned that the additional administrative burden created by a separate but mandatory program will encourage specialists to invest in data reporting infrastructure that leaves them unprepared for APM participation that requires coordination with other physicians involved in the care of each beneficiary, further deterring their participation in population-based models.

We are also concerned that carving out a subgroup of specialists could inadvertently penalize other clinicians in MIPS/MVPs. It is unclear how a new model would allow CMS to exempt certain clinicians from MIPS as the MACRA statute clearly identifies who CMS can exclude. Unless the new model qualifies as an AAPM, we do not believe it is within CMS' statutory authority nor is it appropriate to selectively exempt subsets of eligible clinicians from MIPS. It creates an uneven playing field whereby clinicians who are not eligible for an existing model or in the new mandatory model are forced to participate in MIPS – essentially abandoning those clinicians who are least likely to have the resources to transition to an APM.

Performance Assessment

CMS suggests a potential model could use the same four performance assessment categories included in existing MIPS and MVP frameworks, including quality, cost, improvement activities, and promoting interoperability. We are concerned this approach would carry unresolved issues from the existing MVP structure into a new model. Instead of amplifying these shortcomings by creating a new model based on a flawed foundation, we urge CMS to address concerns about the performance assessment in the existing MIPS and MVP frameworks for all clinicians, as outlined in our comments below.

Quality. We appreciate efforts CMS has made to align quality measures across programs, such as the Universal Foundation. We support CMS' general approach to quality measurement as it exists in the current program and will continue to share comments on specific measures proposed for inclusion in the program. However, the AAFP continues to have concerns about the use of certain measures, such as composite measures, due to the outsized administrative burden they place on practices – due largely to the lack of interoperability across disparate data systems currently.

Cost. The AAFP recognizes CMS is required by statute to measure cost performance in QPP. We continue to press Congress for legislative changes to the MACRA statute that would grant CMS additional authority to modify MIPS and MVP performance assessment. In prior comments, the AAFP has provided extensive details on problems specific to the Total Per Capital Cost (TPCC) measure. The AAFP continues to believe the use of TPCC is inappropriate in a payment model that does not adequately encourage shared accountability. We believe many of those concerns align with broader, foundational concerns about the current approach to measuring resource use, including:

- **Existing cost measures are not designed to capture the long-term cost savings and may penalize near-term investments in comprehensive care.** Primary care is recognized for its ability to improve outcomes and reduce overall spending, and there is evidence demonstrating regular, high-continuity primary care visits in the near term yield total cost of care savings over a three year period.[4,5] However, measures such as TPCC which only consider cost in a single year often penalize primary care clinicians who improve access to comprehensive care (and therefore utilization) for underserved populations, increase utilization of recommended preventive services, and comprehensively address patients' medical, behavioral, and social needs. This issue is further exacerbated by the current design of the TPCC measure which uses a monthly clinician attribution and benchmarking methodology. Episode-based cost measures may be more accurate for shorter term (such as one year) evaluations of resource use.
- **Current cost measures do not provide physicians with the feedback needed to improve over time.** Under the TPCC, physicians are held accountable for costs that are incurred well beyond the scope of their direct care without an actionable data feedback loop that allows them to intervene on a timely basis. Successful continuous improvement efforts are facilitated by actionable information provided as a feedback loop in a timely fashion to those charged with driving change. The cost performance category is unique in that all the data is calculated retrospectively by CMS using claims; nothing is reported by eligible clinicians. This means that physicians are reliant on CMS to share timely, actionable information about their performance, which is an aim of MVPs that is yet to be realized.
- **Family physicians do not have the information or resources needed to influence patient choice and clinician decision making, both of which affect cost.** There are many factors related to utilization driven by patient and specialist choice that family physicians cannot influence as the decisions are made beyond the primary care setting. While the TPCC measure considers multiple factors including patient-level risk, clinician specialty, and payment-rate variation, there other factors (such as Part B drug choices) which drive total cost measure performance that are beyond the primary care physician's influence. Without information about specialist resource use or quality, primary care physicians are left in the dark about the potential cost impact of directing a patient to one specialist over another. Family physicians also have no way to ensure patients ultimately follow their recommendations or referrals to a particular specialist or care plan.

For these reasons, the AAFP supports new episode-based cost measures (EBCMs) that align with conditions actively managed in primary care settings, as they can address some of the concerns above. However, to the extent these conditions require co-management with specialists, we have many of the same concerns noted above and call on CMS to actively equip primary care physicians with timely, actionable information on their overall cost performance, as well as the key drivers of spending across their patient population, including specialist performance. We continue to be supportive of relying on episode-based cost measures relevant to primary care in lieu of the TPCC in MIPS and MVPs.

<u>Care Delivery and Incentives for Partnerships with Accountable Care Entities and the Integration with Primary Care</u>

Greater access to information sharing and communication between primary care and specialists is needed to build partnerships and collaboration to better support high-quality patient care, which we detail in the next section. In addition to health IT and data sharing capabilities, there are also other opportunities to modify the QPP to encourage greater collaboration between PCPs and specialists.

One opportunity to improve collaboration involves ensuring fair and reasonable payment for time clinicians spend on asynchronous patient coordination. One example is the use of electronic consultations between PCPs and specialists. Research suggests that electronic consults improve access to specialty care while reducing overall specialist utilization.[6] The AAFP appreciates CMS efforts to equip primary care physicians with resources for collaboration, including the recent Making Care Primary e-Consult (MEC) code. We encourage similar adjustments to improve coding for and the valuation of asynchronous collaboration between PCPs and specialist care. The AAFP would be supportive of extending the changes made in Making Care Primary to the broader physician fee schedule. We believe this is an opportunity to adjust the fee-for-service payment model to encourage PCP-specialist collaboration at scale, for all beneficiaries, instead of limiting access to a subgroup of specialists in a geographically limited model.

There is also an opportunity to improve the process and outcomes of traditional specialist referrals. There are many barriers to efficient collaboration between PCPs and specialists during the referral process, including insufficient information sharing on both sides of the referral.[7] We encourage CMS to work with industry stakeholders and other agencies to improve interoperability and infrastructure so that clinicians can more easily share information and close the referral loop.

Health Information Technology and Data Sharing

The AAFP encourages CMS to consider additional objectives beyond those specified in the current MVP framework. Currently, MIPS and MVP measures focus on holding clinicians accountable for the use of health IT. However, as detailed in the AAFP's policy and position paper, Information Sharing in Value-based Payment Models for Primary Care, primary care physicians are still largely unable to access the data they need across the continuum of care without significant costs and burden.

Regulatory approaches to date have emphasized requiring clinicians to adopt or use health IT and have not evolved to measures of true meaningful use of these capabilities for the purpose of coordinating care across otherwise disparate organizations. For example, most of the MIPS measures available to assess the Promoting Interoperability category focus on whether a clinician uses existing health IT systems but do not adequately address the underlying issues that would improve. data sharing and coordination. We are concerned that the PI category does not motivate meaningful improvement, making it an ineffective mechanism and added administrative burden.

Implementing new measures of data sharing and coordination is not appropriate until broader, cross-industry action has addressed the systemic problems with health IT interoperability. The AAFP believes actions to focus health IT on information sharing are necessary and must involve purchasers, payers, policymakers, physicians and their staffs, and health IT vendors to be successful. We urge CMS to use all their available authorities to improve collaboration not only between PCPs and specialists, but to bring together cross-industry participants, including payers, to ensure health care information regarding patients, sources of care, and performance are readily available to primary care physicians at the right time. We urge CMS to work with ASTP/ONC and other agencies to support the creation and implementation of minimum health information-sharing requirements that more adequately address the needs of primary care. Practicing primary care physicians representing different settings should be integrated into the process, and vendors should ensure solutions are both practical and affordable.

In the near term, we urge CMS to move away from piecemeal measures of EHR utilization and toward broader attestation of systems. For example, we strongly support full PI category credit to organizations that are a certified Patient Centered Medical Home (PCMH) or another certification that

demonstrates organizational commitment to go beyond simple EHR utilization by sharing data and information across the continuum to improve care.

Expand Colorectal Cancer Screening (section III.K.)

CMS proposes changes to colorectal cancer (CRC) screening coverage to reflect updated guidelines and recommendations from national organizations. Specifically, CMS would remove coverage for the barium enema procedure, add coverage for computed tomography colonography (CTC), and expand the definition of a "complete colorectal cancer screening" to include a follow-on screening colonoscopy in response to a positive result from a blood-based biomarker CRC screening test.

AAFP Comments

Health promotion and prevention of disease are foundational components of family medicine, and family physicians practice evidence-based, cost-effective preventive medicine. AAFP policy supports evidence-based and risk-appropriate screening done as part of a shared decision-making conversation with patients.

We urge CMS to finalize these proposals. The proposed CRC screening changes reflect the most up-to-date evidence and guidelines, and they also enable physicians to offer the most appropriate CRC screening modality based on the individualized risk factors and preferences of each beneficiary. Research indicates that in-office shared-decision making to select the best CRC screening test increases overall screening rates, as patients who are hesitant to invasive colonoscopy may be accept a noninvasive screening method instead.[xlii] Expanding coverage to include additional CRC screening modalities will enable family physicians to offer more options, which in turn is likely to increase overall CRC screening rates.

Expand Hepatitis B Vaccine Coverage (section III.M.)

CMS proposes to update the definition of individuals at intermediate risk for hepatitis B to include any individual who is not fully vaccinated, which will expand coverage under Part B to all beneficiaries. Because screening would not be necessary to define risk, this proposal would allow mass immunizers to vaccinate beneficiaries and roster bill under Part B for payment. CMS notes that individuals who have been found to be positive for hepatitis B antibodies will not be covered (as in current policy), but testing for hepatitis B virus is not a requirement for vaccination.

AAFP Comments

The AAFP supports this proposal. The updated definition of individuals at risk reflects the most current vaccine guidelines and the resulting coverage expansion is aligned with AAFP policy on immunizations. This proposal would enable all beneficiaries to receive hepatitis B vaccines from their family physician without requiring a copay, eliminating the need for family physicians to write an order for beneficiaries to receive hepatitis B vaccines from an in-network Part D provider.

As discussed in our comments on Part B Preventive services, the AAFP believes patients should be vaccinated by their usual source of care and surveys have shown that a patient's own doctor is their most trusted source of information on vaccines.[xliii] Currently, only four preventive vaccines are covered under Medicare Part B which creates barriers to offering in-office administration of newer vaccines, such as shingles and respiratory syncytial virus (RSV) to Medicare beneficiaries during an office visit. We recognize that CMS does not have the authority to add new ACIP-recommended

vaccines to Part B coverage under section 1861(s)(10) of the Act, but we continue to urge CMS to work with Congress to close this known gap that creates access barriers for patients to much needed vaccines and is at odds with CMS' position on the importance of ensuring the availability of high quality, comprehensive, longitudinal primary care for all of its beneficiaries.

Updates to the Quality Payment Program (section IV.)

Transforming the Quality Payment Program Request for Information

CMS continues to strive towards its goal to have all traditional Medicare beneficiaries in an accountable care relationship with their health care provider by 2030. Accordingly, CMS envisions a full transition to MVP reporting and sunset of traditional MIPS to support movement towards value-based payment. CMS states that MVPs provide a pathway to improve value, reduce burden, help patients compare clinician performance to inform patient choice, and reduce barriers to movement into Advanced APMs. CMS included a request for information to collect feedback on policies to support full implementation of MVPs.

AAFP Comments

The AAFP is grateful for the opportunity to provide feedback to CMS' approach towards transitioning the health care system away from fee-for-service payment toward value-based payment. The AAFP appreciates that CMS has made MVPs a cornerstone of this initiative as a steppingstone on the path from MIPS towards advanced APMs. We believe there are a number of opportunities CMS may take advantage of to greatly improve the functionality of MVPs and the QPP generally.

Primary Care vs Specialty Care

One challenge not specifically touched upon in the RFI is the fact that the needs of primary care and other specialists are distinct. Primary care physicians care for a diverse range of patients and conditions and are not limited by problem origin (biological, behavioral, or social), organ system, or diagnosis. Primary care also includes health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis, and treatment of acute and chronic illnesses in a variety of health care settings (e.g., office, inpatient, critical care, long-term care, home care, schools, telehealth, etc.). Accordingly, because of the breadth of care primary care physicians furnish, the applicability of a condition-specific or episode-specific MVP is limited, while the opposite is true for other specialties.

To make MVPs available to more specialties, the AAFP supports an approach that accounts for these distinctions. The AAFP supports the AMA's proposed framework that creates separate MVPs for individual health conditions, episodes of care, and major procedures. However, we believe the comprehensive nature of primary care makes it less suited for such an approach. **The AAFP encourages CMS to continue engaging with specialty societies, including those with and without a current MVP, to develop MVPs that reflect the diverse needs of each unique specialty.** As additional specialty focused MVPs are developed, we ask that CMS be mindful of the need for coordinated care across specialties to ensure truly patient-centered care. To achieve this, all specialty MVPs must be accountable in some way for initiating coordination of care as appropriate with the physician and care team that hold the "accountable care relationship" for each Medicare beneficiary.

Sunset of Traditional MIPS

Physicians should continue to have the flexibility to choose the reporting option that is most appropriate and feasible for them and the AAFP is opposed to sunsetting traditional MIPS until such time MVPs or another replacement strategy have been fully vetted by stakeholders and well implemented. MVPs are largely still in the development phase and have not meaningfully reduced burden or offered an experience any different from MIPS as demonstrated by their extremely low uptake. Since MVPs are merely a version of MIPS, they inherited the same foundational flaws that continue to plague traditional MIPS, including interoperability and data challenges, operationalizing timely and actionable feedback to physicians, and addressing the widespread and persistent concerns with cost measurement. Instead of mandating MVPs, CMS should focus on addressing these foundational issues.

Subgroup Reporting

The AAFP remains opposed to mandatory subgroup reporting. We believe there are significant operational challenges that will only increase burden without yielding the desired outcomes. CMS expects to implement mandated subgroup reporting beginning in 2026, yet the specific requirements have not even been fleshed out nor have MVPs produced any meaningful results. Practices will need to invest substantial time and resources in understanding these to-be-determined requirements and figuring out how to make their IT systems support a reporting requirement that is as of yet unproven in driving better outcomes or lowering administrative burden. Additionally, this burden will be undertaken for a single payer with no guarantee that the requirements will be made permanent.

CMS should contact practices that reported MVPs to better understand if and how subgroup reporting could be operationalized. Until such time, CMS should make subgroup reporting optional.

<u>CY 2025 MVP Development and Maintenance</u>

CMS is proposing to modify the MVP maintenance webinar process to provide them with more flexibility in how they communicate submitted maintenance recommendations prior to proposing them formally in rulemaking. For example, in lieu of a live webinar, they could choose to communicate submitted maintenance via a pre-recorded webinar. CMS seeks feedback on this proposal.

AAFP Comments

The AAFP recommends that CMS continue to offer live webinars as they provide an opportunity for stakeholders to ask questions of CMS directly.

<u>MVP Requirements and Scoring</u>

CMS proposes to revise their policy to state that for the CY 2023-2024 performance periods, MVP Participants will be scored on the selected population health measure. CMS also proposes to apply this policy update to subgroups.

CMS proposes to modify the policy reference related to scoring cost in MVPs so that it aligns with a broader reference to the cost performance category scoring policies at §414.1380(b)(2). CMS proposes a similar change for the policy for scoring subgroups on cost in MVPs.

AAFP Comments

The AAFP opposes the application of population health measures at the individual or practice level and believes they are best assessed at the system level. Additionally, the current population health measure requirements apply a “one-size-fits-all” approach that is not conducive to improved patient outcomes, particularly when the measure is not relevant to or within reasonable control of the practice to impact performance.

The AAFP supports the proposals to align regulatory language across MIPS and MVPs.

Establishment of the APP Plus Quality Measure Set to Align with the Universal Foundation

Five of the 10 Adult Universal Foundation quality measures are included in the APP measure set. To further advance alignment and Medicare’s VBC strategy, CMS is proposing to incorporate all measure within the Adult Universal Foundation quality measure set.

The APP Plus measure set would be a second measure set distinct from the existing APP set that ECs on the Participation List or Affiliated Practitioner List of an APM Entity may optionally choose to report. When a MIPS EC, group, or APM Entity chooses to report the APP, they will then choose whether to report the APP quality measure set or the APP Plus quality measure set. Aside from ACOs participating in the MSSP, the APP Plus measure set will be optional.

CMS is proposing to incrementally add measures to the APP Plus set over the next four years.

AAFP Comments

While the AAFP supports CMS' initiatives to align measures across programs, we continue to have some concerns with the measures included in the Universal Foundation, discussed in detail below. **The AAFP strongly opposes requiring MSSP ACOs to report the APP Plus measure set as well as the abrupt decision to sunset the MIPS CQM option**. Since CMS announced the sunsetting of the CMS Web Interface option, ACOs have spent significant time, money, and resources to shift to reporting the eCQMs/MIPS CQMs. The unintended consequences of these policies have a direct impact on patients and practices. Forcing ACOs to divert shared savings into temporary technologies detracts resources from patient care. Additionally, ACOs are feeling forced to remove practices that may need more time to adopt new technologies. These practices tend to be smaller and independent, creating even more barriers for these types of practices to join.

MIPS CQMs and eCQMs expanded the population on which an ACO’s quality is evaluated from a sample of Medicare beneficiaries to all payers. ACOs continue to face substantial challenges making this transition. These include aggregating data across all participating practices – often across multiple EHRs.

CMS recently recognized the need to assist ACOs in their efforts to aggregate data and complete patient matching and released an open source dedupliFHIR tool. While this is a promising step forward, as with any new technology or tool, its first iteration is not comprehensive and will require refinements. Specifically, testing with real world data needs to be completed to verify its degree of accuracy and ability to handle more complex but necessary tasks such as data normalizing, phonetic matching, and de-duplication/patient matching (i.e. rectifying multiple data elements for one patient), which continues to be a major issue. No other entity that participates in CMS quality programs is required to complete this level of aggregation and reporting and while a tool such as dedupliFHIR will

assist in these efforts, it does not address all the concerns, nor it is prudent to rely on its use without understanding whether it works as intended and produces consistent and accurate results.

The AAFP applauded CMS' decision to establish the Medicare CQM option. However, since CMS has indicated Medicare CQMs are not a permanent option, ACOs and EHR vendors are reluctant to invest time and resources to transition to it. Many vendors have elected not to support Medicare CQMs, while others will not be ready to offer it until late 2025. ACOs and vendors are still trying to operationalize how to identify the Medicare CQM population as the first Medicare CQM patient lists were only shared with ACOs in May of this year.

CMS' sudden decision to eliminate the MIPS CQM option further complicates things for ACOs. ACOs and vendors have little time to accommodate such a significant change. The time and resources spent by those who already invested in the transition will be wasted. Abruptly removing the MIPS CQM reporting option in the same year CMS plans to retire the Web Interface will harm ACOs and the patients they serve and places vendors in an untenable position as most will not be able to support Medicare CQMs just two months following issuance of the final rule.

Initiation and Engagement of Substance Use Disorder Treatment (Quality ID 305)

The AAFP appreciates the intent of this measure and shares CMS' desire to improve the quality of behavioral health care. We understand that measurement is one way to push toward health plan and system improvement. However, it is also important to acknowledge the following:

- The measure is not endorsed, which means it has not been rigorously reviewed by a consensus-based entity. We believe measures should go through a rigorous endorsement process and further tested and refined, as necessary, before they are considered for implementation.
- While this measure is intended to be used only at the health plan level, health plans have historically applied health plan-level measures inappropriately to the individual clinicians and/or clinician groups in their networks. This is not appropriate for measures such as this that have only been tested and validated for use at the health plan level.
- The data sources cited for this measure include EHR data, which means that plans will likely require that providers submit data from their EHR systems, thus increasing burden, and potentially added cost.
- This measure is very difficult, if not impossible, for clinicians to track in the current health care landscape with a lack of interoperability across care settings and providers.
- Patient disinterest and refusal remains a significant challenge. Despite their best efforts, clinicians cannot force a patient to accept treatment for SUD.
- Some communities lack the resources necessary to assist patients with SUD.
- The measure developer and steward did not perform and/or provide any patient/encounter-level reliability or validity testing data.

Accordingly, we do not support this measure for use as a clinician-level measure in CMS' Universal Foundation.

Screening for Social Drivers of Health (Quality ID 487)

The AAFP supports CMS’ goal of reducing health inequities and believes family physicians, along with others, play an important role in helping to identify the health-related social needs of patients.

We also agree that it is important for family and other primary care physicians to be connected to social and community-based organizations that can help to address those needs using an efficient, centralized approach. These are core tenants of comprehensive, longitudinal primary care, though we note that these types of services are often not billable under the MPFS. Moving to APMs that include comprehensive prospective payment must be prioritized if we are to sufficiently and sustainably support primary care's role in improving health equity.

The overarching goal should be to drive improved health for historically marginalized and medically underserved populations. Addressing health equity and social drivers of health are community issues that require community solutions. Many communities simply do not have adequate social resources and community-based organizations available to help meet patients' diverse social needs. Even when those resources exist at the community level, community-based organizations are not typically resourced with the funding, skills, or staff to accept referrals from the health care system. CMS should incentivize the development and use of community care hubs or other payer and provider agnostic centralized referral systems to ease the burden on all parties, including the community-based organizations best equipped to address patients' social needs. However, at a minimum, physicians and other clinicians cannot be held accountable for providing resources to address individual health-related social needs when those resources do not exist in the community.

The AAFP is very supportive of screening for health-related social needs and has equipped its members with the tools to engage in this important aspect of whole-person care through the EveryONE Project. As screening patients for unmet health-related social needs is increasingly common for many provider types and at many points of entry for patients into the health care and health insurance systems, there is increased interest in measurement of these efforts. The AAFP agrees with CMS that the insights gained through these screenings provide important patient and community level insights but urges caution when considering measurement of this activity as an indicator of care quality in a single health care setting.

The immediate priority should be to build the infrastructure and capabilities necessary to share these patient-level insights across provider types in a secure and timely fashion with the patient's permission to do so, just as is done with clinical information. This will ensure that all of a patient's caregivers are aware of their unique needs while not overburdening patients or their physicians and other clinicians with unnecessary, repetitive assessment efforts. Overwhelming patients with different screening mechanisms at different points along the health care spectrum could be counter-productive to building trust with patients.

It is important to recognize that there are challenges and important considerations to address before new measure requirements are introduced. Most importantly, the measure should address those factors or circumstances within the control of the individuals or organizations being measured. CMS' measurement strategy should account for these challenges and ensure quality measurement does not negatively impact underserved patients or the clinicians caring for them.

Adult Immunization Status (Quality ID 493)

The AAFP is a champion of safe and effective vaccines and agree that vaccination is a vital component of comprehensive primary care. However, the AAFP has repeatedly noted that immunization registry challenges create significant administrative burden for primary care physicians reporting the Adult Immunization Status composite measure, which can result in suboptimal performance on the measure at no fault to the physician. Many patients receive vaccines in settings other than their primary care clinic, including pharmacies, health departments, and workplaces. In

fact, certain adult vaccines are only covered and paid for under Medicare Part D and thus most primary care physicians cannot offer them in their offices (but are still held accountable for them under these measures). Despite the use of immunization information systems (IIS), vaccination data from other settings is not consistently or reliably reported back to the primary care physician. Recent reports confirm that interoperability and functionality challenges are common among IIS programs. A recent HHS Office of Inspector General report found that 44 of the 56 IIS programs (immunization registries) reported not receiving complete, accurate, and timely data from retail pharmacy providers during the COVID-19 pandemic. The report notes that many ongoing issues contribute to these challenges, including:

- Some immunization databases do not have bidirectional data exchange capabilities, which limits the ability to share immunization data with providers and other immunization database users who need it.
- Some immunization registries limit their query and/or update functions to individual patients – often tied to a "trigger" event or service encounter making data access for a physician's patient panel time consuming and costly.
- Some immunization programs do not require vaccine providers to report data for individuals over the age of 19.
- Some immunization programs do not require all pharmacists to report vaccinations administered to their immunization database.
- Without complete vaccination data, immunization programs cannot always provide accurate individual vaccination records when requested by residents and health care providers. The report noted this results in barriers to vaccination for patients who are unsure if they've previously received doses of a vaccine.

A report from the Congressional Research Service also notes that "IIS programs operate on different technology platforms that are, in some cases, outdated or not fully interoperable with other IISs or the health care system." The same report notes that some IIS programs do not share data across state borders, limiting the ability to reconcile information about vaccines individuals have received in different jurisdictions.

These reports together confirm that ongoing challenges with immunization registries are common and therefore are likely impacting family physicians across the country on a regular basis. The AAFP strongly urges CMS to partner with the Centers for Disease Control and Prevention (CDC), ASTP/ONC, and other federal partners to advance reliable, interoperable sharing of immunization data across the health care system. As improvements are made to these systems, we encourage CMS to prioritize the use of other measures to measure the quality of care provided by individual clinicians under the MIPS program.

Data Submission for the Performance Categories

Proposed Minimum Criteria for a Qualifying Data Submission for the MIPS Quality, Improvement Activities, and Promoting Interoperability Performance Categories

CMS proposes to consider a submission as valid and scorable (including a potential score of zero) only if the data submission includes: numerator and denominator data for at least one MIPS quality measure; a response of "yes" for at least one improvement activity; and all required elements to report objectives and measures and attestation statements for the promoting interoperability category. CMS seeks comment on this proposal.

AAFP Comments

The AAFP appreciates and supports this proposal. However, we remain concerned with the "all-or-nothing" approach to the promoting interoperability category. We believe this policy is detrimental to practices as it penalizes them for things as simple as an administrative error. This is overly punitive and fails to provide any recognition of a practice's efforts related to the category. We ask CMS to revise its approach and instead score all promoting interoperability measures that include a numerator and denominator.

Treatment of Multiple Data Submissions

CMS is proposing to codify its established policy regarding multiple data submissions. Specifically, CMS proposes for multiple data submissions received in the quality and improvement activities performance categories for an individual MIPS EC, group, subgroup, or virtual group from submitters from multiple organizations (e.g., qualified registry, practice administrator, or EHR vendor), CMS will calculate and score each submission received and assign the highest of the scores. For multiples submissions from the same organization, CMS proposes to score the most recent submission. CMS seeks comment on this proposal.

For multiple data submissions for the promoting interoperability category, CMS proposes to score each submission and assign the highest of the scores. They seek comment on this proposal.

AAFP Comments

The AAFP believes CMS should score all submissions and assign the highest score, regardless of the timing of the data submission. At minimum, CMS should include an option for a submitter to indicate whether they want a submission to override any previous submission.

Quality Performance Category

Data Completeness
CMS proposes to maintain the data completeness threshold of at least 75 percent for the CY2027 and CY2028 performance periods. This threshold would apply to QCDR measures, MIPS CQMs, eCQMs, Medicare Part B claims, and Medicare CQMs. CMS seeks comment on this proposal.

AAFP Comments

The AAFP remains concerned with the data completeness threshold. While we appreciate CMS' efforts to maintain a stable threshold, we still believe it is too high. As noted in our comments on the 2024 proposed rule, until the current barriers related to data sharing and digital measurement are addressed, the increased threshold will increase administrative burden. Data collection and aggregation are incredibly burdensome to practices, and the unfortunate reality is that health information exchange capabilities and health information technology (health IT) standards have not been universally implemented in ways that seamlessly aggregate data from EHRs or registries across multiple sites of service. Data sharing is hindered by a lack of organizational prioritization, as well as a long list of more technical issues such as a lack of agreed upon semantic and syntactic standards, data privacy concerns, and patient misidentification. The lack of payer alignment around measures and the siloed, payer-specific approach to performance measurement further exacerbates these challenges.

The AAFP also asks CMS to provide more transparency regarding how clinicians have fared compared to the data completeness threshold. The 2022 QPP Experience Report did not include data completeness information, and previous reports have only included high-level information for the top reported measures. We believe there would be value in providing breakdowns of data completeness by collection type, participation type, and specialty.

Removal of Quality Measures

CMS is codifying previously established criteria for the removal of MIPS quality measures. CMS established a process to incrementally remove process measures, where consideration would be given to:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the MIPS quality measures address a priority area highlighted in the Measure Development Plan.
- Whether the MIPS measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the MIPS measure is designated as high priority or not.
- Whether the MIPS measure has reached extremely topped out status.

In CY2020, CMS expanded the criteria to include MIPS measures that do not meet the case minimum and reporting volumes required for benchmarking after being in the program for two consecutive performance periods and not available for MIPS quality reporting by or on behalf of all MIPS ECs. CMS would consider the robustness of the measure, whether it addresses a measurement gap, if the measure is a patient-reported outcome, and consideration of MIPS quality measure in developing MVPs prior to determining whether to remove the MIPS quality measure.

AAFP Comments

The AAFP supports the codification of these criteria as *part* of the measure removal process but also encourages CMS to consider multistakeholder feedback provided through the Measure Set Review (MSR) process administered by Battelle's Partnership for Quality Measurement (PQM). Through careful measure evaluation and consensus building, members of the MSR Recommendation Group help optimize and balance the CMS measure portfolio via measure removal recommendations. The MSR Recommendation Group consists of members representing all facets of the health care system. PQM emphasizes the inclusion of patients/recipients of care, caregivers, patient advocates, and traditionally underrepresented groups in this process.

Inventory of Quality Measures

CMS proposes several changes to the MIPS quality measure inventory in Appendix 1 of the proposed rule.

AAFP Comments

We continue to appreciate the "multiple choice" aspect of quality measurement in MIPS. Recognizing that physicians can select which quality measures they want to report, we offer the following feedback on some specific measures relevant to family medicine:

Adult COVID-19 Vaccination Status – Given many previously expressed concerns with this measure and its proposed use as an accountability measure, we appreciate that it is not required. However, we request that CMS more clearly define how the revised measure assesses whether a patient is "up-to-date" on their COVID-19 vaccinations given the constantly changing nature of COVID-19, CDC recommendations, and the vaccines and boosters that are available at any given time. Additionally, we reiterate our concerns about the measure's use as an accountability measure recognizing the well-documented vaccine hesitancy in the United States, as well as concerns about lack of measure testing and validation and lack of approval by the Partnership for Quality Measurement (PQM) Pre-Rulemaking Measure Review (PRMR) multistakeholder committee.

Preventive Care and Wellness Composite Measure - **We continue to oppose the use of this composite measure in any CMS program due to the data interoperability and aggregation challenges noted throughout our comments.** As previously expressed, the AAFP has raised concerns about composite vaccination measures citing ongoing issues with immunization registry interoperability and reporting challenges for primary care physicians (more on this below). We believe these same interoperability challenges could also prevent primary care physicians from reliably receiving data on patients' other screenings, which could negatively impact performance on the composite measure. **Furthermore, reporting the composite measure only counts as one quality measure when it represents the delivery of multiple high-value services.**

Adult Immunization Status (AIS) - **We continue to oppose the use of this composite measure in any CMS program due to the data interoperability and aggregation challenges noted throughout our comments.** The AAFP is a champion of safe and effective vaccines and agree that vaccination is a vital component of comprehensive primary care. However, the AAFP has repeatedly noted that immunization registry challenges create significant administrative burden for primary care physicians reporting the Adult Immunization Status composite measure, which can result in suboptimal performance on the measure at no fault to the physician. We have previously expressed other concerns about this measure as well.

Connection to a Community Service Provider (CSP) - The AAFP appreciates the overall intent of this measure and shares a strong desire to increase social needs screening and intervention with an aim to help patients and improve outcomes. However, it is premature to implement this measure in a payment program that holds clinicians accountable. The distinctly different nature of the health care and social care infrastructures prevent success on this measure in "the real world." Discretely capturing and measuring "connection" to a CSP is very difficult for ambulatory care physicians and other clinicians. As we have previously noted:

- The measure is not endorsed, which means it has not been rigorously reviewed by a consensus-based entity. We believe measures should go through a rigorous endorsement process and further tested and refined, as necessary, before they are considered for implementation.
- The current health and social care systems and IT infrastructure make this measure very difficult to operationalize:
- Many CSPs do not accept electronic referrals.
- CSPs often do not collect any patient-level information when they assist members of the community, and they often do not share data back with the individual's primary care physician. Therefore, closing the loop is challenging, if not impossible, in the current environment.
- Furthermore, there are no claims generated when a patient accesses a CSP.

- Some communities do not have the social resources/CSPs necessary to help alleviate social needs. If the community does not have the resources, then ACOs and PCPs should not be held accountable for connecting to something that does not exist.

Diabetes Hemoglobin A1c Poor Control (>9%) – We appreciate CMS' proposed revisions to update the measure title and specifications, per revised HEDIS specs, so that it now includes glycemic status indicator (GMI). However, we request clarification regarding how the exclusions for frailty and/or advanced illness will work at an operational level in medical clinics. Will these exclusions occur automatically based on claims? If so, how will CMS communicate the exclusions back to each patient's PCP?

Controlling High Blood Pressure - We support the proposed revision. However, we request clarification regarding how the PCP will know when their patient saw a different clinician at a different medical practice and obtained a frailty and/or advanced illness diagnosis which then removes them from the PCP's denominator. Clear communication and attribution are imperative, so PCPs are aware when patients are added or removed from performance measures to which they are held accountable.

Advance Care Plan – We support the proposed revisions to this measure but would like clarification regarding whether these revisions apply only for the MIPS program or whether they apply across all payers and programs. It is imperative that measure specification changes and reporting mechanisms align across all payers and programs. There should be just ***one*** set of specifications and ***one*** consistent reporting mechanism for each measure across all payers and programs.

Anti-Depressant Medication Management – **We urge CMS to remove this measure.** NCQA has already announced that it is retiring this measure at the end of the current measurement year. While there is broad agreement that medication adherence is an important driver of patient-centered outcomes for depression care, several factors informed retirement of this measure:

- The measure does not address other guideline-recommended, non-pharmacological components of care.
- Measure specifications do not adequately capture appropriate clinical judgment to avoid pharmacological treatments.
- NCQA has a more comprehensive set of measures of depression screening, follow-up and routine monitoring, and improvement in outcomes. NCQA is committed to expanding the use of these measures in reporting programs"

Diabetes: Eye Exam - We support the proposed revision. However, we request clarification regarding how the PCP will know when their patient went somewhere else and obtained a frailty and/or advanced illness diagnosis which then removes them from the PCP's denominator. Clear communication and attribution are imperative, so PCPs are aware when patients are added or removed from performance measures where they are held accountable.

Documentation of Current Medications in Medical Record – We appreciate the proposed revisions to this measure. However, we request clarification regarding whether a nurse can complete the documentation. Additionally, we encourage CMS to consider scenarios such as when a PCP may complete a medication reconciliation the day AFTER an encounter (rather than same day), as often occurs when PCPs work to catch up on their documentation. With this scenario in mind, we

encourage CMS to expand the timeframe so that the documentation may occur beyond the actual day of the encounter. We also acknowledge that this measure is a "check box" measure.

Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fractures – We agree with the proposed removal of this measure, particularly given that it is topped out.

Quality Performance Category Requests for Information

Survey Modes for the Administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey RFI
Given the potential for an increased response rate by expanding to a web-mail-phone protocol, CMS seeks comment on the following:

> *Would the increase in survey response rates (as shown from the results of the 2023 CAHPS field test), outweigh a possible increase in the cost of survey administration that would be associated with a three-mode survey protocol (web-mail-phone) compared to the current two-mode survey protocol (mail-phone)?"*

Yes, we believe it likely would increase survey response rates. However, we would like to see how much of an increase in cost medical practices would have to incur to administer the survey with a three-mode protocol (web-mail-phone).

The AAFP appreciates CMS' efforts to modernize the CAHPS for MIPS survey administration to include a web-based option. This is long overdue. For years organizations have highlighted the need for CMS to allow organizations the option to administer the CAHPS for MIPS surveys via more modern technology, such as email and/or web. We also encourage CMS to further modernize and consider the addition of SMS text message as another medium for survey administration given that text is such a widely used form of communication in today's world. (Text Message Notification for Web Surveys | Pew Research Center). This could also help increase survey responses among beneficiaries who have barriers to other survey completion methods.

That said, practices should have the ability to determine which survey administration method is most appropriate based on their patient population and also to determine which method is most cost effective.

We recognize that CAHPS for MIPS is currently optional in the traditional MIPS program. For any CMS programs where the CAHPS survey is required (or becomes a requirement in the future), CMS should cover the cost of the survey administration. We also reiterate previously expressed concerns by other health care stakeholder groups about the difficulty in obtaining an adequate number of survey responses for the CAHPS survey to achieve reliability and validity.

> *Would providing email addresses to vendors be feasible for groups, virtual groups, subgroups, and APM Entities (including Medicare Shared Savings Program ACOs)?*

The AAFP does not support the idea that physician practices would have to provide their patients' email addresses to survey vendors for the following reasons:

Privacy concerns – When physician groups obtain email addresses from their patients, they most often do so with the primary purpose of allowing access to a patient portal where they can

communicate with their PCP, obtain lab results, schedule and change appointments, etc. Patients "opt in" with their email address for this purpose. They likely would not share their email address with their physician group if they believed the clinic was going to share their email address with external third-party vendors of any type.

Added administrative burden - Ideally, CMS should already have beneficiary email addresses on file and thus would not need to put the onus on physician groups to supply them.

Guiding Principles for Patient-Reported Outcome Measures (PROMs) in Federal Models, and Quality Reporting and Payment Programs RFI
CMS seeks feedback on the following questions:

> *Are the aforementioned guiding principles outlined comprehensive or are there additional guiding principles and considerations we should consider for the selection, and implementation of PROM and PRO-PMs?*

We appreciate CMS' commitment to elevate the patient voice in health care through implementation of more PRO-PMs in CMS programs. We share the view that patient-reported outcomes are important and should be carefully measured and subsequently improved whenever possible. However, we encourage careful consideration before implementing new PRO-PMs.

First, we encourage CMS to refer to its own guidance published in the CMS Measures Management System, which states, "the outcomes collected by the tools [PROMs] are insufficient individually for measuring performance, and accountability programs cannot use them directly. Measure developers should construct quality measures that apply the outcome data collected by the tools to measure the quality of care."

In other words, PROMs cannot be used as performance measures for clinician accountability. PRO-PMs, on the other hand, include detailed specifications such as numerator, denominator, and clearly defined measured population criteria that has been tested and validated and thus can be used for comparison across health care facilities and/or physician groups.

We also offer the following feedback in response to CMS' proposed guiding principles:

Data Infrastructure – We request more information to clarify what CMS means when it says, "existing data systems for data collection and reporting." We do not think that CMS should mandate the use of existing PRO data collection systems such as ones used for CAHPS, which are costly and do not provide timely results to physicians. We encourage CMS to incentivize innovative health IT solutions that prioritize meaningful patient engagement strategies and timely and actionable data to physicians. Ultimately, physicians should be able to choose the system that best meets their needs and that of their patients.

Feasible Clinical Implementation – This principle is good in theory but is much easier said than done. Any new surveys or questions clinicians must ask patients have to be built out first in the clinician's EHR system. This takes time, as well as limited resources, away from other aspects of patient care.

Measure Testing – Reliability and validity remain challenges and concerns for PRO-PMs. Small denominators often prevent the data from accurately representing a clinician's "performance." In those many instances, the measure should not be used as an accountability measure for physicians. Physicians cite that it is often difficult to achieve an adequate denominator for many PRO-PMs.

Patient Engagement – It is important to recognize that PROMS can be highly subjective. (i.e. Some patients will never score highly simply because of their perspective.) Additionally, because response rates are typically low for most PROMs, patient engagement should include ways to encourage patients to complete PROMs. This could include education at the point of care and offering the PROM in a variety of methods such as paper in office, QR code, email, regular mail, text, etc.

As with all measures used for physician accountability and payment, score improvements should have meaningful impacts on patients and their physicians. The measure specifications should include a clear link between the PRO-PM and interventions that lead to improvements. In other words, physicians should have the ability to improve their performance on PRO-PMs.

> *How can CMS accelerate the development of PRO-PMs and advance them more rapidly into use? How can CMS support PRO-PM development while balancing the goal of accessible PRO-PMs with the additional time and resources required to construct PROMs and PRO-PMs from a PROM?*

To help accelerate the development of PRO-PMs and advance them more rapidly into use, we encourage CMS to consider the following:

- Continue its investment in applicable National Institutes of Health work.
- Provide additional grant funding to measure developers – This funding should come with requirements so that developers do not create measures that come with a copyright. PROMs and PRO-PMs should not serve as significant revenue generators for measure developers and/or stewards and should be easily accessible and free for clinicians to use.
- Offer funding for clinics to test/pilot measures during development. This would increase the number of clinicians willing to pilot test measures in their real-world clinic settings and provide valuable feedback to developers.

> *How should CMS balance the use of broad PRO-PMs that might be applicable across multiple clinical contexts compared to condition-specific PROMs and PRO-PMs measures that can be more tailored to a given clinical situation but lead to a greater number of tools in use across measures and health care providers?*

Broad measures applicable across multiple clinical settings can create challenges with accurate and appropriate attribution for PRO-PMs. (i.e. A PCP should not be held accountable for PROMs that are directly applicable to one of their patient's visits or episodes with a specialist.)

That said, we recognize the need for both types of measures (broad and condition-specific). Physicians should be able to select the measures that are appropriate for the population they serve.

> *How can CMS support making PROMs broadly accessible without limiting both innovation and resources committed to developing new tools? Are there other examples (beside PROMIS) of currently existing PROMs/PRO-PMs repositories that make their tools widely available to clinicians and healthcare systems?*

We appreciate CMS' interest in making PROMs and PRO-PMs broadly accessible without limiting innovation. As stated in our Performance Measures Criteria policy, the AAFP supports measures that are patient-centered and …"focused on improving important processes and outcomes of care that matter to patients…" We continue to advocate for performance measures that also have the greatest

impact on overall health and unnecessary spending (Value-based Payment Models for Primary Care, Performance Measurement in (Position Paper) | AAFP).

We continue to encourage adoption and implementation of the Person-Centered Primary Care PRO-PM that assesses a patient's personal experience of primary care, which can lead to improvements in individual and population health, health equity, and cost outcomes.

Currently we are not aware of measure databases or repositories specific to PROMs/PRO-PMs other than PROMIS. However, there are larger, widely used measure databases that include PRO-PMs in addition to other types of measures. These include but are not limited to the following:

- Battelle's Partnership for Quality Measurement (PQM) Measure Database
- CMS Measures Inventory Tool (CMIT)

For PRO-PMs, we encourage CMS to consider using one of these existing databases rather than mandate the use of another separate repository or database.

That said, we understand CMS' desire to avoid the evolution of multiple PROM/PRO-PM repositories that may inhibit the development of these measures and potentially impose additional costs on physicians and health care systems. The PROMIS database offers some benefits.

However, it is important to note that even for PROMIS tools and PRO-PMs, physicians and their clinic teams still have to build the tool and/or measure in their EHR environment and integrate it into their clinical workflows. If there are multiple PROMs, imagine providers having to "ask" for completion of multiple PROMs in a 20-minute office visit if the PROM cannot be completed before or after the visit. (Some PROMs have to be administered in an interview format.)

As CMS considers the use of a single PROM/PRO-PM database, we encourage it not to limit the database to only PROMs/PRO-PMs that are already used in "programs and payment systems in health care by Federal, State-based, and commercial payers, and healthcare systems." This could inadvertently hinder the development of new and innovative PROMs/PRO-PMs. Thus, the database should also include PROMs and PRO-PMs that are under development or are developed but have not been adopted and implemented (yet). There are many PROMs that are used within health systems for improvement initiatives that would not be captured if the database or repository included only measures that are already used in payment programs (i.e., Trust PROMs used in primary care).

Cost Performance Category

Proposed Updates to MIPS Episode-based Measure Inventory

The PRMR Clinical Committee Recommendation Group voted "do not recommend" for the Rheumatoid Arthritis (RA) measure. The group supported the measure concept but had reservations about its use in MIPS and concerns about measure performance. While CMS acknowledges the concerns, they disagree that the measure should not be used in MIPS. RA is highly prevalent and common among older adults, and thus costly to the health care system. Certain treatment choices are associated with increased costs due to adverse outcomes. CMS believes the cost of the adverse events are important to assess in terms of spending and impact on the patient population.

Public comments submitted during the PRMR process suggest the measure does not have support from certain rheumatology associations. However, the comments did not include comments from a

major rheumatologic association that has called for the development of an EBCM for rheumatologists.

In response to concerns about the scientific acceptability of the measure, CMS notes that it has a mean reliability of 0.74 at the group level and 0.52 at the individual level. CMS also notes that testing indicates that the risk adjustment model is working as intended and there has not been evidence to suggest that it would negatively impact patient outcomes.

Finally, the Recommendation Group suggested the measure undergo endorsement review and receive CBE endorsement. CMS may pursue endorsement in the future.

AAFP Comments

The AAFP believes the CMS should respect the Clinical Committee Recommendation Group's vote not to recommend the use of the Rheumatoid Arthritis measure. If CMS chooses to move forward with this measure, we recommend implementing it on an information-only basis for at least two years. During that time, CMS should track performance, collect feedback, and work with the Clinical Committee Recommendation Group to ensure their concerns have been sufficiently addressed.

Proposed Removal Criteria for MIPS Cost Measures

CMS proposes to adopt the following factors that can be used to guide the removal of cost measures:

> Factor 1: It is not feasible to implement the measure specifications.
>
> Factor 2: A measure steward is no longer able to maintain the cost measure.
>
> Factor 3: The implementation costs or negative unintended consequences associated with a cost measure outweigh the benefit of its continued use in the cost category.
>
> Factor 4: The measure specifications do not reflect current clinical practice or guidelines.
>
> Factor 5: The availability of a more applicable measure, including a measure that applies across settings, applies across populations, or is more proximal in time to desired patient outcomes for the particular topic.

CMS notes that these criteria would be used as guidance rather than as firm requirements. They may retain a measure that meets one or more criteria if CMS determines the benefit of retaining the measure outweighs the benefits of removing it.

AAFP Comments

The AAFP is supportive of this proposal and strongly urges CMS to remove the total per capita cost (TPCC) measure based on these criteria.

Factor 1 – Feasibility

The AAFP does not believe it is feasible to implement the TPCC measure specifications. The measure includes specialty exclusions so that "clinicians who would not reasonably be responsible for providing primary care are excluded from attribution of the TPCC measure." However, CMS cannot

currently implement the specialty exclusions as written in the measure specifications, and group practices that exclusively provide specialty care are being measured on TPCC based on billing by nurse practitioners, physician assistants, and clinical nurse specialists within the group practice. We have previously written to CMS expressing our concerns that TPCC was inappropriately attributed to radiologists and hospitalists in 2022 due to this problem.
CMS has made repeated modifications to the TPCC measure specifications in an attempt to make it more accurate. However, there are still issues with the attribution methodology, including not appropriately accounting for patients who did not need multiple visits within the attribution window or whose relationship with their primary care physician has ended. Given these ongoing challenges, we believe the measure specifications have proven to be beyond what is feasible to implement.

Factor 3 – Unintended Consequences

Additionally, AAFP believes the unintended negative consequences significantly outweigh the benefits of its continued use in the program. As stated in our previous comments, the TPCC and other cost-based measures such as the Medicare Spending Performance Benchmark (MSPB), and the Episode Based Cost Measures (EBCMs) hold primary care physicians accountable for costs they cannot control, penalize physicians for increasing utilization of recommended preventive health measures, and fail to capture long-term cost savings generated by high-quality, longitudinal primary care. Notably, physicians are held accountable for the total cost of care without being comprehensively paid for providing person-centered primary care services that are proven to reduce health care spending over time. Further, this evaluation occurs within a fee-for-service based system that does not provide the stability and flexibility offered by prospective payments. We therefore continue to believe that TPCC should not be used in the MIPS program.

Successful continuous improvement efforts are facilitated by timely and actionable information provided as a feedback loop to those charged with driving change. The cost performance category is unique in that all the data is calculated retrospectively by CMS using claims; nothing is reported by eligible clinicians. This means that physicians are reliant on CMS to share timely, actionable information about their performance. Under the TPCC, physicians are held accountable for costs that are incurred well beyond the scope of their direct care without an actionable data feedback loop that allows them to intervene on a timely basis.

There are numerous variables that can affect cost, many which primary care physicians cannot control even when providing the best possible care. While CMS is using a TPCC methodology that takes many factors into consideration, including patient risk, clinician specialty, and outlier spending, there are many factors, particularly related to utilization driven by patient choice and other clinicians, which drive TPCC performance that the primary care physician cannot influence when it happens in isolation. Without better information on the drivers of TPCC performance, primary care physicians are left in the dark and cannot be held accountable for spending that they do not direct. This is especially problematic for small, independent practices – especially solo practices.

Factor 4 – Current Clinical Practice

TPCC does not reflect current clinical practice or guidelines because TPCC does not account for differences in cost related to the types of treatments the patient needed during the year. Moreover, the risk adjustment methodology is based only on chronic conditions in a prior year and does not consider current acute conditions or newly diagnosed chronic conditions that are treated for the first time during the current year. For example, a primary care physician who has a higher-than-average number of patients diagnosed with cancer during the year, particularly expensive-to-treat cancers, will

be penalized by the TPCC because neither the risk adjustment methodology nor the specialty adjustment addresses this.

Factor 5- Availability More Applicable Measures

We believe the episode-based cost measures are more applicable than TPCC, as they apply across settings, populations, and are more aligned with performance measures and quality initiatives. While we have concerns, the AAFP is pleased to see the continued development of episode-based cost measures (EBCMs) that align more closely with chronic conditions actively managed in primary care settings. To the extent these conditions require co-management with specialists, we have many of the same concerns noted above relative to the TPCC and call on CMS to actively address these concerns by equipping primary care physicians with timely, actionable information on their overall performance, as well as the key drivers of spending across their patient population. We are supportive of relying on the episode-based cost measures relevant to primary care in lieu of the TPCC in MIPS.

Improvement Activities Performance Category

Codification of Improvement Activity Removal Factors

CMS proposes to codify the existing seven removal factors that were established in the CY2020 MPFS final rule. CMS notes that these criteria are used as guidance but used at CMS' discretion. CMS may retain an activity that meets one or more of these criteria if the benefit of retaining outweighs the benefit of removing.

AAFP Comments

The AAFP supports codification of these criteria. The AAFP asks CMS to consider providing a year's notice before removing an activity. For example, activities proposed for removal in the 2025 NPRM should not be removed from the program until the 2026 performance year. Since the final rule does not come out until roughly a month before the start of the applicable performance year, and practices need ample time to plan for any changes, particularly when reporting a different activity would require a financial investment or increased resource allocation.

Changes to the Improvement Activities Inventory

CMS proposes two new improvement activities, two modified improvement activities and eight improvement activities to be removed.

AAFP Comments

The AAFP supports the two new proposed activities as well as the proposal to modify the IA_PM_XX "Vaccine Achievement for Practice Staff - COVID-19, Influenza, and Hepatitis B."

Rather than limiting IA_BE_4 "Engagement of patients through implementation of improvements in patient portal" to those that have newly implemented a patient portal, the AAFP suggests CMS broaden the activity to include deploying new functionalities. We believe this would still meet the activity's objective of "increasing patient engagement, adherence to treatment plans, and self-management of chronic conditions" as well as continuing to promote continuous practice improvement.

CMS specifically highlighted the importance of real-time access to the medical record in the proposed ACPM service element “24/7 Access to Care and Continuity of Care.” As such, CMS should maintain IA_EPA_1 “Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-time Access to Patient Medical Record.”

The AAFP disagrees with CMS' assertion that IA_PM_12 “Population Empanelment” is obsolete. Empanelment and panel management are ongoing. Practices must continuously review and update their panel lists as their patient population changes. They must also monitor their panel sizes to adjust for patient acuity and physician workloads. Accurate panel information is key to ensuring continuity of care and effectively and proactively identifying patients with care gaps. Again, these skills are emphasized in the APCM service elements.

We ask CMS to maintain IA_CC_1 “Implementation of use of specialist reports back to referring clinician or group to close referral loop.” CMS states it does not align with the quality, cost, or promoting interoperability categories yet is redundant with QCDR measures. These are contradictory claims. Furthermore, it aligns with the promoting interoperability category measures “Support Electronic Referral Loops by Receiving and Reconciling Health Information” and “Support Electronic Referral Loops by Sending Health Information.” CMS also notes this activity is among the top 10 activities reported. According to the 2022 QPP Experience report, this activity was only reported by 4.56 percent of all MIPS ECs scored on improvement activities. This signals that there are still plenty of opportunities to improve closing the referral loop. As discussed throughout our response, interoperability and data exchange continue to be significant challenges. Given CMS' desire to improve communication and collaboration between primary care and specialist physicians – as seen through the MVP Ambulatory RFI and APCM service elements – it is unclear why CMS feels it is appropriate to remove this activity rather than doing everything they can to promote it. Instead of taking steps to remove activities that are, in fact, aligned with other categories, CMS should maintain them and reward those who are taking the steps toward improved communication and collaboration.

For these same reasons, we believe CMS should not remove IA_CC_2 “Implementation of improvements that contribute to more timely communication of test results.”

As stated, many of the activities proposed for removal align with the APCM service elements. We encourage CMS to reexamine its definition of “obsolete,” as the reporting rates for several activities deemed obsolete is low. It is inconsistent to prioritize these activities in one area and deprioritize them in another. CMS should provide consistency and congruency across programs and priorities.

Improvement Activity (IA) Scoring and Reporting Policies

Beginning with the 2025 performance year, CMS proposes to simplify IA category scoring by eliminating the weighting of IAs. CMS is also proposing to reduce the number of activities that must be reported. ECs in traditional MIPS would need to report two activities. Those with special status (small, rural, or HPSA practices, or non-patient facing ECs) would need to report one activity. CMS proposes that MVPs would be required to report one activity. CMS requests comment on this proposal.

AAFP Comments

The AAFP supports this proposal.

Request for Information (RFI) Regarding Public Health Reporting and Data Exchange

CMS is partnering with ASTP/ONC and CDC to explore how advancing the use of health IT and data exchange standards in the Promoting Interoperability performance category could improve and enhance public health infrastructure. Current CMS and ASTP/ONC policy has focused on requiring CEHRT to have public health data exchange capabilities and then rewarding physicians who use them. Joint CMS and ASTP/ONC policy also requires EHRs to be certified to the public health data exchange modules (Base EHR definition).

AAFP Comments

While the AAFP supports the four goals outlined in this RFI, especially the fourth goal of significantly reducing the reporting burden on MIPS eligible clinicians, we have concerns about the potential updates outlined here. Specifically, the AAFP believes it is ineffective for CMS to focus its efforts on just one aspect of data exchange when there are two interdependent – yet independent – groups of organizations that comprise public health data exchange: 1) physicians, practices, and hospitals, and 2) public health agencies. Instead of focusing exclusively on the clinician side of data exchange, we believe CMS would achieve their stated goals more quickly and efficiently if public health agencies nationwide were required to use the same standards as required by CEHRT.

Family physicians want to use the new public health data exchange module, as doing so will help them deliver high-quality, lower-burdened patient care and contribute to the improvement of public health. However, the AAFP believes public health agencies should be required to use the same standards as those that are required of CEHRT. Without this, physicians are left in a situation where they are required to pay the higher cost for CEHRT, required to try and use the functionality, and report that they really tried or that they were successful—and then must still find workarounds to get the job done, i.e., perform the immunization and report the data.

ASTP/ONC's newly proposed CEHRT public health data exchange certification criteria illustrates the great potential for public health data exchange and suggests its capabilities must be advanced. The AAFP agrees that public health data exchange holds considerable promise for the health care system, but we believe meaningful advancement will only take place when all parties actively participate in meeting the data exchange requirements and are incentivized to use the same standards nationwide.

The AAFP is very supportive of public health data exchange and applauds the goals laid out in this RFI, but we do not think doubling down on physicians and clinician's role in public health data exchange will move the health care system closer to those goals; instead, it will just increase the costs and burdens on physicians. We recommend HHS focus its collaboration with CDC, ASTP/ONC, and additional agency partners on ensuring public health agencies' data exchange is properly incentivized and required to be certified to the same standards as physician CEHRT. We believe that is the current best approach to move the health care system closer to the goals laid out by the Public Health Data Strategy.

MIPS Final Score Methodology

Complex Organizational Adjustment for Virtual Groups and APM Entities

Virtual groups and APM Entities may experience technological barriers to electronic reporting, including challenges aggregating patient data across multiple TINs, data deduplication, and interoperability between different health IT/EHR systems.

CMS' assessment shows there are complexities and challenges for Virtual Groups and APM Entities in adopting all-payer/all-patient collection types. To account for these complexities, CMS proposes to establish a Complex Organizational Adjustment to provide Virtual Groups and APM Entities one measure achievement point for each submitted eCQM that meets data completeness and case minimum requirements. Each reported eCQM may not receive more than 10 measure achievement points and the total points may not exceed the total available points for the quality category. The adjustment may not exceed 10 percent of the total available measure achievement points in the category. It would be added for each measure submitted at the individual measure level.
CMS will revisit and end this adjustment as uptake of FHIR API increases, requirements surrounding the use of FHIR API are established, or other barriers posed by organizational complexity are otherwise reduced.

AAFP Comments

The AAFP appreciates this proposal but is skeptical that it will increase eCQM reporting as it does not address the underlying concerns related to data interoperability and aggregation. Providing a scoring adjustment does not remove the significant barriers or costs related to aggregating and reporting data across multiple EHRs. We reiterate our request that CMS delay the sunsetting of the Web Interface for three years as well as maintain the MIPS CQM reporting option.

While we continue to believe the transition to eCQMs poses particular challenges for APM Entities, we must also point out that the cost and administrative burden associated with performance measure reporting impacts all eligible clinicians. Rather than providing short-term relief for subsets of MIPS participants, we encourage CMS to focus its efforts on working with stakeholders to address the underlying interoperability issues that affect the broader health care system. Should CMS move forward with this proposal, we recommend CMS apply it across MIPS rather than for a subset of participants.

Proposed Modifications to Scoring Methodology for the Cost Performance Category Beginning with the CY2024 Performance Period

To address concerns with the cost benchmarking methodology, CMS proposes to modify the scoring methodology to be based on standard deviation, median, and an achievement point that is derived from the performance threshold.

The proposed modification would mean clinicians with costs near the median would not receive a disproportionately low score. CMS' analysis shows the proposed modification supports their goal: MIPS ECs who deliver care at an average cost near the median costs for all MIPS ECs attributed the measure would receive scores at, or very close to, the performance threshold-derived score.
CMS requests comment on this proposal.

AAFP Comments

The AAFP appreciates and is encouraged CMS' efforts to address concerns related to the cost category scoring. According to CMS' data, average cost category scores for the 2022 performance year were consistently lower than the performance threshold as well as average quality category scores. **Given that CMS' analysis has already demonstrated the negative impact of the existing methodology, the ongoing attribution issues for the TPCC measure, and the significant financial implications for practices, the AAFP strongly urges CMS to retroactively implement**

this updated scoring methodology. The AAFP believes such application is consistent with Section 1871(e)(1)(A)(ii) that provides statutory authority to retroactively apply a substantive change in regulation when failure to do so would be contrary to public interest. If CMS is unable to apply the revised methodology, we ask that they reweight the cost category to zero rather than continuing to use an approach that CMS publicly acknowledged is problematic.

Proposal to Permit Exclusion of a Cost Measure when Impacted by Errors and When Significant Changes Occur Outside of the Performance Period

CMS does not currently include "errors" in addition to "significant changes" within their cost measure exclusion policy. CMS proposes if data used to calculate a score for a cost measure are impacted by significant changes or errors affecting the performance period, such that the cost measure score would lead to misleading or inaccurate results, the affected measure is excluded from the MIPS EC's or groups cost score. CMS proposes to make the exclusion policy effective with the 2025 performance period.

AAFP Comments

The AAFP supports this proposal. Consistent with our comments above, we urge CMS to apply this new policy beginning with the 2023 performance period, or no later than the 2024 performance period.

MIPS Payment Adjustments

CMS proposes to continue using the mean of the final scores for all MIPS ECs from a prior period to establish the performance threshold for the 2027, 2028, and 2029 payment years.

CMS proposes to maintain the performance threshold of 75 points for the 2025 performance period. Given issues with underlying data in prior periods because of the COVID-19 pandemic, CMS believes they should wait for more recent data that better reflects ECs' performance. As such, they will continue to rely on data from the 2017 performance period. They are still evaluating the usability of the 2019 performance period data. CMS also notes that the extensive reweighting policies applied for the 2020 and 2021 performance periods may have skewed final scores, so they are not an appropriate indicator for future performance.

AAFP Comments

The AAFP supports the proposal to maintain the performance threshold of 75 points for the 2025 performance period. We appreciate CMS considering how the pandemic may have impacted data. The AAFP supports legislative efforts that would provide CMS more flexibility in setting the performance threshold, including freezing the threshold at 60 points for three years.

Although we appreciate CMS considering how the increases in threshold may disproportionately impact small and solo practices, the AAFP remains extremely concerned by CMS' estimates that 46 percent of solo and 21 percent small practices will receive a negative payment adjustment in the 2027 payment year. Additionally, the median negative payment adjustments for solo and small practices are considerably higher (-6.42 percent and -5.88 percent, respectively) than the overall median negative adjustment (-1.48 percent). These estimates demonstrate the MIPS program is not driving continuous quality improvement and is instead on a path that will accelerate the closing and consolidation of small physician practices. Practices are continuing deal with the ongoing economic challenges sparked by the COVID-19 pandemic, including staffing shortages and persistent burnout.

Furthermore, Medicare physician payment rates have failed to keep up with the cost of inflation and have become increasingly insufficient. These impacts are exacerbated by budget neutrality requirements, congressionally mandated sequestration cuts, and the threat of increasing negative MIPS payment adjustments. Taken together, the financial strain threatens the viability of practices and will continue to drive the already overwhelming consolidation. Evidence clearly shows that consolidation trends increase prices, do not improve quality, and can worsen access to care. Practice owners, particularly primary care physicians, point to persistently low payment rates and increasing administrative requirements to explain this trend.

Proposal to Adopt Reweighting Performance Category(ies) Policy When a Third Party Intermediary Did Not Submit Data Due to Reasons Outside the MIPS EC's Control

Beginning with the 2024 performance period, CMS proposes that they may reweight one or more of the quality, improvement activities, and promoting interoperability performance categories where they determine, based on submitted documentation, that data are inaccessible or unable to be submitted due to circumstances outside of the ECs control because the EC delegated submission to a third-party intermediary. Documentation would need to be submitted before November 1 of the year preceding the relevant MIPS payment year.

AAFP Comments

The AAFP supports this proposal.

Third-party Intermediaries General Requirements

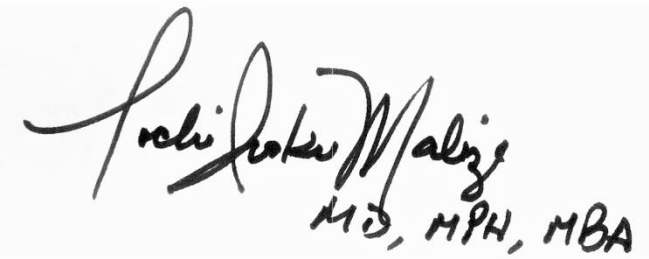
CMS proposes to require that a survey vendor include on its application the range of costs of its third-party intermediary services. Ranges of estimates would vary based on different levels of service. CMS requests comment on this proposal.

AAFP Comments

The AAFP supports this proposal.

Conclusion

The AAFP appreciates the opportunity to provide comments on the proposed rule. We look forward to continuing to partner with CMS to support equitable access to high-quality, comprehensive, person-centered primary care. Should you have any questions, please contact Kate W. Gilliard, Senior Manager of Federal Policy at kgilliard@aafp.org.



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