AMERICAN ACADEMY OF FAMILY PHYSICIANS

September 6, 2023

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 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program**

Dear Administrator Brooks-LaSure:

On behalf of the American Academy of Family Physicians (AAFP), representing 129,600 family physicians and medical students across the country, I write to provide comprehensive comments on the calendar year (CY) 2024 Medicare Physician Fee Schedule (MPFS) & Quality Payment Program (QPP) proposed rule as published in the August 7, 2023 *Federal Register*.

In the press release announcing the proposed rule, the Centers for Medicare and Medicaid Services (CMS) stated "Primary care is instrumental in the delivery of high-quality, whole-person care." The AAFP wholeheartedly agrees. At the population level, primary care is the only health care component for which increased supply is associated with more equitable outcomes, as well as lower mortality rates, health care expenditures, and hospitalizations.[1][2][3][4] On an individual patient level, primary care teams form enduring relationships with their patients to comprehensively treat and manage acute and chronic conditions in the context of a person's overall health and community, coordinate care across the team, address unmet social needs, and optimize a patient's health in a way that is meaningful to them.

**The AAFP appreciates CMS advancing several proposals in this rule to support the provision of comprehensive, whole-person primary care, including full implementation of the G2211**

[1] Starfield B, Shi L, Macinko J. Contribution of primary care to health systems and health. Milbank Q. 2005;83(3):457-502. doi: 10.1111/j.1468-0009.2005.00409.x. PMID: 16202000; PMCID: PMC2690145.
[2] 4 Basu S, Berkowitz SA, Phillips RL, Bitton A, Landon BE, Phillips RS. Association of Primary Care Physician Supply With Population Mortality in the United States, 2005-2015. JAMA Intern Med. 2019 Apr 1;179(4):506- 514. doi: 10.1001/jamainternmed.2018.7624. PMID: 30776056; PMCID: PMC6450307.
[3] Baker R, Freeman GK, Haggerty JL, Bankart MJ, Nockels KH. Primary medical care continuity and patient mortality: a systematic review. Br J Gen Pract. 2020 Aug 27;70(698):e600-e611. doi: 10.3399/bjgp20X712289. PMID: 32784220; PMCID: PMC7425204.
[4] Bazemore A, Petterson S, Peterson LE, Bruno R, Chung Y, Phillips RL Jr. Higher Primary Care Physician Continuity is Associated With Lower Costs and Hospitalizations. Ann Fam Med. 2018 Nov;16(6):492-497. doi: 10.1370/afm.2308. PMID: 30420363; PMCID: PMC6231930.

**add-on code, new coding and payment for screening and addressing unmet social needs, and more accurate payment for behavioral health integration.** Taken together, these proposals represent incremental but meaningful steps toward appropriately paying for and investing in primary care.

**Unfortunately, Medicare beneficiaries and the physicians they rely on will not realize the full benefits of these new investments due to longstanding systemic shortcomings of the laws governing the MPFS and QPP.** In CY 2024, a number of these policies are converging to undermine access to clinician services and destabilize physician practices:

- The statutory freeze on annual payment updates for the MPFS, which is exacerbating already low physician payment rates that have failed to keep up with the cost of inflation – and thus the cost of providing physician services;
- Statutory budget neutrality requirements that require CMS to offset long overdue, urgently needed investments in primary care by lowering the Medicare conversion factor, and therefore payments for every service under the MPFS;
- Across the board sequestration cuts that further reduce payments to physicians and other clinicians;
- 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 who patients in rural and other underserved areas rely on for their care;
- The expiration of the Advanced Alternative Payment Model (AAPM) bonus, which will undermine progress toward value-based payment models that provide clinicians with the support and flexibility they need to deliver better care at lower costs.

The AAFP is deeply concerned that together these outdated policies will further destabilize physician practices, accelerate consolidation, and ultimately worsen access to care for beneficiaries. For community-based primary care practices, these challenges are only piled on top of decades of underinvestment in the comprehensive, whole-person care they provide and overwhelming administrative requirements that divert their time and attention away from patient care. The AAFP has long advocated to accelerate the transition to value-based care using alternative payment models that provide prospective, population-based payments to support the provision of comprehensive, longitudinal primary care. As detailed in our comments, we strongly believe that well-designed APMs provide primary care a path out of the under-valued and overly-burdensome fee-for-service (FFS) primary care payment system that exists today, and in turn will better enable the Medicare program to meet the needs of its growing and aging beneficiary population.

**FFS is not the future of primary care but is the present. That is why the AAFP is committed to advancing legislative reforms that provide a fair and stable foundation for the MPFS, as well as working with CMS to boldly champion new primary care payment strategies.** Since the passage of MACRA, it has become clear that stable, adequate fee-for-service payments are a vital component to this transition, particularly for practices serving rural, low-income, and other underserved communities. Most practices continue to rely primarily on FFS for payment, including those who have transitioned to value-based APMs as most are built on the same underfunded FFS chassis. Physician practices that are struggling with increasingly inadequate Medicare FFS payments cannot make the investments required to transform care delivery in ways that improve care and generate savings. **We call on CMS to work with Congress to enact an annual inflationary update to the MPFS, address budget neutrality limitations, provide relief from the broken,**

**burdensome MIPS program, and provide clinicians across specialties with support and incentives to transition to APMs.**

We recognize that CMS does not have the authority to address many of the challenges detailed here. Nonetheless, CMS has demonstrated that it has many regulatory levers to bolster support for and equitable access to primary care, including by correcting historic imbalances within the MPFS and advancing primary care-led APMs. We urge CMS to continue this vital work by continually investing in primary care in the MPFS and across other programs.

**In this letter, we provide detailed recommendations for supporting primary care across CMS' proposals including in the following ways:**

- **Move forward with fully implementing the G2211 add-on code in 2024;**
- **Finalize proposals to provide separate payment for screening for and addressing patients' unmet social needs within the context of the patient's usual source of longitudinal primary care;**
- **Implement a hybrid payment participation option in the Medicare Shared Savings Program that provides prospective population-based payments for primary care;**
- **Use available authority to refrain from raising the MIPS performance threshold and prevent physicians in small and medium practices from being unfairly penalized;**
- **Work to reduce administrative and regulatory burdens imposed on physicians in the MPFS, MSSP, and QPP.**

Determination of PE RVUs (section II.B.)

Given the American Medical Association's (AMA's) intended data collection efforts in the near future and because methodological and data source changes to the Medicare Economic Index (MEI) finalized in 2023 would have significant impacts on physician fee schedule (PFS) payments, CMS believes delaying implementation of the finalized 2017-based MEI cost weights for the RVUs is consistent with its efforts to balance payment stability and predictability with incorporating new data through more routine updates. Therefore, CMS is not proposing to incorporate the 2017-based MEI in PFS rate setting for CY 2024. CMS is likewise not proposing any changes in the MEI itself.

CMS's proposed clinical labor pricing for CY 2024 is based on the clinical labor pricing CMS finalized in the CY 2023 PFS final rule, incremented an additional step for Year 3 (2024) of the four-year transition, which will be complete in 2025. CMS proposes some technical corrections and refinements to specific direct practice expense inputs for select codes.

Lastly, CMS solicits public comment on strategies for updates to practice expense data collection and methodology. As it prepares to receive information from the current AMA Physician Practice Information Survey (PPIS), CMS seeks comments from interested parties on strategies to incorporate information that could address known challenges CMS experienced in implementing the initial AMA PPIS data. CMS also seeks to understand whether, upon completion of the AMA's updated PPIS data collection effort, contingencies or alternatives may be necessary and available to address lack of data availability or response rates for a given specialty, set of specialties, or specific service suppliers who are paid under the PFS.

*AAFP Comments*

The AAFP supports CMS's proposal to not incorporate the 2017-based MEI in PFS rate setting for CY 2024, and we appreciate that CMS is not proposing any changes to the MEI itself. We urge CMS to collaborate with the AMA on its new 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.**

**The AAFP also supports CMS's proposal to continue its four-year transition in the repricing of clinical labor.** We continue to appreciate that CMS repriced the clinical labor inputs in its direct practice expense methodology and support the ongoing 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, the AAFP encourages CMS to update this data more regularly to ensure payment rates enable practices to employ essential clinical staff and avoid significant redistributive impacts on others.

Regarding strategies for updates to practice expense data collection and methodology, AAFP responses to the specific questions asked by CMS follow:

*(1) If CMS should consider aggregating data for certain physician specialties to generate indirect allocators so that PE/HR calculations based on PPIS data would be less likely to over-allocate (or under-allocate) indirect PE to a given set of services, specialties, or practice types. Further, what thresholds or methodological approaches could be employed to establish such aggregations?*

The current AMA PPI survey is using stratification to control the distribution of sampled cases, either to match the distribution of the population or to differ from it in a controlled way. The use of stratification will improve the precision of estimates, both overall and within subgroups defined by the stratification. The AAFP recommends that CMS postpone any consideration of the level of granularity of specialty-level data until after the current PPI survey demonstrates the differences and similarities of practice costs by specialty. Our understanding is that the AMA and its contractor, Mathematica, could consider recommendations related to this question once the study is completed.

*(2) Whether aggregations of services, for purposes of assigning PE inputs, represent a fair, stable, and accurate means to account for indirect PEs across various specialties or practice types?*

The AAFP supports practice expense RVUs based on the actual resources, both direct and indirect, physicians use to provide services. As such, the AAFP believes it is important for the CMS practice expense methodology to have a sufficient level of granularity to reflect relative actual practice costs incurred by physician practices. Thus, aggregations of services, for purposes of assigning PE inputs, are unlikely to represent a fair, stable, and accurate means to account for indirect PEs across various specialties or practice types.

*(3) If and how CMS should balance factors that influence indirect PE inputs when these factors are likely driven by a difference in geographic location or setting of care, specific to individual practitioners (or practitioner types) versus other specialty/practice-specific characteristics (for example, practice size, patient population served)?*

The AAFP supports the elimination of all geographic adjustment factors from the Medicare Physician Fee Schedule except for those designed to achieve a specific public policy goal (e.g., to encourage physicians to practice in underserved areas). As such, CMS should seek to mitigate, if not eliminate,

factors that influence indirect PE inputs when those factors are likely driven by a difference in geographic location.

Our understanding is that, in the current PPI study, the AMA and Mathematica are controlling for the number of sampled practices within strata defined by (1) specialty, (2) proportion of time in the facility setting, (3) practice size, (4) ownership type (individual ownership vs. more complex ownership types), (5) geographic region, and among practices with complex ownership, whether (6) the practice is part of a vertically integrated health system, and (7) private equity ownership. We also understand that the AMA and Mathematica are using these criteria for initial sampling, and if there is variance in the response rates between different practice types, they will also use these criteria to adjust the sampling midway through the data collection period. We further understand that the AMA and Mathematica will develop final analysis weights to adjust for the probability of selection, practice eligibility, and cooperation, ensuring selected,
weighted totals match marginal population totals from the sample frame. In the survey itself, participating practices are asked to split out their provider compensation and time, staffing and other direct and indirect practice expenses at the Medicare specialty level, if possible.

Lastly, we understand the AMA and Mathematica could provide recommendations related to this question once the PPI survey is completed. The PPI sampling and weighting methodology should account for most of these factors.

*(4) What possible unintended consequences may result if CMS were to act upon the respondents' recommendations for any of highlighted considerations above?*

As noted, the AAFP supports practice expense RVUs based on the actual resources, both direct and indirect, physicians use to provide services. Medicare payment differentials between the MFS and the OPPS are significant and are one factor driving the decline in independent, private practice. The AAFP is a strong advocate for site neutral payment policies that provide the same payment for a service regardless of the setting in which it is delivered. However, the success of site neutral payment policies partially hinges on ensuring the MPFS rate adequately captures the practice expense and other costs of furnishing that service. As we discuss repeatedly throughout our comments, current MPFS payment allowances have failed to keep up with inflation and therefore the cost of running a practice and furnishing services. Taken together, current Medicare payment rates and systems place physician practices in a perilous financial situation while rewarding hospitals and health systems for acquiring practices and moving services to the more costly setting. CMS should take steps to ensure that site neutral payment policies are advanced alongside practice expense updates to prevent unintended consequences, like further accelerating vertical consolidation.

In last year's NPRM, CMS provided an impact table related to the initiative of rebasing and revising the MEI weights. CMS noted that implementation of that change in the PE methodology would have shifted payment weights from physician work to practice expense principally favoring Diagnostic Testing Facility (+13%), Portable X-Ray Supplier (+13%), Independent Laboratory (+10%) and Radiation Therapy Centers (+6%) to the detriment of others, such as primary care, which would face decreases (Family Medicine (-1%), Geriatrics (-2%), Internal Medicine (-2%) and Pediatrics (-2%)). Like that separate policy change, other changes to the PE methodology may cause shifts between specialties, as well as within specialties, and put the solvency of many physician practices and other healthcare organizations in jeopardy. Any changes that are considered should be made carefully to ensure they reflect actual practice costs incurred by physician practices and further the overarching goals of the Medicare program to provide high-quality, comprehensive health care to beneficiaries.

We reiterate our recommendation that CMS defer any significant changes in its PE methodology until the results of the current PPI survey are available.

*(5) Whether specific types of outliers or non-response bias may require different analytical approaches and methodological adjustments to integrate refreshed data?*

Our understanding is that the AMA and Mathematica will develop final analysis weights to adjust for probability of selection, practice eligibility, and cooperation, ensuring selected weighted totals match marginal population totals from the sample frame. We also understand the AMA and Mathematica will evaluate the potential for nonresponse bias by conducting a nonresponse bias analysis. Also, if there is variance in the response rates between different practice types, these criteria will be utilized to adjust the sampling midway through the data collection period. Nonetheless, we encourage CMS to determine if additional actions are needed to address outliers.

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

### Requests to Add Services to the Medicare Telehealth Services List for CY 2024

CMS is proposing that current services on the Medicare Telehealth Services List will remain available on the list through CY 2024. Additionally, CMS proposes to add Health & Well-being Coaching Services to the Telehealth Services List on a temporary basis for CY 2024. If finalized, CMS proposes to add HCPCS GXXX5 to the Telehealth Services List on a permanent basis.

*AAFP Comment*
The AAFP strongly supports CMS' proposal to add HCPCS GXXX5 to the Telehealth Services List on a permanent basis. We encourage CMS to also designate HCPCS GXXX5 as a service that can be provided via audio-only telecommunications technology.

### Proposed Clarifications and Revisions to the Process for Considering Changes to the Medicare Telehealth Services List

Following the end of the COVID-19 public health emergency, CMS proposes to clarify and simplify the approach the agency uses to determine whether new services will be added to the Medicare Telehealth Services List on a temporary or permanent basis.

Section 1848(m)(1) specifies that Medicare telehealth services are limited to those for which payment can be made to the physician or practitioner when furnished using an interactive telecommunications system. When considering whether to add, remove, or change the status of a service on the Telehealth Services List, CMS proposes the following process:

1. *Determine whether the service is separately payable under the PFS (identified by payment indicators A, C, T, or R on the CMS public use files).* CMS proposes that if they find a service identified in a submission is not separately payable under the PFS, they would not conduct any further review of that service. If CMS determines a service is separately payable under the PFS, they would apply Step 2.
2. *Determine whether the service is subject to the provisions of section 1834(m) of the Act.* A service is subject to section 1835(m) when at least some elements of the service, when

delivered via telehealth, are a substitute for an in-person, face-to-face encounter, and all those face-to-face elements of the service are furnished using an interactive telecommunications system as defined in §410.78(a)(3). CMS notes that the application of Step 2 is consistent with longstanding policy.

3. *Determine whether one or more face-to-face component(s) of the service furnished via audio-video communications technology would be equivalent to the service being furnished in-person.* CMS would also look for information from submitters of evidence of substantial clinical improvement in different beneficiary populations that may benefit from the requested service when furnished via telehealth (e.g., rural populations). CMS notes that completing each element of the defined service is a different question than whether a beneficiary receives any benefit at all from the telehealth-only form of a service.
4. *Consider whether the service elements of the requested service map to the service elements of a service on the list that has a permanent status described in previous final rulemaking.* CMS proposes this step because any code that satisfies this criterion would not require further analysis. If a code describes a service that maps to the service elements of a permanent code on the Telehealth Services List, CMS would add the requested code to the list on a permanent basis in the next PFS proposed rule. If Step 4 is not met, CMS proposes to continue to Step 5
5. *Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the in-person service.* CMS would review the submitted evidence to determine the clinical benefit of a service. They would then compare the clinical benefit of the service when provided via telehealth to the clinical benefit of the service if it were to be provided in person.

If CMS determines there is enough evidence to suggest that further study may demonstrate the service's clinical benefit when provided via telehealth, they could assign the service a "provisional" status on the Telehealth Services List. If the clinical benefit of the service when provided via telehealth was determined to be equal to that of the service when provided in person, CMS would assign the service a "permanent" status on the Telehealth Services List.

For services assigned a "provisional" status, CMS may assign "permanent" status in a future year, as evidence builds. CMS may also remove a service from the list in the interest of public safety based on findings from ongoing monitoring of telehealth services within CMS and informed by publicly available information. CMS will revisit "provisional" status through the annual submissions and rulemaking processes.

CMS proposes that services on the Telehealth list with either a Category 1 or Category 2 status will be assigned a "permanent status." Services on a temporary Category 2 or Category 3 basis will be assigned a "provisional" status. Additionally, CMS will not assign a service a provisional status if it is unlikely the code will ever achieve permanent status. CMS requests comment on its proposed process.

*AAFP Comment*
The AAFP appreciates CMS' clarifying and simplifying the categorization of services on the telehealth list. However, we are concerned that the process may slow down the addition of new codes. We ask CMS to develop and publicly share a timeline that specifies codes submitted by the February cutoff are reviewed in a timely manner to ensure this process does not take longer than the current review process. The AAFP encourages CMS to thoughtfully consider implementation processes that could increase transparency for submitters and reduce or eliminate lag time between steps.

While we appreciate CMS' reasoning behind the purpose of Step 4 in the proposed steps of analysis for services, the AAFP is concerned it will promote inefficiency within the process. Since CMS has not yet found a single instance where service elements for a proposed code mapped onto service elements for a service already on the list, the AAFP does not support its inclusion in the analysis process at this time. **The AAFP supports rearranging Steps 4 and 5; the currently proposed Step 5 should instead become Step 4 and be the end of the official analysis**. If CMS chose to rearrange as we suggest, Agency staff could attempt to map the service elements for codes after those codes had been added to the Medicare Telehealth Services List. Should these mapping attempts begin having success in the future, CMS could use that data to then propose reordering the steps and incorporating the currently proposed Step 4 into the analytical process.

Implementation of the CAA, 2023

The *Consolidated Appropriations Act of 2022 (CAA, 2022)* extended several temporary telehealth policies for 151 days after the expiration of the COVID-19 PHE. The *CAA of 2023* further extends these policies through the end of CY 2024. CMS notes that their revisions do not alter payment amounts or billing rules that were in effect as of January 1, 2023. Those policies will remain in effect through December 31, 2024. To comply with the *CAA, 2023*, CMS seeks to address the several policies that were finalized in the CY 2023 Final Rule. Specifically, CMS proposes to revise regulatory text to reflect that:

- For CY 2023 and CY 2024, the list of originating sites remains as listed in §410.78(b)(3), which includes any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home.
- In-person requirements for TH services furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder will be effective January 1, 2025.
- The list of practitioners remains as described in CY 2023 final rule through December 31, 2024. Additionally, effective January 1, 2024, CMS will recognize marriage and family therapists and mental health counselors as telehealth practitioners.
- The audio-only provision applies to services on Telehealth List as of December 29, 2022.

*AAFP Comment*
The AAFP supports CMS' proposals to align regulations with the *CAA, 2023*. We understand that further legislative action is required to extend many of these provisions beyond 2024. The AAFP has supported the *Protecting Rural Telehealth Access Act* and looks forward to working with legislators and CMS to advance long-term solutions that preserve patient access to telehealth services. We urge CMS to work with Congress to enact legislation, such as the *Protecting Rural Telehealth Access Act,* that permanently remove geographic and originating site restrictions and expand the definition of a telecommunication system to include audio-only technology.

Telehealth, when implemented thoughtfully, can improve the quality and comprehensiveness of patient care, and expand access to care for under-resourced communities and vulnerable populations. As discussed in our previous comments and outlined in our Joint Principles for Telehealth Policy, the AAFP strongly believes telehealth policies should advance care continuity and the patient-physician relationship. Telehealth should also enable higher-quality, more personalized care by making care more convenient and accessible for patients. Expanding telehealth services in isolation, without regard for a previous patient-physician relationship, medical history, or the eventual need for a follow-up

hands-on physical examination, can undermine the central value offered by a usual source of primary care, a continuous and comprehensive patient-physician relationship, increase fragmentation of care, and lead to the patient receiving suboptimal care.

**The AAFP strongly believes telehealth is most appropriate when provided by a patient's usual source of care. We have significant concerns about the rapid proliferation of direct-to-consumer (DTC) telehealth vendors and the resulting interference with the established patient-physician relationship.** In the last several years we've seen new and different types of DTC telehealth vendors emerge, including many for-profit start-ups that market themselves in ways that lead a consumer to believe they are providing true, person-centered health care. The dangers of these types of companies extends beyond disrupting the established patient-physician relationship but can range from misusing patient data to making patients vulnerable to medical misinformation and can even lead to patient harm.[5][6][7] The AAFP remains concerned about the lack of regulation and transparency DTC telehealth companies are subject to and how that might impact patient care and outcomes. DTC telehealth cannot replace in-person care and is not an adequate replacement for a longitudinal patient-physician relationship, especially for patients with complex medical conditions.

As the current payment landscape still largely relies on fee-for-service, it is vital to promote telehealth policies that provide adequate payment to protect access and the patient-physician relationship. However, the best long-term solution is a payment system that moves away from the transactional and focuses on payment that better supports whole-person primary care. **Reliable, prospective payment that decouples payment from a specific care modality or encounter fosters innovations that allow practices to meet the diverse needs of their patient populations.** Practices that are not hampered by stringent payment structures and documentation requirements will be better prepared to meet future challenges associated with emergencies and disaster scenarios.

The AAFP deeply appreciates CMS and other agencies taking swift action to expand coverage and payment for telehealth services across programs during the COVID-19 PHE, as well as interagency efforts to maintain patients' access and physicians' ability to provide telehealth services post-pandemic. However, the AAFP remains concerned about CMS' intent to require physicians to report a home address on their Medicare enrollment for telehealth services rendered at home, which is scheduled to begin Jan. 1, 2024. **While we appreciate physicians being permanently allowed to render Medicare telehealth services from home and support transparency in health care, the AAFP urges CMS not to move forward with this plan**.

The digitization of health data has eased patients' access to their own health information but has also elevated the risk of cyberattack 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 against them. **The AAFP stands with family medicine physicians**

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[5] DEA Serves Order to Show Cause on Truepill Pharmacy for its Involvement in the Unlawful Dispensing of Prescription Stimulants. December 2022. Available at: https://www.dea.gov/press-releases/2022/12/15/dea-serves-order-show-cause-truepill-pharmacy-its-involvement-unlawful

[6] Telehealth start-ups are monetizing misinformation – and your data. Coda. May 15, 2023. https://www.codastory.com/waronscience/pseudohealth/telehealth-companies-misinformation/#:~:text=Bypassing%20traditional%20healthcare,your%20health%20itself

[7] Mental-Health Startup Cerebral Investigated by FTC. WSJ. Available at: https://www.wsj.com/articles/ftc-launches-probe-of-cerebrals-business-practices-11655241983?mod=latest_headlines

**and their patients in support of the confidential patient-physician relationship and against the criminalization of medical practice, and we urge CMS not to require physicians include their home address on Medicare enrollment paperwork related to rendering telehealth services**.

Place of Service for Medicare Telehealth Services

CMS proposes to pay telehealth services provided in the patient's home (Place of Service [POS] 10) at the non-facility rate. Beginning January 1, 2024, CMS proposes to pay the facility rate for claims billed with POS 02.

*AAFP Comment*
**The AAFP supports CMS' proposal to pay telehealth services billed with POS 10 at the non-facility rate.** We agree with CMS' assertion that many physician practices continue to offer both in-person and telehealth appointments now that the COVID-19 PHE has concluded, 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 beneficiaries. While absent congressional action only behavioral health services can be billed with a POS 10 code after 2024, the AAFP notes that these practice costs and downstream implications on beneficiaries' access to care apply to family medicine practices as well.

However, we are concerned that CMS intends to pay services billed with POS 02 at the facility rate. During and throughout the PHE, many practices invested in new technologies to shift to a predominantly virtual environment. Although most practices have transitioned to offering in-person care, many 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 may determine which modality is most appropriate for the patient. 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.** As noted in a recent research article examining the use of telehealth by primary care clinicians during the COVID-19 pandemic, "Clinicians are medical professionals, trusted with stewarding the health of the population, and can be trusted to determine on their own when use of telemedicine is appropriate for their patients. Central support for frontline innovation is more likely to be successful than command and control top-down solutions." **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 support more tools, not less, to primary care physicians so they can provide the familiar and quality care their patients seek.

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

CMS proposes to remove the telehealth frequency limitations for Subsequent Inpatient Visits (CPT 99231-99233), Subsequent Nursing Facility Visits (CPT 99307-99310), and Critical Care Consultation Services (HCPCS G0508-G0509) for CY 2024. CMS seeks information on how practitioners have ensured that Medicare beneficiaries receive subsequent inpatient and nursing facility visits, as well as critical care consultation services since the expiration of the PHE.

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

Direct Supervision via Use of Two-way Audio/video Communications Technology

Through December 31, 2024, CMS proposes to define direct supervision to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and video interactive telecommunications. One approach CMS could consider is to extend or permanently establish virtual presence flexibility for services that are valued under the PFS under the presumption that they are nearly always performed entirely by auxiliary staff (e.g., 99211). CMS seeks comment on whether they should extend beyond 2024.

*AAFP Comment*
The AAFP supports CMS' proposal to allow direct supervision using real-time audio/video telecommunications technology. **The AAFP recommends CMS permanently allow direct supervision of non-physician clinicians by physicians through the use of real-time audio/video technology**. 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 areas.

Supervision of Residents in Teaching Settings

Through December 31, 2024, CMS proposes to allow the teaching physician to have a virtual presence in all teaching settings, only in clinical instances where the service is furnished virtually (e.g., a 3-way telehealth visits, with all parties in separate locations). CMS notes that availability or audio-only do not constitute virtual presence. Documentation must demonstrate whether the teaching physician was physically present or present through audio/video real-time communications at the time of the service, including documenting the specific portion of the service for which the teaching physician was present through audio/video. CMS seeks comment on how telehealth services can be furnished in all residency training locations beyond CY 2024. CMS also seeks comment on what other treatment situations are appropriate to permit the virtual presence of the teaching physician.

*AAFP Comment*
The AAFP appreciates the flexibilities CMS has offered throughout the COVID-19 PHE and during the transition period. However, we disagree with CMS' proposal that limits a teaching physician's

virtual presence to virtual encounters (i.e., telehealth). **The AAFP strongly encourages 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 the discretion to determine the appropriateness of a virtual presence rather than in-person depending on the services being furnished and the experience of the resident. 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.

Relatedly, under the "primary care exception," Medicare has made MPFS payment available to teaching physicians for certain services of lower and mid-level complexity furnished by a resident without the presence of a teaching physician in certain teaching hospital primary care centers. Regulations require that the teaching physician must not direct the care of more than four residents at a time, must direct the care from such proximity as to constitute immediate availability, and must review with each resident (during or immediately after each visit) the patient's medical history, physical examination, diagnosis, and record of tests and therapies. The teaching physician must have no other responsibilities at the time, assume management responsibility for the patient seen by the resident, and ensure the services furnished are appropriate. The AAFP is appreciative of CMS exercising enforcement discretion through December 31, 2024, to allow teaching physicians in all teaching settings to be present virtually, through audio/video real-time communications technology, for purposes of billing under the MPFS for services they furnish involving resident physicians.

The AAFP is appreciative CMS expanded the list of services subject to the primary care exception to respond to the PHE for remote precepting of residents. This change provided educational training opportunities for applicable medical residents, expanded patient access to primary care, and improved relational continuity of the patient and primary care physician in teaching centers. Expanding the primary care exception benefitted patients and primary care training programs alike, and we are concerned the return to the previous policy has been disruptive to primary care training programs, as well as created unnecessary barriers to high-value primary care for patients. **Our members report that the absence of high-value services on the primary exception list discourages their integration in residency training and day-to-day medical practice, negatively impacting physician training and patient outcomes in the long term. Additionally, members across the country have reported a shortage of supervising physicians in their locales, making the requirement that a supervising physician be physically present for a level 4 or 5 visit particularly challenging. Thus, the AAFP recommends HHS permanently expand the list of services subject to the primary care exception to include the list of services in *Appendix A*. Permanently expanding the primary care exception could help improve utilization of recommended preventive care services, which is particularly important as many patients are still catching up on preventive care they may have forgone throughout the pandemic.**

Clarifications for Remote Monitoring Services

CMS has received many questions regarding appropriate use of remote patient monitoring (RPM) and remote therapeutic monitoring (RTM) services. CMS wishes to provide clarification on several policies.

With the end of the COVID-19 PHE, CMS reverted to its pre-PHE policies. CMS reiterates that RPM services may only be furnished to established patients. Patients who received initial RPM services during the PHE are considered established patients. Furthermore, RPM and RTM services require 16 days of data and may only be billed by one practitioner during a 30-day period.

Either RPM or RTM (but not both) may be billed concurrently with Chronic Care Management, Principal Care Management, Transitional Care Management, Behavioral Health Integration, and Continuous Passive Motion services. However, time may only be counted once. Additionally, RPM treatment management (CPT codes 99457 and 99458) and RTM treatment management (CPT code 98980) cannot be billed together.

CMS proposes to clarify that RPM and RTM may not be billed together so that time is not counted twice by billing for concurrent RPM and RTM services. If a patient is receiving both RPM and RTM services, there may be multiple devices used. In such cases, CMS will apply to existing rules that the services associated with all devices may only be billed by one practitioner, once per patient, per 30-day period, and must have at least 16 days of data.

CMS proposes to clarify that RPM or RTM may be reported during global period if the remote monitoring services are unrelated to the diagnosis for which the global procedure is performed, and the purpose of the remote monitoring addresses an episode of care that is separate and distinct from the episode of care for the global procedure.

CMS is soliciting comment and requests general feedback that may be helpful in further development of their payment policies.

*AAFP Comment*
The AAFP appreciates CMS' clarifications. We agree that RPM and RTM services should not be reported if they are related to a diagnosis for a global procedure.

Telephone Evaluation and Management Services

CMS states that telephone evaluation and management services (CPT codes 99441-99443) will remain actively priced through CY 2024. CMS notes that CPT codes 98966-98968 are not telehealth services, but CMS proposes to continue to assign an active payment status to them for CY 2024.

*AAFP Comment*
As previously noted here and in our CY 2023 MPFS comments, **the AAFP strongly supports audio-only services. Audio-only telehealth services are clinically effective, valuable for patients, and vital for ensuring equitable access to telehealth services for a range of patient populations. Telephone can be an effective and appropriate means of providing telehealth 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 serving 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.

Valuation of specific codes for CY 2024 (Section II.E)

*(20) General Behavioral Health Integration (GBHI) Care Management (CPT code 99484, and HCPCS code G0323)*

CMS proposes to refine the work RVU of both CPT code 99484 and HCPCS code G0323, as proposed (see section II.J.1.c of the proposed rule), by increasing the work RVU to 0.93 from the current 0.61 and increasing the work time to 21 minutes to match the results of the surveyed work time. For CPT code 99484, CMS proposes the direct PE inputs as recommended by the RUC without refinement. CMS also proposes the same PE inputs for HCPCS code G0323.

*AAFP Comments*

The AAFP advocated for appropriate valuation of GBHI in our previous comments; as such, the Academy strongly supports this revaluation of GBHI. GBHI has become increasingly popular over traditional CoCM codes.[8] Medicare claims data indicates GBHI is used nearly 10 times more than CoCM codes, likely because it covers a wider array of action and does not require consultation with a specified type of behavioral health clinician. Additionally, when compared to CoCM, GBHI has a lower time threshold which may be more accessible by over-burdened primary care physicians.

*(21) Advance Care Planning (CPT codes 99497 and 99498)*

CMS proposes the RUC-recommended work RVU of 1.50 for CPT code 99497 and 1.40 for CPT code 99498, which are the current values for these codes. CMS proposes the RUC-recommended direct PE inputs for these codes without refinement.

*AAFP Comments*

The AAFP supports CMS's proposals for these two codes and encourages the agency to finalize those work value and direct PE inputs in the final rule this fall.

*(22) Pelvic Exam (CPT code 9X036)*

This new code is a practice expense only code that captures the direct practice expenses associated with performing a pelvic exam in the non-facility setting. CMS proposes the RUC-recommended direct-PE inputs for CPT code 9X036 without refinement. As a PE-only service, the RUC did not recommend, and CMS is not proposing, a work RVU for this code.

*AAFP Comments*

The AAFP supports CMS's proposal for this code and encourages the agency to finalize the direct PE inputs in the final rule this fall. Family physicians are an essential source of reproductive health care, with family physicians providing roughly one-third of all outpatient care sought by women over the age of 30.[9] More appropriately accounting for the practice costs associated with providing pelvic exams will advance appropriate payment for primary care practices providing this service, which can advance equitable and timely access to care for Medicare beneficiaries.

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[8] Medicare claims data, 2020: 99492 (Initial psychiatric collaborative care management, 70 min) billed 6,958 times; 99493 (Subsequent psychiatric collaborative care management, 60 min) billed 23,187 times; 99494 (Initial or subsequent psychiatric collaborative care management, 30 min) billed 13,820 times; 99484 (Care management services for behavioral health conditions, 20 min) billed 128,255 times

[9] Hudson Scholle S, Chang JC, Harman J, McNeil M. Trends in women's health services by type of physician seen: data from the 1985 and 1997–98 NAMCS. Womens Health Issues 2002;12:165–77.

*(24) Hyperbaric Oxygen Under Pressure (HCPCS code G0277)*

In 2015, CMS created HCPCS code G0277 (Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval) to describe direct practice expense inputs associated with CPT code 99183 (Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session). At the September 2022 Relativity Assessment Workgroup meeting, HCPCS code G0277 was identified as a high-volume growth code with Medicare utilization of 10,000 or more that has increased by at least 100 percent from 2015 through 2022, and it was reviewed at the January 2023 RUC meeting.

Hyperbaric oxygen therapy is typically administered to one patient in one hyperbaric chamber for two hours. Two hours is typical, and all inputs are prorated for four units being performed (each 30 minutes, totaling 2 hours). All medical supplies and time inputs have been divided into quarters. CMS is proposing to refine the clinical labor time for the CA013 Prepare room, equipment, and supplies from 1.5 minutes to 0.5 minutes, as well as the clinical labor time for the CA016 Prepare, set-up and start IV, initial positioning and monitoring of patient from 1 minute to 0.5 minutes to align with the 2-minute standard for these clinical activities. CMS arrived at these refinements by dividing the standard 2-minutes of clinical labor times for CA013 and CA016 by four to account for all inputs being prorated for four units being performed for one typical two-hour session. CA013 and CA016 would each be 0.5 minutes per 30-minute interval, which amounts to the standard 2 minutes for these clinical activities when four units are reported for the typical two-hour session.

Additionally, CMS proposes to set the time for clinical labor activity CA021 (Perform procedure/service---Not directly related to physician work time (intra-service time) at 15 minutes. Finally, CMS proposes to refine the equipment time for the EQ362 (HBOT air break breathing apparatus demand system (hoses, masks, penetrator, and demand valve)) and EQ131 (hyperbaric chamber) equipment items from the recommended 39.75 minutes to 23.25 minutes to conform to the proposed changes in clinical labor time.

*AAFP Comments*

**The AAFP disagrees with the proposed revisions to CA013 and CA016.** For CA013*,* under G0277, CMS currently has 1.0 minute for staff type L047C *RN/Respiratory Therapist* and 0.5 minute for staff type L037D *RN/LPN/MTA*. Consistent with the rest of the recommendations, the RUC put the entire 1.5 minutes under staff type L047C. Looking at the previous PE inputs for 99183, in addition to 2 minutes for CA013, the RUC recommended either 3 minutes (PE spreadsheet) or 5 minutes (PE summary of recommendation) for *Other clinical activity: Turn on chamber operating panel, check communications with patient and adjust volumes, prepare chamber operating settings per physician order*. It is unclear if that is captured elsewhere in the clinical activities for G0277. If that time is added to the 2 minutes for CA013, the sum is 5-7 minutes, and the 6 minutes (1.5 x 4) currently assigned and recommended for CA013 falls appropriately within that range. This information provides a justification for exceeding the usual 2-minute standard.

For CA016, CMS currently assigns 1 minute, just as the specialties proposed and the RUC recommended. That is consistent with the 4 minutes per session the RUC recommended for CA016 for 99183, on which CMS based the current direct PE inputs for G0277. The March 2014, RUC recommendations for 99183 described the clinical activities required for CA016, which provides a justification for exceeding the usual 2-minute standard:

> Lower chamber gurney to lowest point for ease of patient transfer. Assist / situate patient comfortably on chamber gurney. Wrap external orthotic devices with padding to protect the chamber. Raise patient gurney with assistance to appropriate height, mate to chamber rails. Lock in place. Test ground strap with meter to ensure proper ground per regulation, attach to patient wrist. Slide patient / gurney into chamber and lock in place. Unlock the gurney frame from rails and pull away to ready for door closure. Close and check the seal of the door. Time out to confirm the patient is ready to proceed.

CMS states that the RUC recommended 30 minutes for clinical labor activity CA021 *Perform procedure/service---Not directly related to physician work time* (intra-service time) based on a flawed assumption that the current 15 minutes for CA021 accounts for two patients receiving treatment at the same time. CMS noted that it has been standard for one patient to receive treatment at a time and the current 15 minutes for CA021 is based on a time ratio to the CY 2015 RUC-recommended direct PE inputs for CPT code 99183; therefore, CMS disagrees with this RUC recommendation and is proposing to refine the recommended intra-service CA021 clinical labor time to maintain the current 15 minutes.

The AAFP disagrees with CMS's proposed clinical labor intra-service time of 15 minutes for CA021 and linking it to the old time. The standard of practice for patient safety is 100% attendance and availability of clinical staff. In the event of an emergency, there needs to be one staff per patient available to carry out emergency procedures. Attendance throughout the therapy is important as an emergency can occur at any moment. The chamber side attendant must be there the entire time; this is not a shared work scenario. Therefore, the clinical labor intra-service time should be 30 minutes, consistent with the code descriptor. The same applies to the use of the equipment; the chamber and breathing apparatus are being used the entire treatment time.

In the current proposed rule, CMS states, "We agree with the specialties that the intra-service time is now more appropriately labeled as clinical activity CA021 as opposed to CA018 due to the change in clinical staff type." When the RUC made PE input recommendations for 99183 in 2014, it recommended 60 minutes for the session based on half of the physician time (although the corresponding PE SOR indicates that the activity is 120 minutes). CMSs agreement to divorce clinical staff time from physician time by accepting the change from CA018 to CA021 should further discredit reliance on the 2014 logic for 99183, on which CMS seems to depend in proposing 15 minutes for CA021. **The AAFP urges CMS to adopt the direct PE inputs for G0277 as recommended by the RUC.**

*(27) Services Addressing Health-Related Social Needs (Community Health Integration services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)*

CMS proposes new payments for services that help to identify and address social determinants of health (SDOH) that manifest as individual health related social needs (HRSN) and impact a practitioner's ability to diagnose or treat a patient. In the 2023 proposed physician fee schedule, CMS issued an RFI for services involving Community Health Workers (CHWs). CMS believes that in addition to physicians and non-physician clinicians social workers, CHWs, and other auxiliary personnel are evaluating and addressing patient HRSN needs, and this service is not reflected in current coding. CMS proposes three new services that may be provided incident to the billing physician: community health integration services, SDOH risk assessment, and principal illness navigation.

*AAFP Comments:*

The AAFP appreciates CMS' ongoing efforts to identify and value the growing number of services primary care physicians deliver to patients. **We support proposals that offer appropriate payment to identify, monitor, and address patient-level 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.[10] We believe family physicians have an important role to play 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.

The AAFP agrees with CMS' observation that existing FFS structures do not currently pay for the support to identify and address a patient's identified HRSNs in a meaningful or consistent way. In previous comments, we've noted that family physicians cite the need to expand their capabilities to address a patient's SDOH needs as reason to transition to alternative payment models (APMs) that include prospective population-based payments. Current FFS payment structures do not offer the sufficient or stable funding necessary to establish structures to deliver whole-person care, inclusive of individual health-related social needs. The AAFP appreciates CMS' innovative proposals in this rule to support primary care and improve equitable access to comprehensive care within the FFS structure; however, we believe the piecemeal approach that FFS takes to financing primary care undervalues and overburdens family physicians' and care teams' efforts to provide a whole-person approach that is integral to primary care. Physicians must document several unique screening codes, vaccine administration, other preventative service and counseling codes, in addition to an office visit, care management codes, integrated behavioral health codes, and other services to justify payment for a typical, comprehensive primary care visit. The AAFP urges CMS to implement new payment strategies to more comprehensively and sustainably finance primary care.

*Community Health Integration (CHI) Services (HCPCS GXXX1, and GXXX2)*

CMS proposes to create separate coding and payment for community health integration (CHI) services beginning January 1, 2024. CMS proposes to create two HCPCS G-codes to describe monthly CHI services as follows:

- GXXX1: Community health integration services performed by certified or trained auxiliary personnel, including a community health worker, under the direction of a physician or other practitioner; 60 minutes per calendar month, in the following activities to address social determinants of health (SDOH) need(s) that are significantly limiting ability to diagnose or treat problem(s) addressed in an initiating E/M visit:
    - Person-centered assessment
    - Practitioner, Home-, and Community-Based Care Coordination
    - Health education
    - Building patient self-advocacy skills
    - Health care access / health system navigation
    - Facilitating behavioral change as necessary for meeting diagnosis and treatment goals
    - Facilitating and providing social and emotional support

[10] American Academy of Family Physicians. Advancing Health Equity by Addressing the Social Determinants of Health in Family Medicine (Position Paper). 2019. https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html

    - Leveraging lived experience when applicable
- GXXX2: Community health integration services, each additional 30 minutes per calendar month

CMS proposes that to initiate CHI services, the billing practitioner must furnish an E/M visit where a treatment plan is established and SDOH needs are identified that are barriers to the treatment plan. Subsequent CHI services could be performed by a Community Health Worker (CHW) or other auxiliary staff incident to and under the general supervision of the practitioner who bills for the E/M visit. CMS seeks comment on whether other services, such as an AWV, could serve as an initiating visit for CHI services. CMS believes that practitioners would normally bill an E/M when a problem is identified. Further, CHI services must address a SDOH need that limits a practitioner's ability to treat a specific problem and an initiating E/M visit would ensure CHI services are provided in the context of medically necessary care. CMS notes that if an AWV delivered by a non-billing practitioner is used to initiate CHI services, CHI services would not necessarily be provided "incident to" as proposed.

CMS proposes that auxiliary staff providing CHI services must be trained to deliver CHI services and meet any state laws or licensure requirements to provide the services incident to the billing practitioner. CMS proposes that training must include competencies that reflect existing consensus on core CHW competencies. CMS seeks comment on whether to set specific requirements for the number of training hours required or specific content or trainer requirements.

CMS proposes that time spent performing CHI services must be documented in the patient's medical record, including the relevant SDOH needs. CMS proposes to encourage but not require documentation of associated using ICD-10 Z-codes (Z55-Z65) in the medical record and on the claim.

CMS seeks comment on typical service times, frequency, and duration of CHI services. CMS believes that a substantial portion of CHI services would be delivered in direct contact with the patient (as they involve connecting a patient to resources or providing personalized education). Therefore, CMS is not proposing to require patient consent for CHI services but notes that if comments indicate CHI services are often included without direct patient contact, consent may be required to ensure patients are not surprised to receive a bill for the services. (CMS also notes that they do not have the statutory authority to waive cost sharing for CHI services.) CMS also seeks comment on any potential overlap or duplication with state Medicaid coverage for CHI services, and whether there are other elements of care that CMS should consider including in the proposed service codes.

Finally, CMS proposes that CHI services may be provided by auxiliary personnel who are external and under contract with the practitioner or practice, as long as the third party is sufficiently clinically integrated—specifically, the auxiliary personnel performing CHI must communicate with the billing practitioner consistently to ensure services are documented in the medical record, and the billing practitioner is able to evaluate the continuing need for CHI services. Examples of third-party organizations that CMS believes could provide CHI services include not-for-profit community-based organizations such as aging and disability resource centers. CMS proposes to allow only one practitioner per beneficiary per month to bill for CHI services, and beneficiaries under a home health plan of care under Medicare Part B would not be eligible.

*Proposed CHI Services Valuation*

- GXXX1: CMS proposes a work RVU of 1.00 based on a crosswalk to CPT code 99490 with a service time of 25 minutes

- GXXX2: CMS proposes a work RVU of .70 based on a crosswalk to CPT code 99439 and a work time of 20 minutes

AAFP Comments:

**The AAFP supports the proposal to create new coding and payment for CHI services. As noted in previous comments, CHI services enable physicians to better address a patient's identified social needs within a community context and in coordination with a patient's usual source of primary care.** There is growing evidence that CHWs are uniquely equipped to build relationships with underserved patients and help patients better navigate the primary care system and reduce their use of hospital care. For example, a randomized controlled study found that when patients worked with a CHW on chronic disease management goals established in consultation with their PCP, hospitalizations were lower compared to the control group.[11] Throughout the intervention, CHWs helped navigate patients to their PCP for clinical needs, resulting in improved patient perceptions of quality of care and increased trust. Anecdotal evidence also demonstrates that CHWs are uniquely positioned to reinforce relationships with the patient's primary care team, which ultimately improves outcomes.[12,13] Therefore, we strongly support CMS' proposal to incorporate CHI services into clinical settings in order to address patient-level SDOH needs which we believe result in health inequities.

**The AAFP recommends that CMS allow the following services to serve as a CHI initiating visit: an E/M visit, an Annual Wellness Visit (AWV) when conducted as part of an ongoing relationship, a psychiatric diagnostic evaluation (90791), or a health behavior assessment or re-assessment (96156).** The AAFP also supports CMS' proposal that certain types of E/M visits including inpatient/observation visits, ED visits, and SNF visits would not qualify as a CHI initiating visit as practitioners in these settings are unlikely to furnish longitudinal care. The AAFP recognizes the importance of care team continuity when providing CHI services. Further, a systematic review of published CHW interventions found that CHW outcomes vary by deployment: generally, positive outcomes are associated when CHWs are integrated with the patient's care team.[14] Therefore, we urge CMS to allow the initiation of CHI services via the visit types listed above. We also support CMS' proposal to limit this code to one billing practitioner per month to ensure patient-centered coordinated care.

We recognize CMS does not have the authority to waive cost sharing for CHI services in this rule, however, cost sharing requirements create barriers for patients that are likely to reduce utilization. We are also concerned that given the likelihood this service will be provided to patients with limited financial resources, practices are likely to not bill for the service out of concern for the patient's out of

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[11] Kangovi S, Mitra N, Norton L, et al. Effect of Community Health Worker Support on Clinical Outcomes of Low-Income Patients Across Primary Care Facilities: A Randomized Clinical Trial. *JAMA Intern Med.* 2018. Available: https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2707949

[12] Martha Hostetter, Sarah Klein. The Commonwealth Fund, "In Focus: Integrating Community Health Workers into Care Teams,"2015. "https://www.commonwealthfund.org/publications/2015/dec/focus-integrating-community-health-workers-care-teams

[13] Amber Castillo, "Community health workers, experts in the in-between, fight for their place in the system," STAT, August 7, 2023. https://www.statnews.com/2023/08/07/community-health-workers-montefiore-nachw/

[14] Jack, H.E., Arabadjis, S.D., Sun, L. *et al.* Impact of Community Health Workers on Use of Healthcare Services in the United States: A Systematic Review. *J GEN INTERN MED* **32**, 325–344 (2017). https://doi.org/10.1007/s11606-016-3922-9

pocket cost, limiting the positive impact of these new codes. The AAFP supports minimizing cost sharing for this service.

**The AAFP urges CMS to modify the descriptor code for GXXX1 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 will be too high and create a barrier to integrating CHI services. Therefore, we strongly recommend that CHI services follow a similar format to CCM codes which allow for services to be delivered in 20-minute increments for the first hour. We support CMS' proposal that once CHI services are initiated, they may be furnished for a year before requiring another initiating visit.

CHI services are not always provided entirely in-person; a variety of modalities including audio-video, two-way audio, and text-based communications are used. **We urge CMS to allow the delivery of CHI services in all available communication modalities as this will allow staff to tailor services to a patient's individual needs and preferences and enable culturally and linguistically appropriate care.**

While a portion of CHI services are delivered in direct contact with patients, there are also times when staff are working on behalf of beneficiaries without their direct knowledge. For example, interventions to address housing insecurity may require a significant amount of staff time placing calls to third parties to find vacancies and screen these vacancies based on a patient's financial or other needs. Staff would work directly with a patient to review options; however, a significant portion of time in some months might be spent preparing information and identifying services that could meet a patient's specific needs. Like CMS, we are concerned that patients may receive a bill they may not anticipate. Therefore, **we believe that CMS should require patient consent to initiate CHI services, and we urge CMS to accept verbal consent (similar to Chronic Care Management consent requirements) to reduce administrative burden. In addition, we recommend that CMS require consent once per year, when CHI services are initiated.**

We agree with CMS' proposal to document time spent performing CHI services in the patient's medical record. **We also appreciate the flexibility to allow physicians to contract with community-based organizations to provide CHI services.** However, time spent establishing the infrastructure and connectivity required to adequately document services and establish effective CHI services are not reflected in this proposal. Even well established, highly codified CHI service programs take time to effectively integrate into practice operations. For example, a successful implementation of IMPaCT into three sites required an experienced team to spend more than one month tailoring the program to each site.[15] We strongly support this proposal and believe that it is an important step in supporting highly personalized, effective primary care. However, **we urge CMS to consider the valuation of this code to ensure it reflects the practice expenses of implementing the program.**

We are pleased that CMS proposes to allow FQHCs/RHCs to receive payment for CHI services. Because CHI services are included in code G0511, and claims are permitted to one beneficiary per

[15] Kangovi S, Mitra N, Norton L, et al. Effect of Community Health Worker Support on Clinical Outcomes of Low-Income Patients Across Primary Care Facilities: A Randomized Clinical Trial. *JAMA Intern Med.* 2018. Available: https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2707949

month, we are concerned that FQHCs/RHCs will not receive sufficient payment for CHI services when furnished to a patient enrolled in CCM since both codes are included in G0511 and this code can only be billed once. We ask that CMS consider an alternative approach that allows FQHCs/RHCs to receive separate payment for these services.

With regard to CHW training, we encourage CMS to ensure that any finalized certification and/or training requirements do not inadvertently create barriers which 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, as described in this proposal, CHI services are not medical services, rather, they are services to address SDOH needs which 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.[16] We encourage CMS to evaluate the results of various CHW training and certification requirements and use this information to make a more informed policy decision. 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.**

*Proposed SDOH Risk Assessment Code*

CMS observes that the assessment of health-related social needs or patient-level SDOH need is increasingly integral to patient care, but these activities are not reflected in current coding. Therefore, CMS proposes a new HCPCS G-code, GXXX5 as follows:

GXXX5: Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes, not more often than every 6 months, which must cover at least the following domains:

- Food insecurity
- Housing insecurity
- Transportation needs
- Utility difficulties

CMS proposes that the SDOH assessment must be furnished on the same day as an E/M visit to inform the patient's diagnosis and treatment plan. (There is also a proposal to furnish an SDOH assessment as an optional service in the AWV that is discussed later in the proposed rule.) CMS proposes the SDOH assessment must be delivered using a standardized, evidence-based tool that meets the beneficiary's educational, developmental, and health literacy needs, but CMS does not propose to mandate the use of any specific tool. CMS seeks comment on whether to require billing practitioners to have the capacity to provide CHI services, PIN services, care management services, or partnerships with community-based organizations that address SDOH needs in order to receive payment for the SDOH assessment.

CMS proposes that the SDOH needs identified in the risk assessment must be documented in the medical record and plans to encourage the use of Z-codes. CMS proposes to include this code in the Medicare Telehealth Services list to allow the practitioner (or their auxiliary staff) to complete the

[16] Nielsen VM, Ursprung WWS, Song G, et al. Evaluating the impact of community health worker certification in Massachusetts: Design, methods, and anticipated results of the Massachusetts community health worker workforce survey. Front Public Health. 2023 Jan. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9877511/

assessment in interview format. CMS seeks comment on where and how these services will typically be provided, in addition to any other aspects of the proposed SDOH assessment.

*Proposed Valuation for SDOH Risk Assessment*

GXXX5: CMS proposes a work RVU of 0.18 based on a crosswalk to HCPCS code G0444 with a work time of 15 minutes

AAFP Comments:

**The AAFP strongly supports this proposal.** As noted in comments to Secretary Becerra, we agree on the importance of identifying and treating a patient's SDOH needs. The AAFP supports CMS' proposal that the SDOH assessment must meet the beneficiary's cultural and linguistic needs. The AAFP recognizes the importance of culturally sensitive care and endorsed HHS' National Standards for Culturally and Linguistically Appropriate Services in Health and Heath Care. The AAFP also supports meaningful access to care for individuals with limited English proficiency (LEP) and/or those with disabilities. CMS' proposal also aligns with AAFP's support of the Health IT End Users Alliance Consensus Statement on Data to Support Equity, which states that "there should be appropriate compensation for data collection and management of health-related social needs."

**We strongly support CMS' proposal to not require any single, specific SDOH assessment, allowing physicians to select any tool that is standardized, evidence-based, and meets the beneficiary's educational, developmental, and health literacy needs.** We believe that CMS' proposal will allow practices the flexibility they need to operationalize social needs screening. Moreover, allowing the choice of assessment will allow the health care community time to build consensus on standards and develop technical tools that will allow for the sharing of data, when appropriate. We also appreciate CMS' flexibility to allow the primary care team to select which SDOH domains to assess beyond food insecurity, housing insecurity, transportation needs, and utility difficulties.

**We urge CMS to refrain from requiring practitioners to already have resources in place that address unmet social needs in order to receive payment for conducting the assessment.** We believe that this proposed requirement will only create barriers that slow the adoption of SDOH assessments. Research suggests that physicians view a lack of resources to address SDOH needs as a barrier to social needs screening.[17] We are concerned that creating a resource requirement to receive payment for assessments could create a "catch-22" situation in which primary care physicians are hesitant to implement SDOH assessments because they aren't linked to community resources, yet they are not linked to community resources because they don't have the data to understand their patients' SDOH needs. Further, in some cases, the resources to address a patient-level HRSN may not exist in the community and physicians should not be held accountable for addressing broader SDOH deficits at the community level. In addition to screening tools, the AAFP offers an interactive tool, The Neighborhood Navigator, to help primary care practices connect patients with supportive resources in their local neighborhood when they do exist. Although discussed later in the proposed

[17] Schickedanz A, Hamity C, et al. Clinician Experiences and Attitudes Regarding Screening for Social Determinants of Health in a Large Integrated Health System. Med Care. June 2019. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6721844/

rule, we appreciate the proposal to conduct the SDOH risk assessment as an optional service during a patient's Annual Wellness Visit (AWV), as this eliminates coinsurance, which is a barrier to adoption. We also appreciate CMS' flexibility in recognizing the assessment may be conducted by phone.

In general, the AAFP agrees that a direct crosswalk to code G0444 (Annual depression screening, 5 to 15 minutes) is appropriate for an initial valuation of this service. The time in the descriptors of GXXX5 and G0444 are the same, and the services are similar in nature.

Finally, we want to affirm our support for this, and other related changes proposed by CMS to strengthen physician's ability to identify and address patient-level health related social needs that interfere with the primary care physician's ability to support the patient's achievement of their best health. As noted later in our comments on collaboration with community based organizations, **we encourage CMS to consider these proposed payment changes as part of a broader multi-agency 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.**

*Principal Illness Navigation (PIN) Services*

CMS recognizes that existing care management codes may include some elements of patient navigation, but notes these services typically focus on clinical navigation as opposed to support navigating the social aspects of serious illness. Therefore, CMS proposes new codes for Principal Illness Navigation (PIN) services for patients with serious, high-risk illnesses. Some of the services CMS proposes to include are person-centered assessments, patient referrals to support services, care coordination, patient health education, and peer-provided social and emotional support. CMS proposes to create two HCPCS G-codes to describe PIN services as follows:

- GXXX3: Principal Illness Navigation services by certified or trained auxiliary personal under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist; 60 minutes per calendar month, in the following activities:
    - Person-centered assessment
    - Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services
    - Practitioner, Home, and Community-Based Care Coordination
    - Health education- Helping the patient contextualize health education provided by the patient's treatment team with the patient's individual needs, goals, preferences, and SDOH need(s), and educating the patient (and caregiver if applicable) on how to best participate in medical decision-making.
    - Building patient self-advocacy skills, so that the patient can interact with members of the health care team and related community-based services (as needed), in ways that are more likely to promote personalized and effective treatment of their condition.
    - Health care access / health system navigation.
    - Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or treatment goals.

    - Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.
    - Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.
- GXXX4: Principal Illness Navigation services, additional 30 minutes per calendar month

CMS considers a serious, high-risk illness to have the following characteristics:

- Lasts at least three months and carries high-risk of hospitalization, nursing home placemen, acute exacerbation/decompensation, functional decline, or death
- Requires ongoing development, monitoring, or revision of a disease-specific care plan, or frequent adjustment to the medication/treatment regimen
- Examples include cancer, congestive heart failure, and substance use disorder

CMS proposes to require a PIN initiating visit in order to receive payment for PIN services. The billing practitioner must furnish an E/M visit where a treatment plan is established, and PIN services needs are identified. Subsequent PIN services could be performed by auxiliary personnel incident to and under the general supervision of the practitioner who bills for the initiating PIN services visit. PIN services may be billed monthly after a PIN initiating visit.

CMS seeks comment on whether other services, such as an AWV, could serve as an initiating visit for PIN services. CMS believes that practitioners would normally bill an E/M when a problem is identified, and because PIN services must be related to addressing a need that limits a practitioner's ability to treat a specific problem, an initiating E/M visit would ensure PIN services are provided in the context of medically necessary care. CMS notes that if the AWV can serve as an initiating visit for PIN services, CHI services would not necessarily be provided “incident to” as proposed.

CMS proposes that auxiliary staff providing PIN services must be trained to deliver PIN services and meet any state laws or licensure requirements to provide the services incident to the billing practitioner. CMS notes existing certification programs for patient navigators for specific conditions such as cancer and diabetes, in addition to general patient advocates and nurse navigators. CMS also notes that 48 states have certifications for peer support specialists trained in substance use or mental health conditions. CMS proposes that in states without licensure or certification regulations, auxiliary staff must be trained in core competencies established by existing patient navigation and peer support certification programs. CMS seeks comment on whether to set specific requirements for the number of training hours required or specific content or trainer requirements.

CMS proposes that time spent performing PIN services must be documented in the patient’s medical record, including the relevant SDOH needs. CMS proposes to encourage but not require documentation of SDOH needs using ICD-10 Z-codes (Z55-Z65) in the medical record and on the claim.

CMS seeks comment on typical service times, frequency, and duration of PIN services. CMS believes that a substantial portion of PIN services would be delivered in direct contact with the patient. Therefore, CMS is not proposing to require patient consent for PIN services but notes that if comments indicate a substantial portion of PIN services are likely to be furnished without direct patient contact, consent may be required to ensure patients are not surprised to receive a bill for the

services. (CMS also notes that they do not have the statutory authority to waive cost sharing for PIN services.) CMS seeks comment on any potential overlap or duplication with state Medicaid coverage for PIN services delivered to high-risk populations. CMS also seeks comment on any other elements of PIN services that CMS should consider including in the proposed service codes.

Finally, CMS proposes that PIN services may be provided by auxiliary personnel who are external and under contract with the practitioner or practice, as long as the third party is sufficiently clinically integrated—specifically, the auxiliary personnel performing PIN services must communicate with the billing practitioner consistently to ensure services are documented in the medical record, and the billing practitioner is able to evaluate the continuing need for PIN services to address a serious, high-risk condition. Examples of third-party organizations that CMS believes could provide PIN services include not-for-profit community-based organizations such as disability resource centers or other non-profits that apply for grants or contracts with healthcare entities to perform social services. CMS proposes to allow only one practitioner per beneficiary per month to bill for PIN services to prevent fragmented care.

*Proposed PIN Services Valuation*

- GXXX3: CMS proposes a work RVU of 1.00 based on a crosswalk to CPT code 99490 with a service time of 25 minutes
- GXXX4: CMS proposes a work RVU of .70 based on a crosswalk to CPT code 99439 and a work time of 20 minutes

AAFP Comments:

**The AAFP supports allowing the Annual Wellness Visit (AWV) to serve as an initiating visit for PIN services when the AWV is furnished by a physician or billing practitioner, in addition to an E/M visit.** We also support CMS' proposal to limit this code to one billing practitioner per month to ensure care coordination.

The AAFP urges CMS to modify the descriptor code for GXXX1 to read "20 minutes" instead of "60 minutes." 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 for the first hour. Following a similar format may also reduce confusion and help to facilitate adoption. We support CMS' proposal that once initiated, PIN services may be furnished for a year.

We do not anticipate that PIN services will be provided face-to-face every time. A variety of modalities including audio-video, two-way audio, and text-based communications are likely to be used, based on patient needs. Allowing virtual modalities will also improve access to PIN services that are culturally and linguistically appropriate for each patient.

While a portion of PIN services are delivered with direct patient contact, there may be times when care coordination services are provided on behalf of the patient, but not in direct contact with the patient. We believe that PIN services should require consent, and we ask CMS to accept verbal consent (similar to Chronic Care Management consent requirements) to reduce administrative burden. In addition, verbal consent should be required only once per calendar year.

We agree with CMS' proposal to document time spent performing PIN services in the patient's medical record, but similar to the proposal for CHI services, we are concerned that the time spent establishing the infrastructure and connectivity required to partner with community-based organizations may not be reflected in this proposal. We urge CMS to consider the valuation of this code to ensure it reflects the practice expenses of implementing the program.

*(28) Maternity Services (CPT codes 59400, 59410, 59425, 59426, 59430, 59510, 59515, 59610, 59614, 59618, 59622)*

For CY 2024, CMS proposes to update the work RVUs and work times of these "MMM" global codes to reflect any relevant E/M updates associated with their global periods that were finalized in CY 2023.

*AAFP Response*

The AAFP supports CMS' proposal to update the work RVUs and times of the listed codes for maternity services. We encourage CMS to finalize this proposal in the final rule this fall.

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

Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation (G2211)

CMS finalized the G2211 office/outpatient E/M visit complexity add-on code in the CY 2021 MPFS. Congress delayed full implementation of G2211 until January 1, 2024 in order to finance a temporary across-the-board increase to the conversion factor amid the COVID-19 pandemic. CMS notes in this proposed rule that the agency plans to fully implement G2211 in 2024. In response to feedback from the AAFP and other stakeholders, CMS has modified the utilization assumptions for G2211. Based on these revised assumptions, CMS estimates G2211 will be billed with 38 percent of office visits in 2024 and 54 percent of office visits thereafter – a significant reduction from the utilization estimates CMS published when finalizing G2211.

CMS proposes that G2211 would not be payable when the accompanying E/M visit is reported with payment modifier-25, which denotes a separately billable E/M service by the same practitioner furnished on the same day of a procedure or other service.

*AAFP Comment*

**The AAFP strongly supports CMS' plan to fully implement the G2211 add-on code in 2024 and greatly appreciates CMS adjusting its utilization assumptions for the code according to our feedback.** We strongly supported the finalization of G2211 in the CY 2021 MPFS and agree with CMS that it continues to be an important addition to fully account for the additional time, intensity, and practice expense inherent to longitudinal care.

As we noted in a letter to Administrator Brooks-LaSure in February 2023, G2211 is needed to maintain relativity in the Fee Schedule. **Evidence demonstrates the continuous, comprehensive, and coordinated primary care services family physicians provide are more complex and**

**comprehensive than other types of office visits.**[18][19] While the updated office/outpatient E/M codes more appropriately value the care provided during an office visit, the existing processes for creating, describing, and valuing these codes do not account for unique resources borne by primary care and other physicians providing longitudinal, patient-centered care. **Thus, G2211 is needed to appropriately value primary care and other types of longitudinal care relative to other services in the fee schedule.**

In the comments that follow, we provide further detail for these arguments using existing evidence in peer-reviewed studies and other reports, as well as clinical examples provided by family physicians.

**First, we emphasize that the G2211 add-on code is still necessary despite recent updates to the office/outpatient E/M and other codes.**

In proposing and finalizing G2211, CMS noted that office/outpatient visits that are part of longitudinal care are more complex and require additional resources compared to other office visits and thus Medicare payments should account for this. The AAFP wholeheartedly agrees. Primary care office visits are more complex, comprehensive, and impactful than other office visits reported using the same codes. The existing CPT and RUC methodologies for creating, describing, and valuing office/outpatient E/M services do not account for this additional complexity and comprehensiveness, leaving a gap in office-based coding that must be filled by G2211.

A study published in *Healthcare* in 2015 found that family medicine and general internal medicine encounters were more complex compared to other specialties, especially when the duration of visit is considered. This complexity is due to higher quantities of care (i.e., patient complaints and characteristics, as well as treatments prescribed), high diversity in care inputs and outputs, and high complexity density, meaning primary care physicians pack highly complex care into brief visits, ultimately intensifying the overall workload. The authors note this is consistent with primary care physicians' role in managing multiple chronic problems, balancing multiple guidelines, registries, and interdependent disorders, and coordination of care across several clinicians. While the recent revisions and revaluations of the office/outpatient E/M codes better enable primary care physicians to bill for this complexity, they still do not account for many of these unique costs. According to a study in *Annals of Internal Medicine*, the typical primary care physician caring for Medicare patients must coordinate care with 229 other physicians working in 117 practices.[20]

A study published in the *Journal of Internal Medicine* in 2020 found similar results. The authors found significantly higher diagnostic complexity *and* medication complexity in similar-length office visits provided by family physicians, internal medicine physicians, and neurologists compared to visits provided by procedural specialists.[21] The authors note that the complexity of longitudinally managing conditions like hypertension, diabetes, and hypercholesterolemia have increased over time with the

[18] Katerndahl, D; Wood, R; Jaén, CR. Complexity of ambulatory care across disciplines. Healthcare. 2015, Available at: https://doi.org/10.1016/j.hjdsi.2015.02.002.

[19] Goodson, J. D., Shahbazi, S., Rao, K., & Song, Z. (2020). Differences in the Complexity of Office Visits by Physician Specialty: NAMCS 2013-2016. *Journal of general internal medicine*, *35*(6), 1715–1720. https://doi.org/10.1007/s11606-019-05624-0

[20] Pham HH, O'Malley AS, Bach PB, Saiontz-Martinez C, Schrag D. Primary care physicians' links to other physicians through Medicare patients: the scope of care coordination. Ann Intern Med. 2009 Feb 17;150(4):236-42. doi: 10.7326/0003-4819-150-4-200902170-00004. PMID: 19221375; PMCID: PMC3718023.

[21] Goodson JD, Shahbazi S, Rao K, Song Z. Differences in the Complexity of Office Visits by Physician Specialty: NAMCS 2013-2016. *J Gen Intern Med*. 2020;35(6):1715-1720. doi:10.1007/s11606-019-05624-0

advent of new combination therapies for these conditions, each with more and more potential adverse interactions. They further note the increased numbers of diagnostic tests, the aging demographic, administrative burden, and innovative but higher risk interventions continue to add to this complexity.

As we noted in our February letter to Administrator Brooks-LaSure, the existing processes for creating and valuing codes are not designed to account for this kind of variation. CPT does not capture some types of variation in visit intensity while the RUC surveys and values codes based on the "typical" patient across more than 50 specialty societies. The studies discussed above and the experiences detailed herein by family physicians clearly demonstrate that there is significantly higher complexity and intensity involved in primary care and other longitudinal office visits for which the CPT and RUC processes are not designed to account. Thus, despite improvements to the office/outpatient E/M codes made by CPT, RUC, and CMS in recent years, the updated codes still fail to capture the full time, intensity, and practice expense of primary care office visits.

**Second, we demonstrate how G2211 is distinct from other codes in the MPFS and therefore the additional resources it is meant to account for are not separately reportable using other codes.**

Principal care management (PCM) codes are for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/ decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care. PCM services can only be billed in 30-minute intervals for services provided by a physician or other QHP per calendar month, or alternatively by clinical staff. We note that PCM codes are designed to account for care management and coordination over time as opposed to the additional complexity and resources involved in furnishing an office/outpatient E/M visit.

Further, primary care physicians may provide care management and coordination services for a condition that is first addressed in an office/outpatient E/M visit that will not last as long as 3 months or would not reasonably be expected to result in risk of hospitalization. For example, COVID-19 generally does not last three months but, particularly for patients with comorbidities, may require significant acute management, care coordination, and follow-up within a given month. Alternatively, physicians, QHPs, and/or their staff may provide care coordination and management services for a condition that does meet these conditions – but the time may not reach the required 30-minute interval. Thus, care coordination over the course of a month that includes 20-minutes of consulting with other physicians and modifying medications to address an acute exacerbation of hypertension would not meet the requirements for billing PCM. Despite the inability to bill for these services, ongoing coordination and medication management is a standard part of comprehensive primary care.

The distinctions and limitations of Chronic Care Management (CCM) and complex CCM are similar. Again, these codes are meant to account for services over time for the management of two or more chronic conditions as opposed to the resources involved in furnishing an office/outpatient E/M encounter. Providing longitudinal care to a Medicare patient with multiple chronic conditions will often involve care coordination and management, test result review, updating the medical record, and other services that do not always meet the 20-minute threshold for billing CCM. Further, many primary care patients will have multiple conditions that are not expected to last 12 months or until the death of the

patient or puts them at significant risk of death, acute exacerbation, etc. Nonetheless, optimal management of these conditions may require care coordination and management, medication adjustments, and ongoing communication with the patient, caregivers, or other clinicians.

Transitional Care Management (TCM) codes are limited to patients experiencing a discharge from the hospital/facility setting and focus on care management for 30 days following a discharge rather than the time, intensity, and practice expense involved in furnishing services to patients on an ongoing basis. These codes require physicians to furnish certain services (like a face-to-face visit, medication reconciliation, review of tests) within a defined period after the patient is discharged. Many patients may have conditions that result in a facility stay and need to be monitored on an ongoing basis thereafter, but some patients will not connect with their primary care physician in time to furnish TCM services.
In comparison, as CMS also noted in the CY 2021 MPFS final rule, code G2211 reflects the time, intensity, and practice expense when primary care physicians and their teams furnish services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single-high risk disease) and to address the majority of patients' health care needs with consistency and continuity over longer periods of time. Further, as noted, G2211 is intended to address the additional complexity of certain office visits rather than care management over time.

Prolonged services codes are available when a clinician spends additional time beyond that valued in the office/outpatient E/M code. However, family physicians often provide complex office visits without requiring additional time.[22] Their training enables them to address a significant number of diagnoses, risk factors, and symptoms in a short period of time. Further, when prolonged services codes are billed, they (like the office/outpatient E/M codes discussed above) are not valued to include the additional intensity inherent to primary care. Thus, the availability of the prolonged services codes does not obviate the need for G2211.

**Third, we will demonstrate that G2211 is resource-based by detailing the additional time, intensity, and practice expense that is unique to primary care and other office visits that are part of longitudinal care.**

The MPFS uses the resource-based relative value scale (RBRVS), which is based on the principle that payments for services should vary with the resource costs of providing those services. CMS is charged with maintaining the relativity of the MPFS, ensuring that payment for services that require more resources to furnish are higher than for services that require fewer services. As noted above, the current valuation of office visits does not account for the unique resources in terms of physician work that primary care physicians bring to encounters with their patients. Thus, G2211 is still needed to better account for the unique costs of providing continuous care, like the longitudinal primary care services regularly provided by family physicians. As CMS noted in the CY 2023 MPFS, the existing E/M code sets are designed to be used by all types of clinicians and do not include payment for ongoing care coordination and follow-up. Therefore, the E/M code sets fail to capture the relativity of E/M services that are part of ongoing, continuous care. Far from not being resource-based, G2211 will advance the relativity of the MPFS and better account for the resource costs of providing high-quality, longitudinal primary care.

[22] Katerndahl, D; Wood, R; Jaén, CR. Complexity of ambulatory care across disciplines. Healthcare. 2015, Available at: https://doi.org/10.1016/j.hjdsi.2015.02.002.

Primary care physicians approach patient encounters from a holistic point of view, evaluating how each condition and resulting treatment, new symptom or challenge, unmet social needs, and recommended preventive services interact and impact a patient's overall wellbeing. This involves balancing clinical recommendations from the United States Preventive Services Task Force, the AAFP, the American College of Physicians or the American Academy of Pediatrics (depending on the patient's age), the American Psychiatric Association, the American College of Obstetricians and Gynecologists (when relevant), the Advisory Committee on Immunization Practices, and other clinical guidelines and evidence (such as those published by the Centers for Disease Control and Prevention). It also involves an evaluation of biochemical processes and drug interactions across several medications. In recent years, primary care physicians spend extensive time counseling patients about new and upcoming vaccines, like those for COVID-19 or respiratory syncytial virus. It further involves evaluation of lab and imaging results sent by various members of the care team, reports from home health aides or nurses, and immunization registries. Primary care physicians evaluate the patients' understanding of their diseases and treatments and discuss behaviors or habits that could be impacting their wellbeing. In the same encounter, primary care physicians provide several preventive screenings, including for cancer and behavioral health and substance use disorders. They provide counseling and brief referral based on the results of those screenings, including help connecting patients to facilities providing mammograms, colonoscopies, or behavioral health diagnoses. Given that most Medicare beneficiaries struggle to afford their health care services and medications, many primary care physicians spend time on pharmacy discount websites alongside their patients to help them get lower prices on their medications. Most orders for new screening or diagnostic tests will require prior authorization, in the case of patients with primary or secondary insurance through a plan administered by a health insurance company. All of these findings and processes require documentation in the medical record and updates to other health team members, like a patient's endocrinologist, cardiologist, or psychiatrist.

We believe clinical examples from primary care physicians may be helpful in illustrating the resource costs inherent to primary care office/outpatient visits that are not accounted for in existing office/outpatient E/M codes.

<u>Example one, established patient</u>:

A 64-year-old female with known history of myocardial infarction, presents with headaches and pain on top of head after spending day in the sun. The patient describes hyperparethesias (sensitivity to touch and other stimulation), no rash, no significant sunburn, very painful on top of head down left side, no neurological symptoms. The physician reviews her immunization history, and it appears the patient has only had one shingles vaccine, also reports daughter getting married in a few weeks, under significantly increased stress due to this. The patient reports being very tight in her shoulders and neck. When asked, the patient reports she does not have chest pain. She is taking meds as prescribed, saw cardiology recently, has planned echocardiogram in 5 months before return to cardiologist. The patient has not recently had a mammogram and will be given an order for one. After detailed review of symptoms and exam, diagnosis remains unclear. The physician advises this looks like shingles without rash but is not completely sure. The physician and patient review in detail what shingles is and how it typically presents and who could be at risk for exposure in the house if this is shingles. The physician reviews the need for a second shingles vaccine (after episode resolves), in addition to fall flu and COVID-19 vaccines, reminded when due for an annual wellness visit. The physician prescribes Medrol dose pack and muscle relievers. Explained what to do if symptoms should become worse (including new neurological symptoms) and asks her to check back in with the

physician on the portal after taking meds to see if improving; could consider brain scan if not. The physician conducts a number of preventive health screenings and the patient has a positive screen for generalized anxiety disorder so the physician provides information on counseling, deep breathing exercises, and other options for management, including potentially a warm hand off to the psychologist in the practice. (We recognize general behavioral health integration is separately reportable.) The physician also provides counseling on healthy habits like exercise, healthy eating, and sleeping and notes the importance for maintaining the patient's cardiac health. The physician provides an update or otherwise coordinates with the patient's cardiologist and any other relevant members of the care team.

Example two, establish patient:

A 75-year-old established male patient with history of hypertension, diabetes, and coronary artery disease presents with complaint of urinary frequency (often up four times per night) and a change in urinary stream. The primary care physician reviews the patient's hemoglobin A1c to ensure his diabetes is not contributing to urinary frequency. The primary care physician also reviews the patient's blood pressure history and current medications to determine if the patient's diuretic might be causing urinary frequency. The physician reviews results of the patient's last prostate-specific antigen test before ordering a new one (if the patient has not had one in the last year). Then the physician evaluates the patient's sleep habits and counsels on limiting fluids before sleep and other factors that contribute to poor sleep and nocturia. The physician also reviews options for treatment and conducts shared decision making to determine whether starting a medication for urinary frequency is the best option. If the patient opts for the medication, the physician prescribes Flomax and discuss the possible side effects to watch for as they relate to the patient's other medications. The primary care physician discusses any screening results, like positive screens for behavioral health challenges, unhealthy substance use, and unmet social needs. They would discuss possible options for addressing these challenges and provide counseling on healthy habits as needed, including exercise and balanced diet. The physician would review the patient's immunization history and counsel on any outstanding immunizations, as well as provide counseling on the need for new vaccines this fall, to include RSV, flu, and COVID. The physician will provide an update or otherwise coordinate with other members of the patients care team, including relevant specialists, home health aids, or family caregivers. The physician would follow-up with the patient on whether the new treatment is helping with the nighttime urination and discuss any side effects.

In both of these examples, the primary care physician is providing a number of services that are often not provided by sub-specialists billing for the same office/outpatient E/M encounter to address the same problem. Specialists generally treat the problem that the patient is presenting with, orders necessary tests, and conduct shared decision making regarding treatments. For the 75-year old male patient, we expect a specialist would: order a PSA, counsel on limiting fluids before sleep, provide options for treatment, and prescribe Flomax with directions to follow-up if it is not helping.

By contrast, it is evident that the primary care physician in the examples is addressing a new problem in the context of the patient's overall health, medical history, and social support system. The physician considers how existing conditions and related treatments could be causing or worsening new symptoms and orders follow-up tests with these factors in mind. The physician also provides counseling on the need to stay up to date on immunizations (and would provide them when appropriate) and healthy habits. The primary care physician conducts a number of preventive health screenings and addresses positive results with brief counseling and referral when appropriate. Finally, the primary care physician provides updates and coordinates with other relevant members of

the patient's care team. All of these additional steps and considerations are what make primary care E/M visits more complex and why G2211 is needed to better account for this additional complexity.

Ironically, those who are most opposed to implementation of G2211 are some of the most frequent providers of services demonstrated to not be resource-based. Under the MPFS, surgical services are billed and paid for using global codes that are valued to include most parts of a surgical episode of care. Depending on the service, some include preoperative appointments, the surgery itself, and various types of postoperative care. The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 required CMS to collect data on how best to value global packages and to reassess every four years the continued need for this data collection.

As MACRA required, CMS began data collection in 2017, making 2023 the seventh year of data collection. **As CMS' contractor, RAND, has reported, the data clearly show that the reported number of visits does not match what's expected based on the assumptions underlying the valuation of the 10 and 90-day global procedures. Thus, CMS continues to be concerned that its current valuations of the global packages reflect certain E/M visits that are not typically furnished in the global period. In other words, there is strong evidence suggesting that the current RVUs for global packages are inaccurate in terms of the number and level of post-procedure visits involved and who is providing them when they do occur.**

In their most recent report, RAND outlined an alternative methodology for valuing the global surgical packages and estimated that it would **result in more than $2.5 billion being returned to the Medicare conversion factor.**[23] The AAFP has and will continue to encourage CMS to address the apparent overvaluation of these surgical packages given the negative impact of these overpayments on primary care and other non-surgical services under the MPFS.

The zero-sum, budget-neutral nature of the fee schedule ensures any overvaluation of one part, such as the 10 and 90-day global packages, undervalues the remainder of the fee schedule, including primary care. The continued potential overvaluing of the 10 and 90- day global packages contributes to the MPFS' underinvestment in primary care, which G2211 only partially addresses. Concerns about the resource-based nature of the fee schedule are more appropriately directed at 10- and 90-day global surgical services than G2211.

**Lastly, we emphasize that the complexity and comprehensiveness of primary care are undervalued in the current E/M system but invaluable to the nation's health and essential to achieving CMS' strategic goals. Primary care positively impacts health equity, access to care, and health outcomes, and it is the only part of the health system that has repeatedly demonstrated these attributes.**

- The seminal research led by Barbara Starfield validated that those individuals with access to primary care have better health outcomes and lower mortality rates than those who do not.[24]

[23] RAND Corporation. Using Claims-Based Estimates of Post-Operative Visits to Revalue Procedures with 10- and 90-Day Global Periods Updated Results Using Calendar Year 2019 Data. 2021. Available at: https://www.cms.gov/files/document/rand-revaluation-report-2021.pdf

[24] Starfield B, Shi L, Macinko J. Contribution of primary care to health systems and health. Milbank Q. 2005;83(3):457-502. doi: 10.1111/j.1468-0009.2005.00409.x. PMID: 16202000; PMCID: PMC2690145.

- A subsequent study found that the number of primary care physicians in an area is associated with lower mortality rates at the population level.[25] No other specialties studied in these articles were found to be associated with lower mortality on a population level. Two other studies found that better continuity in primary care can reduce mortality, health care expenditures, and hospitalizations.[26,27]
- Primary care has also been shown to improve access to care for underserved populations and reduce health disparities.[28]

Due to the robust evidence supporting the effectiveness of primary care, the National Academies of Science, Engineering, and Medicine recently urged policymakers to significantly increase investment in primary care, noting that primary care is the only health care component for which increased supply is associated with more equitable health outcomes.[29] Taking this step to more appropriately value primary care visits will help stabilize the primary care workforce, especially community-based primary care practices Medicare beneficiaries rely on for their care. In turn, this will help prevent practice closures and consolidation, which can negatively impact beneficiary access, care quality, and affordability.[30]

Supporting community-based primary care practices in delivering high-value, person-centered care will improve beneficiaries' access to care in their own communities. Although the results are mixed, some evidence from the Affordable Care Act's Medicaid primary care fee bump indicates that increasing payment for primary care services can increase appointment availability and improve health outcomes.[31] Low-income patients and their physicians have also reported that low payment rates lead to shorter, inadequate visit times. Implementing G2211 has the potential to reduce appointment wait times and enable physicians to spend more time with their Medicare patients.

As we noted at the beginning of this letter and in our comments on the CY 2023 MPFS, primary care practices are struggling to transition into value-based care models at current fee-for-service (FFS) payment levels. Successful participation in alternative payment models (APMs) like Medicare Shared

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[25] Basu S, Berkowitz SA, Phillips RL, Bitton A, Landon BE, Phillips RS. Association of Primary Care Physician Supply With Population Mortality in the United States, 2005-2015. JAMA Intern Med. 2019 Apr 1;179(4):506-514. doi: 10.1001/jamainternmed.2018.7624. PMID: 30776056; PMCID: PMC6450307.

[26] Baker R, Freeman GK, Haggerty JL, Bankart MJ, Nockels KH. Primary medical care continuity and patient mortality: a systematic review. Br J Gen Pract. 2020 Aug 27;70(698):e600-e611. doi: 10.3399/bjgp20X712289. PMID: 32784220; PMCID: PMC7425204.

[27] Bazemore A, Petterson S, Peterson LE, Bruno R, Chung Y, Phillips RL Jr. Higher Primary Care Physician Continuity is Associated With Lower Costs and Hospitalizations. Ann Fam Med. 2018 Nov;16(6):492-497. doi: 10.1370/afm.2308. PMID: 30420363; PMCID: PMC6231930.

[28] Starfield B, Shi L, Macinko J. Contribution of primary care to health systems and health. Milbank Q. 2005;83(3):457-502. doi: 10.1111/j.1468-0009.2005.00409.x. PMID: 16202000; PMCID: PMC2690145.

[29] National Academies of Sciences, Engineering, and Medicine. 2021. Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care. Washington, DC: The National Academies Press. https://doi.org/10.17226/25983.

[30] Ho, V., Metcalfe, L., Vu, L. *et al.* Annual Spending per Patient and Quality in Hospital-Owned Versus Physician-Owned Organizations: an Observational Study. *J GEN INTERN MED* **35**, 649–655 (2020). https://doi.org/10.1007/s11606-019-05312-z

[31] Candon M, Zuckerman S, Wissoker D, et al. Declining Medicaid Fees and Primary Care Appointment Availability for New Medicaid Patients. *JAMA Intern Med.* 2018;178(1):145–146. doi:10.1001/jamainternmed.2017.6302

Savings Program Accountable Care Organizations (ACOs) or Primary Care First (PCF) require significant upfront investment in technology and staff. Primary care practices struggling to keep their doors open cannot possibly make these investments. By more accurately paying for the unique costs associated with providing longitudinal primary care, implementing G2211 will help these practices invest in the staff and tools they need to transition to an APM. Given that most APMs are built on a FFS chassis, implementing G2211 will also ensure payment rates in APMs are better supporting the provision of high-quality primary care.

**Taken together, the above conclusions clearly demonstrate there is a gap in current MPFS coding and payment for office visits, which G2211 is needed to help fill. The full resources of providing longitudinal, whole-person primary care are not accounted for under current billing and coding rules. This is despite significant evidence that primary care is highly effective at improving patient and population health outcomes and reducing overall health care spending.[32][33][34][35] In other words, G2211 better supports the provision of services Medicare beneficiaries benefit from most and will strengthen the program by advancing timely access to those services. Therefore, the resource-based relative value mandates this gap be filled by G2211 and doing so is consistent with CMS' mission.**

*Utilization Estimates*

The AAFP commends CMS for modifying its utilization estimates in response to our feedback. We believe the revised estimates are more realistic and better account for both the historically slow uptake of new codes, as well as the varying relationships many physicians and other clinicians have with patients. We continue to believe utilization in the first year is likely to be less than CMS estimates, given potential uncertainty regarding full implementation of the add-on code and the time it takes for CMS, Medicare Administrative Contractors (MACs), and physician practices to communicate billing changes, produce sub-regulatory guidance, and modify administrative workflows. We noted in our previous letter that physicians are wary of being audited by CMS, MACs, and others, and thus we continue to believe use of the G2211 code will be both slow and conservative in the first years after implementation. Acknowledging the impact of the budget neutrality adjustment that results from the implementation of G2211, the AAFP would support additional revisions to the utilization assumptions as CMS deems necessary.

*Modifier -25 Policy*

The AAFP supports CMS' proposal to disallow payments for G2211 when it is billed alongside an E/M visit and a minor procedure provided at the same encounter. Like CMS, we believe office/outpatient E/M services provided in conjunction with minor procedures have

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[32] National Academies of Sciences, Engineering, and Medicine. 2021. Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care. Washington, DC: The National Academies Press. https://doi.org/10.17226/25983.

[33] Basu S, Berkowitz SA, Phillips RL, Bitton A, Landon BE, Phillips RS. Association of Primary Care Physician Supply With Population Mortality in the United States, 2005-2015. JAMA Intern Med. 2019 Apr 1;179(4):506-514. doi: 10.1001/jamainternmed.2018.7624. PMID: 30776056; PMCID: PMC6450307.

[34] Baker R, Freeman GK, Haggerty JL, Bankart MJ, Nockels KH. Primary medical care continuity and patient mortality: a systematic review. Br J Gen Pract. 2020 Aug 27;70(698):e600-e611. doi: 10.3399/bjgp20X712289. PMID: 32784220; PMCID: PMC7425204.

[35] Bazemore A, Petterson S, Peterson LE, Bruno R, Chung Y, Phillips RL Jr. Higher Primary Care Physician Continuity is Associated With Lower Costs and Hospitalizations. Ann Fam Med. 2018 Nov;16(6):492-497. doi: 10.1370/afm.2308. PMID: 30420363; PMCID: PMC6231930.

resources that are sufficiently distinct from those associated with furnishing stand-alone O/O E/M visits to warrant different payment policy. However, we believe CMS needs a more nuanced payment policy than simply prohibiting the reporting of G2211 anytime the O/O E/M visit is reported with modifier –25. Specifically, there should be an exception for E/M services billed on the same day as a Medicare Annual Wellness Visit (AWV), since these services billed together are indicative of a longitudinal relationship and the additional inherent complexity that the AAFP and CMS agree G2211 is needed to account for.

The AAFP urges CMS to allow physicians billing a Medicare AWV on the same day as an E/M visit (and therefore with a -25 modifier) to also be paid for the G2211 add-on code. We believe that the E/M services provided on the same day as an AWV will include the time, intensity, and practice expense that CMS created G2211 to account for. When a physician performs an E/M visit on the same day as an AWV, it is because the patient presents with at least one problem that requires evaluation and management in addition to the services included in an AWV. In these situations, the physician is addressing one or more acute or chronic concerns in the context of the patient's overall health, including as those concerns relate to other chronic conditions and treatments, social needs, and mental and behavioral health. The evaluation and management of this problem(s) may involve additional testing, follow-up, and coordination with other members of the patient's care team, such as a sub-specialist, mental health practitioner, or pharmacist. While the AWV includes updating of a patient's risk factors, performing certain screenings, and updated advanced care plans, it does not include the work associated with comprehensively addressing problems in coordination with and relation to the patient's overall health and existing problems. In these circumstances, we believe G2211 is still needed to account for additional time, intensity, and practice expense, and therefore clinicians should be able to be paid for it accordingly.

<u>Request for Comment About Evaluating E/M Services More Regularly and Comprehensively</u>

CMS has received suggestions and recommendations outside of the rulemaking process that it consider using a different approach for valuing services, one that relies on research and data other than the AMA RUC's specialty-specific valuation recommendations. In response, CMS asks a series of questions about the process used to value physician services and how it can potentially move forward with reforms to the way it establishes values for E/M and other services. The CMS questions, and corresponding AAFP responses, follow.

*a. Do the existing E/M HCPCS codes accurately define the full range of E/M services with appropriate gradations for intensity of services?*

No. The full set of E/M codes is relatively small, given the wide variety of encounters they are meant to describe. For instance, there are only nine CPT codes to describe office/outpatient E/M services, despite the fact office/outpatient E/M services are done hundreds of millions of times by a multiplicity of specialties. In comparison, there are at least 23 CPT codes (44388-44408 and 45378-45398) that describe colonoscopy. O/O E/M encounters represent a much wider and more diverse range of diagnoses and services than does colonoscopy. The fact is that CPT is better at describing discrete procedures than E/M services, especially E/M services that represent continuous, comprehensive primary care.

*b. Are the methods used by the RUC and CMS appropriate to accurately value E/M and other HCPCS codes?*

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, there are reasons to question whether the methods and data used by the RUC and CMS remain appropriate to accurately value 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. That said, it's worth noting that what CMS and the RUC use now is not exactly what Dr. Hsiao and his colleagues did or recommended to CMS. It may be worth exploring/identifying how the current system deviates from RBRVS as initially envisioned and whether returning to RBRVS's roots has any value.

Beyond that, as participants in the RUC, we witness the flaws in the process and data used. For instance, again as noted above in our comments on O/O E/M visit complexity add-on implementation (G2211), the RUC is 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 than for more specific procedural service vignettes.

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 under-values 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 RUC's 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.

The flaws in the RUC process and the questionable accuracy of the RUC's recommendations to CMS are nicely summarized in 2021 National Academies of Science, Engineering, and Medicine (NASEM) report entitled, *Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care.* (See "The Role of the Relative Value Scale Update Committee" beginning on page 290 of that report.) The RUC is entitled to use whatever methods and data it deems appropriate in recommending values to CMS. The more critical question is whether CMS's almost exclusive reliance on the RUC is appropriate to accurately value codes under the fee schedule. In the current proposed rule, CMS offers to adopt 91% of the RUC's recommendations.

After more than 30 years, **we recommend CMS invest resources in additional, supplemental sources of information, especially physician time, rather than relying almost exclusively on the RUC.** We believe there is value in seeking the opinion of a different, additional set of independent experts that have ready access to Medicare claims and other data sets to enable these experts to make supplemental recommendations to CMS. **Establishing another panel of experts would**

**enable CMS to ensure that the experience and opinion of different types of clinicians, as well as beneficiaries, family caregivers, federal agency staff, and other stakeholders are more robustly represented during the development of regulations and establishment of relative values for different services. 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 this expert panel with access to helpful data and analyses will be key in driving its success. 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 contributes to an overreliance on the RUC. This signals that CMS should fill the gap by appointing or otherwise using a separate independent, expert panel in addition to the input of the RUC.

Over the years, multiple individuals and entities have offered suggestions in this regard. For example, in section II.J.5 of this proposed rule, CMS references a 2016 report by the Urban Institute entitled *Collecting Empirical Physician Time Data*. The NASEM report referenced above also speaks to this:

> However, the committee sees no regulatory or institutional barrier to CMS establishing its own parallel capacity to independently value physician services that aligns better with its stated organizational goals to move toward value-based, accountable payment and away from the misvalued PFS. In fact, it is hard to imagine that it could do so in the absence of an independent valuing mechanism within or external to the agency, such as the Medicare Payment Advisory Commission (MedPAC). Establishing such a capacity will require allocating a relatively modest level of resources and staff and would not prevent the RUC from continuing to make its recommendations to CMS and other entities. However, by having an additional resource to evaluate and compare its own estimates with that of the RUC and others, CMS would be able to more adequately and fairly price primary care services in a way that accounts for their complexity and value to patients and society. (Page 294)

*c. Are the current Non-E/M HCPCS codes accurately defined?*

As we noted in our comments on the G2211 add-on code, data collection efforts conducted by RAND have found that the 10- and 90-day global surgery codes are overvalued. RAND found "that the number of visits actually performed was lower than CMS's assumptions when setting payment rates" for these codes. Due to the budget neutral, zero-sum nature of the MPFS, overpayment for these services can distort incentives to provide services, result in greater beneficiary cost-sharing, and contribute to the undervaluation of primary care and other services in the MPFS. Given the available data and significant downstream impacts of the overvaluation of these services, **the AAFP strongly recommends that CMS revalue the global surgical codes.** RAND's most recent report puts forth an option for revaluing the codes based on the number of pre- and post-operative visits that are actually conducted, and estimates adopting this approach would put $2.5 billion dollars back into the Medicare conversion factor.[36]

*d. Are the methods used by the RUC and CMS appropriate to accurately value the non-E/M codes?*

[36] Using Claims-Based Estimates of Post-Operative Visits to Revalue Procedures with 10- and 90-Day Global Periods. RAND Corporation. Available at: https://www.cms.gov/files/document/rand-revaluation-report-2021.pdf

The Medicare Physician Fee Schedule is a resource-based relative value scale, and in general, all services paid under that fee schedule are subjected to the same methodology. The fact this question distinguishes “non-E/M services” from “E/M services” is problematic in that as all services are valued using essentially the same methodology. That means the flaws in the data and process referenced in response question (b) above also apply here.

*e. What are the consequences if services described by HCPCS codes are not accurately defined?*

If not accurately defined, services may be:

- Miscoded/misreported
- Misvalued
- Over or underreported

We note there are HCPCS I (CPT) and HCPCS II (CMS) codes. HCPCS II codes are generally used to report services, supplies, and services not included in CPT codes. However, there are some instances where CMS creates codes that almost mirror CPT codes for the purpose of changing the reporting requirements. For example, add-on code 99417 for prolonged E/M services was added to the CPT 2021 code set, effective January 1, 2021. In lieu of covering code 99417 for Medicare, CMS elected to create similar code G2212. For CPT 2023, code 99418 was created for prolonged services in the inpatient setting. However, in the 2023 Final Rule, CMS affirmed that CPT codes for prolonged services will not be payable and created G0316 to report prolonged inpatient or observation care services, G0317 to report prolonged nursing facility services, and G0318 for prolonged home or residence services. The result of these differing coding methodologies for reporting prolonged services further deepens the administrative burden for health care professionals and increases the potential for improper coding.

It is imperative that physicians have one set of clear codes and guidelines aligned across payers to report medical procedures and services. If other HCPCS II codes are created that are not accurately defined, it could lead to improper reporting of medical services by Medicare and other insurers. For these clearly outlined reasons, code descriptors should be properly vetted via an established, consistent process that includes physician and QHP input when developing the code to assure that no two codes are alike. Moreover, codes should be consistent without variation to increase clarity for all payers. It is critical to ensure consistency and the validity of expertly defined medical codes by aligning CMS coding policy and CPT coding requirements.

*f. What are the consequences if services described by HCPCS codes are not accurately valued?*

As the NASEM report observed, “Inaccuracies in relative pricing along with CMS acceptance of most RUC recommendations have contributed to the differences in compensation across specialties, the distribution of physicians across specialties, inefficient distortions in use, and inadequate beneficiary access to undervalued services….” (Page 291). Thus, if services are not accurately valued, spending may not go where it is most needed and most useful and the medical workforce may be skewed in ways that negatively impact access, equity, etc. In fact, evidence indicates that the passive devaluation of E/M services over time contributes to lower compensation rates for primary care

physicians, resulting in declined interest in pursuing primary care and exacerbates physician shortages in rural and other underserved areas.[37][38]

*g. Should CMS consider valuation changes to other codes similar to the approach in section II.J.5. of this rule?*

Under section II.J.5, CMS would apply an adjustment to the work RVUs for the psychotherapy codes payable under the PFS. CMS would base this adjustment on the difference in total work RVUs for office/outpatient E/M visit codes (CPT codes 99202-99205 and 99211-99215) billed with the proposed inherent complexity add-on code (HCPCS code G2211) compared to the total work RVUs for visits that are not billed with the inherent complexity add-on code. This would result in an approximate upward adjustment of 19.1 percent for work RVUs for these psychotherapy services. CMS proposes to implement the adjustment over a 4-year transition.

It is understandable that policymakers wish to improve access to certain services such as behavioral healthcare and address related shortages in workforce capacity. However, access and shortage issues may be better addressed through properly funded legislative solutions such as transparent bonus payments, grants, loan forgiveness or other programs.

To this point, the United States in general, and Medicare in particular, underinvests in primary care, leading to a shortage of primary care physicians and access and equity issues. As a matter of public policy, Medicare needs to invest more in primary care, and FFS is not the best way to do so. As noted repeatedly throughout our comments, getting primary care physicians out of FFS and into alternative payment models with predictable, prospective payment is essential to increasing our nation's investment in primary care. However, given that most value-based payment models are based on a FFS chassis and many physicians have not yet transitioned out of FFS, accurately valuing primary care within the MPFS is also a vital step toward achieving CMS' policy goals.

Beyond the explicitly numerated questions above, CMS asks:

*We are particularly interested in ways that CMS could potentially improve processes and methodologies, and we request that commenters provide specific recommendations on ways that we can improve data collection and to make better evidence-based and more accurate payments for E/M and other services.*

As noted, we recommend that CMS consider using a supplemental independent panel of experts to provide recommendations on evidence-based and accurate valuation of services under the MPFS. A more formalized process for submitting data to CMS (including publicizing how, where, and by when to submit available data) could also be helpful to stakeholders who are not as regularly engaged with the staff who draft the MPFS proposed and final rules to share any data they do have access to.

*We are particularly interested in recommendations on ways that we can make more timely improvements to our methodologies to reflect changes in the Medicare population, treatment guidelines and new technologies that represent standards of care.*

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[37] Linzer M, Bitton A, Tu SP, et al. The End of the 15-20 Minute Primary Care Visit. *J Gen Intern Med*. 2015;30(11):1584-1586. doi:10.1007/s11606-015-3341-3

[38] Berenson and Rich, "US Approaches to Physician Payment." 2010. Available at: https://pubmed.ncbi.nlm.nih.gov/20467910/.

**CMS may 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.

*We are also interested in recommendations that would ensure that data collection from, and documentation requirements for, physician practices are as least burdensome as possible while also maintaining strong program integrity requirements.*

The AAFP supports efforts to address the significant administrative burden that plagues physicians and other health care professionals. Physicians and other health care professionals have limited time and other resources to participate in data collection efforts.

*Finally, we are also interested in whether commenters believe that the current AMA RUC is the entity that is best positioned to provide -recommendations to CMS on resource inputs for work and PE (Practice Expense) valuations, as well as how to establish values for E/M and other physicians' services; or if another independent entity would better serve CMS and interested parties in providing these recommendations.*

The AMA's RUC certainly has a role to play in advising on resource inputs. The question remains whether an additional, independent entity could contribute to the important work that CMS undertakes to ensure that physician services are valued appropriately in the Medicare program. CMS should not view the RUC as the sole source of knowledge and expertise in this regard. In addition, participants of this body should include more primary care physicians to accurately reflect the proportion of care that they provide the Medicare population. We encourage CMS to invest in additional, adjunctive sources to ensure recommendations informing its decisions are well-informed, balanced, and reflective of the evolving environment.

*Split (or Shared) Visits*

CMS proposes to further delay the implementation of its definition of the "substantive portion" of a split (or shared) visit in the facility setting as more than half of the total time through at least December 31, 2024, for the same reasons outlined in the CY 2023 PFS final rule. To determine who bills the visit, CMS proposes to maintain the current definition of "substantive portion" for CY 2024; that definition allows for use of either one of the three key components (history, exam, or MDM) or more than half of the total time spent.

*AAFP Response*

**The AAFP supports CMS's proposal to effectively maintain its current definition of "substantive portion" of a split (or shared) visit through December 31, 2024.** Some of our members have raised concerns with the alternative definition previously proposed by CMS. They fear defining "substantive portion" based on time alone will be counterproductive to the physician-led, team-based care practiced in many facilities. They also fear redefining "substantive portion" as CMS has otherwise proposed may pit physicians and non-physician practitioners against one another,

leading to one of two scenarios: either the physician is not being recognized for their role in patient care, or the non-physician practitioner is not able to practice to the top of their license. Both of these scenarios are sub-optimal and reduce the benefit provided to the patient by way of collaborative care. We appreciate CMS giving stakeholders more time to address these concerns with CMS in 2024.

Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professional, and DSMT Telehealth Services (section II.I.)

CMS proposes to allow one hour of in-person training for initial and/or follow-up insulin injection training, when required for insulin dependent beneficiaries, to be provided via telehealth. The AAFP agrees with CMS that insulin injection training may be appropriately provided via telehealth for many patients and urges CMS to finalize this proposal.

Advancing Access to Behavioral Health

*Increase Valuation of Psychotherapy Codes*

CMS is proposing to apply an adjustment to the work RVUs for psychotherapy services of an approximately 19.1 percent increase. This increase would apply to specific CPT codes considered psychotherapy, psychotherapy for crisis, psychoanalysis, family psychotherapy, group psychotherapy codes. CMS is proposing to implement this change over 4 years to allow for a more gradual adjustment.

*AAFP Comments:*

The AAFP supports and appreciates the 19.1 percent increase in work values for psychotherapy services. Increased payment that reflects the time and resources of these services will ensure primary care practices can sustain integrated behavioral health care. The AAFP strongly supports the four-year implementation timeframe for these provisions are necessary and should be finalized to ensure physician practices are not adversely impacted because of budget neutrality challenges.

*Crisis Services*

As required by the in the CAA, CMS proposes to establish new HCPCS G-codes (GPFC1 and GPFC2) for crisis services furnished in any non-facility place of service other than the physician's office setting. CMS proposes to use the existing definition of the term "home" for implementation of these codes to broadly include temporary lodging, such as hotels and homeless shelters, and other sites near the home used by the patient for privacy during mental health visits.

*AAFP Comments:*

Primary care physicians and behavioral health providers work to ensure appropriate management of mental health concerns so that a patient does not reach a point of crisis. However, the shortage of primary care physicians and behavioral health providers, as well as exacerbated mental health conditions, has led to an immediate need for investments into and improvements of our crisis response system. The AAFP applauded Congress and the administration for recently implementing the 9-8-8 dialing code to route callers to the National Suicide Prevention Lifeline. Similarly, the AAFP applauds CMS for implementing new codes and flexibilities for crisis services.

*Payment for services by Marriage and Family Therapists, Mental Health Councilors, and Addiction Councilors*

CMS proposes to include Marriage and Family Therapists (MFTs), mental health councilors (MHCs), and addiction councilors who meet the same qualifications as MHCs to bill for Medicare services, as required by the CAA of 2023. CMS will update behavioral health integration codes to allow for billing by MFTs and MHCs. This means MFTs and MHCs will be eligible to provide services to Medicare beneficiaries and receive reimbursement from Medicare.

*AAFP comments:*

The AAFP supports this proposal and appreciates CMS' work to improve access to behavioral health care. Behavioral health integration in primary care settings increases access to mental health care, decreases feelings of stigma for patients, and saves money for practices, payers, and patients.[39] Family physicians regularly work with psychiatrists, psychologists, licensed clinical social workers, MFTs, MHCs, and other behavioral health professionals to provide behavioral health care.[40, 41] MFTs and MHCs are valuable members of physician-led integrated care teams. As such, this proposal will ensure family physicians and other primary care physicians can utilize a care team that best fits the needs of their practice and patient population.

*Comment Solicitation on Expanding Behavioral Health Integration:*

The AAFP supports CMS' commitment to improving access to behavioral health care through this proposed rule and in its overall strategic plan. The AAFP appreciates the proposal to increase the valuation of the GBHI code included in this rule. As we've noted, the flexibility offered by the GBHI timing and clinician-type requirements may contribute to the overall success of the code.

Despite the increased support from CMS, previous and current proposals do not address the start-up costs and other challenges with integrating behavioral health into the primary care setting. These start-up costs include hiring staff, additional training for existing staff, and modifying clinical and administrative workflows to ensure patients in need connect with the appropriate services. The current fee-for-service codes and payment rates do not account for these costs. The zero percent statutory payment update and existing Medicare budget neutrality limitations are also straining primary care practices and further undermining practices' ability to transform to integrate behavioral health care and other services into the primary care setting. **We urge CMS to work with Congress to enact legislation to provide robust financial support for behavioral health integration outside of the confines of MPFS budget neutrality requirements.**

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

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[39] Westfall JM, Jabbarpour Y, Jetty, A, Kuwahara R, Olaisen H, Byun H, Kamerow D, Guerriero M, McGehee T, Carrozza M, Topmiller M, Grandmont J. Rankin J. *The State of Integrated Primary Care and Behavioral Health in the United States 2022*. Robert Graham Center, HealthLandscape. May 31, 2022.

[40] Clatney L, MacDonald H, Shah SM. Mental health care in the primary care setting. Can Fam Physician. 2008;54(6):884 LP - 889. http://www.cfp.ca/content/54/6/884.abstract

[41] Clark, R.E., Linville, D. and Rosen, K.H. (2009), A National Survey of Family Physicians: Perspectives on Collaboration With Marriage and Family Therapists. Journal of Marital and Family Therapy, 35: 220- 230. https://doi.org/10.1111/j.1752-0606.2009.00107.x

CMS proposes to allow FQHCs and RHCs to report RPM and RTM services under the existing general care management code, G0511. This code currently covers general care management services like chronic care management or behavioral health integration. CMS also proposes to include the new CHI and PIN services under the same code. To account for this change, CMS proposes to adjust the payment for this code using a weighted average utilization of all services that full under it.

The AAFP supports the proposal to allow FQHCs and RHCs to bill for CHI, PIN, RPM, and RTM services using the care management code and we appreciate CMS increasing the value of the code to account for this. We are concerned that, since the code can only be billed once per calendar month, the increased payment rate may not sufficiently account for the resources required to provide chronic care management, CHI and/or PIN, as well as remote monitoring when several of these services are provided in the same month. We urge CMS to monitor whether these billing limitations create barriers that prevent FQHCs and RHCs from offering the full range of these services to patients.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Conditions for Certification or Coverage (CfCs) (section III.C.)

CMS is seeking feedback on the definition of nurse practitioners (NPs) eligible to work at RHCs and FQHCs, which currently specifies an NP's certification must be in primary care. Removing this distinction would allow all certified NPs who meet other applicable requirements — such as acute care-certified NPs — to work at an RHC or FQHC.

*AAFP comments:*

**The AAFP does not believe the definition of NPs eligible to work at RHCs and FQHCs should be altered; we support the current requirement for NPs who work in RHCs and FQHCs to be certified in primary care**. While the Academy has supported a wide variety of efforts by policy makers to improve access to health care services in underserved communities, including the innovative utilization of non-physician practitioners like NPs, we believe physician-led, team-based primary care is what's best for patient care and outcomes. Primary care focuses on comprehensive, continuous patient care led by physicians and their teams who are responsible for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Primary care benefits all stakeholders; the care is person-centered, team-based, community-aligned, and designed to achieve better health, better care, and lower costs.

AAFP members who work in RHCs or FQHCs have shared that experienced and highly trained primary care-certified NPs are critical to health care teams being able to provide high-quality, low-cost, effective patient care. Our members have emphasized that acute care is only one part of primary care, sharing that it is much easier to have a primary care NP work in an acute care area than it is for an acute care-only NP to address multifocal health care or polychronic illness care.

The AAFP also believes that CMS' own definitions of RHCs and FQHCs make it necessary for employees, where applicable, to be trained or certified in primary care. CMS defines an RHC as operating "exclusively for the purpose of providing primary care services to Medicare patients located in rural and shortage areas" and defines an FQHC as providing "primary care services and dental

care services to rural/urban areas and shortage areas".[42] **The AAFP strongly supports this emphasis on primary care and will continue to support our members as they proceed in innovating primary care practice with NPs and other non-physician practitioners, especially in underserved communities**.

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

In accordance with section 4114 of the Consolidated Appropriations Act of 2023 (CAA, 2023), CMS proposes to make certain conforming changes to the regulatory data reporting and payment requirements related to the Clinical Laboratory Fee Schedule (CLFS). Specifically, CMS proposes to update the definitions of both the "data collection period" and "data reporting period," specifying that for the data reporting period of January 1, 2024, through March 31, 2024, 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 2024.

In addition, CMS proposes to make conforming changes to its requirements for the phase-in of payment reductions to reflect the amendments in section 4114(a) of the CAA, 2023. Specifically, CMS proposes to indicate that for CY 2023, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2022, and for CYs 2024 through 2026, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

*AAFP Response*

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 that 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. For context, the total CLFS spend for 2020 was only $8 billion, less than 3% of Medicare Part B spending.

Congress has intervened on a bipartisan basis four 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% in January of 2024. This is particularly concerning, given the vital role clinical labs play in responding to public health disruptions and threats, such as COVID-19.

[42] "Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs) Continued Efforts over the Past Years". Accessed Aug. 11, 2023. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/MPD-RHCs-FQHCs.pdf

The AAFP is supporting the *Saving Access to Laboratory Services Act*, 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 this year, 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 allow opioid treatment programs to continue allowing audio-only visits for periodic assessments through the end of CY 2024 to minimize interruptions to care because of changes at the end of the COVID-19 public health emergency.

*AAFP Comments:*

The AAFP applauds CMS for promoting care continuity for opioid treatment programs and urges the agency to finalize this proposal. Family physicians are a critical point of care for many patients with OUD, and the AAFP applauded recent action to remove the X-waiver.

The AAFP recently shared concerns with the DEA's proposed rule on virtual buprenorphine prescribing after the end of PHE. We were pleased to see the DEA adopted temporary guidelines to allow for continued virtual prescribing of buprenorphine as the agency works on final regulations. However, the AAFP remains concerned that patients will lose access to life-saving opioid treatment like buprenorphine.

Moreover, other medications for OUD (MOUD) are only available at OTPs, which often face additional state and federal regulations that limit patient access.[43] While these restrictions are intended to prevent inappropriate diversion of MOUDs with high potential for misuse, it also restricts patient access to life-saving treatment.

**Medicare Shared Savings Program (MSSP) (section III.G.)**

Quality Performance Standard and Other Reporting Requirements

In the CY 2021 MPFS, CMS modified the MSSP quality reporting requirements and quality performance standard. Accountable care organizations (ACOs) are required to report via the Alternative Payment Model (APM) Performance Pathway (APP). Through CY 2024, ACOs must report either 10 CMS Web Interface measures or the three electronic clinical quality measures (eCQMs)/MIPS CQMs and administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey. Beginning in CY 2025, ACOs will be required to report the three eCQM/MIPS CQMs and administer the CAHPS for MIPS survey. ACOs must report on all patients, regardless of payer.

[43] Pew Charitable Trust. *State Opioid Treatment Program Regulations Put Evidence-Based Care Out of Reach for Many.* October 31, 2022. https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2022/state-opioid-treatment-program-regulations-put-evidence-based-care-out-of-reach-for-many

Based on feedback from ACOs that the requirement to report on all patients is burdensome and extremely challenging to implement, CMS is proposing to establish the Medicare CQMs for ACOs Participating in the MSSP (Medicare CQMs) as a new reporting collection type. For CY 2024, ACOs would still have the option to report quality data via the CMS Web Interface, eCQMs, and/or MIPS CQMs. The CMS Web Interface will sunset after the CY 2024 performance period. CMS intends for Medicare CQMs to serve as a transition collection type, as CMS' long-term goal continues to be supporting ACOs in the adoption of all payer/all patient measures.

CMS proposes to amend the definition of "collection type" to include Medicare CQMs as an available collection type in MIPS for ACOs that participate in MSSP. A Medicare CQM is a MIPS CQM reported by an ACO under the APP on only the ACO's Medicare FFS beneficiaries. CMS proposes to define a beneficiary eligible for a Medicare CQM at §425.20 as a beneficiary identified for purposes of reporting Medicare CQMs who is either of the following:

- A Medicare FFS beneficiary (as defined at §425.20) who:
    - Meets the criteria for a beneficiary to be assigned to an ACO at §425.401(a) and
    - Had at least one claim with a date of service (DOS) during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included at §425.402(c), or who is a PA, NP, or CNS.
- A Medicare FFS beneficiary who is assigned to an ACO in accordance with §425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

For Medicare CQMs, CMS proposes a data completeness threshold of 75% for the CY 2024, 2025, and 2026 performance periods. CMS proposes a data completeness threshold of 80% for the CY 2027 performance period.

CMS proposes that new benchmarks for scoring Medicare CQMs under MIPS would be developed in alignment with MIPS benchmarking policies. Historical data will not be available at the time this proposal is finalized. Therefore, CMS proposes to score Medicare CQMs using performance period benchmarks for the 2024 and 2025 performance years. For performance year 2026 and subsequent performance years, CMS proposes to transition to historical benchmarks for Medicare CQMs.

CMS is proposing that ACOs that report Medicare CQMs would be eligible for the health equity adjustment to their quality performance category score when CMS calculates shared savings payments.

*AAFP Comment*

**The AAFP supports CMS' proposal to establish the new Medicare CQM collection type for ACOs.** We thank CMS for responding to stakeholder concerns. As we discuss in the MIPS data completeness section, there are multiple factors that are impacting practices' ability to effectively share and aggregate data. These include lack of agreed upon semantic and syntactic standards, data privacy concerns, and patient misidentification. The challenges are not limited to a specific program or a certain type of practice. Requiring ACOs to report eCQMs/MIPS CQMs while these challenges persist and without adequate transition time and support may ultimately slow progress toward the adoption of all payer measures. In the near term, CMS should continue to allow participants to report on their Medicare

beneficiaries. We urge CMS to work with ACOs, measure stewards, and health IT vendors to develop a long-term plan to adopt all payer measures that provides adequate support and addresses existing interoperability and data completeness barriers.

As it relates to the definition of beneficiaries eligible for the Medicare CQM collection type, we ask CMS to clarify if it is limited to assigned beneficiaries or if it includes all assignable beneficiaries eligible for the measure. We thank CMS for their willingness to provide lists of Medicare CQM beneficiaries to the ACOs.

The AAFP supports CMS' proposal to use performance year benchmarks for the 2024 and 2025 performance years before transitioning to historical benchmarks starting with the 2026 performance year.

Proposals to Modify the Health Equity Adjustment Underserved Multiplier

In 2023, CMS finalized the application of a health equity adjustment that adds up to 10 bonus points to an ACO's MIPS quality performance category score. The adjustment is calculated multiplying the ACO's performance scaler by the ACO's underserved multiplier. The underserved multiplier is based on the higher of (1) the proportion of the ACO's assigned beneficiaries residing in a consensus block group with an Area Deprivation Index (ADI) national percentile rank of at least 85, or (2) the proportion of the ACO's assigned beneficiaries who are enrolled in Medicare Part D low-income subsidy or are dually enrolled in Medicare and Medicaid.

CMS did not include how they would compute the proportion of beneficiaries with an ADI national percentile rank of at least 85 with respect to beneficiaries for whom a numeric national percentile rank value is not available. CMS does not believe it is appropriate to assign a zero to beneficiaries without an ADI national percentile rank.

CMS proposes to revise the underserved multiplier to remove beneficiaries who do not have an ADI national percentile rank from the health equity adjustment calculation for performance year 2023 and subsequent performance years. Removed beneficiaries would not appear in either the numerator or denominator of the proportion.

When calculating the LIS proportion, CMS uses person years. Beginning with the 2024 performance year, CMS proposes to modify the calculation of assigned dually eligible beneficiaries and the calculation of the proportion of assigned beneficiaries enrolled in LIS to use the number of beneficiaries rather than person years.

CMS seeks comment on these proposals.

*AAFP Comment*

**The AAFP supports this proposal.** We note that national benchmarks (in this case, national ADI percentiles) can mask regional variances. CMS could consider modifying the methodology to use a regional approach instead of a national one, as CMMI plans to do for the recently announced Making Care Primary model.

Proposal to Use Historical Data to Establish the 40th Percentile MIPS Quality Performance Category Score

One way for ACOs to meet the quality performance standard and share in the maximum savings for its track is to achieve a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores. CMS calculates the 30th and 40th percentile across all MIPS Quality performance category scores after MIPS final scoring is complete. As such, CMS is unable to provide ACOs with performance rate information prior to or during the performance year. To address stakeholder feedback and concerns, CMS proposes to revise their policy and to use historical submission-level MIPS quality performance category scores to calculate the 40th percentile. CMS proposes to use a rolling three-year performance average with a lag of one performance year. For the 2024 performance year, the quality performance standard for 2024 would be based on averaging the 40th percentile MIPS quality performance category scores from performance years 2020-2022.

CMS would provide ACOs with the performance score that would be used as the quality performance standard prior to the start of the performance year. CMS seeks comment on this proposal.

*AAFP Comment*

The AAFP supports this proposal. However, like with MIPS, data from performance years 2020-2022 are not likely to yield a meaningful comparison given the impact of the COVID-19 pandemic and the exception policies applied in those years. CMS could consider a weighted average approach that gives more credit to the most recent year (2022).

Proposals to Align CEHRT Requirements for MSSP ACOs with MIPS

CMS believes aligning the MSSP CEHRT requirements with the MIPS promoting interoperability requirements will reduce burden. CMS proposes to sunset the MSSP CEHRT threshold requirements and modify regulations at §425.506(f) to indicate that they will be applicable only through PY 2023. CMS also proposes to require (unless otherwise excluded) all MIPS ECs, QPs and Partial QPs participating in the ACO, regardless of track, satisfy the following:

- Report the MIPS promoting interoperability performance category measures and requirements to MIPS according to 42 CFR part 414 subpart O as either of the following:
    - All MIPS ECs, QPs, and Partial QPs participating in the ACO as an individual, group, or virtual group, or
    - The ACO as an APM entity.
- Earn a MIPS performance category score for the MIPS promoting interoperability performance category at the individual, group, virtual group, or APM entity level.

CMS proposes to require ACOs to publicly report the number of MIPS ECs, QPs, and Partial QPs participating in the ACO that earn a MIPS promoting interoperability category score. ACOs would not be required to report on excluded clinicians.

*AAFP Comment*

**The AAFP strongly opposes this proposal. CMS' proposal that all ACOs meet the full requirements of the MIPS promoting interoperability performance category will add reporting and administrative burden to MSSP participants, which could negatively impact future**

**recruitment and retention in the program.** We recognize that CMS' goal was to align CEHRT and Promoting Interoperability requirements across CMS programs. However, we are concerned that this proposal will actually add to ACOs' and their participants reporting burdens, ultimately worsening their administrative workload. Reporting to the MIPS Promoting Interoperability category would require ACO participants to attest and report to several more measures than they do now. The AAFP has previously raised concerns about the burdensome nature of the Promoting Interoperability category, noting that it adds significant burden for clinicians without meaningfully advancing interoperability.

MSSP participants have agreed to take on additional risks with the expectation that they will be afforded additional flexibilities to manage those risks in ways that meet the unique needs of their patient population. These flexibilities include fewer reporting requirements and reduced administrative burden, both of which are major benefits of participation in an APM and are essential to recruiting more participants in the model.

The AAFP is strongly supportive of efforts to advance interoperability. We firmly believe that interoperable health care data is essential to supporting family physicians across health care settings in providing comprehensive, person-centered care. Having access to actionable data at the point of care is even more important for physicians participating in APMs. Such data enables them to better track their patients' conditions, coordinate care across settings, and ensure they are up to date on preventive care. These are essential primary care functions that require accurate and complete data to successfully and efficiently improve patient and population health. Unfortunately, we do not believe that this proposal will meaningfully advance interoperability.

We further note that the timing of this regulatory change would be challenging for ACOs. The deadline for ACOs to submit their participant list has already passed. Complying with this requirement will take significant time and resources, including potential upgrades in software/hardware as well as redesigning and training physicians and staff. ACOs have already established effective ways to leverage their CEHRT to successfully meet their patients' needs and reduce costs. Adding health IT utilization measures to their reporting burden will be disruptive and will not lead to better outcomes. As noted throughout our letter, narrow technology and reporting requirements are not a solution when the technology isn't mature enough to support them.

Further, the final rule will not be released until November. This would provide ACOs less than two months to prepare for a significant shift in their reporting requirements. If CMS chooses to move forward with this proposal, they must at least delay its implementation.

We also note that this proposal appears to be inconsistent with the statute. The MACRA statute expressly excludes QPs and Partial QPs from the definition of a "MIPS eligible professional." Excluding QPs and Partial QPs from the MIPS requirements was meant to be an incentive to transition out of MIPS and to an AAPM.

MVP Reporting for Specialists in MSSP ACOs – Request for Information

CMS believes they need incentives for specialists in MSSP ACOs to report clinically relevant quality measures and to allow patients, referring clinicians, and ACOs to have more information regarding specialists involved in patient care. CMS seeks feedback on their overall approach to align quality measures in the Adult Universal Foundation with measures used for evaluation in the MSSP.

- In order to highlight specialty clinical practice within ACOs, how should CMS encourage specialist reporting of MVPs?
- How should CMS encourage the reporting of MVPs to collect quality data that is comparable to data reported by other specialty providers in quality MVPs and to address clinician concerns over measure appropriateness?
- How should CMS consider encouraging specialists to report the MVP that is most relevant to their clinical practice?
- How should CMS distinguish bonus points for ACOs that report on a larger volume of patients through MVPs?
- How should CMS provide ACOs with bonus points to their health equity adjusted quality performance score when an ACO's specialty clinicians report MVPs?
- What concerns and considerations should CMS be aware of when assessing ACOs for quality performance based on reporting quality measures within MVPs?
- Would incentivizing specialty MVPs create a disincentive for ACOs to report primary care focused APP and/or MVP measures?
- In the event that MIPS quality measures in MVPs are excluded under §414.1380(b)(1)(vii)(A), should CMS apply the proposed MSSP scoring policy for excluded APP measures?
- How long should CMS have bonus points in place to incentivize MVP reporting?
- Should CMS consider assessing overall specialty performance as part of the APP in the future? If so, how?

*AAFP Comment*

**The AAFP supports CMS' efforts to provide different pathways for specialists to participate in MVPs more meaningfully.** However, we fear that the policies around MVPs and subgroups are too new and evolving for them to prove an effective mechanism for specialist reporting in an ACO. Further, there are MVPs not available to all specialties nor are there sufficient APM options for specialists. The AAFP encourages CMS to continue working with CMMI to identify meaningful ways to incorporate specialists into the whole-person orientation that is central to the success of ACOs. As additional specialty-focused MVPs are developed, this more holistic patient-centered view is essential to ensuring that the integration and coordination across primary and specialty care settings continues to improve. The AAFP is pleased CMS is exploring different options to incorporate bundles into the MSSP and hope further definition around CMS' plans in that regard will generate meaningful MVPs. We encourage CMS to keep engaging with stakeholders throughout that process. We reiterate our opposition to mandatory MVP reporting and subgroup formation. MVPs and subgroup reporting should remain optional for the foreseeable future. It is still too premature to propose sunsetting traditional MIPS.

While we agree with CMS that engaging specialists more actively in the overall management of patient and population health outcomes is central to the success of ACOs, we do not believe an ACO should receive bonus points based on specialty participation in available MVPs. Not all specialties currently have an MVP available and MVPs were not necessarily developed with the ACO vision of providing integrated and coordinated whole-person care.

<u>Beneficiary Assignment</u>

CMS proposes modifications to the assignment methodology and the definition of primary care services used for assignment to increase access and result in a greater number of beneficiaries assigned to ACOs, particularly from underserved populations which have been less likely to be assigned to ACOs in the past.

*Modifications to Assignment Methodology*

A beneficiary must see a physician to be eligible for attribution to an ACO. Nurse practitioner and physician assistants only count towards assignment to an ACO if there is a qualifying physician visit. CMS proposes a revision to the two-step beneficiary assignment methodology for MSSP to include a new step three, which would utilize a proposed expanded window for assignment. CMS proposes expanding the window for the qualifying physician visit from 12-months to 24-months. The expanded window is intended to better account for beneficiaries who receive primary care from nurse practitioners, physician assistants, and clinical nurse specialists during the 12-month assignment window and who received at least one primary care service from a primary care physician during the proposed expanded 24-month window for assignment.

*AAFP Comment*

**The AAFP generally supports the proposal to add a third step to the methodology used to assign beneficiaries to an ACO as it is consistent with the important role that non-physician clinicians play in physician-led primary care teams.** Allowing for an additional 12-month window to identify primary care services delivered by a physician is consistent with the importance of physician-led primary care teams and likely to provide a more accurate view of beneficiaries' actual primary care usage. As CMS notes, this methodology change is likely to result in more beneficiaries who are part of underserved populations or regions being assigned to ACOs. However, **we urge CMS to ensure that this methodology change does not have the unintended consequence of assigning beneficiaries to clinicians in specialty care or non-primary care settings, which validates or inadvertently incentivizes care fragmentation outside the beneficiaries usual source of primary care.** There is a known deficiency in the provider taxonomy code classification in that it does not allow for the identification of the specialty for advanced practice clinicians. This creates challenges with determining which advanced practice clinicians work in a primary care setting versus a sub-specialized setting.

Solutions include updating the Provider Enrollment, Chain, and Ownership System (PECOS) to include separate, appropriate specialty designations for advanced practice clinicians. CMS could begin by collecting this information as an optional field in the Medicare enrollment application, which already includes this field for physicians. In the absence of CMS's ability to distinguish between advanced practice clinicians who practice primary care and those who practice specialty care, we advocate that ACOs be permitted to remove specialty focused APPs from assignment.

*Revisions to the Definition of Primary Care Services Used in Assignment*

CMS proposes to revise the definition of primary care services used for assignment in the Shared Savings Program regulations to include:

- Smoking and Tobacco-use Cessation Counseling Services (CPT codes 99406, 99407)
- Cervical or Vaginal Cancer Screening (HCPCS code G0101)
- Complex E/M Services Add-on (HCPCS code G2211)

- Community Health Integration Services (HCPCS codes GXXX1, GXXX2)
- Principal Illness Navigation Services (HCPCS codes GXXX3, GXXX4)
- SDOH Risk Assessment (HCPCS code GXXX5)
- Caregiver Behavior Management Training (CPT codes 96202, 96203)
- Caregiver Training Services (CPT codes 9X015, 9X016, 9X017)

*AAFP Comment*

**The AAFP supports the inclusion of the following codes in the ACO assignment methodology:**

- **Smoking and Tobacco-use Cessation Counseling Services (CPT codes 99406, 99407)**
- **Complex E/M Services Add-on (HCPCS code G2211)**
- **Community Health Integration Services (HCPCS codes GXXX1, GXXX2)**
- **Principal Illness Navigation Services (HCPCS codes GXXX3, GXXX4)**
- **Caregiver Behavior Management Training (CPT codes 96202, 96203)**
- **Caregiver Training Services (CPT codes 9X015, 9X016, 9X017)**

While overall we are supportive of the inclusion of the above codes, we urge CMS to remember there are unique considerations here regarding assignment and attribution between primary and specialty care. **We ask CMS to monitor to ensure the services included in the assignment methodology continue to support the delivery of comprehensive, coordinated, whole-person primary care and do not have unintended consequences that disrupt ongoing patient-physician relationships.**

The AAFP does not support the inclusion of code for cervical/vaginal cancer screening (G0101) as 80% of the time this service is provided by obstetricians or gynecologists under Medicare. By including this code in the assignment methodology risks shifting beneficiary attribution away from primary care relationships in favor of specialty care.

The AAFP does not support the inclusion of the code for SDOH Risk Assessment (HCPCS code GXXX5) as we are concerned about incorporating new codes that have no utilization history. Ideally, those are services that family physicians and other primary care physicians would use most commonly, but until there is evidence that is the case, we believe it is premature to use them for assignment under MSSP.

Benchmarking Methodology

*Eliminating the Negative Regional Adjustment*

CMS proposes to prevent any ACO from receiving a regional adjustment that would cause its benchmark to be lower than it would have been without the regional adjustment, effectively eliminating the negative regional adjustment. ACOs eligible for a prior savings adjustment would not have those savings offset by a negative regional adjustment. If finalized, this change would take effect for new agreements starting in 2024.

*AAFP Comment*

**The AAFP supports this proposal as it would remove the disincentive for ACOs with spending higher than their region to participate in MSSP.** As CMS notes in the rule, ACOs who receive a

negative adjustment are twice as likely to drop out of MSSP. However, we urge CMS to apply this change to all ACOs, not just those starting new agreements in 2024.

*Risk Adjustment within Shared Savings Program Benchmark Calculations*

In the 2024 Medicare Advantage Capitation Rates and Part C and Part D Payment Policy rule, CMS finalized the transition to a revised CMS-HCC risk adjustment model Version 28 (V28). V28 made several changes to the types of codes included and weighting of codes in the HCC calculation. It was unclear how the transition to V28 from the current HCC Version 24 (V24) would be managed for MSSP ACOs. In this Proposed Rule, CMS proposes to apply the same CMS-HCC risk adjustment model used in the performance year for all benchmark years, when calculating prospective HCC risk scores to risk adjust benchmarks for agreement periods beginning on January 1, 2024, and in subsequent years. For new agreements beginning in 2024, CMS proposes to use the same hierarchical condition code (HCC) risk adjustment model for a performance year and the relevant benchmark years. This means as CMS introduces new risk models, including the forthcoming V28, risk scores would be calculated using a consistent model and any impacts a shift in the model version could create should be balanced. These changes will only apply for agreement periods beginning in 2024 with CMS noting it historically incorporates changes to the benchmarking methodology at the start of an ACO's agreement period. ACOs not starting new agreements in 2024 will have risk scores for their benchmark years calculated using different HCC model versions.

This three-year phase-in would align with what is being done in Medicare Advantage and will result in risk adjustment that is weighted at 67 percent of the current 2020 CMS-HCC risk adjustment model and 33 percent of the CMS-HCC risk adjustment model for performance year (PY) 2024. ACOs in an existing agreement period would continue to have the current methodology for calculating benchmark year and performance year prospective HCC risk scores, using different CMS-HCC risk adjustment model(s) applied, and are expected to experience smaller adverse impacts as a result of the phase-in of V28 and CMS's existing approach to renormalize prospective HCC risk scores by Medicare enrollment type, among other factors.

*AAFP Comment*

**The AAFP supports the proposal to use a consistent risk model in both the performance and all benchmark years and appreciates the additional clarity CMS is offering on this policy change.** We support the changes CMS is proposing to make to HCC coding for ACOs signing new agreements on or after January 1, 2024. That said, to create an even playing field, the AAFP strongly encourages CMS to apply this policy uniformly across all ACOs – not only those with new agreements in 2024.

<u>Advanced Investment Payments (AIP)</u>

In the 2023 PFS final rule, CMS finalized a new payment option to make Advance Investment Payments (AIPs) to Accountable Care Organizations (ACOs) that are low revenue, inexperienced with performance-based risk Medicare ACO initiatives, new to the Shared Savings Program, and serve underserved populations beginning January 1, 2024. CMS proposes a series of technical modifications to refine AIP policies for ACOs entering agreement periods on January 1, 2024.

*Modifications to AIP Eligibility Requirements*

In the 2023 PFS final rule, CMS finalized an ACO receiving AIPs must remain in a one-sided model for the duration of its agreement period in which it receives AIPS. Moving to two-sided risk before the agreement period ended would result in the ACO having to repay all of the AIPs within 90 days of receiving written notice from CMS. CMS proposes modifying the AIP eligibility requirements to allow an ACO to advance to a two-sided model in the BASIC track beginning with the third performance year in which the ACO receives AIPs. However, CMS will cease AIPs if an ACO becomes experienced with performance-based risk in the first or second performance year or becomes high revenue during any performance year of the agreement period in which they receive AIPs.

*AAFP Comment*

The AAFP commends CMS' reconsideration of requiring ACOs to remain in one-sided risk for the duration of the agreement period to continue receiving AIPs and supports the modifications to allow ACOs to take on moderate risk while developing experience with MSSP. To facilitate reaching CMS' stated goal of expanding ACO assignment to include more underserved beneficiaries, **we recommend CMS also consider expanding AIP access to existing ACOs that meet specific parameters, such as those that are smaller or serve beneficiaries with high-needs, as well as new applicants that may be considered high-revenue but are serving high-needs beneficiaries.** Preliminary analysis suggests adding FQHCs, RHCs, and/or CAHs to ACOs frequently results in an ACO moving from low-revenue to high-revenue. Disallowing high-revenue ACOs from receiving AIPS without consideration of the level of need represented by their patient population may have the unintended consequence of discouraging ACOs from including these care settings that are essential to addressing disparities. The AAFP recommends CMS consider other criteria which are more reflective of an ACO's level of capital and inclusive of the patient populations they serve to avoid unintended consequences that may hinder efforts to advance VBP, improve health outcomes, reduce costs, and reduce health-related disparities. For example, CMS could consider the proportion of an ACO's aligned beneficiaries who meet the highest risk factors-based score (dual eligible, Part D low-income subsidy, and those with ADIs at or above the 85th percentile). For this option, CMS could research the proportion of a high-revenue new entrant ACO's aligned beneficiaries meeting these requirements, determine a threshold for considering the patient population is at increased risk, and allow the ACO to participate in the AIP. To operationalize this, CMS should allow new high-revenue ACOs to submit the supplemental application for the AIP. We believe this approach is aligned with CMS' goals for the AIP of increasing participation in the program by easing up-front investments for inexperienced, low-revenue, or ACOs providing accountable care for underserved beneficiaries, such as FQHCs, RHCs, and CAHs.

*Modifications to AIP Recoupment*

In the 2023 PFS, CMS finalized that an ACO would be required to repay all AIPs it received if they terminate their participation agreement during the agreement period in which they received an AIP. CMS proposes to create an exception to its AIP recoupment policy for an ACO that terminates its participation agreement early in order to early renew under a new participation agreement to continue their participation in the Shared Savings Program. The ACO may continue to spend the AIPs within five performance years of when it began to receive the AIP and will continue to repay the AIP through shared savings earned in the new agreement period.

*AAFP Comment*

The AAFP appreciates CMS' willingness to allow early renewing ACOs the flexibility and time to pay back AIPs as these ACOs are new to the program and building infrastructure and capabilities that best meet their patient populations' needs and support long term success in value-based arrangements. **The AAFP also encourages CMS to allow ACOs to keep a portion of shared savings each year instead of recouping from all shared savings since ACOs typically reinvest savings to improve care delivery for Medicare beneficiaries. CMS should consider giving ACOs the option to recoup from only half of shared savings each year over the course of the agreement period (or beyond, if necessary).**

We also recommend CMS further reducing barriers to entry by considering a sliding-scale reduced AIP payback for ACOs serving a high proportion of high-need beneficiaries to increase participation of FQHCs, RHCs, and CAH's in the program. This aligns with CMS' Strategic Pillars to advance health equity by addressing the health disparities underlying the US health care system.

The AAFP also asks CMS to monitor the individual circumstances leading to early termination and consider unintended negative consequences it might have on the beneficiary population served by the ACO.

*Modification of Termination Policies*

CMS proposes to modify the termination policies to explicitly state CMS would immediately terminate AIPs to an ACO for future quarters if an ACO voluntarily terminates from the Shared Savings Program and does not immediately enter a new agreement period.

*AAFP Comment*

The AAFP is supportive of the clarification for termination of AIPs for voluntary termination as it aligns with the policy for ceasing AIPs for other causes of termination and protects program integrity.

*Require ACOs to Report Spend Plans to CMS on Use of AIPs*

In the 2023 PFS, CMS finalized ACOs receiving AIPs were required to submit spend plans to CMS. An ACO receiving AIPs are also required to publicly report their spend plan, the total amount of AIP received from CMS, and an itemization of how AIPs were spent each year. While CMS required public reporting of that information, they did not finalize reporting of the same information to CMS. CMS is proposing an ACO must report to CMS the same information on its use of AIPs that it is required to report publicly.

*AAFP Comment*

**The AAFP is supportive of proposal** to require an ACOs receiving AIPs to report the same information to CMS as is reported publicly as long as the process and mechanism to report the information is not unduly burdensome.

<u>Future of the Shared Savings Program</u>

CMS is seeking comments on potential future developments to Shared Savings Program policies, including incorporating a higher risk track than the ENHANCED track and promoting collaboration between ACOs and community-based organizations (CBO).

*Incorporating a Higher Risk Track than the ENHANCED Track*

We applaud CMS' public commitment to moving primary care away from fee-for-service to comprehensive, predictable, prospective value-based payment approaches aligned with the AAFP's Guiding Principles for VBP. **The AAFP is supportive of CMS implementing a higher risk track than the ENHANCED conditional on the inclusion of specific design features necessary to ensure the successful participation of primary care to improve care delivery for Medicare beneficiaries.** As CMS has noted in this rule and in multiple public forums, physician-led ACOs are creating a better experience for patients while lowering costs in the Medicare Shared Savings Program (MSSP). According to CMS data, in 2022, physician-led ACOs in the MSSP achieved net savings that were nearly double that of hospital-led ACOs ($228 per capita versus $140 per capita in net savings). ACOs comprised of 75 percent primary care clinicians or more generated $294 per capita in net savings, clearly demonstrating the essential role primary care plays in delivering high quality care that is also more affordable.

**The AAFP believes to adequately support primary care's unique role in caring for the whole person, payments need to shift away from the predominant reliance on FFS toward prospective payment sufficient to support a comprehensive array of primary care services delivered by physicians and care teams.** One study estimated that more than 60% of a primary care practice's revenue needs to be prospective to sustainably support comprehensive, team-based primary care. Making a hybrid payment option that includes primary care capitation available to all risk tracks in MSSP is a necessary step for CMS to fully realize the benefits of the program and achieve its beneficiary goals – particularly for those with high needs or in underserved areas. Limiting hybrid payment participation to risk-bearing ACOs would be a deterrent for new ACOs or those taking advantage of the new rule that allows certain ACOs to remain in Level A longer. Allowing up-side only ACOs to benefit from hybrid payment aligns with CMS' goal of having 100% of Medicare beneficiaries in an accountable care relationship by 2030.

ACOs have varying organizational structures which will require CMS to take a very thoughtful approach to ensure payments intended to support primary care, including capitated or per patient per month (PMPM) payments, reach the primary care practices where physicians and care teams are delivering the care. To that end, the AAFP suggests two options for consideration:

1. **Pay capitation to primary care practices directly.** This is the preferred approach and guarantees that capitation is invested in the primary care setting where care is delivered to aligned Medicare beneficiaries.
2. **Pay capitation to ACOs with stipulations that establish a maximum level of retention by ACO (for delivery of specific qualified services) and/or minimum percent that must flow to primary care practice.** This option will require that CMS put a strong audit mechanism in place to ensure adherence accompanied by clear and meaningful financial penalties for ACOs that do not abide by these stipulations.

**When designing the capitated primary care payment, ACOs and their primary care practices should have flexibility to select the level of capitation, i.e., the services covered by capitation vs. FFS, that allows them to match their practice capabilities with the payment model. This level of flexibility will allow more small, independent, and new entrant practices to participate**

**in the hybrid payment approach.** Ideally, ACOs would have the ability to gradually increase to higher levels of capitation as they gain more experience and take on more risk.

**Finally, we ask CMS to consider ways to support independent practice participation in a hybrid payment option in MSSP, including:**

- **Ensure independent practices are represented in ACO governance.**
- **Establish clear guidelines for maximum revenue retention by ACOs, including the maximum percentage of the capitation that can be used to fund a clearly defined list of ACO primary care support services.**
- **Require ACOs receiving capitated payments to help participating practices build the capacity to independently receive and effectively use prospective payments to support the provision of comprehensive primary care.**
- **Allow small, independent, or new entrants to be eligible for Advanced Incentive Payment (AIP) and hybrid primary care payment.**
- **Provide the ability to gradually increase to higher levels of capitation, like CPC+ Track 2.**
- **Provide an entry point at a lower beneficiary alignment threshold, like the new entrant track of ACO REACH.**

We are generally supportive of a full risk track in MSSP, however **certain protections are needed to ensure the investments made are used to improve patient care.** One such mechanism is to require representation of beneficiaries and independent primary care physicians in the governance structure of the ACO, including voting rights. Doing so guarantees these crucial voices play a visible role in the decision making of accountable care entities.

We recognize that ACO success is dependent upon the ability of physicians to deliver high-quality, coordinated care across a complex health care system into which patients have multiple access points. **To ensure integration and coordination, CMS must guarantee ACOs and all of its participants have access to the data and analytics necessary to support collaboration across specialties.** We also recognize the need for continuous quality improvement to extend beyond primary care measures. CMS should strive to include meaningful measures for specialists in addition to primary care to incentivize care delivery improvements across specialties. CMS should also require health equity plans that include collaboration with community health organizations and the safety net. Finally, CMS must include guardrails that ensure ACO participants share in the financial rewards that accrue from their performance.

*Promoting ACO and CBO Collaboration*

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

However, existing fee-for-service (FFS) structures typically do not explicitly pay for the services that address health-related social needs (HRSN) within a patient's community context. This disadvantages patients who require more support and the physicians who care for them. Family physicians cite expanded capabilities to address patients' HRSNs as one of the primary reasons for

transitioning to value-based payment: they are looking for a payment model that will provide adequate, stable financial support and flexibility to deliver innovative whole-person care.

**Incorporating a hybrid primary care capitation option in MSSP as previously described is one lever CMS can prioritize if we are to support primary care's role sufficiently and sustainably in improving health equity. When primary care practices are supported by a predictable, prospective revenue stream that recognizes the full range of care needs, both clinical and social, patients have better outcomes, including fewer inequities in care, and primary care practices thrive. It is also important to note that even with the resources to properly assess and connect patients with identified needs using community health workers or care coordinators, family physicians cannot connect to resources that do not exist at the community level. As such, payment must be designed to adequately resource primary care physicians to comprehensively address patients' needs, inclusive of HRSNs, without inappropriately holding primary care physicians responsible for outcomes outside their control, such as the provision of resources that do not exist at the community level.**

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 (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.** While some communities are demonstrating success with this model, building the CCH infrastructure requires coordinated funding from multiple private and public sources.

We call on CMS and its sister agencies within HHS to work together toward a comprehensive approach to CCH development to maximize its impact.

Medicare Part B Payment for Preventive Vaccine Administration Services (section III.H.)

In the CY 2023 MPFS final rule, CMS established that the vaccine administration payment for COVID-19 would reset to the same amount as the vaccine administration payment for the other Part B preventative vaccines beginning January 1, 2024. CMS proposes to update the Part B vaccine administration payment for CY 2024 based upon the increase in Medicare Economic Index (MEI) and to adjust for geography. CMS also proposes to continue the additional payment for in-home administration of the COVID-19 vaccination and to extend this additional payment to other Part B-covered vaccines. Under this proposal, practitioners are limited to one additional payment for in-home administration of a Part B preventative vaccine, but every vaccine administered will still receive a distinct vaccine administration payment. CMS also proposes that the additional payment for in-home administration of a preventative vaccine will be updated annually based upon the MEI and adjusted for geography.

*AAFP Comments*:

**The AAFP supports the annual update of Part B vaccine administration payment rates based on increases in the MEI and adjustment for geography, which ensures payment keeps pace with changing practice costs.** The AAFP continues to advocate for an annual inflationary update

tied to increases in the MEI to be implemented for all services under the MPFS but we appreciate CMS using its authority to apply it here.

**The AAFP also supports CMS' proposal to extend the additional payment for in-home administration of COVID-19 vaccines to all Part B preventive vaccines.** Some family physicians offer home-based primary care services. These physicians report that this extra payment is important for ensuring equitable access to vaccines for patients who have challenges leaving their homes or are living in assisted living facilities, smaller group homes, and other group living environments. We applaud CMS for taking steps to improve access to preventive vaccines under Medicare Part B and urge CMS to finalize these proposals.

**The AAFP notes that, since new vaccines are only covered under Medicare Part D (unless Congress enacts legislation to include them in Part B coverage), primary care physicians face significant barriers to offering Part D-only vaccines in their practices.**[44,45] As a result, most primary care practices do not offer the ACIP-recommended Tetanus, diphtheria, and pertussis (Tdap), shingles, and respiratory syncytial virus (RSV) vaccines in their practices. This creates barriers to vaccine access and contributes to lower than optimal vaccination rates for Medicare beneficiaries.[46] The same challenge will apply to physicians providing home-based primary care services and thus could lead to inequitable vaccine access for patients who face challenges leaving their homes. These patients are often most likely to benefit from new vaccines which may be recommended for elderly patients and others who are at high-risk for contracting severe diseases but may struggle to get to the pharmacy to receive them. While there are certain vendor services that facilitate billing Part D vaccines for physician practices, many practices aren't able to invest in this technology. Due to these challenges, the Medicare Payment and Access Commission has repeatedly recommended covering all preventive vaccines under Medicare Part B.[47] 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.**

**The AAFP urges CMS to swiftly clarify that the agency will continue to pay the enhanced Medicare administration payment rate for COVID-19 vaccines through CY 2024.** As we noted in earlier letters to President Biden and Secretary Becerra, the AAFP is concerned that the transition of COVID-19 vaccines to the commercial market creates financial and operational uncertainty for physician practices that could negatively impact access to and utilization of COVID-19 vaccines. This transition requires primary care practices to make an upfront investment to purchase vaccines and file claims to be paid for vaccine products later, once the vaccines are administered to patients. If the price of COVID-19 vaccines is too high, physician practices may struggle to offer it in their practice. When selecting which vaccines to stock, physicians report that the cost of vaccine, expense of

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[44] McNamara M, Buck PO, Yan S, et al. Is patient insurance type related to physician recommendation, administration and referral for adult vaccination? A survey of US physicians. *Hum Vaccin Immunother*. 2019;15(9):2217-2226. doi:10.1080/21645515.2019.1582402

[45] CMS Bulletin. Payment for Part D Vaccines under the Medicare Drug Benefit (Part D). Available at: https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se0678.pdf

[46] Government Accountability Office. Many Factors, Including Administrative Challenges, Affect Access to Part D Vaccinations. December 2011. Available at: https://www.gao.gov/assets/gao-12-61.pdf

[47] Medicare Payment and Access Commission. Medicare vaccine coverage and payment. June 2021 Report to Congress. Available at: https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/default-document-library/jun21_ch7_medpac_report_to_congress_sec.pdf

maintaining vaccine inventory, and payer reimbursement rates are the most influential factors.[48] For example, physicians are more likely to stock influenza vaccines and research suggests this is because administering influenza vaccine is less costly for practices than other adult vaccines.[49] Therefore, payment rates that accurately reflect the market price of the vaccine itself, as well as the unique costs of vaccine counseling and administration of COVID-19 vaccines, are necessary to ensure access to COVID-19 vaccines in physician practices. Physicians are the public's most trusted source of vaccine and health related information and can support improved adult vaccination rates[50,51,52].

Because of the uncertainty around the commercialization of COVID-19 vaccines, we previously asked CMS to work with the AAFP and other stakeholders to determine if there are any unique administration costs and challenges present when the 2023-2024 COVID-19 vaccine formulations are available, and if so, to ensure that Medicare payment rates account for these potential costs. We now know that some of the formulations for the 2023-2024 vaccination season will be somewhat easier to manage for physician practices but still require several specific practice considerations and additional expense. For example, we expect more vaccines to be available in single dose vials that will not require dilution. Vaccines for younger children, however, will still only be available in multi-dose vials that require dilution, which creates operational challenges for practices. For one of the major vaccine brands, the vial expires 12 hours after it is first punctured. COVID-19 vaccines also expire more quickly than other vaccines, even when refrigerated. One brand of refrigerated COVID-19 vaccines expire in 10 weeks while refrigerated injectable inactivated influenza vaccines have a standard expiration date of June 30.[53] This not only requires additional management by practice staff but it could also preclude practices from stocking and offering this vaccine because wasting any doses will negatively impact practices financially. The expiration timelines, storage requirements, dosage amounts, and other factors also vary by vaccine brand/manufacturer, requiring physician practices to keep track of several sets of guidelines. **Providing primary care practices with clarity about vaccine administration payment rates will give them reassurance that Medicare payment rates will continue to support the work associated with COVID vaccine administration, and ultimately support equitable access to the new vaccines for beneficiaries.**

Medicare Diabetes Prevention Program Expanded Model (section III.I.)

During the COVID-19 PHE, CMS allowed Medicare Diabetes Prevention Program (MDPP) suppliers to offer virtual sessions. CMS proposes to extend these virtual flexibilities through 2027, streamline

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[48] Hutton DW, Rose A, et al. "Importance of reasons for stocking adult vaccines." American Journal of Managed Care. November 2019. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9004468/
[49] Lindley MC, Hurley LP, Beaty BL, et al. Vaccine financing and billing in practices serving adult patients: a follow-up survey. *Vaccine* 2018. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5807000/
[50] Darius Tahir, KFF Health News, "Few Firm Beliefs and Low Trust: Americans Not Sure What's True in Age of Health Misinformation," August 22, 2032. Available: https://kffhealthnews.org/news/article/few-firm-beliefs-low-trust-health-misinformation-kff-poll/
[51] Kaiser Family Foundation. COVID-19 Vaccine Monitor. June 2021. Available at: https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-june-2021/
[52] Edelman. 2022 Trust Barometer Special Report: Trust and Health. Available at: https://www.edelman.com/sites/g/files/aatuss191/files/2022-08/2022%20Trust%20Barometer%20Special%20Report%20Trust%20and%20Health%20with%20Talk%20Track.pdf
[53] Hesse EM, Hibbs BF, Cano MV. Notes from the Field: Administration of Expired Injectable Influenza Vaccines Reported to the Vaccine Adverse Event Reporting System — United States, July 2018–March 2019. MMWR Morb Mortal Wkly Rep 2019;68:529–530. DOI: http://dx.doi.org/10.15585/mmwr.mm6823a3e

the MDPP payment schedule, increase the total number of payable sessions allowed, and align MDPP supplier standards with the CDC's Diabetes Prevention Recognition Program (DPRP).

*AAFP Comments:*

AAFP supports the proposed changes to the MDPP. Obesity is a risk factor for type 2 diabetes, and more than 40% of the population is estimated to live with obesity.[54] The AAFP supports policies to reduce obesity rates as a matter of public health, including supporting Medicare coverage for obesity screening and counseling. A recent evaluation found that the MDPP results in weight loss for beneficiaries, but access to the program has been uneven at the national level.[55,56]MDPP supplier participation may be lower than anticipated due to complex reimbursement and registration requirements.[57] The changes proposed by may address some of these challenges and improve access to the MDPP.

The AAFP is committed to building healthy communities, lowering health care costs, and improving patient health and well-being through high-quality health care delivery and access. Therefore, we encourage CMS to finalize proposals that may result in increased access to the MDPP, including the extension of virtual sessions, improvements to the payment schedule and aligning recognition requirements with CDC's Diabetes Prevention Recognition Program.

Appropriate Use Criteria for Advanced Diagnostic Imaging (section III.J.)

CMS proposes to pause implementation of the Medicare appropriate use criteria (AUC) program for re-evaluation and rescind the current AUC program regulations. CMS does not propose a timeframe for restarting implementation efforts, citing data integrity and accuracy risks and patient access issues. CMS believes the real-time claims-based reporting requirement is an overwhelming barrier to the AUC program becoming wholly operational. CMS also acknowledges that fully implementing the penalty phase of the AUC program in its current form would likely result in inappropriate claims denials. CMS will continue efforts to find a workable implementation approach for the program.

*AAFP Comments:*

**The AAFP strongly supports the proposal to pause implementation of the AUC program**. The AUC program is overly burdensome and complex, and it does not reflect the high level of family physicians' participation in APMs. The program also does not consider quality, patient outcomes, or other important factors, which are more appropriately addressed in APMs. The AAFP has repeatedly advocated for CMS to continue delaying full implementation of the AUC program and publicly report the obstacles to implementation. According to an AAFP survey, more than half of our members report

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[54] Campbell-Scherer D. New Insights and Future Directions: The Importance of Considering Poverty in Studies of Obesity and Diabetes. *Ann Fam Med*. 2023;21(3):205-206. doi:10.1370/afm.2983
[55] Center for Medicare and Medicaid Innovation. Evaluation of the Medicare Diabetes Prevention Program. Second Evaluation Report. November 2022. Available at: https://innovation.cms.gov/data-and-reports/2022/mdpp-2ndannevalrpt
[56] Yan A, Chen Z, Wang M, Mendez CE, Egede LE. Accessibility of Medicare Diabetes Prevention Programs and Variation by State, Race, and Ethnicity. *JAMA Netw Open.* 2021;4(10):e2128797. doi:10.1001/jamanetworkopen.2021.28797
[57] Meyer, H. Medicare Diabetes Prevention: Enrollment Short of Projections. Health Affairs. November 2021. Available at: https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2021.01292

participating in an APM. These physicians are already accountable for the quality and cost of their care, including strong incentives to reduce unnecessary utilization of costly imaging services, rendering the AUC program unnecessary. **The AAFP thanks CMS for being responsive to our recommendations, and we strongly urge CMS to finalize this proposal to delay implementation of the AUC program and rescind related regulations**.

Expand Diabetes Screening and Diabetes Definitions (section III.L.)

CMS proposes adding the Hemoglobin A1C test (HbA1c) to the list of covered diabetes screening tests and streamlining testing coverage limits so all beneficiaries, regardless of their diagnostic status, may receive up to two diabetes screening tests per year.

AAFP Comments:

The AAFP supports these proposals. The AAFP issued a recommendation statement that recommends screening for type 2 diabetes in adults aged 40 to 70 years who have overweight or obesity. CMS' proposal to include HbA1c to the list of covered diabetes screening test will make the recommended screening more convenient, as it does not require fasting.

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

*Standard for CMS Electronic Prescribing for Controlled Substances (EPCS) Program*

CMS clarified that the EPCS program will automatically adopt new electronic prescribing standards as they are updated, including proposals that have not yet been finalized from the CY 2024 Medicare Advantage and Part D Policy and Technical Changes rulemaking process. While NCPDP SCRIPT standard version 2017071 was finalized in the CY 2021 PFS final rule, CMS' intent is for prescribers to be able to use a single version the NCPDP SCRIPT Standard for all Part D electronic prescribing of Schedule II-V controlled substances.

CMS proposes to remove the "same entity exception" finalized in the CY 2022 PFS final rule, which currently applies to prescriptions where the prescriber and dispensing pharmacy are employed by the same entity. CMS notes that prescription drug event data used to evaluate prescriber compliance with the CMS EPCS Program cannot consistently identify when prescribers and dispensing pharmacies are part of the same entity, rendering the exception pointless. CMS also proposes to expand the available standards for same legal entities by adopting language that would allow either HL7 messages or the NCPDP SCRIPT Standard to be used when all actors in an electronic prescribing transaction are employed by the same entity. This would expand the standards prescribers could use and align program requirements with Medicare's E-Prescribing and Prescription Drug Program final rule.

*AAFP Comments*

The AAFP supports EPCS and national-level guidelines to avert a patchwork of policies that ultimately result in greater administrative burden for physicians and delay access to necessary prescriptions. We support prescribers being able to use the same version of NCPDP SCRIPT for electronically prescribing Part D controlled substances as for other Part D drugs being electronically prescribed. The AAFP also appreciates CMS acknowledging that the "same entity exception" finalized

in the CY 2022 PFS final rule is not functionally capable of achieving the exception's stated goal of evaluating prescriber compliance, and we support CMS' proposal to remove it. The AAFP thanks CMS for these clarifications and supports these efforts to streamline processes and standards throughout Agency programs.

The AAFP supports CMS' proposal to expand the available standards for same legal entities by adopting language that would allow either HL7 messages or the NCPDP SCRIPT Standard to be used when all actors in an electronic prescribing transaction are employed by the same entity. As proposed, expanding the standards prescribers could use would align program requirements with Medicare's E-Prescribing and Prescription Drug Program final rule. Disparate data requirements and standards across different health IT and other health care regulations can create confusion and administrative burdens for physician practices working to ensure they are in compliance, and we welcome efforts to streamline regulations and processes for physicians and their patients. The AAFP is strongly supportive of efforts to advance interoperability and improve data sharing with primary care physicians, since improving their access to patients' data facilitates care coordination and can improve patient outcomes.

*Definition of Prescriptions for Compliance Calculation*

CMS proposes to define how the CMS EPCS Program's compliance threshold calculation will be impacted by prescriptions with multiple fills, suggesting renewals would count as an additional prescription in a given measurement year, while refills would not. CMS believes there would be a significant burden increase for small prescribers if every fill were to be included, with many at risk of no longer qualifying for the small prescriber exception.

*AAFP Comments*

The AAFP supports CMS' proposal to count prescription renewals — but not refills — toward the program's compliance threshold calculation, unless it is the first occurrence of that prescription's refill within a measurement year. We agree with the assessment that many prescribers who currently qualify for the small prescriber exception would be at risk of no longer qualifying if each refill of a prescription counted towards the compliance threshold calculation. The AAFP understands family physicians that work in a small or independent practice environment have unique needs and may require specific, targeted support to be successful. We continue to encourage CMS to notify small prescribers when they are approaching the 100-prescription threshold. CMS should include specific instructions on compliance when or if they no longer meet the small prescriber definition, along with appropriate time to comply. **The AAFP recognizes that administrative complexity and regulatory burden are among the top drivers of physician burnout and independent practice closures, and we thank CMS for trying to prevent additional burdens being put on small prescribers through this proposal**.

*Updates to CMS EPCS Program Exceptions for Cases of Recognized Emergencies and Extraordinary Circumstances*

CMS proposes to modify the "recognized emergency" and "extraordinary circumstances waiver" exceptions definitions, which would allow prescribers more flexibility in requesting an extraordinary circumstances waiver and would instruct CMS to identify which events trigger the recognized emergency exception. CMS also intends to align the program's determination of an emergency exception with the MIPS automatic extreme and uncontrollable circumstances policy. CMS proposes

that any prescriber impacted by a recognized emergency exception would be excepted for the whole measurement year, not the length of the emergency. If a prescriber continued to experience exceptional circumstances beyond the measurement year, the prescriber would need to submit a new waiver application.

*AAFP Comments*

The AAFP supports CMS' proposal to update the circumstances applicable for the extraordinary circumstances waiver policy to ensure prescribers are not mistakenly left out of an emergency or disaster-related exception. We appreciate CMS' efforts to align the extraordinary circumstances waiver and recognized emergency exception policies with emergency policies of other CMS programs, especially MIPS' automatic policy for extreme and uncontrollable circumstances. Disparate policies using similar terms across different Agency programs can create confusion and administrative burdens for practices working to ensure they are in compliance, and the AAFP welcomes these efforts to streamline regulations and processes for physicians. Additionally, the AAFP supports the proposal for CMS to review emergency situations and offer blanket exceptions by region on a case-by-case basis using FEMA-designated emergencies and HHS-declared PHEs as a baseline, which also aligns with MIPS program policies.

**The AAFP strongly supports the proposal that any prescriber impacted by a recognized emergency exception would be excepted for the whole measurement year instead of the length of the emergency**. We support CMS' proposal that if a prescriber continued to experience exceptional circumstances beyond the measurement year, they would then need to submit a new waiver application. The AAFP believes these proposals would help reduce administrative burden for practices, and we encourage CMS to continue advancing administrative simplification and burden reduction priorities.

*Actions for Non-Compliance*

CMS proposes to maintain its policy of not financially penalizing clinicians who fail to meet the mandated 70% threshold for electronically prescribing controlled substances under Medicare Part D. CMS will continue issuing notices of noncompliance, with no date given for imposing future financial penalties.

*AAFP Comments*

**The AAFP strongly supports CMS' proposal to maintain its current policy of not financially penalizing clinicians who fail to meet the mandated 70% threshold for electronically prescribing controlled substances under Medicare Part D**. We appreciate CMS choosing to continue issuing notices of noncompliance for subsequent measurement years, as AAFP advocated for in last year's MPFS comment letter. While the AAFP supports the use of electronic prescribing to promote quality patient care, we recognize that there are several circumstances outside the physician's control that may inhibit the use of electronic prescribing, including high cost of implementation of electronic prescribing systems, lack of interoperability between primary care offices and pharmacies, and limited broadband access. Until primary care physician practices of all sizes and in all geographies are supported in implementation, training, maintenance, and security of electronic prescribing infrastructure, the AAFP supports CMS' currently proposed course of action.

The AAFP agrees that the EPCS program encourages the use of interoperable health IT, prevents fraud and abuse, and reduces clinician burden. Physicians who are working in good faith to adopt or implement electronic prescribing practices or are prevented from doing so by lack of broadband connectivity should not be penalized for noncompliance. We support CMS' notification process for noncompliance including both the reason for noncompliance and the opportunity to come into compliance before being penalized. The AAFP urges CMS to continue to work on providing support and incentives for physician practices, especially small, rural, and independent primary care practices, to effectively implement electronic prescribing practices without excessive burden and cost.

Changes to the Basic Health Program Regulations (section III.Q.)

Following an inquiry from a state, CMS proposes to allow states to suspend a Basic Health Program (BHP) if the state submits an application to HHS that meets several requirements. CMS proposes several steps states must take to ensure BHP enrollees receive comparable, comprehensive, affordable health care coverage elsewhere. At this time, only two states are operating BHPs, which cover low-income residents through state-contracting plans outside the marketplace.

The AAFP appreciates and supports the proposed protections for BHP enrollees and requirements to ensure they continue to have comprehensive, affordable health care coverage. The AAFP urges CMS to also require in the application for suspension that states outline a plan to notify physicians who provide care to enrollees enrolled in the BHP about the suspension, share information with physician practices and other clinicians and facilities about how and where patients will receive or can seek alternative comprehensive, affordable coverage, and work with physician practices to minimize any resulting administrative burden.

Updates to the Definitions of Certified Electronic Health Record Technology (section III.R.)

CMS proposes to amend the definitions of CEHRT for Medicare's Promoting Interoperability Program and the Quality Payment Program (QPP) to align with ONC's new approach to health IT certification, as outlined in the ONC HTI-1 proposed rule. Specifically, CMS proposes to include a reference to "Base EHR definition" as proposed in HTI-1 to ensure it would be applicable for CEHRT definitions going forward. CMS also proposes to add related citations to the regulatory text and cross-reference HTI-1's proposed revised terminology for certification criteria. CMS proposes to specify that technology meeting updated CEHRT definitions for these programs would be required to meet ONC's certification criteria "as adopted and updated by ONC". CMS believes these proposals would allow CEHRT definitions to automatically incorporate ONC's updates to certification criteria if the terminology was revised in the future without necessitating further rulemaking; updates would only be necessary if the location of the certification criteria changed.

CMS noted that future updates to ONC's certification criterion would not immediately be required for use in the Promoting Interoperability Program, QPP, or Medicare Shared Savings Program. CMS will continue to determine the timeline of when new or revised measures that require certified health IT would be implemented as compliance requirements for these programs and will consider factors like clinician readiness and time needed for implementation as part of that process. CMS believes this approach will provide flexibility for clinicians and hospitals to adopt and implement ONC's updated certification criteria as it becomes available and without having to wait on CMS to then amend related regulations. CMS believes these proposed changes would be helpful to clinicians and practices, as well as for the Agency itself, even if ONC does not finalize this section of HTI-1.

*AAFP Comments:*

**The AAFP supports CMS' proposals to update CEHRT definitions and incorporate cross-references into Medicare's Promoting Interoperability Program and the Quality Payment Program (QPP) to more closely align with the new naming conventions offered in ONC's HTI-1 proposed rule**. Disparate definitions for the same terms across different health IT and other health care regulations can create confusion and administrative burdens for physician practices working to ensure they are in compliance, and we welcome efforts to streamline regulations and processes for physicians and their patients. The AAFP has long supported CMS' efforts to align regulations and collaborate effectively with other federal agencies and has consistently supported ONC's efforts to advance interoperability of health IT. Interoperability is essential for ensuring family physicians have access to meaningful, actionable data at the point of care, which in turn enables them to provide high-quality, patient centered care across the lifespan. Truly interoperable health records will also reduce administrative tasks for physicians and facilitate patients' access to their health data. The AAFP agrees with CMS' conclusion that this approach will offer flexibility to clinicians and hospitals to adopt and implement ONC's updated certification criteria as it becomes available without having to wait on CMS to amend related regulations.

Given OIG's recently finalized information blocking regulations for health IT vendors and CMS' proposed changes to the CEHRT definition here, we believe there is a critical issue CMS must address. If a CEHRT vendor is found by OIG to have violated those information blocking regulations, that may trigger ONC to decertify the vendor's product(s). This would create a situation for all physicians using the product to no longer qualify for Medicare's Promoting Interoperability Program and negatively impact physician performance in QPP, potentially resulting in a negative payment adjustment. The AAFP strongly urges CMS to act and to establish a safe harbor for those physicians until the product can be reinstated. Practices and hospitals are not able to easily switch EHRs, so this safe harbor must extend for longer than the current reporting year. Enacted safe harbor provisions should apply to all CMS programs that require a CEHRT and ensure physicians are not penalized for information blocking actions of health IT vendors. The AAFP encourages CMS to prioritize communication and transparency with stakeholders to ensure all parties understand what is expected and what the timeline is for achieving any finalized proposals.

A Social Determinants of Health Risk Assessment in the Annual Wellness Visit (section III.S.)

CMS proposes to add a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element of the Medicare Annual Wellness Visit (AWV) with an additional payment. To be eligible for an additional payment, physicians and others must deliver the SDOH Risk Assessment on the same day as the AWV using a standardized, evidence-based tool that aligns with the beneficiary's educational, developmental, and health literacy needs, while also being culturally and linguistically appropriate. CMS does not propose to mandate the use of any specific tool but provides suggested examples. CMS proposes to establish a stand-alone G-code (GXXX5) for SDOH Risk Assessment furnished in conjunction with an E/M visit, which would also be used to report SDOH Risk Assessment in conjunction with the Medicare AWV. The SDOH Risk Assessment would not be subject to beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV.

In response to feedback from interested parties that the AWV may be more effectively furnished if elements were allowed to be completed over multiple visits and days, or prior to the AWV visit, CMS invites public comment on this issue for consideration in future rulemaking.

*AAFP Comments*

**The AAFP fully supports CMS's proposal to add a new SDOH Risk Assessment as an optional, additional element of the Medicare AWV with an additional payment not subject to beneficiary cost sharing.** The elimination of cost-sharing when this is done in conjunction with a Medicare AWV eliminates a barrier that otherwise might discourage or prohibit some beneficiaries from taking advantage of this important service. We appreciate CMS eliminating that barrier.

As noted in the AAFP position paper on "Advancing Health Equity by Addressing the Social Determinants of Health in Family Medicine," SDOH have a greater impact on population health than factors like biology, behavior, and health care and are the primary drivers of health inequities. Like CMS, the AAFP believes an optional SDOH Risk Assessment would ultimately inform and result in the development of steps to address and integrate SDOH in the patient's AWV health assessment and personalized prevention plan.

As noted in the AAFP policy statement on "Advancing Health Equity: Principles to Address the Social Determinants of Health in Alternative Payment Models," the AAFP believes practices should receive appropriate resources and support to identify, monitor, and assess SDOH. The AAFP urges health insurers and payors, including Medicare, to provide appropriate payment to support health care practices to identify, monitor, assess, and address SDOH. Thus, the AAFP supports the current proposal by CMS.

We address the valuation of proposed code GXXX5 in our comments on the section of the proposed rule (II.E) dealing with "Valuation of Specific Codes."

Regarding allowing elements of the AWV to be provided on dates other than that of the AWV itself, we think there is merit in doing so. If interoperability was better and electronic health records (EHRs) functioned the way most family physicians wanted, completing all the elements of an AWV on the same date would be relatively easy. Unfortunately, the current state of EHRs and interoperability makes completion of all elements of the AWV at a single encounter a struggle for some physicians.

We note that CMS already allows the health risk assessment to be completed before the AWV. Other elements (e.g., patient's medical and family history, current providers and suppliers list) could also be collected before the AWV and reviewed with the patient at the AWV. The performance of other elements (e.g., establishment of an appropriate patient screening schedule, provision of personalized patient health advice and referrals) may benefit from being done at a separate encounter following the AWV, allowing more time for the care team to process the information gleaned at the AWV encounter.

We recognize that allowing elements of the AWV to be completed over time rather than all at the same encounter poses potential administrative challenges to both CMS and practices. However, just as CMS allows practices to perform other services over time (e.g., chronic care management, transitional care management), there may be value to allowing practices to perform the elements of a single AWV over time, and we encourage CMS to give serious consideration to that opportunity in future rulemaking.

## IV. Updates to the Quality Payment Program

CMS is seeking feedback on how the agency can modify their QPP policies to foster clinicians' continuous performance improvement and positively impact care outcomes for Medicare beneficiaries.

*AAFP Comments*
The AAFP shares CMS' interest in fostering continuous performance improvement. We appreciate the goals of CMS' National Quality Strategy and its efforts to align quality measures across its many programs through the Universal Foundation. We applaud CMS for taking this positive step toward reducing the burden of measurement, but additional steps are needed to truly make a difference for physician practices and patients. Payers often use different criteria and physicians may be required to report on multiple, overlapping measures across their patient panel using different reporting mechanisms for each payer. When this is multiplied by thousands of patients, across multiple payers (often 10+), potentially across multiple sites of service and data platforms, the associated burden and cost are significant. Continuing to take a payer-specific, siloed approach to quality measurement diminishes the usefulness of the insights that could otherwise be gleaned a more streamlined and holistic understanding of performance improvement achievements as well as pointing to areas for future improvement. **We believe that CMS is uniquely positioned to serve as a convener to advance meaningful multi-payer alignment. We strongly urge CMS to work with all payers, public and private, toward this vision.**

The overarching goal of MACRA was to shift physician payment away from the volume-based FFS system toward APMs that support value-based care. **The AAFP believes primary care is served best by** well-designed value-based payments **that include comprehensive prospective payments that sustainably support person-centered, longitudinal care delivered by physician-led teams. MIPS should serve as a pathway to this vision for primary care and should not be viewed or designed as the end goal.**

The AAFP shares CMS' interest in fostering continuous performance improvements that lead to better outcomes for patients. However, we are concerned that the current design of the program which focuses on individual clinician performance using largely process rather than outcomes measures is not driving care improvements as much as it is adding administrative complexities that detract from patient care.

- A recent analysis by the AMA concluded that the MIPS score assigned to an eligible clinician (EC) does not represent the quality or value of the services provided by that EC. Rather, it represents the services provided by their group or ACO.
- Increases or decreases in an EC's quality score are not always directly linked to the quality of care provided to patients. Changes in quality scores over time may be the result of using different measures or changes in the patient population reported.
- Not all performance measures reliably measure differences in quality of care – which can be especially true for physicians with small numbers of patients.

**The AAFP is concerned that these challenges will only be further exacerbated in 2024 by:**

- **Medicare physician payment rates that are not adjusted for inflation and thus fail to keep up with the cost of running a practice;**
- **Budget neutrality requirements that cause additional annual payment reductions;**
- **A MIPS performance threshold that unfairly penalizes small and rural physician practices, resulting in significant downward payment adjustments that will further destabilize these practices and the access to care their patients rely on;**

- **The expiration of the AAPM bonus, which removes an important incentive for physicians to move into value-based payment arrangements and invest in care delivery transformation that benefits beneficiaries.**

**Based on these concerns and the recognition that the overarching goal of the QPP is to drive toward well-designed value-based payment, the AAFP believes a broader overhaul of the entire program must be considered.** Some of these changes may require congressional action to enact broader MACRA reforms. The AAFP recently submitted robust recommendations to Congress on how to modify the MIPS program to make it a less burdensome, more meaningful on-ramp to APM participation for primary care physicians. We will continue to advocate for legislation that advances these goals.

**In the near term, we strongly recommend CMS take the following steps to improve the MIPS program:**

- **Use any available authority to refrain from raising the MIPS performance threshold and/or minimize the damage to small and medium physician practices;**
- **Move away from using the Total Per Capita Cost (TPCC) measure in the MIPS program now that several episode-based cost measures are available and relevant to primary care;**
- **Continue to advance measure alignment across payers and programs, including by supporting shared mechanisms for measurement and incorporating patient reported and other outcomes measures that are meaningful to beneficiaries and their clinicians;**
- **Minimize the reporting burden for the Promoting Interoperability category, which is not meaningfully advancing interoperability; and**
- **Advance policies that focus on meaningful measurement of care quality and move away from policies that focus on burdensome reporting requirements.**

## Merit-based Incentive Payment System (MIPS)

*MVP Development, Maintenance, and Scoring*

CMS proposes to consolidate the Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single MVP called “Value in Primary Care.” The consolidated MVP aligns with the Adult Universal Core Set.

*AAFP Comments*

We applaud CMS’ efforts to align the primary care MVPs with the Adult Universal Core Set. The AAFP has advocated for CMS to align measures across programs and payers, including by aligning MIPS measures with those used in APMs. The AAFP applauds CMS for including the Person-Centered Primary Care Patient Reported Outcome Measure (PCPCM PRO-PM) in the MIPS program and in this MVP. The AAFP is strongly supportive of the PCPCM as a more holistic measure of primary care from the patient’s perspective and encourages its inclusion in the Universal Foundation as that measure set evolves.

The AAFP is supportive of the consolidated Value in Primary Care MVP as it reflects the comprehensive way in which primary care is delivered. Given that MVPs are still in their initial years, and it is unclear how many physicians are opting to use them, we would also be supportive if CMS elected to continue to offer the Promoting Wellness and Optimizing Chronic Disease Management MVPs for a period to allow physicians to transition to the new combined MVP.

Below we provide feedback on the following MVP measures:

- Q134: Preventive Care and Wellness Composite Measures
- Q493: Adult Immunization Measure
- Q305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment and TBD: Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk
- Cost Measures

*Q 134: Preventive Care and Wellness Composite Measure:* **We do not support the Preventive Care and Wellness composite measure and recommend against finalizing its inclusion in traditional MIPS or any Primary Care MVP in the final rule.** First, we note that this measure is not included in the Universal Foundation. The composite also includes the outdated BMI Screening and Follow-up Plan measure, which is no longer endorsed by a consensus-based entity (like the National Quality Forum or Battelle's Partnership for Quality Measurement). Further, the Core Quality Measures Collaborative notes that the BMI screening and follow-up measure may not be appropriate for elderly patients, which makes it inappropriate for use in the Medicare population. The AAFP has also previously 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' screening mammograms, 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. A physician who elects to report to this measure would need to collect and report a total of 10 measures to satisfy the quality requirements for the MVP, which is higher than traditional MIPS and serves as a disincentive to select it. For all these reasons, we oppose the inclusion of the Preventive Care and Wellness composite measure and urge CMS not to use it in traditional MIPS or this MVP.

Congruent with our recommendation not to include the Preventive Care and Wellness composite measure, we recommend that CMS keep the following individual measures:

- Q112: Breast Cancer Screening
- Q113: Colorectal Cancer Screening
- Q226: Preventive Care and Screening: Tobacco Use Screening and Cessation Intervention

*Q493: Adult Immunization Measure:* 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, the Office of the National Coordinator for Health IT, 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.

*Q305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment and TBD: Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk:* While we agree with CMS that these are important priorities and recognize their clinical significance, the data needed to report on these measures is not discretely captured in EHR systems without a significant investment of time and money. Reporting on these measures will

add significant administrative and financial burden and we request that CMS re-consider inclusion of these measures at this time. We encourage CMS to work with ONC to ensure that health IT vendors are held accountable for supporting this and all other high priority reporting requirements.

*Cost Measures:* As discussed below, the AAFP has repeatedly raised concerns about the use of TPCC as an independent measure of primary care success. We acknowledge that CMS is required by statute to measure cost performance in QPP and that Congress stipulated that CMS work toward capturing 50 percent of Parts A and B spending across measures. TPCC is described to be a measure of high-quality, successful primary care delivery but **the AAFP firmly believes that MIPS does not provide primary care physicians with the support and flexibility they need to invest in continuous improvement and care delivery transformation.** Our concerns related to TPCC are based on its incongruence with these foundational principles that should guide any attempt to hold primary care accountable for the total cost of care:

- As CMS notes, primary care is recognized for its ability to improve outcomes and reduce overall spending. These are long-term outcomes that are achieved with an appropriate level of investment in primary care services. **TPCC is not designed to capture the long-term cost savings that primary care is known to achieve. Rather, it's likely that TPCC penalizes primary care clinicians by capturing only the near-term investment in primary care services that improve access to comprehensive care (and therefore utilization) for underserved populations, increase utilization of recommended preventive services, and comprehensively addressing patients' medical, behavioral, and social needs**.
- 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. **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.**

The AAFP is pleased to see the new 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 would be supportive of relying on the episode-based cost measures relevant to primary care in lieu of the TPCC in MIPS.**

As the new primary care MVP is currently constructed, the cost category for this MVP will consider the impact of specific condition-related costs at least twice (and sometimes more) in the EBCM and the TPCC. While we understand that the methodology does not "double count" costs because each measure is independently calculated and CMS is applying an average of scores on all of the measures to get an EC's final cost performance score, we continue to believe that certain costs will repeatedly impact this score. For example, a patient with diabetes will have related costs attributed to the diabetes episode-based cost measure and to TPCC.

We also note the difficulty of providing CMS with detailed feedback about how best to publicly report cost measures as CMS itself has provided very little information about the current cost measures. No cost measure information has been made available since the 2019 performance period due to reweighting the cost performance category to zero percent of the final score in 2020 and 2021 due to COVID-19. Since then, 15 new EBCMs and the revised TPCC and MSPB measures have entered the program. The AAFP requests that CMS make more information about performance on these measures available as soon as possible.

Further, despite the fact that the cost performance category accounted for 15% of the final score in 2019 and there were 10 cost measures, there is almost no information about this category in the 2019 QPP Experience Report. The only information that CMS made available is about how the cost measures were calculated. We do not know how many eligible clinicians or groups were scored on the cost measures, how many patients were attributed to each clinician or group, how far the scores deviated from the mean or median, whether performance largely hovered around the mean or was spread across the 10 deciles, and so on.

**Therefore, the AAFP urges CMS to include detailed cost measure information in each QPP Experience Report and to host a Town Hall or solicit feedback in another informal format following the release of each QPP Experience Report.** This would allow interested parties, including MIPS eligible clinicians, to provide informed input about the ways in which CMS should publicly report cost measures for patients and their caregivers.

<u>Subgroup Reweighting</u>
CMS previously finalized a policy that would apply reweighting to subgroups based on any reweighting applied to its affiliated group. Additionally, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting under circumstances described at §§414.1365(e)(2)(ii)(A) and (B). CMS has since identified technical restraints that affect their ability to implement this policy. CMS is concerned that the time required to adjudicate reconsideration requests for both a subgroup and its affiliated group could result in the subgroup not knowing its reweighting status during a significant portion of the performance period. Therefore, CMS is proposing to limit the reweighting applied to a subgroup to that which is also applied to its affiliated group beginning with the CY 2024 performance period. CMS will use a manual process to review subgroup reweighting applications for the CY 2023 performance period. CMS believes that, because subgroup reporting is not mandatory at this time, subgroups that are unable to participate in MIPS reporting as a subgroup (e.g., due to a natural disaster at the subgroup's practice location), the ECs in the subgroup would participate in MIPS via another reporting option. CMS also notes their previously established policy to not assign a score to a registered subgroup that did not submit data for the applicable performance period. In such instances, CMS would apply the highest of the available final scores associated with the EC's TIN/NPI for the ECs in the subgroup. CMS requests comment on this proposal.

*AAFP Comments*
While we understand there are operational challenges, the AAFP encourages CMS to explore additional avenues that would allow subgroups to request reweighting independent of the affiliated group's reweighting. In instances when both a subgroup and their affiliated group apply for reweighting for separate reasons, it's not clear how CMS' proposal would significantly impact the timing of a reweighting decision for the subgroup. Even though the affiliated group's reweighting would be applied to the subgroup, the subgroup's application should still be considered independently and regardless of the outcome of the affiliated group's application.

CMS acknowledges there are valid reasons when an extreme and uncontrollable circumstance may impact a subgroup and not the affiliated group (e.g., natural disaster). CMS notes subgroup reporting is voluntary right now and the subgroup could report as individuals or as a group if they are not able to report as a subgroup. If a natural disaster impacts a subgroup's practice, it's not clear how the subgroup would be able to report as individuals or as part of the group. The availability of alternative reporting options may not change whether the subgroup has access to their data, and the affiliated group may still want to report to potentially receive a positive payment adjustment. Additionally, CMS will require subgroup reporting beginning with the 2026 performance period and indicated that they will revisit their current policy to assign the group's score to subgroups that register but do not report. We are opposed to mandatory subgroup reporting and are concerned that mandatory subgroup reporting combined with this proposal will increase the potential damaging effects not allowing subgroups to request reweighting. MVPs and subgroup reporting are still in their initial years. We ask CMS to monitor the volume of reweighting applications from subgroups before making proposals to change its policy.

Subgroup Scoring Policies
CMS proposes to modify its policy to state that if an MVP participant, that is not an APM Entity or a subgroup, is eligible for facility-based scoring, a facility-based score will also be calculated in accordance with §414.1380(e). CMS seeks comment on this proposal.

The AAFP supports this proposal.

CMS previously finalized that they would permit subgroups to receive the complex patient bonus, which would be based on the patient population of the subgroup. CMS has since identified issues with using claims data associated with the clinicians in a subgroup that prevents them from calculating the complex patient bonus at the subgroup level. CMS proposes that an affiliated subgroup's complex patient bonus will be added to the final score of subgroup participants. CMS proposes to apply this policy beginning with the CY 2023 performance period. CMS seeks comment on their proposal.

*AAFP Comment*
The AAFP opposes this proposal. We believe it is important to calculate the complex patient bonus at the subgroup level given that the quality score is calculated at the subgroup level. It is unclear why CMS is unable to identify beneficiaries seen by clinicians in the subgroup given that subgroup composition must be submitted as part of MVP registration. We ask that CMS explore alternative options that would allow them to calculate the complex patient bonus at the subgroup level. If CMS wishes to transition more ECs to MVP participation, they must address these operational challenges.

*Targeted Review for Subgroups*

CMS had not proposed changes to existing language to reflect that subgroups may request a targeted review. CMS is proposing modifications to state that a MIPS EC, group, or subgroup may request a targeted review. CMS also proposes codification of previously finalized proposals, including updating the definitions of "attestation" and "submitter type" to include subgroups.

The AAFP supports these proposals.

APM Performance Pathway (APP)

*Definition of Collection Type*

Beginning in 2024, CMS proposes to establish a new collection type "Medicare Clinical Quality Measure for ACOs Participating in the MSSP (Medicare CQM)" collection type. The collection type will only be available to ACOs meeting the reporting requirements of the APP.

*AAFP Comment*

The AAFP supports CMS' proposal to include Medicare CQMs in the definition of collection type. As noted elsewhere in our comments, the AAFP supports creation of the Medicare CQM collection type.

*Data Submission Requirements*
CMS proposes technical amendments to data submission criteria. Specifically, CMS proposes amendments that:

- recognize that a virtual group, subgroup, and APM entity can meet data submission requirements pertaining to the quality performance category at §414.1325(a)(1), (c), and (d),
- a virtual group and APM entity can meet the data submission requirements at §414.1335(a)(1)(i) and (ii) for the submission criteria pertaining to Medicare Part B claims measures, MIPS CQMs, eCQMs, and QCDR measures,
- revise §414.1335 (a)(3)(i) to recognize that a virtual group, subgroup, and APM Entity can administer CAHPS for MIPS,
- revise §414.1335(a)(1)(i) and (ii) to clarify that data submission of eCQMs must be submitted using CEHRT,
- revise the definition of CEHRT in §414.1305(2)(ii) by broadening the applicability of the health IT certification criteria identified in 42 CFR 170.315 that are necessary to report objectives and measures specified under MIPS, and
- establish data submission criteria for Medicare CQM collection type – data submission criteria would be met by a MIPS EC, group, and APM Entity reporting the Medicare CQMs within the APP measure set and administering the CAHPS for MIPS survey.

The AAFP supports these proposals.

*Require the Submission of the CAHPS for MIPS Survey in the Spanish Translation*
The Consumer Assessment of Healthcare Providers and Systems (CAHPS) may be reported by groups, virtual groups, subgroups and APM entities of two or more ECs reporting via traditional MIPS or MVPs. It is required for MSSP ACOs reporting via the APP. In addition to English, the survey is also available in Cantonese, Korean, Mandarin, Portuguese, Russian, Spanish, and Vietnamese. CMS proposes to require groups, virtual groups, subgroups, and APM entities to contract with a CMS-

approved survey vendor to administer the Spanish translation to Spanish-preferring patients. Additionally, CMS is recommending administering in other available languages (Cantonese, Korean, Mandarin, Portuguese, Russian, and Vietnamese) based on the preferences of their patients.

*AAFP Comment*
The AAFP supports this proposal. The AAFP appreciates CMS' commitment to language accessibility through its programs and we share this commitment.

*Data completeness Criteria for Quality Measures, Excluding the Medicare CQMs*
Based on their analysis, CMS believes it is feasible for ECs and groups to achieve a higher data completeness threshold without jeopardizing their ability to succeed in MIPS. The data completeness threshold was 70% for the CY 2020-2023 performance periods. It will increase to 75% for the CY 2024 and 2025 performance periods. CMS is proposing to maintain the data completeness threshold to 75% for the CY 2026 performance period. CMS proposes to increase the threshold to 80% for the CY 2027 performance period. CMS believes the use of EHRs and eCQMs can reduce the burden associated with meeting a higher data completeness threshold. CMS does not believe the increased threshold will pose a substantial burden unless participants are manually extracting data. This threshold applies to QCDR measures, MIPS CQMs, and eCQMs. CMS proposes the same thresholds for Medicare Part B claims measures.

*Data Completeness Criteria for the Medicare CQMs*
For the CY 2024, 2025, and 2026 performance periods, CMS is proposing that an APM entity, specifically an MSSP ACO that meets the reporting requirements under the APP, submitting Medicare CQMs must submit data on at least 75% of the APM entity's applicable beneficiaries eligible for the Medicare CQM (defined at §425.20) who meet the measures denominator criteria. CMS proposes to increase the threshold to 80% for the CY 2027 performance period.

CMS seeks comment on these proposals.

*AAFP Comment*
**The AAFP strongly opposes increasing the data completeness threshold.** We believe there is promise in a future of digital quality measurement. However, there are several barriers that are hindering meaningful progress toward this goal. **It is premature to increase the data completeness threshold until these barriers are addressed and doing so will add additional administrative burden and potentially penalize primary care practices for challenges outside their control. We urge CMS to reconsider the finalized policy and reduce the data completeness threshold in MIPS.**

**We are concerned that physicians are being held to a higher bar than any other CMS quality program.** For example, health plans report on a sample of patients for each of the measures that require clinical data beyond administrative claims in the Medicare Part C and D Star ratings. Hospitals also extract clinical data on a sample of patients for the clinical process of care measures. None of these sample sizes, which are based on the number of plan participants or individuals admitted to the hospital for a specific diagnosis or procedure, come close to the current 70 percent data completeness requirement in MIPS. **If CMS determined that smaller sample sizes provide sufficient information on which CMS and others can make informed decisions on the quality of care delivered for health plans and hospitals, we believe that this same logic should also apply to MIPS.**

As we pointed out in our comments regarding the composite measures, 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 are not mature enough to 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.

Selection of MIPS Quality Measures

CMS is proposing 200 measures for the MIPS quality measure inventory. They are proposing 14 new measures, seven high priority measures, four of which are also PROMs. CMS proposes to remove 12 measures and partial removal of three measures. They are proposing substantive changes to 59 measures, including three measures to be retained under MVPs. CMS proposes substantive changes to the CMS Web Interface measures. CMS seeks comment on their proposals.

*AAFP Comment*

We appreciate that CMS continues to offer a robust measure set from which eligible clinicians can choose when participating in traditional MIPS. The current family medicine specialty set includes 64 measures. CMS is proposing the addition of 7 measures to this specialty set and the removal of 8 measures, netting 63 measures for CY 2024. Given that family physicians who participate in traditional MIPS must choose 6 of these 63 measures (including one outcome measure or high priority measure,) there are plenty of options from which to choose. This allows them to select measures that are the most meaningful and impactful to the patients and communities they serve but also are feasible to report using their current health IT capabilities.

We appreciate CMS's efforts to offer more patient-reported outcome measures, and we reiterate our support for the Person-Centered Primary Care Patient-Reported Outcome-based Performance Measure (PCPCM-PRO-PM)

We would like to note that many of the seven measures CMS proposes for addition to the family medicine specialty set come with good intent and solid clinical purpose and value, but the current health care landscape and fragmented health IT environment do not support easy, seamless reporting of the data elements necessary. Therefore, most physicians will choose not to report on these measures because the burden associated with reporting is too great (e.g., Gains in Patient Activation Measure [PAM] scores at 12 months).

**We strongly oppose addition of the Preventive Care & Wellness composite measure**, as noted earlier in our MVP comments. With this opposition, we request that CMS not remove the individual component measures that it proposes to remove, including:

- Breast Cancer Screening
- Colorectal Cancer Screening
- Preventive Care and Screening: Tobacco Use Screening and Cessation Intervention

- Preventive Care and Screening: Screening for high blood pressure and follow-up documentation

Cost Performance Category

*New Episode-based Measures Beginning with the CY 2024 Performance Period/2026 MIPS Payment Year*
CMS proposes five new episode-based cost measures:

- Depression
- Emergency Medicine
- Heart Failure
- Low Back Pain
- Psychoses and Related Conditions.

Each measure has a case minimum of 20 cases. CMS is proposing to add the five new measures and remove the Simple Pneumonia with Hospitalization measure from the operational list of care episode and patient condition groups and codes. This proposal would increase cost coverage of care episode and patient condition groups – moving closer to the statutory goal of 50% of A and B expenditures.

For chronic condition episode-based measures, episodes are attributed to the clinician group that renders services that constitute a trigger event (i.e., two claims billed in close proximity by the same clinician group). Both claims must have a diagnosis code indicating the same chronic condition related to the specified episode-based measure. The trigger event opens a year-long attribution window from the date of the initial E/M outpatient service. If CMS sees evidence that the relationship is ongoing through a reaffirming claim, the window can be extended. For individual MIPS ECs, CMS would attribute episode to each individual MIPS EC within an attributed clinician group that renders at least 30% of trigger or reaffirming codes on Part B claim lines during the episode. ECs must have provided condition-related care to the patient prior to or on the episode start date. CMS seeks comment on their proposal to add the five episode-based measures.

*AAFP Comment*
**As noted previously, the AAFP continues to oppose the use of total per capita cost (TPCC) in MIPS and MVPs. We ask that CMS remove it from MIPS, or at a minimum, remove it from the Value in Primary Care MVP.** This 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 being 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. The use of TPCC and similar measures in MVPs will serve as a deterrent to participation in MVPs and in APMs in the future. The AAFP also reiterates its strong belief that population health measures are best measured at the system level and not at the individual physician or other clinician level.

There are now 23 episode-based MIPS cost measures currently in use and many more in the development pipeline. Many of these measures address the costs of primary care. In fact, in the Chronic Condition Episode-Based Cost Measures Attribution Methodology FAQ document, CMS provides the top five specialties for each of the 10 chronic condition episode-based cost measures developed to date. Of the 10 measures, internal medicine is in the top five for all. In addition, family medicine is in the top five for seven of the 10 measures. **We therefore note that there are now several other measures available to measure primary care clinician performance in the Cost Performance Category and so TPCC is no longer needed.** Further, including the Wave 4 episode-based cost measures, which CMS is proposing to include in MIPS in this rule, episode-based cost measures now account for 36.8 percent of all Medicare Parts A and B spending.

While the AAFP prefers use of the EBCM measures over TPCC to satisfy CMS's requirement to measure cost, we echo the concerns regarding the EBCM noted previously in our comments on the new MVP. Namely that EBCMs are likely to consider the impact of specific condition-related costs at least twice (and sometimes more) in multiple EBCMs as well as in the TPCC if CMS chooses to continue to use this measure. We are concerned this may have a bigger impact on primary care. Given the breadth of care provided by primary care physicians, they are likely to be attributed multiple episode-based cost measures in addition to TPCC. The Value in Primary Care MVP currently has four episode-based cost measures, making it the MVP with the highest number of episode measures. It is also one of the two MVPs with the highest number of overall cost measures.

**The AAFP does not support attribution of the same costs to multiple physicians in different practices when there is no evidence that they are practicing as a team.** We have concerns about the impact of spreading accountability so widely, which CMS believes will improve care coordination. Yet this assumes data regarding services provided by other physicians is readily available and therefore actionable by the attributed physician. CMS does not provide this information, and the health information exchange infrastructure that could provide this information does not exist in most places. It is unreasonable to expect that physicians have the capacity to track patients across the wide range of care settings available to them under the current Medicare beneficiary benefit design without CMS either providing physicians with the information needed to actively coordinate care in real-time with other physicians and/or ensure that the health information exchange infrastructure to support this kind of real-time coordination is available. If CMS continues using a TPCC measure, the attribution methodology should be changed to eliminate the problems created by adding 12 months of prospective accountability for multiple physicians.

We urge CMS to include information about the extent of this overlap such as the distribution of the number of cost measures attributed to each TIN and TIN/NPI in its annual experience report. In addition, we request that CMS elaborate on how different comparison groups and benchmarks under different measures address the issue of double counting costs and demonstrate that CMS can analyze the overlap between the revised TPCC and MSPB clinician measures and the episode measures.

Finally, we believe it is inappropriate to prioritize measuring the largest number of physicians in the Cost Performance Category over getting the measures and methodology right. We are pursuing legislative refinements to MACRA that would give CMS more flexibility to develop and use cost measures without an arbitrary target of Medicare Part A and Part B expenditures and to score cross-category measures. We hope the agency will work with stakeholders and Congress to seek this authority so CMS can prioritize actionable measures with a demonstrated need for improvement and that measure cost within the context of quality.

*Reliability Case Minimum*

CMS proposes to clarify that the case minimum established in §414.1350(c)(4) through (6) establishes the case minima for episode-based measures of each episode type (i.e., procedural, acute inpatient medical condition, and chronic condition) such that the case minimum specified therein applies to all episode-based measures of that episode type, regardless of when the measure is adopted for inclusion in the cost performance category, unless specified for individual measure(s). CMS also proposes that this interpretation will apply to §414.1350(c)(7) for care setting episode-based measures. CMS notes that the case minima for any future measure under consideration would still be evaluated against reliability testing and could be different from the standard case minima. CMS invites comment on these proposals.

*AAFP Comment*
The AAFP believes measures should meet at least a 0.7 reliability and all case minima should ensure a measure can meet or exceed this threshold at both the individual NPI and TIN level. We believe the case minima and reliability of all existing measures should be reviewed regularly and adjusted based on whether the measure meets at least a 0.7 reliability.

Improvement Activities Performance Category

CMS is proposing to add five new improvement activities, modify one existing activity, and remove three activities. CMS notes that the proposed removal of "Implementation of co-location PCP and MH Services" (IA_BMH_6) is to ensure the Behavioral and Mental Health subcategory reflects current clinical practice and does not reflect a de-emphasis on behavioral and mental health.

*AAFP Comment*
The AAFP encourages CMS not to remove the "Implementation of co-location PCP and MH Services (IA_BMH_6)" from the improvement activity inventory. We understand that CMS is not de-emphasizing behavioral and mental health, but we do not feel it is necessary to remove this activity. The AAFP strongly supports integrated behavioral health and primary care physicians play an integral role in treating patients with mental and behavioral health conditions.

Promoting Interoperability Performance Category

*Promoting Interoperability Performance Category Performance Period*

CMS previously finalized a continuous 90-day performance period for the promoting interoperability (PI) performance category. CMS is proposing to increase the performance period to 180 days beginning with the CY 2024 performance period. CMS states the proposal would minimally increase the information collection burden on data submitters. They do not believe the current 90-day performance period is representative of an EC's overall use of CEHRT throughout the entire calendar year. CMS wants to move toward reporting on a full years' performance, which can be achieved by incrementally increasing the number of days in the performance period. CMS invites comment on this proposal.

*AAFP Comment*

**The AAFP opposes this proposal.** CMS' rationale for wanting to expand the performance period is that they believe it will promote health information exchange. We do not believe this is an effective or appropriate policy lever that would move the needle on health information exchange, given that the

legacy Meaningful Use program and the current promoting interoperability requirements have clearly failed to advance this goal. CMS also believes extending the performance period will only incrementally increase the data collection burden on submitters. While this may be true, we note that incrementally increasing burden on an already overly burdensome category does not make it appropriate. **The AAFP has long called for CMS to move away from health IT utilization measures and identify ways to provide cross-category credit or attestation for this category.**

*Certified Electronic Health Record Technology Requirements*

CMS is proposing to modify definition of CEHRT for the purposes of the QPP to no longer refer to year-specific editions, and to incorporate changes made by ONC to its definition of Base EHR and its certification criteria for health IT.

*Changes to the Query of the Prescription Drug Monitoring Program under the e-Prescribing Objective*

The Query of the Prescription Drug Monitoring Program is worth 10 points. It includes two exclusions: (1) any MIPS EC who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law; and (2) any MIPS EC who writes fewer than 100 permissible prescriptions during the performance period. CMS has become aware that their second exclusion option does not consider ECs who do not prescribe Schedule II opioids or Schedule III and IV drugs. Therefore, they are proposing to modify the exclusion criterion to state that any MIPS EC who does not electronically prescribe any Schedule II Opioids or Schedule III or IV drugs during the performance period can claim the second exclusion.

*AAFP Comment*

The AAFP supports these proposals.

*Proposed Technical Update to the e-Prescribing Measure*

CMS proposes technical corrections to e-prescribing measure to address the removal of “drug-formulary and preferred drug list checks” that was finalized in 2021 PFS. This policy was inadvertently omitted from the CY 2023 PFS final rule.

The AAFP supports this proposal.

*Changes to the Safety Assurance Factors for the EHR Resilience Guides (SAFER Guides) measure*
Beginning with the CY 2022 performance period, CMS finalized a requirement for practices to attest to whether they have conducted an annual self-assessment using the High Priority Practices SAFER Guide at any point during the CY in which the performance period occurs. Either a “yes” or a “no” can satisfy the measure.

Starting with the CY 2024 performance period, CMS proposes to amend Proposing to amend SAFER Guides measure to require ECs to conduct the self-assessment annually and attest “yes.” Attesting “no” will result in a 0 for the whole PI category. CMS believes ECs have had enough time to become familiar with the use of the SAFER guides and notes that there are resources available to help ECs with completing the self-assessment. CMS is not proposing to require attestation as to whether ECs have implemented any best practices “fully in all areas” nor will ECs be scored on how many of the practices they have fully implemented. CMS invites comment.

*AAFP Comment*
**The AAFP did not support the inclusion of this measure and are opposed to this proposal.** We strongly agree with the need to protect patient health information, particularly since it is essential to protecting the patient-physician relationship. We have advocated for these protections to be fortified as interoperability advances and information becomes more readily accessible. There are many laws in place to require the protection of such data. This MIPS measure adds administrative burdens associated with reporting and understanding the potential nuances between the measure definition and the requirements under the law (i.e., HIPAA, information blocking). We also note that the availability of resources to help ECs complete the self-assessment do not alleviate the burdensassociated with having to complete the assessment in the first place. **Further, we have and will always remain opposed to all-or-nothing measures. These do not advance programmatic goals, nor do they foster improvement.**

The AAFP has previously recommended that CMS, ONC, and other agencies harmonize the requirements across programs and regulations to address confusion and compliance burden for physician practices. For these reasons, we do not support the reporting of measures on protecting health information.

APM Improvement Activities Performance Category Score

CMS is aware that there is confusion as to whether the baseline score for the improvement activities category for MIPS APMs is applied automatically. CMS proposes amend §414.1380 to clarify that an EC or group with APM participation must have submitted data for two performance categories (i.e., quality and promoting interoperability) or attest to having completed an IA to receive the 50% of the baseline improvement activities category score. CMS also proposes to add a paragraph stating that they will not apply the baseline score if they have also approved a request for performance category reweighting or a hardship exception affecting the improvement activities performance category. CMS seeks comment on this proposal.

The AAFP supports this proposal.

MIPS Final Score Methodology

CMS is proposing a technical change to reflect the end-to-end measure bonus points, which was finalized not included in finalized regulatory text at §414.1380(a)(1)(i) or §414.1380(b)(1)(v)(A). CMS requests comments on these technical updates.

CMS previously established that they would consider a quality measure significantly impacted by ICD-10 coding changes if there was more than a 10% change in the codes in the measure numerator, denominator, exclusions, and exceptions. CMS has found that a 10% change to ICD-10 codes does not necessarily reflect a meaningful impact on clinicians' ability to report and be fairly scored on a quality measure. CMS proposes to eliminate the 10% change and instead assess how the coding changes affect the measure numerator, denominator, exclusions, and exceptions in ways that could lead to misleading or harmful results. CMS would assess whether the changes change the scope or intent of the measure. Changes in measure or scope would be considered significant changes that affect the applicability of the historical benchmark.

CMS is also proposing to assess the impacts of coding changes and their associated course of action (suppression, truncation, or standard 12-month reporting) by collection type.

eCQM specifications are designed only for a 12-month reporting period. If a measure is significantly impacted by ICD-10 coding changes, it cannot be reported for a truncated 9-month performance period. To address this, CMS proposes that measure specifications for eCQMs include the capability to be truncated to a 9-month performance period.

CMS seeks comment on these proposals.

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

Cost Performance Category Score

CMS implemented cost improvement scoring in the CY 2022 performance period and established a maximum cost improvement score of 1 percentage point. Due to the COVID-19 PHE, CMS reweighted the cost performance category to zero percent for the CY 2019-CY 2021 performance periods. To date, CMS has not applied a cost improvement score.

CMS has identified issues with their previously finalized cost improvement scoring methodology. CMS also identified issues with operationalizing their current policy to score improvement at the individual cost measure level.

- The number of cost measures is growing, making it difficult to maintain measure level improvement scoring.
- Using two different methods of improvement scoring for the quality and cost categories would increase complexity, CMS proposes to revise their policy to determine cost improvement at the category level.
- ECs may not meet the volume threshold for the same measure for two consecutive performance periods.

To address these issues, CMS proposes to determine each MIPS EC's cost improvement score at the category level, CMS also proposes to remove the requirement that they compare measures with a "statistically significant change in performance" as determined by the application of a t-test. CMS proposes these changes beginning with the CY 2023 performance period.

CMS would determine cost improvement score by subtracting the cost performance category score from the previously performance period from the cost performance category score from the current performance period, and then dividing the difference by the category score from the previous performance period and dividing by 100. Beginning with the 2025 payment year, the maximum cost improvement score is one percentage point.

CMS seeks comment on these proposals.

*AAFP Comment*
The AAFP encourages CMS to provide more data before implementing this proposal. It is difficult to assess the impact or effectiveness of this proposal given that many of the cost measures are either new or have been revised significantly.

MIPS Payment Adjustments

CMS is statutorily required to establish a performance threshold using the mean or median (as selected by the Secretary) of scores for all MIPS ECs for a "prior period" specified by the Secretary. For CY 2022-2024, CMS established the threshold using a single performance period and selected the mean as the methodology.

CMS does not believe the statutory language requires use of a single performance period to set performance threshold. The statutory language specifies a "prior period" rather than a year, which it uses in other sections of the Act. As such, CMS proposes that, beginning with the CY 2024 performance period, the "prior period" for the purposes of establishing a performance threshold is a span of three performance periods. CMS believes this will smooth out year-to-year fluctuations in the performance threshold and develop greater consistency and stability in MIPS. CMS requests comments.

CMS is not considering using CY 2020 through CY 2021 to establish the performance thresholds because of issues with the underlying data. CMS proposes to use the mean final score from the CY 2017-CY 2019 performance periods to establish the performance threshold for the CY 2024 performance period. The proposed threshold is 82 points, an increase of seven points from the CY 2023 threshold (75 points). The increase would be more substantial if CMS used more recent data from the CY 2018 or CY 2019 performance periods. CMS estimates 46% of ECs would receive a negative adjustment for the CY 2024 performance period if policies proposed in this proposed rule are finalized and the performance threshold is equal to 82 points. CMS requests comments on these proposals as well as whether they should use alternative years to set the performance threshold for the CY 2024 performance period.

*AAFP Comment*
The AAFP appreciates CMS' proposal to revise the definition of the "prior period" used to determine the MIPS performance threshold. We agree that using a longer timeframe can help stabilize the score. **However, we have concerns that implementing based on existing data is not an accurate representation of performance within the program and sets a perilously high threshold that would negatively impact the healthcare system.** We agree that it would not be appropriate to use data from the CY 2020 through CY 2021 performance periods, but we do not believe the current proposal to use CY 2017-2019 is appropriate either. These years reflect transition policies rather than the program as it stands today and using them to establish the 2024 performance threshold will not be a fair comparison.

The estimated impact of the increased threshold is significant – nearly half of all ECs would receive a negative payment adjustment based on the proposed increase. Even more alarming, CMS estimates that nearly 65% of ECs in solo practices, 60% of ECs in small practices, and 62% of ECs in practices with 16-99 clinicians will receive a negative payment adjustment, confirming that **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. These estimates demonstrate that 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 to adjust to a post-PHE environment and dealing with the broader impacts of 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. They struggle to pay their staff, rent, and other expenses all while recovering from a global pandemic.**

We know many of these challenges are beyond the scope of CMS' authority, but we strongly recommend against raising the performance threshold. **The AAFP urges CMS to use its available authority to prevent the damage that will occur from raising the performance threshold.** In the long term, we remain committed to working with Congress and CMS to enact legislative and regulatory reforms to MACRA that accelerate the transition to value-based care.

Targeted Review

Requests for targeted review must be submitted within a 60-day period, beginning with the day CMS makes MIPS payment adjustment factors available. The current submission period makes it challenging as CMS prepares to apply the different PFS conversion factors for QPs, beginning with the CY 2024 QP performance period. CMS must submit the final list of QPs to MACs by October 1 of the preceding year. Under the current timeline, this information would not be available until early December. Over the course of the program, CMS has found instances where an EC was not initially identified as a QP, but upon review, was found to have achieved QP status. Since the review process is essential to CMS accurately identifying who should receive the higher conversion factor, CMS is proposing to shorten the review timeframe. Specifically, CMS is proposing to permit submission of a request for targeted review beginning on the day they make available the MIPS final score and ending 30 days after publication of the MIPS payment adjustment factors for the corresponding MIPS payment year. This will allow approximately 60 days for the review period (30 days before publication of MIPS payment adjustment factors and 30 days after).

CMS also proposes to require that additional information requested by CMS must be provided to and received by CMS within 15 days of receipt of the request.

Finally, CMS proposes to add virtual groups and subgroups as being eligible to submit a request for a targeted review.

CMS invites comment on these proposals.

*AAFP Comment*
The AAFP supports the proposal to add virtual groups and subgroups as eligible but is concerned with the shortened turnaround time for practices to review the information from CMS and provide additional information when requested by CMS. We encourage CMS to review its processes and identify potential operational efficiencies that would allow more flexibility this timeline.

Public Reporting on Compare Tool
*Telehealth Indicator*

In the CY 2023 PFS final rule, CMS finalized a policy to add a telehealth indicator to clinician profile pages on the Compare Tool website. CMS would use POS 02 and POS 10 as well as modifier 95 to identify clinicians who furnish telehealth services. To ensure the Compare Tool is accurate, CMS is proposing to update their policy to specify that they would use the most recent codes at the time the data are refreshed that identify a clinician as furnishing services via telehealth. CMS would publish the details of which codes are used through education and outreach.

*AAFP Comment*
The AAFP supports this proposal as it would allow CMS to maintain more accurate information about which clinicians provide telehealth services.

*Publicly Reporting Utilization Data on Profile Pages*
CMS proposes to allow that they may use alternate sources to create clinically meaningful and appropriate procedural categories, particularly when no relevant grouping exists. This would be in addition to the two previously finalized sources (Restructured BETOS categorization system and code sources used in MIPS).

CMS finalized a policy to include procedure counts on clinician profile pages. They found that approximately 50% of clinician-procedure combinations fell into the low volume category, meaning CMS could only publish an indicator that a clinician has experience with a procedure rather than specific counts. CMS has determined that it would be technically feasible to integrate MA encounter data into procedure category counts. CMS proposes to publicly report aggregated counts of procedures performed by providers based on MA encounter data in addition to Medicare FFS utilization data.

*AAFP Comment*
The AAFP is pleased that CMS has identified ways to include MA encounter data in procedure category counts. We remain concerned that the number of clinicians with low-volume counts is still too high and could be misleading to patients. We are also concerned that patients may equate volume with quality. While the utilization and quality information may be presented simultaneously, it may be difficult for patients to distinguish them – especially if the volume represented is at the individual clinician level but the quality information represents the clinician's group performance.

*RFI: Publicly Reporting Cost Measures*
CMS is required to publicly report MIPS ECs final scores and performance category scores. They are authorized to, but not required to, publicly report MIPS ECs' performance with respect to each measure or activity. Performance in the quality, improvement activities, and promoting interoperability performance categories that meet public reporting standards are available on the Compare tool profile pages. Cost is not currently included. CMS intends to propose in future rulemaking to publicly report cost measures, beginning with data from the CY 2024 performance period and is seeking coming on how to best establish public reporting of cost measures.

*AAFP Comment*
As noted elsewhere in our comments, the AAFP is extremely concerned with the cost measures currently used in MIPS. **We strongly oppose the inclusion of EC-level cost performance in public**

**reporting until CMS remedies the larger issues with the cost category.** ECs are not assessed on the same number of cost measures, nor are they assessed on the same type of cost measures. Additionally, each cost measure has different attribution and benchmarking methodology that would make it difficult to present cost information in any sort of understandable or meaningful way to consumers. The AAFP encourages CMS to conduct additional research with consumers to better understand whether consumers would find value in view cost information or if they are more concerned with the price of a service. Cost performance is not an indicator of price, and it may cause confusion for consumers rather than supporting them in making informed decisions about their health care.

## Advanced Alternative Payment Models

### Overview of QP Determinations and the APM Incentive

CMS generally makes QP determinations at the APM entity level. It has been brought to CMS' attention that this may inadvertently discourage some APM entities from including certain types of ECs, leading those clinicians to be excluded form participation in Advanced APMs. CMS proposes to amend §414.1425(b) so that, beginning with the 2024 QP Performance Period, CMS would make all QP determinations at the individual level. CMS would calculate threshold scores for QP determinations at the individual level for each unique NPI associated with an eligible clinician participating in an AAPM. They would use all covered professional services furnished across all TINs to which the EC has reassigned their billing rights.

CMS proposes to change the definition of "attribution-eligible beneficiary" at §414.1305 so that a single definition using covered professional services will be applied regardless of the AAPMs in which the EC participates. The new definition would be any beneficiary who has received a covered professional service furnished by the EC for whom CMS is making the QP determination.

In accordance with the *CAA, 2023* the AAPM incentive payment will be 3.5% of covered professional service payments for the 2023 performance year.

Beginning with the 2024 QP performance period, CMS is proposing to adjust the Targeted Review period to meet the operational timelines to ensure that they can meet the statutory requirements for the application of the differential PFS conversion factors to QPs and non-QPs.

*AAFP Comment*
The AAFP appreciates CMS' desire to address concerns with calculating QP determinations, but we think this alternative approach could still serve as a disincentive for specialists to participate in an AAPM since it will make it more difficult for them to reach QP status. We suggest that CMS calculate both the entity-level and NPI-level and use whichever calculation is most advantageous to the EC. We think this approach would still provide an incentive for both APM entities and specialists. However, we believe there are two major issues that are the underlying problems that need to be addressed.

First, regardless of whether the QP calculation is done at the individual or APM entity level, the QP thresholds are too high. Beginning in 2024, the Medicare QP payment threshold will increase by 25 percentage points and the patient threshold will increase by 15 percentage points. These steep increases will likely make it difficult to achieve QP status for large numbers of AAPM participants. The

AAFP is advocating for legislation to provide CMS with additional authority to determine the appropriate QP threshold.

An additional barrier to continued AAPM participation is the expiration of the AAPM bonus. The *CAA, 2023* extended the bonus for an additional year at a reduced 3.5%. Beginning with the CY 2024 performance period, QPs will no longer receive a bonus. Furthermore, **the higher QP conversion factor is not likely to keep pace with the positive MIPS adjustments. We believe this poses a broader threat to AAPM participation as ECs may elect to leave an AAPM altogether because they could potentially receive a larger positive MIPS payment adjustment and would be statutorily excluded from receiving a MIPS adjustment if they were to receive QP status.** Given MIPS APM participants have historically performed well in MIPS, it would seem likely that these ECs would also perform well. Since more ECs are expected to receive a negative MIPS payment adjustment, the opportunity for a larger positive MIPS payment adjustment is greater as well.

As we've repeatedly emphasized, FFS fails to robustly and sustainably support comprehensive primary care and the AAFP strongly supports federal policies that help physicians (and our larger health care system) transition to risk-adjusted prospective payment models. The AAPM incentive payments have served as an important tool for attracting physicians to participate in advanced APMs and the expiration of the AAPM bonus will have negative impacts on family physicians' ability to transition value-based payment models. Primary care practices have also used the AAPM bonus payments to invest in care delivery transformation that drives success in these models by improving patient outcomes and lowering spending.

**We are concerned a diminished incentive and higher bar to achieve QP status will damage the transition to AAPMs. We urge CMS to work with the AAFP and others to support legislation such as the *Value in Healthcare Act* that would extend the AAPM bonus and allow CMS to adjust the QP thresholds through rulemaking and make varying thresholds and scaled incentive payments for more targeted models where participants cannot meet the existing one-size-fits-all thresholds.**

<u>Advanced APMs</u>

CMS is also proposing to amend the current AAPM CEHRT criterion to end the current 75% CEHRT use requirement and to add a new paragraph to specify that, to be an AAPM, the APM must require all ECs in each participating APM Entity, or for APMs in which hospitals are the participates, each hospital, to use CEHRT that meets CMS' new CEHRT definition. CMS proposes the same changes for Other Payer AAPMs. CMS seeks comment on this proposal.

*AAFP Comment*
The AAFP does not support the proposed increase in this threshold. We believe the established 75% threshold is adequate. Increasing this threshold will increase administrative burden and diminishes the additional flexibilities afforded to AAPM participants.

<u>Regulatory Impact Analysis (Section V.II)</u>

We generally incorporated our input on the estimated impacts of each proposal in our comments throughout this letter. However, CMS specifically seeks comment on the inclusion of analyses focused on beneficiaries and health equity in future MPFS rules. CMS included in this year's rule a baseline beneficiary utilization table that shows what percentage of beneficiaries with different demographic characteristics, SDOH indicators, and income assistance eligibility utilized services from each specialty.

The AAFP strongly supports the inclusion of analyses to estimate the impact of various proposals on beneficiary health equity, including impacts on vulnerable beneficiary groups. We note that these types of impact analyses, in addition to the more standard analyses estimating impacts on clinicians, may provide stakeholders with a clearer picture of how policies may impact Medicare beneficiaries and facilitate the implementation of positive policy changes under the MPFS. We appreciate CMS sharing Table 107 as a baseline for use and comparison in the future.

CMS notes and the AAFP agrees that the existing table probably underestimates the rate of disability among Medicare beneficiaries, in addition to other characteristics. We expect the data used to estimate the proportion of beneficiaries with unmet social needs/SDOH is a severe underestimation. As CMS notes, Z codes are not payable and are not consistently used across the health care system to document unmet social needs. The AAFP supports a variety of efforts to advance the identification of unmet social needs in Medicare and other data as a vital step to address these needs and mitigate health disparities. In the future, we urge CMS to use other data elements and sources to more accurately represent beneficiaries with unmet social needs. We also urge CMS to further stratify these beneficiaries in the baseline and any impact tables instead of lumping them all together.

The AAFP appreciates CMS including indicators for low-income beneficiaries, as well as an indicator for rurality. CMS could consider including beneficiary service utilization for those who receive care at an FQHC and an RHC. We urge CMS to include beneficiary impact and utilization estimates in future rulemaking.

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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 Meredith Yinger, Senior Manager of Federal Policy at myinger@aafp.org or (202) 235-5126.

Sincerely,

Sterling N. Ransone, Jr. MD FAAFP

Sterling N. Ransone, Jr., MD, FAAFP
Board Chair, American Academy of Family Physicians

## ***Appendix A*: Codes Recommended for Addition to the Primary Care Exception**

To continue to address the needs of beneficiaries, the AAFP strongly recommends HHS permanently expand the primary care exception to include:

- CPT codes 99201-99204 and 99212-99214
- G0402, G0438, G0439 – Welcome to Medicare and Annual Wellness Visits
- Telehealth CPT codes 99421-99423 both audio visual and audio only
- Transitional care management CPT code 99495
- G0444 - Annual depression screening, 15 minutes
- G0442 - Annual alcohol misuse screening, 15 minutes
- G0443 - Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes
- 99406 - Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes
- 99407 - Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes
- G0446 - Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes
- G0447 - Face-to-face behavioral counseling for obesity, 15 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
- 99491 - Chronic Care Management services provided personally by a physician or other qualified health care professional, first 30 minutes
- 99437 – Add-on code for CPT 99491 for each additional 30 minutes provided personally by a physician or other qualified health care professional
- 99487 - Complex Chronic Care Management services; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month
- 99489 - Add-on code for CPT 99487 that pays for each additional 30 minutes of Complex Chronic Care Management services per calendar month
- 99497 - Advance Care Planning including the explanation and discussion of advance directives; first 30 minutes, face-to-face
- 99498 - Add-on code for CPT 99497 (Advance Care Planning, each additional 30 minutes)
- 99341-99344 - Home visits, new patient
- 99347-99349 - Home visits, established patient