

August 31, 2022

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-1770-P; Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared **Savings Program Requirements**

Dear Administrator Brooks-LaSure:

On behalf of the American Academy of Family Physicians (AAFP), representing 127,600 family physicians and medical students across the country, I write in response to the calendar year (CY) 2023 Medicare Physician Fee Schedule (MPFS) and Quality Payment Program (QPP) proposed rule, as published in the July 27 version of the Federal Register.

The AAFP shares CMS' goals of advancing health equity, increasing beneficiaries' access to preventive health services and integrated behavioral health care, and accelerating the transition to value-based care. Achieving each of these goals is integral to improving individual beneficiary and population health, as well as protecting and strengthening the Medicare program.

To reach these goals, CMS must continually invest in community-based 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.¹ Beneficiaries receive the vast majority of their preventive care from their trusted primary care physician and are increasingly relying on primary care for their behavioral health needs.^{2, 3} Many primary care physicians have embraced opportunities to transition into value-based care models that enable them to better meet their patients' needs, ultimately driving the success of the Medicare Shared Savings Program (MSSP).4 We appreciate CMS acknowledging the central role primary care plays in the health and wellbeing of Medicare beneficiaries, as well as achieving the agency's strategic goals.

Nonetheless, the AAFP is deeply concerned that, without congressional intervention, the implementation of the CY 2023 MPFS and QPP proposed rule will undermine the viability of community-based primary care practices and stymie progress toward meeting these shared goals. Due to budget neutrality requirements the proposed conversion factor for CY 2023 is about 4.5 percent lower than the current CY 2022 conversion factor, which alone will result in payment cuts for family physicians and all other Part B clinicians. On top of these cuts, CMS estimates that community-

President Sterling Ransone, MD

Deltaville, VA Speaker

Russell Kohl MD Stilwell, KS

President-elect Tochi Iroku-Malize, MD Islip, NY

Vice Speaker Daron Gersch, MD Avon, MN

Board Chair Ada Stewart, MD Columbia, SC

R. Shawn Martin Leawood, KS

Directors Andrew Carroll, MD, Chandler, AZ Steven Furr, MD, Jackson, Al. Teresa Lovins, MD, Columbus, IN Executive Vice President Jennifer Brull, MD, Plainville, KS Todd Shaffer, MD, Lee's Summit, MO

STRONG MEDICINE FOR AMERICA

Gail Guerrero-Tucker, MD, Thatcher, AZ Sarah Nosal, MD, New York, NY Karen Smith, MD, Raeford, NC Samuel Mathis, MD (New Physician Member), Galveston, TX Mary Campagnolo, MD, Borderntown, NJ Amanda Stisher, MD (Resident Member), Owens Cross Roads, AL Amy Hoffman (Student Member), State College, PA

Administrator Brooks-LaSure August 31, 2022 Page 2 of 97

based family medicine practices will see a reduction in allowed charges in 2023 as CMS further shifts Medicare payments toward facility-based services. Thus, the proposed rule fails to sufficiently invest in community-based primary care and is inconsistent with CMS' strategic pillars.

At the same time as these cuts are proposed, physician practices are facing steep increases in practice costs and yet another public health emergency. **Medicare physician payment rates have failed to keep up with the cost of inflation and have become increasingly insufficient. These impacts have only been exacerbated by budget neutrality requirements and congressionally mandated sequestration cuts.** As a result, independent, community-based physician practices are closing or being sold to health systems and other corporations. Evidence clearly shows that these trends increase prices, do not improve quality, and can worsen access to care. Fractice 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 providing care on the frontlines of a global pandemic.

The AAFP has long advocated to accelerate the transition to value-based care (VBC) using alternative payment models (APMs) that include comprehensive prospective payment to better support the provision of person-centered, longitudinal primary care. Since the passage of MACRA, it has become clear that stable, adequate fee-for-service payments are also a vital component to this transition, particularly for practices serving rural, low-income, and other underserved communities. Physician practices that struggle to keep their doors open cannot possibly transition into alternative payment models or hire care managers and behavioral health professionals on the under-valued and over-burdensome fee-for-service (FFS) primary care payment system that exists today. Practice transformation and quality improvement require significant investment in practice capabilities including technology, people, and new workflows. Most practices continue to rely on FFS rates and/or payments for most of their payment and do not have the capital to begin transitioning into APMs. This is particularly true when the APM is built on an underfunded FFS chassis, as most are. As FFS rates increasingly fail to cover practice costs and support the advanced capabilities and services these practices provide, physicians find it increasingly challenging to generate shared savings or invest in new interventions for their patients, including robust integration of behavioral health care.

Comprehensive and sustainable primary care payment enables practices to accept more low-income patients and is associated with better health outcomes.^{6, 7, 8} FFS payments that fully support and invest in primary care services will secure primary care access in beneficiaries' own neighborhoods, drive meaningful quality improvement, and advance equity.

CMS must work with Congress to immediately avert forthcoming payment cuts and strengthen the Medicare physician fee schedule by addressing budget neutrality limitations and enacting positive annual payment updates that account for rising costs. The uncertainty surrounding annual MPFS payment cuts only worsens the detrimental impact of low payments. The AAFP recognizes that CMS alone does not have the authority to make these needed improvements. However, there are many regulatory levers under the MPFS and QPP that CMS can and should use to bolster support for and equitable access to comprehensive primary care. CMS has demonstrated a strong commitment to correcting historical MPFS imbalances that have devalued and driven

underinvestment in primary care. We urge CMS to use its available authority to boldly and continually invest in primary care in the CY 2023 MPFS and in the years to come.

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

- Ensure equitable access to and appropriate payment for audio/video and audio-only telehealth services provided by patients' trusted primary care physicians after the COVID-19 public health emergency and related flexibilities expire.
- Finalize proposals to provide primary care practices with needed flexibility and financial support to integrate behavioral health services into the primary care setting.
- Update payments for vaccine administration and opioid use disorder treatment to account for rising practice costs.
- Provide continual support to small practices, federally qualified health centers (FQHCs), and rural health centers (RHCs) to transition into and successfully participate in APMs.
- Work to reduce administrative and regulatory burdens imposed on physicians in the MPFS, MSSP, and QPP.

Determination of PE RVUs (section II.B.)

Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection and Methodology

The value assigned to each service code under the Medicare Physician Fee Schedule is based in part on the practice expense (PE) relative value units (RVUs) assigned to each code. The PE RVUs are meant to capture the resource costs associated with furnishing each service. PE is broken into direct and indirect components. Direct PE includes nonphysician clinical labor, disposable medical supplies, and medical equipment that are typically used to provide a service. Indirect PE relates to such expenses as administration, rent, and other forms of overhead that cannot be attributed to any specific service. In this proposed rule, CMS signals its intent to move to a standardized and routine approach to valuation of indirect PE and welcomes feedback from interested parties on what this might entail. In this context, CMS seeks comments on:

- Identification of the appropriate instrument, methods, and timing for updating specialty-specific PF data
- Alternatives that would result in more predictable results, increased efficiencies, or reduced burdens
- The cadence, frequency, and phase-in of adjustments for each major area of prices associated with direct PE inputs (Clinical Labor, Supplies/Equipment)
- Current and evolving trends in health care business arrangements, use of technology, or similar topics that might affect or factor into indirect PE calculations.

AAFP Comments:

Administrator Brooks-LaSure August 31, 2022 Page 4 of 97

The AAFP agrees with CMS that its data and methodology associated with indirect practice expenses needs a refresh. We agree with CMS that old data are a problem with indirect practice expenses, just as they were with elements of direct practice expenses.

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. Family physicians continue to report that adequately paying clinical and administrative staff is a major challenge for independent practices, indicating that further, regular updates are essential for supporting Medicare beneficiaries' access to community-based primary care. We strongly urge CMS to continue updating clinical labor pricing as finalized in the CY 2022 MPFS.

For indirect practice expenses, CMS relies primarily on the Physician Practice Information Survey (PPIS), fielded by the American Medical Association (AMA) in 2007 and 2008 (reflecting 2006 data). The data is now 15 years old, and much has changed in the delivery and practice of physician services in that time. Additionally, the PPIS respondents were typically self-employed physicians and selected non-physician practitioners, whereas, in 2022, many physicians (and most family physicians) are employed.

In terms of identification of the appropriate instrument and methods for updating specialty-specific PE data, we note that the AMA developed a strategy to collect data in 2021, based on 2020 cost information, but it was postponed until physician practices resumed to normalcy after the COVID-19 public health emergency. It is anticipated that 2022 data could be collected, beginning in mid-2023. We urge CMS to collaborate with the AMA and the rest of organized medicine on this effort. The AAFP contributed to and participated in the PPIS in 2007 and 2008. We look forward to participating in the current effort to update that data and CMS' indirect practice expense methodology.

In terms of cadence and frequency of updates to both direct and indirect practice expenses, in the future, all significant data updates (e.g., PPI Survey results, supply and equipment pricing, and clinical staff wage rates) should occur simultaneously on previously established "milestone" years. We suggest those "milestone" years occur every five years. This approach would contribute to predictability (i.e., physicians would know in advance when updates would occur) and stability between updates. This approach would also be consistent with the historical "five-year review" of the RBRVS in the statute.

Finally, concerning changes to Health Care Delivery and Practice Ownership Structures, and Business Relationships Among Clinicians and Health Care Organizations that may be relevant, we want to comment on CMS' treatment of laptops and other personal computers in its practice expense methodology. With few exceptions, CMS considers laptops and other personal computers as indirect practice expenses and does not permit them to be counted among the medical equipment associated with individual services. We believe this is an antiquated approach. In family medicine and many other specialties, the laptop travels with the physician from one patient encounter to another and is a vital piece of medical equipment in the service provided to the patient. It is as much a direct piece of medical equipment as the exam table and otoscope/ophthalmoscope CMS otherwise counts as direct

practice expense inputs in, for example, office visits. Real time use of laptops and personal computers enable clinicians to refer to a patient's medical record during the patient encounter, as well as attempt to look up the cost of various services and treatments that they may be recommending to the patient. These functions are integral to providing person-centered care and further CMS' goals of advancing interoperability and increasing price transparency. We strongly urge CMS to rethink how it views laptops and other personal computers in future updates to direct practice expense inputs

Soliciting Public Comment on Strategies for Improving Global Surgical Package Valuation

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. CMS solicits comments on strategies for improving global surgical package valuation. This includes comments on:

- Sources of data and data collection methodologies
- The impact of changes in health care delivery and payment for E/M services
- Strategies to address global package revaluation

AAFP Comments:

As noted in this proposed rule, in the final rule on the 2015 Medicare physician fee schedule, CMS finalized a policy to, over a period of several years, transition all services with 10-day and 90-day global periods to 0-day global periods. Implementation of this policy, however, was halted by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which instead required CMS to collect additional data on how best to value global packages and to reassess every 4 years the continued need for this data collection.

As MACRA required, CMS began data collection in 2017, making 2022 the sixth 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.

We share CMS' concern. Like CMS, we continue to believe that: (1) 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; (2) that the current values for global packages should be reconsidered, and (3) it is necessary to act to improve the valuation of the services currently valued and paid under the MPFS as global surgical packages.

CMS has fulfilled its MACRA requirements. As noted, it is in the sixth year of data collection, while MACRA only required four years. We believe the need for data collection has ended and urge CMS to take action to revalue the global packages. Namely, we recommend CMS transition all services with 10-day and 90-day global periods to 0-day global periods. Whether CMS does this using the revaluation strategy suggested by RAND or by subjecting all of the 10 and 90-day global period codes to RUC review is less important than CMS finally making the transition for all these codes. If it's not possible for CMS to transition all these codes at the same time, then we would support a

Administrator Brooks-LaSure August 31, 2022 Page 6 of 97

staggered implementation over a defined, brief number of years with priority given to those 10 and 90-day global period codes that have the greatest impact on the fee schedule in terms of total allowed charges.

The continued potential overvaluing of the 10 and 90- day global packages contributes to the MPFS' underinvestment in primary care. 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. As we noted at the beginning of this letter, stabilizing community primary care practices requires a comprehensive and sustained investment in primary care under the MPFS. Revaluing the surgical global packages is one action CMS should take to address the pervasive imbalance in physician payments across specialties. Therefore, we urge CMS to move forward with the revaluation of the 10 and 90-day global packages.

Finally, we note that our recommendations for revaluing the global surgical packages pertain only to the 10 and 90- day global packages, not the obstetric (MMM) global packages.

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

Telehealth Services List and 151 Day Extension

CMS is not proposing to modify the length of time that services temporarily included on Medicare's List of Telehealth (TH) Services on a Category 3 basis will remain on the list. Services temporarily included on the list on a Category 3 basis will be included through the end of CY 2023. CMS may revisit the policy if the public health emergency (PHE) extends well into CY 2023.

To align with the flexibilities provided in the Consolidated Appropriations Act, CMS proposes to continue to allow certain telehealth services that would otherwise not be available via telehealth after the expiration of the PHE to remain on the Medicare Telehealth Services List for 151 days after the expiration of the PHE. CMS also proposes to continue several other policies for 151 days after the expiration of the PHE, including:

- Paying for services included on the TH List as of March 15, 2022, that are furnished in an audio-only telecommunications system
- Reporting TH services using the POS that would have been used had the service been provided in-person.

AAFP Comments:

The AAFP supports CMS' proposal to maintain the services temporarily included in the Medicare List of TH Services on a Category 3 basis until the end of CY 2023. While the AAFP appreciates CMS' proposal to continue the flexibilities for the 151-day period after the PHE, we are extremely concerned that CMS does not intend to cover audio-only services beyond the 151-day post-PHE extension period. We strongly recommend CMS finalize regulations to secure permanent coverage and appropriate payment for audio-only services, along with the necessary guardrails to ensure high-quality, continuous care and to protect the established patient-physician relationship.

Administrator Brooks-LaSure August 31, 2022 Page 7 of 97

Additionally, once the 151-day extension period expires, physicians will report TH services using the place of service (POS) 02 or 10, which will be paid at the facility rate. The AAFP does not support CMS' plan to pay for all services using POS 02 or POS 10, including those provided by clinicians in the non-facility setting, at the facility rate. Our concerns are detailed below.

In-person Requirements for Tele-mental Health

CMS is also delaying the in-person requirements for tele-mental health visits, including those furnished by rural health centers (RHCs) and federally qualified health centers (FQHCs).

The AAFP supports and appreciates CMS' proposal to delay the in-person requirements for mental health visits, including those furnished by RHCs and FQHCs. In our comments on the CY 2022 MPFS, we advocated for the removal of the in-person requirement for tele-mental health visits in order to facilitate access to behavioral health services. Family physicians report that behavioral health workforce shortages create significant barriers to care for their patients. Arbitrarily requiring an in-person visit prior to coverage of tele-mental health services will unnecessarily restrict access to behavioral health care. We noted that removing the in-person requirement for FQHCs and RHCs would improve equitable access to care for low-income patients and those in rural communities. We note that our position on in-person visit requirements is unique to tele-mental health services.

Telehealth Coverage and Payment After the PHE and 151-day Extension

For telehealth services provided on the 152nd day after the end of the PHE, CMS will require services to be reported using either place of service (POS) 02 (Telehealth Provided Other than in Patient's Home) or POS 10 (Telehealth Provided in a Patient's Home). Payment for telehealth services using POS 02 or POS 10 will be made at the facility rate.

Services provided using audio-only communications technology should include modifier -93. This would apply only to services for which use of audio-only technology is permitted. CMS proposes to require RHCs, FQHCs, and OTPs to use modifier -93 for audio-only services furnished under the PFS. Supervising practitioners would continue to use the -FR modifier on applicable claims when required to be present through an interactive real-time audio and video telecommunications link, as reflected in each service's requirements.

AAFP Comments:

CMS intends to revert to pre-PHE billing and coding policies on the 152nd day after the end of the PHE. The AAFP does not have concerns regarding the reversion to POS 02 or 10. Modifier -93 will be appended to services provided via audio-only communications technology, which currently only includes tele-mental health services. However, the AAFP does not support CMS' plan to pay for all services using POS 02 or POS 10, including those provided by clinicians in the non-facility setting, at the facility rate.

Paying for telehealth services at the facility rate inherently creates a disincentive for office-based practices that do not receive a facility fee to provide telehealth services, ultimately undermining equitable access to care for Medicare beneficiaries. While the practice expenses associated with providing a service via telehealth rather than in-person may differ, CMS should not assume that they are automatically less, which payment at the facility rate does. In fact, family physicians consistently

report that there are unique practice expenses associated with fully integrating telehealth into primary care practices. Practices have to purchase HIPAA-compliant telehealth platforms, train staff to use new telehealth technologies, and hire new staff or divert existing practice staff to ensure patients can easily connect to telehealth platforms. The existing facility rate does not account for these costs and will therefore fail to adequately support telehealth integration within primary care practices. Payment rates should appropriately and adequately reflect the practice expense inputs for a service and not incentivize one modality of care over another.

The AAFP strongly believes that permanent telehealth coverage and payment policies should:

- Ensure coverage and access to audio/video and audio-only telehealth services for all Medicare beneficiaries, regardless of their physical or geographic location
- Include guardrails to ensure care continuity and quality by encouraging the use of telehealth with a patient's usual primary care physician or another trusted care relationship
- Enable patients, in consultation with their trusted primary care physician, to determine the most appropriate modality of care for each encounter.

We recognize that legislative action is needed to remove existing statutory restrictions on Medicare telehealth services and continue to advocate for Congress to remove geographic and originating site restrictions. The AAFP has supported the Preventing Rural Telehealth Access Act, which would permanently allow all Medicare patients to receive telehealth services at home, allow federally qualified health centers (FQHCs) and rural health clinics (RHCs) to continue providing telehealth services, and codify coverage and payment for audio-only telehealth appointments, all for established patient relationships. The AAFP has also supported the Evaluating Disparities and Outcomes in Telehealth (EDOT) Act, which would ensure that continuation of current telehealth policies, including those previously mentioned, does not exacerbate inequities in access to care.

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 outlined in our Joint Principles for Telehealth Policy, in partnership with the American Academy of Pediatrics and the American College of Physicians, 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 physician-patient 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 patientphysician relationship, , increase fragmentation of care, and lead to the patient receiving suboptimal care. In fact, a recent nationwide survey found that most patients prefer to see their usual physician through a telehealth visit, feel it is important to have an established relationship with the clinician providing telehealth services, and believe it is important for the clinician to have access to their full medical record. However, telehealth services provided by direct-to-consumer telehealth companies, which typically do not have access to patients' medical records and are not usually integrated with a patients' usual source of primary care, can result in care fragmentation.

Administrator Brooks-LaSure August 31, 2022 Page 9 of 97

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 physician-patient relationship. Studies have shown that DTC telehealth can lead to increased utilization and may ultimately increase overall health care spending. A recent Health Affairs study found patients with initial DTC telemedicine visits for acute respiratory infections were more likely to obtain follow-up care within seven days after the DTC encounter when compared with patients with initial in-person visits. ¹⁰ This suggests that seeking initial care from a DTC setting may lead to avoidable higher spending on follow up care.

The AAFP also has concerns with potential fraudulent behavior by DTC telehealth vendors. The OIG recently released a <u>Special Fraud Alert</u> regarding fraud schemes where telemedicine companies offer kickbacks for prescribing medically unnecessary items and services for individuals with whom the clinician often does not have a relationship. As noted by the OIG, "These types of volume-based fees not only implicate and potentially violate the Federal and anti-kickback statute, but they also may corrupt medical decision-making, drive inappropriate utilization, and result in patient harm." **CMS** should ensure policies do not inadvertently provide a pathway for DTC vendors to disrupt the comprehensive and longitudinal relationships between patients and their primary care physicians by including guardrails that protect the quality and continuity of care delivered virtually in the context of the patients' usual source of primary care.

For these reasons, the AAFP urges CMS to ensure telehealth regulations in effect after the end of the PHE (and accompanying 151-day extension of PHE flexibilities) promote the use of telehealth from a patient's usual source of care. This includes coverage and payment policies that provide family physicians with the flexibility they need to provide optimal care to their patients, in addition to necessary guardrails to prevent care fragmentation, as well as program integrity.

To enable patients and physicians to determine the most appropriate modality of care, payment rates must appropriately account for unique practice expenses and fairly value physician work. The cognitive work of the physician does not differ based on the modality of care. Payment rates should appropriately and adequately reflect the level of physician work for a service and should not incentivize one modality of care over another. Furthermore, payment rates should reinforce receiving care from a patient's usual source of care by accounting for the unique practice resources required to provide comprehensive, longitudinal, and patient-centered in-person care in addition to addressing patients' needs via telehealth modalities. We again note that paying for all telehealth services at the facility rate will fail to support telehealth integration into primary care and will undermine equitable access for beneficiaries.

While telehealth services should be adequately paid in fee-for-service, the AAFP continues to believe that comprehensive, prospective payment is the optimal payment model for primary care. Physicians in value-based payment arrangements with a significant share of prospective payment relative to fee-for-service, consistently cite VBP as the reason they were able to quickly pivot to offer telehealth when the PHE started. The flexibility of these types of VBP arrangements makes it easier for physicians to provide care in whatever manner makes the most sense for the patient, while the accountability for total cost of care creates a natural guard against unnecessary utilization.

Administrator Brooks-LaSure August 31, 2022 Page 10 of 97

Audio-only Telehealth Services

CMS believes statute requires that telehealth services be so analogous to in-person care that the telehealth service is essentially a substitute for a face-to-face encounter. CMS reiterates that they do not view audio-only telephone E/M services as analogous to or a substitute for face-to-face services. CMS is not proposing to keep telephone E/M services (CPT codes 99441-99443) on the Medicare Telehealth Services List after the end of the PHE and the 151-day post-PHE extension period. Following the extension period, CMS will assign the codes a "bundled" status.

The AAFP is extremely concerned that CMS does not intend to cover audio-only services beyond the 151-day post-PHE extension period. We strongly recommend CMS finalize regulations to secure permanent coverage and appropriate payment for audio-only services, along with the necessary guardrails to ensure high-quality, continuous care and to protect the established patient-physician relationship.

Evidence clearly indicates that 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. A comprehensive review of literature comparing the effectiveness of videoconference versus telephone in the delivery of health care found that patient outcomes were generally comparable between videoconference and phone with no consistent differences in patient mortality or satisfaction. These findings underscore that 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.

Evidence suggests that telephone visits played a large role in ensuring access to continuous primary care during COVID-19, with about half of primary care telehealth visits being eligible for reimbursement via audio-only interactions in 2020. 12 A survey of AAFP members conducted in May 2020 found that audio-only telephone was the most commonly used tool for conducting virtual visits. 13 Interviews with family physicians identified three main reasons for the popularity of telephone visits: lack of reliable, high-speed internet connection, patients' inability to navigate technology required for video visits, and physicians had not yet adopted or encountered challenges with a video visit platform. Family physicians also list coverage and payment policies related to telehealth and patient access to hardware/software and broadband as critical factors in their ability to provide telehealth services. Roughly 30 percent of family physicians expect audio-only encounters to represent nearly a quarter of their telehealth visits over the next 12 months.

Many patients experience technology and infrastructure barriers to using video telehealth visits, making audio-only a valuable method to accessing care. The lack of modern broadband infrastructure has proven to be a primary barrier to equitable telehealth and digital health access for rural Americans, who are 10 times more likely to lack broadband access than their urban counterparts, leading to fewer audio/video visits. ^{14, 15, 16} There also exist disparities in access to technology that is essential for successful video telehealth visits. One in three households headed by someone over the age of 65 do not have a computer and more than half of people over age 65 do not have a smartphone. ¹⁷ A report from the Assistant Secretary for Planning and Evaluation (ASPE) also found that Black, Latino, Asian, and elderly patients, as well as those without a high-school diploma, were more likely to rely on audio-only telehealth visits. ¹⁸ **The available data clearly indicate that**

coverage of and fair payment for audio-only services is essential to facilitating equitable access to care after the PHE-related telehealth flexibilities expire.

We again note that 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. Some patients and some cases are better suited to virtual care, and others require in-person care; some issues can be effectively treated through a phone call, whereas others require a visual examination. **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.** 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 geared at providing more tools, not less, to primary care physicians so they can provide the familiar and quality care their patients seek. Audio-only visits should be adequately paid so physicians can provide equal access to all types of telehealth services and patients can access care through the modality that best suits their needs and preferences. CMS should create policies that strengthen patients' relationships with their primary care physician, and physicians should not be paid less for providing patient-centered care.

Direct Supervision and Supervision of Resident Physicians

CMS is not making any proposals related to direct supervision but points out that the pre-PHE rules for direct supervision will resume after December 31 of the year in which the PHE ends. CMS continues to seek comment on whether the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time audio/video technology should potentially be made permanent.

AAFP Comments:

The AAFP <u>recommends</u> 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 <u>physician-led team-based care</u> 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; and it decreases the spread of communicable diseases.

In addition, the AAFP strongly encourages CMS to make supervision of residents in teaching settings through audio/video real-time communications technology permanent policy, regardless of the location of the patient or resident physician. The virtual presence promotes patient access, continuity, convenience, and choice; and it decreases the spread of communicable diseases.

This 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. However, surgical, high-risk, interventional, endoscopic, or other complex procedures under anesthesia should remain excluded from this policy.

The AAFP recommends payment for the teaching physician's virtual presence through audio/video real-time communication technology during the resident's telehealth service is made permanent

Administrator Brooks-LaSure August 31, 2022 Page 12 of 97

policy. The teaching physician can review the service with the resident during or immediately after the visit to exercise full and personal control over the service.

Relatedly, under the "primary care exception," Medicare makes MPFS payment 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 beneficiary'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 beneficiary seen by the resident, and ensure the services furnished are appropriate.

In response to the COVID-19 PHE, CMS amended regulations to allow all levels of outpatient evaluation and management (E/M) visits to be furnished by the resident and billed by the teaching physician under the primary care exception. CMS further expanded the list of services included in the primary care exception during the PHE. Additionally, Medicare payment was allowed to the teaching physician for services furnished by residents via telehealth under the primary care exception if the services were on the list of Medicare telehealth services. 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 provides educational training opportunities for applicable medical residents, expands patient access to primary care, and improves relational continuity of the patient and primary care physician in teaching centers. Expanding the primary care exception has benefitted beneficiaries and primary care training programs alike and we are concerned that returning to the previous policy will create disruption in primary care training programs, as well as unnecessary barriers to high-value primary care for beneficiaries. Thus, the AAFP recommends HHS permanently expand the list of services subject to the primary care **exception to include all services listed in Appendix A.** Permanently expanding the primary care exception could help improve utilization of recommended preventive care services, which is particularly important as many beneficiaries have yet to catch up on preventive care they may have forgone throughout the pandemic.

Valuation of Specific Codes (section II.E.)

Immunization Administration (CPT codes 90460, 90461, 90471, 90472, 90473, and 90474)

CMS proposes the RUC-recommended work RVU for all six codes in the Immunization Administration family. CMS also proposes the RUC's recommended direct PE inputs (with minor refinements) for these vaccine administration services. Additionally, CMS continues to seek additional information from commenters that specifically identifies the resource costs and inputs that should be considered to establish payment for these vaccine administration services on a long-term basis, consistent with CMS policy objectives for ensuring maximum access to immunization services. (See related proposal in section III.H of this proposed rule.)

AAFP Comments:

Administrator Brooks-LaSure August 31, 2022 Page 13 of 97

The AAFP strongly supported CMS' decision to implement a flat payment of \$30 for the administration of Part B preventive vaccines beginning January 1, 2023. We continue to believe this payment rate more accurately reflects the resource costs involved with furnishing preventive vaccinations in a physician practice and is therefore better supporting beneficiaries' access to recommended vaccines in their own communities. We appreciate CMS' continued efforts to ensure adequate payment for Part B vaccines and offer additional comments on this point in section III.H.

While CMS pays Part B clinicians a flat (adjusted) rate for providing vaccine administration to Medicare beneficiaries, it is our understanding that other payers use the RVUs associated with these codes to determine their own payment rates for these services. As such, keeping the values accurate and current is important. The AAFP appreciates CMS' review of these services and acceptance of the RUC's recommendations regarding the physician work involved. However, we disagree with CMS' proposed refinement to the equipment time for these codes. CMS proposes to reduce RUC-recommended medical equipment times for a vaccine medical grade refrigerator (EF049) and a temperature monitor with alarm (ED043) to conform with established policy for non-highly technical equipment. This would result in a 50 percent reduction (from 20 minutes to 10 minutes) in medical equipment time for both pieces of equipment.

In February 2008, the RUC recommended, and CMS accepted, use of total clinical staff time as the time of medical equipment use for the service of vaccine administration. This established an exemption specific to the service of vaccine administration. Prior to that, the intra-service clinical staff time had been used based on CMS' methodology. Therefore, the 20 minutes as recommended by the RUC for each piece of medical equipment should not be refined to align with established CMS policy. Rather, CMS should accept the RUC recommendations for each piece of medical equipment as established by the 2008 exemption.

Regarding additional information on resource costs and inputs, we would observe that clinical staff immunization confirmation protocols have changed since the Immunization Administration codes were last valued due to the explosion in the number of new vaccines introduced since 2009. For example, there are 15 different influenza vaccine presentations available today. This may explain why 20% of all vaccine error reports have to do with influenza vaccine. While electronic health records (EHRs) offer vaccine clinical decision support to predict (although not 100% accurately) the antigens required, they do not give decision support on the brand and presentation of a vaccine. Physicians typically give orders for the antigen (e.g., DTaP), but not the brand and presentation (e.g., Daptacel, Infanrix, Kinrix, Pediarix, Pentacel, or Quadracel).

Determining which of these vaccine products to use is a clinical staff decision, based on the patient's age and vaccination history and potentially complicated by restrictions specific to the administration of combination vaccines (e.g., Kinrix (DTaP-IPV) can be given to patients who need both DTaP and IPV, but only if the patient is between ages 4-6, has had four prior doses of DTaP, and at least two prior doses of IPV). Additionally, some vaccines have different dosing requirements based on age (Hep A, Hep B, influenza), while others are the same regardless of patient age. Finally, while the Advisory Committee on Immunization Practices (ACIP) recommends that a vaccine series be completed with the same brand whenever possible, in some cases it is acceptable to use the alternative brand in stock if the original brand is not known (DTaP), while, in other cases, using only the brand from the original dose is acceptable (MenB). Each time a vaccine is administered, clinical staff must follow

Administrator Brooks-LaSure August 31, 2022 Page 14 of 97

these immunization confirmation protocols. For this reason, we believe that these clinical staff activities are appropriately attributed to direct PE for the IA CPT codes, and we would encourage CMS to include clinical staff time for such activities in those direct PE inputs to the extent they are not already accounted for.

Code Descriptor Changes for Annual Alcohol Misuse and Annual Depression Screenings (HCPCS codes G0442 and G0444)

As requested by the AAFP, CMS proposes to modify the descriptor for HCPCS code G0442 to read "Annual alcohol misuse screening, 5 to 15 minutes" and for HCPCS code G0444 to read "Annual depression screening, 5 to 15 minutes."

AAFP Comments:

The AAFP fully supports this proposal and urges CMS to finalize it for 2023. Some Medicare administrative contractors (MACs) are interpreting the "15 minutes" in the current descriptors to be a threshold, meaning the physician providing the service must provide a full 15 minutes of alcohol misuse or depression screening to report the service. However, like CMS, we understand these screening services typically take less than 15 minutes to provide. Consequently, the MACs' interpretation of the "15 minutes" in the descriptor as a threshold effectively prevents reporting these services in many cases, negatively impacting access to these evidence-based screenings.

It is widely recognized that screening for unhealthy alcohol use and depression are vital, and evidence indicates these screenings effectively detect behavioral health concerns and can facilitate access to treatment. The U.S Preventive Services Task Force (USPSTF) recommends screening for unhealthy alcohol use in primary settings in adults 18 years or older and providing persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce unhealthy alcohol use. ¹⁹ The USPSTF found evidence that brief screening instruments can detect unhealthy alcohol use in primary care settings. ²⁰ Similarly, the USPSTF recommends screening for depression in the general adult population because the Task Force found convincing evidence that screening improves the accurate identification of adults with depression in primary care settings. ²¹ The AAFP, which reviews all USPSTF recommendations for preventive services, supports the recommendations on screening for alcohol misuse and depression. ^{22, 23}

According to the CMS Office of Minority Health, only about 6 percent of Medicare beneficiaries received covered depression screening services in 2018, suggesting that this service is severely underutilized among all beneficiaries. ²⁴ The AAFP is particularly concerned that the misinterpretation of the code descriptors for these services and the resulting negative impact on access to screenings may be disproportionately affecting Black and Hispanic Medicare beneficiaries, as well as dual eligible beneficiaries, and contributing to health disparities. Based on Medicare claims data, the 2019 utilization of these services by race was as follows:

- Alcohol misuse screening (G0442): White, 86.5%; Black, 7.2%; Hispanic, 2.0%; Other, 4.4%
- Depression screening (G0444): White, 86.9%; Black, 7.1%; Hispanic, 1.7%; Other, 4.3%

Administrator Brooks-LaSure August 31, 2022 Page 15 of 97

Meanwhile, the distribution of Medicare beneficiaries by race in 2019 was as follows: White, 74.8%; Black, 10.4%; Hispanic, 9.0%; Other, 5.8%.²⁵ These data indicate that Black, Hispanic, and other beneficiaries of color are less likely to receive these essential screenings.

The screening rates for depression and alcohol misuse within the general population are similarly lower among Black and Hispanic adults compared to White adults, based on an analysis of data from the National Survey of Drug Use and Health, 2016- 2019. According to that data, 19% of non-Hispanic White adults surveyed were screened for depression as compared to 11% of non-Hispanic Black adults and 12% of Hispanic respondents. According to the same data, 91% of non-Hispanic White respondents were screened for alcohol misuse as compared to 78% of non-Hispanic Black respondents and 79% of Hispanic respondents. Improving equitable access to and utilization of these screenings in Medicare could help address these disparities. To the extent private payers or state Medicaid programs also use these G codes, revising their descriptors may have a positive impact across payers.

Mental illness and alcohol and substance use disorders are highly prevalent in the United States and associated with an increased risk of morbidity and mortality. ²⁶ Before the pandemic, the Centers for Disease Control & Prevention reported that Hispanic and non-Hispanic Black adults are more likely to suffer from depression. ²⁷ Dual-eligible beneficiaries also had higher rates of depression than traditional beneficiaries. ²⁸ The overall incidence of unhealthy alcohol use and depression has only risen during the pandemic and the associated health disparities have also worsened. For example, Black and Hispanic adults have been more likely than White adults to report symptoms of depression during the pandemic. ²⁹ Health care and other essential workers were also likely to report increases in alcohol consumption. These data highlight the urgency and importance of improving equitable access to and utilization of alcohol misuse and depression screenings. Unfortunately, the AAFP believes the current descriptors of G0442 and G0444 and their interpretation by the MACs may be contributing to gaps in care for beneficiaries of color and those with low incomes.

Accordingly, we support the proposal to revise the descriptors to reflect "5 to 15 minutes" and urge CMS to finalize it. When CMS does finalize it, we also ask CMS to alert its MACs and audit contractors, so claims for these services will not continue to be denied in instances where records suggest that a full 15 minutes was not reached by the physician when furnishing the service, as referenced in the proposed rule.

Chronic Pain Management and Treatment (CPM) Bundles (HCPCS GYYY1, and GYYY2)

CMS proposes to create separate coding and payment for chronic pain management (CPM) services beginning January 1, 2023. Specifically, CMS proposes to create two HCPCS G-codes to describe monthly CPM services as follows:

 HCPCS code GYYY1: Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care (e.g. physical therapy and occupational therapy, and community based care), as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using GYYY1, 30 minutes must be met or exceeded.)

 HCPCS code GYYY2: Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for GYYY1). (When using GYYY2, 15 minutes must be met or exceeded.)

CMS proposes to value codes GYYY1 and GYYY2 based on a crosswalk to the principal care management codes 99424 and 99425, respectively.

AAFP Comments:

As noted in our response to the proposed rule on the 2022 Medicare physician fee schedule, we are overall supportive of the concept of separate coding and payment to better account for the complexity of care management. Patients with chronic pain are complex cases requiring a lot of time currently not captured effectively using existing E/M codes, even when time-based. While we remain concerned with the piecemeal fashion of paying for services that are part of comprehensive, longitudinal primary care, as well as the documented underutilization of care management codes like this one, valuing and enabling physicians to bill for these services is a necessary intermediate step to more comprehensively and sustainably pay for primary care under the MPFS. We view separate coding and payment for chronic pain management as potentially useful for several reasons and encouraged CMS to consider a mechanism that might offer a bundled per patient, per month payment, utilizing a code or another value-based payment that aligns with a patient-centered process.

With that in mind, we are generally supportive of what CMS proposes in this regard. Where we deviate or otherwise have questions are the following:

- The descriptor for code GYYY1, which would also apply to GYYY2, includes the phrase, "personally provided by physician or other qualified health care professional." As we noted in our comments last year, chronic care management, whether it be for pain or some other condition(s), is best provided in a team-based approach. The physician should be involved closely but not necessarily required to do every task. Application of the phrase "personally provided by physician or other qualified health care professional," will limit the utility of these codes. We believe the proposed codes would be more useful if that phrase was replaced with "clinical staff time directed by a physician or other qualified health care professional," which is common to many of the other care management codes recognized and paid by Medicare. We recommend modifying the code descriptors accordingly.
- The descriptor for GYYY1 includes a long list of included elements that are presumably applicable to GYYY2, too. CMS calls out some of these elements (e.g., administration of a validated pain assessment rating scale or tool, development of and/or revisions to a personcentered care plan, health literacy counseling) in the preamble to this proposed rule. We agree with CMS that a chronic pain management monthly bundle would include such

elements. However, we do not believe every element must be provided every month to report the service(s). For instance, the descriptor includes "development, implementation, revision, and maintenance of a person-centered care plan." (Emphasis added) Some months, chronic pain management may require revision of the care plan; other months it may not. And a care plan may need to be developed one month and maintained the next. It seems unlikely a care plan would need to be developed, implemented, revised, and maintained all in the same month and even less likely that this would be required month after month. We urge CMS to treat the elements in the descriptors as included in the service as appropriate and when needed/provided and to not require all elements be provided in a given month to report the service(s).

- The descriptor for code GYYY1 includes "Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional." CMS equates this to a visit with a new patient in the preamble and notes that "follow-up or subsequent visits could be non-face to face." We are unclear if this 30-minute face-to-face visit is required every time GYYY1 is reported or just the first time GYYY1 is reported for a given patient (I.e., is it the initial visit for that month or the initial visit for that patient). However, we recommend against requiring a face-to-face visit every time the code is reported for established patients with diagnosed chronic pain. CMS should allow the physician (or other clinician) and patient to decide whether a face-to-face visit is necessary for the care of that patient. The patient may still benefit from other elements in the bundle over the month but not need the face-to-face visit. We urge CMS to clarify these points in the final rule.
- We encourage CMS to include these services on the Medicare Telehealth Services list and allow the physician-led care team, in consultation with the patient, determine which elements require face-to-face interaction and which can be done effectively via other means, either by the physician or other members of the care team. To the extent elements are done by auxiliary staff incident to the physician's services, we believe general supervision is sufficient, just as with other care management services covered and paid by Medicare.
- We support CMS' proposal to permit documentation of verbal consent for chronic pain
 management services at the visit where such services are initiated. We would urge CMS to
 refrain from requiring consent at each visit or each month. We also urge CMS to allow consent
 to be obtained and documented by members of the care team other than the physician/QHP.
 The initial consent for this program is just as well explained and obtained by team members
 under general supervision as it is by the physician or under the physician's direct supervision.

CMS requests comments on whether it should consider creating additional coding and payment to address acute pain. The AAFP does not support additional coding and payment for acute pain at this time. We believe that coding and payment for acute pain can be adequately handled via existing E/M coding and payment, just as other acute conditions can.

Regarding the valuation of these services, we believe CMS may be undervaluing GYYY1 by crosswalking it to 99424, which has 1.45 work RVUs. The descriptor for GYYY1 says it requires an initial 30-minute face-to-face visit with the patient, and CMS equates this to a visit with a new patient

in the preamble. If such a visit is required to bill GYYY1, then it's undervalued at 1.45 work RVUs, because a 30-minute new patient office visit, 99203 (Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 30-44 minutes of total time is spent on the date of the encounter), is valued at 1.60 work RVUs. Thus, 1.45 RVUs does not account for the work of the required visit, let alone any other elements of chronic pain management the physician may provide or supervise during the month. The proposed value is also undervalued for an established patient, given that a 30-minute office visit with an established patient (99214) is valued at 1.92 work RVUs.

A more appropriate valuation would account for the work of the required visit plus care management done or supervised by the physician. We recommend CMS look to the transitional care management codes (99495 and 99496) for a possible crosswalk in this regard. Both of those codes include a face-to-face visit plus care management over an extended period, which is more akin to the proposed descriptor for GYYY1.

The proposed valuation of GYYY2 makes sense to us, given the crosswalk to 99425 and the time difference between the two codes.

Our final observation is that it would be helpful if CMS subsequently advanced such coding proposals through the CPT process. The creation of "G" codes, while sometimes expeditious and necessary, creates administrative complexity for physician practices. The AAFP believes CPT describes the services that physicians provide and that inclusion of a service in CPT reflects contemporary medical practice. Working through the CPT process facilitates coding for physician services and may help support utilization and billing of these new care management codes, which are often underutilized.

Request for Information: Medicare Part B Payment for Services Involving Community Health Workers (CHWs)

Considering the benefits that services involving CHWs can potentially offer the health of Medicare beneficiaries, including a reduction in health disparities, CMS is interested in learning more about how services involving CHWs are furnished in association with the specific Medicare benefits established by the statute. CMS is interested in learning whether and how CHWs, as auxiliary personnel of physicians and hospitals, may provide reasonable and necessary services to Medicare beneficiaries under the appropriate supervision of health care professionals that are responsible more broadly for medical care, including behavioral health care. CMS also seeks to understand whether and how services involving CHWs are accounted for under the existing CCM codes or other care management or behavioral health integration services, including whether the employment and supervision arrangements ordinarily adopted within the industry would meet the requirements that allow for billing by supervising professionals or providers, including RHCs and FQHCs. CMS also seeks other information on potential Medicare Part B payment for services involving CHWs.

AAFP Comments:

The AAFP appreciates CMS' interest in potential Medicare Part B payment for services involving CHWs and is willing to explore that subject in greater depth with CMS outside the rulemaking

Administrator Brooks-LaSure August 31, 2022 Page 19 of 97

process. Community health workers may be part of a physician-led team in the primary care setting, both in physician practices and in FQHCs and RHCs. When they are, their responsibilities include:

- Determining resources available in the community and completing an action plan prior to the visit
- Facilitating referrals to community resources based on patient needs
- Case management and follow-up between patient visits

CHWs are often members of the communities in which they work, which makes them uniquely equipped to connect patients to community-based resources and help address barriers patients face in continually accessing the care they need. For example, CHWs can help patients follow-up with various clinicians.

We would <u>observe</u> that existing FFS structures typically do not pay for or wraparound patient activities, such as community health workers or care coordination, but these interventions enable family physicians' to better address a patient's identified health-related social needs (HRSNs) 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 an important reason for transitioning to alternative payment models (APMs): they are looking for a payment model that will provide adequate, stable financial support and flexibility to deliver the kind of whole-person care their patients deserve in new and innovative ways.

In the end, every patient, practice, and community is different. There is not a one-size-fits-all approach to addressing individuals' unique health-related social needs. Inclusion of a <u>community health worker in the practice</u> is one way to provide help and resources to patients. We look forward to working with CMS to explore ways in which Medicare Part B might better support inclusion of community health workers within primary care settings, including FQHCs and RHCs. We also urge CMS to consider the ways in which it can support the development and use of <u>community care hubs</u> or other payer and provider agnostic centralized referral systems to ease the burden on all parties, including the community-based organizations best equipped to address patients' social needs.

Request for Information: Medicare Potentially Underutilized Services

CMS seeks comments on ways to identify specific, underutilized services and to recognize possible barriers to improved access to these kinds of high value, potentially underutilized services by Medicare beneficiaries. CMS also seeks comment regarding how it might best mitigate some of these obstacles, including for example, through examining conditions of payment or payment rates for these services or by prioritizing beneficiary and provider education investments.

AAFP Comments:

The AAFP appreciates CMS' interest in facilitating access to and greater utilization of high value services that are otherwise underutilized by Medicare beneficiaries. We agree this is a worthwhile pursuit on the part of CMS and look forward to exploring the matter further with CMS outside the rulemaking process.

Primary care services are proven, high-value health care services that improve health outcomes and decrease costs.^{30, 31} In the U.S., an increase of one PCP per 10,000 people found a decrease in both infant and adult mortality and a 3.2 percent reduction in low birth weight.^{32, 33} States with higher ratios

Administrator Brooks-LaSure August 31, 2022 Page 20 of 97

of PCPs have lower smoking rates, lower obesity rates, and higher seatbelt use compared to states with lower ratios of PCPs. ^{34, 35} Further, Medicaid-enrolled children who have access to high-quality, timely, family-centered primary care have experienced both lower nonurgent and urgent emergency department utilization rates. ³⁶ Health care systems that prioritize primary care have lower health care costs, including decreases in costly hospitalizations and emergency department visits. ³⁷ By contrast, a survey of 11 developed countries, including the U.S., found that patients with poorer levels of primary care were notably more likely to report higher out of pocket expenses, increased emergency room use in the past two years, greater physician turnover, and a lower likelihood of patients receiving critical immunizations or screenings, such as those for high blood pressure or cholesterol. ³⁸

Removing cost sharing for primary care services increases access to these services and reduces emergency department and other outpatient visits without increasing overall health care spending.³⁹ Taken together, the available evidence indicates that reducing or removing cost barriers to primary care increases utilization of preventive and other recommended primary care services, which improves both individual beneficiary and population health.

In response to a similar request for information on improving utilization of high-value services in Medicare Advantage, the AAFP urged CMS to remove cost-sharing barriers to primary care services, as well as integrated behavioral health and substance use disorder care. We urge CMS to do the same in traditional/fee-for-service Medicare.

In a recent letter to Secretary Becerra, the AAFP provided comprehensive <u>recommendations</u> for strengthening primary care in the US. We urged HHS to increase our nation's investment in primary care, improve patients' access to and connections with primary care, grow and diversify the primary care workforce, and address the administrative requirements that drive care delays and physician burnout. CMS has the authority to implement many of these recommendations through the MPFS and other Medicare programs and we stand ready to work with CMS to do so.

As we noted in our RFI response, the piecemeal approach FFS takes to financing primary care undervalues, and overburdens family physicians and care teams' efforts to provide the whole-person approach integral to primary care. In Medicare, physicians must document several unique screening codes, vaccine administration, other preventive services and counseling codes, an office visit, care management codes, integrated behavioral health codes, and several other services to justify payment for typical, comprehensive primary care, even though these services are all foundational aspects of high-value primary care. In addition to being administratively burdensome, a more fragmented payment approach encourages carve-outs of behavioral health, telehealth, and other services that are more accessible and effective when they are integrated in or coordinated with a patient's trusted primary care physician. 40, 41, 42 A recent study published in the *Annals of Internal Medicine* confirms that this piecemeal approach is not translating into a meaningful investment in primary care and may be precluding access to these high-value services for beneficiaries. 43 The study found that MPFS billing codes for preventive medicine and care management services are being underutilized even though primary care physicians were providing code-appropriate services to many patients. The median use of the preventive and care coordination billing codes was 2.3 percent among eligible patients. The authors concluded that creating additional billing codes for distinct activities may not be effectively supporting primary care.

FFS also fails to account for the complexity of primary care by undervaluing the component parts of primary care, like care management and integrated behavioral health. The Medicare Payment Advisory Commission has long advised policymakers to address the underpricing of PC services in FFS and the National Academies of Science, Engineering, and Medicine (NASEM) consensus report confirmed that FFS does not adequately value or support the longitudinal, person-centered care that is the hallmark of primary care. For example, many patients benefit from regular care management and coordination services that are not billable under FFS. The AAFP urges CMS to examine opportunities to more comprehensively and sustainably finance primary care. In the interim, CMS should examine outreach and educational opportunities to improve the utilization and billing of preventive care and care management services under the MPFS and ensure these codes are appropriately valued year over year.

New Coding and Payment for General Behavioral Health Integration (BHI) billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs):

CMS is proposing to establish a new code that mirrors current CPT code 99484, or General Behavioral Health Integration (GBHI). The new code, HCPCS code GBHI1, would be billable by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs) on a monthly basis. CMS is proposing to allow general supervision for this service and to allow a psychiatric diagnostic evaluation (CPT code 90791) to serve as the initiating visit.

AAFP Comments:

The AAFP supports CMS' proposal to create the GBHI1 code for CPs and CSWs and allow general supervision for this service. 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. Family physicians regularly work with psychiatrists, psychologists, CPs, CSWs, Licensed Marriage and Family Therapists (LMFTs), and other behavioral health professionals to provide behavioral health care. CPs and CSWs 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. Furthermore, allowing a psychiatric diagnostic evaluation to serve as the initiating visit for GBHI1 will likely facilitate timely access to behavioral health services by allowing the initiating visit to be within the scope of a CP, instead of requiring it be performed by a physician.

Proposed Revisions to the "Incident to" Physicians' Services Regulation for Behavioral Health Services:

To improve access to behavioral health services, CMS is proposing to allow behavioral health services to be furnished under general supervision, instead of direct supervision, of a physician or non-physician provider (NPP) when these services are provided incident to the services of a physician or NPP.

AAFP Comments:

As mentioned above, family physicians rely on a variety of mental health professionals for teambased, integrated behavioral health services. As such, the AAFP supports this proposal to allow behavioral health services to be provided incident to a physician under general, instead of direct, Administrator Brooks-LaSure August 31, 2022 Page 22 of 97

supervision. The AAFP believes this will improve access to this much needed care from behavioral health professionals and primary care physicians by reducing oversight of certified behavioral health professionals.

Comment Solicitation on Payment for Behavioral Health Services under the PFS

CMS solicits comments on how it can best ensure beneficiary access to behavioral health services, including any potential adjustments to the MPFS rate setting methodology, for example, any adjustments to systematically address the impact on behavioral health services paid under the PFS.

AAFP Comments:

The AAFP supports CMS' commitment to improving access to behavioral health care through this proposed rule and in its overall strategic plan. We appreciate the direction of the changes and valuation of behavioral health services detailed in this proposed rule and the additional solicitation of information related to the rate setting methodology. However, the AAFP agrees with the previous commenters CMS referenced that additional action is needed to ensure access to behavioral health is appropriately increased to match the current level of need.

The AAFP supported the inclusion of collaborative care management CPT codes (99492, 99493, 99494, HCPCS G2214) and general behavioral health integration codes to enable primary care physicians to be paid for addressing behavioral health concerns in the primary care setting. Utilization of collaborative care management (CoCM) codes has remained low since their introduction, likely due to the complexity of the billing and coding requirements, relative low payment levels, a shortage of necessary psychiatrists and other behavioral health practitioners, and the need for improved training for staff and physicians alike.

The general behavioral health integration care management code (general BHI code) (CPT code 99484) has become increasingly popular over traditional CoCM codes. Medicare claims data indicates the general BHI code is used nearly 10 times more than CoCM codes. One primary difference is that the general BHI code covers a wider array of action and does not require consultation with a specified type of behavioral health clinician, while CoCM requires a psychiatric consult. Many family physicians report challenges with connecting to local psychiatrists. It is possible that primary care physicians have greater access to and need for other behavioral health provider types and are therefore more likely to bill for general BHI instead of CoCM. Over-burdened primary care physician may struggle to find time to reach the 60- or 70-minute threshold required by CoCM. As such the CoCM codes are insufficient to support widespread behavioral health integration in the primary care setting and it is vital to ensure the general BHI codes are appropriately valued to reflect the important role these codes play in facilitating access to behavioral health care. The AAFP looks forward to continuing to work with CMS to advance this shared goal.

While the changes CMS proposes will provide primary care practices with needed flexibility to bill for integrated behavioral health services provided by various types of behavioral health professionals,

^a 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;

these 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. Further, CMS notes in the proposed rule that some behavioral health services with very low direct PE, like therapy and counseling, may have become passively devalued over time as CMS has added new services to the MPFS and applied the statutorily required budget neutrality adjustments. The values of these codes may no longer accurately reflect the relative indirect costs in furnishing behavioral health in the primary care setting. Addressing these fundamental challenges is essential to meaningfully improve access to behavioral health services for Medicare beneficiaries.

Primary care practices participating in APMs with prospective payments may be better equipped to make the financial investments required to integrate behavioral health services. However, existing collaborative care is primarily paid on a FFS basis, and many APMs for primary care have generally not included collaborative care codes in their calculations for care management fees or other prospective payments, which has further limited behavioral health integration. To correct this, APMs need to be designed to provide sufficient, prospectively paid resources to primary care practices to adequately support the integration of behavioral health.

Value-based payment arrangements that incorporate prospective payments or capitation, allow physicians the flexibility to innovate their practice to meet their patients' behavioral health needs. APMs designed to support behavioral health integration should also be fully risk-adjusted (including patients' demographic and clinical information as well as health-related social needs), to promote quality care. APMs must also promote care provided within or in close coordination with a patient's medical home to avoid care fragmentation, such as from third-party telehealth providers. Not only is this integrated payment infrastructure beneficial to practices intent on delivering holistic, personcentered care, it is essential to ensuring access to high quality, continuous primary care and behavioral health care for patients. When primary care practices are supported by a predictable, prospective revenue stream that is risk-adjusted for the clinical and social complexity of their patients, primary care practices thrive, and patients have better outcomes.

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

The AMA CPT Editorial Panel has revised the rest of the E/M visit code set to match the general framework adopted for the Office/Outpatient E/M visits. The updated guidelines will impact inpatient and observation visits, emergency department visits, nursing facility visits, domiciliary or rest home visits, home visits, cognitive impairment assessment, and prolonged services in some of these settings.

CMS proposes to adopt the general CPT framework for Other E/M visits, which allows a practitioner to select the visit level using time or medical decision making.

Administrator Brooks-LaSure August 31, 2022 Page 24 of 97

CMS generally proposes to adopt the revised CPT codes and descriptors. However, CMS would not adopt the new codes and descriptors for prolonged services and instead proposes Medicare-specific codes. CMS intends to adopt the CPT E/M guidelines for levels of MDM.

The RUC recommended direct work RVU comparisons for many Other E/M CPT codes to those currently assigned to Office/Outpatient E/M codes. CMS feels the direct comparison may not be appropriate or accurate given some of the differences between the institutional and office visit settings. CMS continues to believe the current visit payment structure among and between care settings does not fully account for the complexity of certain kinds of visits, particularly those in the office setting, and does not fully reflect appropriate relative values as separate payment is not yet made for HCPCS code G2211.

AAFP Comments:

The AAFP recommends that CMS finalize the RUC recommended values for all the E/M visits as proposed in this rule. As noted throughout our comments on the specific code families below, the AAFP does not support CMS' proposals to create separate prolonged services codes and guidelines. Maintaining varying sets of codes and guidelines across payers is confusing and unnecessarily burdensome for physicians and other clinicians billing under the MPFS. We recommend CMS modify these proposals to rely on CPT codes and guidelines.

While the AAFP is supportive of updating the Other E/M codes, we are concerned about the negative impact these updates will have on community-based primary care and other physician practices due to budget neutrality requirements. As CMS notes in the regulatory impact analysis, updating the Other E/M codes (and then applying budget neutrality adjustments) will result in an increase in allowed charges for facility-based clinicians while reducing allowed charges for non-facility clinicians, such as community-based primary care practices. This is yet another example of how budget neutrality requirements prevent CMS from adequately investing in and ensuring access to a wide variety of essential services for Medicare beneficiaries, including primary care. The AAFP is concerned that this redistribution of Medicare payments will drive practice closures, vertical consolidation, and price increases. We will continue to press Congress to enact legislation to address budget neutrality limitations. However, we also urge CMS to use its available authority to continually invest in community-based primary care.

In the preamble of the proposed rule, CMS correctly notes that relativity across the E/M codes, including office/outpatient and other E/M codes, is not currently being achieved because CMS has been prevented from implementing the G2211 add-on code. The AAFP agrees that the office/outpatient E/M code values fail to account for the complexity of many comprehensive, longitudinal primary care encounters. Implementing this add-on code is one important step toward comprehensively paying for primary care under the MPFS. We urge CMS to implement G2211 in the CY 2024 MPFS, when the statutory moratorium has expired.

As noted elsewhere in our comments, we believe serious questions remain about the validity of assumptions underlying the E/M portion of global surgical services. Until those questions/issues have been satisfactorily addressed, we urge CMS <u>not</u> to apply the E/M visit increases to the office visits, hospital visits and discharge day management visits included in surgical global payment.

Hospital Inpatient or Observation Care (CPT codes 99218-99236)

CMS proposes to adopt the revised CPT codes 99221-99223 and 99231-99236. When a physician or practitioner selects the visit level based on time, the number of minutes specified in the relevant code's descriptor must be "met or exceeded." CMS does not propose to adopt the CPT codebook instructions for prolonged services to codes 99223, 99233, and 99236.

The code descriptors for CPT codes 99221-99223 and 99231-99236 specify that time counted toward the code is "per day." CMS proposes to adopt the CPT Codebook instruction that "per day" (or "date of encounter") means the "calendar date." CMS also proposes to adopt the instruction that a continuous service that spans two calendar dates is a single service and is reported on one date, which is the date the encounter begins. If the service is continuous before and through midnight, all time may be applied to the reported DOS (i.e., the calendar date the encounter began). CMS notes that nothing in this proposal is intended to conflict with their proposal to retain the "8 to 24-hour rule" regarding payment of discharge CPT codes 99238 and 99239. The rule is described in further detail in Chapter 12 of the Medicare Claims Processing Manual. CMS believes it is necessary to retain the rule to prevent overpayments or create incentives to unnecessarily extend a beneficiary's stay past midnight.

Finally, CMS proposes to retain their policy that a billing practitioner shall bill only one of the hospital inpatient or observation care codes for an initial visit, subsequent visit, or inpatient or observation care (including admission and discharge) once per calendar date. The practitioner would select a code that reflects all their services provided during the DOS, as provided in the Chapter 12 of the Medicare Claims Processing Manual.

Proposed Definition of Initial and Subsequent Hospital Inpatient or Observation Visit

The 2023 CPT Codebook includes definitions of "initial" and "subsequent." The CPT definitions rely on whether a patient has received services from a physician or other QHP of the same specialty or subspecialty. CMS does not recognize subspecialties and therefore proposes amended definitions of "initial" and "subsequent" service.

- Initial a service that occurs when the patient has not received any professional services from the physician or other QHP or another physician or other QHP of the same specialty who belongs to the same group practice during the stay.
- Subsequent a service that occurs when the patient has received any professional services from the physician or other QHP or another physician or other QHP of the same specialty who belongs to the same group practice during the stay.

CMS proposes the same definitions for nursing facility visits. CMS is also proposing that for both initial and subsequent visits, when advance practice nurses and physician assistants are working with physicians, they are always classified in a different specialty than the physician.

Transitions between Settings of Care and Multiple Same-day Visits for Hospital Patients Furnished by a Single Practitioner

CMS proposes to retain their current policies regarding transitions between settings of care and multiple same-day visits of hospital patients furnished by a single practitioner.

Administrator Brooks-LaSure August 31, 2022 Page 26 of 97

CMS also proposes to retain their billing policies that a physician may bill only for an initial hospital or observation care service if the physician sees a patient in the ED (or another site of service, such as the office) and decides to either place the patient in observation status or admit the patient as a hospital inpatient. This differs from the new CPT guidelines, which otherwise permit a physician to report two E/M codes in that situation.

CMS proposes to retain their billing policies for patients in swing beds. If the inpatient care is being billed by the hospital as inpatient hospital care, the hospital care codes (CPT codes 99221-99223 and 99231-99239) apply. If the inpatient care is being billed as nursing facility care, then the nursing facility codes (CPT codes 99304-99316) apply.

AAFP Comments:

In general, the AAFP supports CMS' proposals regarding these codes and appreciates that CMS has, with a few exceptions, proposed to follow the related CPT coding structure and guidelines. One of the exceptions with which the AAFP disagrees is the CMS' proposal to maintain current billing policy regarding billing only one code when a patient is seen at one site (e.g., office) and subsequently admitted to a hospital or nursing facility. Similar to CMS proposals regarding separate prolonged services G codes, which we address below, this policy does not align with the CPT guidance and will create additional confusion and burden for physicians. Our strong preference is that CMS would reconsider this proposal and rely on the current CPT codes and guidelines. We believe it is critical to ensure consistency, and we urge CMS to work with the CPT/RUC E/M Workgroup immediately to bring CMS and CPT policies on this point into alignment. As noted in our policy on Coding and Payment, we believe it is important for physicians and health plans to abide by CPT rules when CPT codes are available.

Prolonged Services for Hospital Inpatient and Observation Care

Effective January 1, 2023, Prolonged Service with Direct Patient Contact CPT codes 99356 and 99357 will be deleted from the CPT code set. The CPT Panel created CPT code 993X0 to replace them. CMS does not propose to adopt CPT code 993X0. Instead, CMS proposes to establish a new G-code that applies to CPT codes 99223, 99233, and 99236. The code would be GXXX1:

GXXX1: Prolonged hospital inpatient or observation care evaluation and management service(s) beyond the total time for the primary service (when the primary service has been selected using time on the date of the primary service); each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (list separately in addition to CPT codes 99223, 99233, and 99236 for hospital inpatient or observation care evaluation and management services). (Do not report GXXX1 on the same date of service as other prolonged services for evaluation and management 99358, 99359, 993X0, 99415, 99416). (Do not report GXXX1 for any time unit less than 15 minutes).

GXXX1 may only be applied to the highest level of hospital inpatient or observation care visit codes (CPT codes 99223, 99233, and 99236), and can only be used when time has been used to select the level of service.

Similar to their assessment of CPT code 99417, CMS does not agree with the CPT instructions regarding when the prolonged code should apply. CMS believes the prolonged service code is only

Administrator Brooks-LaSure August 31, 2022 Page 27 of 97

applicable after both the total time described in the base E/M code descriptor is complete and the full 15 minutes described by the prolonged code are completed.

CMS notes that the RUC-recommended times for CPT code 99236 includes 85 minutes of intraservice time and an additional 12 minutes of post-service time. CMS is concerned the instructions for CPT code 993X0 would result in duplicative payment since the 12-minute post-service time was already factored into the proposed valuation of CPT code 99236.

CMS proposes that the prolonged service period for GXXX1 can begin 15 minutes after the total times (as established in the Physician Time File) for CPT codes 99223, 99233, and 99236 have been met. GXXX1 would be for a 15-minute increment and the entire 15-minute increment must be met to bill GXXX1. For administrative simplicity, CMS proposes to round the time when the prolonged service period begins to the nearest five minutes. For example, CPT code 99223, which has a RUC-proposed total time of 74 minutes, would be treated as though it has 75 total minutes.

GXXX1 would apply to both face-to-face and non-face-to-face time spent on the patient's care. For CPT codes 99223 and 99233, this would include time spent on the date of the encounter. For CPT code 99236, it would include time spent within three calendar days of the encounter. CMS is proposing that CPT codes 99358 and 99359 would not be reportable for base CPT codes 99221-99223 and 99231-99236. This is consistent with the approach CMS took for prolonged services for office/outpatient E/M services.

AAFP Comments:

The AAFP believes it is imperative that physicians have one set of clear codes and guidelines to report prolonged services. This proposal creates additional administrative complexity, which is counter to all the work that has been done over the past three years. Having both a CPT code and a HCPCS II G code for the same service creates unnecessary complexity. Furthermore, having to reference a separate table imbedded in CMS rulemaking adds burden to simply having the time ranges included in the CPT codes themselves.

Without the table, it is unclear what "total time for the primary service" means. Most readers would interpret it as the time on the date of the encounter as we are unaware of a case wherein prolonged services' start times have ever been based upon the total time in the CMS time file. It also remains unclear, even after reviewing the table, whether the prolonged services time is only that time on the date of the encounter or over the whole service. The base code selection method is clear and familiar and thus why CPT chose it.

The CMS methodology, as shown in Table 18 of the Proposed Rule, varies across families and thus is inconsistent with relativity. It is not evident from Table 18 is that the office visits have 14 minutes of unrecognized time; the inpatient or observation services have 15 minutes of unrecognized time; and the nursing facility and home or residence services have prolonged services start without a gap time. In each case, the prolonged service is 15 minutes and 0.61 work RVUs, but the time and method of determining the time beyond the base code minimum threshold for time-based reporting varies. As Table 18 illustrates, CMS' approach to reporting prolonged E/M services is a convoluted mess likely to generate confusion more than accurate claims.

Administrator Brooks-LaSure August 31, 2022 Page 28 of 97

In sum, the AAFP strongly recommends CMS reconsider the proposed policy related to prolonged services and rely on the current CPT codes and guidelines. We believe it is critical to ensure consistency between CPT and CMS policy, when possible, and we urge CMS to work with the CPT/RUC E/M Workgroup immediately to bring CMS and CPT prolonged services policies into alignment.

Emergency Department (ED) Visits

CMS proposes the RUC-recommended work RVUs for four of the five codes in the ED visit family. The one exception is code 99284. For this Level 4 ED visit, CMS proposes to maintain the existing work RVU (2.74) for CPT code 99284 rather than accepting the RUC-recommended wRVU of 2.60. Consistent with the current valuation of these codes, CMS is not proposing any direct PE inputs for the codes.

AAFP Comments:

As noted, the current work relative value unit (RVU) for the ED E/M Level 4 service (CPT 99284) is 2.74. CMS had increased the work RVU to 2.74 from 2.60 in 2021 to maintain the relativity in service levels between the ED E/M codes and the office and outpatient E/M codes. However, based on an AMA RUC survey, the AMA RUC recommended that the work RVU should drop back down to 2.60 starting in 2023.

In this instance, the AAFP supports CMS' proposal to reject the AMA RUC recommendation and keep the value at 2.74. The RUC has three times (1997, 2007, and 2018) recommended that the ED E/M codes should be the same value as the new patient Office or Other Outpatient E/M codes for levels 1 through 3 and that levels 4 and 5 should be higher. A Level 4 new patient Office or Other Outpatient E/M visit (code 99204) is currently valued at 2.60 work RVUs. We appreciate that CMS continues to give credence to the argument that a Level 4 ED visit should be higher than that and support CMS' proposal to retain the historic relativity between the new patient office or other outpatient codes and the ED E/M codes.

Nursing Facility Visits (CPT Codes 99304-99318)

The CPT Editorial Panel deleted CPT code 99318 and revised the remaining nursing facility codes at its February 2021 meeting. CMS is proposing that both face-to-face and non-face-to-face time personally spent by the physician may be totaled to select the appropriate level of nursing facility visit code. Initial nursing facility care (CPT codes 99304-99306) may be used once per admission, per practitioner, regardless of the length of stay in the SNF/NF.

CMS proposes to accept the RUC recommendations for these codes but notes they have concerns regarding instances of inconsistences and errors where the time described in certain CPT code descriptors does not correctly relate to the time that would be used to select visit level for the NF visit. The specialty societies of the RUC have advocated for increased wRVUs for the NF visits, regardless of some of the survey times, on the basis that NF visits should be valued the same as values for the comparable office/outpatient E/M services. CMS does not feel these two code families are comparable for a few reasons, including, but not limited to: (1) the two families have a different number/stratification of levels for the visits and a one-to-one crosswalk is not possible, (2) times in the code descriptors detailing the typical time spent at the patient's bedside or hospital unit vary

Administrator Brooks-LaSure August 31, 2022 Page 29 of 97

significantly; and (3) the populations differ substantially when considering typical patients who require NF services versus those in the general beneficiary community.

For instance, CMS considered maintaining the current wRVU of 3.06 for CPT code 99306 since there was no change in the overall time. The survey key reference service (CPT code 99205) has a much higher time in its code descriptor and CMS does not feel it was a valid comparison or support the increase in value to the RUC survey 25th percentile. CMS requests comment on the accuracy of the time noted in the descriptor for CPT code 99306. CMS notes that it is not clear why CPT code 99306 would have the same descriptor time and medical decision making as CPT code 99310, which is a subsequent visit, thus appearing like they are the same service.

Despite its concerns, CMS is proposing to accept the RUC recommendations for the work time values and wRVUs for the NF visit codes. CMS is seeking comment on their concerns for some of the codes.

CMS is proposing to adopt a number of billing policies reflected in Chapter 12 of the Medicare Claims Processing Manual. CMS notes that ED visits provided on the same day as a comprehensive nursing facility visit assessment are not paid, regardless of whether the ED and nursing facility visits are by the same or different practitioners. CMS is proposing to retain this policy and that more than one ED and nursing facility visit could not be billed if both visits are furnished by the same practitioner on the same date of service.

CMS proposes to adopt the CPT guidance that, for reporting initial nursing facility care, transitions between SNF level of care and NF level of care do not constitute a new stay. CMS proposes the same definitions for initial and subsequent as proposed for inpatient and observation services.

AAFP Comments:

As previously noted, the AAFP disagrees with CMS' proposal to maintain current billing policy regarding billing only one code when a patient is seen at one site (e.g., office) and subsequently admitted to a hospital or nursing facility. Similar to CMS' proposals regarding separate prolonged services G codes, this policy does not align with the CPT guidance and will create additional confusion and burden for physicians. Our strong preference is that CMS would reconsider this proposal and rely on the current CPT codes and guidelines. We believe that it is critical to ensure consistency and we urge CMS to work with the CPT/RUC E/M Workgroup immediately to bring CMS and CPT policies into alignment in this regard. As noted in our policy on Coding and Payment, we believe it is important for physicians and health plans to abide by CPT rules when possible.

Regarding CMS' concerns with the recommended value for code 99306, the AAFP would like to note that although the total time stayed the same, the intra-service and post-service times have changed. Currently, the pre-service time = 15, intra-service time = 45 and post-service time = 20 minutes. The RUC recommended 15 minutes pre-service time, 50 minutes intra-service time, and 15 minutes post-service time. Each of these components represents a different intensity. This increase in intra-service time represents approximately a 14% increase in work per unit of time, therefore the increase in the work RVU to 3.50 is appropriate.

Both the initial nursing facility care CPT code 99306 and the subsequent nursing facility care CPT code 99310, indicate high level decision making or 45 minutes must be met to report either. Although

reporting by time or medical decision-making appears the same in the descriptors, physicians will know which code to report based on whether it is an initial or subsequent visit. The RUC and CPT Editorial Panel intentionally worded the descriptor for CPT code 99306 initial nursing facility visit, high MDM, to 45 minutes must be met or exceeded, although the intra-service time is 50 minutes. This was to maintain the "pattern" of time increments to make it easier for individuals to recall which code to report if they are using time-based reporting. Therefore, the initial nursing facility visits are in 10-minute increments, 25 minutes for the straightforward/low level MDM (99304), 35 minutes for the moderate level MDM (99305) and 45 minutes for the high-level MDM (99306). Likewise, the CPT Editorial Panel maintained generally a 15-minute increment for the subsequent nursing facility visits. It is not exactly 15 minutes for all since for the subsequent nursing facility visits, the straightforward MDM and low-level MDM are represented in separate codes. Therefore, the time increments in the descriptors are 10 minutes for straightforward MDM, 15 minutes for low level MDM, 30 minutes for moderate level MDM and 45 minutes for high level MDM.

As stated above, the time in the descriptor for 99308 should be 15 minutes to maintain the 15-minute increment pattern for the subsequent nursing facility visit codes.

The AAFP urges CMS to accept the times listed in the code descriptors for the initial and subsequent nursing facility visits codes to maintain an easy incremental pattern for those who are reporting these services based on time.

Prolonged Services

CMS proposes that prolonged nursing facility services by a physician or NPP would be reportable under GXXX2 (*Prolonged nursing facility evaluation and management service(s) beyond the total time for the primary service; each additional 15 less than 15 minutes*).

CMS proposes that the practitioner would include any prolonged service time spent within the surveyed timeframe, although how CMS expects practitioners to know the surveyed timeframe is not clear. There would be no frequency limitation. CMS proposes to assign the payment status "I" (Not valid for Medicare purposes. Medicare uses another code for reporting of, and payment for, these services) for CPT codes 99358 and 99359.

AAFP Comments:

As noted, the AAFP is concerned that CMS' proposal to create separate prolonged services codes will cause confusion and add complexity. The AAFP believes it is imperative that physicians have one set of clear codes and guidelines to report prolonged services. Our recommendation is for CMS to rely on the current CPT codes and guidelines. To ensure consistency across codes and guidelines, we urge CMS to work with the CPT/RUC E/M Workgroup immediately to bring CMS and CPT prolonged services policies into alignment.

Annual Nursing Facility Assessment (CPT Code 99318)

CMS proposes to accept CPT's deletion of CPT code 99318. However, CMS is concerned that the absence of a similar code could cause an unwarranted increase in valuation of other services and CMS would not have a means of tracking how often these visits are occurring. CMS seeks comment on whether there is a need to keep the code.

Administrator Brooks-LaSure August 31, 2022 Page 31 of 97

AAFP Comments:

The AAFP agrees with the decision to delete CPT code 99318 and agree that it is reported sufficiently with other codes.

Home or Residence Services (CPT codes 99341, 99342, 99344, 99345, 99347-99350)

CMS is proposing to adopt the CPT restructuring of the Home and Residence Services codes and the RUC-recommended wRVU for all eight codes in that code family. CMS is proposing the RUC-recommended direct PE inputs for CPT codes 99345 and 99347-99350 without refinement. For CPT codes 99341 and 99342, CMS is removing supply item SK062 (patient education booklet). For CPT code 99344, CMS is removing supply items SK062 (patient education booklet), SJ053 (swab-pad, alcohol), and SJ061 (tongue depressor). CMS proposes to accept the remaining RUC-recommended direct PE inputs for the codes without refinement.

CMS proposes that prolonged home or residence services by a physician or NPP would be reportable under GXXX3 (*Prolonged home or residence evaluation and management service*(s) beyond the total time for the primary service; each additional 15 minutes). CMS would allow the physician or NPP to include any prolonged service time spent within the surveyed timeframe for the home and residence services code family, although, again, how CMS expects a physician or NPP to know that timeframe is unclear.

CMS proposes that CPT codes 99358, 99359, and 99417 cannot be billed with CPT codes 99345 and 99350. CMS proposes to change the status indicator for CPT codes 99358 and 99359 to "I."

AAFP Comments:

As noted elsewhere in our comments, the AAFP is concerned that CMS' proposal to create separate prolonged services codes will cause confusion and add complexity. We urge CMS to modify these proposals to rely on the CPT codes and guidelines.

Geographic Practice Cost Indices (GPCI) (section II.G.)

As required by law, CMS has reviewed the GPCIs and proposes an adjustment, half of which CMS will phase in during 2023 and the other half of which CMS will phase in during 2024. Per CMS, the changes to the proposed CY 2023 GPCIs for each locality reflect updated resource cost data in each area and statutory floors and limitations on variation that may advantage some rural localities. Updates include:

- Using more recent (2017-2020) Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) wage data
- Using more recent (2015-2019) American Community Survey data for the for the office rent index component of the practice expense GPCI
- Using malpractice premium data presumed in effect no later than December 31, 2020, for the malpractice GPCI (rather than the current data presumed in effect as of December 10, 2017)

Administrator Brooks-LaSure August 31, 2022 Page 32 of 97

For the CY 2023 GPCIs, CMS proposes to continue to use the current 2006-based MEI cost share weights rather than the rebased and revised MEI cost share weights discussed elsewhere in the proposed rule.

CMS proposes technical refinements to consolidate unique fee schedule areas and their locality numbers in California, and CMS proposes four technical refinements to the GPCI methodology.

AAFP Comments:

As a matter of <u>policy</u>, 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). Understanding that the law otherwise requires the use of GPCIs and obligates CMS to periodically update them, we appreciate that CMS is doing so using the most recent data available.

We also appreciate that CMS intends to continue to use the current 2006-based MEI cost share weights rather than the rebased and revised MEI cost share weights discussed elsewhere in the proposed rule. Given potential concerns associated with rebasing and revising the MEI, we agree it would be prudent to continue using the current 2006-based MEI until those concerns have been addressed.

The AAFP has no concerns with the proposed technical refinements to consolidate unique fee schedule areas and their locality numbers in California nor with the proposed technical refinements to the GPCI methodology.

Determination of Malpractice Relative Value Units (RVUs) (section II.H.)

Proposed Methodological Refinements

CMS proposes methodological improvements to the development of the professional liability insurance (PLI) premium data and resulting malpractice RVUs. The proposed methodologic changes relate to the approach for the imputation of missing malpractice premiums. CMS is also proposing to change from using risk factor score, which benchmarked each specialty to the physician specialty with the lowest premiums, to a risk index score which benchmarks each specialty's premiums to the volume-weighted average of all specialties.

AAFP Comments:

The AAFP commends CMS' continued improvement in data collection to ensure as much specialty-specific data as possible is used to reflect the most accurate trends in professional liability premiums. With its current proposals, CMS has come much closer to achieving the ideal of updated premium data for all Medicare physician specialties, other health care professionals and facility providers, in all fifty states. For the first time, all non-physician providers now have a proposed premium that more closely reflects the actual premiums these providers typically pay.

Phased-in Reduction in Malpractice RVUs

For specialties for which the use of newly available premium data would result in a 30 percent or greater reduction in the risk index for CY 2023 as compared to the current risk index value for CY

Administrator Brooks-LaSure August 31, 2022 Page 33 of 97

2022, CMS is proposing to phase in the reduction in PLI RVUs over the 3 years that precedes the next update. Per CMS, the purpose of this transition would be to "promote payment stability and prevent potential reductions in access to services for beneficiaries."

AAFP Comments:

The AAFP appreciates CMS' desire to promote payment stability and prevent potential reductions in access. However, the proposed transition would prolong the large, systematic overvaluation of the PLI RVUs for the services predominantly performed by non-physician professions, as well as the systematic underpayment of all other Medicare specialty codes as all PLI RVUs share the same PLI RVU pool in MFS rate setting methodology. It's the AAFP's understanding that, when CMS was able to collect premium data for optometry for the CY 2020 rulemaking cycle (which also had a much lower PLI normalized premium rate relative to the lowest physician specialty) CMS implemented the 83% PLI risk premium reduction for optometry in CY 2020 without a transition. We recommend CMS follow that precedent and implement the new CY 2023 PLI premium data for all professions without a transition to correct this longstanding issue, which was first raised by the RUC to CMS in 2009.

<u>Proposals and Request for Information on Medicare Parts A and B Payment for Dental</u> <u>Services (section II.L.)</u>

Currently, Medicare does not cover dental services under Medicare Part A or B, unless the dental service requires hospitalization due to severity, underlying medical condition, or other reasons. One additional exception is when a dental service, performed by a Doctor of Dental Medicine or dental surgery, is necessary to other covered primary procedures or services furnished by a physician. In such a case, Medicare Administrative Contractors (MACs) make claim-by-claim determinations as to whether a patient's circumstances do or do not fit within the terms of the preclusion and exception. CMS is proposing to codify that payment can be made under Medicare Part A and Part B for dental services that are closely linked to or required for an otherwise covered medical service. This includes both inpatient and outpatient settings, ancillary services, and other facility services. CMS is seeking comment on other dental services that are inextricably linked to other covered services and should be automatically included under this rule.

AAFP Comments:

The AAFP supports CMS' efforts to clarify and codify payment for necessary dental services. As proposed, this rule will reduce coverage inequities and reduce burdensome prior authorization and inappropriate denials of coverage for dental services resulting in delayed care and worsening of underlying health conditions. At this time, the AAFP believes CMS' proposed list of covered dental services is sufficient. The AAFP <u>acknowledges</u> that compromised oral health is associated with cardiovascular disease, diabetes, premature birth, and low-birth weight. ^{48, 49} As a result, the AAFP supports action to address the inequitable access to dental health services and the coordination of primary care physicians with oral health professionals to support dental health. This includes support for expanded Medicare coverage of dental services as long as such an expansion is provided outside of MPFS budget neutrality requirements to avoid negative impacts on Part B clinicians and Medicare beneficiaries' access to other essential services.

Rebasing and Revising the Medicare Economic Index (MEI) (section II.M.)

CMS Proposal on Updates to the Medicare Economic Index (MEI)

The MEI, first implemented in 1975, has long served as a measure of practice cost inflation and a mechanism to determine the proportion of payments attributed to physician earnings and practices costs. The MEI measures changes in the prices of resources used in medical practices including, for example, labor (both physician and non-physician), office space and medical supplies. These resources are grouped into cost categories and each cost category is assigned a weight (indicating the relative importance of that category) and a price proxy (or proxies) that CMS uses to measure changes in the price of the resources over time. The MEI also includes an adjustment to account for improvements in the productivity of practices over time.

From 1975, when payments reflected the usual, customary and reasonable charge payment methodology, through 1993, the year after implementation of the Resource Based Relative Value Scale (RBRVS), the physician earning component was 60% and the practice expense component, including professional liability insurance (PLI) costs, was 40%. These initial weights were derived from data obtained from the AMA. In the nearly 50 years since the initial establishment of the MEI, data collected by the AMA has served as the consistent source of information about physicians' earnings and their practice costs.

In 1993, the MEI components were updated, using AMA data and then proportioned to 54.2% Physician Work, 41% Practice Expense and 4.8% PLI. Currently, the allocation is 50.9% Physician Work, 44.8% Practice Expense and 4.3% PLI., based on data obtained from the AMA's Physician Practice Information (PPI) Survey. This survey was last conducted in 2007/2008 and collected 2006 data.

MEI History

	1975-1992	1993	Current	Proposed
Physician Work	60%	54.2%	50.9%	47.3%
Practice Expense	40%	41.0%	44.8%	51.3%
Professional Liability Insurance	(incl with PE)	4.8%	4.3%	1.4%

The CMS proposal is to dramatically shift payment allocation away from physician earnings (work) to practice expense: 47.3% Physician Work, 51.3% Practice Expense and 1.4% PLI using non-AMA data. CMS proposes to update the MEI weights using 2017 data from the United States Census Bureau's Service Annual Survey (SAS). However, CMS clarifies that they will not implement these new weights in 2023 as they must first seek additional comments due to significant redistribution.

The proposed shift in payment weights from physician work to practice expense principally favors Diagnostic Testing Facility (+13%), Portable X-Ray Supplier (+13%), Independent Laboratory (+10%) and Radiation Therapy Centers (+6%). Modest increases occur to specialties who provide services in the office with extremely expensive disposable supplies embedded into physician payment. Primary Care would face decreases (e.g., Family Medicine (-1%)).

Administrator Brooks-LaSure August 31, 2022 Page 35 of 97

In addition to significant specialty redistribution, geographic redistribution would also occur, as CMS proposes to modify weights of the expense categories (employee compensation, office rent, purchased services and equipment/supplies/other) within the practice expense Geographic Practice Cost Index (GPCI). A significant reduction in the weight of office rent from 10.2% to 5.9% would lead to reductions in the payment to urban localities and increases to payment in rural areas and states with a single GPCI.

AAFP Comments:

CMS' proposal redistributes physician payment from physician work to the business side of health care. The AAFP is concerned that CMS' proposal relies on data that does not accurately capture the costs of physician practice. As proposed, we understand that rebasing and revising will negatively impact family medicine, particularly community-based primary care practices, by shifting payment weights to practice expense. The AAFP remains concerned that further destabilizing community-based primary care practices will undermine progress toward CMS' strategic goals, such as advancing health equity and improving access to integrated behavioral health services. We recommend CMS revise this proposal.

The changes in the MEI that CMS is proposing are almost entirely related to the category weights. A change in the price proxy is recommended for just one of the cost categories, which accounts for only 2% of the index. CMS is not proposing a change to the productivity adjustment. The proposed changes in the category weights are primarily derived from the Census Bureau's 2017 SAS for the "Offices of Physicians" industry, which was not designed with the purpose of updating the MEI. As a result, there are key areas (physician work, nonphysician compensation and medical supplies) where CMS must use data from other sources to work around this important gap.

Several of the flaws in utilizing the SAS data for this purpose, include:

- Seven percent of the revenue for "Offices of Physicians" on the 2017 SAS was from nonpatient care sources (e.g., grants, investment income), and any expenses associated with these sources cannot be excluded.
- The SAS for "Offices of Physicians" collects payroll and benefits for all staff combined, but the MEI has separate cost categories for physician and non-physician compensation. Non-physician compensation is further broken out in the MEI by staff type. CMS is proposing to use the Bureau of Labor Statistics' (BLS) 2017 Occupational Employment and Wage Statistics (OEWS) data to estimate the share of SAS personnel costs that apply to physicians (including qualified health care professionals (QHPs)) and non-physicians. Based on the 2017 OEWS, CMS states that 63.2% of employee compensation for "Offices of Physicians" is for physicians and QHPs. CMS appears to have misclassified registered nurse salaries in this estimate. Additionally, the OEWS only covers employees, so it is missing compensation for a large segment of the physician population (practice owners). To compensate, CMS is proposing to estimate total compensation for practice owners as a share of practice net income from the 2017 SAS (the difference between total revenue and total expense which amounted to \$44.9 billion out of \$490.9 billion in revenue for 2017). The share of net income proposed is the estimated percent of patient care physicians that are owners (46.5%), averaged from the 2016 and 2018 AMA Physician Practice Benchmark Surveys, resulting in an estimated \$20.9 billion

in compensation for owners. CMS' estimate of \$20.9 billion in compensation for owners represents just 10% of total compensation for all physicians and QHPs (\$203.8 billion), which is far out of line with any reasonable estimate since nearly half of physicians in the United States are owners.⁵⁰

- CMS used BLS data to split out the US Census SAS data using the North American Industry Classification System (NAICS) 6211 "Offices of Physicians" category. However, only 64% of employed physicians are in this category in both the US Census SAS and BLS OEWS datasets. This analysis excludes 36% of physicians who are employed in other health care settings, such as hospitals. For example, the NAICS 6221 "General Medical and Surgical Hospitals" category was not included in CMS' analysis, and this category includes 158,880 employed physicians according to the 2017 BLS OEWS data. Hospital-based physicians have a higher proportion of physician earnings and PLI cost relative to other practice costs, as many of these other costs are the responsibility of the hospital or other facility. The CMS proposal greatly underrepresents the cost share of physician work and PLI relative to practice expense due to this inappropriate exclusion.
- In the current MEI, CMS excludes expenses for separately billable supplies and drugs. The 2017 SAS for "Offices of Physicians" has a single category for Medical Supplies without any breakout for the separately billable component. To estimate separately billable supply and drug expense, CMS proposes to age forward AMA-PPI results for these expenses and then compare the estimated total to Medical Supplies expense from the SAS (finding that 80% of Medical Supplies expense is for separately billable medical supplies or drugs). There are two problems with the CMS proposed approach: 1) The measures used to age expenses forward are not entirely appropriate (using growth in Medicare Part B drug spending when an all-payer measure would be better, and using measures of inflation (CPI and PPI from BLS) to age spending); and 2) totals estimated from two entirely different surveys are being compared when those surveys may have different populations and methods (for example, the wording of the questions and direction on what to include in the category could be entirely different).
- The dramatic decrease in the weight for PLI cost seems unrealistic. In 2021, the Medicare physician payment schedule allowed charges were \$91 billion. If PLI payment only represented 1.4% of this payment, total Medicare spending on its share of these premiums and self-insured actuarial costs would be \$1.274 billion. With more than one million physicians and other health care professionals billing Medicare, this would compute to Medicare paying an average of \$1,275 per individual. Assuming Medicare represents approximately 25% of physician payment, an understated \$5,100 in PLI premium cost results. This is in direct contradiction to the volume weighted PLI premium costs of \$21,700 computed by CMS elsewhere in the Proposed Rule. It appears that a 4-5% PLI weight is more appropriate than the proposed 1.4%.

The AAFP acknowledges that the data currently utilized for the MEI are outdated, and we understand the CMS desire to update these data. In 2019, the AMA House of Delegates also discussed the need for updated data and asked the AMA Board of Trustees to consider a new practice cost data collection effort. As a result of this action, we understand the AMA hopes to collaborate with CMS on a new physician practice cost survey and that 2022 data could be collected, beginning in mid-2023.

The AAFP supports CMS' call for comment on the frequency of the updates. In the future, all significant data updates (PPI Survey results, supply and equipment pricing, and clinical staff wage rates) should ideally occur simultaneously to ensure more stability in the fee schedule between updates. We understand the need for consistent and timely updates to the practice cost data and look forward to working with CMS, the AMA, and others in developing a mechanism to update these data on a more frequent basis. 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.

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

CMS proposes to clarify that when CPs and CSWs provide the services described in HCPCS code GBHI1 in an RHC or FQHC, they can bill HCPCS code G0511. The AAFP is strongly supportive of the proposal to ensure FQHCs and RHCs can utilize the new GBHI1 code. Ensuring proper payment and adequate regulatory billing flexibility for behavioral health integration in these settings is essential to ensuring equitable access.

Millions of low-income beneficiaries and those living in rural communities rely on FQHCs and RHCs for primary care and other comprehensive services. A significant proportion of family physicians practice in FQHCs and RHCs. The AAFP is strongly supportive of federal policies that bolster financial and workforce support for these essential care providers. We urge CMS to ensure they can benefit from and participate in new FFS billing policies and alternative payment models.

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

In accordance with current law, CMS proposes to make certain conforming changes in the regulations related to the data reporting and payment requirements. 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, 2023, through March 31, 2023, 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 2023. In addition, CMS proposes to make conforming changes to its requirements for the phase-in of payment reductions to reflect the amendments in the law. Specifically, CMS proposes to indicate that for CY 2022, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2021, and for CYs 2023 through 2025, payment may not be reduced by more than 15% as compared to the amount established for the preceding year. As a result, the CYs 2022 and 2023 CLFS payment rates for CDLTs that are not ADLTs are based on applicable information collected in the data collection period of January 1, 2016, through June 30, 2016. Under current law, the CLFS payment rates for CY 2024 through CY 2026 will be based on applicable information collected during the data collection period of January 1, 2019 through June 30, 2019 and reported to CMS during the data reporting period of January 1, 2023 through March 31, 2023.

AAFP Comments:

The AAFP appreciates CMS updating its regulations to conform with the current statutory provisions governing data reporting and payment requirements related to the clinical laboratory fee schedule.

Administrator Brooks-LaSure August 31, 2022 Page 38 of 97

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 Clinical Laboratory Fee Schedule (CLFS) to a single national fee schedule based on private market data from all types of laboratories that service 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 commonly 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 three times to delay the next CLFS reporting periods and twice to 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 2023. This is particularly concerning, given the vital role clinical labs play in responding to public health disruptions and threats such as COVID-19 and Monkeypox virus.

The AAFP is supporting the *Saving Access to Laboratory Services Act* (SALSA/H.R. 8188/S.4449), a permanent solution that would set Medicare payment for lab services on a sustainable path forward. SALSA will give CMS with 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.

Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers (section III.D.)

Following updates from the USPSTF in 2021, CMS proposes to reduce the minimum age for colorectal cancer screening tests from 50 to 45 years of age for certain Medicare covered screening tests. CMS also proposes to expand coverage of colorectal cancer screening to include a follow-on screening colonoscopy after a non-invasive stool-based test returns a positive result. This would remove beneficiary cost-sharing requirements and Medicare would pay for the entirety of these services.

AAFP Comments:

The AAFP supports these proposals. The AAFP issued a <u>separate recommendation statement</u> for colorectal cancer screening following the release of the updated USPSTF recommendation in 2021 to reduce the minimum age from 50 to 45 years of age. At that time, the AAFP determined there was insufficient evidence to assess the benefits and harms for screening for colorectal cancer in adults aged 45 to 49 years who are asymptomatic and have no known risk factors (e.g. family history, prior diagnosis of colon cancer, adenomatous polyps, or inflammatory bowel disease). However, a shared decision-making process taking into consideration individual health status, patient preferences, as

Administrator Brooks-LaSure August 31, 2022 Page 39 of 97

well the clinical discretion of the patient's physician, may lead to the reasonable consideration of this reduced screening age. While we may have differed with the USPSTF on the evaluation of the available evidence supporting the 2021 recommendation change, **the AAFP strongly supports comprehensive coverage of recommended preventive care, including cancer screenings.** As such, the AAFP supports CMS' proposal to reduce the minimum age for colorectal cancer screening tests from 50 to 45 years of age for certain Medicare covered screening tests in appropriate circumstances.

The AAFP strongly supports CMS' proposal to expand the availability of colorectal cancer screening by expanding Medicare coverage of follow-on colonoscopy when warranted by a screening test. The AAFP has long advocated to remove cost-related barriers to care, particularly cancer screenings and related services. When a patient receives a positive result on a stool-based test, inability to pay out of pocket to fulfill cost-sharing requirements should not be a deterrent or barrier to seeking a follow-on screening colonoscopy. The AAFP believes follow-up care for a positive screening result is part of preventive, early cancer care. Medicare coverage and payment for these services will contribute to more equitable access to colorectal cancer screening and treatment and improved health outcomes in early detection and treatment of colorectal cancer.

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

Methadone Pricing

CMS proposes to update the pricing for the methadone weekly bundle and the add-on code for takehome supplies of methadone and to update payment for the drug component to account for inflation. CMS acknowledges that previously finalized rate setting procedures for methadone, and the reporting requirements on which they rely, have not kept pace with the prescribing practices, drug development, and usage of methadone in different forms (i.e. oral concentrate vs. tablets, etc.). As such, CMS used their authority in CY 2022 to avert an inappropriate reduction in the payment for methadone. This year, CMS is proposing to update the payment methodology to better align with changes in prescribing and use of methadone. The proposed CY 2023 methadone payment amount would be \$39.29, which is the CY 2022 payment amount of \$37.38 increased by a projected 5.1 percent growth in the Producer Price Index for Pharmaceuticals for Human Use (Prescription) from CY 2021 to CY 2023.

AAFP Comments:

The AAFP <u>supports</u> this proposal and appreciates the attention and consideration CMS has given to addressing payment changes for methadone. Family physicians play a crucial role in screening patients for opioid use disorder (OUD), naloxone administration, and medication assisted treatment (MAT), which includes methadone, for patients with OUD or other substance use disorders (SUD). As such, the AAFP appreciates CMS using its authority to modify the payment methodology for methadone and taking into consideration the ongoing OUD epidemic. This proposal will ensure payment rates keep pace with increasing practice costs, thereby ensuring patients are able to access OUD treatment services. This is aligned with the Biden administration's <u>broader plan</u> to end the OUD epidemic and reduce overdose deaths by expanding access to treatment.

Proposed Changes to the Rate for Individual Therapy in the Bundled Rate

Currently, CMS pays for non-drug components of individual therapy as part of a weekly bundle based on a crosswalk to CPT code 90832, which includes 30 minutes of psychotherapy. After reviewing utilization data, CMS indicates patients diagnosed with OUD typically receive 50-minute psychotherapy sessions per week in the first several months of treatment. To address this discrepancy, CMS is proposing to slightly increase the payment rate for the non-drug component of the bundled payment on a crosswalk to CPT code 90834, which describes 45-minutes of weekly psychotherapy. CMS also proposes to apply Medicare Economic Index (MEI) updates to determine the payment amount. CMS notes that the add-on code, HCPCS code G2080, which describes an additional 30-minutes of counseling weekly, is still applicable under this proposal and has not changed.

AAFP Comments:

The AAFP supports CMS accounting for the additional time required for individuals receiving MAT and counseling by updating the crosswalk described above. The AAFP notes that some patients may require more than 45-minutes of weekly therapy but may not meet the additional 30-minutes required for the add-on code. Accordingly, the AAFP recommends CMS consider revising the add-on code, G2080 to describe each additional 15 minutes of counseling in a week of MAT treatment and revalue it as needed to reflect the decreased time. This would enable clinicians to bill for additional time under 30 minutes, as well as allow for billing of 30 minutes or more by billing the add-on code two or more times. Regardless, the AAFP agrees with CMS that the proposed update to account for 45-minutes of therapy instead of 30-minutes better aligns with the current behavioral health practices and keeps pace with increasing practice costs. The MEI adjustments will also make appropriate changes to ensure payment keeps pace with increasing costs. As stated above, the AAFP believes this is closely aligned with the Biden administration's broader plan to end the OUD epidemic and reduce overdose deaths by expanding access to treatment.

Mobile Components operated by OTPs

A recent DEA final rule allows opioid treatment providers (OTPs) to add a "mobile component" to their existing registration, which streamlined registration requirements for mobile medication units operated by OTPs. As such, CMS is offering clarification that OTPs can bill for services provided under the Medicare OTP bundled payment codes and/or add on codes in a mobile unit. Any associated geographic adjustments furnished via a mobile unit will be treated as if the services are provided at the physical location of the OTP, not the location where the mobile unit operates.

AAFP Comments:

The AAFP supports CMS' clarification and appreciates CMS aligning policies with other agencies in an effort to expand treatment. As proposed, CMS' clarification will reduce duplicative requirements and ensure OTPs are paid for services provided by mobile units. This proposal will ensure access to OUD treatment, which is aligned with the Biden administration's <u>broader plan</u> to end the OUD epidemic and reduce overdose deaths.

However, the AAFP recommends CMS monitor the actual cost and associated payment of mobile units when a geographic adjustment is applied or when a mobile unit operates in an area that would

Administrator Brooks-LaSure August 31, 2022 Page 41 of 97

normally receive a geographic adjustment. The AAFP has concerns that the actual cost of operating mobile units, which are especially crucial in rural and underserved areas, may not be reflected without a geographic adjustment specific to the area and services provided by the mobile unit. The AAFP would appreciate additional monitoring and data from CMS to ensure any geographic adjustments are not inappropriately withheld from OTPs.

Flexibilities for OTPs to Use Telecommunications for Initiation of Treatment with Buprenorphine

CMS proposes to allow the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with buprenorphine, to the extent that the visit is consistent with existing regulations. CMS also proposes to permit the use of audio-only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary. CMS also seeks comment on whether they should allow periodic assessments to continue to be furnished using audio-only communication technology following the end of the PHE for COVID-19 for patients who are receiving treatment via buprenorphine, and if this flexibility should also continue to apply to patients receiving methadone or naltrexone.

AAFP Comments:

The AAFP has strongly <u>advocated</u> for use of telehealth and audio-only resources for mental health visits, including for SUD treatment and for the <u>DEA to finalize</u> special telehealth regulations that would enable this proposal. Thus, the AAFP supports this proposal. Current data supports the use of telehealth visits for initiation and ongoing MAT, including but not limited to buprenorphine. Studies have shown that telehealth visits increased patient satisfaction, reduced costs, maintained treatment retention rates, and increased access and use of MAT.^{51, 52} Additional studies focused on veteran populations found that discontinuation of buprenorphine treatment was lower for individuals using telehealth compared to in-person, regardless of the rural or urban location.⁵³ While the AAFP acknowledges telehealth treatment using buprenorphine has a stronger evidence-base, additional studies relating to methadone and naltrexone also show benefits of telehealth visits.^{54, 55} Accordingly, the AAFP recommends CMS collect additional data on methadone and naltrexone use and diversion when prescribed and maintained via telehealth visits.

Medicare Shared Savings Program (section III.G.)

CMS proposes to make a number of changes to the Shared Savings Program which are directionally consistent with the AAFP's advocacy to improve value-based care participation opportunities for FPs, particularly those caring for rural and other underserved populations.

<u>Increasing Participation in Accountable Care Models in Underserved Communities by Providing an Option for Advance Investment Payments to Certain ACOs</u>

CMS proposes incorporating an option into the Shared Savings Program to make advance shared savings payments to ACO's who are low-revenue, inexperienced with performance-based risk Medicare ACO initiatives, new to the Shared Savings Program, and who serve underserved populations. Advance investment payments (AIPs) would increase when more dual-eligible beneficiaries or beneficiaries who live in areas with high deprivation are assigned to the ACO. Payments would be used to improve health care provider infrastructure, increase staffing, or provide

Administrator Brooks-LaSure August 31, 2022 Page 42 of 97

accountable care for underserved beneficiaries. CMS proposes AIPs be comprised of two types of payments: a one-time payment of \$250,000 and eight quarterly payments based on the number of assigned beneficiaries, capped at 10,000 beneficiaries. CMS would recoup prepaid shared savings (AIP) from any shared savings earned by an ACO in its current agreement period, and if necessary, future agreement periods.

Proposed Eligibility Criteria for AIP

CMS proposes an ACO must meet all the following criteria for the ACO to be eligible to begin receiving AIPs:

- The ACO is not a renewing ACO or re-entering ACO.
- The ACO has applied to participate in the Shared Savings Program under any level of the BASIC track glide path and is eligible to participate in the Shared Savings Program.
- The ACO is inexperienced with performance-based risk Medicare ACO initiatives.
- The ACO is a low revenue ACO defined as an ACO whose total Medicare Parts A and B FFS revenue of its ACO participants is less than 35 percent of the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries.

CMS proposes to exclude all Parts A and B fee-for-service payment amounts for a beneficiary's episodes of care for treatment of COVID-19 from expenditure and revenue calculations for purposes of determining an ACO's eligibility to receive AIPs (i.e., determination of low revenue).

CMS proposes to limit AIP eligibility to ACOs applying to participate under any level of the BASIC track glide path because this participation option is indicative of an ACO's inexperience with performance-based risk and these ACOs are more likely to benefit from up-front funding or ongoing financial assistance.

AAFP Comments:

The AAFP recommends CMS consider expanding access to AIPs to some existing ACOs, 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 beneficiaries with high-needs. Preliminary analysis suggests adding FQHCs, RHCs, and/or CAHs to ACOs typically results in an ACO moving from low-revenue to high-revenue. Penalizing ACOs who may be serving a high proportion of beneficiaries who are underserved may further exacerbate disparities and slow the transition to value for these practices who, to date, have lacked value-based accountable care model options. 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.

Administrator Brooks-LaSure August 31, 2022 Page 43 of 97

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.

Proposed AIP Application Procedure

The application cycle for AIPs would be conducted as part of and in conjunction with the Shared Savings Program application process with instructions and the timeline published through the Shared Savings Program website. The initial application cycle to apply for AIPs would be for a January 1, 2024, start date.

CMS proposes an ACO would be required to submit a spend plan as part of its application for AIPs. The plan must identify how the ACO will spend the AIPs during the agreement period to build care coordination capabilities (including coordination with community-based organizations, as appropriate), address specific health disparities, and meet other criteria. In addition, CMS proposes the spend plan must identify the categories of goods and services to be purchased, the dollar amounts to be spent on the various categories, and such other information as may be specified by CMS. ACOs will be required to segregate AIPs from all other revenues by establishing and maintaining a separate account into which the ACO must immediately deposit all AIPs.

CMS also proposes to require ACOs to post on its dedicated public reporting web page: (1) the total amount of AIPs received from CMS for each performance year; (2) the ACO's spend plan; and (3) an itemization of how the AIPs were actually spent during the year, including expenditure categories, the dollar amounts spent on the various categories, any changes to the spend plan as submitted, and such other information as may be specified by CMS.

AAFP Comments:

While the AAFP is supportive of the application procedure proposal overall, we are concerned the start date of January 2024 combined with the eligibility requirement of being a new ACO will exclude new ACOs applying to start in 2023 or cause new ACOs to delay their start date a year. This proposal will unintentionally delay the transition to value pathways. The AAFP recommends CMS add an opportunity for ACOs joining the program in 2023 be allowed to submit the supplemental materials to apply for AIPs and start receiving advanced payments in 2024.

The AAFP urges CMS to minimize administrative tasks and reporting requirements associated with the AIPs. Fulfilling these requirements costs physician practices and ACOs staff time and financial resources, both of which ACOs want to focus on improving care and health outcomes for patients. Minimizing additional administrative tasks will help attract new ACOs and facilitate successful participation.

Proposed Use and Management of AIP

AIPs are intended to provide the means to build the ACO's population health management capabilities, including the provision of accountable care for underserved beneficiaries. CMS proposes AIPs must be used to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of

Administrator Brooks-LaSure August 31, 2022 Page 44 of 97

health. CMS seeks comment on whether there are additional categories of expenses that should be permitted in light of the purposes of AIPs. CMS will monitor how ACOs are spending these funds and will revisit these categories in future rulemaking if additional flexibilities or guardrails are required.

CMS proposes to prohibit the use of AIPs for any expenses that would not constitute a permitted use of the funds, including management company or parent company profit, performance bonuses, other provider salary augmentation, provision of medical services covered by Medicare, or items or activities unrelated to ACO operations that improve the quality and efficiency of items and services furnished to beneficiaries. However, bonuses could be tied to successful implementation of SDOH screenings or care management guidelines, or ACOs could pay a higher salary as necessary to retain a clinician who treats underserved beneficiaries. CMS seeks comments on these examples of prohibited uses and whether there are additional categories of expenses that should be prohibited in light of the purposes of AIPs.

ACOs participating in Level E of the BASIC track are considered advanced alternative payment models and have agreed to take on downside risk. CMS proposes an ACO participating in Level E of the BASIC track may not use any advance shared savings payments to pay back any shared losses that it would have incurred. The level of risk in an Advanced APM is greater than a nominal amount; therefore, an ACO eligible to receive advance shared savings payments that is willing to take on such additional risk must remain liable for any losses incurred regardless of advance payments received.

AAFP Comments:

Overall, the AAFP is supportive of this proposal however we ask for further clarification for the exclusion for medical services covered by Medicare as the approved uses, such as paying for a new care manager, is an allowable expense.

Proposed AIP Payment Methodology

CMS proposes to provide an ACO that CMS determines meets the eligibility criteria described above with AIPs during the first two performance years of the ACO's participation agreement. CMS proposes that AIPs will be comprised of two types of payments: a one-time payment of \$250,000 and eight quarterly payments based on the number of assigned beneficiaries, capped at 10,000 beneficiaries.

CMS believes initial ACO start-up costs do not vary significantly by the size of an ACO or by the underlying level of risk of an assigned beneficiary population. However, CMS is considering alternative values of the one-time payment, such as allowing the one-time payment to vary by ACO based on the number of assigned beneficiaries, the risk factors of the ACO's assigned beneficiary population, or both. CMS seeks comment on the proposal to provide ACOs with a one-time payment of \$250,000, as well as these alternatives.

CMS proposes to determine the value of an ACO's upcoming quarterly payment amount prior to the start of the quarter based on the latest available assignment list for the performance year for ACOs with preliminary prospective assignment with retrospective reconciliation, since the assignment list is updated quarterly based on the most recent 12 months of data. For ACOs under prospective assignment, the assignment list is updated quarterly to exclude beneficiaries that meet any of the exclusion criteria during the performance year.

CMS is also seeking input on an alternative proposal for the timing of the quarterly payment calculation. Under this alternative, CMS would determine the ACO's quarterly payment at the start of the performance year based on the beneficiaries assigned to the ACO at the beginning of a performance year, allowing the quarterly payments to remain fixed during the performance year. This alternative carries the risk that CMS would underpay or overpay an ACO relative to an approach of redetermining the quarterly payment amount prior to the start of each quarter.

CMS proposes the following steps to calculate an ACOs quarterly payment amount:

- 1. Determine the ACO's assigned beneficiary population.
- 2. Assign each beneficiary a risk factors-based score.
- a. If the beneficiary is dually eligible for Medicare and Medicaid, they will be assigned a risk factors-based score of 100.
- b. If the beneficiary is not dually eligible, a risk factors-based score equal to the ADI national percentile rank of the census block group corresponding with the beneficiary's primary mailing address will be assigned.
- c. If the beneficiary is not dually eligible and cannot be matched with an ADI national percentile rank due to insufficient data, a risk factors-based score of 50 will be assigned.
- 3. Determine a beneficiary's payment amount.
- a. For each beneficiary in the assigned population, CMS would determine the payment amount that corresponds to the beneficiary's risk factors-based score according to the per beneficiary payment amounts as follows:

Proposed Quarterly Per Beneficiary Payment Amounts								
Risk Factors- Based Score	1-24	25-34	35-44	45-54	55-64	65-74	75-84	85-100
Per beneficiary payment amount	\$0	\$20	\$24	\$28	\$32	\$36	\$40	\$45

- 4. Calculate the ACO's total quarterly payment amount.
- a. The ACO's quarterly payment amount would be the sum of the payment amounts corresponding to each assigned beneficiary's risk factors-based score, capped at 10,000 beneficiaries. If the ACO has more than 10,000 assigned beneficiaries, CMS would calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest risk factors-based scores.

CMS is also seeking input on alternatives to assigning 100 points to the beneficiary for dual eligibility status. One alternative CMS is considering is to calculate a beneficiary's risk factors-based score as

Administrator Brooks-LaSure August 31, 2022 Page 46 of 97

the sum of the ADI national percentile rank of the beneficiary's census block group and 25 points if the beneficiary is dually eligible for Medicare and Medicaid. The maximum risk factors-based score would therefore be 125, and CMS would revise the payment amount ranges to account for a higher maximum score. CMS is also considering alternative methodologies to calculating an ACO's quarterly payment by using an ACO's average risk factors-based score based on all the ACO's assigned beneficiaries. CMS would take the sum of the risk factors-based scores for each of the ACO's assigned beneficiaries and divide by the total number of the ACO's assigned beneficiaries. In this alternative, ACOs with an average risk factors-based score above the median would have their per beneficiary payment amount scaled upward and those with an average risk factors-based score below the median would have their per beneficiary payment amount scaled downward. This alternative approach would allow CMS to consider the risk factors-based scores of all of an ACO's assigned beneficiaries, not only the 10,000 assigned beneficiaries with the highest risk factors-based scores, in determining the ACO's quarterly payment.

CMS is also considering an alternative proposal to identify underserved beneficiaries based on whether their mailing address is located in a Health Professional Shortage Area (HPSA) for primary care instead of the beneficiary's mailing address' ADI percentile rank. Under this alternative, the risk factor-based score would be based on the sum of points assigned based on whether an assigned beneficiary is residing in an area designated as a geographic HPSA, as determined by the beneficiary's mailing address, and whether a beneficiary is dually eligible for Medicare and Medicaid.

CMS is also considering an alternative methodology that additionally considers whether a beneficiary receives a Part D low-income subsidy from Medicare in CMS' calculation of the quarterly payment amount. In this alternative, the risk factors-based score would be equal to the assigned beneficiary's ADI national percentile or 100 points if the beneficiary is dually enrolled in Medicare and Medicaid or receives a Part D low-income subsidy from Medicare.

AAFP Comments:

The AAFP has long advocated for prospective payment models for primary care. Primary care practices need a stable suite of multi-payer models, including models that incorporate Medicaid beneficiaries, across the risk spectrum with predictable, prospective revenue streams adequate to meet patient and practice needs. In today's environment, primary care teams intent on delivering well-coordinated, advanced primary care continue to be hampered by the persistently low payments and limitations related to fee-for-service and burdened by the unique requirements of each payer. Streamlined prospective payment models that adequately support and sustain comprehensive, longitudinal patient-physician relationships that address the whole patient, including health-related social needs (HRSN), are essential. The AAFP commends CMS on their proposal to add advanced payments to the Shared Savings Program to increase participation by easing the up-front costs for new entrants and providing on-going prospective payments for the first two years of the ACO's agreement. In addition, we encourage CMS to explore options to provide advance payments for physicians and practices in non-ACO accountable care models.

However, we are concerned that the proposed lump sum payment of \$250,000 is the same as the payment made to AIM model participants beginning in 2016 and is not reflective of inflation nor

Administrator Brooks-LaSure August 31, 2022 Page 47 of 97

current day start-up costs. The AAFP recommends increasing the lump sum payment to reflect inflation and ensure robust upfront financial support is available to new ACOs.

CMS seeks comment on a number of proposals to calculate the risk-factors based score for the quarterly AIP payments. The AAFP supports CMS' proposal to determine the value of an ACO's prospective quarterly payment amount prior to the start of the quarter based on the latest available assignment list for the performance year as opposed to the alternative proposal to determine the ACO's quarterly payment at the start of the performance year based on the beneficiaries assigned to the ACO at the beginning of a performance year. While the alternative proposal allows quarterly payments to remain fixed, the AAFP is concerned this proposal may result in over or under payment. Over payment would require additional recoupment of funds which would be logistically complicated, burdensome to practices, and cause instability to practice revenue streams.

The AAFP also prefers CMS' proposal to assign a score of 100 to dual eligible beneficiaries over the alternative proposal to calculate the beneficiary's risk factors-based score by taking the sum of the ADI national percentile rank where the beneficiary lives and adding 25 points if the beneficiary is dually eligible for Medicare and Medicaid with a maximum score of 125. The alternative proposal is overly complicated and will be less clear to program participants. The AAFP also supports the alternative proposal to assign 100 points to Medicare beneficiaries who qualify for Part D low-income subsidies.

The AAFP does not support the alternative proposal to calculate an ACO's quarterly payment by using an ACO's average risk factors-based score for all the ACO's assigned beneficiaries. While this alternative approach would allow CMS to consider the risk factors-based scores of all an ACO's beneficiaries, not just the 10,000 beneficiaries with the highest risk factors-based score, it also masks variation. Averaging percentages in particular, such as the ADI percentiles, may improperly distribute funds by not accounting for the spread or distribution of scores.

The AAFP supports CMS' proposal to use the ADI national percentile rank of the census block group corresponding with the beneficiary's primary mailing address to assign the risk factors-based score to determine the quarterly payment amounts. We believe this proposal better represents the variety of health-related social needs a beneficiary may face as opposed to the alternative proposal of using Health Professional Shortage Areas (HPSA). The AAFP is supportive of risk-adjusted payment methodologies using deprivation indices like the ADI as they use pre-existing data to not further exacerbate burden on practices.

In summary, the AAFP recommends CMS calculate the quarterly AIP at the individual beneficiary level for the 10,000 beneficiaries with the highest risk factors-based score, using the 100-point scale with dual eligibility status or Part D low-income subsidy equaling 100 points, and giving a risk factors-based score equal to the ADI national percentile rank of the census block group corresponding with the beneficiary's primary mailing address for those beneficiaries who are not dual eligible.

Proposed Duration of AIP

CMS seeks comment on the proposal to provide AIPs to ACOs for the first two years of the ACO's performance period, to allow ACOs to spend those payments over the duration of their five-year

Administrator Brooks-LaSure August 31, 2022 Page 48 of 97

agreement period, and to send a demand letter for any unspent funds at the end of the ACO's agreement period.

AAFP Comments:

The AAFP recommends recouping from only half of an ACO's shared savings to allow practices to keep some shared savings to reinvest in improved care delivery to better meet their patients' needs. Reinvesting shared savings into practice improvements is one important incentive to practices looking to transition into an ACO. A longer repayment period would allow new ACOs the option to use shared savings to continue bolstering the practice infrastructure and staffing capabilities they need to be successful in the earliest years of participation and ultimately help new ACOs more rapidly move into more advanced participation levels. Therefore, the AAFP recommends pay back continue after five-year agreement period if funds are not recouped in full at the end of the agreement. If an ACO terminates after the agreement period, they would owe repayment of the remainder of the AIPs owed to CMS. Additionally, we suggest CMS consider allowing ACOs the option for the speed at which AIPs are recouped by allowing them the choice between full recoupment by the end of the 5-year agreement period or over a longer period.

Proposed Compliance and Monitoring of AIPs

CMS proposes to monitor the spending of AIPs to provide CMS with a clear indication of how ACOs intend to spend AIPs, provide adequate protection to the Medicare Trust Funds, and to prevent funds from being misdirected or appropriated for activities that do not constitute a permitted use of the funds. This would be accomplished by comparing the anticipated spending as set forth in the spend plan submitted with an ACO's application against the actual spending as reported on the ACO's public reporting webpage, including any expenditures not identified in the spend plan. The reported annual spending must include any expenditures of AIPs on items not identified in the spend plan. ACOs would be required to annually report their actual expenditures via an updated spend plan on their public reporting webpage.

CMS proposes to monitor ACOs that receive AIPs to determine if they remain low revenue ACOs that are inexperienced with performance-based risk. CMS would monitor ACOs for changes in the risk experience of ACO participants that would cause an ACO to be considered experienced with performance-based risk or a high revenue ACO and therefore ineligible for AIPs. If an ACO that receives AIPs and becomes experienced with performance-based risk Medicare ACO initiatives or becomes a high revenue ACO during any performance year of the agreement period, CMS will cease paying the ACO AIPs starting the quarter after the ACO became experienced with performance-based risk Medicare ACO initiatives or became a high revenue ACO.

AAFP Comments:

The AAFP is supportive of the proposal to monitor the spending of AIPs in comparison to the submitted spend plan. However, we have concerns with the proposal to require ACOs to remain low-revenue during the agreement period. The penalties proposed, including the halting of payments, are counter to CMMI's goals of having 100 percent of Medicare beneficiaries in accountable care relationships by 2030 and to improve participation in value-based models by safety net practices and facilities. Preliminary analyses suggest adding FQHCs and RHCs to ACOs may result in an ACO

moving from low-revenue to high-revenue. Penalizing ACOs who may be serving a high proportion of beneficiaries who are underserved may further exacerbate disparities and slow the transition to value for these practices who, to date, have lacked value-based accountable care model options. 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.

Proposed AIP Recoupment

CMS proposes to recoup AIPs from any shared savings earned by the ACO in any performance year until CMS has recouped all AIPs. CMS also proposes that if there are insufficient shared savings to recoup the AIPs made to an ACO for a performance year, they would carry forward that remaining balance owed to the subsequent performance year(s) in which the ACO achieves shared savings, including any performance year(s) in a subsequent agreement period.

CMS is also proposing to require an ACO to repay all AIPs it received if they terminate their participation agreement during the agreement period in which they received an AIP. This proposal ensures AIPs are used by ACOs that complete their agreement period and reduces the risk of ACOs using termination to avoid repayment of the AIPs.

AAFP Comments:

The AAFP encourages CMS to allow ACOs to keep a portion of shared savings 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). If an ACO terminates before repaying all AIPs, CMS should require repayment of any outstanding advanced payments. We also recommend CMS consider a sliding-scale reduced AIP payback for ACOs serving a high proportion high-need beneficiaries to increase participation in the program by further reducing barriers to entry. 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.

MSSP Participation & Quality Proposals

Smoothing the Transition to Performance-based Risk

CMS is proposing to allow an ACO that enters the BASIC track's glide path at Level A to remain at Level A for all subsequent years of the agreement period. To be eligible to participate in Level A for the subsequent years of the agreement period, CMS is proposing that the ACO:

- Must be participating in its first agreement period under the BASIC track,
- Is not participating under the BASIC track as a renewing ACO or a re-entering ACO,
- Is inexperienced with performance-based risk.

Eligibility will not consider an ACO's revenue status. An ACO that elects to remain in Level A for the entirety of its agreement would still be eligible to enter a subsequent agreement under the BASIC track, which could include an additional two years (seven years total) in Level A.

CMS proposes to allow ACOs inexperienced with performance-based risk to participate in two agreement periods under the BASIC track. The ACO must complete one agreement under the BASIC track and continue to meet the definition of inexperienced with performance-based risk to be eligible to enter into a second agreement in the BASIC track's glide path. ACOs that are inexperienced with risk but not eligible to enter the glide path may enter either the BASIC Track E or the ENHANCED track for all performance years of the agreement. ACOs currently in the BASIC track Level A or B may elect to continue in their current level for performance year 2023 and the remainder of the agreement period. Currently participating ACOs that elect to remain in Level A or B for the remainder of their agreement period would be eligible to enter into a subsequent agreement period under the BASIC track.

CMS proposes to change the definition of *Performance-based Risk Medicare ACO initiative* to remove Levels A and B of the BASIC track and only Levels C through E. To determine eligibility for the new participation options, CMS proposes to consider an ACO's experience with performance-based Medicare ACO initiatives only, rather than also considering the ACO's status as high- or low-revenue. CMS will monitor ACOs identified as inexperienced with performance-based risk participating in the BASIC track under a one-sided under the new participation options for changes in their participant list that would cause the ACO to be considered experienced with risk and ineligible to participate in a one-sided model. If the ACO is found to be experienced with risk, they would be permitted to complete the remainder of the performance year but would be ineligible to participate in a one-sided model. If the ACO continues to meet the definition of experienced with risk at the end of the performance year, it will be advanced to Level E of the BASIC track and required to meet all requirements to participate under performance-based risk.

CMS proposes to allow ACOs experienced with performance-based risk to participate in BASIC Track level E or the ENHANCED track indefinitely rather than requiring all ACOs to eventually transition to the ENHANCED track. This would be available to all ACOs regardless of their high- or low-revenue status. It would also be available to all ACOs that currently participate in the ENHANCED track or that participate in the ENHANCED track in the future (i.e., ACOs would be able to move from the ENHANCED track to Level E if they find it is more appropriate).

AAFP Comments:

The AAFP supports this proposal. The current glide path presents a challenge and acts as a deterrent for new ACOs to join the program, particularly for physician-led ACOs and those that serve vulnerable populations. Data consistently show that physician-led ACOs earn a bonus and generate higher savings than hospital and integrated ACOs.⁵⁶ It's also been demonstrated that ACOs generate more savings over time – with savings increasing by the third year of participation. The rapid transition to downside risk accelerates the speed with which ACOs must develop and hone the skills and capabilities required to succeed in value-based payment arrangements. The result of this has caused more ACOs to drop out of the program after the first three years, undermining the goals of value-based payment.

We appreciate that CMS is recognizing that low-revenue ACOs may need additional time in upsideonly and providing ACOs the opportunity to remain in Level A for the full agreement period. The AAFP supports policies that recognize that the rapid assumption of downside financial risk has prevented many practices and ACOs that serve vulnerable populations from transitioning to valuebased payment. Providing practices with additional opportunities to participate in value-based payment arrangements, including non-ACO models, is an important step in advancing health equity.

As it relates to CMS' proposal to require ACOs that have elected to remain in Level A and become experienced with risk during the agreement period to transition to Level E, the AAFP recommends allowing those ACOs to choose between advancing to Level C, D, or E. We are concerned that requiring ACOs to move directly from Level A to Level E will be too big of a jump for some ACOs and cause them to drop out of the program.

The AAFP supports CMS' proposal to allow ACOs experienced with performance-based risk to choose to participate in Level E or the ENHANCED track indefinitely, as this will allow ACOs to determine which option is most suitable for them.

Determining Beneficiary Assignment

CMS proposes to revise the definition of primary care services used for assignment in the Shared Savings Program regulations to include the following additions: (1) Prolonged services HCPCS codes GXXX2 and GXXX3, if finalized; and (2) Chronic Pain Management HCPCS codes GYYY1 and GYYY2, if finalized.

Prior to the start of the performance year and periodically during the performance year, CMS proposes to determine the CMS Certification Numbers (CCNs) for all federally qualified health centers (FQHCs), rural health clinics (RHCs), Method II Critical Access Hospitals (CAHs), and Elected Teaching Amendment (ETA) hospitals enrolled under the TIN of an ACO participant, including active enrollment and all CCNs with a deactivated enrollment status. CMS would use those CCNs in determining beneficiary assignment for the performance year.

CCNs that enroll under a participant TIN during the performance year would be reflected in program operations including, but not limited to, beneficiary assignment and revenue and expenditure calculations. Services provided by a CCN with a deactivated enrollment status prior to the CCN becoming deactivated will be considered in determining beneficiary assignment to the ACO for the applicable performance year.

AAFP Comments:

Administrator Brooks-LaSure August 31, 2022 Page 52 of 97

The AAFP recommends CMS monitor the specialty of physicians billing the chronic pain management codes before using them for assignment in an ACO. If they are primarily being billed by non-primary care physicians, it would not be appropriate to use these codes for assignment to an ACO. This is particularly important given that the quality standard continues to rely on measures that assess the performance of primary care physicians without equal measurement of other specialties.

Quality Reporting Performance Standard and Reporting

CMS is proposing to reinstate a modified sliding scale approach for determining shared savings for all ACOs, regardless of how they report data. Beginning with performance year 2023, if an ACO fails to meet the existing criteria under the quality performance standard to qualify for the maximum sharing rate but the ACO achieves a quality performance score in the 10th percentile or higher for at least one of the four outcome measures of the APP measure set, the ACO would share in savings at a rate that reflects the ACO's quality score. The ACO's final sharing rate would be scaled by multiplying the maximum sharing rate for the ACO's track by the ACO's quality performance score.

For the ENHNACED track, CMS is proposing to determine an ACO's shared loss rate using a sliding scale approach for ACOs that have losses that exceed the minimum loss rate and either meet the existing quality performance standard or does not meet the standard but achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark for at least one of the four outcome measures in the APP measure set. The scaled rate would be equal to one minus the product of the maximum sharing rate for the ENHANCED track and the ACO's health equity adjusted quality performance score. The scaled loss rate is subject to a 40 percent minimum and 75 percent maximum.

In order for BASIC track Level E and the ENHANCED track to retain their status as AAPMs, CMS is proposing to modify the criteria to be considered an APM. Should that proposal not be finalized, CMS would consider finalizing an alternative proposal to scale an ACO's shared savings. An ACO that fails to meet the existing criteria but achieves a quality performance score equivalent to or higher than the 10th percentile on at least one outcome measure and a quality performance score equivalent or higher than the 30th percentile on at least one of the remaining measures in the APP set would be eligible to receive shared savings at a lower rate. CMS would consider a parallel approach to determine scaled losses for the ENHANCED track.

These proposals would apply to all qualifying ACOs regardless of how the ACO reports quality data to CMS.

CMS is proposing to extend the incentive for reporting eCQMs/MIPS CQMs through the 2024 performance year to allow ACOs to allow an additional year to gauge their performance. CMS seeks comment on whether it should incorporate the above amendments into the eCQM/MIPS CQM incentive. This would result in an ACO only having to achieve a quality performance score equivalent to or higher than the 10th percentile of the benchmark on at least one of the four outcome measures to qualify for the incentive in the 2023 and 2024 performance years.

AAFP Comments:

While the AAFP is supportive of CMS' proposal to reinstate the sliding scale approach for determining shared savings, we have concerns that the measures within the APP measure set rely heavily on

primary care physicians. ACOs can include physicians in many specialties and subspecialties, however the performance measures represent actions and outcomes primarily attributed to primary care physicians. The result is that other specialties are assessed on measures that are not appropriate or measures they cannot influence. The limited scope of the performance measures used in the quality standard means the ACO disproportionately relies on primary care physicians instead of holding all ACO participants equally accountable. The AAFP encourages CMS to continue exploring ways to modify the SSP that promotes equal accountability across all specialties participating in the ACO. We ask that CMS expedite its focus on this issue.

The AAFP supports incorporating the proposed amendments into the eCQM/MIPS CQM incentive since it may ease the transition into the APP measure set.

Health Equity Adjustment for ACOs that Report All-payer eCQMs/MIPS CQMs, and are High Performing on Quality, and Serve a High Proportion of Underserved Beneficiaries

Starting with the 2023 performance year, CMS proposes to add a health equity adjustment to the MIPS Quality performance scores of ACOs that report the three eCQM/MIPS CQMs in the APP measure set, meet the data completeness requirement and administer the CAHPS for MIPS survey. The adjustment would be the sum of the ACO's MIPS Quality performance category score for all measures in the APP measure set and the ACO's health equity adjustment bonus points, if applicable. CMS would limit the adjustment to certain SSP determinations and calculations. CMS proposes to apply an ACO's health equity adjusted quality performance score in determining:

- final sharing rate for calculating shared savings payments under the BASIC and ENHANCED tracks for ACOs that meet the proposal alternative quality performance standard.
- the shared savings loss rate when the ACO meets the quality performance standard or the proposed alternative standard,
- the quality performance score for an ACO affected by extreme and uncontrollable circumstances if the ACO can report quality data via the APP and meet data completeness and case minimum requirements.

CMS proposes to create three groups based on measure performance: (1) a group comprised of the top third performing ACOs, (2) a group comprised of the middle third performing ACOs, and (3) a group comprised of the bottom third performing ACOs.

CMS would assign an ACO a value of four for each measure in the top performance group, two points for each measure in the middle group, and zero for each measure in the bottom group. The sum of the values assigned to each measure would make up the "measure performance scaler."

CMS intends to award higher positive adjustments to ACOs providing higher quality of care to underserved beneficiaries. CMS proposes to identify ACOs serving larger populations of underserved beneficiaries by calculating an "underserved multiplier" based on the higher value of either the proportion of dual-eligible beneficiaries or the proportion of beneficiaries residing in areas of high socioeconomic disadvantage (based on ADI) within the ACO's performance year assigned beneficiary population. The multiplier would be between zero and one. The proportion of beneficiaries residing in areas of high socioeconomic disadvantage would be determined based on whether the

Administrator Brooks-LaSure August 31, 2022 Page 54 of 97

beneficiary resided in a census block group with an ADI national percentile rank of at least 85. ACOs serving mostly beneficiaries residing in areas of high socioeconomic disadvantage or serving a larger proportion of dual-eligible beneficiaries would receive a multiplier closer to one.

CMS considered and seeks comment on an alternative approach that uses a combination of the proportion of an ACO's beneficiaries residing in areas of high socioeconomic disadvantage and an ACO's proportion of dually eligible Medicare and Medicaid beneficiaries. CMS also considered and seeks comment on an approach that incorporates the proportion of beneficiaries receiving the low-income subsidy (LIS).

CMS proposes calculating an ACO's health equity adjustment bonus points by multiplying the measure performance scaler and the ACO's underserved multiplier. ACOs with an underserved multiplier of less than 20 percent would be ineligible to receive bonus points. ACOs could be awarded up to 10 bonus points and added to the ACO's MIPS Quality performance category score and capped at 100 percent.

CMS seeks comment on the three-tiered approach to determine values assigned to each measure, the scale of values attributed to the three performance groups, and the overall amount of the adjustment maximum of 10 bonus points. CMS also seeks comment on the eligibility requirement (i.e., an ACO's underserved multiplier be at least 20 percent). Finally, CMS is looking for feedback on alternative methodologies for calculating the underserved multiplier.

AAFP Comments:

The AAFP supports these proposals. We appreciate CMS' incorporation of a health equity adjustment and are supportive of adding the low-income subsidy to its calculation. We recommend that CMS apply the health equity adjustment to ACOs that report via the Web Interface. An ACO's population does not differ based on the reporting mechanism and restricting the adjustment to just ACOs that report via the APP does not align with the intent of the adjustment. Practices and ACOs that serve beneficiaries in areas of high socioeconomic advantage provide vital care to communities. It has been difficult for these practices to participate in the existing models and created a gap between those who are able to transition out of FFS and those who cannot. Without viable opportunities, practices will be left in a payment system that does not provide adequate support and serve as a mechanism to perpetuate inequities. Ensuring all types of practices have opportunities to transition to a more sustainable payment model is critical to promoting a more equitable health system.

Addressing MIPS Quality Performance Category Score Corrections

CMS is clarifying that they would reopen the initial determination of an ACO's financial performance to correct errors in the determination of whether an ACO is eligible for shared savings, the amount of shared savings due to the ACO, or the amount of the shared losses by the ACO. Specifically, they would use their discretion in the event they learn of errors in the calculation of the MIPS quality performance category scores that change the percentile score an ACO must achieve to meet the quality performance standard. CMS seeks comment on this clarification.

The AAFP supports this clarification.

Administrator Brooks-LaSure August 31, 2022 Page 55 of 97

Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health Measures and Future Measure Development (RFI)

Health equity and addressing health disparities are priorities for CMS. CMS is seeking comment on two new structural measures for the APP measure set: Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health. Both measures have conditional support from the National Quality Forum (NQF). NQF also indicated the measures would be appropriate for the SSP.

Screening for Social Drivers of Health assesses the percentage at which providers screen their adult patients for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. The measure is currently proposed for use in traditional MIPS. If it is approved for MIPS, CMS will consider proposing to add it as an eCQM/MIPS CQM under the APP beginning in the 2025 performance year. CMS notes that measure specifications for EHR reporting are not being developed at this time but would be considered for purposes of any future rulemaking. CMS believes this measure may help clinicians develop treatment plans that focus on beneficiaries' unique needs and priorities. CMS may consider additional measures in the future that would assess how well ACOs address the social needs of beneficiaries more directly.

The Screen Positive Rate for Social Drivers of Health assesses the percentage of patients who screened positive for health-related social needs. CMS is interested in feedback on the value of implementing a measure that indicates patient's social needs as part of the quality of care provided to them.

CMS also seeks comment on:

- How to best implement the measures and how they could further drive health equity and health outcomes under the SSP?
- What are the possible barriers to implementation of the measures in the SSP?
- What impact would the implementation of these measures in the SSP have on the quality of care provided to underserved populations?
- What type of flexibility with respect to the social screening tools should be considered should the measures be implemented? How can CMS advance the use of standardized, coded health data within screening tools?
- Should the measures, if implemented in the future, be considered pay-for-reporting measures?

AAFP Comments:

The AAFP supports CMS' goal of reducing health inequities and believes family physicians, along with others, play an important role in helping to identify the health-related social needs of patients. We also agree that it is important for family and other primary care physicians to be connected to social and community-based organizations that can help to address those needs using an efficient, centralized approach. These are core tenants of comprehensive, longitudinal primary care, though we note that these types of services are often not billable under the MPFS. Moving to APMs that include comprehensive prospective payment must be prioritized if we are to sufficiently and sustainably

Administrator Brooks-LaSure August 31, 2022 Page 56 of 97

support primary care's role in improving health equity. Further, **physicians and other clinicians** cannot be held accountable for providing resources to address individual health-related social needs when those resources do not exist in the community.

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

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

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

It is important to recognize that there are challenges and important considerations to address before new measure requirements are introduced. Most importantly, the measure should address those factors or circumstances within the control of the individuals or organizations being measured. CMS' measurement strategy should account for these challenges and ensure quality measurement does not negatively impact underserved patients or the clinicians caring for them. We appreciate that implementation of the proposed screening measures is voluntary in CY2023 and look forward to working with CMS outside of the rule-making process on future plans.

The AAFP does not support the introduction of the Screen Positive Rate for Social Drivers of Health as a measure of ACO performance as it does not reflect the quality of care delivered by family physicians or other clinicians. Rather, it reflects a variety of factors or circumstances beyond the control of the physician, such as the lack of resources in the community or patients not wanting assistance from available organizations. A high "screen positive rate" indicates that the clinician cares for a high proportion of patients with unmet social needs and should not be disadvantaged in any

quality or performance-based program. Physicians and other clinicians should not be held accountable for these circumstances, which are beyond their control and doing so could worsen health inequities by discouraging ACOs from working with under-resourced populations. Performance on this measure may be better suited for use in risk-adjustment methodologies or to help CMS understand which ACOs are caring for underserved patient populations. We would support use of this measure for these purposes, including as a pay for reporting requirement. We again note that this measure should not be used to measure an ACO's performance.

Addition of New CAHPS for MIPS Survey Questions RFI

CMS believes certain provisions of the No Surprises Act are relevant to the questions in the CAHPS for MIPS survey. The interim final rule Requirements Related to Surprise Billing, Part 1, encourages regulated entities to address barriers to access of care, including trust concerns with the health care system, and to communicate with individuals in a language they can understand, in a respectful way that addresses cultural differences, and at an appropriate level of literacy. CMS also believes the question aligns with the goals of the quality performance standard to assess the quality of care furnished by ACOs. As such, CMS seeks input the following question that would be added to the CAHPS for MIPS survey:

"In the last six months, did anyone from a clinic, emergency room, or doctor's office where you
got care treat you in an unfair or insensitive way because of any of the following things about
you?"

The potential responses include health condition, disability, age, culture, sex (including sexual orientation and gender identity), and income. CMS seeks comment on additional or modified potential response categories.

CMS feels the question would allow them to better understand the extent to which patients perceive discrimination in their health care, align with the five priorities outlined in the CMS Framework for Health Equity 2022-2032, and provide insight to providers on how to improve patient interactions.

The measure is already being tested in the Medicare Advantage program. Based on the findings from its use in MA, CMS may consider including the question in the CAHPS for MIPS survey through future rulemaking.

CMS is also considering adding a question related to price transparency, such as whether the patient talked with anyone on their health care team about the cost of health care services and equipment.

CMS seeks comment on the potential addition of the health disparities and price transparency questions. CMS also seeks comment on shortening the survey to remove survey items that are only relevant to primary care providers or creating an alternate shortened version of the survey for specialty groups.

AAFP Comments:

The AAFP appreciates CMS' efforts to measure and improve patient experience, including perceived discrimination. However, we are concerned that the proposed CAHPS question includes treatment by clinicians who may not be in the ACO. Therefore, patients' experiences with non-ACO clinicians could impact the ACO's performance.

Administrator Brooks-LaSure August 31, 2022 Page 58 of 97

The AAFP has long supported CMS' price transparency efforts across programs and would support the addition of this question.

Financial Methodology

Incorporating a Prospective, External Factor in Growth Rates Used to Update the Historical Benchmark

CMS proposes to incorporate a prospectively projective administrative growth factor (referred to as the Accountable Care Prospective Trend [ACPT]) into a three-way blend with national and regional growth rates to update an ACO's historical benchmark for each performance year in the ACO's agreement period. Since the ACPT is set at the beginning of an agreement period, any savings generated by the ACO would not be reflected in the ACPT. CMS would not revise the methodology used to trend forward per capita expenditures from benchmark years one and two to benchmark year three. CMS would calculate the three-way blend as the weighted average of the ACPT and the existing national-regional blend ("two-way blend") to update the ACO's historical benchmark between benchmark year (BY) 3 and the performance year.

CMS would calculate the ACPT component of the update using an annualized growth rate based on five-year projections in per capita spending as of the start of an ACO's agreement period. It would be projected by the Office of the Chief Actuary (OACT), with a modification of the existing FFS United States Per Capita Cost (USPCC) growth trends projections used for establishing Medicare Advantage MA rates. CMS proposes using the end-stage renal disease (ESRD) ACPT in calculating update factors for the ESRD population and the combined Aged/Disabled ACPT in calculating update factors for the remaining three enrollment types.

CMS proposes to calculate flat dollar amounts for each enrollment type by applying the relevant projected growth rate to truncated national per capita FFS expenditures for assignable beneficiaries for BY3 for the given enrollment type. CMS would risk-adjust the flat dollar amounts.

CMS proposes to include a guardrail to ensure the three-way blend does not result in benchmarks lower than the current two-way blend that would negatively impact an ACO. If an ACO generates losses that meet or exceed the minimum loss rate (MLR) or negative maximum savings rate (MSR) under the three-way blend, CMS would recalculate the updated benchmark using the two-way blend. If the ACO generates a smaller amount of losses using the two-way blend, CMS would use the smaller amount to determine the ACO's responsibility for shared losses and determining the ACO's financial performance for monitoring purposes. If an ACO generates savings using the two-way blend but does not generate savings using the three-way blend, the ACO would not be responsible for shared losses or eligible for shared savings, even if the ACO exceeded the MSR.

CMS would not adjust the ACPT for external factors such as geographic price changes, efficiency discounts, or other retrospective updates occurring during the agreement period unless there are significant deviations from projections (e.g., economic recession, pandemic). If CMS determines that expenditure growth has differed significantly from projections, they may reduce the weight placed on the ACPT.

AAFP Comments:

Administrator Brooks-LaSure August 31, 2022 Page 59 of 97

The AAFP appreciates CMS' efforts to address concerns with financial benchmarking methodology. The downward ratchet effect of benchmarks based on historical spending combined with the long-term impacts of rebasing and the goal of having all Medicare fee-for-service beneficiaries in an accountable care arrangement by 2030 make current benchmarking strategies untenable. We believe the proposal to recognize the broader impact of ACOs on Medicare spending via the ACPT is a positive short-term step to ameliorating some of these issues while CMS works to refine its administrative benchmarking strategy.

We support including a guardrail that protects ACOs if the three-way blend negatively impacts an ACO. However, we feel protection from losses is not the only way the three-way blend could have a negative impact on an ACO. As proposed, an ACO would not be eligible for shared savings if it generates savings under the two-way blend but does not generate savings under the three-way blend. ACOs use shared savings to reinvest and sustain important initiatives in the ACO. An ACO that is ineligible for shared savings that it would have otherwise received under the two-way blend may be hesitant to invest in new initiatives or expand existing initiatives. We urge CMS to consider calculating shared savings for both the two- and three-way blend and pay out shared savings from whichever is greater.

Adjusting ACO Benchmarks to Account for Prior Savings

Beginning with agreement periods on January 1, 2024, CMS is proposing to incorporate an adjustment for prior savings that would apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs that were reconciled for one or more of the three performance years immediately preceding the start of their agreement period.

CMS proposes to calculate the simple average of per capita savings or losses generated by the ACO during the three performance years that immediately precede the start of the ACO's current agreement period. They would use all savings generated during the prior three performance years, not just savings that met or exceeded the MSR. If the ACO is not eligible to receive the prior savings adjustment, it would receive the regional adjustment to its benchmark.

CMS would apply a proration factor to the adjustment to account for situations where an ACO's assigned beneficiary population is larger in the benchmark years for the current performance year than the ACO's beneficiary population was when the ACO was reconciled for the three performance years preceding the current agreement period. If an ACO was not reconciled for one or more of the three performance years immediately preceding the start of the current agreement, the ACO would receive zero savings or losses in the calculation of average per capita prior savings for the relevant year(s). CMS would exclude years an ACO was not reconciled when calculating the proration factor. CMS would calculate the final prior savings adjustment separately depending on whether an ACO is higher or lower spending relative to its regional service area.

CMS proposes to reduce the cap on negative regional adjustments from -5 percent of national per capita expenditures for Parts A and B under original Medicare in BY3 for assignable beneficiaries to - 1.5 percent. CMS also proposes to gradually decrease the negative regional adjustment amount as an ACO's proportion of dual-eligible beneficiaries increases or its weighted average prospective hierarchical condition category (HCC) risk score increases. CMS would continue to apply a cap equal to +5 percent of national per capita expenditures for assignable beneficiaries to positive regional adjustments for each enrollment type.

Administrator Brooks-LaSure August 31, 2022 Page 60 of 97

CMS proposes to also apply an offset factor for negative regional adjustments. The offset factor would be applied to the negative regional adjustments after the -1.5 percent cap is applied. CMS has determined there is a bias in the calculations that use county-level expenditures that favors ACOs under prospective assignment. To correct this, CMS proposes to calculate risk-adjusted regional expenditures using county-level values computed using an assignment window that is consistent with an ACO's assignment methodology selection for the performance year.

CMS is proposing to modify the existing three percent cap on risk score growth. Under the proposal, an ACO's aggregate prospective HCC risk score would be subject to a cap equal to the ACO's aggregate growth in demographic risk scores between benchmark year three and the performance year, plus three percentage points. The three percent cap would apply in aggregate across the four enrollment types. CMS would calculate an aggregate value for the cap. CMS would only apply the cap for a particular enrollment type if the aggregate growth in prospective HCC scores exceeds the value of the cap.

AAFP Comments:

The AAFP Guiding Principles for Value-Based Payment call for financial benchmarks to incentivize high-quality, efficient, accountable care delivery by establishing targets that reward both improvement and sustained performance over time. We recognizes the need to account for the prior efforts of ACOs – and all APM participants – to generate savings when negotiating new model agreements. The failure to recognize and account for these efforts is one of the primary barriers to the long-term sustainability of participation in MSSP and other CMS payment models. We appreciate that CMS is addressing this issue by proposing an upward adjustment to benchmarks for renewing and reentering ACOs that will account for prior savings. While generally supportive of its goals, we believe the current proposal would have minimal impact. The intent of this policy is to boost incentives for high-performing ACOs – especially in low-cost regions – to remain in MSSP by reducing the ratchet effect. Yet, the proposal to apply the higher of either: (1) the positive regional adjustment, or (2) a prior savings adjustment equal to the lesser of 50 percent of an ACOs prior savings capped at five percent of national FFS spending for assignable beneficiaries means that the majority of low-cost ACOs would not experience a meaningful benefit from this policy change. We recommend that CMS recognize the efforts of these ACOs by applying the actual average shared savings rate over the previous three years as the upward adjustment factor for new agreement periods.

The AAFP supports CMS' proposal to reduce the cap on negative adjustments from 5 percent to 1.5 percent of national per capita Part A & B spending and further decrease negative adjustments as the proportion of dually eligible beneficiaries or average prospective HCC risk score increases. This policy aligns with the broader goal of increasing ACO participation rates by creating an incentive for ACOs that are high-cost relative to their regions to join MSSP and maintain participation.

The AAFP appreciates the attention CMS is paying to improving the MSSP risk adjustment methodology. The current three percent flat cap approach to risk adjustment places ACOs serving disabled and dual-eligible Medicare beneficiaries at a disadvantage as these populations are much more likely to hit the risk score cap compared to the aged non-dual population. The CMS proposal to modify the current three percent HCC risk score cap to account for demographic changes before applying the three percent cap is a positive step. However, there are additional changes CMS should make to advance the stated goal of supporting ACOs with small panel sizes or high proportions of dually eligible/ESRD/complex patients.

For example, primary care physicians and their care teams with accountability for cost and quality have a clear incentive to identify, treat, and attempt to prevent chronic conditions to both improve quality and control costs. The current risk adjustment cap is a meaningful disincentive for treating underserved communities that CMS should address if it is to be successful in meeting the goal of increasing ACO coverage in these areas. By definition, patients in underserved communities have not had appropriate access to high quality care. It is reasonable to expect that as ACO coverage increases in traditionally underserved communities, physicians in the ACO will identify and document a wide range of previously underreported health needs. A static cap on risk score growth penalizes both inappropriately intensive coding as well as appropriate – even desirable – efforts to accurately document the burden of disease in a community. If CMS intends to retain a static cap on risk score growth, we recommend that the cap amount be increased to reduce the negative impact on physicians appropriately identifying and documenting patient needs, particularly for underserved communities.

Increased Opportunities for Low Revenue ACOs to Share in Savings

CMS proposes to allow ACOs participating in the BASIC track that do not meet the MSR requirement, but meet the quality performance standard or the proposed alternative quality performance standard would qualify for a shared savings payment if the following are met:

- The ACO has average per capita Medicare Parts A and B fee-for-service expenditures below the updated benchmark.
- The ACO is low revenue at the time of financial benchmark for the relevant performance year.
- The ACO has at least 5,000 assigned beneficiaries at the time of financial reconciliation for the relevant performance year.

ACOs that meet the quality performance standard and qualify for the maximum sharing rate would receive half of the maximum sharing rate for their level of participation. ACOs that do not meet the quality performance standard required to share in savings at the maximum rate would receive a sharing rate based on a sliding scale approach.

AAFP Comments:

The AAFP supports CMS' proposal to allow ACOs that do not meet the MSR to earn shared savings if they meet the quality performance standard. ACOs that serve vulnerable populations may have difficulty generating savings in their first few years in the program. It is important to recognize that increased engagement and uptake of preventive services may increase short-term spending, and it is not equitable or accurate to restrict shared savings to ACOs that are improving utilization of preventive and care management services. Expecting ACOs to reduce the total cost of care while also improving uptake of recommended preventive services undermines the importance and value of these services and is contrary to the goals of CMS and the SSP. ACOs can reinvest the savings into initiatives that help practices meet the needs and improve the health of their patients.

Reducing Undue Admin Burden

Administrator Brooks-LaSure August 31, 2022 Page 62 of 97

CMS proposes to remove the requirement that ACOs must submit marketing materials and activities to CMS before use. CMS would maintain the requirement that ACOs must provide marketing materials upon request. The proposal does not affect an ACO's obligation to comply with marketing requirements. CMS proposes modifications to clarify that ACOs must post signs in all its facilities and make standardized written notices available in all settings in which beneficiaries receive primary care services.

CMS proposes to reduce the frequency with which an ACO or ACO participant must provide standardized written notifications to beneficiaries from five times per agreement period to once per agreement period. CMS proposes to add a new follow-up beneficiary communication that must occur no later than the earlier of the beneficiary's next primary care service or 180 days from the date of the first standardized notice. The follow up may be verbal or written. ACOs must track and document how the follow up beneficiary notification is implemented. The follow up communication must not be the same standardized initial notice. It must provide the beneficiary an opportunity to ask any outstanding questions they may have.

CMS proposes to remove the requirement for ACOs to submit three narratives of how the ACO plans to implement the Skilled Nursing Facility (SNF) 3-day Waiver. ACOs would be required to certify that they have a communication plan, care management plan, and beneficiary evaluation and admission plan.

Beginning in 2023, CMS proposes that ACOs operating as organized health care arrangements (OHCAs) may request aggregate reports and beneficiary-identifiable claims data from CMS.

AAFP Comments:

The AAFP appreciates CMS' efforts to reduce administrative requirements for ACOs. Reporting, patient notification, and other administrative requirements cost ACOs staff time and financial resources. Minimizing these requirements enables ACOs to redirect those resources toward patient care initiatives and also reduces disincentives to participation in an ACO.

<u>Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment (section III.J.)</u>

Expansion of Authority to Deny or Revoke Based on OIG Exclusion and Associated Definitions

CMS proposes to expand the categories of parties listed within the denial and revocation provisions for OIG exclusions to include: (1) managing organizations; and (2) officers and directors of the provider or supplier if the provider or supplier is a corporation. CMS proposes the following definitions in this regard:

- "Managing organization:" an entity that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operations of the provider or supplier, either under contract or through some other arrangement.
- "Officer:" an officer of a corporation, regardless of whether the provider or supplier is a nonprofit entity

"Director:" a director of a corporation, regardless of whether the provider or supplier is a non-profit entity, including any member of the corporation's governing body irrespective of the precise title of either the board or the member (e.g., board of directors, board of trustees, or similar body)

CMS also proposes to add a new paragraph to its related regulations to clarify that the persons and entities listed in these provisions include, but are not limited to, W-2 employees and contracted parties of the provider or supplier.

AAFP Comments:

In general, the AAFP supports CMS' proposals in this regard. As described in the proposed rule, they appear consistent with the statute and existing regulations.

Expansion of Authority to Deny or Revoke Based on a Felony Conviction

Under current regulations, CMS may deny or revoke enrollment if the provider or supplier, or any owner or managing employee of the provider or supplier was, within the preceding 10 years, convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries. CMS proposes to expand these regulatory provisions to include therein managing organizations, officers, and directors (as CMS proposes to define those terms above).

AAFP Comments:

As with the proposals above, the AAFP supports CMS' proposals in this regard.

Reversal of Revocation or Denial

Current regulations state that if a revocation or denial, respectively, was due to a prior adverse action (such as a sanction, exclusion, or felony) against a provider's or supplier's owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, the revocation or denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 30 days of the revocation or denial notification. To maintain consistency with the changes proposed above, CMS proposes to add managing organizations, officers, and directors to these regulations.

AAFP Comments:

The AAFP supports this proposal for the sake of consistency.

Medicare Revocation Based on Other Program Termination

Current regulations state, in part, that CMS can revoke enrollment if the provider or supplier is terminated, revoked, or otherwise barred from participation in a State Medicaid program or any Federal health care program, but revocation cannot occur unless and until the provider or supplier has exhausted all applicable appeal rights. To clarify the intent of this language in situations where the provider or supplier does not appeal the program termination at all, CMS proposes to add the

Administrator Brooks-LaSure August 31, 2022 Page 64 of 97

language "or the timeframe for filing an appeal has expired without the provider or supplier filing an appeal" to the end of the regulations in question.

AAFP Comments:

The AAFP supports the proposed addition.

Categorical Risk Designation – Ownership Changes and Adverse Actions

Federal regulations at 424.518 outline levels of screening by which CMS and its MACs review initial applications, revalidation applications, and applications to add a practice location. CMS proposes to add the following transactions to the list of those requiring screening:

- Change of ownership applications
- The reporting of any new owner (regardless of ownership percentage) via a change of information or other enrollment transaction (such as a full or partial certified supplier ownership change)

Additionally, CMS proposes to add a new paragraph to its regulations that would state that any adjustment in the screening level for an entity would also apply to all other enrolled and prospective providers and suppliers that have the same legal business name (LBN) and tax identification (TIN) number as the provider or supplier for which the risk level under was originally raised. This means, for example, that a physician group at the limited-risk level of categorical screening could be bumped up to the high-risk level if any other entity with the same LBN and TIN (e.g., another physician group) was bumped up.

AAFP Comments:

The AAFP supports the proposed additional transactions for the reasons outlined in the proposed rule. We are concerned about the proposal to apply an increased level of screening to all entities sharing the same LBN and TIN when the screening level is increased for any one of them. Given many family medicine practices are affiliated with health systems and other medical groups, it seems likely this proposal could unnecessarily result in increased screening for many practitioners and possibly delay care for beneficiaries. Should CMS move forward with this proposal, we recommend communicating this change well in advance of implementing it, as well as monitoring to ensure this does not negatively impact beneficiaries or significantly increase administrative burden for clinicians who have not broken any rules. To ensure it is communicated and understood before enforcement, we recommend CMS delay its application until at least July 1, 2023.

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

In the CY 2022 MPFS final rule, CMS established a flat payment amount of \$30 for Part B vaccine administration. In this rule, CMS proposes to implement annual adjustments to this flat payment amount to ensure payments account for changes in the cost of administering vaccines. CMS proposes to annually update payment amounts for Part B vaccine administration based upon the MEI and to adjust for geography. CMS proposes to apply these adjustments to payments for COVID-19 vaccine administration. CMS also proposes to continue the additional payment for at-home COVID-19 vaccination in CY 2023. CMS proposes to clarify that coverage and payment policies for COVID-19

Administrator Brooks-LaSure August 31, 2022 Page 65 of 97

vaccines and monoclonal antibodies will remain the same (that is, the policies implemented during the PHE will continue) until the HHS emergency use authorization (EUA) declaration ends, instead of when the federal COVID-19 PHE ends.

AAFP Comments:

The AAFP supports the proposals to adjust Part B vaccine administration payment rates by geography and based on the MEI. The AAFP strongly supported CMS' policy finalized in the CY 2022 MPFS. These proposals build on the flat payment rate to ensure payments keep pace with changing practice costs, which are currently placing significant strain on family medicine practices. In fact, the AAFP is advocating for Congress to enact annual positive updates for all services under the MPFS based on the MEI. A recent study reviewed 2017 Medicare Part B FFS data and the Medical Expenditure Survey. ⁵⁷ The authors found that primary care physicians provided the largest share of services for vaccinations. It is vital that Medicare payment policies support primary care physicians' ability to offer recommended immunizations in their practices, as they continue to be the primary setting beneficiaries get their vaccines. 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 supports CMS' proposal to continue the additional payment for at-home COVID-19 vaccination. 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.

The AAFP appreciates CMS' ongoing work to ensure access to and proper payment for COVID-19 vaccines and monoclonal antibodies. We support CMS' proposal to continue current coverage and payment policies until the EUA declaration ends, instead of when the PHE ends. New treatments and vaccines may continue to be authorized, recommended, and available to the public very quickly as long as the EUA declaration is in place. The emergency policies provide physicians and other Part B providers with needed support and flexibility to ensure ongoing, easy access to new COVID-19 vaccines, boosters, and treatments. We urge CMS to finalize this proposal.

Finally, the AAFP is concerned that CMS plans to automatically revert payment rates for COVID-19 vaccine administration to equal payment for other Part B preventive vaccines once the EUA declaration ends. As we noted in a <u>recent letter</u> to Secretary Becerra, the AAFP is concerned that transitioning COVID-19 vaccine purchasing, distribution, coverage, and payment away from emergency policies and processes will result in operational and administrative challenges for primary care practices, which will ultimately cause delays and access challenges for Medicare beneficiaries. Automatically reverting to a lower payment rate for vaccine administration could contribute to these challenges. CMS should work with the AAFP and other stakeholders to determine what unique administration costs and challenges may still be present once the EUA declaration ends, and then ensure that Medicare payment rates account for these costs.

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.L.)

Administrator Brooks-LaSure August 31, 2022 Page 66 of 97

Prescription drug event (PDE) data is provided to CMS by drug plan sponsors every time a beneficiary fills a prescription under Medicare Part D; this data is used to evaluate prescriber compliance with Electronic Prescribing for Controlled Substances (EPCS) requirements. Enforcement of EPCS compliance begins in CY 2023; CMS planned to use PDE data from the preceding year to evaluate EPCS compliance for the current year. CMS instead proposes to use current year data as soon as it is available to evaluate EPCS compliance.

AAFP Comments:

The AAFP supports EPCS and national-level guidelines to <u>avert a patchwork</u> of policies that ultimately result in greater physician administrivia and delayed access to necessary prescriptions. Additionally, the AAFP supports clear guidance from CMS to ensure family physicians are compliant with regulations aimed at reducing drug diversion. To this end, the AAFP supports this proposal to use current year data to evaluate EPCS compliance given the anticipated improved accuracy this data will provide. The AAFP supports CMS' overall efforts to prevent diversion of controlled substances but encourages CMS to evaluate other opportunities and agency engagement to limit diversion by using other levers instead of implementing additional requirements for prescribers. We are also 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. We encourage CMS to continue advancing these priorities as part of the agency's efforts to reduce administrative burden and minimize diversion.

Small Prescribers

Regarding EPCS, CMS has historically included certain exceptions for "small prescribers" or those issuing less than 100 controlled substance prescriptions per year. CMS notes that "neither CMS nor an individual prescriber will be able to determine until after the evaluation year whether or not the individual prescriber qualifies as a "small prescriber" ...unless the prescriber tracks the number of Medicare Part D controlled substance prescriptions the prescriber issues during the evaluation year." CMS seeks comment on the possibility that prescribers would avoid prescribing controlled substances to Medicare beneficiaries, particularly where they are approaching the 100 Part D controlled substances prescriptions threshold late in a calendar year, to remain a small prescriber.

AAFP Comments:

The AAFP understands the delay in small prescriber status is a necessary adjustment to better account for prescribing levels using current year data. The AAFP requests CMS provide clarification that prescribers are not *required* to track the number of Medicare Part D controlled substance prescriptions to qualify as a small prescriber, and that non-compliance letters will not be issued before CMS determines a prescriber's small prescriber status. Additionally, the AAFP does not believe family physicians would avoid prescribing controlled substances in order to retain small prescriber status. Family physicians provide the care that their patients need regardless of associated administrative complexities. However, it is likely that smaller prescribers could assume they are covered by exceptions when approaching or exceeding the 100-prescription mark. CMS should notify "small prescribers" that they are approaching the 100-prescription threshold and CMS should include specific instructions on compliance when or if they no longer meet the "small prescriber" expectation,

Administrator Brooks-LaSure August 31, 2022 Page 67 of 97

along with appropriate time to comply. We also believe that if a prescriber was a "small prescriber" the prior year, they should not be penalized the current year but rather offered a warning.

Address Database

CMS also proposes to determine whether a prescriber qualifies for the emergency or disaster exception based on the prescriber's valid address in PECOS (Medicare Provider Enrollment, Chain, and Ownership System), instead of the NCPDP Pharmacy Database address, and for prescribers who are not enrolled or do not have a valid PECOS address, CMS proposes to use the address in the National Plan and Provider Enumeration System (NPPES) data.

AAFP Comments:

The AAFP supports this proposal as PECOS is already used to determine if a MIPS eligible clinician is located in an area that has been affected by extreme and uncontrollable circumstances. This proposal will streamline eligibility for exceptions when a physician is located in an area effected by an emergency or disaster, resulting in administrative simplification which the AAFP strongly supports. The AAFP agrees with CMS' reasoning that PECOS is a more accurate database for physician practices and service areas when compared to the current pharmacy database.

CMS Proposal:

Starting in CY 2025, CMS plans to begin increasing the severity of penalties for noncompliant prescribers, from issuance of non-compliance letters to other penalties, and is seeking comments on potential non-compliance penalties.

AAFP Comments:

While the AAFP <u>supports</u> the use of electronic prescribing to promote quality patient care, the AAFP recognizes that there are several circumstances outside the physician's control that may <u>inhibit the</u> <u>use</u> 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 recommends CMS begin with warning letters and corrective action plans before moving to penalization for noncompliant prescribers. Physicians should be notified of noncompliance with both the reason for noncompliance and the opportunity to come into compliance before being penalized. 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. 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.

Updates to the Quality Payment Program (section IV.)

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

Administrator Brooks-LaSure August 31, 2022 Page 68 of 97

CMS is continuing to define how to leverage existing policy to transform all CMS quality measurement to digital reporting. In the 2022 Final Rule, CMS outlined actions in four areas to transition to quality measures:

- 1. Leverage and advance standards for digital data and obtain all electronic health record data required for quality measures via provider FHIR-based application programming interfaces,
- 2. Redesign quality measures to be self-contained tools,
- 3. Better support data aggregation,
- 4. Work to align measure requirements across reporting programs, other Federal programs and agencies, and the private sector where appropriate.

Additional information is available in CMS' Digital Quality Measurement Strategic Roadmap. The RFI included in this rule focuses on data standardization activities related to leveraging and advancing standards for digital data and approaches to transition to FHIR eCQM reporting in the future as initial steps in the transition to digital quality measurement.

CMS plans to incrementally transition to digital quality measurement, beginning with the adoption of FHIR API technology and shifting to eCQM reporting FHIR standards as discussed elsewhere in this rule.

CMS received feedback on their previous RFI that the term "software" is confusing. CMS is refining the definition of dQM such that a dQM is a quality measure, organized as self-contained measure specification and code package, that uses one or more sources of health information that is captured and can be transmitted electronically via interoperable systems. Potential data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, laboratory systems, PDMPs, instruments (e.g., medical devices and wearable devices), patient portals or applications, or registries. CMS is currently considering how eCQMs, which use only EHR data, can be refined or repackaged to fit within the potential definition of a dQM. CMS seeks comment on a refined definition of dQM. CMS also seeks feedback on potential considerations or challenges related to non-EHR data sources.

CMS intends to use standardized data for quality measurement as one use case of digital data in a learning health system.

CMS aims to align with the standardized data requirements consistent with the 21st Century Cures Act final rule and any potential future updates made in rulemaking.

CMS is considering how best to leverage existing implementation guides that are routinely updated and maintained by HL7 to define data standards and exchange mechanisms for FHIR-based dQMs, in a fashion that supports the learning health system and alignment across use cases.

CMS is considering how best to leverage the ONC interoperability certification criteria related to implementing FHIR API technology to access and electronically transmit interoperable data for quality measurement. CMS seeks comment on additional approaches to optimize data flows for quality measurement to retrieve data from EHRs via FHIR, and to combine data needed for measure score calculation for measures that require aggregating data across multiple providers. CMS is interested in data flows that support using the same data for measurement and to provide feedback to providers at multiple levels of accountability.

Administrator Brooks-LaSure August 31, 2022 Page 69 of 97

AAFP Comments:

The AAFP supports CMS' goal of transitioning to full digital quality measurement by 2025 and agrees that standardization and interoperability enabled by APIs are essential to this transition. Performance measure data should be informed by all relevant data sources. Not doing so leads to less accurate and reliable data that misinforms performance measurement in ways that wrongly inflict financial penalties on participating physicians based on under- or non-reporting. This is a very real problem that can impact any practice and disproportionately impacts small practices. The AAFP also agrees that performance measurement should not rely on physicians and their teams to self-report data. Moving to dQMs that extract data from multiple sources will reduce administrative burden and help resolve comparability problems with performance data submitted through various mechanisms. Until such time that CMS can complete this transition and ensure that performance assessments are based on complete and timely data that truly reflect the quality of care and not the quality of data, the AAFP recommends that CMS permit and use supplemental data submitted by practices (in addition to claims data) when tabulating completion rates for all quality metrics required in value-based payment arrangements, including the QPP.

The AAFP agrees with CMS' refined definition of dQM and encourages CMS to ensure the relationship between dQMs and eCQMs is clear. We urge CMS to engage with practicing physicians to continue refining the definition so that it is meaningful to those impacted by it.

We urge CMS to ensure that physician practices do not bear the brunt of the costs when transitioning to dQMs. Health IT updates are extremely costly, particularly for smaller practices and those that care for a high proportion of underserved patients. CMS should not impose new or unnecessary costs on these practices as a requirement for demonstrating successful performance in quality programs. Instead, we urge CMS to work with ONC to ensure standardization and other regulatory mechanisms are used to hold health IT vendors accountable for making the necessary updates without inflicting new and burdensome cost on physician practices.

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

The AAFP has been and continues to be a strong champion for near real-time feedback that supports physicians' ability to deliver the best care to their patients. Improving quality at the point of care is the desired goal while the ability to learn from the past is also an important consideration. To accomplish both important goals, feedback is most beneficial when delivered in a push and pull environment that allows for maximum flexibility. Practices should receive important alerts regarding transitions in care while also having the ability to query the data and drill down into the data to continually identify and address care gaps and/or opportunities for improvement as needed.

Administrator Brooks-LaSure August 31, 2022 Page 70 of 97

We would like to see additional functionalities in quality measure tools, including flexible queries, push and pull real-time feedback, graphing abilities (e.g., run charts) to support QI, ability to drill down to the patient level to identify quality gaps, and aggregating data at multiple levels (geographic) for public health and research. Physician practices should be able to use the same calculation and data sources as payers and thus calculate real-time scores and identify gaps with identical results as payers. This would improve practices' ability to address performance concerns in real time instead of being surprised at the end of the performance year. To the extent cost is a measure of performance, primary care physicians should have access to the cost of all referral care to ensure their ability to proactively identify and manage the most effective and efficient referral strategies, as well as to validate performance assessments.

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

Enhancing the Trusted Exchange Framework and Common Agreement (TEFCA) Request for information

CMS believes the exchange of information enabled by TEFCA can advance their policy and program objectives related to care coordination, cost efficiency, and patient-centeredness in a variety of ways. In addition to the proposed "Enabling Exchange Under TEFCA" measure that CMS is proposing for the promoting interoperability category, CMS is considering other ways available CMS policy and levers can advance information exchange under TEFCA. CMS is interested in ways to encourage exchange under TEFCA through CMS regulations for certain health care payers, including Medicare Advantage, Medicaid Managed Care, and CHIP issuers. They are also considering opportunities to encourage information exchange under TEFCA for payment and operations activities such as submission of clinical documentation to support claims adjudication and prior authorization processes.

AAFP Comments:

TEFCA is a potentially important step in moving toward a national interoperable clinical data network. If done right, it can help to fill existing information gaps and address the increased burdens placed on family physicians and others in the health care system working to deliver continuous, comprehensive, person-centered care in a more integrated fashion. This kind of care requires an efficient and timely exchange of patient information in a standardized and secure manner across multiple organizations.

The AAFP is aligned with and supports the goals of TEFCA. We are encouraged by CMS' interest and next steps to improve information exchange across patients' care teams and payers and are eager to engage in efforts to ensure its implementation is done in a manner that meaningfully improves care and health outcomes for patients. It is essential that costly and unnecessary administrative burdens on physicians and their care teams are minimized. Reducing and eliminating burdens on physicians will be the best approach to driving physician excitement and adoption of TEFCA exchange.

Success will require multiple organizations, such as health information exchanges, regional health information organizations, electronic health record companies, and other HIT vendors, to actively engage in this new voluntary framework for national exchange. Putting patients at the center of this endeavor is essential for its success. CMS should work with its counterparts at ONC and other agencies to ensure that the incentives for all key stakeholders are appropriately aligned around the needs of patients and those who care for them to ensure a disproportionate burden is not placed on primary care physicians who provide the majority of health care services and that the implementation of TEFCA leads to more seamless, coordinated, and improved care for patients.

MIPS Value Pathways (MVPs)

MVPs and APM Participant Reporting Request for Information

MVPs and APMs share the goals of meaningful performance measurement and burden reduction, while also scoring equity and advancing value. CMS acknowledges the current APP measure set does not fully represent the services and types of patients treated by all clinician types in a group. CMS seeks information on how they could obtain more robust reporting of both primary care and specialty care performance measurement information from APM participants. CMS envisions MVP reporting to complement APP reporting and enhance performance measurement and available information while minimizing additional burden. CMS is seeking feedback on:

- Using MVPs to obtain more meaningful performance data from both primary care and specialty clinicians and drive improvements for APP reporters and APM participants
- Aligning clinician experience with MVPs and APMs, and ensure that MVP reporting serves as a bridge to APM participation
- Limiting burden and developing scoring policies for APM participants in multispecialty groups who choose to participate in MVPs and report specialty care performance data

AAFP Comments:

In the CY 2022 MPFS, CMS finalized regulations to begin implementing MVPs, a new MIPS reporting pathway, beginning on January 1, 2023. CMS developed and proposed MVPs with the goal of providing physicians and other clinicians with a more meaningful, less burdensome MIPS reporting option. The AAFP has been supportive of this goal and the development of MVPs while also raising concerns about whether MVPs will meaningfully improve participation for family physicians and better facilitate the transition to APMs.

Family physicians continue to report significant frustration with MIPS participation. Reporting to MIPS is both costly and administratively burdensome for family medicine practices, which are already struggling to remain viable amid increasingly insufficient Medicare payment rates and a constant barrage of administrative tasks from CMS and other payers. QPP participation data shows that MIPS has failed to help physicians transition into APMs. As currently finalized, we are concerned that MVPs will not meaningfully address these ongoing issues.

As a first step to addressing these concerns, we've <u>recommended</u> that CMS eliminate siloed, category-based scoring in MVPs and adopt a multi-category scoring approach. Requiring separate attestation and reporting across the four categories is unnecessarily burdensome and does not reflect

Administrator Brooks-LaSure August 31, 2022 Page 72 of 97

how family physicians regularly improve quality and patient outcomes. Improvement activities are inherently linked to quality improvement and cost containment goals. Practices already use certified EHR technology to coordinate care, track patient progress, and share health information with patients because doing so improves patient experience and health outcomes.

The AAFP has also consistently opposed the use of the Total Per Capita Cost (TPCC) measure. This and other cost-based measures such as the Medicare Spending Performance Benchmark (MSPB) 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 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 is occurring within a fee-for-service based system that does not provide the stability and flexibility offered by prospective payments. 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.

The AAFP is hopeful that MVPs and subgroup reporting will encourage the development of measures for specialty care and promote more robust performance measurement of physicians in other specialties. We've previously expressed concern that physicians in multi-specialty practices currently lean on the successful performance of primary care physicians, due to the plethora of primary carefocused measures. Physicians and clinicians in other specialties should also be held accountable for the quality and cost of care they provide. Ultimately, this will help accelerate the transition to value-based care. The AAFP urges CMS to continue to encourage subgroup reporting and the integration of specialty care measures into value-based care programs.

Moving away from siloed category scoring and problematic cost and promoting interoperability measures has the potential to make MVP reporting more like participating in an APM. We urge CMS to ameliorate these problems with MVPs to encourage participation and help ensure successful implementation.

Finally, following the sunset of the Comprehensive Primary Care Plus (CPC+) and introduction of the Primary Care First (PCF) model, the AAFP notes that many primary care physicians outside of the 26 regions and/or lacking the advanced capabilities required for PCF, lack appropriate APM participation options should they wish to transition out of MIPS. The dearth of model options in most areas of the country, particularly APMs that are appropriate for small and independent practices without experience participating in a value-based care model, mean that many practices are effectively stuck in MIPS. Primary care physicians need a range of model options that span the value spectrum and are aligned across payers, including models that provide an on-ramp to participation and practice transformation. While we appreciate and are supportive of the steps CMS has taken in this rule to help family physicians move into ACOs, non-ACO models are the preferred option for many practices that are ready to move out of fee-for-service. In addition to improving MIPS reporting options, providing practices with stable, risk-adjusted model participation opportunities is essential to realizing CMS' goal for 100 percent of people with Original Medicare to be in a care relationship with

Administrator Brooks-LaSure August 31, 2022 Page 73 of 97

accountability for quality and total cost of care by 2030. With these concerns and recommendations in mind, we offer comments on CMS' MVP related proposals below.

MVP Maintenance Process and Engagement with Interested Parties

CMS proposes to modify the MVP development process. MVPs that CMS determines are "ready" for feedback would be posted on the QPP website and available for feedback for a 30-day period. CMS would review the feedback and determine if any changes should be made to the candidate MVP. CMS would not notify the MVP submitters in advance of the rulemaking process.

CMS also proposes to modify the MVP maintenance process and allow the general public to submit their recommendations for potential revisions to established MVPs on a rolling basis throughout the year. If CMS identified potentially feasible and appropriate recommendations, they would hold a public webinar to allow the general public to offer feedback on the potential revisions. Any revisions to an established MVP would be made through notice and comment rulemaking.

AAFP Comments:

The AAFP supports these proposals and encourages CMS to ensure there is adequate communication so that stakeholders know when an MVP has been posted for feedback. We appreciate that CMS will make potential revisions through notice and comment rulemaking.

However, the AAFP remains concerned that early MVP development happens in a black box and may not include input from all relevant specialty societies. We urge CMS to establish a process for conducting robust outreach to impacted specialty societies at the beginning of MVP development to ensure the relevant clinician groups can have a meaningful and productive dialogue with CMS throughout the entirety of the MVP development process.

Definitions of a Single Specialty Group and a Multispecialty Group

CMS proposes to modify the definition of a single specialty group to mean a group that consists of one specialty type as determined by CMS using Medicare Part B claims. A multispecialty group is a group that consists of two or more specialty types as determined by CMS using Medicare Part B claims. CMS seeks comment on these proposals and requests comment on additional data sources CMS could use to determine a group's specialty type or types.

AAFP Comments:

The AAFP is concerned that using Part B claims to determine specialty groups may create additional burden and frustration for clinicians. For example, many family physicians practice in multiple settings and provide a broad scope of services to Medicare beneficiaries. Some family physicians have particular expertise in providing certain types of care, such as urgent care/emergency services, HIV care, or geriatrics. Medicare claims data may not accurately identify what type of group they are in. We recommend allowing subgroups to attest to their specialty as part of the registration process.

Subgroup Description Requirement

CMS is not proposing any requirements or restrictions on the composition of subgroups but may do so in the future. To inform future policies, CMS proposes that TINs must provide a description of each subgroup that is registered.

AAFP Comments:

The AAFP is pleased that CMS is not proposing any requirements or restrictions on the composition of subgroups. We encourage CMS to fully understand the implications of such a policy should they choose to develop one in the future. We appreciate CMS' intent to review the subgroup descriptions and believe this will provide useful information to inform future policies. Unless CMS finds issues with the integrity of subgroup reporting, we do not believe placing restrictions or requirements on subgroup reporting is necessary. The AAFP also strongly cautions CMS to monitor subgroup reporting before requiring multi-specialty groups to split into subgroups.

Limitation of one subgroup per TIN-NPI combination

CMS proposes to limit individual eligible clinicians, represented by a TIN-NPI combination, to one subgroup within a group's TIN. However, CMS believes there may be clinicians who work in multiple capacities within the same clinic that would be limited to one subgroup in the TIN. CMS is interested in hearing how common this is and whether they could match a clinician to a subgroup for measures reported through Part B claims or calculated using administrative claims.

CMS proposes to apply the low-volume threshold criteria for a subgroup using information from the initial 12-month segment of the applicable MIPS determination period.

AAFP Comments:

We again urge CMS to ensure that MVPs are clinically relevant and promote coordinated, teambased care. As we noted previously, many family physicians provide a broad scope of services. In the future, depending on what MVPs are available and relevant to family physicians, there may be situations in which a family physician should be able to participate in multiple subgroups.

Subgroup scores for administrative claims measures and cost measures

CMS proposes to assess subgroups on measures in the cost performance category and population and outcomes-based administrative claims measures based on their affiliated group. For each selected population health measure, the subgroup would be scored based on their affiliated group score. If the subgroup's affiliated group score is not available, then each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points. If a subgroup's affiliated group does not have a score for a selected outcomes-based administrative claims measure, each measure will receive zero measure achievement points. Each subgroup will be scored on each cost measure included in the MVP they select and report based on its affiliated group score for each measure. If a subgroup's affiliated group does not have a score for a cost measure, the measure would be excluded from the subgroup's total measure achievement points and total available measure achievement points.

CMS wants to encourage subgroup reporting and does not intend to penalize subgroups that register but do not submit data. During the voluntary years of subgroup reporting, CMS would not assign a subgroup score in instances where they do not receive any MVP data for clinicians in registered subgroups. CMS expects that clinicians registered in subgroups would participate in MIPS via another reporting option.

AAFP Comments:

Administrator Brooks-LaSure August 31, 2022 Page 75 of 97

The AAFP continues to have concerns about the application of population health measures and believes population health measures are best assessed at the system level. We have repeatedly noted our opposition to the use of the TPCC and MSPB measures, which hold family physicians accountable for costs outside of their control.

We support CMS' proposal to score subgroups based on their affiliated group score for cost and administrative claims measures and support CMS' intent to explore ways to address the technical limitations that would allow them to evaluate performance at the subgroup level. Meaningful measurement and relevant data will help MVPs meet their goal of transitioning physicians to value-based payment arrangements.

Promoting Wellness MVP

AAFP Comments:

The AAFP is pleased to see the Promoting Wellness MVP and is generally supportive of the measures included in the proposal. We appreciate CMS prioritizing the development of MVPs relevant to family physicians and the agency's efforts to collaborate with the AAFP and our partners in other societies during the development process. This proposal and the measures included in it reflect much of the AAFP's feedback.

CMMI's Strategy Refresh included a commitment to include more outcome measures that are meaningful to people, such as patient-reported outcome measures (PROMs). The AAFP agrees that PROMs provide a more appropriate and accurate way to assess the value of primary care. We strongly support the Person-centered Primary Care Measure (PCPCM) and urge CMS to finalize its inclusion in the Promoting Wellness MVP. We believe its sole inclusion as a measure of patient experience would encourage broader adoption of the PCPCM rather than including both the PCPCM and the Consumer Assessment of Healthcare Providers and Systems (CAHPS) measure. Promoting the use of the PCPCM in the MVP is a step toward aligning with the agency's stated goal and provides a consistent and meaningful connection between the Promoting Wellness MVP and value-based payment models.

It is vital that Medicare payment policies support primary care physicians' ability to offer recommended immunizations in their practices. However, we remain concerned that CMS intends to include the adult immunization status composite measure in the future. As we have shared previously, current immunization registries and health data information sharing systems must first be fixed to more effectively aggregate patient information, including immunization records, to evaluate the quality of the care reliably and accurately. This is particularly true for the influenza vaccine which is frequently received by patients in the community at grocery stores, pharmacies, workplaces, etc. Inadequate data aggregation and information sharing increases the burden of reporting, as physicians and their staff must manually track down and enter information for immunizations received outside of their clinic. Despite their best efforts, there will undoubtedly be data gaps that will inappropriately be identified as care deficiencies under this measure. We encourage CMS to explore the use of their regulatory authority to address this long-standing gap in data aggregation and information sharing which results in unnecessary administrative time and burden placed on patients and physician practices. Until these changes are in place, we encourage CMS to prioritize measures

Administrator Brooks-LaSure August 31, 2022 Page 76 of 97

that are supported by more efficient and accurate data sources and do not increase burden to physician practices.

As mentioned previously, the AAFP also opposes the use of the TPCC measure in the Promoting Wellness MVP.

MIPS Performance Category Scoring

Quality Data Submission Criteria

CMS proposes to modify the definition of high priority measure to mean an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, opioid, or health equity-related measure. CMS seeks comment on this proposal.

CMS proposes to revise the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey case-mix adjustment model to remove the existing adjustor for Asian language survey completion and to add adjustors for Spanish language spoken at home, Asian language spoken at home, and other language spoken at home. CMS seeks comment on this proposal.

AAFP Comments:

The AAFP strongly supports this proposal. The AAFP appreciates CMS' commitment to advancing health equity through its programs. The AAFP shares this commitment. Our position paper on Advancing Health Equity: Principles to Address the Social Determinants of Health in Alternative Payment Models outlines how family physicians are uniquely qualified to identify the social needs of their patients and to connect them to community resources through an efficient, centralized process. This is an important step to mitigate health disparities. Still, most payment methodologies and models do not sufficiently account for patients' social risk factors which can disadvantage the physicians caring for the most vulnerable, high-risk patients.

Data Completeness Criteria

Based on their analysis, CMS believes it is appropriate to increase the data completeness threshold. Therefore, CMS proposes to increase the data completeness criteria threshold to 75 percent for the 2024 and 2025 MIPS performance years.

AAFP Comments:

The AAFP shares CMS' interest in having more comprehensive patient data to facilitate efficient and accurate measurement. While CMS and many payers have agreed to implement measures from the Core Sets developed by the Core Measures Quality Collaborative, the data collection and aggregation required to demonstrate performance on these measures continues to place a heavy burden on those delivering the care

We reiterate our concern regarding increasing the threshold when physicians continue to lack access to timely notifications when a patient is included in the denominator of a quality measure. We encourage CMS and other payers to establish a process that will allow practices to verify which patients should be in the denominator of a selected measure on a timely basis, including when they have a scheduled service with regular updates occurring monthly at minimum.

Administrator Brooks-LaSure August 31, 2022 Page 77 of 97

Performance measurement reporting remains a heavy burden for practices, as the lack of measure alignment across payers means a physician may be required to report on multiple overlapping measures across their patient panel as payers often use different criteria. This lack of alignment also prevents meaningful analysis and comparison of performance across payers. We strongly urge CMS to work with payers and purchasers toward measure alignment, including the reliance on standardized and centralized measurement processes whenever possible and does not support increase of the data completeness threshold until meaningful progress is made.

Screening for Social Drivers of Health Proposed Measure

CMS proposes to adopt a new evidence-based drivers of health (DOH) measure to support identification of specific DOH associated with inadequate health care access and adverse health outcomes. The measure would assess the percent of patients who are 18 years or older screened for food insecurity, housing instability, transportation problems, utility difficulties, and interpersonal safety.

AAFP Comments:

The AAFP supports CMS' goal of reducing health inequities and believes family physicians, along with others, play an important role in helping to identify the health-related social needs of patients. We also agree that it is important for family and other primary care physicians to be connected to social and community-based organizations that can help to address those needs using an efficient, centralized approach. These are core tenants of comprehensive, longitudinal primary care, though we note that these types of services are often not billable under the MPFS. Moving to APMs that include comprehensive prospective payment must be prioritized if we are to sufficiently and sustainably support primary care's role in improving health equity. Further, physicians and other clinicians cannot be held accountable for providing resources to address individual health-related social needs when those resources do not exist in the community.

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

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

Administrator Brooks-LaSure August 31, 2022 Page 78 of 97

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

It is important to recognize that there are challenges and important considerations to address before new measure requirements are introduced. Most importantly, the measure should address those factors or circumstances within the control of the individuals or organizations being measured.

CMS' measurement strategy should account for these challenges and ensure quality measurement does not negatively impact underserved patients or the clinicians caring for them. We appreciate that implementation of the proposed screening measures is voluntary in CY2023 and look forward to working with CMS outside of the rule-making process on future plans.

Assessing the Collection and Use of Self-reported Patient Characteristics

CMS is considering ways to encourage clinicians to collect social risk information, including developing a measure that tracks the completeness of self-reported patient characteristics such as race, ethnicity, preferred language, gender identity, sexual orientation, disability status, income, education, employment, food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. CMS seeks comment on the usefulness and feasibility of such a measure.

Which self-reported patient characteristics, including but not limited to those listed above, are important to collect in a standardized format to facilitate future use in quality measures, such as stratification? Which characteristics would you consider lower priority for CMS to collect for use in quality measurement?

The AAFP believes each of the patient characteristics CMS listed are important. However, asking physicians and practices to collect more information will increase burden. Even if a workflow can be adjusted to obtain the information from the patient in a relatively seamless manner, updating an EHR system to include additional data fields and extracting and sharing data can be costly and burdensome.

While we agree that self-reported race and ethnicity data is the gold standard, we caution against mandating this data collection as it could be burdensome and erode patients' trust in physicians and other health professionals. This type of data collection should be done separately from direct patient care discussions.

Primary care physicians are trusted partners in patients' health care experience. They are well suited to act as an important partner in the data collection process, however they should not be considered the sole source for collection of patients social needs and demographic data. To better foster

Administrator Brooks-LaSure August 31, 2022 Page 79 of 97

collaboration in data collection, required data should be standardized to ensure the uniform collection of many types of health care data, including HRSNs and demographic characteristics, such as race, ethnicity, and preferred language (REL). Many states have taken steps to standardize collection of REL data, using legislative and regulatory processes to ensure appropriate collection and use of data to protect patient privacy. Additional efforts are needed to standardize the collection of other types of data that may be important for identifying health disparities and ensuring robust risk adjustment. Standardizing the data elements used for race, ethnicity, primary language, gender identity, sexual orientation, income status, and other characteristics will help ensure primary care teams can identify and facilitate addressing HRSNs. The AAFP encourages CMS to explore options for collecting this data at various touch points, not just when they seek care at a physician's office. For example, this data may also be collected at enrollment and shared with the patient's preferred source of primary care.

How important is it to use a standardized tool with coded questions and data elements to collect self-reported patient characteristics across clinicians and practices and what challenges and limitations present without use of a coded and standardized instrument?

While using a standardized tool would be beneficial, there are a variety of factors that would make it challenging to implement given the number of stakeholders who would need to agree to use it. To ease burden on physicians, CMS would need to ensure that all health IT and EHR vendors are willing to integrate the tool into their systems. This should ideally be done without additional cost to the practice. Additionally, a standardized tool would need to be adopted by all payers. The AAFP also believes physicians should maintain the ability to use the tool that makes the most sense for their practice and patient population. Given these challenges, CMS will need to find a balance between complete and mandated standardization of a single tool and providing physicians with the flexibility to use a tool that meets their needs. Standardizing the data elements that are collected through a wide variety of tools may be a better mechanism for supporting a common understanding of the data while allowing for flexibility in the tools used to collect these data.

Would the use of a consistent screening tool(s) to collect social drivers of health information improve our ability to meaningfully compare performance across physicians, such as performance on a measure assessing referrals for identified social needs or if measures are stratified based on identified needs? How are clinicians collecting and using this type of information to inform clinical care?

The AAFP appreciates efforts to build greater understanding of the role of the health system in screening and referral for HRSNs through such efforts as the CMMI Accountable Health Communities model. We believe it is premature to introduce performance measures for two key reasons. First, we do not have reliable evidence-based actions that merit measurement as we are in a collective learning curve, and secondly, assessing physician referrals based on screenings presupposes that there are sufficient community resources to receive these referrals. As we know, this is not always the case.

Administrator Brooks-LaSure August 31, 2022 Page 80 of 97

We look forward to exploring this subject with CMS as learnings evolve outside of the rulemaking process.

In addition to quality measures, cost measures, and improvement activities applicable to the clinical aspect of an MVP, each MVP includes a foundational layer of population health and promoting interoperability measures, broadly applicable to most, if not all, clinicians. Is the proposed quality measure, "Screening for Social Drivers of Health," appropriate for use in the foundational layer of MVPs? If so, then such inclusion would require most or all ECs to screen for social drivers of health during patient encounters.

As noted previously in our comments on the proposal to adopt the Screening for Social Drivers of Health as a MIPS measure, the AAFP is very supportive of screening for health-related social needs and has <u>equipped its members with the tools</u> to engage in this important aspect of whole-person care through the <u>EveryONE Project</u>.

We also note the many measurement challenges that exist, especially given the active learnings that are occurring in many places, including the CMMI Accountable Health Communities model. CMS' measurement strategy should account for these challenges and ensure quality measurement does not negatively impact underserved patients or the clinicians caring for them. We appreciate that implementation of the proposed screening measures is voluntary in FY2023 and look forward to working with CMS outside of the rule-making process on future plans.

Is it appropriate to develop a quality measure to assess clinician referrals to community-based services upon screening positive for a social driver of health, including food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety?

As we've noted throughout our comments, primary care physicians regularly screen patients for unmet social needs and refer them to community-based services. Family physicians consistently note that they are uniquely positioned to identify and address these unmet needs, due to their strong longitudinal relationships with patients. It may be appropriate to measure referrals to community-based services at some point, but practices and communities must be appropriately resourced first. Many physicians work in communities that lack robust community-based services to address health-related social needs. Practices are not adequately paid for the practice staff time required to make meaningful, helpful connections to many community-based programs. Further, some patients will not want to be referred to a community-based service. A referral measure would have to account and adjust for these challenges. Additionally, CMS and other relevant federal, state, and local agencies would need to equip physician practices and other health care entities with education and contact information for how to efficiently and effectively refer patients to the right services at the right time. Unfortunately, we believe we are a long way off from it being appropriate to use this type of measure in performance-based programs and would not support inclusion until a measure has been thoroughly tested and is considered valid and reliable.

CMS seeks comment on whether it would be beneficial to: stratify either outcome or process measures by patient demographics; and/or stratify either outcome or process measures by identified

Administrator Brooks-LaSure August 31, 2022 Page 81 of 97

social needs, such as food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety?

AAFP Comments:

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

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

CMS (or other government agencies) should already have data that could be analyzed at the population level using geographic algorithms, billing data, HCC scores, and other data elements to determine where potential health inequities exist. This information should be shared with physicians and hospitals to help them target improvement efforts. Targeting would be much more efficient than attempting to collect specialty-specific, self-reported data from physicians and hospitals. Providing physician practices with ongoing data will help them address disparities within their patient panel.

Assessing Patient-Clinician Communication

CMS is considering developing a patient-reported outcome measure that assesses the receipt of appropriate language services and/or the extent of clinician-patient communication. If developed, it could be considered for the foundational layer of MVPs. CMS is seeking feedback on the feasibility and usefulness of such a measure, as well as the appropriateness of requiring all clinicians to report on such a measure.

AAFP Comments:

The AAFP supports the Person-centered Primary Care Measure (PCPCM) to assess the core elements of primary care, including physician-patient communication. Primary care requires a whole-person approach, prioritization of needs, sophisticated primary care team, and consideration of the patient's goals within the context of their social system. The PCPCM assesses whether the patient's needs, goals, and social systems – the whole person – are being considered when providing care.

The AAFP recognizes the importance of physician-patient communication and shares CMS' goal of ensuring patients have access to appropriate language services. Should CMS move forward with developing a measure to assess patient-clinician communication, we strongly urge CMS to ensure patients and caregivers are included and consulted through all stages of the process. CMS should also take into account cost and other barriers practices may face providing language-appropriate care.

Developing Quality Measures that Address Amputation Avoidance in Diabetic Patients – RFI

CMS is considering developing process and composite measures designed to reduce the risk of lower extremity amputation (LEA) among patients with diabetes. The measure would assess the percent of patients with diabetes who receive neurologic and vascular assessments of their lower extremities to determine ulcer risk, have a documented ulcer risk level, and who receive a follow-up plan of care if identified as high risk for ulcer. CMS seeks feedback on several questions.

AAFP Comments:

The AAFP supports the overall intent of quality measures aimed at reducing the risk of lower extremity amputation (LEA) among patients with diabetes. However, it is imperative to appropriately risk adjust and ensure that physicians are not penalized for variances and outcomes that are beyond their control.

Below we address CMS' specific questions.

1. Are neurological and vascular assessments, and the determination of risk the most important care processes in the prevention of foot ulceration among individuals with diabetes?

While neurological and vascular assessments and determination of risk are important care processes in the prevention of ulceration, there are several additional factors that should be considered, including:

- a. Prior history of ulceration and/or amputation
- b. Social drivers of health and available resources (ie flooring in one's home, heat source, transportation, phone for sharing photographs with one's physician)
- c. Past and current tobacco use
- d. Glucose control by A1C and postprandial glucose
- e. Patient compliance rating (shoes, socks, vision) and follow-up history
- 2. Once a process quality measure concept would be fully developed and implemented, would high performance on the measure contribute to a reduction in diabetes-related LEA? Why or why not? If a process quality measure were fully developed and implemented, high performance on the measure could possibly contribute to the reduction of diabetes-related LEA. However, it is important to acknowledge that there are many other factors that affect this outcome, including time of patient identification (ie late-stage disease likely has a poor prognosis). Thus, CMS might consider including patients with pre-diabetes.
- 3. Once developed and implemented, would clinicians be able to report performance without undue burden? Why or why not?

Once developed and implemented, clinicians that already have a robust EHR system may be able to report performance without significant undue burden if their EHR system already has the measure available and already built in. If this is not the case, it's likely reporting will be burdensome.

4. Once developed and implemented, should performance be measured at the clinician level or group level? Is the measure appropriate for all clinicians? If not, to whom should the measure apply?

Measures should be used at the level for which they are developed, tested, and validated to produce reliable results that successfully improve the quality of care. Many measures are designed and should be used at population levels, such as the payer or system level. Additionally, this measure may not be appropriate for all clinicians. For example, this measure does not seem applicable to a dermatologist, OB/GYN, and other sub-specialists. However, it does apply to primary care physicians and endocrinologists.

5. What would be the benefits and/or unintended consequences of the process quality measure concept?

This measure could possibly result in fewer amputations. However, physicians tend to focus intensely on that which is being measured and could have less time to focus on other important measures that have a significant impact on patients' overall health and wellbeing (i.e. social drivers of health, lipid and BP control, overall compliance, etc.) Reporting could also result in additional administrative burden for already over-burdened clinicians.

- 6. Would a process quality measure concept contribute to health equity? Why or why not? The AAFP believes that to the extent a process of care has a significant impact on outcomes of interest, that it merits consideration for measurement, but it is unlikely that a process measure such as this is going to contribute to improvements in health equity which are attributable to much more significant and entrenched problems that extend well beyond the care process.
- 7. Would the single measures comprising the composite be appropriate? Why or why not? A potential composite measure would be appropriate if it meets all of the following criteria as stated in the official AAFP policy on Performance Measures Criteria: "For composite measures, the components must be rationally related and weighted, and the composite must provide added value over the individual component measures, avoid all-or-none scoring, and not create undue burden."

Cost Performance Category

CMS proposes to add the Medicare Spending per Beneficiary (MSPB) Clinician measure to the operational list as a care episode group. The MSPB Clinician measure is constructed using many aspects of the same logic as episode-based measures based on the care episode groups currently on the operational list. CMS seeks comment on this proposal.

AAFP Comments:

The AAFP has concerns with the use of administrative claims population cost measures, including MSPB. While CMS did not make any proposals related to the total per capita cost measure, the AAFP reiterates our steadfast opposition to its use in MIPS. Primary care physicians provide continuous, longitudinal care, which includes focusing on prevention and wellness. Expecting primary care physicians to reduce the total cost of care based on preventive services is not an appropriate measurement of the value of these services. Preventive measures have long-term benefits to both patients and the health care system, but they may increase short-term spending. However, investing in preventive services is a critical element of the transformation to value-based health care spending. While higher utilization of preventive care may reduce costs in the long term, the TPCC measure and MIPS are not designed to capture those savings and do not account for the value of such services. In addition to developing episode-based cost measures, we encourage CMS to review more appropriate

Administrator Brooks-LaSure August 31, 2022 Page 84 of 97

ways to measure cost and believe CMS should explore using non-preventive utilization measures as a proxy for cost.

In the 2022 Medicare Physician Fee Schedule Final Rule, CMS finalized a policy that allows them to exclude a cost measure from an eligible clinician's (EC) score if the data used to calculate the measure are impacted by significant changes during the performance period. The AAFP was supportive of this proposal and encourages CMS to do a thorough assessment of the impact of the COVID-19 PHE on cost measures for the 2022 performance year. The COVID-19 pandemic has continued to ebb and flow and its impact on cost will be long-lasting. Missed preventive care services during 2020 and 2021 may have led to additional illness for which patients are now seeking care. Increased utilization and costs during this period may be necessary as patients begin seeking care management and preventive care services again.

Improvement Activities Performance Category

CMS is proposing to add four new improvement activities, modify five activities, and remove six activities. The activities CMS proposes to add align with the Administration's goal to advance health equity for all. The new activities include:

- Use Security Labeling Services Available in Certified Health Information Technology for Electronic Health Record Data to Facilitate Data Segmentation
- Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients
- Create and Implement a Language Access Plan
- COVID-19 Vaccine Promotion for Practice Staff

AAFP Comments:

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

Promoting Interoperability

Changes to the Query of Prescription Drug Monitoring Program Measure under the Electronic Prescribing Objective

CMS believes it is feasible to require ECs to report on the Query of Prescription Drug Monitoring Program (PDMP) measure. CMS believes ECs have had sufficient time to become familiar with the measure and believes there has been sufficient progress in the availability of PDMPs as all 50 states now have a PDMP.

Beginning with the 2023 performance period, CMS proposes to require ECs to report the Query of Prescription Drug Monitoring Program (PDMP) measure for the promoting interoperability category. The measure requires reporting a "yes/no" response and would be worth 10 points. CMS also

Administrator Brooks-LaSure August 31, 2022 Page 85 of 97

proposes to expand the measure to include Schedule III and IV drugs in addition to Schedule II opioids. CMS proposes the following exclusions:

- ECs who are unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period, and
- ECs who write fewer than 100 permissible prescriptions during the performance period.

If an EC claims an exclusion on the measure, CMS will redistribute the points associated with it to the e-Prescribing measure.

AAFP Comment:

The AAFP opposes the proposal to require ECs to report the Query of PDMP measure and we urge CMS to continue allowing ECs to elect whether to report this measure. We also oppose the proposal to include Schedule III and IV drugs and recommend against including Schedule V drugs. As we've noted throughout our comments, reporting to the MIPS program is burdensome and costly for physician practices. These proposals will add significant burden for many ECs who may face varying challenges integrating the PDMP with their EHR for easy querying.

If CMS moves forward with requiring ECs to report on this measure, we urge CMS to expand the list of exclusions to include prescriptions for certain chronic conditions and treatment plans, such as cancer treatment and hospice care.

Health Information Exchange (HIE) Objective: Proposed Addition of an Alternative Measure for Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) CMS proposes to add a new measure that would allow ECs to earn credit for the Health Information Exchange (HIE) Objective. ECs would be able to meet the objective requirements through the following three options:

- Report on both the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure.
- Report on the HIE Bi-directional Exchange measure, or
- Report on the proposed Enabling Exchange Under Trusted Exchange Framework and Common Agreement (TEFCA) measure.

To report the Enabling Exchange Under TEFCA measure, an EC would attest "yes/no" to the following:

- Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the FR and on ONC's website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition, or referral, and record stored or maintained in the electronic health record (EHR) during the performance period, in accordance with applicable law and policy.
- Using the functions of certified EHR technology (CEHRT) to support bi-directional exchange of patient information, in production, under this Framework Agreement.

Administrator Brooks-LaSure August 31, 2022 Page 86 of 97

The measure would be worth 30 points.

AAFP Comments:

The AAFP supports the addition of this measure.

Additional Considerations

CMS is not proposing to continue its reweighting policy for nurse practitioners, physician assistants, certified registered nurse anesthetist, or clinical nurse specialists for the 2023 performance period. CMS is seeking comment on whether they should continue the policy and may decide to take a different approach in the final rule based on the comments they receive. CMS is, however, proposing to continue the existing reweighting policy for physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals. CMS is only proposing to continue this policy for the 2023 performance year.

The AAFP supports this proposal.

Patient Access to Health Information Measure Request for Information

In response to feedback, CMS removed the standalone View, Download, Transmit measure from the promoting interoperability category. CMS is seeking feedback on how to further promote equitable patient access and use of their health information without adding unnecessary burden on the MIPS EC or group.

AAFP Comments:

The AAFP supports improving patients' access to their data and the important role this can play in improving individualized, whole-person patient care and care coordination across a patient's care team. The AAFP has long <u>supported</u> policies that guarantee the appropriate security of protected health information while working to improve patients' access to their data, as well as the ability to share patients' health information across the care team. We are strongly supportive of making data reliably interoperable while maintaining patient confidentiality. Access to, and use of data, should always be based on the patient's expressed desires and valid authorizations. The sharing of information among physicians and other clinicians <u>should</u> focus on facilitating care coordination, patient wellness, and the expressed wishes of the patient themself.

Information blocking regulations now require physicians to make health information available to patients. Physician practices are expected to continue to comply with HIPAA, which requires them to safeguard the confidentiality of patients' electronic health information, while also complying with information blocking regulations, which penalize them for failing to share information. Complying with both sets of regulations and their accompanying enforcement frameworks puts physicians in a challenging position, especially given that many physicians are still <u>underinformed</u> about information blocking requirements and doing their best to come into compliance. In addition to providing more specific guidance on information blocking regulations and implementation, these information sharing

Administrator Brooks-LaSure August 31, 2022 Page 87 of 97

regulations must be harmonized to meaningfully improve patients' access to their health data and advance interoperability while also safeguarding patient privacy and security. Thus, the AAFP strongly recommends against an additional measure or incentive in MIPS for physicians to make health information available to patients as doing so will only add burden and confusion to physicians and their practices who are already working to comply with the current regulatory environment of information sharing. Below we answer two of CMS' specific questions.

With the advancement of HIT, EHRs and other health-related communication technologies, there are concerns that implementation of these technologies can lead to unintended consequences that exacerbate existing health disparities within populations who could receive greater benefits but are less likely to adopt them. What policy, governance and implementation strategies or other considerations are necessary to ensure equal access to consumer-facing health technologies including patient portals and mobile health applications, as well as equitable implementation and appropriate design and encouragement of use across all populations?

The lack of modern broadband infrastructure has <u>proven</u> to be a primary barrier to equitable digital health access for rural Americans, who are <u>10 times more likely</u> to lack broadband access than their urban counterparts, and Black and Hispanic Americans, whose access to broadband is an <u>estimated</u> 10 years behind that of white Americans. Inadequate access to broadband internet is a direct barrier to access to patient portals. When implemented intentionally and appropriately, digital health technology can advance health equity by enabling patients with transportation, time, distance, and language barriers to connect with their trusted primary care physicians through their patient portals and EHRs. Similarly, enhancing interoperability of EHRs improves care coordination and enables primary care physicians to address unmet needs. Further, many <u>mobile health apps</u> are above the recommended reading level for patient materials, and many are not available in Spanish or other languages. To ensure that all patients can access digital health, policymakers must expand and support programs that distribute technology along with effective patient education on how to use digital health technologies. The AAFP urges greater investment in broadband internet and funding and patient-centered training for digital health technology so patients are comfortable interacting with their physicians and EHRs using such technology.

For patients who access their health information, how could CMS, HHS, and health care providers help patients manage their health through the use of their personal health information?

Many family physicians help patients utilize their personal health information to conduct shared decision making, track patients' progress in a treatment plan, and help coordinate care across different clinicians and settings.

In addition to in-person care, physicians and their staff spend <u>additional time and resources</u> communicating with patients through EHR messaging and patient portals, leading to additional burnout related to inbox burden. The ideal process to fulfill patient requests for personal health information from their EHRs is the development of uniform electronic processes and real-world testing of those processes to move towards efficient and seamless health information exchange in a way that does not add administrative burden on physicians and their practices. CMS may consider working with physician groups to determine best practices, guidelines, and resources for such processes in a way that is aligned with other information sharing regulations. Until those are developed and

Administrator Brooks-LaSure August 31, 2022 Page 88 of 97

incorporated into existing workflows and EHRs in a way that can allow physicians to easily fulfill these requests, the AAFP urges CMS and HHS to consider ways, including through resources and appropriate payment, to support physicians who are helping patients manage their health through manual fulfillment of patient requests for personal health information.

Calculating the MIPS Final Score

Request for Information on Risk Indicators for the Complex Patient Bonus Formula

The complex patient bonus currently calculates the complex patient bonus using HCC risk scores and the proportion of dually eligible patients. CMS is considering whether to incorporate the area deprivation index (ADI) measure within the complex patient bonus. CMS seeks comments on the potential future incorporation of the measure.

AAFP Comments:

The AAFP is supportive of using the ADI in the calculation of the complex patient bonus. We believe incorporating additional risk factors beyond those represented by HCC and dual-eligible status is a more accurate reflection of the factors influencing a patient's health. We've encouraged CMS to seek areas of alignment between MIPS and APMs as a way to prepare practices for transitioning out of FFS. Using ADI in the complex patient bonus would be one way to accomplish this.

Establishing the Performance Threshold

CMS is bound by statute to set the MIPS performance threshold using the mean or median of a prior year's final scores. CMS previously finalized that they would use the mean final score to determine the performance threshold for MIPS payment years 2024-2026. CMS is proposing to use the calendar year 2019 MIPS payment year as the prior period for the purposes of establishing the 2025 payment year performance threshold.

For the 2023 performance year/2025 payment year, the MIPS performance threshold will be 75 points. ECs with a final score of 75 will receive a neutral payment adjustment. ECs with a final score greater than or equal to 75.01 will be eligible for a positive payment adjustment based on a linear sliding scale. ECs with a final score below 75 will receive a negative payment adjustment based on a sliding scale. ECs in the bottom quartile (final score of 18.75 or below) will receive the maximum -9 percent payment adjustment in the 2025 MIPS payment year. There is no exceptional performance threshold as the funding for the exceptional performance adjustment ended with the 2022 performance year.

AAFP Comment:

The AAFP is generally supportive of these proposals.

Public Reporting on the Compare Tools Hosted by HHS

CMS proposes to add a telehealth indicator to the Medicare Compare Tool. It would be added to clinician and group pages. CMS would identify clinicians who perform telehealth services using claims data (POS 02 or modifier -95) and use a six-month lookback period. They would update the pages

Administrator Brooks-LaSure August 31, 2022 Page 89 of 97

bimonthly. CMS also proposes to add procedural utilization data to the Compare Tool, beginning no earlier than the 2023 calendar year. CMS would use a 12-month lookback period and update bimonthly.

AAFP Comment:

The AAFP is supportive of adding a telehealth indicator to the Medicare Compare Tool.

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

Incorporating Health Equity into Public Reporting Request for Information

CMS seeks comment on ways to incorporate health equity into public reporting on doctor and clinician profile pages with the goal of ensuring that all patients and caregivers can easily access meaningful information to assist with their health care decisions. For the purpose of this request, health equity means, "the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes." CMS has considered including additional information on Compare tool clinician and group profile pages, such as whether the clinician or group has language services available, speaks other languages besides English, and whether they accept insurance outside of traditional Medicare FFS such as Medicaid, Medigap, MA, and other commercial insurance.

AAFP Comment:

The AAFP agrees with CMS that it is important to empower patients with information that enables them to select high-quality, high-value physicians. The AAFP believes the information CMS has outlined above would be beneficial to add to the Compare tool profile pages. As CMS considers ways to incorporate this information, we ask that CMS develop processes to ensure the information is accurate and up to date. Any information or data collection by CMS should be done in a way that does not add burden to physicians or their practices.

Advanced Alternative Payment Models

Request for Information on Quality Payment Program Incentives Beginning in Performance Year 2023

The AAPM bonus expires after the 2024 payment year, per federal statute. Beginning in 2025, qualifying APM participants (QPs) will not receive a bonus for their participation in an AAPM. QPs will still be exempt from reporting to MIPS. QPs will also receive a 0.75 percent update to the conversion factor beginning in with the 2026 payment year. There is no bonus or conversion factor update for QPs for the 2025 payment year. CMS is concerned the expiration of the AAPM bonus may act as a

Administrator Brooks-LaSure August 31, 2022 Page 90 of 97

deterrent for ECs to participate in AAPMs as they may be able to earn a higher payment adjustment if they were to participate in MIPS instead of an AAPM. CMS is also concerned a reduction in AAPM participation may impact the evaluation of CMMI models.

CMS is not proposing any administrative action to address these problems but seeks comment on what administrative actions ECs and APM Entities would potentially find helpful to better balance the incentives in the QPP.

AAFP Comment:

The AAFP shares CMS' concern and is strongly urging Congress to pass legislation that would extend the AAPM bonus. 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.

Transitioning to a value-based payment arrangement requires significant upfront investments. Moreover, ongoing participation requires continued financial support to sustain APM Entities. While AAPMs have financial incentives as part of their model design, the AAPM bonus augmented the investments APM Entities were able to make in important programs and initiatives that benefit beneficiaries. Insufficient FFS payment rates are also undermining practices' ability to make the needed upfront investments, exacerbating the challenges practices will face if the AAPM bonus expires as planned.

The AAPM bonus is an important factor in attracting participants to AAPMs. However, model design plays a critical role in the ability of physicians to transition to VBP arrangements. CMS and the Innovation Center should build and test models that are stable and appropriately value primary care. Model design, when done well, can be an incentive in and of itself for physicians who are intent on delivering high-value, person-centered care but are not well supported by FFS.

AAPMs provide a mechanism for physicians to be paid for services that are not otherwise covered under FFS. Primary care AAPMs should provide risk adjusted prospective payments that represent a meaningful increased investment. Payment within an AAPM should give physicians the flexibility and resources to provide care in more innovative ways than they can under the restrictive FFS system.

In addition, AAPMs should reduce burden so that physicians have more time to spend providing care. Reduced burden can also help lower the administrative costs associated with participation, which would allow participants to reinvest in other patient-related initiatives. Continually reducing administrative and reporting burdens within AAPMs will help attract new participants.

Medical Home Model 50 Eligible Clinician Limit

CMS is proposing to amend the 50-clinician limit for APM Entities participating in Medical Home Models. CMS would apply the limit directly to the APM Entity rather than the parent organization of

Administrator Brooks-LaSure August 31, 2022 Page 91 of 97

the APM Entity. However, the APM Entity must remain below the 50-clinician limit for all three determination dates during the QP Performance Period. If the APM Entity exceeds the limit, the Medical Home Model financial risk and nominal amount standards would not apply, and no ECs would achieve or retain QP status for the corresponding payment year.

AAFP Comment:

CMS initially instituted the 50-clinician limit as CMS believed organizations of such a size have demonstrated the capability and interest in taking on higher levels of two-sided risk. We have been opposed to the 50-clinicinal limit since its inception and continue to believe it is an arbitrary and unnecessary limit. CMS is proposing policies in this rule to encourage participation in alternative payment models, specifically the SSP. The AAFP applauds CMS in their effort to make participation programs more attractive for small and rural ACOs. While we are supportive of many of CMS' proposals related to the SSP, not all physicians and practices want to join ACOs. CMS should continue to develop policies that encourage participation in any type of alternative payment model. The 50-clinician limit can disincentivize participation in Medical Home Models and we ask that CMS remove it entirely.

Qualifying APM Participation Determination

Request for Information: Potential Transition to Individual QP Determinations Only
Under current policy, QP determinations for most ECs participating in an AAPM are made at the APM
Entity Level. CMS is requesting public comment on the idea of transitioning away from an APM Entity
level QP determination and instead calculating Threshold Scores and making QP determinations at
the individual clinician level for all eligible clinicians in AAPMs and Other Payer AAPMs.
CMS believes a change in policy would have several benefits:

- Substantially reduce the practice of APM Entities removing specialists from their participation lists.
- Increase the number of ECs who are determined to be QPs at the individual level when their APM Entity does not qualify,
- Eliminate the number of ECs who become QPs for a year, but whose individual participation in their AAPM is well below the threshold score.

Under an updated approach, CMS would calculate a threshold score for each EC, identified by their NPI, based on all the covered professional services furnished by that individual EC, including services billed across all the TINs to which the individual has reassigned their Medicare billing rights. Current policy can cause APM Entities to consider how an EC affects their QP threshold score rather than considering whether the EC provides the necessary services to meet the needs of the APM Entity's patient population. CMS is considering whether a policy change would a have a positive health equity impact since the APM would no longer need to consider whether the EC impacts their QP threshold score.

AAFP Comment:

The AAFP believes CMS should continue exploring a change in policy to make QP determinations at the individual EC level. We agree that this would be a better representation of the QP's level of

participation in an AAPM and address instances where an EC is designated a QP without meaningful participation in the AAPM. The AAFP also believes the updated approach more closely aligns with the language and intent of the MACRA statute.

QP Thresholds and Partial Thresholds

Per statute, for performance year 2023, the QP thresholds for the Medicare Option will increase to 75 percent for the payment amount method and 50 percent for the patient count method. The partial QP thresholds will be 50 percent and 35 percent for the payment and patient count methods, respectively.

The QP thresholds for the All-Payer Combination Option align with the Medicare Option. ECs must first meet certain thresholds under the Medicare Option to be considered a QP under the All-Payer Combination Option. The Medicare Option threshold is 25 percent for the payment amount method and 20 percent for the patient count method.

The AAFP is very concerned that the increase in the QP thresholds will stymie the progress we've made in transitioning toward value-based payment. Based on CMS' estimates, thousands of ECs may fall back into FFS due to these increases. Many primary care practices that are looking to move into APMs will not be able to meet these thresholds and will be forced to stay in FFS. We are urging Congress to stop the increases to the QP thresholds and provide CMS with the authority to establish them in the future. We will continue to advocate for legislative and regulatory policies that accelerate the transition to value-based care.

Thank you for the opportunity to provide comments on the proposed rule. The AAFP looks forward to continuing to partner with CMS to continually support primary care and improve beneficiaries' equitable access to comprehensive care. Should you have any questions or wish to discuss our comments further, please contact Meredith Yinger, Manager, Regulatory Affairs at myinger@aafp.org or 202-235-5126.

Sincerely,

Ada D. Stewart, MD, FAAFP

Gda D. Stewart, No

Board Chair, American Academy of Family Physicians



¹ 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.

- ³ Jetty, A., Petterson, S., Westfall, J. M., & Jabbarpour, Y. (2021). Assessing Primary Care Contributions to Behavioral Health: A Cross-sectional Study Using Medical Expenditure Panel Survey: Https://Doi.Org/10.1177/21501327211023871
- ⁴ Muhlestein D, Tu T, Colla CH. (2020). Accountable Care Organizations Are Increasingly Led by Physician Groups Rather Than Hospital Systems. *Am J Manag Care*. 2020;26(5):225-228. https://doi.org/10.37765/ajmc.2020.43154
- ⁵ 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
- ⁶ 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
- ⁷ Jabbarpour Y, et al. (2019). Investing in Primary Care: A State-Level Analysis. Patient-Centered Primary Care Collaborative and Robert Graham Center.

https://www.pcpcc.org/sites/default/files/resources/pcmh evidence report 2019 0.pdf

- 8 Increased Medicaid Reimbursement Rates Expand Access to Care. (2019). *National Bureau of Economic Research*. https://www.nber.org/bh-20193/increased-medicaid-reimbursement-rates-expand-access-care
 9 Welch BM, Harvey J, O'Connell NS, McElligott JT. Patient preferences for direct-to-consumer telemedicine services: a nationwide survey. BMC Health Serv Res. 2017 Nov 28;17(1):784. doi: 10.1186/s12913-017-2744-8
 10 Yinran Li K, Ng S, Ellimoottil C. (2021). Direct-To-Consumer Telemedicine Visits For Acute Respiratory Infections Linked To More Downstream Visits. *Health Affairs*. https://doi.org/10.1377/hlthaff.2020.01741
 11 Rush KL, Howlett L, Munro A, Burton L. Videoconference compared to telephone in healthcare delivery: A systematic review. Int J Med Inform. 2018 Oct;118:44-53. doi: 10.1016/j.ijmedinf.2018.07.007. Epub 2018 Jul 25. PMID: 30153920.
- ¹² Samson LW, Tarazi W, Turrini G, Sheingold S. (2021). Medicare Beneficiaries' Use of Telehealth in 2020: Trends by Beneficiary Characteristics and Location. *Assistant Secretary for Planning and Evaluation*. https://www.aspe.hhs.gov/sites/default/files/documents/a1d5d810fe3433e18b192be42dbf2351/medicare-telehealth-report.pdf? ga=2.263152908.1288477598.1638811694-1417522139.1637192937 https://ga=2.263152908.1288477598.1638811694-1417522139.1637192937 https://ga=2.263152908.1288477598.1638811694-1417522139.1637192937 https://ga=2.263152908.1288477598.1638811694-1417522139.1637192937 https://ga=2.263152908.1288477598.1638811694-1417522139.1637192937 https://ga=2.263152908.1288477598.1638811694-1417522139.1637192937 https://ga=2.263152908.1288477598 https://ga=2.263152908 <a href=mailto:ga=2.263152908 <a href=mailto:ga=2.263152908 <a href=mailto:ga=2.263152908 <a href=mailto:ga=2.263152908
- ¹⁴ Kelly A Hirko, Jean M Kerver, Sabrina Ford, Chelsea Szafranski, John Beckett, Chris Kitchen, Andrea L Wendling, Telehealth in response to the COVID-19 pandemic: Implications for rural health disparities, *Journal of the American Medical Informatics Association*, Volume 27, Issue 11, November 2020, Pages 1816–1818, https://doi.org/10.1093/jamia/ocaa156
- ¹⁵ Congressional Research Service. (2019). Broadband Loan and Grant Programs in the USDA's Rural Utilities Service. https://sgp.fas.org/crs/misc/RL33816.pdf
- ¹⁶ Velasquez D, Mehrotra A. (2020). Ensuring The Growth Of Telehealth During COVID-19 Does Not Exacerbate Disparities in Care. *Health Affairs*. 10.1377/forefront.20200505.591306
- ¹⁷ Ryan C, Lewis JM. (2017). Computer and Internet Use in the United States: 2015. *American Community Survey Reports*. https://www.census.gov/content/dam/Census/library/publications/2017/acs/acs-37.pdf

STRONG MEDICINE FOR AMERICA

President Sterling Ransone, MD Deltaville, VA

Speaker
Russell Kohl MD

Stilwell, KS

President-elect Tochi Iroku-Malize, MD Islip, NY

Vice Speaker Daron Gersch, MD Avon, MN Board Chair Ada Stewart, MD Columbia, SC

Executive Vice President
R. Shawn Martin
Leawood, KS

Directors
Andrew Carroll, MD, Chandler, AZ
Steven Furr, MD, Jackson, AL
Teresa Lovins, MD, Columbus, IN
Jennifer Brull, MD, Plainville, KS
Mary Campagnolo, MD, Borderntown, NJ
Todd Shaffer, MD, Lee's Summit, MO

Gail Guerrero-Tucker, MD, *Thatcher, AZ*Sarah Nosal, MD, *New York, NY*Karen Smith, MD, *Raeford, NC*Samuel Mathis, MD (New Physician Member), *Galveston, TX*Amanda Stisher, MD (Resident Member), *Owens Cross Roads, AL*Amy Hoffman (Student Member), *State College, PA*

² Wilkinson, E., Jetty, A., Petterson, S., Jabbarpour, Y., & Westfall, J. M. (2021). Primary Care's Historic Role in Vaccination and Potential Role in COVID-19 Immunization Programs. Annals of Family Medicine, 19(4), 351–355. https://doi.org/10.1370/AFM.2679

- ¹⁸ Karimi M, Lee EC, Couture SJ, et al. National Survey Trends in Telehealth Use in 2021: Disparities in Utilization and Audio vs. Video Services.
- $\underline{https://aspe.hhs.gov/sites/default/files/documents/4e1853c0b4885112b2994680a58af9ed/telehealth-hps-ib.pdf}$
- ¹⁹ U.S Preventive Services Task Force. Final Recommendation Statement. Unhealthy Alcohol Use in Adolescents and Adults: Screening and Behavioral Counseling Interventions. November 13, 2018. Available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/unhealthy-alcohol-use-in-adolescents-and-adults-screening-and-behavioral-counseling-interventions
 ²⁰ Ibid.
- ²¹ U.S Preventive Services Task Force. Final Recommendation Statement. Depression in Adults: Screening. January 26, 2016. Available at:
- https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/depression-in-adults-screening
- ²² American Academy of Family Physicians. Clinical Preventive Service Recommendation: Alcohol Misuse. Available at: https://www.aafp.org/family-physician/patient-care/clinical-recommendations/all-clinical-recommendations/alcohol-misuse.html
- ²³ American Academy of Family Physicians. Clinical Preventive Service Recommendation: Depression. https://www.aafp.org/family-physician/patient-care/clinical-recommendations/all-clinical-recommendations/depression.html
- ²⁴ Centers for Medicare & Medicaid Services. Data Snapshot: Depression Disparities in Medicare Fee-For-Service Beneficiaries. February 2021. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH Dwnld-DataSnapshot-Depression.pdf
- ²⁵ Kaiser Family Foundation. State Health Facts: Distribution of Medicare Beneficiaries by Race/Ethnicity Distribution of Medicare Beneficiaries by Race/Ethnicity | KFF
- ²⁶ Brody DJ, Pratt LA, and Hughes JP. Prevalence of Depression Among Adults Aged 20 and Over: United States, 2013–2016. February 2018. Available at: https://www.cdc.gov/nchs/data/databriefs/db303.pdf lbid.
- ²⁸ Centers for Medicare & Medicaid Services. Data Snapshot: Depression Disparities in Medicare Fee-For-Service Beneficiaries. February 2021. Available at: https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH Dwnld-DataSnapshot-Depression.pdf
- ²⁹ Panchal N, Kamal R, Cox C, Garfield R. The Implications of COVID-19 for Mental Health and Substance Use. Kaiser Family Foundation. February 10, 2021. Available at: https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/
- ³⁰ 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.
- ³¹ James Macinko, Frederico C. Guanais, Population experiences of primary care in 11 Organization for Economic Cooperation and Development countries, *International Journal for Quality in Health Care*, Volume 27, Issue 6, December 2015, Pages 443–450, https://doi.org/10.1093/intghc/mzv074
- ³² Shi L, Mackino J, Starfield B, Xu J, Regan J, Politzer R, Wulu J. (2004). "Primary care, infant mortality, and low birth weight in the states of the USA." J Epidemiol Community Health. Web.
- Machinko J, Starfield B, Shi L. (2007). "Quantifying the health benefits of primary care physician supply in the
 United States. International Journal of Health Services. Web
 Ibid.
- ³⁵ Gaglioti AH, Petterson S, Bazemore A, Phillips R. (2016). "Access to primary care in US counties is associated with lower obesity rates." J Am Board Fam Med. Web.
- ³⁶ Brousseau DC, Gorelick MH, Hoffman RG, Flores G, Nattinger AB. (2009). "Primary care quality and subsequent emergency department utilization for children in Wisconsin Medicaid." Acad Pediatr. Web. ³⁷ Leiyu S. (2012). "The Impact of Primary Care: A Focused Review." Scientifica. Web.
- ³⁸ James Macinko, Frederico C. Guanais, Population experiences of primary care in 11 Organization for Economic Cooperation and Development countries, *International Journal for Quality in Health Care*, Volume 27, Issue 6, December 2015, Pages 443–450, https://doi.org/10.1093/intghc/mzv074
- ³⁹ Ma, Q. Sywestrzak, G. Oza, M. Garneau, L. DeVries, A. "Evaluation of Value-Based Insurance Design for Primary Care." (2019). The American Journal of Managed Care. 25: 5. https://www.ajmc.com/view/evaluation-of-valuebased-insurance-design-for-primary-care

- ⁴¹ Ross KM, Klein B, Ferro K, McQueeney DA, Gernon R, Miller BF. The cost effectiveness of embedding a behavioral health clinician into an existing primary care practice to facilitate the integration of care: a prospective, case-control program evaluation. J Clin Psychol Med Settings. 2019;26(1):59-67
- ⁴² Welch BM, Harvey J, O'Connell NS, McElligott JT. Patient preferences for direct-to-consumer telemedicine services: a nationwide survey. BMC Health Serv Res. 2017 Nov 28;17(1):784. doi: 10.1186/s12913-017-2744-8. PMID: 29183372; PMCID: PMC5704580.
- ⁴³ Sumit D. Agarwal, Sanjay Basu, Bruce E. Landon The Underuse of Medicare's Prevention and Coordination Codes in Primary Care: A Cross-Sectional and Modeling Study. Ann Intern Med.2022;175:1100-1108. [Epub 28 June 2022]. doi:10.7326/M21-4770
- ⁴⁴ Medicare Payment Advisory Commission. Physician and other health professional services. March 2022 Report to Congress. Available at: https://www.medpac.gov/wp-content/uploads/2022/03/Mar22 MedPAC ReportToCongress Ch4 SEC.pdf
- ⁴⁵ https://www.graham-center.org/content/dam/rgc/documents/publications-reports/reports/state-of-integrated-pc-and-bh.pdf
- ⁴⁶ 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
- ⁴⁷ 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
- ⁴⁸ Li X, Kolltveit KM, Tronstad L, Olsen I. Systemic diseases caused by oral infection. Clin Microbiol Rev. 2000 Oct;13(4):547-58. doi: 10.1128/CMR.13.4.547. PMID: 11023956; PMCID: PMC88948.
- ⁴⁹ Oral Health in America: A Report of the Surgeon General. U.S. Department of Health and Human Services. 2000. https://www.nidcr.nih.gov/sites/default/files/2017-10/hck1ocv.%40www.surgeon.fullrpt.pdf
- ⁵⁰ Kane, C. (2019). Policy Research Perspectives Updated Data on Physician Practice Arrangements: For the First Time, Fewer Physicians are Owners Than Employees. https://www.ama-assn.org/system/files/2019-07/prp-fewer-owners-benchmark-survey-2018.pdf
- ⁵¹ Aileen G. Guillen, Minal Reddy, Soheil Saadat, and Bharath Chakravarthy. Utilization of Telehealth Solutions for Patients with Opioid Use Disorder Using Buprenorphine: A Scoping Review. Telemedicine and e-Health. Jun 2022.761-767. http://doi.org/10.1089/tmj.2021.0308
- ⁵² Mark TL, Treiman K, Padwa H, Henretty K, Tzeng J, Gilbert M. Addiction Treatment and Telehealth: Review of Efficacy and Provider Insights During the COVID-19 Pandemic. *Psychiatr Serv.* 2022;73(5):484-491. doi:10.1176/appi.ps.202100088
- ⁵³ Vakkalanka, J.P., Lund, B.C., Ward, M.M. *et al.* Telehealth Utilization Is Associated with Lower Risk of Discontinuation of Buprenorphine: a Retrospective Cohort Study of US Veterans. *J GEN INTERN MED* **37**, 1610–1618 (2022). https://doi.org/10.1007/s11606-021-06969-1
- ⁵⁴ Mark TL, Treiman K, Padwa H, Henretty K, Tzeng J, Gilbert M. Addiction Treatment and Telehealth: Review of Efficacy and Provider Insights During the COVID-19 Pandemic. *Psychiatr Serv*. 2022;73(5):484-491. doi:10.1176/appi.ps.202100088
- Hunter SB, Dopp AR, Ober AJ, Uscher-Pines L. Clinician perspectives on methadone service delivery and the use of telemedicine during the COVID-19 pandemic: A qualitative study. J Subst Abuse Treat. 2021
 May;124:108288. doi: 10.1016/j.jsat.2021.108288. Epub 2021 Jan 13. PMID: 33771285; PMCID: PMC7833320.
 McWilliams JM, Hatfield LA, Landon BE, Hamed P, Chernew ME. Medicare Spending after 3 Years of the Medicare Shared Savings Program. N Engl J Med. 2018;379(12):1139-1149. doi:10.1056/NEJMSA1803388

⁴⁰ Balasubramanian BA, Cohen DJ, Jetelina KK, et al.; Outcomes of integrated behavioral health with primary care. J Am Board Fam Med. 2017;30(2):130-139.

Administrator Brooks-LaSure August 31, 2022 Page 96 of 97

⁵⁷ Wilkinson, E., Jetty, A., Petterson, S., Jabbarpour, Y., & Westfall, J. M. (2021). Primary Care's Historic Role in Vaccination and Potential Role in COVID-19 Immunization Programs. Annals of Family Medicine, 19(4), 351–355. https://doi.org/10.1370/AFM.2679

Appendix A: Recommended Codes for Primary Care Exception

To continue to address the needs of beneficiaries, the AAFP <u>strongly recommends</u> 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