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September 9, 2024

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1784-P Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Payment Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (CMS-1807-P)

Dear Administrator Chiquita Brooks-LaSure:

The Association of American Medical Colleges (the AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Calendar Year 2025 Physician Fee Schedule and Quality Payment Program (QPP) proposed rule published July 31, 2024 (89 *Fed. Reg.* 61596).

The AAMC (Association of American Medical Colleges) is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened participation in the AAMC by U.S. and international academic health centers.

Through their mission of providing the highest quality patient care, teaching physicians who work at academic health systems provide care in what are among the largest physician group practices in the country, often described as "faculty practice plans," because many of these physicians teach and supervise medical residents and medical students as part of their daily work. They are typically organized into large multi-specialty group practices that deliver care to the most complex and vulnerable patient populations, many of whom require highly specialized care. Care is often multidisciplinary, and team based. These practices are frequently organized

under a single tax identification number (TIN) that includes many specialties and subspecialties. Recent data shows that faculty practice plans range in size from a low of 311 individual national provider identifiers (NPI)s to a high of 5,503 NPIs, with a median of 1,574. These practices support the educational development of residents who will become tomorrow's practicing physicians.

Teaching physicians are vital resources to their local and regional communities, providing significant primary care services and other critical services, including a large percentage of tertiary, quaternary, and specialty referral care in the community. Their patient base may span regions, states, and even the nation. They also treat a disproportionate share of patients for whom issues associated with social determinants of health, such as stable housing, food security, and transportation, contribute significantly to additional health challenges, adding greater complexity to their care.

The AAMC strongly supports the agency's efforts to allow telehealth services to be available to patients in all regions of the country and to patients in their homes and other locations. We support efforts by Congress to continue many of the telehealth flexibilities allowed during the public health emergency (PHE) in the future to continue providing greater access and improved care modalities for patients.

The AAMC commends CMS for its commitment to promoting health and health care equity and expanding patient access to comprehensive care. Our members have been working to implement new strategies aimed at promoting health and health care equity through the delivery of value-based, patient-centered care. We also applaud the agency for its proposals in this rule to expand access to vital medical services, such as behavioral health services. These efforts will improve the health of Medicare beneficiaries and reduce costs in the long term.

While we support the direction CMS has taken on a number of issues, we are concerned with proposed policies for the Quality Payment Program (QPP) that would make Merit-Based Incentive Payment System (MIPS) more challenging by forcing clinicians to MIPS Value Pathways (MVPs) before reporting options are robust and operational for large multispecialty practices. We are committed to working with CMS to ensure that Medicare payment policies support access to high quality care for patients, accurately reflect the resources involved in treating patients, are not overly burdensome to clinicians, and reduce health care disparities.

The following summary reflects the AAMC's key recommendations on CMS' proposals regarding physician payment updates, telehealth payment policy, Medicare Shared Savings Program (SSP) accountable care organizations (ACOs), requests for information (RFIs), and the QPP in the Calendar Year (CY) 2025 Physician Fee Schedule Proposed Rule:

PHYSICIAN FEE SCHEDULE (pp. 4-34)

• *Payment Updates:* Given the critical importance of patient access to health care services and the ongoing challenges faced by physicians, the AAMC encourages CMS to support

¹ Data derived from The Clinical Practice Solutions Center (CPSC), developed by the Association of American Medical Colleges (AAMC) and Vizient.

- stakeholders' efforts to have Congress pass legislation that would provide an annual inflation-based payment update based on the Medicare Economic Index (MEI).
- *Telehealth:* Ensure appropriate payment for telehealth services, extend COVID-19 telehealth flexibilities where CMS has the authority to do so, and encourage CMS to work with Congress to make permanent, or at a minimum to provide a two-year extension, of the remaining COVID-19 telehealth flexibilities.
- *Virtual Supervision:* Finalize proposed policy to allow teaching physicians to virtually supervise resident physicians for telehealth services in all residency training locations through the end of CY 2025 and recommend that CMS permanently allow virtual supervision in all training locations (MSAs and non-MSAs) for telehealth and in-person services rendered by residents. Also finalize policies to permanently allow physicians to directly supervise clinical staff for incident-to services through audio-video technology.
- *Primary Care Exception (PCE):* Expand the PCE to include level 4 E/M visits and allow residents in their third year to perform level 5 E/Ms. Additionally, expand the list of primary care services covered under the PCE to include certain preventive services and care management services to support physician training in primary care and access to care.
- Advanced Primary Care: Finalize new codes to support the delivery of advanced primary care with modifications to ensure practices are best able to offer these services to patients and consider implementing hybrid payments for primary care through total cost of care alternative payment models.
- Accuracy of Global Surgery Payment: Ensure that policies for global surgery payment reflect patient preferences for receiving post-operative care during the global period.
- Advancing Access to Behavioral Health Services: Finalize policies to expand coverage and payment for behavioral health services to promote access to care and enable academic health systems to deliver high-quality behavioral health care.

DISCRETIONARY PROVISIONS (pp. 34-54)

- *Medicare Prescription Drug Inflation Rebate Program:* Finalize proposal to use an estimation methodology to identify 340B units to exclude from Part D inflationary rebates and clarify how a retrospective claims repository model would function.
- *Preventive Services:* Finalize proposals to expand access to preventive services in the Medicare Program, including coverage and access to Hepatitis B vaccine administration and coverage for colorectal cancer screenings.
- *Medicare Shared Savings Program ACOs:* Modify quality measurement policies to support ACO participation and reduce burden by providing time to ramp up reporting new electronic clinical quality measures under the proposed Alternative Payment Model (APM) Performance Pathway (APP) Plus measure set, allow simultaneous alignment with episodic models in certain cases, and revise the proposed health equity benchmark adjustment to ensure meaningful benefit for ACOs caring for underserved communities.
- Building Upon the MIPS Value Pathways Framework to Improve Ambulatory Specialty Care: Ensure meaningful model design elements for specialists, including clear and transparent patient relationship attribution methods, use of registry and cross-cutting

measures, and actionable financial benchmarks, as well as clarifying model's interactions with MIPS as an advanced APM.

QUALITY PAYMENT PROGRAM (QPP) (pp. 54-63)

- *Improving the QPP*: Considering the ongoing operational challenges with the QPP, the AAMC encourages CMS to work with stakeholders to identify longer term policy solutions that would drive improvements in health care quality, attain health equity for all beneficiaries, and reduce burden for clinicians.
- Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs): Retain MVP reporting as a voluntary MIPS reporting option and retain traditional MIPS as the agency works to develop the comprehensive, meaningful measures needed to advance MVP adoption and ensure that rules for subgroup reporting allow practices who opt to report MVPs can best represent the clinical context of care delivered within their practice.
- *Traditional MIPS:* Maintain the overall performance threshold at 75 points for the foreseeable future to provide stability for clinicians as they adjust to significant programmatic changes and ensure policies for reporting and scoring quality, cost, improvement activities, and interoperability support meaningful measurement for clinicians and care delivery enhancements for patients.
- *APM Performance Pathway (APP):* Finalize policies that standardize quality metrics across APMs and Medicare programs under the APP and support APM Entities coordinating reporting across platforms through the proposed Complex Organization Adjustment.
- Advanced APMs: Take administrative actions to best support participation in advanced APMs (AAPMs), and work with Congress to freeze qualifying participation thresholds and extend the AAPM bonus beyond PY 2024 performance to ensure clinicians have incentives to participate in AAPMs.

PHYSICIAN FEE SCHEDULE [II]

PAYMENT UPDATE TO THE PHYSICIAN FEE SCHEDULE CONVERSION FACTOR FOR 2025

CMS Should Work with Congress to Increase the Medicare Payment Update

CMS sets forth the dollar conversion factor that would be used to update the payment rates. For 2025, the conversion factor (CF) would be \$32.3562, which is a 2.8 percent reduction from the 2024 conversion factor. This reflects the expiration of the 2.93% increase for services furnished from March 9 through December 31, 2024² and a budget neutrality (BN) adjustment of 0.05 percent. (p. 62158) Physicians also face a statutory freeze in annual Medicare Physician Fee Schedule (PFS) updates until next year, when updates will resume at a rate of only 0.25 percent, which is well below the rate of inflation. In addition to these reductions, we are alarmed by CMS estimates in the rule that more than 15 percent of MIPS eligible clinicians will receive a payment penalty of up to -9 percent in performance year 2025 (payment year 2027) with its proposals to the program. (p. 62192)

² Consolidated Appropriations Act, 2024; Pub. L. 118-122 (Mar. 2024).

Physician payments have failed to keep pace with rising inflation and practice costs. AMA analysis found that from 2001-2024, Medicare physician payments have increased only ten percent, while the cost of running a medical practice has increased over 50 percent.³

We are deeply concerned about the impact of these significant cuts. Payment reductions of this magnitude would pose a major problem at any time, but to impose these cuts at a time when teaching physicians and other health care professionals are still managing record-setting inflation and rising practice costs while also recovering from historic workforce shortages will be extremely harmful. Prior to the pandemic there were major concerns about physician well-being, and the financial pressures and administrative burdens only increased those concerns. Simply put, the continued reductions based on the existing formula make delivering care a worsening challenge that is unsustainable.

This year, the Medicare Payment Advisory Commission (MedPAC) recommended that Congress increase the 2024 Medicare physician payment rate with an inflation-based payment update tied to 50 percent of the Medicare Economic Index (MEI). According to MedPAC, a minority of Medicare beneficiaries have difficulty finding a new provider each year, with more beneficiaries looking for a new specialist physician having greater difficulties finding one than those searching for a new primary care doctor, and of those beneficiaries looking for a new mental health professional, nearly two-thirds struggled to find a provider. The Commission's recommendation to improve the stability of Medicare physician payment recognizes that it is critically necessary to ensure patient access to care is not further hindered by faulty payment policy. In the 2024 Medicare Trustees Report, the trustees also expressed concern with the failure of Medicare payments to keep pace with the average costs of running a practice and warned that they expect access to Medicare-participating physicians to become a significant issue in the long-term. According to the AAMC's projections, by 2036 the country could experience a shortfall of up to 86,000 physicians. These shortages may be exacerbated if physicians face these cuts in payment.

We are concerned that the additional reductions in revenue for physicians combined with workforce shortages could result in even greater access problems for patients. A cut in physician payment will add to the stress and is likely to trigger further retirement or reduction in physician services during a time when physicians are needed the most in their communities. Given these unprecedented challenges and the critical importance of patient access to health care services, we encourage CMS to support stakeholders' efforts urging Congress to pass legislation, including H.R. 2474 (The Strengthening Medicare for Patients and Providers Act) that would provide an annual inflation-based payment update based on the full

³ AMA Snapshot, Medicare updates compared to inflation (2001 – 2024) (2024)

⁴ MedPAC, <u>Report to Congress: Medicare Payment Policy</u>, Chapter 4 (Mar. 2024), specifically noting that roughly one-third of beneficiaries are looking for a specialist compared to roughly 12 percent who looking for a new primary care physician (PCP), thus roughly 4 percent of *all* beneficiaries struggle to find a specialist relative to less than 2 percent of beneficiaries struggling to find a PCP, which suggests that access to specialists is a larger problem for the beneficiaries served under the Medicare program.

⁵ 2024 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (Mar. 2024)

⁶ AAMC, The Complexities of Physician Supply and Demand: Projections From 2021 to 2036 (Mar. 2024).

Medicare MEI. This would help to ensure that physicians and other health care providers can continue to provide high quality care to their patients by giving them crucial short-term financial stability and allowing time for long-term payment reform.

Looking ahead, we believe that there are ongoing structural problems with the Medicare PFS that must be addressed. Medicare provider payments have been constrained for many years by the budget neutral system, which has led to arbitrary reductions in reimbursement. At a minimum, we recommend that budget neutrality policies be revised to ensure that utilization estimates are accurate, that certain categories of services (e.g., newly covered Medicare services, health professions added, new technology, etc.) are exempt from future budget neutrality adjustments, and the \$20 million threshold that triggers budget neutrality is raised to at least \$53 million. We welcome an opportunity to work collaboratively with CMS, Congress, and other stakeholders to address these long-term challenges in the future.

REBASING AND REVISING THE MEDICARE ECONOMIC INDEX (MEI)

In the 2023 PFS rule, CMS finalized a policy to rebase and revise the MEI weights for the different cost components of the MEI to reflect more current market conditions, beginning in 2024. The current MEI weights are based primarily on results from the AMA's Physician Practice Information (PPI) survey, which is based on 2006 data. CMS had planned to use data from the Census Bureau's 2017 Service Annual Survey (SAS) as the primary source for the new weights and to supplement the SAS data with other sources when SAS does not provide the necessary detail. The MEI is used to proportion the components of the resource-based relative value scale (RBRVS) between work, practice expense, and professional liability insurance and to update the Geographic Practice Cost Indices (GPCIs). The use of this new data to determine the MEI weights would result in significant specialty redistribution of payments, in addition to geographic redistribution. CMS delayed implementation of the 2017-based cost weights in the 2024 physician fee schedule rule. Similar to last year, CMS is not proposing to incorporate the 2017-based MEI in rate setting for 2025 due to concerns raised by stakeholders regarding the data source and methodology. (p. 61614)

We support CMS' announcement in the proposed rule to delay the finalized 2017-based MEI cost weights, pending the completion of AMA's PPI survey and the contracted work underway by RAND corporation on analysis and development of alternative methods for measuring practice expense for implementation of updates. While the AAMC recognizes that the data currently utilized for the MEI is outdated and that there is a need to update this data, we had serious concerns with the use of the 2017 SAS data from the "Offices of Physicians" industry, which was not designed for the purpose of updating the MEI. As a result, there are key areas, including physician work, nonphysician compensation, and medical supplies, where CMS would need to use data from other sources. Along with 173 health care organizations, the AAMC supports the AMA's PPI survey, which was launched on July 31, 2023 and anticipated to produce final data by the end of CY 2024. The 2023-24 AMA PPI survey will provide data from more than 10,000 physician practices (including both small practices and large health systems

⁷ CY 2023 Physician Fee Schedule, 87 FR 69404, 69429-69432 (Nov. 18, 2022).

⁸ CY 2024 Physician Fee Schedule, 88 FR 78818, 52271 (Nov. 16, 2023).

and across specialties) on practice costs and the number of direct patient care hours provided by both physicians and qualified health professionals.

Given the significant impact of rebasing and revising the MEI, we recommend that CMS collaborate with the AMA and other physician organizations on this extensive effort to collect new data to ensure that the data used for physician payment is valid and reliable. Additionally, CMS should postpone any updates to the MEI weights using other practice cost data until this new survey data is available for consideration.

PAYMENT FOR MEDICARE TELEHEALTH SERVICES UNDER SECTION 1834(M) OF THE ACT Congressional Telehealth Waivers and Flexibilities

CMS Should Work with Congress to Permanently Implement Telehealth COVID-19 Policies

The AAMC commends CMS for the telehealth waivers, flexibilities, and regulatory changes established in response to the COVID-19 (PHE) that have facilitated the widespread use of telehealth and other communication technology-based services and have improved access to health care. These waivers and flexibilities have increased patient access to care and allowed for a more efficient use of in-person resources. Despite this success, without Congressional action, many of the key telehealth waivers and flexibilities will expire at the end of CY 2024. Expiration of these flexibilities and waivers could reduce access to care, particularly impacting patients in rural and other underserved areas, those with lower socio-economic status, those with disabilities, and those from certain racial and ethnic backgrounds that have historically experienced limited healthcare access. We urge CMS to work with Congress to make permanent, or at a minimum to provide a two-year extension, of the following telehealth flexibilities.

Eliminate the Geographic Location and Originating Site Restrictions

During the COVID-19 PHE, CMS paid for telehealth services furnished by physicians and other health care practitioners to patients located in any geographic location and at any site, including the patient's home. Payment for these telehealth services was then extended until the end of CY 2024¹⁰. This has allowed patients to remain in their home, reducing their exposure to COVID-19 and other infectious diseases, and reducing the risk that they expose another patient or their physician and other health care professionals. It also expands access to care for patients who find travel to an in-person appointment challenging, which may be particularly important to patients with disabilities or chronic conditions who need regular monitoring. It also helps individuals receive care who, because of their job, caregiving responsibilities, transportation issues, and other limitations, find it difficult to attend an in-person visit. The AAMC acknowledges that the geographic location and originating site restrictions are mandated by statute;¹¹ therefore, we urge CMS to work with Congress and other stakeholders to permanently

⁹ Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency, 85 FR 19230 at 19232 (Apr. 6, 2020).

¹⁰ *Supra*, note 8 at 78852.

¹¹ 42 U.S.C §1834(m)

eliminate the geographic and patient location restrictions to allow telehealth services in all locations, including the home.

Expand The Definition of Eligible Telehealth Providers

The COVID-19 pandemic exacerbated existing workforce shortages and intensified the ongoing deficit of healthcare practitioners. Addressing workforce shortages will require a multipronged approach, including innovation in care delivery; greater use of technology; increased Medicare support for Graduate Medical Education; and improved, efficient use of all health professionals on the care team. During the PHE, CMS extended eligible telehealth providers to include physical therapists (PTs), occupational therapists (OTs), speech-language pathologists (SLPs), and audiologists. 12 This expanded definition of eligible telehealth practitioners was then extended until the end of CY 2024. 13 These practitioners have proven that they are able to furnish high-quality care via telehealth effectively, safely, and efficiently to patients. Expanding the definition of eligible providers has resulted in increased access to care, making it obtainable to those who might not otherwise be able to receive it. Patients have come to rely on being able to obtain these services virtually. If PTs, OTs, SLPs, or audiologists are no longer able to furnish telehealth services to patients beyond CY 2024, it will result in lapses in care that may negatively impact patient health. The AAMC acknowledges that the definition of eligible telehealth providers is mandated by statute; 14 therefore, the AAMC recommends that CMS work with Congress and other stakeholders to permanently expand the definition of eligible telehealth providers to include physical therapists (PTs), occupational therapists (OTs), speech-language pathologists (SLPs), and audiologists.

Eliminate the In-Person Visit Requirement for Mental Health Telehealth Services

AAMC commends CMS for providing permanent coverage and payment of telehealth for mental health services. In previous rulemaking, CMS permanently removed geographic restrictions and permitted the home to be an originating site for telehealth services furnished for the treatment of mental health disorders. According to data from the Health Resources and Services Administration (HRSA), as of September 9, 2024, approximately 123 million people currently reside in Mental Health Professional Shortage Areas (HPSAs), and there is a shortage of 6,244 practitioners. The removal of Medicare's geographic and originating site requirements for behavioral telehealth services has significantly increased access to care. According to data from faculty practices participating in the Clinical Practice Solutions Center (CPSC), the use of telehealth for mental health services remained a significant portion of mental health services in 2023, following the end of the COVID-19 PHE. Behavioral health practitioners continue to use telehealth modalities to provide telehealth services at consistently high levels.

¹² COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers (Updated Nov. 13, 2022).

¹³ *Supra*, note 8 at 78874.

¹⁴ *Supra*, note 7 at 70187.

¹⁵ CY 2022 Physician Fee Schedule, 86 FR 64996 at 65058 (Nov. 19, 2021).

¹⁶ Health Resources & Services Administration, Health Workforce Shortage Areas (as of Sep. 9, 2024).

¹⁷ Supra, note 1.

The AAMC believes that the in-person requirements will act as a significant barrier to care for mental health services. Continuation of care is crucial for mental health services, and this inperson visit requirement may result in a lapse of care and ultimately negatively affect clinical outcomes for patients. Mental health services are the only type of service provided by telehealth that would require an in-person visit at a specific interval, which is arbitrary and discriminatory against this particular type of service. Furthermore, the in-person requirement will increase wait times for those in need of an in-person visit due to workforce shortages. It also adds an additional burden of commuting to see the provider. This burden will disproportionally affect those in underserved communities, rural areas and anyone who does not have reliable transportation.

AAMC acknowledges that the statute mandates an initial in-person visit prior to the mental health telehealth visit, as well as a subsequent in-person visit at an interval determined by the Secretary of HHS. ¹⁸ Through previous rulemaking, CMS has established that subsequent in-person visits must occur at 12-month intervals. The AAMC recommends that CMS work with Congress and other stakeholders to permanently remove the in-person visit requirements for mental health telehealth services.

While we are concerned that the in person visit requirements may interfere with continuity of care, the AAMC supports CMS's establishment of an exception to the 12-month in-person visit requirement when the burden to the patient outweighs the potential benefit, to help mitigate the potential for unnecessary and dangerous interruptions in care. ¹⁹

CY 2025 Physician Fee Schedule Telehealth Proposals

CMS Should Ensure Appropriate Payment for Telehealth Services in Line with Statutory Requirements

CMS notes in the proposed rule that section 1834(m)(2)(A) of the statute requires the agency to apply equal payment for services furnished via telehealth as for the service furnished in-person (p. 61653). The AAMC agrees with CMS' interpretation of the statute. Equal payment for telehealth services incorporates the infrastructure and staffing costs, beyond the clinicians' time and clinical expertise. For example, providers must establish a video platform that is HIPAA compliant, accessible, user-friendly, and compatible with patient-owned devices, and that integrates with EHR scheduling and enables multiple concurrent participants (e.g., learners, patients' family members, etc.). Providers must ensure that both they and their patients have sufficient internet access and bandwidth, and in some instances must supply the appropriate devices, for example webcams, headsets, smartphones, for patients and clinicians. They must establish workflows and staffing to ensure effective appointment scheduling, notifications, reminders for providers and staff, and learner supervision, as necessary. Protocols and infrastructure must be in place for managing patients' emergencies. Providers must also offer effective technology training for providers and staff, including real time technical support for providers and patients, with contingency plans in place for when failures occur, as well as private locations where others cannot hear or see the patient during the video visit. Providers also need to employ nurses, medical assistants, and other staff to engage patients before, during, and after

¹⁸ 42 CFR 410.78(b)(4)(iv)(D).

¹⁹ Supra, note 15 at 65059.

telehealth visits to coordinate care pre- and post-visit and ensure a seamless experience. We refer CMS to an AAMC resource document which further describes these costs.²⁰

Align Payment Policies Across Payment Systems

The AAMC strongly recommends that CMS align policies for telehealth and remote services across payment systems. Aligning policies for telehealth and remote services across payment systems, including the PFS and the Outpatient Prospective Payment System (OPPS) ensures that Medicare beneficiaries can have access to telehealth and remote services provided by practitioners in physician offices/clinics and institutional staff in outpatient hospital departments. Specific to coverage and payment for outpatient therapy services, diabetes self-management training, and medical nutrition therapy when furnished by institutional staff in hospitals to beneficiaries in their homes through communication technology, CMS references the CY 2025 OPPS proposed rule. (p. 61637) Patients have come to rely on receiving these services virtually, while practitioners have demonstrated that they can provide these services safely and effectively through audio-video technology. We urge CMS to permanently pay for these services provided by institutional staff and billed by the hospital to promote continuity of care. We provided more detailed recommendations in our comment letter on the CY 2025 OPPS proposed rule. ²¹

CMS Should Add Certain Services to the Medicare Telehealth Services List

In previous rulemaking, CMS streamlined telehealth by creating both a permanent and provisional category, replacing Categories 1, 2, and 3.²² This approach promotes continuity in care and prevents confusion that could arise from various telehealth services that were added to the telehealth list during the PHE expiring at different times. New services can be added to the provisional list when public comments express support for possible clinical benefit, without the required evidence supporting clinical benefit for addition to the permanent list. The provisional list provides time for CMS to gather evidence to determine if a telehealth service can be provided safely, effectively, and efficiently via telehealth. The decision to add or remove services is based on evidentiary support instead of assigning an arbitrary deadline. CMS anticipates conducting a comprehensive review of the entire provisional list in future rulemaking but will not be recategorizing telehealth services during this rule cycle. (p. 61625) CMS is also proposing to add PrEP for HIV (HCPCS G0011 and G0013) to the permanent category and Home INR Monitoring (HCPCS G0248) and the Caregiver Training (CPT® 97550, 97551, 97552, 96202, 96203, GCTD1, GCTD2, GCTD3, GCTB1, and GCTB2) to the provisional category. (p. 61627)

The AAMC strongly supports CMS' proposal to add PrEP for HIV to the permanent category as well as the proposal to add Home INR Monitoring and the Caregiver Training to the provisional category on the telehealth list. Maintaining a permanent Medicare telehealth list, while also allowing services expected to provide a clinical benefit when furnished to patients safely and effectively via telehealth to be on the provisional list, is an efficient and predictable

²⁰ AAMC, Understanding a Video Visit at the Health System Level (2021).

²¹ See, AAMC Comments CY 2025 OPPS Proposed Rule, at p. 7 (Sep. 9, 2024), regarding payment for remote services.

²² Supra, note 8 at 78866.

way for practitioners to provide telehealth services. This consistent and structured approach for additions to the telehealth list greatly benefits practitioners and the patients they serve.

CMS Should Remove Frequency Limitations for Subsequent Inpatient Visits, Subsequent Nursing Facility Visits, and Critical Care Consultation Services Furnished via Telehealth

Before the COVID-19 PHE, telehealth services were restricted to once every three days for subsequent inpatient visits, once every 14 days for subsequent nursing facility visits, and once per day for critical care consultation services. CMS temporarily suspended these limitations during the COVID-19 PHE.²³ CMS then extended the temporary suspension of frequency limitations through the end of CY 2024.²⁴ CMS is now proposing to extend the removal of these frequency limitations through CY 2025. (p. 61631)

The AAMC strongly supports CMS' proposal to extend the removal of these frequency limitations through December 31, 2025; however, we urge CMS to make this proposal permanent to support continuity of care. Returning to these frequency limitations may result in decreased access to care, potentially leading to negative clinical outcomes. We believe that providers are best situated to determine when subsequent inpatient visits, subsequent nursing facility visits, and critical care consultation services furnished via telehealth are medically necessary.

CMS Should Permanently Allow Payment for Audio-only Telehealth Services

During the COVID-19 PHE, CMS established separate payment for audio-only E/M services, CPT® codes 99441-99443.²⁵ CMS recognized these services as telehealth services and added them to the Medicare telehealth list. CMS then continued payment for certain services on the Medicare telehealth list when furnished using audio-video technology through CY 2024.²⁶ CMS is now proposing to permanently allow payment for any of the services on the telehealth list when furnished using audio-only technology. (p. 61632) Under this proposal the practitioner must be technically capable of using audio-video technology, but the patient is not capable of, or does not consent to, the use of video technology. (p. 61632)

The AAMC strongly supports a permanent policy to allow payment for all services on the telehealth list when furnished via audio-only technology. Eliminating coverage for these important audio-only services would result in inequities in access to services for specific populations. Coverage of these audio-only services is particularly important for Medicare beneficiaries who may not have access to, or may not feel comfortable with, interactive audio/video technologies. Analysis by the HHS Office of the Inspector General suggests that lack of video services or discomfort regarding the use of video may particularly affect certain populations, some of whom have high-risk and chronic conditions, including older adults, those who have dually eligible status for Medicare and Medicaid, and certain races and ethnicities.²⁷

²³ Supra, note 9 at 19241.

²⁴ *Supra*, note 8 at 78878.

²⁵ *Supra*, note 9 at 19265.

²⁶ Supra, note 8 at 78874.

²⁷ HHS OIG Data Brief, <u>Certain Medicare Beneficiaries</u>, <u>Such as Urban and Hispanic Beneficiaries</u>, <u>Were More Likely Than Others to Use Telehealth During the First Year of the COVID-19 Pandemic (Sep. 2022)</u>.

Researchers have also noted that audio-only services for Medicare FFS beneficiaries have only decreased from 31% to 25.4% of all telehealth visits between 2020 and 2022, ²⁸ suggesting the critical importance of continuing to allow equitable coverage and payment for audio-only services to Medicare beneficiaries.

In addition, patients in rural and other underserved areas and those with lower socioeconomic status are more likely to have limited broadband access, making it more difficult to receive telehealth services by audio and video interactions. For these patients, their only option to receive services remotely may be through a phone. Not only is audio-only access a health disparities issue, but covering audio-only visits is an important recognition of practitioner effort. The services on the telehealth list can be provided in a clinically appropriate way via an audio-only interaction, and patients and practitioners should be able to choose this option when clinically appropriate.

CMS Should Allow Payment to Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) for Telehealth Services Beyond Non-Behavioral Health Visits

During the COVID-19 PHE, FQHCs and RHC were allowed to furnish Medicare telehealth services to patients in any location, including the patient's home. ²⁹ CMS implemented payment for FQHCs and RHC telehealth services through CY 2024. ³⁰ For CY 2025, CMS proposes to allow RHCs and FQHCs to bill for telehealth services furnished by reporting HCPCS code G2025 on the claim, including services furnished using audio-only communications technology. (p. 84576) The costs associated with non-behavioral health telehealth visits are not included in the calculations for the RHC All-Inclusive Rate (AIR) methodology and FQHC Prospective Payment System (PPS); therefore, CMS believes it is appropriate to create a proxy that would account for the cost of these resources. (p. 84576) CMS will continue to calculate the payment amount based on the average amount for all PFS telehealth services on the telehealth list, weighted by volume for those services reported under the PFS. (p. 84576)

The AAMC recommends that CMS provide adequate payment for telehealth services furnished by FQHCs and RHCs. RHCs and FQHCs have proven that they are able to effectively furnish medically necessary telehealth services and should be allowed to continue to do so. If FQHCs and RHCs are no longer able to furnish telehealth services to patients after CY 2024, this will limit access to care, which may negatively impact patient health.

CMS Should Permanently Allow Practitioners Furnishing Telehealth Services from Home to Use an Enrolled Practice Location with a Valid Reassignment Relationship

During the COVID-19 PHE, CMS allowed practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from the location where they had been enrolled. CMS then extended this flexibility until the end of CY 2024.³¹ CMS now proposes to continue to permit practitioners to use their enrolled

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²⁸ Yu J, Civelek Y, Casalino LP, et al. <u>Audio-Only Telehealth Use Among Traditional Medicare Beneficiaries</u>. *JAMA Health Forum*. (May 10, 2024).

²⁹ Supra, note 9 at 19254.

³⁰ *Supra*, note 8 at 79066.

³¹ *Id.* at 78874.

practice location instead of their home address when providing telehealth services from their home through CY 2025. (p. 61633) According to CMS, given the shift in practice patterns toward models of care that include the practitioner's home as the distant site, it would be appropriate to continue this flexibility as they consider various proposals that may better protect the safety and privacy of practitioners. (p. 61633)

The AAMC supports the proposal to continue to permit practitioners to use their enrolled practice location instead of their home address when providing telehealth services from their home through CY 2025. However, we strongly recommend that CMS make this proposal permanent. Requiring reporting of practitioner's home addresses for enrollment is likely to discourage practitioner's from providing telehealth services from their home, limiting access to care. As CMS notes, practitioners have expressed privacy and safety concerns associated with enrolling their home address. They fear the unintended consequences of their personal information becoming available to the public, especially if it is displayed on Medicare websites that include physician look-up features, such as *Care Compare*. There has been an increased trend toward violence against physicians and other health care professionals in recent years. The inclusion of a physician's home address poses a potential threat for a physician and their family.

In addition to privacy and safety concerns, this requirement poses operational challenges and creates an undue administrative burden to update and change provider addresses. Updating the 855B forms or PECOS to include home addresses of the many practitioners that are employed by large multispecialty practices would be challenging, particularly as practitioners join and leave the group practice or move to new homes. This policy complicates the Medicare Administrative Contractor (MAC) assignment if the home is located in a different MAC jurisdiction than the practitioner's physical office location. In such cases, the group practice would be required to enroll with multiple MACs to ensure practitioners receive payment at the payment amount for services based on where they are located when performing telehealth services. This policy does not consider where the practitioner performs the telehealth services (i.e., their home) may differ from where the patient is located and from the location where the practitioner generally practices and is licensed.

Removing this requirement would make it more feasible for practitioners to provide safe and effective telehealth services from their homes and expand access to medically necessary care by increasing the availability of practitioners. Practitioners could be available to furnish telehealth services during extended hours and on weekends. Access to specialists for which there are shortages would be improved. Additionally, patients with urgent clinical needs outside of business hours would be able to receive care.

Provider enrollment requirements are designed to protect the Trust Fund by ensuring the accuracy of payments and that providers meet appropriate qualifications and requirements for participation in the Medicare program. We believe that if there is a valid reassignment relationship between the remote practitioner and a Medicare-enrolled practice with a physical

³² O'Brien, et al, <u>The growing burden of workplace violence against healthcare workers: trends in prevalence, risk factors, consequences, and prevention – a narrative review, eClinical Medicine (Jun. 2024).</u>

office location where care is delivered to patients, safeguards would be in place. The benefits of providing telehealth to patients far outweigh any compelling reason to require enrollment of home addresses.

Given the privacy and safety concerns and operational challenges, if a practitioner is enrolled in Medicare and reassigns payment to a physical office location where he or she practices, CMS should not require that practitioner to enroll other addresses, such as their home, where they provide telehealth services.

Permanently Allow Direct Supervision Through Virtual Supervision

Direct supervision is required for various types of services, including most incident-to services, and many diagnostic tests. Generally, direct supervision requires the supervising practitioner to be immediately available within the office suite. During the COVID-19 PHE, CMS adopted a policy on an interim basis that direct supervision for services billed "incident to" a physician service could be met through virtual supervision. 33 CMS then extended this policy to the end of CY 2024. 4 CMS proposes to continue to define direct supervision to permit the presence and "immediate availability" of the supervising practitioner using audio-video technology through CY 2025. (p. 61633) CMS also proposes to permanently allow audio-video direct supervision requirements for services furnished incident to a physician or other practitioner's service when provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision, and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5' and; services described by CPT code 99211 (office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional. (p. 61633)

The AAMC strongly supports continuing to define direct supervision to permit the presence and "immediate availability" of the supervising practitioner using audio-video technology through CY 2025. The AAMC also supports CMS permanently allowing direct supervision services that are identified with a PC/TC indicator of '5' and CPT code 99211 as we agree that these services inherently pose lower risk. We thank CMS for adopting these virtual supervision policies because they enable expanded access to health care services while reducing risk of exposure to all infectious diseases (e.g., coronavirus, seasonal flu, and others). Our members have found virtual supervision of clinical staff to be safe and effective, and improved access to care.

Allow Virtual Supervision of Residents for Both Telehealth and In-person Services

During the COVID-19 PHE, CMS allowed the supervisory requirement for teaching physicians "to be present for the key portion of the service through real-time audio/ video technology" (herein referred to as virtual supervision) for both services when the resident and patient are together in-person (herein referred to as in-person services) and telehealth services in all residency training locations.³⁵ In previous rulemaking, CMS finalized a policy to permanently

³³ *Supra*, note 9 at 19246.

³⁴ *Supra*, note 8 at 78882.

³⁵ *Supra*, note 9 at 19259.

allow virtual supervision of residents in training sites located in non-Metropolitan Statistical Areas (non-MSAs). ³⁶ CMS stated that this policy would improve access to care in these underserved areas. In previous rulemaking, CMS also extended the COVID-19 flexibility to allow virtual supervision of residents furnishing telehealth services in all residency training locations through CY 2024. ³⁷ CMS is now proposing to allow virtual supervision of residents for telehealth service in any residency training location through CY 2025. (p. 61635) This proposal does not include virtual supervision of **in-person** services.

The AAMC strongly supports the proposal to allow virtual supervision of residents for telehealth services in all residency training locations through the end of CY 2025. However, we urge CMS to allow virtual supervision of residents for both in-person and telehealth services in all residency training locations permanently. At a minimum, CMS should allow virtual supervision of residents for both in-person and telehealth services in underserved areas, as well as in non-MSAs.

Residents have been virtually supervised safely and effectively during the PHE, for both inperson and telehealth services. In both cases, the teaching physician is present virtually during key and critical portions of the service through interactive audio/video real time communications technology, and both the attending physician and resident have access to the electronic health record. Teaching physicians render personal and identifiable physician services and exercise full personal control over the management of the care for which payment is sought. CMS requires that the documentation in the patient's medical record must clearly reflect how and when the teaching physician was present during the key and critical portion of the service, along with a notation describing the specific portions of the service for which the teaching physician was virtually present. After the visit, if medically necessary, the teaching physician continues to engage with the patient through phone calls, messages, video updates, study reviews, and collaboration with other providers.

The use of telehealth has been of great benefit for patients, both during and after the PHE. It maintains and expands access to safe and effective care, particularly for patients in rural and other underserved areas, those with lower socio-economic status, those with disabilities, the elderly, and those from certain racial and ethnic backgrounds that have historically experienced limited healthcare access. It also helps those who, because of their job, lack of care for dependents, transportation issues, and other limitations, find it difficult to attend an in-person visit to receive care. Furthermore, physicians can effectively use telehealth to monitor the care of patients with chronic conditions, such as diabetes and heart conditions, reducing their risk of hospital admissions. Telehealth also protects patients from exposure to infectious diseases, such as COVID-19 and the seasonal flu. Allowing residents to provide these telehealth services while being supervised virtually further expands access and promotes training opportunities.

As part of their training, it is essential for residents to have experience with providing telehealth services, as they will be providing them to their patients independently in the future to ensure that they are adequately trained before they enter the physician workforce. Virtual supervision of

³⁶ CY 2021 Physician Fee Schedule, 85 FR 84472 at 84582 (Dec. 28, 2020).

³⁷ *Supra*, note 8 at 78882.

residents allows the teaching physician and residents to provide telehealth services safely and effectively from different locations. They interact with the patient virtually, receiving real-time information from the patient simultaneously. This enables the supervising physician to take an active role in patient evaluation and treatment. Video platforms allow the resident and teaching physician to communicate seamlessly by sending real-time private messages to each other and/or by meeting virtually face-to-face in a private breakout room separated from the patient. As a result, the teaching physician and resident do not need to be in the same room. The need and demand for these services is expected to increase as remote digital tools for at-home health monitoring continue to expand, and the population continues to age, resulting in transportation and mobility challenges.

Virtual supervision of in-person services improves access to care by bringing more care directly where patients are and allowing teaching physicians to oversee care across multiple locations. It also offers the added advantage of having residents onsite with the patient to facilitate audio/video communication and observations for the remote teaching physician. An example of the benefits of virtual supervision of an in-person service is where a psychiatric resident is caring for patients overnight in the emergency department and evaluates a patient with the attending psychiatrist remotely supervising through a secure platform. This teaching physician can communicate directly with the patient and the resident and has access to the patient's medical record. Under such an arrangement, the attending psychiatrist would be available in the case of a psychiatric emergency to virtually supervise the resident involved in the patient's care, thereby increasing access.

Additionally, training programs have increased the practice of sending residents to medically underserved areas for rotations. For example, residents may be involved in providing care to patients through mobile treatment units and in hospital at home programs. During the COVID-19 PHE, teaching physicians and residents have demonstrated their ability to effectively provide care through virtual supervision, which improves access, ³⁸ outcomes and patient satisfaction, ³⁹ through these mobile service lines. Not allowing virtual supervision could impact mobile training programs to the extent they will no longer be able to continue if teaching physicians were required to be physically present at mobile locations.

While we appreciate that CMS finalized a policy to increase access by allowing virtual supervision of residents for both in-person and telehealth services in non-MSAs, it is important to recognize that significant workforce shortages are also impacting access to care in MSAs. According to data from the HRSA, 123 million people currently reside in a Mental Health HPSAs and there are 6,244 fewer practitioners than are needed. Approximately 32% of Mental Health HPSAs are located in non-rural areas and 6% are in partially non-rural areas. Currently, 75 million people reside in a Primary Care Shortage Area and there are 13,166 primary care

³⁸ How Do Mobile Health Clinics Improve Access to Health Care? Tulane University School of Public Health and Tropical Medicine Blog (Jun. 2021).

³⁹ Caplan GA, et al, <u>A meta-analysis of "hospital in home</u>," Med J Aust. (Nov. 2012).

⁴⁰ *Supra*, note 16.

⁴¹ *Id*.

practitioners that are needed. 42 Additionally, a March 2024 report from the AAMC predicts a shortage of up to 86,000 physicians by $2036.^{43}$

These shortages have a real impact on access to care for all patients. During the PHE, specialties such as Psychiatry and Behavioral Health, Family Medicine, Internal Medicine, Primary Care, Endocrinology, Dermatology, Nephrology, Allergy/Immunology, Radiology, Cardiology, Infectious Diseases, and more have provided high-quality oversight through virtual supervision for both in-person and telehealth to help ensure access to care. Teaching physicians have more time to educate residents and provide comprehensive patient care, ultimately improving patient outcomes. For example, allowing teaching physicians to supervise residents virtually increases the availability of the teaching physician, including extended weekday and weekend hours to address patient needs. They can continue to supervise residents even when experiencing periods of quarantine or mild illness. Additionally, this policy helps residency programs access a broader diverse pool of experienced teaching physicians and specialists and reduces provider burnout by allowing them to practice more efficiently, for example, by reducing travel time.

Guardrails exist through the Accreditation Council for Graduate Medical Education (ACGME) and other accrediting organizations that have standards and systems that will ensure patient safety and oversight of residents when virtual supervision of residents occurs for both in-person and telehealth services. ACGME sets forth extensive program requirements, including requirements related to supervision. ⁴⁴ ACGME recognizes that direct supervision occurs when either the supervising physician is physically present with the resident during the key portions of the patient interaction; or the supervising physician and/or patient is not physically present with the resident and the supervising physician is concurrently monitoring the patient care through appropriate telecommunication technology. 45 The program must also demonstrate that the appropriate level of supervision is in place for all residents and is based on each resident's level of training and ability guided by milestones, as well as patient complexity and acuity. 46 The faculty must assess the knowledge and skills of each resident and delegate to the resident the appropriate level of patient care authority and responsibility, and each resident must also know the limits of their scope of authority. Teaching physicians are ultimately responsible for determining the level of supervision required and any adverse events that occur. ACGME, other accrediting organizations, and the medical education community work hard to monitor, report, and address any issues related to workload, patient safety, medical error, resident well-being and burn-out, professionalism, and resident learning and outcomes.⁴⁷

The AAMC supports the current exclusion from direct supervision by interactive telecommunications technology of surgical, high risk, interventional and other complex procedures, endoscopies, and anesthesia services. For these services, we believe that the requirement for the physical presence of the teaching physician for the entire procedure or the key portion of the service with immediate availability throughout the procedure, is necessary for

⁴² *Id*.

⁴³ Supra, note 6.

⁴⁴ ACGME Common Program Requirements

⁴⁵ *Id*.

⁴⁶ *Id*.

⁴⁷ *Id*.

patient safety given the risks associated with these services. When providing these types of services, a patient's clinical status can quickly change and there is a need for the rapid onsite decision-making and procedural skills of the supervising physician.

It is imperative that we continue with the progress in improving access that has been made during the PHE. We urge CMS to allow virtual supervision of residents in all geographic regions for in-person services and telehealth services that may be furnished safely and effectively.

Request for Information: Teaching Physician Services Furnished under the Primary Care Exception (PCE)

The PCE currently permits teaching physicians to bill for certain lower and mid-level complexity E/M services performed by residents without being present with the resident, under certain conditions: residents must have more than six months of training and a teaching physician must assume management responsibilities, may not supervise more than four residents at a time, may not have any other responsibilities while directing the care, must be immediately available to the resident, and must review the key elements of the patient encounter with each resident during or immediately after the visit.⁴⁸ Specifically, CMS allows teaching physicians to receive payment for E/M CPT codes 99202, 99203, 99211-99213 and annual wellness visits (HCPCS codes G0402, G0438, G0439) when the resident furnishes these services under the PCE. For residency training sites located in areas outside of an MSA, CMS also permits teaching physicians to receive payment for the following additional services when furnished by the resident under the PCE: e-visits (CPT codes 99421–99423), interprofessional consultation (CPT 99452), virtual visits (HCPCS codes G2010 and G2012), and Medicare telehealth services. 49 Under the current policy, services must be provided in a primary care center within the hospital outpatient department, or clinical training site that is included in a teaching hospital's direct graduate medical education (DGME) program.⁵⁰

During the COVID-19 PHE, CMS temporarily expanded the PCE to allow teaching physicians to bill for higher level 4 and 5 E/M codes. As stated above, when the COVID-19 PHE ended on May 11, 2023, the PCE was once again limited to services of lower and mid-level complexity, and teaching physicians practicing in residency training locations within MSAs could no longer receive payment for e-visits, interprofessional consultation, virtual visits, and Medicare telehealth services furnished by the resident under the PCE.

The AAMC commends CMS for its efforts to expand access to care and training opportunities and prevent the spread of COVID-19 through the expansion of the PCE during the PHE. We thank CMS for the opportunity to provide feedback on the potential for further expansion.

Expand the PCE to Include Level 4 E/M Visits

The AAMC recommends that CMS expand the PCE to include level 4 E/Ms (99204 and 99214) for all residents. CMS limited it to CPT codes 99201-99203 and 99211-99213 when it established the PCE in the mid-1990s. This limitation was appropriate at that time because CPT

⁴⁸ 42 CFR § 415.174.

⁴⁹ *Supra*, note 36 at 84588.

⁵⁰ 42 CFR § 415.174(a)(1).

codes 99204 and 99214 described complex visits that often involved patients with acute or unstable chronic conditions that required a higher level of physician participation in the care. Since that time, there has been a significant change to the CPT codes describing E/Ms. Today, in general, the level of an E/M can be selected based on time or medical decision making (MDM) of the physician or qualified health practitioner. However, under the PCE, CMS limits level selection to MDM in order to prevent inappropriate coding for services as a result of the additional time a resident in training may need as compared to a non-resident physician in order to furnish a service. In order to bill a level 4 E/M under MDM at least two of the three elements must be met: moderate number and complexity of problems addressed; moderate amount and/or complexity of data to be reviewed and analyzed; or moderate risk of complications and/or morbidity or mortality of patient management. We believe that the MDM described by CPT codes 99204 and 99214 (which is moderate complexity) does not involve a complexity that is beyond the resident's competency to provide under the PCE's required level of supervision.

Furthermore, residents are required to demonstrate competency in the services offered before they can utilize the PCE. The Accreditation Council for Graduate Medical Education (ACGME) has put in place requirements that ensure that residents are properly trained and supervised to ensure safety and quality of care. In 2023, the ACGME updated its requirements to state that every residency curriculum must include "competency-based goals and objectives for each educational experience to promote progress on a trajectory toward autonomous practice." The guidance supports tailoring the supervision of each resident according to their level of competency, training, and specialty. The teaching physician is still required to use their professional judgement when determining the appropriateness of the resident providing this level of care to the patient.

The PHE provided a valuable testbed for assessing the viability of expanding the PCE to include higher-level E/M visits. During the PHE, these services were performed competently, safely, and effectively by residents under the PCE. **Based on this trial phase, and for the reasons discussed above, we believe that the PCE can safely and effectively be expanded to include level 4 E/Ms permanently.**

Expand the PCE to Include Level 5 E/M Visits for PGY3 Residents

For residents that have completed two years of residency (PGY-3), we recommend expanding the primary care exception to include level 5 E/Ms. In order to bill a level 5 E/M under MDM at least two of the three elements must be met: high number and complexity of problems addressed; high amount and/or complexity of data to be reviewed and analyzed; or high risk of complications and/or morbidity or mortality of patient management.⁵⁴ By PGY-3, with two years of training completed, residents have enough experience to provide level 5 E/M safely and effectively under the PCE. Allowing PGY-3s to provide level 5 E/M services would also prepare residents for the transition to independent clinical practice. It would allow residents to take on increased responsibility and autonomy, which would build confidence and enhance the

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⁵¹ *Supra*, note 15 at 65167.

⁵² CPT E/M Office Revisions Level of Medical Decision Making (MDM) (Jan. 2021).

⁵³ Accreditation Council for Graduate Medical Education (July 2023).

⁵⁴ Id

skills of the resident while maintaining appropriate oversight. The teaching physician would ultimately be responsible for determining the appropriateness of the resident providing this level of care to the patient.

Expand the List of Primary Care Services Covered under the PCE

During the PHE, CMS permanently expanded the PCE to include: Medicare telehealth services, online digital E/M services (CPT 99421–99423), interprofessional telephone/internet/electronic health record consultation (CPT 99452), remote evaluation of recorded video and/or images submitted by an established patient (HCPCS G2010) and brief communication technology-based service (HCPCS G2012) for residency training sites located in a non-MSA. The AAMC appreciates that permanently expanded access to these services under the PCE in non-MSAs. We recommend that CMS allow these services to be provided under the PCE in all geographic regions. Including these services under the PCE in all geographic locations increases access to care, enables training opportunities for residents, and is safe and effective.

In addition, we support the addition of the following services to be covered under the PCE:

- Transitional Care Management (CPT 99495),
- Advance Care planning (99497),
- Chronic Care Management Services (99490),
- Office/Outpatient E/M Visit complexity add on code(G2211)
- Annual depression screening (HCPCS G0444),
- Annual alcohol misuse screening (G0442),
- Brief face-to-face behavioral counseling for alcohol misuse (HCPCS G0443),
- Smoking and tobacco use cessation counseling visit (CPT 99406),
- Smoking and tobacco use cessation counseling visit (CPT 99407),
- Annual face-to-face intensive behavioral therapy for cardiovascular disease (HCPCS G0446),
- Face-to-face behavioral counseling for obesity (HCPCS G0447),
- Chronic Care Management services (CPT 99490, 99439, 99491 and 99437),
- Complex Chronic Care Management services (CPT 99487 and 99489),
- Advance Care Planning (CPT 99497 and 99498),
- Home visits, new patient (CPT 99341-99344),
- Home visits, established patient (CPT 99347-99349),
- Virtual check-in service (CPT 9X091), if finalized in this rulemaking to replace G2012, and
- Advanced Primary Care Management services (HCPCS GPCM1, GPCM2, GPCM3), if finalized in this rulemaking.

It is important for residents to obtain the necessary experience to become primary care physicians that provide team-based care and to collaborate with other providers and settings to integrate care. Allowing these services to be provided under the PCE will enable them to enhance

⁵⁵ *Supra*, note 36 at 84588.

their skills and expand access to these important services. Regarding preventive services, residents with an ongoing relationship with the patient can be helpful in encouraging their patients to receive these high value services.

Permanently expanding PCE to include the above-mentioned services would also significantly enhance access to care while broadening training opportunities for the future physician workforce. With a projected national shortage of up to 40,000 primary care physicians by 2036, increasing patient access through expanded teaching physician services could help address future shortfalls. ⁵⁶ Additionally, residents would benefit from increased training opportunities, allowing them to provide higher complexity E/M visits and a wider array of services.

VALUATION OF SPECIFIC CODES

Continue Current Policy of Not Applying Any Budget Neutrality Associated with Changes in Utilizations for Telehealth Services

CMS seeks feedback on the agency's historical policy of not considering "changes in Medicare telehealth policies to result in significant impact on utilization such that a budget neutrality adjustment would be warranted." (p. 61654) Historically, CMS only considers service utilization when determining budget neutrality if there is a price/RVU change associated with a given service. CMS did not change the RVUs or prices for any PFS services when it used the COVID-19 PHE waiver authority under section 1135 of the Act to pay for telehealth services in additional circumstances. Therefore, budget neutrality has appropriately not applied to any additional utilization associated with the telehealth waivers. The AAMC recommends CMS continue this policy in the future.

Finalize a New Add-on Complexity Code for Hospital-based Infectious Diseases Services

CMS proposes to establish additional payment for infectious disease physicians' services with a new HCPCS add-on code for CY 2025 to describe the intensity and complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease. (p. 61663) CMS expects that this code would be reported by physicians with specialized infectious disease training capable of providing disease transmission risk assessment and mitigation; public health investigation, analysis, and testing; and complex antimicrobial therapy counseling & treatment. CMS proposes to value the code to match the existing G2211 complexity add-on code. (p. 61664) **The AAMC supports this proposal in recognition of the services infectious disease doctors provide both for the patient and for broader public health goals.** Infectious disease physicians practicing in the hospital setting are unable to bill the existing G2211 complexity add-on code, as it is limited to the outpatient/office setting and intended for ongoing patient care relationships. Appropriately valuing and compensating for the work of infectious disease specialists in part with this new add-on code could help drive better patient and public health outcomes, as well as reduce overall costs to the healthcare system.⁵⁷

⁵⁶ Supra, note 6.

⁵⁷ Schmitt et al., <u>Early Infectious Diseases Specialty Intervention Is Associated With Shorter Hospital Stays and Lower Readmission Rates: A Retrospective Cohort Study, Clinical Infectious Diseases, Vol. 68, Issue 2 (Jan. 2019)</u>

Finalize the Work RVUs for CAR-T Therapy Services and Identify an Adequate Practice Expense Value that Accounts for the Costs Associated with These Services

In September 2023, the CPT Editorial Panel deleted four category III codes (0537T–0540T) and approved the addition of four new category I codes (3X018–3X021) that describe steps of the complex chimeric antigen receptor T-Cell (CAR-T) therapy process performed and supervised by physicians. These codes describe cell collection, cell processing, dose preparation, and administration of the CAR-T therapy biologic. Cell collection and processing occur before the cells are sent to the drug manufacturer to genetically engineer the patient's T-cells with the appropriate chimeric antigen receptors. Once the modified cells are prepared, the manufacturer sends the cells back to the treatment center, which then prepares the dose, prior to administering the treatment to the patient.

The RUC recommended four different work relative value units (RVUs) for these four new codes and only recommended a direct practice expense (PE) value for code 3X021. It did not recommend a non-facility PE value for codes 3X018-3X020 but recommended that the nonfacility PE RVU for these codes be contractor-priced. 59 CMS proposes to adopt the RUCrecommended work RVUs for all four CPT codes, as well as both the work and PE values for 3X021. (p. 61645) However, CMS says that contractor pricing can only be applied at the whole code level and not to a single component of the valuation (e.g., the practice expense). We thank CMS for accepting the CPT codes for CAR-T and adopting the RUC's recommendations on the work RVUs for these codes. To the extent that these services are provided in the non-facility setting, we urge CMS to collaborate with physicians and facilities that provide CAR-T to identify an adequate practice expense value that accounts for the costs associated with these procedures. Innovative gene and cell therapies, such as CAR T-cell therapy are revolutionizing the treatment landscape, offering potential cures for previously untreatable diseases. While CAR T-cell therapy is mostly provided in the inpatient setting, its use in the outpatient setting is increasing. 60 To expand access to these services and ensure practitioners are adequately reimbursed for their costs, CMS should finalize its proposed work RVUs for the four CAR-T therapy codes and adopt practice expense RVUs for the remaining three codes (3X018, 3X019, 3X020).

EVALUATION AND MANAGEMENT (E/M) VISITS

Allow Providers to Bill the Complexity Add-on Code for Preventive E/M Visits Reported with Modifier -25 to Support Longitudinal Patient Care Relationships

Last year, CMS finalized the effectiveness of the G2211 complexity add-on code beginning January 1, 2024. The policy specified that the code would not be paid when the E/M visit is reported with a payment modifier -25.61 CMS now changes course and proposes to allow

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and Schmitt et al, <u>Infectious Diseases Specialty Intervention Is Associated With Decreased Mortality and Lower Healthcare Costs</u>, Clinical Infectious Diseases, Vol. 58, Issue 1 (Jan. 2014).

⁵⁸ American Medical Association, CPT Editorial Summary of Panel Actions, (May 2023).

⁵⁹ AMA/Specialty Society RVS Update Committee Meeting Minutes, (Sep. 28-30, 2023).

⁶⁰ The Impact of Outpatient versus Inpatient Administration of CAR-T Therapies on Clinical, Economic, and Humanistic Outcomes in Patients with Hematological Cancer: A Systematic Literature Review.

⁶¹ Supra, note 8 at 78974.

payment for the G2211 add-on code where the E/M visit is for the annual wellness visit, preventive vaccine administration service, or Medicare preventive service and is reported with a payment modifier -25. (p. 61697) CMS believes this is appropriate regarding the intent of the code to recognize the inherent costs of building trust with the patient to deliver longitudinal care. The AAMC agrees and we support this policy proposal to acknowledge the alignment of these codes with the intent of the complexity add-on code.

ENHANCED CARE MANAGEMENT

In this section of the proposed rule, CMS proposes new policies to recognize and support care delivery practices that improve patient experience and enhance quality of care. Specifically, CMS proposes new codes to support advanced primary care, seeks feedback on future hybrid payment models for advanced primary care, establishes new codes to support care for patients at risk for atherosclerotic cardiovascular disease, and proposes to amend policies for global surgery payment codes. The AAMC's comments to each policy concept within this section follow.

Advanced Primary Care Management Services

The AAMC strongly supports efforts to use payment levers to improve access to high quality primary care services and to better support practices delivering comprehensive services to their patients. CMS proposes to establish three new HCPCS codes for Advanced Primary Care Management (APCM) to describe and pay for a set of care management services and communications technology-based services (CTBS) furnished when the practitioner is the continuing focal point for all needed health care service and is responsible for all primary care services. In doing so, CMS recognizes the broader range of services and simplifies billing requirements relative to existing care management and CTBS codes for practices able to meet capabilities for delivering advanced primary care. (p. 61702) The AAMC commends CMS for crafting payment policy to support advanced primary care and urges the agency to modify these new codes and payment policy based on stakeholder feedback and clinicians' experiences.

Ensure That Practice-level Capabilities Appropriately Align to Best Support Practice Uptake of the New Codes to Best Serve Medicare Patients

CMS proposes an expansive list of service elements and practice capabilities a practice must support and be able to deliver to patients for whom it bills the APCM service codes, including 24/7 access to care; practitioner, home-, and community-based care coordination; enhanced communication options; population-level management; and performance management. (pp. 61709-61710) Clinicians participating in primary care-focused alternative payment models and clinicians participating in accountable care organizations (ACOs) in the Medicare Shared Savings Program (SSP) will be assumed to meet the practice requirements for population-health management and data analytics as well as performance management through existing quality measurement requirements in the other program and model requirements. Specific to performance management, clinicians not in APMs or SSP ACOs will be required to report the Value in Primary Care MIPS Value-Pathway (MVP) as a condition of billing the APCM codes. (p. 61710).

The AAMC appreciates the thorough cataloguing of practice-level capabilities for delivering advanced primary care and we agree that high-level primary care requires certain investments in redesign care delivery and enhanced opportunities for patient-centered care communications and coordination. However, we are concerned that the extent to which CMS will require such practice-level capabilities for billing these new codes may significantly limit their use, similar to the Chronic Care Management (CCM), Principal Care Management (PCM), and Transitional Care Management (TCM) codes. 62 Some AAMC members have expressed interest in these new APCM codes but are concerned about the upfront investment to implement the robust practicelevel capabilities in order to bill these codes. And those that might be further along in that care re-design are concerned with the documentation burden to ensure that their practice-level capabilities are fully represented in the medical record to support billing for the new APCM codes. CMS should consider modifications to the practice-level capability requirements in response to stakeholder feedback to ensure APCM services are best set up for success in serving Medicare patients and their families. This could include allowing practices to attest to meeting all capabilities through ACO participation, NCQA Patient-Centered Medical Home recognition, 63 or state Medicaid Advanced Medical Home status rather than trying to document capabilities for each patient in the medical record.⁶⁴

Support Specialist Engagement in Advanced Primary Care Within Large Multispecialty Practices by Removing Consulting Physician Services from the List of Duplicative Services

CMS believes that certain care management and CTBS are substantially duplicative of APCM services and proposes that no clinician could bill for those duplicative services for any patient for which the clinician or another clinician in the same practice bills the APCM services. A full table of services is in Table 22 and includes CPT® codes 99446-99449 and 99451, the interprofessional consultation codes used by a consulting physician (specialist) to report their effort to access data/information and provide a written report with their recommendations to the requesting physician. (p. 61720) **The AAMC strongly believes these codes should not be included in the list of duplicative services, as it could chill specialist support for advanced primary care within the same multispecialty practice.** Faculty practices are large multispecialty practices that provide multidisciplinary, team-based care. These practices range from a low of 46 specialties/ subspecialties to a high of 212, with a median number of 142 specialties/subspecialties, that are typically included under one group practice TIN. ⁶⁵ Advanced primary care service should encourage primary care physicians to seek consultations when clinically necessary and coordinate care with specialists inside their practice, and those specialists should be reimbursed when supporting their primary care colleagues.

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⁶² Senate Committee on Finance, <u>Bolstering Chronic Care through Physician's Payment: Current Challenges and Policy Options in Medicare Part B</u>, p. 19 (May 17, 2024), citing evidence that only 4 percent of eligible Medicare beneficiaries are enrolled in CCM services and that quantification and billing requirements are responsible for the low uptake of the CCM code.

⁶³ See, NCOA, Patient-Centered Medical Home (PCMH) Recognition.

⁶⁴ See, for example, North Carolina Medicaid, <u>Advanced Medical Home</u>.

⁶⁵ Supra, note 1.

Base APCM Code Levels on the Number of Chronic Conditions a Patient is Managing and Create an Add-On Payment for Patients who are Qualified Medicare Beneficiaries

In Table 20 of the proposed rule, CMS proposes a patient-centered risk stratification for billing APCM codes, where Level 1 would be for patients with one or fewer chronic conditions, Level 2 for patients with two or more chronic conditions, and Level 3 for patients with two or more chronic conditions and who are Qualified Medicare Beneficiaries (QMBs). (p. 61706) The **AAMC supports CMS taking a patient-centered approach to risk stratification for setting the billing levels for APCM services.** We suggest CMS modify the proposed approach and instead determine each Level solely based on a patient's chronic conditions, as currently set for Levels 1 and 2, and modify Level 3 to three or more chronic conditions. Then, in addition, have an add-on adjuster, applicable at any Level, for a patient's QMB status, to reflect patients who are more medically complex and have higher healthcare needs. This would allow appropriate payment based on chronic conditions, while also recognizing that some patients who are QMBs might not have two or more chronic conditions (and yet still have higher healthcare needs) and that other patients who do not have QMB status might be managing multiple chronic conditions and require the highest level of APMC services. ⁶⁶

Conduct Greater Research to Determine Appropriate Values for the APCM Codes

CMS proposes to crosswalk each level APCM code to an existing CPT® code or codes, or in the case of GPCM3, as a relative increase from GPCM2. Altogether, CMS approximates a national payment rate ranging from \$10 per month to \$110 per month for CY 2025 payment. (p. 61723) The AAMC is concerned that the proposed cross walking and valuation does not fully reflect the full resources and infrastructure necessary to furnish these services given the service elements and requisite practice-level capabilities. For example, the GPCM1 code is cross walked to CPT® 99490, which for non-complex CCM services pays nearly \$63 per month. Similarly, the GPCM2 code includes a crosswalk to CPT® codes 99490 and 99487 (complex patient), which vary in national payment from \$62.58 to \$134.15 per month in 2024.⁶⁷ (p. 61723) It is unclear why a practice would choose to make such investments in APCM services, when they could instead focus on existing CCM services with significantly more remuneration and less upfront investment in infrastructure and service re-design. This is to say nothing of the fee-for-service billing the practice would elect to forgo under APCM services for CTBS codes when providing comprehensive care management and enhanced communication opportunities to patients. Altogether, we are concerned that the potentially significant undervaluation proposed for these codes will significantly limit their use and reduce the availability of advanced primary care delivery for Medicare patients. To this end, we recommend that CMS conduct further research on the resources necessary to deliver advanced primary care to determine appropriate values for the APCM codes.

⁶⁶ Peña, M, et. al., <u>A profile of Medicare-Medicaid Enrollees (Dual Eligibles)</u>, KFF (Jan. 31, 2023), finding that 54% of Medicare beneficiaries without Medicaid coverage have 3 or more chronic conditions and that 37% of Medicare beneficiaries with QMB status have zero to two chronic conditions.

⁶⁷ See, CMS PFS Look up Tool.

RFI: Advanced Primary Care Hybrid Payment

The AAMC supports innovative payment design to better support primary care providers (PCPs) and the critical services they deliver to patients. Testing hybrid payments in primary care offers an opportunity to improve the financial sustainability of primary care practices, creates an environment to address provider burnout and workforce shortages, and facilitates the adoption of team-based primary care and innovative ways to address health equity. These payments would allow practices to determine how best to provide care outside of in-person visits, especially with the rapidly evolving digital health space, and could help spur innovation and leverage team-based approaches to care. Careful design consideration is imperative to ensure patients have access to high-quality, high-value care coordination services, and that providers receiving hybrid payment continue to treat all and do not avoid high-need or high-risk patients. Additionally, the design of the hybrid payments must reduce challenges associated with managing both volume-based and value-based care payments and models and ensure participating providers do not have increased reporting requirements that detract from patient care. Hybrid payments alone are unlikely to transform primary care delivery as transformation will require additional policy reforms to address broader issues with the Medicare physician payment policy, like the lack of an inflationary adjustment for annual updates to the conversion factor, budget neutrality constraints, and ensuring that the Quality Payment Program appropriately measures and rewards physicians for providing high value care. Finally, given the limited time to provide feedback through the comment period, we encourage CMS to continue to solicit ongoing feedback for hybrid payment design. We look forward to continuing to provide input to CMS on this work.

Implement Hybrid Payments for Advanced Primary Care Through Total Cost of Care Alternative Payment Models

Considering the potential benefits and risks of a hybrid payment model, we encourage CMS to consider limiting their design to be within total cost-of-care alternative payment models (APMs), like accountable care organization (ACO) models and programs, rather than as a standalone model or payment system. This would have two primary benefits: reduce design complexity and provide additional incentives to participate in such models as existing AAPM bonus payment incentives wind down. Several of the questions note the design challenges with an additive hybrid payment model – attribution, appropriate service utilization, beneficiary access to care, quality measurement, and data sharing to support population health management. Those facets are already designed within total cost-of-care AAPMs and would allow hybrid payments to complement high-value care and reduce the burden for primary care participants in AAPMs. Additionally, the agency has already begun to model this concept with the new ACO Primary Care Flex Model. This model allows PCPs participating in ACOs in the Medicare Shared Savings Program (SSP) and in ACO PC Flex to receive predictable primary care revenue that replaces fee-for-service reimbursement for primary care services. Therefore, a platform already exists for the hybrid payment concept to improve upon.

Hybrid Payments Should Account for Both Clinical and Social Risk Factors for Equitable Access to Advanced Primary Care Services

The AAMC has long supported policies aimed at best using data to improve outcomes, in part by identifying the clinical and social factors influencing health. To this end we have supported the use of ICD-10 diagnostic codes, including Z-codes for social risk factors, to best capture clinical and social context that can in turn inform appropriate risk adjustment models that will help transform our health care system away from fee-for-service payment towards paying for value and outcomes. ⁶⁸ In recent years CMS has enacted policies to encourage providers to screen patients for health-related social needs (HRSNs) and to utilize the information collected to inform patient-centered treatment plans and to connect patients with community-based resources, where appropriate. Academic health systems have embraced this new approach to whole person care and have worked to generate the evidence and implementation science to support best practices for collecting and integrating HRSN data into clinical care delivery. ⁶⁹ To this end, we continue to urge CMS to adopt payment policies that incorporate ICD-10 codes inclusive of Z-codes to improve payment accuracy and reduce health disparities. The use of Z codes will enable more robust risk adjustment, while also reducing burden on providers who are already familiar with capturing clinical factors through ICD-10 coding.

Waive Patient Cost Sharing for Services Rendered Under Hybrid Payments

The AAMC strongly urges CMS to use its waiver authority under Section 1115 to fully waive any patient cost sharing associated with services paid through hybrid payments and for CMS to pay the full amount that the provider would otherwise receive if cost sharing were applied. This would improve patient trust in providers and satisfaction with advanced primary care services, while also reducing the administrative burden on participating providers. We believe that doing so within the broader framework for a total cost-of-care APM with downside financial risk would sufficiently protect the Medicare program from the additional Medicare trust fund payment responsibility, and thus should not require a budget neutrality adjustment to physician payment.

Cardiovascular Risk Assessment and Risk Management

Finalize New Codes Cardiovascular Disease Risk Assessment and Risk Management

CMS proposes two new stand-alone HCPCS codes to pay for services that assess patient's risk for and manage the risk of atherosclerotic cardiovascular diseases (ASCVD). These codes follow from the Innovation Center's success with the Million Hearts® Cardiovascular Disease Risk Reduction model, which built upon the understanding that a proportion of ASCVD is attributable behavioral causes that can be modified through risk management services to reduce the burden of ASCVD across the population. (p. 61727) The AAMC supports the addition of these two new codes to better expand access to proven risk assessment and management services to address a leading cause of death and disability in the United States.

⁶⁸ See, generally, <u>AAMC Comments to CMS on the ICD-10 Coordination and Maintenance Committee</u> (May 2019) and AAMC Comments to CMS on Reducing Provider and Patient Burden (Jan 2021).

⁶⁹ See, for example, the <u>Gravity Project</u>, led by the University of California San Francisco and the Social Interventions Research & Evaluation Network (SIREN).

Strategies for Improving Global Surgery Payment Accuracy

The Use of Transfer of Care Modifiers for Global Surgery Payment Should Reflect Patient Preferences for Receiving Post-Operative Care During the Global Period

CMS proposes to broaden the applicability of the transfer of care modifiers for 90-day global packages beginning in January 2025 as a "first step toward improved valuation and payment" and to provide the agency with more accurate information on the resources involved in furnishing components of global surgical packages. Specifically, CMS proposes to require the use of the appropriate transfer of care modifier (modifier -54, -55, or -56) for all 90-day packages in any case where a practitioner plans to furnish only a portion of a global package, including but not limited to where there is a formal, documented transfer of care as under existing policy. CMS notes that the transfer of care modifiers are infrequently used, and when used, tend to be for certain ophthalmology global packages. (p. 61733)

The AAMC understands CMS' desire to steward Medicare funds to accurately pay for services. However, we are concerned that this proposal might not be consistent with practice, where generally pre-operative and post-operative follow-up care are indeed provided by the same practitioner or other practitioners in the same group practice furnishing the surgical procedure, as envisioned by CMS when creating the global surgery codes. The exception to this is in ophthalmology, where care delivery has shifted to meet patient preference for post-operative follow-up visits with their local optometrist. In such cases, there is significant coordination between the referring optometrist and the proceduralist ophthalmologist to plan for transfer of care following surgery, following best practices set forth by specialty societies.⁷⁰

This is not to say such transfers of care are limited to ophthalmology. Indeed, care delivery has shifted to team-based care and care that is responsive to patient preferences. And in such surgical cases where it is safe and the patient preference is to do so, post-operative care may be transferred formally or informally to another practitioner outside of the proceduralist physician's group practice. We agree that in such cases, the proceduralist should work with the patient and the patient's referring physician (if applicable) to best understand the patient's preferences for post-operative care and whether to anticipate that another practitioner or practice will furnish such portions of the global package and append the appropriate modifier when billing the global package services. CMS should consider providing additional resources to physicians to help them best understand this policy and best practices for incorporating patient preferences into planning for potential transfers of care within global packages.

SUPERVISION OF OUTPATIENT THERAPY SERVICES IN PRIVATE PRACTICES, CERTIFICATION OF THERAPY PLANS OF CARE WITH A PHYSICIAN OR NPP ORDER, AND KX MODIFIER THRESHOLDS

Regulations prior to CY 2024 specified that all occupational and physical therapy services must be performed by, or under the direct supervision of, the occupational or physical therapist, in private practice. ⁷¹ However, in 2024 CMS allowed remote therapeutic monitoring (RTM)

⁷⁰ See Comprehensive Guidelines for the Co-Management of Ophthalmic Postoperative Care (Sep. 7, 2016).

⁷¹ 42 CFR § 410.59(a)(3)(ii) and 410.60(a)(3)(ii).

services to be furnished by occupational therapy assistants (OTAs) and physical therapy assistants (PTAs) under the general supervision of occupational therapists in private practice (OTPP) and physical therapists in private practice (PTPP). ⁷² CMS is now proposing to allow OTAs/PTAs to furnish all services under general supervision of the OTPPs/PTPPs respectively. (p. 61737) **The AAMC supports allowing OTAs and PTAs to provide all services under general, rather than direct supervision, to improve access to therapy services.** Changing supervision requirements from direct to general would allow supervision to occur under the OTPP's/PTPP's overall direction and control, but the OTPP/PTPP would not have to be physically present. This change would increase access to therapy services by increasing the availability of practitioners.

ADVANCING ACCESS TO BEHAVIORAL HEALTH SERVICES

The AAMC supports CMS' efforts to promote access to behavioral health services and is committed to advancing policies that enable academic health systems to deliver high-quality behavioral health care to their patients. The nation is experiencing a mental health and substance use disorder crisis that has worsened due to the long-lasting impact of the COVID-19 pandemic. Ensuring meaningful access to mental health and substance use disorder treatment is essential to addressing this crisis.⁷³

Create Add-on Code for Safety Planning Interventions (SPI) with Adequate Valuation to Support Services in More Complex Situations

CMS proposes to create a new add on HCPCS code GSPI1 for SPI services. This code would be billed along with an E/M visit or psychotherapy code when SPI interventions are personally performed by the billing practitioner in a variety of settings. GSPI1 would be valued based on one third of the valuation for CPT code 90839 (Psychotherapy for Crisis), which describes 60 minutes of time, because the agency believes that GSPI1 could typically be performed in 20 minutes. (p. 61741)

The AAMC appreciates CMS' recognition of the critical importance of safety planning interventions, and we support the adoption of the proposed add-on code. As CMS notes, death by suicide is a growing problem within the Medicare population. The proposed add-on code would align with the Stanley Brown Safety Planning Intervention, an approach designed to assist individuals experiencing self-harm or suicidal thoughts by offering concrete strategies to reduce risk and enhance safety. Although we believe that in many cases 20 minutes of time would be appropriate to address all six elements of SPI, additional time and resources may be necessary for more complex situations (i.e., treatment of teenagers). We recommend that CMS establish a separate add-on code or allow billing of more than one unit of this add-on code to address more complicated cases.

⁷² *Supra*, note 8 at 78990.

⁷³ Kaiser Family Foundation, <u>The Implications of COVID-19 for Mental Health and Substance Use</u> (Mar. 2023).

⁷⁴ The Stanley-Brown Safety Planning Intervention.

Create Code for Post-Discharge Telephonic Follow-up Contacts (FCI)

CMS also proposes to create a monthly billing code HCPCS code GFCI1 for post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter. The proposal includes bundling the service to include four calls per month, with each call lasting between 10 to 20 minutes. There must be at least one successful telephone interaction with the patient; unsuccessful attempts to reach the patient will not be counted as an encounter. This code can be billed with the Safety Planning Interventions HCPCS code GSPI1 discussed above. (p. 61742) CMS also notes this will not be classified as a Medicare telehealth service, and therefore not subject to 1834(m) restrictions. (p. 61741)

We appreciate CMS' recognition of the critical importance of post discharge follow-up services, and we support the proposed establishment of HCPCS code GFCI1 for FCI. This code is also aligned with the Stanley Brown Safety Planning Intervention, discussed above. One study conducted by the Stanley Brown Safety Planning Intervention showed that combined SPI with follow-up and monitoring by telephone showed promise as an ED intervention for suicidal patients. We applied the work that CMS is doing to increase access to care by expanding available treatment to prevent death by suicide.

Finalize Payment for Digital Mental Health Treatment (DMHT) Devices

CMS proposes payment for services utilizing Digital Mental Health Treatment (DMHT) devices for behavioral health by establishing three new HCPCS codes, including initial supply of the device education and onboarding (GMBT1), first 20 minutes (GMBT2), and each additional 20 minutes of monthly treatment management (GMBT3). (p. 61742) As proposed, the DMHT device services will be payable only if the device is FDA cleared under 21 CFR 882.5801. ⁷⁶ Additionally, CMS proposes that the billing practitioner be required to diagnose the patient and prescribe or order the device and either the billing practitioner or their clinical staff must monitor the patient's therapeutic response to the device and adjust the behavioral health therapy plan as necessary. (p. 61744)

The AAMC strongly supports CMS' proposal to provide payment for services using DMHT devices for treatment of behavioral health. We commend CMS for addressing previous recommendations through the proposal of these DMHT codes for behavioral health, including the time and resources necessary to set-up and implement the use of the device. ⁷⁷ However, we are concerned that limiting payment to devices FDA cleared under 21 CFR 882.5801 may be overly restrictive. We recommend that CMS explore potentially expanding this definition to promote greater access to clinically safe and effective DMHT devices that have come to market under alternative FDA pathways.

⁷⁵ Stanley, B., et al., An Emergency Department Intervention and Follow-Up to Reduce Suicide Risk in the VA: Acceptability and Effectiveness. Psychiatric Services (2016).

⁷⁶ 21 CFR 882.5801, describing FDA-approved devices for psychiatric disorders.

⁷⁷ AAMC, Comments on the CY 2024 Physician Fee Schedule Proposed Rule (Sep. 2023).

CMS should not limit payment if a patient discontinues the use of a DMHT device before completing treatment. As proposed, the practitioner must be responsible for the costs associated with the device. (p. 61744) In many cases the cost of the DMHT device, including initial set up costs and analysis of the data, is not likely to decrease if the patient chooses to discontinue treatment. The practitioner should not be disincentivized for adopting novel treatment practices out of concern that a patient might choose to forgo completing treatment in accordance with the full prescribed plan.

CMS should also refrain from limiting payment to a set number of DMHT devices per calendar month per patient. We believe that practitioners are best situated to determine which DMHT devices are medically necessary to incorporate into patient care. The number of medically necessary devices would likely vary depending on the patient's condition and the severity of that condition. It would be inappropriate for CMS to arbitrarily impose a blanket restriction to limit the quantity of devices, as this could restrict access to care.

Establish Interprofessional Consultation Codes Billed by Practitioners Authorized by Statute to Treat Behavioral Health Conditions

CMS previously finalized payment for six CPT codes to recognize interprofessional consultations (99446, 99447, 99448, 99449, 99451, 99452). 78 The AAMC and its member health systems have found interprofessional consultations utilizing provider-to-provider modalities and peer-mentored care as an effective way to improve access to care. However, current restrictions only allow practitioners who can independently bill Medicare for E/M visits to use these codes, which significantly limited the potential of interprofessional consultations, particularly in expanding access to behavioral health services. Specialists who are statutorily restricted to Medicare payment for behavioral health services are not permitted to bill for E/M services and, therefore, cannot bill for interprofessional consultations, including, for example, clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors. This is particularly concerning given the significant access and workforce challenges within behavioral health care. According to data from the Health Resources and Services Administration (HRSA), as of September 9, 2024, approximately 123 million people currently reside in Mental Health Professional Shortage Areas (HPSAs), and there is a shortage of 6,244 practitioners. Notably, around 32% of Mental Health HPSAs are located in non-rural areas, and 6% are in partially non-rural areas.⁷⁹

CMS is now addressing this issue through its proposal to create six new interprofessional consultations codes for practitioners statutorily restricted to Medicare payment for mental health services. GIPC1, CIPC2, GIPC3, GIPC4, and GIPC5 would be used by the consulting practitioner based on the amount of time spent on the consultation and whether a written and verbal consultation is provided or only a written consultation is provided, while GIPC6 is reserved for the treating/requesting clinician. (p. 61745) In the rule, CMS notes that there may be two cost sharing obligations: one for the services provided by the treating (requesting) practitioner's service and one for the services provided by the consultant practitioner. (p. 61746)

⁷⁸ CY 2019 Physician Fee Schedule 83 FR 59452 at 59489 (Nov. 23, 2019).

⁷⁹ *Supra*, note 16.

Valuation of the mental health interprofessional consultation codes are cross-walked and can be used in conjunction with the six CPT codes for interprofessional consultation for practitioners who can independently bill Medicare for E/M visits. (p. 61746) This means that a practitioner who is authorized to bill Medicare for E/M services would continue to bill the existing interprofessional consultation codes while mental health providers would bill these newly proposed mental health interprofessional consultation codes. This would allow even more practitioners to work together through provider-to-provider modalities and peer-mentored care to increase access for patients. We support the establishment of these new codes to enable billing for interprofessional consults by mental health providers. However, as discussed below, because these codes mirror the existing CPT® E/M interprofessional consultation codes, the same barriers, detailed below, are likely to apply. We urge CMS to address barriers that will continue to restrict providers from reporting the existing E/M interprofessional codes (CPT 99451 and 99452) and these new codes.

Address Barriers to Uptake & Sustainability of Interprofessional Consults

By way of background, the AAMC has partnered with over 50 adult and pediatric health systems through Project CORE (Coordinating Optimal Referral Experiences) to implement interprofessional consults ("eConsults") and continues to engage new health systems and other health care organizations, including payers, interested in implementing and scaling this high value service. In the CORE model, eConsults are an asynchronous exchange in the electronic health record (EHR) that are typically initiated by a primary care provider (PCP) to a specialist for a low acuity, condition-specific question that can be answered without an in-person visit. The goals of the program include increasing timely access to specialty input and reducing unnecessary specialty referrals while maintaining continuity of care for patients with their PCP. Patients benefit from more timely access to the specialist's guidance and payers benefit from a less costly service by avoiding the new patient visit with a specialist, not to mention likely downstream costs, when eConsults take the place of a referral. The AAMC believes that investing in these technologies will extend the capacity of the existing behavioral health workforce and promote access to care in historically underserved communities. The AAMC continues to develop resources for health systems to aid in the adoption and evaluation of both synchronous and asynchronous telehealth modalities.

The following describes three of the major policy barriers to uptake and sustainability of the E/M interprofessional consultation codes. These barriers will likely also impact the proposed mental health interprofessional consultation codes. Once these barriers are addressed, patients will benefit even more from the change in practice patterns that leverage provider-to-provider modalities and peer-mentored care.

Two Coinsurances Issue

CMS requires that providers collect coinsurance from their patients when billing for CPT® codes 99451 and 99452 and will do so for GIPC5 and GIPC6. While the AAMC understands that CMS may not have the authority to waive coinsurance for CPT® codes 99451 and 99452 or GIPC5 and GIPC6 under the Medicare fee-for-service program, we remain concerned that the coinsurance requirement is a barrier to providing these important services for several reasons. First, given the

structure of two distinct codes, patients are responsible for two coinsurance payments for a single completed interprofessional consultation - one for the treating (requesting) provider (99452 and GIPC6), and one for the consulting provider (99451 and GIPC5). While we believe that it is appropriate to reimburse both providers for their work in conducting the interprofessional consultation, two coinsurance charges to the patient for what they perceive is a single service predictably induces confusion. Interprofessional consultations are often used for patients with new problems who are not established within the consulting specialty's practice and therefore do not have an existing relationship with the consultant. A coinsurance bill for a service delivered from a provider that is unknown to the beneficiary could cause the patient to believe a billing error has occurred. This would place an undue burden on the practice's billing staff to address questions about billing. Additionally, if presented with the option of an interprofessional consult coinsurance payment versus a visit coinsurance payment, patients may elect to see the specialist in-person, which would be unnecessary and negatively impact the potential savings of these interprofessional consultations.

The AAMC recognizes there are typically limited scenarios where the fraud and abuse laws allow the waiver of coinsurance in the Medicare program. However, we continue to believe that the "two coinsurances" issue will stifle use of these value-promoting, physician-to-physician services that analyses of the CMMI-funded CORE model show to be cost-saving to CMS. Therefore, the Agency should explore a pathway to waiving the patient coinsurance for 99451 and 99452 as well as GIPC5 and GIPC6. CMS should explore whether there may be avenues available to waive the specialist coinsurance (99451 and GIPC5) to minimize overall administrative complexity and confusion for beneficiaries who have no established relationship with the specialist consulting provider. At a minimum, the coinsurance should be waived in circumstances where there is a straightforward mechanism to do so, such as CMMI's waiver authority for specific services in alternative payment models (APMs), including the new Making Care Primary model.

Barriers to Billing by the Treating (Requesting) Clinician

Guidance for CPT® code 99452 clarifies that it should be reported by the treating physician/QHP for 16-30 minutes in a service day preparing the referral and/or communicating with the consultant. We believe that this guidance will likely apply to the proposed code GIPC6 because CMS is proposing to cross-walked to CPT 99452. We believe that the time for these codes should include all the activities associated with the interprofessional exchange between the treating provider and consulting physician, including follow through on the consultant's recommendations. For an interprofessional consultation to have its intended value for the patient, the treating physician must receive a response from the specialist, review it in the context of the patient's needs, and make a clinical decision about how best to incorporate the specialist's guidance. Therefore, we recommend that these follow-up activities be considered part of the minimum 16 minutes of time for the treating provider to bill this code. This clarification would help to expand the use of these valuable services in the future and ensure from a program integrity standpoint that patients and payers are realizing the intended value of this service. Interprofessional consultation is only valuable to providers, patients, and payers when the treating provider poses a question, the specialist consultant provides recommendations and a

contingency plan, and the plan is implemented and communicated back to the patient by the treating provider.

Interoperability

Our experience working with member academic health systems through Project CORE to implement electronic interprofessional consults has highlighted significant interoperability issues across systems, even in cases where they are operating within the same platform or using the same EHR tools developed by the same EHR vendor. When a consulting provider seeks to respond to a request for an eConsult from the treating physician, they often must also confront interoperability issues to be able to fully evaluate the relevant clinical data and provide a thorough consultation For example, a call at one institution for the value of a white blood count lab may return the value but using the same vendor platform (or a FHIR API) to call at another institution might not result in a returned value due to semantic inconsistency. Currently, there are no feedback loops to address such inconsistencies in the implementation of normative standards across the nation. The AAMC has previously commented to the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT (ASTP) on interoperability hurdles for clinical practice, including challenges when working across health systems or EHR systems. 80 While HHS has worked to improve common data standards for EHRs as part of its health IT certification efforts, this has not solved interoperability issues due to semantic differences when implementing such standards. We continue to urge CMS coordinate with the ASTP to support broader semantic standardization through the development of national and regional user groups that provide feedback loops on semantic differences, helping to serve as a mechanism for truly normalizing national data standards into clinical practice. Additionally, CMS should work with the ASTP to support broader adoption and implementation of standard ontologies with quality assurance processes (i.e., LOINC, RxNorm, SNOMED, etc.) which may help improve semantic differences between health systems.

DISCRETIONARY PROVISIONS [III]

MEDICARE PRESCRIPTION DRUG INFLATION Rebate Program

Finalize Proposal to Use an Estimation Methodology to Identify 340B Units to Exclude from Part D Inflationary Rebates, Clarify How a Retrospective Claims Repository Model Would Function

The Inflation Reduction Act of 2022 (IRA) requires drug manufacturers to provide rebates to Medicare on Part B and Part D drugs for which prices increase faster than the rate of inflation. For Part B drugs, the determination of whether a drug's price increased faster than inflation is made on a quarterly basis, while this determination is made over a 12-month period for Part D drugs. The IRA also requires that units of drugs on which the manufacturer provides a discount through the 340B Drug Pricing Program be excluded from inflationary rebates. The requirement to exclude 340B drug units went into effect for Part B drugs in 2023 and goes into effect for Part

⁸⁰ AAMC, Comments to ONC on HTI-1 (June 2023).

D drugs in 2026. The following comments pertain to CMS' proposals specific to identifying 340B units from Part D inflationary rebates.

Proposed Estimation Methodology

In the rule, CMS proposes a methodology for excluding 340B drug units from "rebatable" Part D drugs beginning in 2026. (p. 61969) Under this approach, CMS would estimate the number of 340B units that should be excluded from the inflationary rebate in an applicable period by applying an estimation percentage to the number of drugs expected to receive an inflationary rebate. The estimation percentage would be calculated at the national drug code (NDC) level and based on the number of 340B drug units for an NDC in the applicable period divided by the total number of drug units sold for the same NDC. CMS proposes to use data on the number of 340B units from the Health Resources and Services Administration's (HRSA's) Prime Vendor Program (PVP), managed by Apexus. For the denominator of the estimation percentage (total number of drug unit sales for an NDC in the applicable period), CMS proposes to use data manufacturers report under the Medicaid Drug Rebate Program for purposes of calculating the average manufacturer price. These data include drugs for an NDC across all payers.

The AAMC supports CMS' proposed estimation methodology to calculate the number of 340B units that should be excluded from inflationary rebates. In previous guidance on Part D inflationary rebates, CMS had suggested requiring a 340B indicator or modifier be included on pharmacy claims denoting when a 340B discounted drug was dispensed to a Part D beneficiary. We are pleased that CMS now acknowledges the impracticability of that approach given the realities of 340B dispensing and inventory management practices. However, CMS does not foreclose the possibility of using a claims-based identifier in the future (p. 61972), and we urge CMS to rule this option out for future use.

Part D drugs are dispensed to the beneficiary in the retail pharmacy setting, either at a hospital-owned pharmacy or an independent pharmacy. For multiple reasons, retail pharmacies cannot (and do not currently) identify at the time of dispensing whether a prescription being filled is a 340B-eligible prescription. First, pharmacies rarely have separate physical inventories for 340B and non-340B drugs. Instead, they use a "virtual inventory" that entails the pharmacy replenishing its inventory with 340B drugs when it retrospectively determines how many units were dispensed to 340B-eligible beneficiaries. Additionally, when a patient fills a prescription at an external, independent pharmacy, which has different electronic medical record systems than the covered entity, the pharmacy is not able to make a real time determination of whether the patient qualifies as a patient of 340B covered entity. The determination of whether a drug is 340B-eligible is a retrospective determination that involves the sharing of information by the covered entity, the pharmacy, the pharmacy's switch vendor, and a third-party administrator (TPA) that works on behalf of the covered entity. Due to these complexities, we believe an estimation methodology, which would rely on data through the 340B PVP, would be preferable to any methodology that requires point-of-sale or retrospective identification by covered entities

⁸¹ CMS, Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments, (Feb. 9, 2023).

⁸² IQVIA. Can 340B Modifiers Avoid Duplicate Discounts in the IRA? (Feb. 28, 2023).

⁸³ Amerisource Bergen. How are retail prescriptions captured into the 340B program? (Jan. 6, 2023).

or pharmacies through the use of a claims-based modifier. An estimation methodology would rely on existing data and not require hospitals, pharmacies, or their TPAs to put in place new systems for the identification of 340B drugs.

CMS mentions some of the potential shortcomings of the estimation methodology, such as that the estimation percentage is based on 340B units for an NDC as a share of all drug units sold under that NDC, as opposed to limited specifically to Part D drugs. (p. 61970). Moreover, not all covered entities participate in the 340B PVP, meaning data on their 340B drug units would not be included in the estimation percentage, resulting in the possible undercounting of 340B drug units. However, CMS also notes that the PVP data includes both retail drugs as well as drugs administered in the outpatient setting, which could overstate the number of 340B drug units sold in an applicable period. We encourage CMS to work with stakeholders to identify ways to refine its estimation methodology and to better capture Part D 340B drug units without adding undue burden or implementing new reporting mechanisms. CMS presents the idea of requiring drug manufacturers to report 340B units and total drug units sold but notes this would require new tracking and reporting mechanisms. We strongly caution against the idea of shifting the responsibility of identifying 340B units to drug manufacturers, which would not only require new processes but would necessitate the sharing of covered entity claims information with drug manufacturers.

Medicare Part D Claims Data Repository

CMS seeks comment on establishing a Medicare Part D claims data repository, which could be used to identify and remove 340B units from Part D drug inflation rebate calculations. (p. 61971) 340B covered entities would be required to enroll in the repository and retroactively submit data to CMS identifying 340B claims dispensed under Part D. The AAMC believes that an independent claims repository could be a viable and accurate option to identify 340B drug units. Oregon has long had a process through which covered entities retroactively identify and send to a clearinghouse 340B retail pharmacy claims so that 340B drug units can be identified and excluded from Medicaid rebates. ⁸⁴ If CMS proceeds with this option, it can be a model for use in other contexts, such as for purposes of identifying 340B units for the Medicare Drug Price Negotiation Program maximum fair price deduplication provisions. ⁸⁵ Before CMS goes forward with the use of a retrospective claims data repository model, we encourage the agency to address the following concerns:

- Ensure the repository is an independent entity that is free from conflicts of interest relating to relationships with any parties involved in the 340B program, including manufacturers and covered entities.
- Ensure the protection of 340B-related claims information, as well as other sensitive or proprietary information, that covered entities submit to the repository and ensure that its

⁸⁴ Oregon Health Authority, <u>Pharmaceutical Services Program</u>.

⁸⁵ CMS, Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.

use is limited to identification of 340B units for exclusion from Part D inflationary rebates.

- Verify that any claims data submitted retroactively be final adjudicated claim information to ensure the finality of information being relayed to the repository.
- To streamline the reporting process, minimize the required data elements to be reported to those elements necessary for the identification of and matching of 340B information with Part D claims.
- Provide ample time to covered entities to submit claims information.

While CMS uses the proposed estimation methodology, it can work to address the above questions and other implementation issues related to a potential claims data repository model. We urge CMS to thoroughly evaluate the issues we have identified and work with stakeholders to ensure that a claims data repository is accurate and effective, minimizing burden on providers and all involved parties.

MEDICARE PART B PAYMENT FOR PREVENTIVE SERVICES

The AAMC strongly supports cost-free access to preventive care services. Preventive care services and early interventions are essential for improving the quality and longevity of life for millions of individuals. Early detection of disease often saves lives, improves patient health, and reduces patient suffering. Comments in support of CMS' proposals to expand access to preventive services in the Medicare Program follow.

Finalize Payment Rates for Preventive Vaccine Administration Services Including Additional Payment for In-home Vaccine Administration

CMS proposes two different payment scenarios for Part B Payments for preventive vaccine administration for CY 2025, in part dependent on whether the COVID-19 vaccination's emergency use authorization (EUA) declaration is terminated before January 1, 2025. (p. 61927) Additionally, CMS proposes to maintain an additional payment for the administration of a COVID-19 vaccine in the home in specific circumstances, and to extend that in-home additional payment to the administration of the other three preventive vaccines in the Part B vaccine benefit: influenza, pneumococcal and hepatitis B. (p. 61926) **The AAMC supports these policies to support access to preventive vaccines.** We commend CMS for proactively considering the impacts of the EUA declaration on the COVID-19 vaccine and providing a clear path forward on payment depending on both scenarios for 2025.

Expand Coverage and Access to Hepatitis B Vaccine Administration

CMS proposes to improve access and utilization of hepatitis B vaccines by expanding the list of individuals who are at high or intermediate risk of contracting hepatitis B in payment regulations at §410.63. (p. 61929) Specifically, individuals who have not received a completed hepatitis B vaccination series and those whose vaccination history is unknown would be deemed intermediate risk and have access to the vaccine. (p. 62000) Additionally, a doctor's order would no longer be necessary for the administration to be covered under Medicare Part B. CMS believes that these proposed coverage and payment changes will protect Medicare patients from hepatitis B infection and help to eliminate viral hepatitis B as public health threat. **The AAMC**

agrees and supports these proposals to improve access and utilization of hepatitis B vaccines in the Medicare program and to support broader public health goals.

Establish a Fee Schedule for Drugs Covered as Additional Preventive Services

CMS proposes to use its authority under Section 101 of the Medicare Improvement for Patients and Providers Act of 2008 (Pub. L. 110-275) to determine payment for drugs covered as additional preventive services (DCAPS) based on a fee schedule using existing Part B drug pricing mechanisms. (p. 61930) Specifically if Average Sales Price (ASP) data is available for the DCAPS drug, the payment limit would be 106% of ASP; and if ASP data is not available, CMS would turn to National Average Drug Acquisition Cost (NADAC) prices for the drug. Where neither ASP nor NADAC are available, the payment limit would be calculated using the Federal Supply Schedule (FSS) prices for the drug. If FSS price is similarly not available, CMS proposes to allow the payment limit to be the invoice price determined by the Medicare Administrative Contractor (MAC). CMS highlights that as preventive services, coinsurance does not apply to DCAPS drugs. The AAMC supports this proposed approach to establishing pricing mechanisms under a new DCAPS fee schedule due to its consistency with other Part B drug pricing policies.

EXPAND COLORECTAL CANCER SCREENING

Finalize Policies to Coverage for Colorectal Cancer Screenings in the Medicare Program

CMS proposes to update and expand coverage for colorectal cancer screenings in regulations at §410.37 by: (1) removing coverage for the barium enema procedure; (2) adding coverage for the computed tomography colonography (CTC) procedure; and (3) expanding a "complete colorectal cancer screening" to include a follow-on screening colonoscopy after a Medicare-covered blood-based biomarker CRC screening test. (p. 61991) **The AAMC supports these proposals that will promote access.** We agree with CMS that screening tests are critical to detect cancer early. Colorectal cancer screenings dramatically decrease the mortality rate associated with colorectal cancer, which is the third leading cause of cancer death for men and women. ⁸⁶. Additionally, some studies suggest Medicare coverage of CTC in particular could help reduce income-related disparities in beneficiaries' adherence to colorectal cancer screening guidelines. ⁸⁷ Medicare coverage for screening should follow National Cancer Institute and specialty society recommendations and ensure Medicare patients have access to widely recommended best practices.

MEDICARE PARTS A AND B OVERPAYMENT PROVISIONS OF THE AFFORDABLE CARE ACT

In the rule, CMS proposes to add a provision that specifies the circumstances under which the deadline for reporting and returning Medicare overpayments would be suspended to allow time for an investigation and calculation of any related overpayments. Specifically, CMS proposes that the 60-day deadline for returning overpayments would be suspended when: 1) a person has

⁸⁶ US Preventive Servs. Task Force Recommendation Statement, <u>Screening for Colorectal Cancer</u>, J. Am. Med Ass'n (May 2021). *See also* CDC, <u>Colorectal Cancer Screening Tests</u> (Feb. 2023).

⁸⁷ Emily Harris, <u>Change in Medicare Policy Might Increase Colorectal Cancer Screening</u>, J. Am. Med Ass'n (Aug. 2023).

identified an overpayment but has not yet completed a good-faith investigation to determine the existence of related overpayments, and 2) the person conducts a timely, good-faith investigation to determine whether related overpayments exist. (p. 62006) In this case, the obligation to return the overpayment would remain suspended until the earlier of the date that the investigation has concluded and the aggregate amount of the overpayment is calculated or 180 days after the date on which the overpayment was identified. We support this proposal in recognition of the importance of allowing adequate time for providers to investigate and calculate overpayments to be reported and returned. We recommend that CMS consider one modification to the policy – to create a process to request an extension beyond 180 days for complex investigations. Large integrated health systems might require additional time beyond 180 days to fully investigate the initial overpayment and any related overpayments, which could span multiple across sites. Requiring such an investigation to conclude within 180 days without any opportunity for an extension could result in rushed conclusions that could misidentify a proper payment as an overpayment, ultimately resulting in a loss to the health system. To balance the potential for rushed investigations, we urge CMS to develop a process to request an extension to allow the time necessary for a thorough investigation in complex situations.

MEDICARE SHARED SAVINGS PROGRAM (SSP)

Quality Reporting

Modify the APP Plus Universal Foundation Requirements to Ensure Successful Reporting

CMS proposes to establish the APM Performance Pathway (APP) Plus quality measure set under the APP, which would be required for MSSP ACOs starting with the 2025 performance year. The APP Plus quality measure set would gradually increase to eventually 11 measures, consisting of six measures in the existing APP quality measure and five new measures from the Universal Foundation measure set. These five quality measures are part of a larger initiative to use measures that can cut across multiple Medicare programs and models, introducing into MSSP measures for Breast Cancer Screening, Colorectal Cancer Screening, Initiation and Engagement of Substance Use Disorder Treatment, Screening for Social Drivers of Health, and Adult Immunization Status (p. 61862). CMS plans to update the APP Plus Quality measure set as new measures are added to the Universal Foundation Measure set in the future. The AAMC supports implementing the Universal Foundation measure set, as these measures are a step towards creating standardization across models and Medicare programs. CMS also proposes to require the ACOs to report the measures as electronic clinical quality measures (eCQMs) or Medicare Clinical Quality Measures.

While we support the new measures, we recommend some modifications to the proposal to prevent unintended consequences. CMS should consider postponing the rollout of new measures by one year to allow time for participants to integrate new electronic clinical quality measures (eCQMs) into workflows across electronic health record (EHR) systems used by ACO participants. The vast majority of ACOs consist of multiple practice Tax Identification Numbers (TINs), and these practices may use a variety of different EHRs, which may not easily work together to transmit data. Reporting eCQMs can be particularly burdensome for ACOs with small practice participants, as smaller practices often utilize EHRs developed by vendors with

less market share or that have developed specialty specific platforms. With these EHR system differences, it will take time to integrate and to test all elements necessary for reporting new eCQMs. Given that the final rule will not be released until November, participants will have limited time to prepare for the introduction of these measures for performance in 2025. Meeting the reporting requirements in a short amount of time may create unintended consequences, such as ACOs removing smaller practices from their ACOs to avoid penalties or a lack of shared savings because of an inability to fully report quality measures. Furthermore, many of these small practices are specialty-focused, leading to decreased integration between primary and specialty care, should ACOs choose to drop these practices. This would lead to fewer beneficiaries being included in an ACO and may delay meeting CMS' goals to include 100% of Medicare beneficiaries in an accountable care relationship by 2030. Additionally, the tight timeframe requires ACOs to postpone meaningful initiatives to improve care delivery and, instead, focus on the administrative elements related to the introduction of new quality measures.

Relatedly, CMS proposes future measures that are not currently specified as eCQMs, including the Screening for Social Drivers of Health and Adult Immunization measures. CMS should consider the process and time necessary to convert these measures into eCQMs and the time necessary for participants to initiate essential changes in the EHR to appropriately capture these measures. CMS should delay the requirement for reporting these measures if the agency is not able to provide full eCQM specifications at least two years prior to the date that reporting would be due to the agency.

Lastly, CMS should consider making these new measures pay-for-reporting before initiating a pay-for-performance requirement. ACOs should have at least one year to prepare for performance on new measures, with the first year being pay-for- reporting. Using the measures for performance and payment determinations should be delayed until ACOs can prepare for the implementation of those measures and understand early drivers of performance.

Merit-based Incentive Payment System Policies for ACO Quality Measurement

Implement Flat Benchmarks for MIPS Measures Until Historical Benchmarks are Available

CMS proposes to introduce flat benchmarks for Medicare CQMs the first two years of any newly introduced ACO measure that is also used to report under MIPS for their participation in the Quality Payment Program, starting in CY 2025 (p. 61860). A flat benchmark would be utilized until two years of data are made available for the introduction of historical benchmarks. The AAMC supports the proposal to implement a flat benchmark until historical data becomes available.

Introduce the Complex Organization Adjustment to Incentivize Reporting eCQMs

CMS proposes to introduce a Complex Organization Adjustment in CY2025 that would attach one achievement point for each eCQM submitted in order to incentivize providers to report eCQMs (p. 61859). The AAMC supports incentives to encourage the adoption of eCQMs, as long as CMS maintains the option to report quality using Medicare CQMs. Medicare CQMs often are a more manageable option for many ACOs with smaller associated practices that may not have the infrastructure to report eCQMs.

Beneficiary Assignment

Allow ACOs Whose Assigned Beneficiaries Fall Below 5,000 to Remain in the Program

CMS proposes to remove the termination requirement for ACOs that fail to maintain 5,000 assigned beneficiaries during a performance year, starting in CY2025, to increase the number of beneficiaries in an accountable care relationship (p. 61842). The AAMC supports the proposal to remove the language around termination for ACOs to increase participation in SSP and the number of patients in an accountable care relationship.

Allow Simultaneous Alignment with Episodic Models for Patients Voluntarily Aligned to an ACO

CMS proposes to allow for claims-based alignment for patients voluntarily assigned to an ACO in episodic value based care models, starting in CY2025 (p. 61851). The AAMC supports CMS' efforts to streamline model attribution and allow for those voluntarily assigned to an ACO to be attributed to other non-ACO value based care models. Given CMS' prediction that this change would only affect approximately 1% of those beneficiaries voluntarily assigned to an ACO, the AAMC believes this change will lead to a more efficient attribution process.

Amend the Definition of "Primary Care Services" to Recognize Care Furnished Under Newly Adopted Codes

CMS proposes to add several proposed and existing services, as identified by specific billing codes, to the definition of primary care services it uses to identify primary care delivered on behalf of ACO professionals for beneficiary assignment (p. 61843). These additional services reflect services that are provided in conjunction with office/outpatient E/M services or other preventive services and care management services currently included in the definition. The AAMC agrees and supports these proposed additions to the definition of primary care services, effective with PY 2025 ACO assignment.

Financial Benchmarking & Methodology

Modify the Health Equity Benchmark Adjustment (HEBA) to Ensure a Meaningful Benefit for ACOs Caring for Underserved Populations

CMS proposes the inclusion of a new health equity benchmark adjustment, starting in CY2025, that would serve as an upward-only adjustment to the benchmark to account for ACOs who serve a higher proportion (≥20%) of beneficiaries that are dually eligible or LIS recipients (p. 61885). The purpose of this adjustment is to advance CMS' work around health equity by accounting for inequities in care through the benchmark modification and to encourage future participation from providers that serve a greater proportion of underserved patient populations.

The AAMC supports CMS' efforts to address the higher cost and resource utilization associated with dually eligible and LIS patients, however, modifications to the HEBA adjustment should be implemented to ensure the adjustment provides a benefit. First, the AAMC has concerns with the percent threshold for HEBA eligibility being set at ≥20%. CMS should consider a sliding adjustment based on the proportion of dually eligible and LIS beneficiaries assigned to an

ACO, rather than an adjustment that is only achieved by reaching 20%. A flat adjustment will unfairly penalize those ACOs who fall just below the threshold. CMS should match the precedents established in the Hospital Value Based Purchasing Program, which allows for a varying adjustment based on the proportion of underserved patients. 88 This would ensure that all ACOs are incentivized to care for underserved patients and receive the assistance necessary to do so

Additionally, CMS should consider applying the HEBA adjustment as a separate benchmark adjustment, independent from the Regional or Prior Savings adjustments.

Since this adjustment is designed to account for the increased costs and resources associated with underserved patients, CMS should apply the HEBA adjustment variable separately to ensure those providers who do serve a higher number of dually eligible and LIS patients are able to receive benefit from the HEBA adjustment. As designed, it is likely that many ACOs will not receive the adjustment, due to the 20% requirement, as well as the requirement that the HEBA will only be applied if it is the highest of the three adjustments available. CMS estimates that approximately 20 ACOs would be eligible for this adjustment, demonstrating that the adjustment would not provide benefit for the majority of ACOs as it is currently designed (p. 61888). However, studies show that approximately 49% of safety net hospitals participate in an ACO and a quarter of all participating SSP ACOs include a Federally Qualified Health Center, thus demonstrating that the proposed methodology would not provide benefit to the majority of ACOs regularly serving dually eligible and LIS beneficiaries. 89 Furthermore, ACOs are starting to take on more underserved patients, which requires investment to bring these patients to an appropriate level of resource and service utilization compared to this population's previous use of health care services. 90 This change in utilization would not currently be captured in the benchmark and would, therefore, unduly penalize providers working to provide appropriate care to underserved patients. This creates disincentives for establishing new care relationships with underserved beneficiaries, as appropriate care might create short-term increases in service utilization with little room for risk adjustment to appropriately increase benchmarks from historical low utilization of services.

Implement a Prepaid Shared Savings Option to Support High Performing ACOs

CMS proposes to implement a prepaid shared savings option to allow high performing ACOs to receive an upfront payment to support investments in care delivery at the start of a performance year (p. 61869). Prepaid funds must be spent in specific ways, with a minimum of 50% of prepaid shared savings required for services directed to beneficiaries and a maximum of 50% of

⁸⁸ 42 CFR 412.165(b)(5), as established in the CY 2024 Inpatient Prospective Payment System rule, 88 FR 58640, at 59093 (Aug. 28, 2023).

⁸⁹ Machta, R., et. al., <u>Safety Net Hospitals in Health Systems: Variation in ACO Participation and Other Characteristics</u>. *Mathematica. (2019)*. and Wang, A., et. al., <u>Medicare Accountable Care Organizations In 2022:</u> Renewed Growth And Improved Savings Show Small Rebound From The COVID-19 Pandemic. *Health Affairs*. (2023).

⁹⁰ CMS, CMS Announces Increase in 2023 in Organizations and Beneficiaries Benefiting from Coordinated Care in Accountable Care Relationship, (2023) and Person-Centered Innovation – An Update on the Implementation of the CMS Innovation Center's Strategy, (2022).

shared savings for infrastructure investments. The AAMC supports a prepaid shared savings option to allow ACOs the opportunity for upfront investments in care.

Establish Policies to Remove Significant, Anomalous, and Highly Suspect Billing (SAHS) from Financial Performance

In a separate proposed rule that was published July 3, 2024 (referred to as the SAHS billing activity proposed rule), CMS proposed to exclude SAHS billing for catheter spending for performance year 2023 from expenditure and revenue calculations used for the following: assessing PY 2023 financial performance of Shared Savings Program ACOs; establishing benchmarks for ACOs starting agreement periods in 2024, 2025, and 2026; and calculating factors used to determine revenue status and repayment mechanism amounts. (p.61909). This change was proposed due to significant concerns about an increase in billing to Medicare for these urinary catheter supplies that represents potentially fraudulent activity. In this rulemaking, CMS proposes to establish considerations for reopening a payment determination to account for improper payments, that would result in a significant adjustment to the ACO's initial performance determination, and a methodology to recalculate performance to account for improper payments. (p. 61898)

The AAMC thanks CMS leadership for ensuring that ACOs are held harmless from anomalous Medicare spending outside their control. ACOs and their participant clinicians, hospitals, and other healthcare providers need predictable and stable approaches when being held accountable for costs and quality. Addressing the anomalous spending will help keep participants in the models, continuing progress on CMS' goal of having all Medicare patients in an accountable care relationship by 2030. The AAMC urges CMS to finalize the proposal and apply similar policies for the ACO REACH model and all impacted alternative payment models. We also appreciate that CMS has proposed permanent policies in the 2025 proposed physician fee schedule rule that will address future instances of anomalous billing.

The AAMC asks that CMS also examine if additional codes should be considered for mitigation in 2023. Many ACOs have reported significant increase in billing for skin substitutes, with Medicare payments rising from \$1.3 billion in 2022 to \$3.9 billion in 2023. Similar to the catheters, this will detrimentally impact ACO savings unless accounted for by CMS.

Enact the Payment Determination Reopening Process and Methodology for Improper Payments and Fraud

CMS proposes to establish a written and formal process for reopening past payment determinations to alleviate issues with fraud or improper payments (p. 61899). The AAMC supports codifying a process for reopening a payment determination, as it provides clarity on the steps an ACO needs to take and will, subsequently, encourage institutions to pursue the process. A formal process is necessary for any and all value based care models that involve two-sided risk, as it clarifies how the agency will address any issues regarding miscalculations or fraud.

⁹¹ See, Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023, 89 FR 55168 (Jul. 3, 2024).

Request for Information

Considerations for Designing a Higher Risk and Reward Track for the Program

CMS seeks feedback on the future incorporation of a higher risk track than the current ENHANCED track, which is based on the Pioneer ACO Model that ended in 2016 (p. 61916). CMS notes that it could use the experiences of the Next Generation ACO Model, which ended in 2021, and the ongoing ACO Realizing Equity, Access, and Community Health (ACO REACH) model to inform the design of such a track for the SSP.

The AAMC encourages CMS to use the experience of those two higher risk models to inform design of a new, permanent participation track in the SSP. We believe there are two primary features that would improve a higher risk/reward track in the SSP: payment-based participation incentives and meaningful policies to promote health equity. Payment-based incentives are necessary to support care transformation. These could include creating a 100% financial risk option, offering primary care capitation payments above current levels of primary care spending, and payment incentives for team-based care (such as the benefit enhancements offered in NGACO supporting post-discharge home visits and payment for specified asynchronous telehealth services,). Additionally, financial benchmarking should encourage long-term participation for long-term savings due to evidence-based care transformation. Risk adjustment policies should influence both clinical complexity and the promotion of health equity by ensuring through design that it allows for the allocation of more resources to underserved and socially disadvantaged beneficiaries, rather than from simply coding intensity. Currently, SSP risk adjustment policies are based on prior service utilization and coding intended to predict future spending. This creates disincentives for establishing new care relationships with underserved beneficiaries, as appropriate care might create short-term increases in service utilization with little room for risk adjustment to appropriately increase benchmarks from historical low utilization of services. Lastly, the AAMC urges CMS to create a separate, new track within the ENHANCED track, rather than replacing what currently exists, to support ACOs seeking a glide path from BASIC to higher risk track participation.

RFI: BUILDING UPON THE MIPS VALUE PATHWAYS (MVPS) FRAMEWORK TO IMPROVE AMBULATORY SPECIALTY CARE

CMS seeks feedback on designing a new ambulatory specialty model that would be announced in future rulemaking and begin no sooner than 2026. In this new model, CMS considers leveraging the MIPS Value Pathways (MVP) framework to increase specialist engagement in value-based care and expand incentives for primary and specialty care coordination.

The AAMC shares CMS' commitment to value-based care. The AAMC has supported more than 30 academic health systems participating in multiple CMS models including accountable care models such as the ACO Realizing Equity, Access, and Community Health Model and episode-based models such as the Comprehensive Care for Joint Replacement (CJR) Model. We are pleased that CMS is invested in improving the quality and value of care, and we appreciate the opportunity to offer feedback on the request for information.

Confirm This Model is an Advanced APM and Exempt from MIPS

While CMS has noted in the proposed rule that currently they do not envision participants under this model would receive a MIPS payment adjustment, additional clarification is needed. Under the statutory requirements for the Quality Payment Program, Advanced Alternative Payment Models (APMs) are exempt from MIPS. ⁹² Within MIPS, clinicians may choose to report through their APM Entity via the APM Performance Pathway, as an alternative to traditional MIPS and MVPs. CMS should confirm if this ambulatory specialty care model would qualify as an Advanced APM and thus participants would be exempt from MIPS, including MVPs. The agency should be explicit if CMMI is using its waiver authority to waive the statutory distinction between AAPMs and MIPS. The AAMC strongly discourages CMS from designing a model that requires MIPS reporting burden in addition to assuming downside financial risk under an AAPM.

Continue to Seek Feedback on the Model Design

Given the limited time to provide feedback through the comment period, we encourage CMS to continuously seek feedback throughout the design of an ambulatory specialty care model. We look forward to continuing our work with CMS as the agency creates new models.

Participant Definition

CMS is designing an ambulatory model for a subset of specialties. The agency is seeking public comment on how to identify specialty groups and if there are clinician or practice characteristics that warrant policy flexibilities.

Make Participation Voluntary

CMS is considering mandating participation in a future model for MIPS eligible clinicians with ambulatory-based specialties. Many specialty practices do not have the resources and are not in a financial position to support the necessary investments and take on the financial risk to participate in a mandatory model. We recommend that CMS make the model voluntary for all participants. Practices will elect to participate in models that they believe will support the delivery of high-quality patient care and allow clinicians to focus on patients over incentives subject to significant administrative requirements.

Use a Combination of the Tax Identification Number and National Provider Identifier to Identify Participants

The AAMC supports CMS' efforts to better align primary and specialty care to increase care coordination and improve outcomes. Improving the transition from primary to specialty care and back is vital to ensuring that patients' experience of care is seamless. Often, this integration occurs in the context of and because of a health system – rather than an individual hospital or physician group practice. Therefore, CMS should ensure that any new models do not artificially silo participants. CMS can accomplish this by identifying participants via a combination of Tax Identification Number (TIN) and National Provider Identifier (NPI), as has been done for

⁹² See Section 1848(q)(1)(C)(ii)(I) of the Social Security Act, as amended by The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10).

multiple episode- and population-based models. Participants could supply NPI lists for the clinicians working in the specialties relevant to any specified clinical areas prioritized in the model. This will prevent CMS from creating artificial silos among providers, as it allows a degree of rigidity in definition while preserving the ability of providers to indicate with whom they work. In addition, CMS should exempt specialty care providers who are participating in CMS models that have full TIN participation like the Shared Savings Program (SSP).

Establish a Clear and Transparent Attribution Method that Accurately Determines the Patient/Provider Relationship

It is critical that when measuring costs and performance there be an accurate determination of the relationship between a patient and a provider to ensure that the correct provider is held responsible for the patient's outcomes and costs. This is complicated given that patients often receive care from numerous providers across several facilities and teams within a single practice or facility. The attribution method should be clear and transparent to model participants. We suggest that better data sources and analytic techniques should be explored in the future to support more accurate attribution of these episodes. Attribution is a key component of a value-based care model.

Provide Policy Flexibilities for Rural and Safety Net Providers, and Providers New to Value-Base Care

Providers that care for a large portion of underserved populations, such as safety net providers and rural providers, often have limited resources to participate in value-based care models. The AAMC is concerned that these providers do not have the established infrastructure necessary for successful participation in Innovation Center models and lack the financial resources to build the infrastructure necessary to provide coordinated care under a mandatory model. If CMS were to make this a mandatory model, CMS should exclude rural and safety net providers or must provide policy flexibilities to ensure these providers succeed in the model. Flexibilities can include no or limited downside risk, low discount rates, and achievable benchmarks. CMS should also create meaningful readiness metrics that would allow these providers to better understand their performance and give them adequate time for internal process improvements before being held accountable.

CMS should also offer a glide path for all participants new to value-based care. It takes time to establish the care pathways necessary for success in a new model. For example, in episodic models, research shows that participants in BPCI Classic and BPCI Advanced were more likely to achieve success in years 2 and 3, than in year 1. 93, 94, 95 The first year of any model, especially a mandatory model, should acknowledge the necessity of time to create alignment within

⁹³ Joynt Maddox KE, et al., <u>Learning and the "early joiner" effect for medical conditions in Medicare's Bundled</u> Payments for Care Improvement Program: retrospective cohort study. *Medical Care*. 2020;58(10):895-902.

⁹⁴ Rolnick JA, et al. Spending and quality after three years of Medicare's bundled payments for medical conditions: quasi-experimental difference-in-differences study. *BMJ* 2020;369:m1780.

quasi-experimental difference-in-differences study. *BMJ* 2020;369:m1780.

95 Joynt Maddox KE, et al., <u>Year 1 of the Bundled Payments for Care Improvement-Advanced Model</u>. *New England Journal of Medicine*. 2021;385(7):618-627.

practices and establish the appropriate care management necessary to follow patients longitudinally.

MVP Performance Assessment

The ambulatory specialty model would operate within the MVP measures framework and collect data on quality, cost, and improvement measures relevant to specialties and sub-specialties identified by the model. CMS is seeking feedback on measurement selection and measure focus areas that should be prioritized.

Clarify Use of MVP Cost Measures for Payment Methodology

Each MVP identifies measures that are relevant to the MVP specialty, which include episode-based cost measures, a total per capita cost measure, and a Medicare Spending Per Beneficiary Clinician measures. CMS calculates cost performance based exclusively on these measures included in the MVP. If the model is designed as an AAPM excluded from MIPS, CMS should clarify how the MVP cost measures will be used in the benchmarking and payment methodology.

Clarify Use of the MIPS-only Population Health Measure Foundational to MVPs

The existing Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Q484) is specified to exclude patients attributed to qualifying participants in AAPMs, based on statutory restrictions to include such providers in MIPS. ⁹⁶ CMS should clarify how this foundation MVP measure will be used in the model if the model is designed as an AAPM excluded from MIPS.

Select Registry and Cross-Cutting Measures

The AAMC is concerned that currently, there are not sufficient MVPs available for all specialties and subspecialties, and it is highly unlikely this will be resolved in time for a 2026 model start. We recommend that CMS should include registry-derived, quality metrics. CMS should choose registries that already have high uptake with specialties and health systems nationwide. Choosing well-established registries also provides opportunities for physician engagement by using familiar measure sets they are accustomed to reviewing. CMS should also select measures that are the cross cutting across multiple pathways (e.g., MIPS #487 "Screening for Social Drivers of Health") or measures that providers most likely already have in place [e.g., MIPS #001 "Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)"] to reduce reporting burden. If multiple specialties are selected for this model, it can be challenging for large multispecialty practices that will need to monitor and report measures across several subgroups, as is currently the case for MVPs (please reference comments beginning page 55 of this letter for additional information). CMMI should design specialty quality measure reporting that is more meaningful and less burdensome than reporting MVPs as an incentive for participation in the model.

⁹⁶ See, CMS Measure Inventory Tool (CMIT), <u>Measure Specifications for Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions for MIPS</u>, stating denominator exclusion (4) "Patients assigned to clinician who achieve QP status and therefore do not participate in MIPS."

Use Patient-Reported Outcome-Based Performance Measures from the Patient-Reported Outcomes Measurement Information System (PROMIS)

The AAMC supports patient-reported outcome-based performance measures (PRO-PMs) that are valid, reliable, and capable of informing performance improvement. PRO-PMs provide information on a patient's well-being and functional status that can enhance quality of care. However, CMS should monitor the proliferation of PRO-PMs to ensure that the PRO-PMs in use are the most meaningful to patients. These measures should also be able to provide clinically relevant information to guide person-centered care. We want to be mindful of the administrative burden of many specialty-specific PRO-PMs layered on top of other survey methods. It is also important to ensure that patients are not overburdened with surveys at every visit. AAMC members report current utilization of PROMIS as an effective tool to evaluate health-related quality of life in their patient populations. PROMIS PRO-PMs are well validated measures with several included in MIPS.

Payment Methodology

This model would create the opportunity to compare similar specialists which can determine future Medicare Part B payment adjustments. CMS believes a targeted approach to financial performance relative to similar clinicians could incentivize shared accountability for care and lead to increased beneficiary access to coordinated specialty care. CMS is seeking public comment on what range of risk could incentivize specialist participation and what model design features should CMS consider to designing a model that increases risk over time.

Limit Downside Risk and Offer a Glide Path to Two-Sided Risk

As noted above, for rural providers and safety net providers, CMS should consider no or limited downside risk. These providers lack the foundation and readiness to be accountable for downside risk. They also take a form of risk when making investments in staff hires and training, technology enhancements, and population health tools to participate in value-based care as this may initially reduce revenues and they may not recoup their upfront investment. CMS should also offer a glide path to more financial risk for any safety net providers, rural providers, and providers new to value-based care. This will allow more time for these types of providers to establish care teams needed to participate in the model and prepare for two-sided financial risk.

Include a Modest CMS Discount, Favorable Benchmarks, and Sophisticated Risk Adjustments as Part of the Model Design

To incentivize meaningful participation in a new model, CMS should include multiple model design features: (1) a modest, achievable CMS discount, (2) favorable benchmarks, and (3) risk adjustments that accurately reflect the patient population being served.

A participant's ability to earn shared savings may be limited if the discount factor is set too high. For example, when investigating the Medicare spend for clinical episodes in the new Transforming Episode Accountability Model, we found that a 3% discount factor would require 11% to 17% reduction in post-anchor spending for half of the included episodes. By setting a reasonable discount factor, providers may be motivated to reduce unnecessary spending and reach their target goal.

CMS should develop favorable benchmarks that will allow providers to meet target prices and not make it difficult for providers to achieve significant improvements in efficiency and savings in the future. The AAMC suggests that CMS test administratively set benchmarks as part of the payment methodology to address the problematic ratchet effect. Administratively set benchmarks avoid the ratchet effect as it is not directly linked to ongoing observed fee-for-service spending. CMS could set the benchmark to allow for spending to rise at a slower rate over time than projected FFS levels. This would not only allow for efficient providers to achieve savings but could support safety net providers and other providers new to episode-based payment models to be successful. ⁹⁷ If CMS uses regional benchmarks, CMS should calculate historical benchmarks for safety net and rural providers. Research shows safety net providers in the CJR model were disproportionately disadvantaged by the 100% regional benchmark. ⁹⁸ Providers with limited experience in value-based payment models and those that care for more complex patients will not be able to compete against their peers in their region.

It is critical that CMS apply sophisticated risk adjustment to financial targets to ensure that providers are measured fairly based on the care they provide, not based on the patients that come through their doors. This includes adjustment for practice-level characteristics and patient-level risk, as measured by dual eligibility, disability, and Part D Low Income Subsidy status. AAMC has long flagged that dual eligibility is an imperfect proxy of social need and vulnerability. We ask CMS to commit to evaluating and sharing information on potential new indicators for assessing individual-level health-related social needs (HRSNs) correlated with negative health outcomes to move away from the use of a blunt proxy indicator such as dual eligibility. CMS should do this by identifying a short list of the most essential social needs, collecting this data in a standardized manner across models, and using the data to create upside incentives to close gaps, while also risk adjusting financial measures. CMS should explore whether HRSN data reported in the Hospital Inpatient Quality Reporting (IQR) program can be correlated to health outcomes, such as those measured in the Value-Based Purchasing program. Additionally, CMS should use this model to create an incentive for documenting HRSNs through the use of ICD-10 Z-codes on claims and to test whether increased coding for HRSNs better identifies vulnerable Medicare patients for purposes of risk adjusting target prices to better support health equity.

CMS should include adjustment factors for rural/urban location and size. Providers in rural areas have a higher burden because of fewer resources and a smaller workforce. A recent study demonstrates that the risk adjustment methodology previously used in other CMS value-based care models does not appropriately capture rural patients' complexity, leading to underpayment of rural providers. ⁹⁹ Safety net providers also have a higher burden because a large portion of their population are underserved and high-risk patients. Given the resource constraints for rural and safety net providers, lower payments will only increase the burden on these types of

⁹⁷ Chernew, M. E., Heath, J., & McWilliams, J. M., <u>The merits of administrative benchmarks for population-based payment programs</u>. *The American Journal of Managed Care*, 28(7), e239–e243 (2022).

⁹⁸ Carey, K., & Lin, M-Y. <u>Safety-net hospital performance under Comprehensive Care for Joint Replacement</u>. *Health Services Research*, 2022(1-6).

⁹⁹ Rogers, G., et al., <u>Bridging The Home-Based Primary Care Gap In Rural Areas</u>. Health Affairs Forefront (2024).

providers and could potentially lead to worse health outcomes for their patients. The inclusion of practice-level characteristics will further improve the pricing accuracy for participants.

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

CMS is exploring how an ambulatory specialty model could encourage coordination and partnership between specialist clinicians, accountable care entities, and primary care clinicians. The agency is seeking feedback on model features that could improve care coordination, incentivize partnerships between primary care and specialty care providers, and foster a collaborative environment to enhance healthcare outcomes and reduce costs.

Use Electronic Consults and Quality Metrics that Support Coordination between Specialists and Primary Care Providers

CMS can increase coordination between specialists and primary care providers by incorporating additional support for this coordination. For example, models can incorporate the use of electronic consults (eConsults) to encourage communication between providers. Ideally, while carving the cost of eConsults out of any target price to encourage its uptake, like the BPCI Advanced Model carve out for cardiac rehab. In addition, CMS can incorporate quality metrics related to closing the referral loop, like MIPS #374 "Closing the Referral Loop: Receipt of Specialist Report," to ensure that patients are receiving appropriate follow-up from their primary care and specialty providers.

Provide Up-front Infrastructure Payments, Waivers, and Data to Encourage Collaboration

CMS should consider creating up-front infrastructure payments to participants, like what is being included in the Making Care Primary Model. Many specialty and primary care practices lack the necessary infrastructure and resources to transform care delivery. These payments could be used to implement eConsults and enhanced referral programs which can be used to drive collaboration and improve care coordination between primary and specialty care.

CMS can also continue to encourage the use of waivers to enable patients to receive care at the most appropriate setting such as the Care Management Home Visit waiver offered under the Next Generation ACO Model and the Enhancing Oncology Model. This waiver would increase access to services in the home by allowing additional personnel to provide care in a patient's home. CMS should also consider an environmental modifications waiver or beneficiary enhancement, similar to what is seen in the Guiding an Improved Dementia Experience Model. This would allow providers to get an understanding of a patient's home environment and determine if there are modifications needed to assist a patient in recovering at home, such as grab bars or other accommodations. The incentives and waivers do not need to vary based on whether a participant is in an ACO.

Additionally, the AAMC has found that access to comprehensive, timely data has been key to successful collaboration in these programs. We recommend that all data for the proposed model is provided monthly to ensure that the data is as timely as possible. Timely and accurate data are vital to understanding the patient's journey through care to ensure appropriate coordination and improve outcomes.

Health Information Technology and Data Sharing

CMS acknowledges that clinicians frequently request more timely and expansive data to help guide improvement efforts. The agency is seeking public comment on what issues should CMS consider around the use of health information technology (IT) beyond those currently specified in the MVP framework, how CMS should structure health IT and data sharing requirements in the model, and what health IT investments would be beneficial to model participants.

Establish Relationships with EHR Vendors to Increase Interoperability Between Platforms

CMS should establish relationships with electronic health record (EHR) vendors with substantial health system market share (e.g., EPIC and Cerner) and vendors with smaller market-share (e.g., MEDHOST and ModMed) that are often used by smaller practices to assist in creating better communication tools between these platforms. These communication tools are especially important at the primary/specialty interface and with tools like eConsults. CMS should work with EHR vendors to establish uniformly defined, machine-readable fields that capture all data elements that participants are required to report, including both clinical and social risk data. Additionally, CMS should partner with the / Office of the National Coordinator for Health Information Technology to commit resources to address semantic differences to health system implementation of burgeoning data standards under the US Core Data for Interoperability (USCDI). One method of doing so would be through an open-source, interoperable Fast Healthcare Interoperability Resources (FHIR) and application program interface (API) software. This would reduce burden by facilitating communication across care types and health systems to ensure that a patient's records can easily follow them between physicians without data loss.

Our experience working with member academic health systems through Project CORE, an eConsult and enhanced referral program, has highlighted significant interoperability issues across systems, even in cases where they are operating within the same platform or using the same EHR tools developed by the same EHR vendor. For example, a call at one institution for the value of a white blood count lab may return the value but using the same vendor platform (or a FHIR API) to call at another institution might not result in a returned value, due to semantic inconsistency. Currently, there are no feedback loops to address such inconsistencies in the implementation of normative standards across the nation. CMS could support broader semantic standardization through the development of national and regional user groups that provide feedback loops on semantic differences, helping to serve as a mechanism for truly normalizing national data standards into clinical practice.

Provide Claims and Non-Claims Data and Benchmarking Metrics

The AAMC has found that access to data and benchmarking has been key to improving performance in these models. We recommend that all relevant claims and non-claims data be provided monthly to ensure providers have the most up to date data on their patient population to assist with care planning and quality improvement initiatives. Model participants are often concerned with the long data lags that currently occur in many Innovation Center models. This is often a major area of concern for AAMC members who want actionable data to make real time improvements. It may be difficult to act when the data is further lagged. Minimal data lag also increases the ability for providers to engage in continuous quality improvement. The AAMC

recommends that the beneficiary-level data provided by CMS include data from all claim types, including inpatient, outpatient, and post-acute care services, as well as data on any of the elements included in the risk adjustment or target price methodology.

Use Registries to Reduce Data Collection and Reporting Burden

To decrease the burden of data collection and measure reporting, CMS should choose registries that already have high uptake with health systems nationwide. Choosing well-established registries and evidence-based clinical guidelines also provides opportunities for physician engagement by utilizing familiar measure sets they are accustomed to reviewing. Registries reduce the reporting burden for participants because they are already reporting this registry data. Registries already have physicians engaged in their reporting structures, so it is not additional data they need to collect. In addition, registries are focused on clinically actionable metrics which makes them more useful in a clinical setting.

Health Equity

While several MVPs include equity-focused measures and MVPs provide reporting and scoring flexibilities for certain special status designations, CMS recognizes that there are additional clinician, practice, and beneficiary-level characteristics to account for to support model participants in identifying and working to improve disparities. The agency is seeking feedback on how CMS might support the participation of clinicians that serve a higher proportion of underserved patients, and how could the model support the identification of health disparities and related improvement strategies as well as the collection and reporting of HRSN data.

Offer an Upfront Infrastructure Investment to Rural and Safety Net Providers

As noted earlier, rural providers, safety net providers, and other providers that care for a large portion of underserved populations have little room for investment in value-based care infrastructure due to low operating margins. If CMS wants to include new types of providers in value-based care to expand the reach to underserved patient populations, CMS needs to make accommodations to encourage active participation from these providers that experience high burden and minimal resources. CMS should provide an upfront infrastructure investment to these types of providers to support their participation in an ambulatory specialty model. An upfront infrastructure investment would support safety net and rural providers to make necessary health IT enhancements and staff hires needed to successfully participate in an ambulatory specialty model.

In addition, CMS should not require a repayment of the upfront infrastructure investment payment. Currently, the ACO Primary Care Flex model has proposed an upfront infrastructure investment that requires safety net providers to repay that amount. Requiring a payback could prevent safety net providers from seeking the investment. In general, safety net providers have not previously engaged with value-based care because of their narrow operating margins, which prevents them from investing in the appropriate EHR technology, additional staff, and other resources typically used in value-based care. ¹⁰⁰ Safety net and rural providers are often the only

¹⁰⁰ Cuellar, A., et al., <u>Value-Based Payment, the Safety Net, and Rethinking Risk</u>. *American Journal of Managed Care* (28) 8 (2022).

point of care for many patients in the community and if unintended consequences occur from participating in a CMS model, such as a reduction in funds or hospital closures, this could result in patients losing their sole care provider.

Provide Monthly Data to Help Participants Identify Health Disparities and Develop Equity Goals

Providers need complete and accurate data to identify health disparities and develop actional goals. CMS should provide all available data with participants monthly to ensure they can address any gaps in a timelier way. This data would allow providers to develop individualized interventions for the highest risk patients and track how those interventions are impacting care to ensure their effectiveness. CMS should provide participants with all available data on claims and social risk (including any HRSN reporting and Z-codes). CMS should also provide technical assistance and data analytic support to safety net and rural providers, who may not have a built-in data analytics team to determine major gaps and disparities faced by a provider's patient population. Analyses from these types of providers may be qualitative, based on experience with patients in the community, rather than extensive quantitative data.

Eliminating health disparities requires a multi-faceted approach from payers, providers, and community-based organizations. CMS should work with participants and states to establish partnerships with community-based organizations to link participants with organizations that can provide support for social needs such as transportation, housing, and food insecurity. Knowing the capacity of community-based organizations will allow providers to develop actionable strategies to improve disparities.

Use Existing Policies to Collect and Report HRSN Data

Differing data collection approaches can create an undue burden and confusion for providers. CMS should implement model policies that align with measure reporting in SSP to create alignment between programs and increase data consistency. CMS proposes a screen positive rate for Social Drivers of Health measure with mandatory reporting starting in CY 2026. This measure assesses the number of patients who screened positive for five HRSNs, housing instability, food insecurity, transportation needs, utility difficulties, and interpersonal safety. All new CMS models should require the collection of the same five HRSNs to alleviate burden on providers and streamline reporting. Requiring the collection of the same HRSNs would create a more robust and standardized data set. CMS should encourage the collection of additional HRSNs but only require the five HRSNs outlined in SSP. CMS should also commit to using ICD-10 diagnostic codes inclusive of Z-codes to improve payment accuracy as the use of Z-codes will enable more robust risk adjustment.

Multi-Payer Alignment

The Innovation Center at CMS has a strategic goal of making multi-payer alignment available in all new models by 2030. CMS is seeking feedback on how to reduce clinician burden between CMS and other payer models and align value-base care approaches across models.

Promote Alignment of Quality Measurement and Data Sharing to Reduce the Administrative Burden for Participants

Many of the AAMC's members seek to create more multi-payer alignment within their value-based care programs, so we appreciate CMS' attention to this important issue. Providers can be better incentivized to implement value-based care programs when performance, quality, and financial arrangements are aligned across payers. This is especially true for safety net and rural providers who often lack the infrastructure and resources to participate in value-based models. While total alignment may be challenging, alignment on quality measures, data collection and reporting, and reconciliation timelines can alleviate participation burden.

CMS should require alignment on a reasonable number of clinically meaningful quality measures, using aligned specifications to minimize participant burden and increase the ability to accurately monitor quality and outcomes. Without agreement in quality metrics, it is difficult to create true alignment across payers and promote, or evaluate, meaningful change. These measures should be registry based whenever possible, as many clinical service lines already participate in several registries that could provide valuable quality data to CMS, without creating additional administrative burden for the participants. BPCI Advanced serves as an excellent example of adopting registry measures, and AAMC members have shared that the use of registry-based quality measures increased their specialists' engagement in the model. Registries offer the opportunity to identify the exact causes of risk and address those risks. Where available, CMS should use existing registries that are well-adopted across provider types. When those registries do not exist, CMS should partner with appropriate providers and patient groups to create them. Registries can aid in model evaluation by giving more dimensions of care that are consistent across providers for the evaluators to analyze. Additionally, registries are national, clinically vetted, audited, and drive evidence-based practice.

Data sharing also provides an opportunity for greater alignment across payers. CMS should require any participating commercial payers to provide timely data to participants. This data should mirror what CMS provides, including patient-level data on cost, utilization, and quality measures, to ensure that participants can holistically evaluate the approach to care across payers. Readily accessible data from all payers allows participating providers to gain a more comprehensive view of their patient population and deliver more efficient care.

QUALITY PAYMENT PROGRAM [IV]

The AAMC appreciates the agency's efforts to continue to develop Quality Payment Program (QPP) policies that more effectively reward high-quality care of patients and increase opportunities for Advanced APM participation. While we support the goals of the program to deliver high-value care for Medicare patients, we believe that significant refinements to the program are needed. We encourage CMS to work with key stakeholders to identify longer term policy solutions that would improve quality, attain health equity for all beneficiaries, improve patient outcomes, and reduce burden. Our comments on the proposals in the rule related to the QPP follow.

MIPS VALUE-BASED PATHWAYS (MVPS)

Do Not Sunset Traditional MIPS Until Significant Conceptual and Operational Challenges with MVPs are Adequately Addressed

CMS established a new MIPS participation framework, referred to as MIPS Value Pathways (MVPs) in the CY 2020 rulemaking cycle. ¹⁰¹ CMS eligible clinicians have been able to meet MIPS reporting requirements through the MVPs since 2023. CMS has indicated its goal to move away from Traditional MIPS and to have MVPs become the only method available to participate in MIPS in future years; and in this rule includes a request for information on the potential readiness to require MVPs and sunset MIPS beginning with 2029 performance. CMS also includes proposals that address operational aspects of subgroup reporting, the MVP development and maintenance process, and scoring for MVPs. CMS proposes to add 6 new MVPs and revise 12 existing MVPs so that there will be 21 MVPs available to report for performance year 2025.

It is important for CMS to understand the unique challenges posed by the QPP for large multi-specialty practices such as those typically found in academic health systems.

Physicians at AAMC member institutions are organized into large multi-specialty groups known as faculty practice plans which often have a single TIN. Recent data shows that the practice plans range in size from a low of 311 individual NPIs to a high of 5,503 with a mean of 1,834 and a median of 1,574. On average these practices have over 137 adult and pediatric specialties and subspecialties, such as burn surgery, gastroenterology, and pediatric endocrinology, to name a few. In some cases, faculty practice plans are highly integrated and make decisions about quality and care coordination as a single entity. In other instances, such decision-making occurs at the departmental or specialty level. Given the size of these practices and numerous specialties that report under one TIN, we believe MVPs should remain optional for participating in MIPS.

With the large number of distinct specialties reporting under one TIN, it will be very challenging to identify MVPs that will be meaningful for the myriad of specialties and subspecialties in the practice and encompass the scope of conditions treated in academic health systems. Mandatory reporting will require significant administrative capacity to identify appropriate MVPs, map out applicable subgroups, and track and report metrics across each MVP. An additional challenge for faculty practice plans will be tracking physicians that join and leave the practice throughout the course of the year, including transitions from residency to practice around July 1 each year. These shifts in practice add complexity for identifying which physicians should be included in a particular subgroup during a calendar-year based performance period. CMS must address these administrative challenges for large multispecialty practices before mandating MVP reporting.

Therefore, we urge CMS to continue to make MVP reporting voluntary for the foreseeable future. We have significant concerns with plans to sunset the traditional MIPS reporting option in future years, making MVPs, APM Performance Pathway, or qualified participation in Advanced APMs the only mechanisms for participating in the QPP. There are several conceptual challenges with the MVP program and sufficient time will be needed to

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¹⁰¹ CY 2020 Physician Fee Schedule, 84 FR 62568, at 62949 (Nov. 15, 2019).

¹⁰² Supra, note 1.

¹⁰³ *Id*.

address them before sunsetting traditional MIPS. First, there must be enough clinically relevant measures available to create MVPs that are meaningful to the over 1 million eligible clinicians that participate in the MIPS path of the QPP. Given the numerous physician specialties and subspecialties, it will be difficult to create enough MVPs, especially within the next five years. Development of and refinement of existing MVPs to support required reporting will require significant input from physicians. Practices should be given the opportunity to assess the advantages and disadvantages and select whichever option is most meaningful and least burdensome for participating in the QPP under MIPS.

Ensure Comprehensive, Meaningful MVPs are Available to All Specialties and Sub-specialties

CMS proposes to adopt six new MVPs and modify all 16 previously finalized MVPs (pp. 62016-62018). Together, these proposals, if finalized, would result in 21 MVPs available to clinicians to report for 2025 performance. The AAMC supports the agency's efforts to develop sufficient MVPs to meaningfully engage all specialties and sub-specialties, but we do not believe the portfolio of MVPs will meet that mark in the near future. Not all existing MVPs fully capture the clinical care delivered within the specialty and across sub-specialties. For example, the Advancing Cancer Care MVP is predominantly focused on medical oncology, and would not be meaningful for radiation oncologists, despite the name. Similarly, the Complete Ophthalmologic Care MVP has been improved upon, but the lone cost measure focuses on cataracts care, leaving out specialists whose practice is entirely sub-specialized within retinal or glaucoma care. This says nothing of the challenges with MVPs for non-patient facing specialties, like radiology and pathology, who provide clinically significant services in a manner that is challenging to meaningfully measure under the MVPs framework. CMS seeks feedback on temporary solutions for specialties without an existing MVP, such as developing MVPs based on multiple specialty measure sets applicable to multiple conditions or MVPs on broadly applicable measures. Rather than working on developing temporary solutions to the insufficient MVP coverage for all specialists, CMS should retain traditional MIPs as a reporting option and invest in developing the comprehensive, meaningful measures needed to advance MVP adoption.

Practices Must Have the Flexibility to Compose Subgroups for Reporting MVPs Based on Clinical Practice and Team-Based Care Patterns

CMS seeks feedback on the potential future establishment of limits on practices when composing subgroups to report MVPs. Such limitations could include limits on the size of a subgroup or whether to use Medicare claims data to potentially inform subgroup composition restrictions. (p. 62015) The AAMC strongly opposes such limits. Faculty practices are large multispecialty practices with a median of 1,574 clinicians, including physicians and non-physician eligible clinicians. ¹⁰⁴ The care provided is team-based, often with collaboration across specialties. Non-physician practitioners (NPPs) are critical to care design within academic health systems and may rotate across specialties within the performance period to best serve patients. Claims-based subgroup composition restrictions might inadvertently limit full representation of team-based care and frustrate health system efforts to meaningfully report on the value of care delivered within their practices. While most MVPs are designed around specialty, a few are designed

around a condition that can cross specialties and be more appropriate for some specialists than the specialty-specific MVP. A couple of examples of such instances are the Advancing Care for Heart Disease MVP (cardiology, internal medicine, family medicine, as well as nephrology) and Advancing Rheumatology Patient Care MVP (internal medicine, family medicine, in addition to rheumatologists). Given these dynamics, we strongly believe that rules for subgroup composition be flexible to ensure practices can best report MVPs in ways that make sense for the clinical context of care delivered within their practice and that best represent teambased care delivery. Requirements for the size of a given subgroup or limitations determined by the information available in claims data will likely hinder practice reporting administration without meaningful benefits to the agency when assessing performance.

TRADITIONAL MIPS

Maintain MIPS Performance Threshold for Foreseeable Future to Provide Stability for Clinicians

CMS establishes a performance threshold score that eligible clinicians must meet to avoid a negative payment adjustment. CMS proposes to maintain the MIPS performance threshold at 75 points for 2025. (p. 62091) The AAMC supports maintaining the 75 point performance threshold beyond 2025 to provide stability for providers as they adjust to scoring the Cost performance category and reporting MVPs. Additionally, we urge CMS to support any efforts in Congress that would allow CMS to have more flexibility to set MIPS performance thresholds based on current circumstances rather than a preset formula.

MIPS Performance Category: Quality

Maintain Data Completeness Threshold at 75 Percent for Three Years

CMS intends to increase the data completeness criteria for quality reporting slowly and incrementally over time to achieve a higher data completeness without jeopardizing clinicians' ability to successfully participate and perform well in MIPS. CMS maintained a data completeness criteria threshold of at least 70 percent for four years from CY 2020 through CY 2023 performance. In CY 2024, CMS raised the data threshold requirement to 75 percent. CMS proposes to maintain the data completeness criteria threshold of at least 75 percent for two additional years. (p. 62039)

The AAMC supports the proposal to maintain the data threshold at 75 percent and we recommend that CMS maintain the data threshold for three years. The 75 percent threshold is already high, and CMS should consider the additional reporting requirements that practices are expected to implement, such as reporting multiple MVPs and eCQMs and new digital quality measures. Some physicians under the same TIN provide services at multiple sites and not all sites have the same electronic health record (EHR) platform or use the same option for reporting MIPS. Data must be integrated across settings to facilitate reporting, which can be difficult in these situations. Maintaining the threshold for four total years promotes consistency, predictability and provides additional time to better integrate data to meet increased data reporting requirements in the future. We also believe maintaining the data threshold for four years supports CMS' efforts to reduce administrative burden within MIPS.

Retain Current Policy for Multiple Submissions to Apply the Highest of the Scores Received

CMS proposes to use the most recent submission to score organizations with multiple submissions from submitters within the same organization, differing from the long-standing policy of applying the highest of scores for organizations with multiple submissions from submitters from separate organizations. (p. 62036) We support the long-standing policy to score the highest of scores received. Creating two separate policies for a nearly identical issue, multiple submissions, is confusing. Additionally, CMS' data submission tool does not allow for corrections once data has been submitted, necessitating multiple submissions for which CMS should give practices the benefit of the doubt.

Codify Criteria for the Removal of MIPS Quality Measures

In prior rulemaking, CMS has established criteria for measure removal where the agency determines that the MIPS quality measure is no longer meaningful, such as MIPS quality measures that are topped out or if a measure steward is no longer able to maintain the quality measure. Over the years, CMS has expanded these criteria, including where measures that are duplicative, not maintained or updated to reflect current clinical guidelines. Och now proposes to codify the criteria previously established for the removal of MIPS quality measures from the MIPS quality measure inventory in § 414.1330(c). (p. 62040) The AAMC supports CMS' proposal to codify previously established criteria for the removal of MIPS quality measures. We recognize that the measure inventory cannot remain static over the long-term.

However, annual program changes increase administrative burden, add complexity to reporting compliance, decrease effectiveness of ongoing quality efforts, and increase the cost of program compliance for practices. The imposed burden of measure churn is substantial. Faculty practices invest time and resources to implement their chosen quality measures and update their systems accordingly. Removing or changing measures forces a practice to pick new measures to satisfy reporting requirements, requiring additional system changes, workflow adjustments, and clinician education. Measure inventory changes, therefore, require careful consideration from the stakeholder perspective as well as the agency's viewpoint. When considering the removal of a quality measure, we urge CMS to weigh the impact of removal based on the totality of the circumstances or all relevant factors before removal. Furthermore, we ask that CMS limit measure removal, when possible, to prevent clinician burnout, by limiting administrative burden associated with changing measures.

Remove Scoring Cap for Topped Out Measures in Specialty Measure Sets With Limited Measure Choice

Topped out measures are measures for which measure performance is considered so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. ¹⁰⁸ If a measure has been identified as topped out for three consecutive years after being

¹⁰⁵ Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, 81 FR 77008, 77136 - 77137 (Nov. 4, 2016).

¹⁰⁶ Supra, note 78 at 59763.

¹⁰⁷ Supra, note 101 at 62958-62959.

¹⁰⁸ Supra, note 105 at 77293.

originally identified through the benchmarks, the measure may then be proposed for removal. The list of quality measures has decreased from 271 to 198 which includes the removal of 34 topped out measures. CMS acknowledges that this is a problem for certain specialties facing both limited measure choice and limited scoring opportunities.

To address this issue CMS proposes beginning with the CY 2025 performance to remove the 7-point cap for certain topped out measures. This would allow clinicians who practice in specialties impacted by limited measure choice to be scored according to defined topped out measure benchmarks that do not cap scores at seven measure achievement points. Under the proposed topped out measure benchmarking methodology, those achieving high performance rates would be rewarded for high performance. (p.62077) **The AAMC commends CMS for identifying this issue and we strongly support this proposal to address the issue.** Topped out measures often remain clinically meaningful even with consistently high performance, especially for specialties with limited available measures. Specialties with limited measure sets should not be arbitrarily penalized in program scoring for maintaining high performance.

Provide Timely Benchmarks for Quality Metrics

CMS publishes data during the performance period setting benchmarks for quality measures, including information when a quality measure does not have a benchmark. The AAMC urges CMS to provide more timely benchmarks ideally in advance of the performance period or at least no later than the first quarter of the performance period for all active measures. And, if unable to set a benchmark for a given measure at such time, provide bonus points for providers who submit measures that lack benchmarks to encourage submission of the measure to be able to develop a future benchmark.

Expand Survey Modes of the CAHPS for MIPS Survey

CMS is seeking public comment on the potential expansion of the survey modes of the CAHPS for MIPS Survey from a mail-phone protocol to a web-mail-phone protocol. (p. 62042) Currently, the survey is administered first through the mail and then by phone interview. During the 2023 CAHPS for MIPS Web Mode Field Test adding the web-based survey mode to the current mail-phone protocol of CAHPS for MIPS survey administration resulted in an increased response rate. The AAMC strongly supports expanding to a web-mail-phone protocol, given the potential for an increased response rate.

MIPS Performance Category: Cost

Amend Cost Measure Scoring to Standard Deviations Relative to Median Cost Performance

Previously, CMS scored the cost performance based on decile performance, where clinicians with the lowest average cost per episode per beneficiary would be in the top decile and receive the highest number of available achievement points. CMS proposes to change scoring beginning with CY 2024 performance to instead base scoring on standard deviations relative to the median cost for all MIPS eligible clinicians scored on the cost measure. (p. 62085) Clinicians with costs near the 50th percentile would not receive a disproportionately low score, as they do under the current methodology. (p. 62096). **The AAMC supports this proposed methodological change.** We agree that it is more appropriate to assess clinician performance relative to median cost.

Attribution for Cost Measures Should be Transparent and Accurately Reflect Patient and Clinician Relationships

It is critical that when measuring costs there is an accurate determination of the relationship between a patient and a clinician to ensure that the correct clinician is held responsible for the patient's outcomes and costs. This is complicated given that patients often receive care from multiple clinicians across several facilities and teams within a single practice or facility. The attribution method to establish care relationships and measure costs of care must be clear and transparent to clinicians. We suggest that better data sources and analytic techniques should be explored in the future to support more accurate attribution of these episodes.

Remove Costs of Preventive Services from Cost Measures

The AAMC recommends that CMS remove the cost of all Medicare-covered preventive services from cost measures to remove potential disincentives to furnish high-value care. Potential savings from preventive services are unlikely to be realized during the performance period in which they are providers, setting up a potential penalty for clinicians seeking to expand availability of such services. Elsewhere in this proposed rule CMS seeks to expand coverage and access to preventive services, and the agency should ensure its pay-for-performance methodologies do not frustrate those policy aims.

All Cost Measures Should Account for Clinical Complexity and Social Risk Factors

The AAMC recommends that all cost measures used in the MIPS program be appropriately adjusted to account for clinical complexity and social risk factors. The episode cost measures are risk-adjusted based on variables such as age and comorbidities by using Hierarchical Condition Categories (HCC) data and other clinical characteristics. While the Total Per Capita Cost (TPCC) measure and the Medicare Spending Per Beneficiary (MSPB) measures are risk adjusted to recognize demographic factors, such as age, or certain clinical conditions, these measures are not adjusted for other social risk factors. In addition to differences in patient clinical complexity, social risk factors can drive differences in average episode costs. A report from the National Academies of Science, Engineering and Medicine 109 noted that sociodemographic status variables (such as low income and education) may explain higher costs.

Without accurately accounting for clinical complexity and social risk factors, the cost measure scores of physicians that treat vulnerable patients will be negatively and unfairly impacted and their performance will not be equitably reflected in MIPS scoring. The AAMC has long supported policies aimed at best using data to improve outcomes, in part by identifying the clinical and social factors influencing health. To this end we have supported the use of ICD-10 diagnostic codes, including Z-codes for social risk factors, to best capture clinical and social context that can in turn inform appropriate risk adjustment models that will help transform our health care system away from fee-for-service payment towards paying for value. 110 CMS has enacted policies to encourage providers to screen patients for health-related social needs

¹⁰⁹ National Academies of Sciences, Engineering, and Medicine. Accounting for social risk factors in Medicare payment: Criteria, factors, and methods. The National Academies Press. 2016. Doi: 10.17226/23513 ¹¹⁰ *Supra*, note 68.

(HRSNs) and to utilize the information collected to inform patient-centered treatment plans and to connect patients with community-based resources, where appropriate. We continue to urge CMS to adopt policies, including cost measurement methodologies, that incorporate ICD-10 codes inclusive of Z-codes to improve payment accuracy and reduce health disparities. The use of Z codes will enable more robust risk adjustment, while also reducing burden on providers who are already familiar with capturing clinical factors through ICD-10 coding.

CMS Should Provide Timely Cost Performance Feedback to Clinicians

We also urge CMS to provide more timely feedback to physicians on their performance on cost measures. Physicians do not know at the time that they provide services or throughout the performance year how they are performing on these measures, including which patients are attributed to them and what costs or services provided by other health care professionals or facilities outside of their practice for which they will be held accountable. Without this information, it is difficult for physicians to identify ways to improve care delivery and avoid unnecessary costs.

MIPS Performance Category: Improvement Activities

Simplify Scoring by Removing Weighting & Reducing the Number of Activities Clinicians Must Report

To simplify the scoring of the category CMS proposes to eliminate the weighting of improvement activities (p. 62059). CMS previously established a differently weighted model where clinicians receive 10 points for each medium weighted improvement activity and 20 points for each high-weighted improvement activity. CMS continues to streamline the measure inventory with the goal of ensuring that every improvement activity is considered high-priority as it represents a unique and vital aspect of clinical practice improvement. CMS also proposes to simplify scoring requirements by reducing the number of activities necessary for clinicians to attest to achieve a full score. Specifically, the agency proposes that MIPS eligible clinicians participating in traditional MIPS would be required to report two activities and clinicians reporting through MVPs would be required to report one activity. (p. 62059)

The AAMC supports CMS efforts to streamline the improvement activities performance category by eliminating the weighting of activities and reducing the number of activities that eligible clinicians are required to report. We believe that applying differential weight is overly complicated and unnecessary given the refinements to the program that CMS has implemented. We also support CMS' intention to create an inventory where all activities are considered high priority.

ALTERNATIVE PAYMENT MODEL (APM) PERFORMANCE PATHWAY (APP)

CMS established the APM Performance Pathway (APP) for MIPS reporting and scoring for clinicians in MIPS APMs in the CY 2021 rulemaking. Clinicians in MIPS APM Entities may participate in MIPS using any available MIPS reporting pathway, including the APP, Traditional MIPS, and MVPs. CMS proposes to establish a new APP Plus quality measure set based off the

¹¹¹ Supra, note 105 at 77311.

agency's Universal Foundation adult measure set. APM Entities other than Shared Savings Program (SSP) ACOs would have the choice to report the APP quality measure set or the APP Plus quality measure set. (p. 62023) The AAMC supports implementing the Universal Foundation measure set as a step towards creating standardization across APMs and Medicare programs. Additionally, CMS proposes to apply a Complex Organization Adjustment for APM Entities, including SSP ACOs, that report eCQMs. (p. 62080) The AAMC supports this adjustment to recognize the challenges APM Entities face when reporting eCQMs across APM participants utilizing different EHR platforms. We refer CMS to additional comments on the APP Plus measure set and Complex Organization Adjustment in our comments on proposals for SSP ACOs, beginning on page 40 of this letter.

ADVANCED ALTERNATIVE PAYMENT MODELS (AAPMs)

If an eligible clinician participates in an Advanced APM and is a qualifying APM participant (QP) or a partial qualifying APM participant (partial QP), the MIPS reporting requirements and payment adjustment do not apply to that clinician. For payment years 2019-2024 (performance years 2017-2022), QPs received a 5 percent APM incentive payment, for the 2025 payment year (2023 performance year), QPs receive a 3.5 percent APM incentive payment, and for the 2026 payment year (2024 performance year), QPs receive a 1.88 percent APM incentive payment. Beginning with payment year 2027 (performance year 2025), there is no further statutory authority for an APM Incentive Payment. However, for payment year 2026 (performance year 2024) and beyond, clinicians in AAPMs have the opportunity for a 0.75% update to the CF while those not in AAPMs would receive a 0.25% update.

We are deeply concerned that the expiration of the AAPM incentive payment will have a chilling effect on participation in alternative payment models. We urge CMS to include in its legislative agenda support for the continuation of the AAPM bonus. If Congress does not act to extend the bonus, we urge CMS to take administrative actions within its authority that would mitigate the effects of the sunsetting bonus. This could include changes to benchmarking, increasing shared savings opportunities, reducing administrative burden, allowing more flexibility, and allowing longer transitions for APMs to downside risk.

Encourage Congress to Freeze QP Thresholds or Grant Authority to Set Thresholds at a Level That Would Encourage Participation in APMs

To be classified as a qualifying participant (QP) or partial QP in an AAPM, providers must meet or exceed thresholds based on patients seen or payment received for services provided through AAPMs. Congress established these thresholds in the Medicare Access and CHIP Reauthorization Act of 2015, setting a higher thresholds for the payment years 2023 and beyond that required clinicians to have at least 75% of their revenue in the Medicare FFS program received through a Medicare APM, or 50% of their Medicare FFS patients would need to receive services through the APM, in order be considered a QP. ¹¹² These thresholds are too high and would have made it much more difficult for an eligible clinician to be considered a QP and to receive the 5% bonus payment in 2023. Congress recognized this problem and addressed it in the

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¹¹² *Supra*, note 92.

Consolidated Appropriations Act, 2022 which froze the thresholds for payment years 2023 and 2024 at the 2021 and 2022 payment year levels. The Consolidated Appropriations Act, 2023¹¹³ froze the thresholds for an additional year through payment year 2025, and again through the Consolidated Appropriations Act, 2024, through payment year 2026.¹¹⁴

We remain deeply concerned about the increase to the thresholds that will occur in the 2027 payment year (2025 performance year). The increasing thresholds that must be met to be considered QPs in AAPMs will discourage participation, thereby limiting beneficiary access to high quality and high value care. It is very difficult for APMs to increase the volume of payments received through the APM or amount of Medicare FFS patients who receive services through the APM, due to intentional attribution design within the models. For example, episodic models attribute patients based on a triggering procedure and ACOs attribute specifically based on receipt of primary care services.

We urge CMS to encourage Congress to freeze QP thresholds, or, at a minimum, give CMS the authority to set thresholds in the future at a level that will incentivize participation in advanced alternative payment models. Additionally, should Congress extend bonus payments for participants in AAPMs beyond 2024 performance, we suggest a modification to the bonus payment system. Rather than using QP thresholds to award bonuses on all Medicare payments to instead forgo thresholds and assess bonuses solely on Medicare payments for care delivered to patients under the AAPM, thus rewarding providers for the care delivered to patients attributed to their APM participation.

Amend the Definition of an Attribution Eligible Beneficiary for Purposes of Assessing QP Thresholds

CMS proposes to amend the definition of an attribution-eligible beneficiary at § 414.1305 for purposes of making QP determinations. (p. 62098) Prior policy limited attribution-eligible to those patients who had at least one *E/M service* furnished by an eligible clinician participating in an APM Entity during the QP Performance Period. CMS proposes to revise this to *any covered professional service* to "more accurately reflect eligible clinicians' actual participation in Advanced APMs[.]" (p. 62099) **The AAMC supports this proposed change.** We agree that this would better align the QP determination methodology with the universe of services to which the QPP applies, rather than the subset of E/M services. As noted by CMS, E/M services tend to be furnished at a higher proportion by primary care practitioners than specialists for the same patient, and by narrowly measuring patients through E/M services, CMS might have inadvertently encouraged APM Entities to reconsider inclusion of specialists in APM participation.

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¹¹³ Consolidated Appropriations Act, 2023; Pub. L. 117-328 (Dec. 2022).

¹¹⁴ *Supra*, note 2.

CONCLUSION

The AAMC appreciate your consideration of the above comments. We would be happy to work with you on any of the issues discussed above or other topics that involve the academic medicine community. Please contact my colleagues Gayle Lee (galee@aamc.org), Phoebe Ramsey (pramsey@aamc.org), Ki Stewart (kstewart@aamc.org), and Erin Hahn (ehahn@aamc.org) with any questions about these comments.

Sincerely,

Jonathan Jaffery, MD, MS, MMM

Chief Health Care Officer

AAMC

Cc: David Skorton, MD, AAMC President and CEO