Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400
www.aamc.org

Via electronic submission (www.regulations.gov)

September 13, 2021

The Honorable Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Attention: CMS-1751-P

Re: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements (CMS-1751-P)

Dear Administrator Brooks-LaSure:

The Association of American Medical Colleges ("the AAMC" or "Association") welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) 2022 Physician Fee Schedule and Quality Payment Program (QPP) proposed rule published July 13, 2021 (86 Fed. Reg. 39104). The AAMC (Association of American Medical Colleges) is a nonprofit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, 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 and teaching hospitals and the millions of individuals employed across academic medicine, including more than 186,000 full-time faculty members, 94,000 medical students, 145,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

Through their mission of providing the highest quality patient care teaching physicians who work at academic medical centers (AMCs) 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 supervise medical residents and 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. Often care is 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 128 individual national provider identifiers (NPI)s to a high of 4,319 NPIs, with a mean of 989 and a median of 816. These practices support the educational development of residents and physicians who will

become tomorrow's physicians. Teaching physicians also provide significant primary care services to patients in their local communities.

In addition to primary care, teaching physicians provide other critical services for their local communities, including a large percentage of tertiary, quaternary, and specialty referral care. Also, teaching physicians may have a patient base that spans regions, states and even the nation. They also treat a disproportionate share of patients for whom social determinants of health, such as housing, nutrition, and transportation, contribute significantly to additional health challenges, adding greater complexity to their care. Academic medical centers, where teaching physicians work, deliver a disproportionate share of undercompensated and uncompensated care.

The COVID-19 pandemic has posed enormous challenges and placed tremendous stress on our entire health care system – and teaching hospitals, medical schools, and teaching physicians have mobilized on all fronts to contain and mitigate COVID-19. We thank CMS for reducing regulatory burden and providing flexibility during the public health emergency (PHE). These flexibilities have enabled providers to be more innovative in their care of patients. We believe that many of these changes, such as the expansion of telehealth and use of other communication-based technologies, can provide greater access and improved care if they are continued in the future.

The AAMC commends CMS for its commitment to promoting health equity and expanding patient access to comprehensive care. The COVID-19 pandemic has highlighted the gap in health equity as data have shown the virus has disproportionately affected Black, and Latinx, American Indian/Alaska Native, Asian-American, and Pacific Islander communities. We share CMS' goal to reduce disparities in health care and support initiatives to close the equity gap. Our members have been working to implement new strategies aimed at promoting health equity.

While we support the direction CMS has taken on some issues, we also are concerned about some of proposed policies in the rule, especially those that are made more problematic by the COVID-19 pandemic. Among those is the significant reduction to the Medicare conversion factor in 2022 due to budget neutrality. Payment reductions are a major problem at any time, but to cut payment at a time when teaching physicians and other health care professionals are on the frontlines treating COVID-19 patients while at the same time caring for a large number of patients who postponed needed care because of COVID-19, would be devastating to their practices and the patients they treat.

We are committed to working with CMS to ensure that Medicare payment policies ensure access to high quality care for patients, accurately reflect the resources involved in treating patients, are not overly burdensome to clinicians, and reduce health disparities. We believe that there is much that we can learn from care delivery during the PHE to improve access for all.

The AAMC's key recommendations on the 2022 proposed rule include the following:

PHYSICIAN FEE SCHEDULE

- ***Payment Updates and Budget Neutrality:*** The AAMC encourages CMS to support stakeholder's efforts to urge Congress to maintain the 3.75% increase to the Conversion Factor for at least 2022 and 2023, and to prevent the additional potential reductions in 2022

due to sequestration. If Congress does not take action on budget neutrality before January 1, 2022, we strongly urge HHS to use the public health emergency declaration as a basis to ensure access to care and mitigate financial impacts due to the COVID-19 pandemic by waiving budget neutrality adjustments**.**

- ***Clinical Labor Update to Practice Expense***: The AAMC strongly recommends that at a minimum, CMS transition the clinical labor pricing updates over a 4- year period to help to mitigate the impact of the steep cuts on certain specialties.
- ***Split (Shared Visits):*** CMS should determine the "Substantive Portion" of a split (shared) visit based on medical decision-making and allow shared visits in institutional and non-institutional settings for new and established patients. We oppose defining "substantive portion" based on the time.
- ***Critical Care Visits:*** The AAMC urges CMS to take time to investigate further and seek input from stakeholders before implementing changes to the critical care visit policies. CMS should continue to allow payment for E/M visits and critical care services for the same patient on the same day by practitioners in the same specialty as appropriate. CMS should not bundle critical care visits in the global surgical package.
- ***Teaching Physicians:*** The AAMC supports CMS' proposal that when total time is used to determine office/outpatient E/M visit level, only the time that the teaching physician was present should be included, and for the primary care exception, only medical decision-making should be used to select the E/M visit level. We urge CMS to permanently allow virtual supervision (using real-time audio/video communications technology) of residents in all geographic locations.
- ***Virtual Supervision*****:** The AAMC recommends CMS continue to allow direct supervision for services billed "incident to" a physician' service to be met through virtual supervision on a permanent basis.
- ***Category 3 Telehealth Services:*** The AAMC strongly supports retaining the services on the Category 3 list of services until the end of 2023 as an option to temporarily allow services to be billable, while the benefits are studied. We also recommend CMS implement the concept of Category 3 as a permanent option.
- ***Telehealth for Mental Health Services****:* The AAMC strongly supports the proposal to implement changes in the Consolidated Appropriations Act of 2021 that allow coverage and payment for telehealth for mental health services in all geographic regions and to allow the patient's home as an originating site for these services. We recommend that CMS pay for these telehealth services without requiring an in-person visit every 6-months.
- ***Audio-only for Mental Health Services:*** The AAMC strongly supports the use of audio-only communication to provide mental health services. We believe services provided by audio-only technology should not preclude higher-level mental health services, for example, level 4 and level 5 E/M.
- ***Telehealth in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs):*** The AAMC strongly supports the proposal to allow RHCs and FQHCs to furnish telehealth services for mental health.
- ***Telehealth in Rural Emergency Hospitals:*** The AAMC strongly supports establishing a rural emergency hospital as a telehealth originating site starting in 2023.
- ***Virtual Check-in and Audio-Only:*** While the AAMC supports the establishment of HCPCS code G2252 for virtual check-in visits for longer units of time, the AAMC strongly urges

CMS to continue to allow separate payment for the telephone E/M codes (99441-99443) after the public health emergency ends. Health system data shows that audio-only is an important access point, particularly for Medicare beneficiaries who may not have access to, or may not feel comfortable with, interactive audio/video technologies.

- ***Remote Therapeutic Monitoring (RTM) Codes:*** The AAMC commends CMS for establishing five new RTM codes that allow data to be self-reported as well as digitally uploaded. We recommend CMS remove the specialty and condition-specific limitations in the code definitions which create unnecessary barriers.
- ***Appropriate Use Criteria Program:*** The AAMC supports CMS's proposal to delay enforcement of the Appropriate Use Criteria (AUC) program by at least one year until the later of January 1, 2023, or the January 1 that follows the end of the COVID-19 PHE. We strongly recommend that CMS exclude advanced diagnostic imaging services that are performed as part of a clinical trial from the AUC program.

MEDICARE SHARED SAVINGS PROGRAM (MSSP) ACOS

- ***Web Interface for ACOs****:* To give ACOs more time to prepare for quality reporting changes, we urge CMS to finalize its proposal to maintain the Web Interface as a reporting option for ACOs for at least the next two years while also allowing ACOs the option of using other reporting mechanisms. We ask that CMS remove its proposal to require reporting on at least one eCQMs/MIPS CQM in 2023**.**
- ***Regional Benchmarks:*** The AAMC urges CMS to remove ACO Beneficiaries from the regional benchmark to ensure ACOs are not penalized as they achieve savings for their assigned populations**.**
- ***3 Percent Cap on Risk Score Growth:*** The AAMC recommends CMS re-evaluate the current 3 percent cap on risk score growth in light of the COVID-19 PHE and evaluate the inclusion of social risk factors into risk adjustment models for ACO benchmarking**.**

QUALITY PAYMENT PROGRAM

- ***MIPS Value Pathways (MVPs):*** The AAMC strongly supports CMS' proposal to delay implementation of the MVPs until 2023. The MVPs should be gradually implemented to ensure that they are meaningful for clinicians and their patients, and not burdensome to report.
- ***Sunsetting MIPS After 2027:*** The AAMC has significant concerns with sunsetting the traditional MIPS program at the end of 2027, making MVPs or the APP performance pathway the only mechanism for participating in the quality payment program. There are a number of conceptual challenges with the MVP program and sufficient time will be needed to address them before sunsetting traditional MIPS.
- ***MVPs Should be Voluntary:*** Under the MIPS program, the practices should be given the opportunity to assess the advantages and disadvantages and select whichever option is most meaningful and least burdensome for reporting in the MIPS program.
- ***MVPs and Large Multi-Specialty Practices:*** With the large number of distinct specialties reporting under a single tax identification number (TIN) in academic medical centers, the AAMC believes it would be very challenging to identify MVPs that would be meaningful for

all specialties in the practice. The AAMC supports CMS' proposal that other physicians in the group practice (same TIN) who are not affiliated with the subgroup that is participating in an MVP would retain the option to participate as a group practice in traditional MIPS**.**

- ***Subgroups:*** The AAMC supports the concept of subgroup identifiers that would allow reporting and performance measurement at the subgroup level. The physician practice should be allowed to identify and provide a list to CMS of the physicians within a subgroup.
- ***Removal of Web Interface:*** The AAMC strongly urges CMS to provide a gradual transition away from the use of the Web Interface reporting option. We support CMS' proposal to continue the Web Interface for at least one additional year to give sufficient time for affected practices to implement a new reporting method.
- ***Cost Category:*** Given the multiple concerns under the cost performance category, including the impact of COVID-19 on patterns of care, clinicians' lack of familiarity with cost measures, the need for risk adjustment, and the need for better attribution methodologies, the AAMC strongly urges CMS to maintain the weight of the cost category at 20%.
- ***Risk Adjustment***: As appropriate, the AAMC recommends CMS risk-adjust outcome measures, population-based measures, and cost measures for clinical complexity and sociodemographic factors.
- ***Advanced Alternative Payment Models:*** The AAMC recommends CMS support any Congressional efforts that would give the Agency the discretion to set the thresholds to be qualified participants in an advanced APM at an appropriate level to encourage AAPM participation.

REQUESTS FOR INFORMATION

- ***Potential Efforts to Address Health Equity in the QPP***: CMS should take a thoughtful and considered approach working with stakeholders to improve data collection in order to better measure and analyze disparities in a manner that builds an evidence-based, valid, and reliable framework towards provider accountability for health equity.
- ***Future Stratification of Hospital Quality Measures by Race and Ethnicity***: CMS should invest in data collection improvements that standardize and use data already collected by hospitals. The Agency also should encourage the reporting and use of actionable data on health-related social needs instead of using indirect estimates of race and ethnicity data to stratify measure reporting. Race and ethnicity themselves are not risk factors and reliance on immutable characteristics alone is not informative for intervention.
- ***Improving Demographic Data Collection for Quality Measurement***: CMS should pursue a policy supporting the collection of standardized multi-sector risk information that will aid improved stratification and risk adjustment beyond individual-level demographic data elements. Data collection and systems for capturing unmet social need at the individual and community levels should be used in conjunction to best identify disparities in quality and equity and guide interventions for improvement.
- ***Advancing Digital Quality Measurement:*** CMS should refine its definition of digital quality measures to focus first on currently available valid and reliable digital data sources, set clear and specific parameters for what the agency hopes to achieve, and make clear what it expects of providers as it aims to transition to digital quality measurement by 2025.

PHYSICIAN FEE SCHEDULE

PAYMENT UPDATES

Update to the Physician Fee Schedule Conversion Factor for 2022

The 3.75% Increase to the Conversion Factor Should be Maintained and Sequestration Cuts Should be Prevented

In the proposed rule, CMS sets forth the dollar conversion factor that would be used to update the payment rates. For 2022, the conversion factor would be $33.58, which is a 3.75% reduction from the 2021 conversion factor. This reflects the expiration of the 3.75 percent increase for services furnished in 2021 under provisions included in the Consolidated Appropriations Act of 2021 (CAA, P.L. 116-260).

On top of this 3.75% CF reduction, on January 1, 2022 physician practices are facing additional payment cuts from the expiration of the moratorium on the Medicare 2% sequester reduction and imposition of a 4% PAYGO sequester reduction that was triggered by the increase in spending under the American Rescue Plan Act. Taken together, these three cuts would total a 9.75% reduction in payment. In addition, physicians face a statutory freeze in annual Medicare PFS updates until 2026, when updates will resume at a rate of only 0.25%, which is well below the rate of inflation.

We are deeply concerned about the significant cuts that many clinicians will experience. Payment reductions of this magnitude would be a major problem at any time, but to impose these large cuts at a time when teaching physicians and other health care professionals continue to be on the front lines treating patients with COVID-19 will be devastating.

The COVID-19 pandemic has caused significant disruption to physician practices. Physician practices are still recovering from the financial impact of the COVID-19 PHE. Faculty practices have estimated that they have lost between 25% and 50% of their revenue in April and May 2020 as compared to 2019. While the telehealth waivers and flexibilities granted by CMS were beneficial to physicians and their patients, payment for telehealth services only made up a small portion of this lost revenue. In addition, practices benefited from the stimulus funds provided by the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136), but these much-appreciated dollars have not filled the gap from financial losses stemming from the pandemic. While Congress authorized $186.5 billion in relief funds to compensate providers for expenses and lost revenue due to COVID-19, a significant portion of the CARES funds remain undistributed.

Continued implementation of infection control protocols has also increased the cost of providing care. Practices have had to purchase additional protective equipment (PPE), update cleaning protocols, maintain adequate social distancing, create physical barriers, and undertake other costly measures.

Physician well-being has been measured and found to be low due to concerns regarding their well-being and that of their staff and family, increased hours of care, and challenges with providing care during a pandemic that requires additional procedures and protocols. Payment for services should be commensurate with services provided during an extremely challenging time

for the country. An almost 10% 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.

We are concerned that the additional reductions in revenue from the budget neutrality adjustments and sequester could result in significant access problems for patients. **Given these unprecedented challenges and the critical importance of patient access to health care services, we encourage CMS to support stakeholders' efforts to have Congress maintain the 3.75% increase to the Conversion Factor for at least 2022 and 2023, and to prevent the additional reductions in 2022 due to sequestration. If Congress does not take action on budget neutrality before January 1, 2022, we strongly urge HHS to use the public health emergency declaration as a basis to ensure access to care and mitigate financial impacts due to the COVID-19 pandemic by waiving budget neutrality adjustments.** This will help to ensure that physicians and other health care providers can continue to provide high quality care to their patients. While CMS does not have explicit authority to waive the budget neutrality requirements for the PFS under section 1135 of the Act, CMS has waived other provisions of statute or regulations not specifically waivable under section 1135 of the Act using the PHE as its justification. For instance, CMS has waived the provider-based rules in their entirety without an explicit waiver authority.

Looking ahead, we believe that there are ongoing structural problems with the Medicare Physician Fee Schedule that need to be addressed. Medicare provider payments have been constrained for many years by the budget neutrality system. The updates to the conversion factor have not kept up with inflation, while the cost of running a medical practice has increased significantly. The budget neutrality requirement has led to arbitrary reductions in reimbursement. We would welcome an opportunity to work with CMS, Congress, and other stakeholders to address these long-term challenges in the future.

CMS Should Phase-In Clinical Labor Pricing Updates to Minimize Redistributive Effects

CMS proposes to update the clinical labor pricing for 2022 (using 2019 BLS data) in conjunction with the final year of the supply and equipment pricing update. Clinical labor rates were last updated in 2002 using Bureau of Labor Statistics (BLS) data. The updated data significantly increases the overall pool of direct costs. CMS explains in the rule that specialties that perform high supply and equipment procedures would receive a decrease in payment due to this change, and office-based specialties with high clinical labor costs would benefit from this change. Because the PFS is budget neutral, any changes to the codes that increase the payment amounts under the fee schedule need to be offset by decreases elsewhere within the fee schedule.

Table 135 in the rule (86 Fed Reg 39563) shows that certain specialties, such as vascular surgery, interventional radiology and radiation therapy centers would see significant decreases from this change in clinical labor, while family practice, endocrinology, and portable X-ray suppliers will experience increases. Analysis of a database of claims data from faculty physician practices (CPSC) showed that when combined with the 3.75% CF reduction, there would be significant reductions in payment for the following specialties: interventional radiology (-17.8%), vascular surgery (-15%), medical oncology with infusion (-9.0%), and pathology: clinical (-9%). While we recognize the need to update the clinical labor data, we are deeply concerned about the redistributive impacts on specialties. Significant reductions in payment to these specialties could

reduce access to medically necessary services. These reductions would be very difficult for these specialties to absorb, particularly given the financial losses due to the COVID-19 pandemic and the fact that there are no payment updates in the fee schedule for 6 years from 2020-2025.

Given these potential significant shifts in payment, CMS is considering the use of a 4-year transition to implement the clinical labor pricing update. **AAMC strongly recommends that at a minimum, CMS transition these clinical labor pricing updates over a 4- year period to help mitigate the impact of that such steep cuts may have on access to care. As discussed previously in this letter, we urge CMS to work with the medical community and others to encourage Congress to waive budget neutrality or take other necessary steps that would mitigate the impact of these changes to clinical labor.**

Solicitation for Impact of Infectious Disease on Codes and Rate Setting

CMS recognizes that physicians have incurred many additional costs due to the COVID-19 pandemic. The Agency seeks comments on whether Medicare should make changes to payments for services or develop separate payments to account for these PHE-related costs, such as disease control measures, research related activities, and PHE-related preventive or therapeutic counseling services. While the COVID-19 pandemic has posed enormous challenges and placed tremendous stress on our entire health care system, teaching hospitals, medical schools, teaching physicians, and researchers have mobilized on all fronts to treat and mitigate COVID-19. For academic medical centers, ensuring the health and safety of their health care workers and the patients they serve has been of primary importance. They have made substantial investments to achieve this goal as well as comply with the Centers for Disease Control and Prevention (CDC) guidelines and OSHA requirements related to COVID-19. Our members have supplied personal protective equipment to employees, updated cleaning and disinfecting standards, followed additional infection control standards, established protocols for screening employees and visitors (e.g., check patient temperatures on arrival pre-screening phone calls), limited the number of patients in waiting rooms, provided employee training, made structural changes to facilities, and much more.

In September 2020, the CPT Editorial Panel approved CPT code 99072 to address the financial impact of the new protocols related to COVID-19 in practices. CPT code 99072 is used to report the additional supplies, materials, and clinical staff time over and above the practice expenses included in an office visit when performed during a PHE. **We urge CMS to allow payment for CPT code 99072 to account for these additional costs during the PHE.**

E/M Clarifications (Split/Shared Visits, Critical Care, Teaching Hospitals)

Effective January 1, 2021, CMS implemented major revisions to office and outpatient E/M visits, which allow physicians to select the E/M visit level to bill based on either total time spent on the date of the patient encounter or medical decision-making used to provide the visit. Because of these changes, CMS is proposing clarifications regarding split (or shared) visits, critical care services, and teaching physician visits.

Split (or Shared) Visits

CMS Should Determine the "Substantive Portion" of Split (Shared) Visit Based Only on Medical Decision-Making

CMS proposes to define a split (or shared) visit as an E/M visit in the facility setting that is not "incident to" and is performed by both a physician and a non-physician practitioner in the same group. Under the proposal, only the physician or nonphysician practitioner (NPP) who performs the substantive portion of the split (or shared) visit would be allowed to bill for the visit. CMS proposes that the physician or NPP who provides the substantive portion is the one who performs more than 50% of the total time. The distinct time of the service spent by each physician or NPP would be summed to determine total time. Even though CMS proposes to define the substantive portion based on time, CMS clarifies that the practitioner providing the substantive portion of the visit could still select the level of the split (shared) visit based on medical decision-making. The medical record must identify the 2 individuals who performed the visit and be signed and dated by the individual who performed the substantive portion.

CMS explains that manual instructions that were withdrawn in May 2021 contained several definitions of "substantive portion." One section defined substantive portion as any face-to-face portion of the visit while another section defined it as one of the three key components of a visit (either history of present illness [HPI], physical exam, or medical decision-making). CMS feels that defining "substantive portion" as one of these three components is no longer a viable approach since HPI and physical exam or no longer required for outpatient/office E/M visits.

We strongly urge CMS not to finalize the definition of "substantive portion" of the visit based on time. Instead, we recommend that CMS determine who is responsible for the "substantive" portion based on the physician or NPP who performs the key medical decision-making component of the service that is used to determine the visit level.

While CMS asserts that "time is a more precise factor than medical decision-making to use as a basis for deciding which practitioner performs the substantive portion of the visit," time is not always the essence of patient care. Physicians are compensated for their ability to synthesize complex medical problems and undertake appropriate treatment actions. An NPP may be involved in tasks that require significant time, such as preparing the medical record, taking a history, performing a physical exam, inputting orders, obtaining lab or test results, requesting consultations, and doing preliminary documentation. Synthesizing the patient's symptoms and other information such as test results and then devising the plan of care are the substance of the visit and typically are done by a physician. However, in many instances the activities performed by the physician, which are the key portion of the visit, take less time than the activities that are required to provide the additional information needed for medical decision-making and the plan of care. This lower physician time is likely related to the fact that the NPP gathered the disparate data for careful review or because of the experience and training of the physician. For example, if an NPP and surgeon both see a patient after surgery, the NPP may spend more time gathering information, but it is only the physician who can make the critical decision to return to the operating room. In another example, for patients with cancer the oncologist (not the NPP) makes the key recommendations of chemotherapy and radiation protocols. Time can be measured but measurement doesn't make it the most critical component of a complex medical decision.

CMS recognizes that this proposed policy would require practitioners to track and document the time that they spent on these visits, even though they would be able to select the visit level based on medical decision-making. However, CMS believes that practitioners are likely to increasingly time their visits for purpose of visit level selection independent of the split (or shared) visit policies, given the recent changes to the E/M guidelines. We believe that this assumption is incorrect. Currently, the vast majority of physicians are selecting the outpatient/office E/M visit level based on medical decision-making (not time). In addition, the office/outpatient E/M visit policies on time for selection of level and documentation do not apply to the inpatient hospital E/M visits. As a result, most physicians are **not** tracking and documenting their time. Tracking the precise time spent by the physician and NPP (including when it is spent simultaneously) and summing it together to determine the total time, and 50% threshold, would be extremely burdensome to physicians and NPPs, particularly when they are not using time to select the visit level. Tracking the time is only important for billing purposes when selecting E/M level based on time and does not benefit patient care, However, it would place a significant regulatory burden on both the physician and NPP.

Regarding the Medical Record Documentation section, we do not support the proposal that only the billing provider sign and document the medical record entry for the split (shared) visit. We recommend that all clinicians sign, date, and time their documentation in the inpatient medical record. When providing team-based care, it is important to know which practitioners were involved in providing the service and for the note to reflect their contributions.

Split (Shared) Visits Should be Allowed for New and Established Patients and Initial and Subsequent Visits

The AAMC supports CMS' proposal to allow the physician and NPP to bill for split (or shared) visits for both new and established patients, and initial and subsequent visits. This approach is consistent with the CPT E/M Guidelines for split (or shared) visits. This change will support the team-based approach to care where physicians and NPPs work together to coordinate and manage care at initial visits with the patient and follow-up visits.

Split (Shared) Visits Should be Allowed in SNFs/NFs and Ambulatory Care Settings

CMS proposes to allow billing of split (or shared) visits, including critical care visits, when they are performed in any institutional setting. Previously, CMS did not allow practitioners to bill for split (or shared) visits that are SNF/NF visits or critical care services or procedures**.** We support CMS' proposal to allow split (shared) visit billing for SNF/NF visits. The practice of medicine has changed to a more team-based approach to care, and we believe this policy will support team-based care and the evolving role of NPPs. There is close coordination when a visit is shared between a physician and an NPP in the same group practice.

We urge CMS to expand its policy to allow split (shared) visits in both institutional and non-institutional settings (i.e., office settings). Practice has evolved, especially in academic medical centers, to a more team-based approach to furnishing care in both institutional and non-institutional settings. In some specialty settings it is common for both a physician and an NPP to share a visit for the same patient in the office setting and to closely coordinate that care.

CMS states that it does not see a need for split (or shared) visit billing in the office setting because the "incident to" regulations govern the situations where the NPP works with a

physician who bills for the visit. While we agree that there are instances when the services could be billed "incident to," there are also circumstances where services are provided by both the physician and NPP in the office-based settings that could not be billed as "incident to" services. For example, a physician and an NPP may both see a new patient in the office, each providing services to the patient. This service could not be billed as an "incident" to service because it is a visit for a new patient and "incident' to services may only be billed for established patients. Therefore, the participation of both the physician and NPP in providing the service to the patient would not be recognized. In academic medical centers, it is common for physicians and NPPs to rotate among multiple clinical settings, some of which are institutional settings (e.g. provider-based hospital) and others are office-based settings. For these physicians and NPPs, it would be very confusing if the rules related to billing and documentation for split (shared) visits differ depending on whether they are in a provider-based setting verses an office-based setting. Billing rules should not influence care provision.

Tax ID Should Be Used to Define Same Group Along with Specialty

CMS proposes that a physician and NPP must be in the same group in order for the physician and NPP to bill for a split (or shared) visit and seeks public comment on whether they should further define "group." One option considered is whether the physician and NPP must be in the same clinical specialty. For this option CMS would adopt the CPT definition that the NPP is considered to be in the same specialty and subspecialty as the physician with whom they are working. Another approach would be to consider the physician and NPP to be in the same group if they meet the group definition of "physician organization." A third approach would be to consider practitioners with the same billing tax identification number as being in the same group. **We recommend that the Tax ID be used as the basis to determine whether clinicians are part of the same group, and that the physician and NPP should be working as part of the team that provides the same clinical services.** For example, if an NPP is working with a group of orthopedic surgeons to treat the patient, the NPP should be considered part of the orthopedic surgery group when determining whether split (shared) visits can be provided.

Prolonged E/M visits:

CMS proposes to allow a practitioner to bill for a prolonged E/M visit as a split (or shared) visit. CMS proposes to permit the physician or NPP to bill for split (or shared) visits for both new and established patients, as well as for initial and subsequent visits. Practice of medicine has evolved towards a more team-based approach of care delivery and greater integration in the practice of physicians and NPs, particularly in the facility setting.

Critical Care Services:

CMS proposes that critical care may be furnished as concurrent (or concurrently) to the same patient on the same day by more than one practitioner in more than one specialty (e.g., an internist and a surgeon), regardless of group affiliation, if the service meets the definition of critical care and is not duplicative of other services. CMS seeks comments on when it would be appropriate for more than one physician or NPP of the same or different specialties, and within the same or a different group, to provide critical care services. We appreciate CMS' interest in finding out more information on how critical care services are delivered. **Before making any significant changes to critical care payment policies, we urge CMS to investigate further**

and meet with stakeholders who provide these services to obtain more information about the delivery of these services.

Critical care involves the physician's direct delivery of medical care for a critically ill or critically injured patient. It requires decision making of high complexity to assess, and support vital organ systems and/or to prevent further life-threatening deterioration of the patient's condition**.** Critically ill patients often require more than one physician or NPP of the same specialty or from different specialties to be involved in providing critical care services. Surgeons, intensivists, hospitalists, cardiologists, emergency medicine physicians, pediatricians, pulmonologists, anesthesiologists, and others may be involved in the patient's care.

A critically ill patient may have more than one medical condition requiring diverse specialized medical services provided by multiple practitioners from multiple specialties, each playing an active role in the patient's treatment. For example, a trauma surgeon might provide critical/life-saving or conserving care and another specialist, such as a pulmonologist, may need to provide critical care services to the patient also.

In addition, a patient may have several physicians from the same practice and specialty treating the same condition, such as cardiologists involved in his/her critical care. One cardiologist from the practice may perform a percutaneous coronary intervention to treat an acute myocardial failure and another cardiologist may then be needed to manage the patient's post-MI heart failure in an intensive care unit. Critical care is a team-based approach. It is important that CMS does not create policies that would create financial incentives for team members to compete rather than collaborate CMS should take more time before finalizing its proposals described below related to critical care to better understand the delivery of these services.

CMS Should Allow Payment for Critical Care Visits and Same-Day Emergency Department, Inpatient or Office Outpatient Visits

The CPT codebook states that critical care and other E/M services may be provided to the same patient on the same date by the same individual. Due to concerns with duplicative payment, CMS proposes that no other E/M visit can be billed for the same patient on the same day as critical services when the services are furnished by the same practitioners, or by practitioners in the same specialty in the same group. CMS seeks comments on this proposal to better understand clinical practice for clinical care.

We oppose this proposal and urge CMS to continue to allow payment for E/M visits and critical care services for the same patient on the same day by practitioners in the same specialty. A patient may be stable and not require critical care when seen earlier in the day by the physician yet deteriorate clinically that same day and require critical care services. As long as the physician documents that the E/M service was provided prior to the critical care service at a time when the patient did not require critical care, that the service is medically necessary, and the service is separate and distinct (non-duplicative) from the critical care service provided later in the day, we believe it is appropriate to allow billing for the service. This has been the longstanding Medicare policy.

CMS Should Not Bundle Critical Care Visits with Global Surgery

Because critical care visits are included in some 10 and 90-day global packages, CMS proposes to bundle critical care visits with procedure codes that have a global surgical period. **We strongly urge CMS not to bundle critical care services into the global package.** In academic medical centers, it is typical for the surgical team to perform surgery and then other physicians who are not part of the surgical team (such as critical care/ intensivists) to care for the patient in the ICU after the surgery. The intensivist/critical physicians manage the patient whose condition can change rapidly. They need to be proactive and continually monitor and modify the care to ensure good outcomes. Caring for these patients requires a team approach. If the critical care services are bundled into the surgery global package, th**e**y would become dependent on the surgeon sharing a portion of compensation. This situation would undermine the critical care physician services that have grown over the years to significantly improve recovery after surgery

In addition, there are circumstances where critical care services are unrelated to the surgery or typically not seen in relation to the operation for which payment for critical care services should be allowed. An example would be a patient who has had a joint replacement and subsequently has heart failure. Global packages do not include critical care services provided unrelated to the surgery in the value computations. Moreover, patients receiving critical care postoperatively unrelated to surgery generally have longer lengths of stay. Modifiers and diagnosis codes could be used to identify a significantly separate, identifiable service from the surgical procedure that is different from the usual pre- and post-operative care associated with the procedure.

PAYMENT FOR SERVICES OF TEACHING PHYSICIAN

General Policy for E/M Visits

Prior to the public health emergency, Medicare policy required that if a resident participates in a service furnished in a teaching setting, a teaching physician can bill for the service only if they are physically present for the key or critical portion of the service. During the PHE, CMS has allowed virtual supervision (using audio/video real time communications technology) of residents during the key or critical portion of the visit. After the PHE ends, virtual supervision of residents will be allowed only in residential training sites that are located outside a metropolitan statical area. In the case of E/M services, the teaching physician must be present during the portion of the service that determines the level of service billed. For the primary care exception (under section 415.174 c) CMS adopted a policy during the PHE that allows the teaching physician to direct the care furnished by the resident, and to review the services furnished by the resident during or immediately after the visit, remotely using audio/video real-time communications technology.

We commend CMS for adopting these virtual supervision policies as they have been critical in reducing exposure to COVID-19 for physicians and enabling expanded access to health care services. Continuing these policies will reduce risk exposure to all infectious diseases (e.g., coronavirus and seasonal flu), increase the workforce capacity of teaching institutions, increase access to care for patients, and allow important experience and training for the future physician workforce under appropriate supervision. **We recommend that CMS continue to allow these virtual supervision policies for residents on a permanent basis in all geographic regions rather than limiting virtual supervision to only rural sites. If CMS chooses not to extend its**

policy to all geographic regions, at a minimum virtual supervision should be allowed in medically underserved areas.

We believe that the teaching physician is able to exercise full, personal control over the management of the key portion of the care to bill Medicare Part B when the services are furnished by the resident with the teaching physician present through audio/video real time communications technology. The teaching physician should have the discretion to determine whether it is appropriate to be present virtually rather than in person depending on the services being furnished and the experience of the particular residents involved.

We believe that 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. ACGME sets forth extensive program requirements, including requirements related to supervision. ACGME recognizes that supervision may be exercised through a variety of methods, as appropriate to the situation, including through telecommunication technology. The program must 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. 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.[1]

This change to CMS policy will improve patient access to care while also enhancing the resident's skills. As discussed above, ACGME supports the use of audio-visual communication devices by residents and their physicians. We believe that as long as the virtual presence of the teaching physician complies with the standards of ACGME and other accrediting organizations, teaching physicians, residents, and their patients will benefit from the provision of telehealth by residents.

The AAMC supports the 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 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 of the supervising physician.

We support CMS' proposal in the rule that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present should be included. This is consistent with the policy that PFS payment is made when a teaching physician involves a resident in providing the care only if the teaching physician is

[1] *See* ACGME program requirements (common program requirements residency)

present for the key or critical portion of this visit, including the portion used to select the visit level. **In addition, we support CMS' proposal that under the primary care exception, only medical decision making (not time) can be used to select the office/outpatient E/M visit level**. We agree that medical decision making would be a more accurate indicator of the complexity of the visit than time.

VACCINE ADMINISTRATION SERVICES

The AAMC supports CMS' decision to cover COVID-19 Vaccinations and COVID-19 Monoclonal Antibodies Treatment

The AAMC commends CMS for adding the COVID-19 vaccine and its administration to the list of preventive vaccines including the influenza, pneumococcal, and HBV vaccines covered under Part B. There is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccinations or the services to administer them. We applaud AAMC for increasing the payment rate for administering a COVID–19 vaccine to $40 per dose from $28.39 for COVID-19 vaccines that require one dose and $40 to administer the first and second dose in a two-dose regime ($80 total) from $16.94 and $28.39 respectively.

The AAMC supports CMS establishing a new add-on payment with a national rate of $35.50 that allows the administration of the COVID-19 vaccine in the beneficiary's home. Under this new policy, providers and suppliers that administer a COVID–19 vaccine in a beneficiary's home can receive payment from Medicare for one of the existing COVID–19 vaccine administration CPT codes. Providers and suppliers administering a COVID–19 vaccine in the home will be paid a national average of $75.50 dollars per dose ($40 for COVID–19 vaccine administration and $35.50 for the additional payment for administration in the home). This policy requires the patient to have difficulty leaving the house or the patient must be hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID–19 vaccine in settings other than their home. We believe the option for home vaccination will greatly improve access to the vaccine. Increasing the vaccination rate is crucial as we attempt prevent the spread of COVID-19 and end the PHE.

Furthermore, we support CMS' decision to cover COVID-19 Monoclonal Antibodies treatment. There are currently several approved treatments for COVID-19 in the hospitals setting; however, there are limited treatments for those with COVID-19 symptoms who are not being treated in the hospital. Early data suggest those with severe COVID-19 symptoms benefit from early administration of the Monoclonal Antibodies treatment[2]. This treatment can be administered outside the hospital setting. And it is especially important for those who have not been vaccinated and are therefore at greater risk of contracting severe COVID-19.

[2] *See* Chitsike, L., Duerksen-Hughes, P. Keep out! SARS-CoV-2 Entry Inhibitors: Their Role and Utility as COVID-19 Therapeutics. *Viral J* **18,** 154 (2021); *see also* Weinreich DM, et al., REGN-COV2, a Neutralizing Antibody Cocktail, in Outpatients with Covid-19. N Engl J Med. 2021;384:238–51 (January 21, 2021).

APPROPRIATE USE CRITERIA

AAMC Supports Delay in the Appropriate Use Criteria Program

We support CMS' proposal to delay enforcement of the Appropriate Use Criteria (AUC) program by at least one year until the later of January 1, 2023, or the January 1 that follows the end of the public health emergency. The AUC program requires ordering physicians to consult appropriate use criteria using a clinical decision support mechanism prior to ordering advanced imaging services for Medicare beneficiaries and furnishing physicians to report this information on the claim. Currently, CMS is scheduled to begin denying claims that do not report AUC information on January 1, 2022. The COVID-19 pandemic has caused significant disruptions to physician practices and this delay will allow more time for the education and operations testing period. This extra time is critical given CMS' finding that only 9-10 percent of 2020 diagnostic imaging claims would have met the AUC reporting requirements to be paid if enforcement had been in effect. This low compliance rate is due in part to lack of knowledge of the changes and complexity of reporting and billing requirements

CMS also seeks comment on several claims processing proposals meant to address scenarios that have been identified as challenging or impractical for AUC compliance and areas that need more education and outreach. We urge CMS to ensure that there is a simplified tracking and reporting system. The claims processing proposals involves a complex system of tracking consultation of AUCs. G-codes and modifiers that must be included on the claim form in order for the furnishing provider to be paid. It can be difficult for the furnishing professional to supply the ordering physician's AUC-use information to CMS. In many cases, the ordering physician and furnishing professional will not share the same office space or EHR system. To share this information will require additional health IT interoperability between the ordering physician's EHR and the systems used by the furnishing physicians in their practices.
CMS should not finalize its proposal to retire or redefine Modifier MH, which is used to identify claims for which AUC consultation information was not provided to the furnishing professional and furnishing facility. Without this modifier, imaging services would most likely be delayed until the furnishing provider is able to get in touch with the ordering provider. These delays would negatively impact Medicare patients. **Furthermore, we do not support CMS' proposal to redefine the Modifier MH so that it is used in scenarios where an "AUC consultation is not required." Instead, CMS should create a new modifier to describe those situations.**

The AAMC supports CMS' proposal to allow the furnishing professional to update or modify an imaging order in certain circumstances when the beneficiary is under their care. We agree with CMS' proposal that in these circumstances the ordering professional and the furnishing professional should not be required to consult the AUC for additional services. However, we find the claims submission process proposed by CMS for these updated orders to be confusing. We recommend that CMS develop other solutions for how AUC data should be reported on claims for revised/additional imaging orders.

CMS is considering whether claims that do not pass the AUC claims processing edits, and therefore will not be paid, should be initially returned to the provider to be corrected and resubmitted or should be denied so they can be appealed. **We recommend that CMS initially**

return claims for correction and resubmission and revisit in the future whether this approach needs to be revised. This approach gives providers time to better understand AUC claims processing and provides the agency with data to better understand potential areas where provider education is needed.

CMS requests feedback on whether there are additional scenarios not identified in this rule that are potentially challenging or impracticable for application of the AUC program. **The AAMC has concerns about the application of the AUC program to clinical trials.** Advanced diagnostic imaging services may be ordered because a patient is participating in a clinical trial and the advanced diagnostic imaging service is part of the clinical trial protocol - either as the investigational item/service itself or ordered to monitor for complications related to the investigational item or service. When advanced diagnostic imaging services are ordered/performed as part of a clinical trial protocol, it is possible that the order for the imaging service will not adhere to the AUC in the qualified clinical decision support mechanism consulted by the ordering professional, resulting in placement of the MF modifier on the claim(s). Therefore, applying AUC to clinical trials has the potential to inappropriately identify physicians who are participating/conducting clinical trials as outliers. Not only could this result in the physician being subject to prior authorization in the future, it could potentially discourage physicians/providers from participating in clinical trials that include Medicare beneficiaries. The intent of AUC is to ensure appropriate use of advanced diagnostic imaging services provided to Medicare beneficiaries. However, the AUC requirements should not apply to advanced diagnostic imaging tests that are part of clinical trials as there are long-standing CMS policies related to approval and coverage of clinical trial items/services that are protective of Medicare beneficiaries. Additionally, human research / clinical trials are highly regulated by multiple other agencies, including FDA and NIH. **We strongly recommend that CMS exclude advanced diagnostic imaging services that are performed as part of a clinical trial from the AUC program and establish a separate HCPCS modifier that will be used to identify the claims for these tests.**

MEDICARE TELEHEALTH AND COMMUNICATION TECHNOLOGY-BASED SERVICES

All Services Added to the Medicare Telehealth Services List on a Category 3 Basis Should be Retained Until at Least the End of 2023

CMS' authority to add services to the telehealth list based on their similarity to other services already on the telehealth list (Category 1) or based on an assessment of whether the services would provide clinical benefit to the patient if provided by telehealth (Category 2) is not dependent on the declaration of a public health emergency. In 2021 CMS finalized a new Category 3 group of services which would be included on the Medicare telehealth list until the end of the calendar year in which the PHE ends to allow more time to study the benefit of providing these services outside the context of the pandemic. This new Category 3 provided a basis for adding or deleting services from the Medicare telehealth list on a temporary basis where there is likely clinical benefit, but where there is not yet sufficient evidence available to permanently consider the services under Category 1 or 2 criteria. The AAMC strongly supported the establishment of Category 3 and the services that CMS included on the Category 3 list. CMS is proposing to extend the duration of the services included on the Category 3 list until the end of CY 2023. **We strongly support retaining these services on the Category 3 list of services**

until the end of 2023 as an option to temporarily allow services to be billable, while the benefits are studied. We also recommend CMS consider implementing the concept of Category 3 as a permanent option. This would allow potential codes time to be considered a telehealth service and CMS would be able to obtain sufficient evidence demonstrating the benefit of providing the service by telehealth.

Mental Health Services Furnished via Telehealth Should be Permitted Without Restrictions by Geographic Location, In-person Visit or Audio-only Limitations

AAMC strongly supports coverage and payment of telehealth for mental health services. In this proposed rule CMS is implementing provisions in the Consolidated Appropriations Act, 2021 (CAA) that remove geographic restrictions and permit the home to be an originating site for telehealth services for the treatment of mental health disorders, as long as the practitioner has seen the patient in person within the last 6-months. During the PHE, the removal of Medicare's geographic and site of service limitations for services furnished via telehealth significantly increased access to care, particularly for behavioral telehealth services. In April 2020, at the height of the PHE, telehealth visits for psychiatry and psychology surpassed fifty percent of the total services. According to data from faculty practices included in the Clinical Practice Solutions Center (CPSC)[3], the use of telehealth for mental health services remained high throughout 2020 and 2021, at roughly fifty percent. In addition, there has also been a reduction in missed appointments for behavioral health services because telehealth expansion has made it easier for patients to access care. This is particularly important in mental health because there is a shortage of providers.

CMS proposes to require that an in-person, non-telehealth service be furnished by the physician or practitioner at least once within 6-months before each telehealth service for mental health disorders. CMS seeks comment on whether the 6-month interval is appropriate and whether the required in-person non-telehealth service could also be furnished by another physician or practitioner in the same specialty or subspecialty and within the same group as the practitioner who furnishes the telehealth visit to furnish the in-person visit.

The AAMC believes mental health services furnished via telehealth should be permitted without requiring an in-person visit. While we recognize that the statute requires an initial in-person visit prior to the telehealth visit, we believe that an in-person requirement would act as a significant barrier to care for those who rely on mental health services. This barrier will disproportionally affect those in more vulnerable populations who, because of their job, lack of others to help care for their dependents, transportation issues and other limitations, are not able to attend an in-person visit. Continuation of care is crucial for mental health services, and in-person visit requirement may result in a lapse of care and ultimately negative clinical outcomes for patients. If finalized, mental health services would be the only type of service provided by telehealth which would require an in-person visit at a specific interval, which is arbitrary and discriminatory against this particular type of service.

[3] The Clinical Practice Solutions Center (CPSC), developed by the Association of American Medical Colleges (AAMC) and Vizient, is the result of a partnership that works with member practice plans to collect data on provider practice patterns and performance.

The statute gives CMS flexibility related to subsequent in-person visit requirements, and therefore we recommend CMS not require an in-person visit every 6-months. Physicians are responsible for the quality of care delivered to their patients. As such, physicians should be responsible for determining when, if at all, it is appropriate for the patient to have an in-person visit. While we oppose the in-person requirement, if CMS does decide to institute an in-person requirement, the interval should be longer than 6-months to ensure access to care and lessen the burden on patients and providers. The establishment of a 6-month in-person requirement does not seem to be medically driven and is instead being offered as a billing requirement which conflicts with CMS' patient first objectives. If a patient has received appropriate, medically necessary behavioral health services and they wish to continue receiving care virtually they should be able to do so. Furthermore, the 6-month requirement adds the additional burden of commuting to see the provider every six months. This burden will disproportionally affect those in underserved or rural areas and anyone who does not have reliable transportation.

CMS should permit another practitioner in the same specialty or subspecialty within the same group as the practitioner who furnishes the in-person visit to provide the telehealth visit. This policy should not be limited to instances where the provider of the telehealth service is unavailable or in the case of two professionals who are practicing as a team.

Even before the COVID-19 PHE there was a shortage of mental health providers as noted as we looked for solutions to the opioid crisis. The PHE has led to a drastic increase in people seeking treatment for their mental health which has led to an even greater shortage of providers. Both new and existing patients are experiencing extremely long wait times for appointments. Requiring the same provider who performs the telehealth visit to provide the in-person visit will only further exacerbate the problems with access. Furthermore, because COVID-19 PHE waivers removed geographic restrictions, many patients sought treatment from providers located outside their communities. As a result, they may not have the ability to commute the distance required to see their same provider in-person. Academic medical centers may have providers within the practice that are at a location closer to the patient's home, making the commute to their required in-person visit less difficult. If these practitioners are in the same specialty or subspecialty and within the same group as the practitioner providing telehealth, they should be permitted to see the patient for the in-person visit.

The AAMC strongly supports the use of audio only communication to provide mental health services. During the PHE, coverage and payment for audio-only calls has been critical to ensure access to care for some patients. Physicians have been able to provide a wide array of services efficiently, effectively, and safely to patients using the telephone

CMS did not specifically include substance abuse services (SUD) in its definition of "mental health services" that could be provided using audio-only technology. We recommend CMS explicitly state in the final rule that "SUD" services are considered "mental health services" that could include audio-only services under the revised definition of "interactive telecommunications system" under 42 C.F.R. § 410.78(a)(3).

The AAMC believes mental health services should be furnished via telehealth without limiting audio-only communication technology to instances where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology. 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. Initial reports suggest that lack of audio-only services particularly affects vulnerable populations, including the elderly, those with low socioeconomic status, and certain races and ethnicities.

Providers have found that when treating certain mental health conditions, such as post-traumatic stress disorder, patients often benefit from obtaining services without visual contact with their provider. Audio-only technology allows patients to communicate with providers while maintaining a sense of privacy. **Physicians and other health care professionals are responsible for the quality of care delivered to their patients. As such, they should be responsible for determining when audio-only technology is appropriate**. To effectively treat a patient a physician needs the discretion to make clinical decisions based on the needs of the patient. Limiting audio-only technology to instances where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology will ultimately prevent patients from receiving the care that they need.

The AAMC believes services provided by audio-only technology should not preclude higher-level mental health services, for example, level 4 and level 5 E/M. The AAMC believes physicians should be responsible for the quality of care delivered to their patients. Providers should be permitted to furnish higher-level services via audio-only technology if they believe it is clinically appropriate to do so.

The AAMC supports creating a service-level modifier that would identify mental health telehealth services permitted under the CAA and those that are not and a separate modifier to identify mental health telehealth services furnished to a beneficiary in their home using audio-only communications technology. These modifiers would allow the collection of claims-based data and lead to the analysis of the use of telehealth and audio-only services. This information can then be used to determine the ways in which mental health services are being provided, improve clinical outcomes, and benefit patients.

CMS proposes requiring additional documentation in the patient's medical record to support the clinical appropriateness of audio-only technology. **The AAMC believes that documentation requirements for audio-only visits should be consistent with requirements for in-person visits to support the service.** We support CMS' proposal to establish a modify for "audio-only technology" and we believe that reporting that modifier is sufficient. However, if CMS decides to require additional documentation for audio only, we recommend allowing physicians to document one of the following three reasons that the visit is audio-only.

1. 'Audio-only; patient unable to use two-way audio-visual technology'
2. 'Audio-only; patient does not wish to use two-way audio-visual technology'
3. 'Audio-only; patient does not have access to two-way audio-visual technology'

The AAMC Strongly Supports Permitting Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) to Furnish Telehealth Services for Mental Health

During the PHE, the CARES Act established Medicare payment for telehealth services when RHCs and FQHCs serve as the distant site during the COVID-19 PHE. RHCs and FQHCs were able to effectively furnish mental health services and treat patients via telehealth during the PHE and should be allowed to continue to do so after the PHE ends. For the same reasons mentioned above, we do not support limiting audio-only mental health visits provided by RHCs and FQHCs

to cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction.

In summary, **we acknowledge the statutory requirement for one in-person meeting within the 6-months prior to the telehealth visit but strongly support permitting telehealth for mental health services without requiring an in-person visit. If CMS does institute an in-person requirement we believe the interval should be longer than 6 months to lessen the burden on patients and providers.** And CMS should permit another practitioner in the same specialty or subspecialty and within the same group as the practitioner who furnishes the telehealth visit to furnish the in-person visit. This should not be limited to instances where the provider of the telehealth service is unavailable or in the case of two professionals who are practicing as a team. **The AAMC believes that documentation requirements for audio-only visits should be consistent with requirements for in-person visits to support the service.** We also believe telehealth services provided by audio-only should not preclude higher-level services, for example, level 4 and level 5 E/M. The AAMC supports creating a service-level modifier that would identify mental health telehealth services permitted under the CAA and those that are not and to identify mental health telehealth services furnished to a beneficiary in their home using audio-only communications technology.

The AAMC strongly supports establishing a rural emergency hospital as a telehealth originating site starting 2023. CMS interim final rules related to the PHE waived patient location restrictions that applied to telehealth services. Under this change, CMS pays for telehealth services furnished by physicians and other health care providers to patients located in any geographic location and at any site, including the patient's home, during the PHE. At the end of the PHE, the geographic restriction will resume for most telehealth services. As a result, patients in rural areas will have to travel to an originating site to receive telehealth services. Establishing additional originating site locations in rural emergency hospitals will make it easier for patients in rural communities to receive care through telehealth services.

CMS Should Continue to Allow Direct Supervision through Virtual Supervision on a Permanent Basis

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. Direct supervision generally requires immediate availability within the office suite. We commend CMS for adopting these virtual supervision policies as they have been critical in reducing exposure to COVID-19 and enabling expanded access to health care services. Continuing these policies once the PHE ends will reduce risk exposure to all infectious diseases (e.g., coronavirus, seasonal flu, and others), and increase access to care for patients.

CMS Should Permanently Finalize HCPSC code G2252 for Virtual Check-In Visits

While the AAMC supports the establishment of HCPCS code G2252 for virtual check-in visits for longer units of time, we strongly urge CMS to continue to allow separate payment for the telephone E/M codes (99441-99443) after the public health emergency ends. In the CY 2021 PFS final rule CMS established HCPCS code G2252 (Brief communication technology-based service, for 11–20 minutes of medical discussion) on an interim basis. This code was meant to address the widespread concerns that payment for audio-only E/M visits

would not continue after the conclusion of the PHE. Although this code allows for payment for a longer virtual check-in necessary to determine whether an in-person visit is needed, it does not take the place of a telephone E/M visit. Eliminating coverage for telephone E/M services will result in inequities in access to services for specific populations. AAMC believes that CMS should permanently finalize HCPCS code G2252 and continue payments for E/M telephone visits. Please see below for additional comments on audio-only E/M codes.

AAMC Commends CMS for Establishing Five New Remote Therapeutic Monitoring (RTM) Codes

These codes monitor health conditions, including musculoskeletal system status, respiratory system status, therapy (medication) adherence, and therapy (medication) response, and as such, allow non-physiologic data to be collected. We strongly support CMS' decision to allow data to be self-reported as well as digitally uploaded. This will allow physicians to collect additional information such as pain, appetite, and other subjective metrics which could be beneficial when managing the patient's care. We also recommend that CMS allow practitioners, such as physical therapists and nurses, to bill the RTM codes. We further recommend CMS remove the specialty and condition-specific limitations in the code definitions which create unnecessary barriers. Qualified practitioners, such as physical therapists, should be able to bill the RTM codes.

We appreciate and commend the work CMS is doing to expand telehealth for mental health and virtual supervision, virtual check-in, and RTM codes. We believe this expansion will greatly benefit patients, especially those struggling with mental health issues in the aftermath of the PHE. However, it is imperative that the progress continue in telehealth. We urge Congress and CMS to make changes to legislation and regulations that will allow the remaining COVID-19 PHE telehealth waivers to be made permanent while ensuring that reimbursement remains at a level that will support the infrastructure needed to continue to provide telehealth services at a level far above that of the pre-pandemic world. Please see below for comments pertaining to the Covid-19 telehealth and communications technology-based services waivers.

CMS Should Waive Patient Location Restrictions and Rural Site Requirements

The AAMC strongly supports changes made in the CMS interim final rules related to the PHE that waived patient location restrictions that applied to telehealth services. Under this change, during the PHE CMS pays for telehealth services furnished by physicians and other health care providers to patients located in any geographic location and at any site, including the patient's home. This has allowed patients to remain in their home, reducing their exposure to COVID-19 and reducing the risk that they expose another patient or their physician to COVID-19. It also means that patients who find travel to an in-person appointment challenging can receive care which may be particularly important to patients with chronic conditions or disabilities who need regular monitoring. It also helps those in more vulnerable populations 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. The AAMC acknowledges that CMS does not have the authority outside of the PHE to make the changes related to geographic locations and originating sites permanent. **However, we encourage CMS to work with Congress to waive the geographic site requirements and allow the home to be an originating site.**

Providers Should be Paid the Same Amount for Telehealth Services as Services Delivered In-Person

CMS does not address payment rates for Medicare telehealth services in this proposed rule. **The AAMC strongly recommends that providers be paid the same for furnishing telehealth services as services delivered in person.** Medical care and the complexity of medical decision making often does not change in situations where telehealth is appropriate and thus the provider should be compensated similarly. In discussions with faculty practice plan leaders, the AAMC has heard from members that there are significant infrastructure costs to fully integrate their electronic health record systems with HIPAA-compliant telehealth programs. Physicians employ medical assistants, nurses, and other staff to engage patients to coordinate care, regardless of whether the services are furnished in person or via telehealth. We commend CMS for acknowledging these expenses in the first COVID-19-related interim final rule (March 31, 2020 IFC)[4] by stating that telehealth services would be reimbursed to physicians at the non-facility fee schedule rate.

We recommend CMS provide a facility fee under the outpatient prospective payment system (OPPS) for telehealth services provided by physicians that otherwise would have been provided in the provider-based entity. Similar to the physician office-based setting, the provider-based entity will continue to employ nurses, medical assistants, and other staff to engage patients during telehealth visits or to coordinate pre-or-post visit care. The provider-based entity incurs these costs associated with providing the telehealth service and should be reimbursed as if the services were provided in person. We were pleased that in the second interim final rule (May 8, 2020 IFC)[5] CMS decided to pay an originating site fee to recognize the costs incurred by hospitals.

CMS Should Continue to Allow Payment for Telehealth Services Delivered Across State Lines

As part of the COVID-19 PHE response, CMS has allowed providers to be reimbursed by Medicare for telehealth services across state lines with permission from the individuals states. This waiver creates an opportunity to improve patient access to services and to help improve continuity of care for patients that have relocated or who have traveled to receive their surgery or other services from a specialist in another state. While CMS has the authority to allow for payment, states need to act to allow practice across state lines to occur. **We urge CMS to continue this flexibility with regard to payment for services and to study opportunities for national medical licensing. Until this is available, we encourage CMS to work with states to participate in interstate medical licensure compacts or other mechanisms that would allow care delivery across state lines in the future after the pandemic ends**. In addition, we urge CMS to support the Temporary Reciprocity to Ensure Access to Treatment (TREAT) Act (S. 4421, HR. 8283), which would provide temporary licensing reciprocity for health care professionals in all states for all types of services during the COVID-19 pandemic.

[4] 85 *Fed. Reg.* 19320 (March 31, 2020)
[5] 85 *Fed. Reg.* 27550 (May 8, 2020)

Residents Should be Allowed to Provide Medicare Telehealth Services While the Teaching Physician is Present Virtually without geographic restriction

CMS has finalized policy that allows teaching physicians to bill for telehealth services when a resident located in a rural training site furnishes services to a beneficiary who is in a separate location within the same rural area as the residency training site. A resident located in rural training site may also furnish telehealth services to a beneficiary who is located in a different rural location. In these cases, the teaching physician is present, through interactive, audio/video real-time communications technology, in a third location, either within the same rural training site as the resident or outside of that rural training site. When a resident furnishes Medicare telehealth services in a rural residency training site and the teaching physician is present using interactive, audio/video real-time communications technology, the patient's medical record must clearly reflect how and when the teaching physician was present during the key portion of the service.

The AAMC believes that residents should be allowed to provide Medicare telehealth services while teaching physician is present through interactive technology. Enabling virtual supervision of a resident during telehealth services is crucial to expanding patients' access to appropriately supervised care while enhancing the resident's skills. As part of this development, it is essential for residents to have experience with telehealth visits while supervised to prepare them to provide telehealth services once they complete their training. **Due to the nature of interactive, audio/video real-time communications technology, the AAMC believes that it is not appropriate to limit virtual supervision based on geographic location.** We recommend that CMS allow residents to provide telehealth services permanently while a teaching physician is present via real-time audio-visual communications technology without geographic restriction. If CMS does not extend this policy in all geographic locations, at a minimum, it should be expanded to include medically underserved areas.

AAMC Strongly Supports Continued Payment for all Audio-only/Telephone-only Evaluation & Management Codes

The AAMC commends CMS for allowing payment for audio-only technology for mental health services. We strongly believe that payment should be extended to Audio-only/Telephone-only E/M Codes. In the March 31st COVID-19 IFC, CMS established separate payment for audio-only E/M services, CPT codes 99441-99443. CMS initially finalized payment based on the RVUs recommended by the RUC. Based on stakeholders' feedback, in the 2nd COVID-19 IFC,[6] CMS established new RVUs for the audio-only E/M services based on crosswalks to the most analogous office/outpatient E/M codes. In addition, CMS recognized these services as telehealth services and added them to the Medicare telehealth list for the duration of the PHE. For audio-only E/M services, CMS issued a waiver of the requirements under section 1834(m) of the Act and its regulation at § 410.78 that Medicare telehealth services must be furnished using video technology. CMS is proposing that it will not recognize these codes for payment under the PFS after the PHE. However, CMS acknowledges that the need for audio-only interaction could remain after the PHE as beneficiaries continue to avoid sources of potential infection.

[6] Ibid.

The AAMC strongly supports payment for the audio-only E/M codes after the PHE ends. Eliminating coverage for these important audio-only services will 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. Initial reports suggest that lack of video services or discomfort regarding the use of video may particularly affect vulnerable populations, including the elderly, those with low socioeconomic status, and certain races and ethnicities.

Data from the Clinical Practice Solutions Center (CPSC),[7] which contains claims data from 90 physician faculty practices, shows that approximately 30% of telehealth services were provided using audio-only telephone technology in April and May 2020. The proportion of telephone/audio-only visits increased with the age of the patient, with 17% of visits delivered via audio-only interaction for patients 41-60 years of age, 30% for patients 61-80 years of age, and 47% of visits for patients over 81. CMS also released data showing that nearly one third of Medicare beneficiaries received telehealth by audio only telephone technology.[8, 9] This demonstrates the importance of continuing to allow equitable coverage and payment for telephone services to Medicare beneficiaries.

In addition, patients in rural areas and those with lower socio-economic 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 is through a phone. Many services can be clinically appropriate when provided via an audio-only interaction, and that option should exist for patients.

PULMONARY REHABILITATION PROGRAM

CMS Should Expand the Pulmonary Rehabilitation (PR) Program

In the 2022 PFS, CMS proposes to expand the PR program to include more covered conditions. Currently PR is a physician-supervised program for patients with COPD and certain other chronic respiratory diseases. CMS proposes to cover PR for Medicare beneficiaries who have been diagnosed with severe manifestations of COVID-19, defined as requiring hospitalization in the ICU or otherwise, and who experience continuing symptomatology, including respiratory dysfunction, for at least four weeks post discharge. **The AAMC is glad that CMS recognizes the pulmonary issues associated with severe COVID-19. We suggest consulting with pulmonary specialists to determine the most effective way to incorporate severe COVID-19 into the PR program**.

VALUING INNOVATIVE TECHNOLOGY

CMS solicits comments on how to better understand resource costs for services involving innovative technologies, including but not limited to software algorithms and artificial

[7] The Clinical Practice Solutions Center (CPSC), developed by the Association of American Medical Colleges (AAMC) and Vizient, is the result of a partnership that works with member practice plans to collect data on provider practice patterns and performance. This analysis included data from 65 faculty practices.
[8] HHS ASPE Issue Brief: Medicare beneficiary use of telehealth visits: Early Data from the Start of the COVID-19 Pandemic (July 27, 2020).
[9] Seema Verma, Health Affairs Blog: Early Impact Of CMS Expansion Of Medicare Telehealth During COVID-19. (July 15, 2020)

intelligence (AI). The AAMC supports physician use of evolving innovative technology to supplement the delivery of high-quality care. We urge CMS to consider payment policies for such technology that encourage their use while avoiding inadvertent disincentives.

Time and Effort

At this stage innovative software algorithms and AI are used as an aid for physicians in the care of their patients. Innovative technologies supplement but do not replace a physician's judgment and medical decision-making, intensity of work, or responsibility associated with patient care. **The AAMC urges CMS to rely on the knowledge and expertise of clinicians, who provide a given service with the use of innovative technology to best understand the impacts on physician time and effort, as it will be specific to each service and technology.**

Cost

Cost is unlikely to be reduced substantially over time after a physician's initial upfront investment to acquire innovative technology. In the case of software in particular, developers often build on-going revenue streams through licensing and servicing fees. **CMS should consider additional ongoing costs when valuing innovative technologies to ensure that physicians are not disincentivized from the use of promising care innovations due to reimbursement that only supports initial costs.**

Bias

Bias is a real concern, and one that is best addressed in the research and development phase of a given software algorithm or AI-based technology. The AAMC recently submitted comments[10] to a White House Office of Science and Technology Policy (OTSP) and National Science Foundation (NSF) request for information on an implementation plan for a national AI research resource. We noted that there are formidable barriers to the implementation of an inclusive AI research infrastructure due to the long-standing and systemic discrimination, biases, and inequities that exist in the U.S. – all of which are present in the many overlapping sectors that converge upon the field of AI. Data demonstrate that the U.S. clinical and research enterprise is likewise marbled with biases and inequities, which can potentially preclude the formation of an equitable AI framework that, when operationalized, benefits all communities.

Specific to innovation technological solutions for clinical practice, the background coding is typically a "black box," and end users cannot identify -the human biases that are baked in. In the case of medical innovative technologies, clinicians must be trained on the use of the tool, including how to interpret its outputs, and to understand potential areas of bias when incorporating the tool into clinical practice. We urge CMS to consider collaboration with external stakeholders and other federal policymakers that might be better suited to evaluate potential bias in technology, such as the OSTP, NSF, National Institutes of Health, and the Food and Drug Administration, to best understand how the agency could incorporate bias review into health care payment considerations. As demonstrated by the OTSP and NSF RFI, this is a new area of focus, and CMS should proceed cautiously.

[10] *See* AAMC Submits Comments to OSTP and NSF on an Implementation Plan for a National Artificial Intelligence Resource (August 31, 2021).

Improving Medicare Beneficiary Access to Care

Incorporating innovative technology into practice holds the potential for improving patient access to care, and reducing inequities in access, especially with tools that improve population health analysis and tools that are able to appropriately pre-screen patients. As an example of the latter, there has been some evidence[11] of successful use of AI to initially assess images of a patient's skin to accurately screen for melanoma, the most serious form of skin cancer. In this instance, the use of the innovative technology could improve efficiencies for triaging patients to ensure more timely access to necessary care.

MEDICARE SHARED SAVINGS PROGRAM (MSSP)

CMS finalized a major overhaul of the quality reporting program for accountable care organizations (ACOs) at a time when ACOs are experiencing major challenges due to the COVD-19 PHE in the 2021 PFS rule. We urge CMS to phase in the restructuring of the MSSP quality program that was included in last year's rulemaking. We appreciate CMS' proposal in the rule to postpone some of the changes to the quality scoring program and the proposals to give ACOs several options for reporting quality in 2022. Comments on the specific ACO proposals in the rule follow.

Amended Quality Reporting

CMS Should Maintain the Web Interface Reporting Option At least for the Next Two Years and Allow ACOs to Use Other Reporting Mechanisms

In the 2021 Physician Fee schedule Final rule, CMS finalized a number of policies related to quality reporting and measurement for ACOs. Under these policies, for 2022, accountable care organizations (ACOs) would be required to report quality data on three electronic clinical quality measures/MIPS clinical quality measures (eCQMs/MIPS CQM). CMS proposes to delay the requirement that ACOs report all-payer eCQMs/MIPS CQMs and to extend the CMS Web Interface as a collection type for MSSP ACOs under the APM Performance Pathway for 2022 and 2023. In 2023, ACOs would be required to report on at least one eCQMs/MIPS CQM measure in addition to the Web Interface Measures.

We urge CMS to finalize its proposal to maintain the Web Interface as a reporting option for ACOs for at least the next two years while also allowing ACOs the option of using other reporting mechanisms. In addition, we ask that CMS remove its proposal to require reporting on at least one eCQMs/MIPS CQM in 2023. The operational challenges associated with reporting one eCQMs/MIPS CQM will be as difficult as reporting all three. Making the transition from the Web Interface to alternative reporting options (such as eCQMs) will cost many ACOs considerable time, money, and effort in changing workflows, paying for registries and adapting and modifying EHRs to comply with eCQM standards. Physicians and other health care professionals will need training to adjust to the new workflows.

[11] *See* Soenksen et al., "Using deep learning for dermatologist-level detection of suspicious pigmented skin lesions from wide-field images," Science Translational Medicine, Vol. 13, No. 581 (February 17, 2021).

It is important to recognize that ACOs use different approaches to combining clinical data across the ACO, which makes changes to reporting more challenging. Some ACOs have all of their participants on the same EHR platform, while others have participants that use different EHRs. For the ACOs with participants that do not use a common platform, and possibly even those on the same platform, it will be challenging to merge the data from the various EHRs to report MIPS CQMs or eCQMs. It will be necessary to determine how to combine the data from each system, which will require the use of an outside vendor and will be costly.

In addition, CMS clarifies in the rule that an ACO that submits eCQM quality data to CMS must de-duplicate the patient level measures data across its ACO providers to ensure that the aggregated QRDA III file that is submitted to CMS incorporates only quality data that meets the intent of the measure. QRDA III files are aggregate files with no patient identifier. Providers will need to work with their EHR vendors to develop systems that will enable de-duplication of the measures. At this time, most EHR vendors have not developed systems that aggregate data from all the practices and deduplicate at the ACO level.

The requirement that quality scoring for eCQMs is based on the ACO's patients from all payers, is also challenging for ACOs. To accurately measure the ACO's quality efforts, we recommend that the ACOs quality score be based only on the Medicare patients assigned to the ACO. The ACO does not have the same flexibilities to design care interventions for all patients treated by the ACO's participant clinicians nor the ability to access patient data for the patients not attributed to the ACO but treated by ACO participants. If CMS continues with scoring based on all patients, across all payers, the AAMC urges a pay-for-reporting approach to performance for at least one year. This approach will provide ACOs time to better understand the broader patient populations their participants serve and how to appropriately access the necessary data to design quality improvement activities for this expanded patient population.

Given the challenges with implementing this change in quality reporting, combined with the significant disruptions to patient care caused by the COVID-19 pandemic, the delay in mandatory eCQM reporting is critical to allow ACO's more time to prepare for these significant changes. In addition, we support CMS' proposal to allow an ACO that decides to report both the ten CMS Web Interface measures and the three eCQM/MIPS CQM measures to receive the higher of the two quality scores for purposes of the MIPS Quality performance category. This will enable ACOs to test how reporting eCQMs will work for their practice in 2022 without the risk of being penalized.

Lastly, we oppose the proposal to increase the quality data completeness standard from 70 percent to 80 percent beginning in 2023. If CMS chooses to move forward with the all payer requirement, we request CMS lower the data completeness level to no more than 60% and have a more phased in approach to any increases. As stated earlier, it will be difficult due to challenges with access to data for ACOs to track patients and provide interventions when there is no direct relationship with the ACO. As ACOs implement system changes needed to report eCQMs, additional issues may be discovered that could also impact data completeness. Lowering the data completeness score to 60% will give additional flexibility and time to become familiar with the new quality reporting requirements and address any issues that are identified.

Quality Performance Standard Should Remain at 30th Percentile

In last year's rule, CMS required that to meet the quality performance standard, the ACO score must be higher than the 40th percentile across the MIPS quality performance category. In this rule CMS proposes to delay adoption of a higher standard (40th percentile) until performance year 2024, allowing ACOs additional time to prepare for the transition to APP reporting. Specifically, CMS proposes in 2022 to apply the 30th percentile standard to only one (of three) specified APP measures for PYs 2022 and 2023 if all three are reported by an ACO. An ACO that fails to report on at least one specified APP measure for PY 2023 will not meet the quality standard regardless of its performance on the remaining measures.

The AAMC supports maintaining the 30th percentile standard in 2022. According to CMS, for performance year 2019 the MIPS Quality performance category score at 30th percentile was equivalent to 87.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 95.7, an almost perfect score. We are concerned that the score needed for the 40th percentile is very high and ACOs would be considered poor performers on quality if they did not have an almost perfect score. Roughly 1-in-5 ACOs, or approximately 20 percent, could fall below the 40th percentile MIPS Quality performance category score by performance year 2023, and would not be eligible to share in savings or would owe maximum shared losses, if applicable.

CMS seeks comment on whether publicly displaying prior year performance scores that equate to 30th or 40th MIPS quality performance category score would be helpful for providers. The AAMC supports displaying this information, which will promote transparency and enable ACOs to be better informed about the quality standards they must meet.

CMS Should Give ACOs Options for Reporting eCQMs, Including TIN-Level Reporting and Potential Sampling

CMS seeks comment on whether to allow ACO providers to submit eCQMs/MIPS CQM measures to CMS at the ACO participant tax identification number (TIN)-level and whether to incorporate a sampling approach as an intermediary step for ACOs before reporting measures across all patients.

As we noted previously in these comments, it is critical for CMS to recognize that ACOs use different approaches to combining clinical data. This presents challenges for ACOs in responding to significant changes, such as adopting ACO-level reporting for measures requiring clinical data abstraction and increasing the patient population on which the ACOs must report. Under the Web Interface reporting, ACOs are able to set up each participant TIN to report necessary data and have CMS aggregate submitted data for ACO-level scoring. Allowing this process to continue for ACOs that struggle to aggregate and de-duplicate patient data for ACO-level eCQM/MIPS CQMs could be a solution, while also recognizing that some ACOs have the capability to manage this new way of reporting and are ready to report across their participants. CMS should at a minimum maintain ACO-level reporting options in order to allow ACOs that have invested in the systems and infrastructure to manage wide-scale reporting and de-duplication.

Similarly, in regard to patient sampling as an approach to migrating to eCQMs/MIPS CQMs, we believe CMS should have a choice-based framework for ACOs. Sampling might be preferable for ACOs struggling to implement the technological changes necessary to manage reporting for a significantly larger patient population across EHRs. But for ACOs that have invested in tools to adopt eCQMs/MIPS CQMs, sampling would defeat the purpose of eCQM reporting by removing the streamlined approach to clinical data abstraction and frustrate their efforts by adding a complicating factor after the fact.

The AAMC urges CMS to provide options to ACOs to address the significant shifts in quality reporting through eCQMs/MIPS CQMs to ensure that ACOs are neither unfairly left behind and unable to continue participation in the program nor halted in their current efforts to adapt to a changing quality reporting paradigm.

CMS Should Not Mandate Additional Measures When Considering Quality Reporting Options for Specialists Within ACOs

CMS seeks feedback on how best to balance the population health and primary care focus of measures in the new APP measure set and the reality that such measure may not always be applicable to specialists within an ACO. One option CMS could consider is for ACO participant TINs to report applicable MIPS Value Pathways (MVPs) as a part of assessing ACO quality performance. Alternatively, CMS could modify the Shared Savings Program measure set and/or the APP measure set to better incorporate measurement of specialists. The AAMC urges CMS not to increase measurement burden on ACOs in an effort to assess the role of specialists, as this could chill participation in ACOs. Currently, specialists serve an important role in ACO's by providing high quality care to their patients and ensuring that their patients are referred to the primary care physicians to receive appropriate preventive health care to improve population health.

Additional measures for the MSSP measure set would be counter to the intent of CMS to align the MSSP quality measure set with the APP performance measures in the MIPS program. Instead, CMS should allow ACOs the option to supplement ACO performance scoring if they wish to submit and incorporate MVPs scoring for certain specialists on a set of optional specialist-focused measures for more meaningful measurement of specialist performance within the ACO.

CMS Should Invest in Supporting Data Collection Improvements and Encourage the Reporting and Use of Actionable Social Risk Factor Data to Promote Health Equity

CMS seeks feedback on how ACOs can improve the quality of care provided across all patients they serve and address disparities that currently exist, as well as how the agency can encourage health care providers serving patients and communities with unmet social needs to participate in ACOs and other value-based care initiatives. The AAMC applauds CMS for its efforts to inform future proposals to address inequities in access to and outcomes of health care. As noted elsewhere in this letter, the COVID-19 pandemic laid bare the realities of longstanding inequities in our communities that must be addressed. Furthermore, we believe value-based payment initiatives are a complimentary tool for addressing inequities in health care delivery.

Specific to the promoting health equity in the Medicare Shared Savings Program, we urge CMS to invest resources into improving data collection in a way that supports the collection of standardized multi-sector information regarding individual and community-based social needs. This might begin with the improved collection of demographic data that captures self-reported gender, race and ethnicity, though we urge CMS to be unambiguous that those factors themselves do not represent an individual's inherent risk. Rather that such data is serving as a proxy for unmet social needs until such valid, reliable, and actionable data for quantifying and capturing the actual risks of bias and unjust distribution of resources and opportunity that create the social and structural conditions that heighten inequities. CMS should not stratify quality performance on the basis of indirectly estimated race and ethnicity data while the field develops this gold standard of data collection and use for capturing individual and community-based unmet social needs. The AAMC discusses our strong concerns with such indirectly estimated data elsewhere in these comments.

One way CMS should invest resources is by committing to the development and evaluation of improved stratification and risk-adjustment models (for both quality and financial benchmarks). Many AAMC member teaching hospitals and health systems, including those who participate in ACO payment models, use electronic health records (EHR)-based screening tools in data collection to be better informed about the broader unmet health-related social needs in their communities. CMS should actively invest resources to explore whether there are ideas and solutions from the data science and research community on how best to standardize a roll-up of granular data for community use into a format for broader evaluation and analysis. CMS could partner on an effort led by the Office of the National Coordinator for Health Information Technology (ONC) to evaluate interoperability standards that roll data collected through screening tools up into social determinants of health (SDOH)-related ICD-10 z-codes to capture social risk factors and provide actionable data to inform intervention and be used for improved stratification and risk adjustment.

CMS Should Seek Stakeholder Input on the ACO Quality Measure Set

In the 2021 final physician fee schedule rule, CMS identified the list of quality measures that would apply under the APM Payment Pathway (APP) and to ACO clinicians. The APP measure set consists of 6 measures chosen to focus on population health and care delivered through APMs. MSSP ACOs would be required to report three measures (HbA1c Poor Control, Depression Screening and Follow-Up Plan, Controlling High Blood Pressure) and field the CAHPS survey. CMS would score the remaining two measures using administrative claims. The APP measure set would suffice for reporting under MIPS and, under the MSSP, the measure set also would be used to determine quality-based eligibility for sharing in any savings.

We appreciate the significant reduction in measures as it eases reporting burden. However, we recommend CMS seek stakeholder input on measure sets for ACOs from the Measures Application Partnership (MAP) and others. The MAP is responsible for evaluating measures for the MSSP to ensure the measures fit the program prior to implementation.

AAMC Supports the Update to Extreme and Uncontrollable Circumstances Policies

CMS proposes to update the extreme and uncontrollable circumstances policy under the MSSP to reflect its proposals related to the quality performance standard. Specifically, for performance year 2021 and 2022 if the ACO is able to report quality data and meets the MIPS data completeness and case minimum requirements, CMS would use the higher of the ACO's MIPS Quality performance category score or the 30th percentile MIPS quality performance category score. If the ACO is unable to report quality data and meet the MIPS standards due to extreme and uncontrollable circumstances, CMS would apply the 30th percentile MIPS Quality performance category score. In future years, it would be set at the 40th percentile. AAMC supports this update.

Other ACO Topics

AAMC Supports Expanding the Definition of Primary Care Services Used in MSSP Assignment

CMS proposes to expand the definition of primary care services used to determine MSSP assignment in its regulations to include the following additional billing codes beginning January 1, 2022:

- 99X21 (chronic care management [CCM])*
- 99X22, 99X23, 99X24, and 99X25 (principal care management [PCM])*
- G2212 (prolonged office or other outpatient E/M service) *
- G2252 (communication technology-based service) *not yet finalized

The AAMC supports the addition of these services to the primary care services used for MSSP assignment.

Remove ACO Beneficiaries from the Regional Benchmark to Ensure ACOs are Not Penalized as They Achieve Savings for Their Assigned Populations

CMS seeks feedback on the regional adjustment of MSSP benchmarks. Specifically, CMS wants feedback on how to account for the removal of ACO-assigned beneficiaries from the regional reference population, which is used to determine the regional portion of benchmarks.

When determining the ACO's benchmark, the AAMC urges CMS to remove an ACO's assigned patients when calculating the costs of patients in the ACO's region. This policy has a chilling effect on program participation. The CMS definition of the "region" for ACOs unfairly disadvantages ACOs that make up a large part of their market, which especially affects rural ACOs. It has been referred to as the "rural glitch" because of its negative impact on rural ACOs. Exclusion of assigned ACO patients from the benchmark would more fairly and accurately compare an ACO's spending to its surrounding area. We urge CMS to support legislation in Congress, the Accountable Care in Rural America Act (H.R. 3746), which addresses this problem.

CMS suggests a formula to account for the removal of ACO-assigned beneficiaries. When the benchmarks were calculated using the formula, CMS found that some ACOs would benefit while others would be harmed by the change. **The AAMC recommends that CMS set a cap on the adjustment to the benchmark for ACOs that would be harmed by fixing the "rural glitch."**

CMS Should Re-Evaluate the Current 3 Percent Cap on Risk Score Growth in Light of the COVID-19 Public Health Emergency and Evaluate the Inclusion of Social Risk Factors into Risk Adjustment Models for ACO Benchmarking

CMS seeks feedback on approaches to improve the risk adjustment methodology for the Shared Saving Program, specifically for ACOs with medically complex, high-cost patients. Inadequate risk adjustment as part of ACO financial benchmarking is an area of ongoing concern for the AAMC, especially in light of the COVID-19 PHE. We believe that CMS should reevaluate current policy to cap risk score growth at three percent over the course of five years, to instead consider whether a higher cap is necessary to address the significant reduction in clinical encounters since March 2020 and the beginning the pandemic. This reduction in encounters is likely to reduce the appropriate documentation of clinical risk and result in a significant temporary reduction in risk scores. The scores are likely to dramatically increase when clinical practice resumes to pre-pandemic levels. For example, hospitals have already noted a significant increase in CMI for hospitalized patients related to delayed diagnosis and delay in seeking care. This drastic artificial fluctuation is likely to hit the bounds of the current cap and could force some ACOs to exit the program.

As previously mentioned in these comments, the AAMC strongly believes that CMS should consider a variety of policy levers to improve social risk and demographic data collection as a path to addressing health equity. While mandating minimum data collection as a requirement may be one solution, we urge evaluation of incentives for ACOs to improve data collection in part through a commitment to improving risk adjustment models for the inclusion of social risk factors and/or for additional stratification of quality performance. The AAMC believes that patients, payers, and providers will benefit from partnership to improve health equity. CMS should lead the effort to demonstrate the benefit of better data to inform solutions.

LABORATORY SPECIMEN COLLECTION AND TRAVEL ALLOWANCE

CMS Should Continue Payment for the Travel Allowance for COVID-19 Specimens

During the PHE, CMS established a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses for trained personnel to collect specimens from homebound patients and inpatients, in addition to the amounts provided under the Clinical Laboratory Fee Schedule. In the interim final rule for the response of the COVID–19 Public Health Emergency CMS established two new level II HCPCS codes, code G2023 and G2024 to identify specimen collection for Covid–19 testing for the duration of the PHE. This policy provides independent laboratories with additional resources to provide COVID–19 testing and helps with efforts to limit patients' exposure to others. CMS does not plan to continue this allowance after the PHE. However, stakeholders believe that even after the Covid-19 PHE has expired, testing will still be necessary to track the prevalence of the virus, prevent new outbreaks and identify new variants. The continued need for testing will mean that additional laboratory

expenses and professional resources will still be incurred. Therefore, the AAMC encourages CMS to continue payment for specimen collection and the travel allowance for Covid-19 specimens, even after expiration of the PHE.

OPIOID USE DISORDER TREATMENT SERVICES

CMS Strongly Supports Extending the COVID-19 Flexibilities for the Opioid Use Disorder Treatment

For the same reasons mentioned in the previous section of our comment letter on audio-only mental health, the AAMC recommends Opioid Use Disorder (OUD) Treatment services should be furnished via telehealth and audio-only technology. Audio-only services improve access to virtual care for patients who do not have access to the devices or broadband for audiovisual calls, are not comfortable with digital technology, or do not have a caregiver available to assist them. During the PHE, coverage and payment for audio-only calls has been critical to ensure access to care for some patients. Physicians have been able to provide a wide array of services efficiently, effectively, and safely to patients using the telephone. Examples of services include taking medical histories, ordering, or following up on lab and imaging tests, monitoring symptoms, and starting medications. Data from the Clinical Practice Solutions Center (CPSC), which contains claims data from 90 physician faculty practices, shows that approximately 30% of telehealth services were provided using audio-only telephone technology in April and May 2020. The proportion of telephone/audio-only visits increased with the age of the patient, with 17% of visits delivered via audio-only interaction for patients 41-60 years of age, 30% for patients 61-80 years of age, and 47% of visits for patients over 81.

Providers have found that when treating certain mental health conditions patients often benefit from obtaining services without visual contact with their provider. Audio-only technology allows patients to communicate with providers while maintaining a sense of privacy. This is particularly true in small towns and tightknit communities because of the negative stigma attached to seeking treatment for substance abuse. Therefore, it is critical that audio-only technology be permitted in instances where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology.

The AAMC supports creating a service-level modifier: Opioid Use Disorder Treatment furnished using audio-only technology. This modifier would allow the collection of claims-based data and lead to the analysis of the use of telehealth and audio-only services. This information can then be used to determine the ways in which mental health services are being provided, improve clinical outcomes, and benefit patients.

CMS proposes requiring additional documentation in the patient's medical record to support the clinical appropriateness of audio-only technology. **The AAMC believes that documentation requirements for audio-only visits should be consistent with requirements for in-person visits to support the service.** We have supported CMS' proposal to establish a modify for "audio-only technology" and we believe that is sufficient**.** However, if CMS decides to require additional documentation for audio only, we recommend allowing physicians to document one of the following three reasons that the visit is audio-only.

1. "Audio-only; patient unable to use two-way audio-visual technology"

2. "Audio-only; patient does not wish to use two-way audio-visual technology"
3. "Audio-only; patient does not have access to two-way audio-visual technology"

The AAMC Supports Establishing a New G-code for Take-Home Naloxone

Naloxone is an extremely effective treatment for opioid overdose. Higher doses of take-home naloxone are necessary to combat more potent synthetic opioids[12]. This treatment is an important tool needed to combat the opioid crises and ultimately save lives.

ELECTRONIC PRESCRIBING

CMS Should Delay Electronic Prescribing Compliance Date for Electronic Prescribing of controlled substances

In the 2021 PFS final rule CMS provided a January 1, 2022, compliance date for electronic prescribing of controlled substance (ECPS) for a covered Part D drug under a prescription drug plan or an MA-PD plan. In the 2022 Proposed Rule, CMS expresses difficulties with implementation and proposes to change the EPCS compliance date from January 1, 2022, to January 1, 2023. **The AAMC supports the delay in the date for electronic prescribing of controlled substances for at least one year to address implementation concerns.**

OPEN PAYMENTS

CMS requests input on specific aspects of the Open Payments program that could benefit from clarification to improve the quality of information published on the Open Payments website. The AAMC has engaged with CMS and our members throughout the development of Open Payments and appreciates the opportunity to improve the process and publicly available information. AAMC commends CMS' continued efforts to engage and educate the stakeholder community through guidance, "listening sessions," educational materials, and updated FAQs.

Payment Context Field for Teaching Hospitals

The AAMC is supportive of CMS' proposal that a mandatory "context field" be added to reports of payments or transfers of value to teaching hospitals. Since implementation of the Open Payments program, the reporting of payments or other transfers of value by applicable manufacturers and group purchasing organizations (GPOs) have presented several challenges for covered recipients, and the AAMC continues to receive feedback that the review and dispute process is viewed as a significant barrier to meaningful participation in the Open Payments program. In the proposed rule, CMS acknowledges the feedback it has received from teaching hospitals, that "Open Payments submissions do not contain sufficient information to identify reported payments or other transfers of value in their own records," and proposes inclusion of a mandatory context field for payments or other transfers of value attributed to teaching hospitals.

In response to CMS' request for feedback on the CY 2017 Physician Fee Schedule Proposed Rule, the AAMC recommended the inclusion of "additional required non-public text fields to assist in the review and affirmation of disputes," and reiterated this recommendation in our response to the CY 2020 Proposed Rule, emphasizing here that additional context would

[12] Moss, R.B., Carlo, D.J. Higher doses of naloxone are needed in the synthetic opioid era. *Subst Abuse Treat Prev Policy* 14, 6 (2019).

improve communication between the covered recipient and manufacturer, increase the accuracy of information in the Open Payments system, and build public confidence in the information reported. **The AAMC strongly supports CMS' proposed addition of a context field that may include data such as a check number, electronic wire number, or related department of the hospital to better identify payments or transfers of value attributed to teaching hospitals.** We also agree that the additional field would help reduce burden for both reporting entities and teaching hospitals.

Updated Contact Information

CMS notes that in order to uphold the integrity of the data in the Open Payments program, it is essential for the agency to be able to contact reporting entities in cases of perceived irregularities or potential noncompliance, proposing that companies making reports into the system must have updated contact information in the Open Payments system at least every two years.

While we support this proposal and agree that effective communication between CMS and applicable manufacturers and GPOs is critical, it is equally important that CMS also consider the need for efficient and effective communication between covered recipients and manufacturers. **We urge CMS to require that contact information be provided with reported payments or transfers of value in a format that is readily available to covered recipients.** This will better facilitate timely communication between manufacturers and covered recipients and resolution of potential disputes within the review and dispute window.

We recognize that previous changes to the review and dispute process now include required non-public text fields for covered recipients (i.e., "Dispute Details and Contact Information"), which we expressed support for in our response to the CY 2020 Physician Fee Schedule Proposed Rule. However, as we highlight in our letter, covered recipients "have no systematic mechanism through which they can contact an applicable manufacturer with questions about payment records other than by disputing an unrecognized record." Covered recipients still experience these difficulties and are unable to contact applicable manufacturers to clarify reported information during the review and dispute period before publication on the Open Payments website.

Reducing Burden - Registration and Extension of Review and Dispute Period

The AAMC appreciates CMS' continued concern for the burdens associated with Open Payments reporting and related processes and recognize the system enhancements that have been made in direct response to stakeholder feedback. The responses to stakeholder feedback are evident and we encourage these continued collaborations before system or registration modifications are publicly released. Consistent with CMS' efforts to reduce burden, we propose review of two areas: 1) Open Payments registration and 2) the length of the review and dispute window.

There continue to be difficulties associated with accessing the review and dispute system, including the amount of time it takes covered recipients to register in the CMS Enterprise Portal and Open Payments system has proven extensive. Efforts to streamline this process would decrease burden, frustration, and greatly increase involvement in the Open Payments program. In our response to the 2020 CY Proposed Rule, we offer the following potential solutions for consideration: 1. extend the timeframe for which a registration and password remains valid

because the review and dispute process is annual and registered users find that they have been removed from the system each time they return; 2. eliminate or streamline the two-part registration in the CMS Enterprise Portal and the Open Payments system, and 3. increase the variety and number of characters for acceptable user passwords.

Additionally, the AAMC recommends that the review and dispute period last longer than 45 days. While we recognize the statutory parameters pertaining to the 45-day review and dispute period, we note that this time period must be *at least* 45 days and can be extended with no rulemaking change. The benefit of a longer review and dispute window would be ensuring that covered recipients have ample opportunity to review payments reported about them and work to resolve disputes prior to publication of the data.

The AAMC community has greatly benefited from the Association's relationship with the Open Payments team and look forward to continued engagement in support of CMS' efforts to improve clarity and build public confidence in the Open Payments program.

QUALITY PAYMENT PROGRAM

The AAMC appreciates CMS' 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. We commend CMS' efforts to support clinicians on the front lines during the COVID-19 pandemic by providing burden relief through the extreme and uncontrollable circumstances policy. We support CMS' proposal to delay implementation of MIPS value pathways and to continue to allow quality reporting through the Web Interface in light of the COVID-19 pandemic. **The AAMC recommends that all measures used in the quality payment program be appropriately adjusted to account for the clinical and social complexity of patients. We encourage CMS to work with key stakeholders to identify longer term policy solutions in the future that would attain health equity for all beneficiaries and minimize unintended consequences.** Our comments on the proposals in the rule related to the QPP follow.

MIPS VALUE PATHWAYS (MVPS)

In the 2020 PFS final rule, CMS established a new MIPS participation framework, referred to as MIPS Value Pathways (MVPs), that was scheduled to begin with the 2022 performance year; however, due to the COVID-19 public health emergency CMS proposes to delay MVP implementation until 2023. For 2023, CMS proposes seven MVPs and to make MVP reporting voluntary. CMS indicates that traditional MIPS will be maintained while a robust inventory of MVPs is built. The Agency expects to propose that after 2027 traditional MIPS would sunset and all MIPS eligible clinicians would be required to participate in MIPS via an MVP or an APM Performance Pathway.

The AAMC strongly supports CMS' proposal to delay implementation of the MVPs until 2023. Clinicians are on the frontlines treating COVID-19 patients. Now is not the time to burden clinicians with learning a new method of reporting under the MIPS program. The MVPs should be gradually implemented to ensure that they are meaningful for clinicians and their patients and not burdensome to report.

We support CMS' proposal to make MVP reporting voluntary over the next few years. However, we have significant concerns with CMS' proposal to sunset the traditional MIPS program at the end of 2027, making MVPs or the APP performance pathway the only mechanism for participating in the quality payment program. There are a number of conceptual challenges with the MVP program and sufficient time will be needed to address them before sunsetting traditional MIPS. First, there would need to be enough measures available to create MVPs that are meaningful to the over 1 million eligible clinicians that participate in the MIPS program. Given the numerous physician specialties and subspecialties, it will be difficult to create a sufficient number of MVPs, especially by 2027. Development of MVPs will require significant input from physicians. **Under the MIPS program, the practices should be given the opportunity to assess the advantages and disadvantages and select whichever option is most meaningful and least burdensome for reporting in the MIPS program.**

Subgroup Reporting

To generate more clinically relevant information about clinician performance, particularly for clinicians in large multispecialty groups, CMS proposes to establish "subgroup" reporting for MVPs, which would be voluntary for the 2023 and 2024 performance years. Beginning in 2025, multispecialty groups would be required to report MVPs as subgroups. Subgroups would consist of a subset of a group that is identified by a combination of the group Tax Identification Number (TIN), the subgroup identifier, and each eligible clinician's National Provider Identifier (NPI).

We appreciate CMS' recognition of the importance of allowing a portion of a group to report as a separate subgroup on measures and activities that are more applicable to the subgroup than to the larger group, and to be assessed and scored based on the subgroup's performance. We also appreciate the information CMS has provided in the rule regarding its initial thinking on how subgroups would be formed, opt-in to MVPs, and be scored, accompanied by a request for feedback.

As CMS considers how MVPs and subgroups would be operationalized, it is important to understand the unique challenges posed by the QPP for large multi-specialty practices such as those typically found in academic medical centers. 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 128 individual NPIs to a high of 4,319 with a mean of 989 and a median of 816. On average these practices have over 70 adult and pediatric specialties and numerous subspecialties, such as burn surgery, cardiac surgery, and general surgery, 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. 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. Even if multiple MVPs are selected for reporting, it will still be challenging to identify MVPs that encompass the scope of conditions treated and the vast number of specialties included in academic medical centers.

The AAMC supports the concept of subgroup identifiers that would allow reporting and performance measurement at the subgroup level. We also agree with the following approaches to subgroup reporting outlined in the proposed rule:

- Requiring the subgroup to register.
- Establishing a unique subgroup identifier after registration submission
- Requiring a list of participants (TIN/NPI) who would be part of the subgroup identifier be provided to CMS and the name for the subgroup
- Assessing performance for quality, cost, and improvement activities at the subgroup level.

There are advantages and disadvantages to reporting under a subgroup MIPS identifier, an NPI, a TIN, or a combination depending on the physician practice. Under the MIPS program, the practices should be given the opportunity to select among these options. **We support CMS' proposal that other physicians in the group practice (same TIN) who are not affiliated with the subgroup that is participating in an MVP would retain the option to participate as a group practice in traditional MIPS**. We also support the proposal to allow the participant to receive the highest final score that can be attributed to their TIN/NPI combination from any reporting option (traditional MIPS, APM Performance Pathway reporting, or MVP reporting and participation option (as an individual, group, subgroup, or APM entity).

Development of MVPs Should be Collaborative

Physician input is critical in the selection of measures and activities for MVPs in the future. **AAMC supports a collaborative process for the development of MVPs that includes physicians, medical societies, and other stakeholders.** Representatives from appropriate specialties and subspecialties should be consulted as MVPs are developed. CMS should ensure that criteria used to select MVPs are well defined and transparent to give developers clear guidance. MVPs should be required to help to improve the quality of care, provide value, be feasible to implement, be reliable, be meaningful to clinicians and their patients, and be actionable. Given that burden reduction was a rationale for moving to MVPs, we believe that these principles and burden reduction should be included in the criteria for development.

Subgroup Policy Should Allow the Physician Practice to Identify and Provide a List to CMS of the Physicians Within a Subgroup

CMS asks for specific feedback on the composition of the subgroup. As stated previously, practices would need to identify which MVPs are meaningful for which physicians in the practice. Many specialties have multiple subspecialties. Within one specialty, the MVP that a subgroup chooses to report may be meaningful for one subspecialty but not for another subspecialty. In some instances, it may be appropriate for multiple specialties (such as internal medicine, family medicine, and endocrinology) to report the same MVP and be part of the same subgroup. We believe that the group practice is in the best position to determine which physicians in the practice should be part of the sub-group to which the MVP applies. Therefore, we recommend that the practice identify which specific physicians in the group practice would be participants in the subgroup and provide that list of participants' NPIs to CMS.

Population Health Administrative Claims Measures Should Not be Required in MVPs

The AAMC does not support the use of population health administrative claims measures as foundational to MVPs. Instead, CMS should make population health administrative claims

measures voluntary and allow practices to notify CMS about whether they want these measures to apply to their practice.

Administrative claims measures, such as hospital wide readmissions, are often not appropriate to attribute to individual physicians or practices, who may be unable to meaningfully influence their outcome. For example, specialties that are primarily ambulatory, such as dermatology, may have very little ability to impact hospital readmission. CMS' reliance on retrospective attribution for these measures also limits the ability of a physician or practice to make improvements in care since they do not know who their predetermined set of patients are.

Subgroups Should Not have to Duplicate Reporting of Promoting Interoperability Data

CMS states that the foundational layer of MVPs includes the full set of traditional MIPS Promoting Interoperability performance category measures. For 2023 and 2024 MIPS performance years, CMS proposes that an MVP subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category and the subgroup will be scored on those data. If the affiliated group also chooses to report as a group for the Promoting Interoperability category, the group would be required to separately submit its own data for that purpose. **The AAMC recommends that CMS not require subgroup level reporting of the Promoting Interoperability data if the affiliated group is also reporting that data.** Reporting the same data from the subgroup and affiliated group is duplicative and overly burdensome. CMS should be able to identify that the affiliated group has reported the PI information and use the data reported by the group to determine the subgroup's performance.

ALTERNATIVE PAYMENT MODEL PERFORMANCE PATHWAY (APP)

In 2021, CMS terminated the MIPS APM scoring standard, and in its place added the APM Performance Pathway as a new option for MIPS reporting and scoring for the clinicians in MIPS APMs. Alternatively, eligible clinicians in the APM can report through any other MIPS reporting option and be scored under the general MIPS standards.

Under the APP approach one set of six quality measures is used for all APMs subject to MIPS. CMS proposes to extend the CMS Web Interface as a reporting option for clinical quality measures under the APP Performance Pathway for use by clinicians of Shared Savings Program ACOs for 2022 and 2023 performance years (as was done for 2021, instead of requiring them to report only electronic clinical quality measures (eCQMs) through the APP). In 2023, ACOs would need to report at least one of the APP's three eCQMs in order to have their Web Interface data submissions scored. Beginning with 2024, only eCQM reporting under the APP would be available to ACOs.

The AAMC supports the proposed extension of the Web Interface reporting as ACOs need more time to complete technology upgrades and make changes to clinical workflow in order to move exclusively to eCQM reporting. There continue to be technical obstacles to aggregating data across multiple ACO participant TINs. We request that CMS remove the requirement for reporting at least one eCQM in 2023. It will be just as difficult to make the systems changes needed to report one eCQM as to report all three.

ADVANCED ALTERNATIVE PAYMENT MODELS (AAPMS)

CMS Should Encourage Congress to Grant Authority to Set Thresholds in the Future at a Level That Would Encourage Participation

To be classified as a qualifying participant (QP) or partial qualifying participant in an APM, providers need to meet or exceed thresholds based on patients seen or payment received for services provided through APMs. These thresholds, which were established by Congress, have been increased since the start of the program.

Originally, the Medicare statute had set higher thresholds for the payment years 2023 and beyond, where clinicians would need 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. These thresholds are 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 that this would be a problem and addressed this in the CAA that that froze the thresholds for payment years 2023 and 2024 at the 2021 and 2022 payment year levels. The thresholds for 2022 performance year, will remain at 50% of the revenue received through the APM and 35% of their Medicare patients receiving services through the APM.

We support the change to these thresholds, which is included in this proposed rule. However, we remain concerned about the increase to the thresholds that will occur in the 2025 payment year. The increasing thresholds in the future that must be met to be considered qualified participants in an advanced APM will discourage participation, thereby limiting beneficiary access to high quality and better coordinated 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. It is especially difficult for ACOs in rural areas and those that include specialists since primary care determines ACO assignment.

TRADITIONAL MIPS

MIPS Performance Category: Quality

For the 2022 performance year, CMS proposes to set the quality performance weight at 30%, a 10% decrease from 2021. As in the past, there are several ways to report quality. Eligible clinicians can report a minimum of six measures and one of those six measures must be an outcomes measure or a high priority measure. CMS is proposing to extend the GPRO Web Interface reporting option for one more year until the end of 2022. CMS is proposing substantive changes to195 existing quality measures, changes to specialty measure sets, and removal of 19 quality measures. CMS is also adding five new MIPS quality measures, two of which are administrative claims quality measures.

The AAMC Recommends Maintaining the Quality Category Weight

CMS proposes to reduce the weight of the quality measure to 30% to account for the 10% increase in the cost measure category weight. We have significant concerns regarding attribution and risk adjustment of the cost measures and the impact that the COVID-19 pandemic will have on the benchmarks and performance of the cost measures. **Given these concerns, the AAMC**

strongly recommends that CMS maintain the weight of 40% for the quality performance category for the 2022 performance year and maintain the cost weight at 20% to provide additional time to address concerns with the cost measures. While we acknowledge the statute includes language requiring a 30% weight for cost measures and 30% for quality, we believe that CMS could use some of the flexibilities granted due to the PHE to set category weights for 2022 that are different.

AAMC Recommends Maintaining Existing MIPS Quality Measures

The AAMC has concerns with the removal of additional quality measures from the MIPS program. There should be an opportunity for stakeholder input before any measures are removed from the program. Removing measures creates a lack of consistency of available measures in the program, which prevents CMS from measuring practices on improvement. It also impedes practices from focusing on applying improvement strategies and reduces the number of measures available to form MIPS Value Pathways (MVPs).

Faculty practices invest time and resources to implement quality measures and update their systems. **We recommend maintaining the existing MIPS quality measures to ensure consistency, reduce burden, and allow options in the future for MVPs.** Removing or changing measures forces a practice to pick new measures to satisfy MIPS requirements, requiring changes to systems and more education to clinicians. Often quality improvement takes several years and significant work to note consistent and improved change. Removal of existing MIPS measures thwart these efforts and measures should only be removed after extensive review and study. It also affects the ability to document and track performance improvement. Annual program changes increase administrative burden, add to complexity, decrease effectiveness of ongoing quality efforts, increase the cost of the program, and run counter to the Agency's *Patients Over Paperwork Initiative.*

AAMC Supports Use of Performance Year Benchmarks for 2022

CMS proposes to use actual 2022 performance period data to set 2022 quality benchmarks rather than the default historical baseline period, which would be performance year 2020. Due to COVID-19 flexibilities regarding data submission in the first half of 2020, it is likely that CMS has substantial data gaps in 2020 data. Care has also been drastically changed due to the pandemic so the 2020 data should not be used to determine baseline performance for 2022. Therefore, **we support CMS' proposal to use performance year benchmarks for 2022 to ensure more accurate and reliable data.**

CMS Should Provide a Gradual Transition Away from GPRO Web Interface Reporting Option

CMS proposes to extend the GPRO Web Interface (Web Interface) Reporting Option until the end of 2022. The AAMC commends CMS for proposing an extension of the Web Interface reporting option; however, we believe that it should be extended at least two years. Many faculty practice plans report quality in the MIPS program via the Web Interface. When the Web Interface is eliminated, eligible clinicians will need to use a different reporting mechanism. It will take considerable time, money, and effort to change workflows, pay for registries, and adapt and modify EHRs to comply with electronic clinical quality measure (eCQM) standards. **For these reasons, we strongly urge CMS to provide a gradual transition away from the use of**

the Web Interface reporting option. More time and thought must be given regarding how this will be implemented, and for group practices to assess their alternatives. At a minimum, the Web Interface should be continued for at least two additional years to give sufficient time for affected practices to implement a new reporting method.

CMS Should Maintain a Data Completeness Threshold at 70 Percent

CMS proposes to retain the current data completeness thresholds at 70 percent through performance year 2022 and to raise the threshold to at least 80 percent beginning with performance year 2023. **The AAMC recommends maintaining the data completeness threshold at 70 percent instead of increasing it to 80 percent in 2023**. The 70 percent threshold is already very high, and providers need to focus efforts on addressing the COVID-19 PHE instead of taking on greater reporting requirements at this time. 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 under MIPS. In these instances, the data needs to be seamlessly integrated across settings to facilitate reporting, which can be difficult. It is important to maintain the threshold at 70 percent until systems are better able to integrate data for reporting.

AAMC Urges CMS to Consider Critical Questions Related to Measurement Design for COVID-19 Vaccination by Clinicians Measure

To address the ongoing COVID-19 PHE, CMS seeks feedback on a draft *SARS-CoV-2 Vaccination by Clinicians* measure that would assess the percentage of patients aged 18 and over seen for a visit during the measurement period who completed a COVID-19 vaccination series. CMS intends for the measure to capture whether during each visit clinicians are ascertaining vaccination status and starting the vaccination series for patients who are not vaccinated, when applicable and feasible.

The AAMC strongly supports vaccination as critical protection against COVID-19, and we support[13] vaccine requirements for medical school and all hospital and ambulatory care setting employees based on the large and convincing body of evidence on the safety and efficacy of the vaccine. Recent surges in COVID-19 cases have emphasized the critical need to continue to get individuals vaccinated. We have partnered with the CDC to build confidence in vaccines in part by engaging member medical schools and teaching hospitals in outreach efforts to communicate transparently and dispel myths, with the goal of increasing vaccination rates. **We encourage CMS to take a deliberative approach to adopting measurement of clinicians on the basis of the vaccination rates of their patients due to the critical questions associated with measure design**.

Regarding measurement design, we believe there are significant questions remaining regarding the period of immunity conferred and whether (or how frequently) booster shots may be required. Those questions include:

- If boosters are required, must the booster be made by the same manufacturer as the original vaccine received?

[13] *See* AAMC Press Release, "AAMC Statement on COVID-19 Vaccine Requirements for Medical School and Teaching Hospital Employees," (July 16, 2021).

- And critically, will vaccine supply remain sufficient to ensure individuals can receive boosters if necessary?
- CMS notes that exclusions apply where a clinician documents that there is a patient contraindication, patient refusal, and/or a vaccination course was not administered due to vaccine being unavailable. Will the "unavailable" exclusion apply in cases where a clinician does not give a booster by the same manufacturer as the patient's previous vaccination?
- Will reporting require clinicians to capture vaccination record cards in their EHRs as appropriate documentation?
- Will each patient visit contribute to numerator and denominator where a patient has multiple visits during the (unspecified) measurement period?
- Will all patients count towards all clinicians who furnish their care during the measurement period?

These questions directly impact the design and feasibility of a vaccination measure, and thus we believe such a measure may be premature to implement in the MIPS quality measure set due to unpredictable shifts in reporting requirements that could lead to unreliable data to CMS, clinicians, and the public.

MIPS Performance Category: Cost

For the 2022 performance year, CMS proposes to weight the cost category at 30 percent, an increase from the 2021 weight of 20 percent. CMS plans to assess performance in the cost category by utilizing: 1) the Total Per Capita Cost of Care (TPCC) measure; 2) the Medicare Spending Per Beneficiary (MSPB) measure; and 3) episode-based cost measures (including five new episode-based measures). The AAMC is concerned about the cost measures used to measure clinician's performance, particularly given the challenges with attribution and risk adjustment, which need further study.

The AAMC Recommends Maintaining the Cost Category Weight

The AAMC acknowledges that statute requires CMS to increase the weight of the cost measure to 30 percent. **However, given the multiple concerns under the cost category, including the impact of COVID-19 on patterns of care, clinicians' lack of familiarity with cost measures, the need for risk adjustment, and the need for better attribution methodologies, the AAMC strongly urges CMS to maintain the cost category at 20 percent**. We believe that CMS has flexibilities associated with the PHE that would enable CMS to maintain the of the cost category at 20 percent. Our concerns are enumerated in further detail below.

Cost Category Measures

All Cost Measures Must be Appropriately Adjusted to 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 recent report from the National Academies of Science, Engineering and Medicine[14] clearly acknowledged that sociodemographic status variables (such as low income and education) may explain adverse outcomes and higher costs.

The COVID-19 pandemic has demonstrated the importance of accurate risk adjustment. The virus has a disproportionate impact on racial and ethnic minorities, the homeless, individuals in long-term care facilities, the elderly, and those with underlying conditions. Literature has shown that patients who are already at high-risk due to social factors are at increased risk of serious illness related to COVID-19.[15]

Without accurately accounting for clinical complexity, and social risk factors, the scores of physicians that treat vulnerable patients will be negatively and unfairly impacted and their performance will not be adequately reflected in their MIPS score. Physicians at academic medical centers care for a vulnerable population of patients who are sicker, poorer, and more complex than many patients treated elsewhere.

The AAMC believes that there are ways to appropriately incorporate patient complexity and social risk factors in the risk adjustment methodology. We request that these measures be adjusted to account for these risk factors.

Attribution Method Should be Clear and Transparent and Accurately Determine Patient/Clinician Relationship

It is critical that when measuring costs there be 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 should 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. Attribution is a key component of these cost measures.

Cost Measures Feedback

As cost measures are still being developed and implemented, clinicians need time to gain more familiarity and experience with them before those measures represent a greater portion of the MIPS final score. In CY 2019 the first wave of episode-based cost measures went into effect and in 2020 CMS added ten new cost measures. CMS is proposing to add five new cost measures in 2022. Additionally, CMS significantly revised the total per capita cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) measures in 2020. These major changes occurred in 2020 at a time when physicians had to focus their attention on treating

[14] 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.
[15] Koma, W. et al. *Low-Income and Communities of Color at Higher Risk of Serious Illness if Infected with Coronavirus.* Kaiser Family Foundation. May 7, 2020.

patients with COVID-19, implementing telehealth, obtaining PPE, and addressing financial challenges due to loss of revenue.

Physicians need time to closely review feedback to determine the extent of unwarranted variation in spending and understand their patterns of care. Reports with detailed actionable data on performance on the cost measures are essential for providers to understand how they are performing, how they compare to other providers, and to identify what improvements they need to make.

Beyond the individual clinician reports, we also recommend that CMS analyze their aggregate data for each cost measure and release the data and their analysis publicly on an annual basis. This will enable a transparent assessment of whether the cost measures are working as intended.

The Impact of COVID-19 On Cost Measures Needs to be Explored; Cost Measures That Would Lead to Inaccurate Results Must Be Excluded

We are concerned that physicians and practices that have been on the frontlines treating COVID-19 patients will be unfairly penalized by cost measures. Physicians treating COVID-19 may have patients that are more likely to have complications, admissions, and readmissions due to the COVID-19 pandemic which may cause these physicians to receive lower scores on cost measures. It also is possible that the PHE may cause disruptions to attribution, reliability, and validity.

We are pleased that CMS recognizes in this rule that there is a need for additional flexibility in calculating the scores for cost measures to account for the impact of changing conditions beyond the group of MIPS eligible clinicians and groups, such as the COVID-19 pandemic. **We support CMS' proposal for the 2022 performance year and beyond to provide scoring flexibility by excluding a cost measure score in instances where changes during a performance period impede the effective measurement of resource use for that measure. We urge CMS to consider an option to reweight the entire cost category to zero (rather than excluding specific measures) when cost performance is impacted due to factors that are outside the control of the clinicians, such as the COVID-19 PHE.** The COVID-19 PHE has demonstrated that the assessment of costs can be significantly affected by substantial changes to clinical practice and service utilization.

CMS Should Address Ongoing Concerns with Medicare Spending Per Beneficiary (MSPB) Measure and Total per Capita Cost Measure (TPCC)

Despite concerns previously raised by many stakeholders, including AAMC, CMS plans to continue to include the MSBP and TPCC measures in the MIPS program for the cost category. While we appreciate CMS' recent efforts to refine this measure, we continue to have significant concerns. For cost measures, an accurate determination of the relationship between a patient and a clinician is critical to ensure that the correct clinician is held responsible for the patient's outcomes and costs. This is complicated since most patients receive care from numerous clinicians across several facilities. The MSPB measure and the TPCC measures holds physicians accountable for costs related to patients' medical conditions that are managed outside of their organization, and for costs they cannot control, such as drug prices. The measures also fail to risk-adjust for health-related social needs. In addition, the measures capture the same costs as the episode-based measures, effectively "double counting" the costs. Attribution, benchmarks, and

risk adjustments for both measures also need to be reexamined in light of the COVID-19 pandemic.

In light of concerns[16] raised by stakeholders, and the impact of COVID-19 on these measures, we recommend that CMS address the ongoing concerns with the validity, reliability, and risk adjustment for the MSBP and TPCC measures.

MIPS Performance Category: Promoting Interoperability

For the 2022 performance year, the weight for the Promoting Interoperability (PI) category remains unchanged at 25%. CMS proposes to retain the Query of Prescription Drug Monitoring Program (PDMP) measure and make some changes to the Health Information Exchange Objective Measures.

CMS Should Maintain Query of Prescription Drug Monitoring Program (PDMP)

Specifically, CMS proposes to retain the Query of Prescription Drug Monitoring Program (PDMP) as an optional measure eligible for 10 bonus points for 2022. This decision was made due to several challenges that have been identified with implementing this measure, including difficulties in implementing it in electronic health record (EHR) clinical workflow and state variations in PDMP structure.

The AAMC supports maintaining the PDMP measure as voluntary and providing a 10-point bonus if reported. The AAMC recognizes the value of new tools to assist with the opioid addiction epidemic but cautions against making this measure required until the measure is more clearly defined and there is better evidence of integration of these tools in certified EHR technology (CEHRT) by vendors and into clinical workflows.

Proposed Changes to Provide Patients Electronic Access to Their Health Information Measure Under the Provider to Patient Exchange Objective

CMS proposes to modify the *Provide Patients Electronic Access to Their Health Information Measure* to require MIPS eligible clinicians to ensure that patient health information remains available to the patient (or patient-authorized representative) to access *indefinitely*, using any application of their choice that is configured to meet the certified technical specifications of the application programming interface (API) in the eligible clinician's CEHRT. CMS proposes indefinite access would apply to all patient health information from encounters on or after January 1, 2016 and invites comments on alternative dates.

The use of the term "indefinitely" is described as "that is, not merely for a defined period of time," could mean that a clinician may be required to maintain patient health information well beyond a patient's death. This not only assumes that future generations will have the appropriate legal authority to access an ancestor's health information but also that electronic storage capacity is infinite. There are limits to data retention, and increased data stored simply means increased time for computing to filter the information and delays in the response time of EHR systems, directly impacting patient care. Increased data storage comes at a cost, which would have to be born somewhere. Furthermore, requiring indefinite data access would necessitate a drive to storing records via "cloud" services, where control and security of data is less certain and not

[16] NQF Cost and Efficiency Standing Committee Draft Report – Spring 2020 Cycle.

guaranteed to be safe from bad actors. This of course says nothing to the environmental impact of data storage.[17] **For these reasons, requiring indefinite access is simply unreasonable, costly, and unsafe. The AAMC urges CMS to limit the requirement for patient health information to be accessible for a fixed minimum retention period such as ten years from last patient contact, matching its own current records retention requirements.[18]**

Revised Information Blocking Attestation

As part of PI category reporting, clinicians currently must attest to three statements concerning information blocking related to the CEHRT they use in their practices. We support CMS' proposal in the rule to delete two of the attestation statements, which are unnecessary and could create confusion.

Request for Feedback – Patient Access Outcomes Measures

CMS seeks comments on potential changes to the MIPS PI category to better target patient access outcomes related to the use of patient portals or third-party applications and asks a series of specific questions. We support broader patient access to their own health information as partners in care, but we caution against a future measure of patient access and use of such information. Patients use of their own health information is well beyond the control of providers and simply should not be used to reflect upon a provider's use of EHR technology. We oppose requiring providers to generate figures for the frequency of logins, number of messages sent, or lab results viewed as we do not believe that this information will inform improved patient outcomes or validly and reliably measure provider's use of EHR technology. The most a provider can do is to make options for access available and encourage patients to use them. **The PIP should focus on elements of EHR use well within a clinician's control, and not patient choices regarding how and when they access their health information.**

Request for Feedback – Clinical Notes

CMS seeks feedback on changes that will better support the availability of clinical notes to patients. Currently the ONC's rules for certified EHR technology require inclusion of clinical notes as a health data class as part of the United States Core Data for Interoperability (USCDI) to support the access, use, and exchange of electronic health information under the information blocking rules. With the information blocking rules in full effect as of April 2021, providers must provide access to clinical notes. It is unclear how incorporating measurement of access to clinical notes is separate and distinct from maintaining compliance under the information blocking rules and using CEHRT under the PIP. **The AAMC supports transparent communication among patients, families, and clinicians, but we believe this is best left to the purview of the ONC CEHRT and information blocking rules and should not be a new measure of meaningful use of EHR technology.**

---

[17] AJ Dellinger, Mic.com, "The environmental impact of data storage is more than you think – and it's only getting worse, (June 19, 2019), describing in general the environmental costs of expanded data storage, including citing to a 2015 report that found data centers to be responsible for about 2 percent of global greenhouse gas emissions, similar to that of the aviation industry.

[18] *See* CMS MLN Matters® SE1022 "Medical Record Retention and Media Formats for Medical Records" (August 2012).

MIPS Performance Category: Improvement Activities

AAMC Applauds CMS' efforts to Close the Health Equity Gap in Quality Programs

AAMC supports CMS' proposals to address health inequity and promote anti-racism in part by adding a new improvement activity "create and implement an anti-racism plan", modifying five existing improvement activities to focus on health equity, and updating the complex patient bonus formula to include a social complexity component. We agree that the inclusion of a proposed improvement activity titled "create and implement an anti-racism plan" is an important activity that will address systemic racism as a root cause of inequity. Our members have been focusing on efforts to address health inequity and promote anti-racism. We support CMS' efforts to improve demographic data collection to create a more accurate and robust data set that can be used to identify and address racial disparity within the program. To accomplish this CMS should focus on building trust within communities that have been historically marginalized in medicine. Building trust is pivotal to make patients feel safe and comfortable with disclosing demographic information. Although technology can be used to effectively collect and analyze data, in-person face-to-face conversations explaining how demographic information is being used to combat inequities and the privacy protocols that are implemented to protect patients' information could lead to a greater willingness for patients to self-report personal information.

MIPS Final Scoring Methodology

AAMC Supports Continuing the Complex Patient Bonus for 2023 Payment Year

CMS is required by statute (section 1848(q)(1)(G)) to consider risk factors in the MIPS scoring methodology. In CY 2018, CMS established a complex patient bonus of up to 5 points to be added to the final score for the 2020 MIPS payment year and continued this complex patient bonus in the 2021 and 2022 MIPS payment years. CMS proposes to continue to double the bonus to a maximum of 10 points for performance year 2021/payment year 2023. CMS determines eligibility for the complex patient bonus by measuring medical complexity through Hierarchical condition Category (HCC) risk scores, and social risk as measured through the proportion of patients with dual eligible status. CMS makes five proposals to better target clinicians who treat a higher caseload of more complex and high-risk patients, starting with performance year 2022.

The AAMC supports doubling the patient bonus to account for the difficulty of managing complex patients during the pandemic. It is important that clinicians are recognized for treating increasingly complex patients due to COVID. We are pleased that CMS is identifying approaches other than HCC scores and dual eligible patient status to better represent the clinical and social complexity of patients. **We request the CMS share more information on the proposed methodologies and provide testing and modeling of the proposals to enable providers to determine the impact of the approaches**

REQUESTS FOR INFORMATION

Advancing Digital Quality in Physician Quality Programs

CMS seeks feedback to inform future rulemaking to support the Agency's goal of transitioning to digital quality measurement in its quality reporting and performance programs by 2025. Comments specific to topics raised in the RFI follow.

Definition of Digital Quality Measures (dQMs)

The AAMC believes that improved EHR interoperability for the exchange and use of electronic health data has great promise to not only improve quality measurement and patient outcomes, but also to reduce burden on providers. **However, we encourage CMS to refine its definition of dQMs and set clear and specific parameters for what it hopes to achieve and what it expects of providers, especially physicians.**

The definition presented in this Request for Information is incredibly broad, and lists data sources including "administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges or registries, and other sources." Not all of these data sources are ready for "prime time" and inclusion in quality measurement. For example, wearable devices and patient-generated health data hold great promise for the future but have not been vetted as valid and reliable interoperable data sources or as usable for clinical quality improvement and assessment. CMS should more clearly define what it expects the future of dQMs to look like, and how those expectations differ from the current state of quality measurement. The agency should also outline plans for piloting new data sources for quality measurement, identifying reasonable near-term and longer-term priorities. As we have seen with the transition to eCQMs from chart-based measurement, the goal for a future state might not be as easily met as initially envisioned. This is especially true for physicians, who are only beginning to implement reporting of eCQMs/MIPS CQMs. Finally, CMS should engage NQF in this work, to ensure that digital measure specifications are appropriately evaluated for utility in improving quality of care. The AAMC and our members are excited to partner with CMS and to collaborate on more specific plans for digital quality measurement for the future.

Changes Under Consideration to Advance Digital Quality Measurement: Potential Actions in Four Areas to Transition to Digital Quality Measures by 2025

Leveraging and Advancing Standards for Digital Data and Obtaining All EHR Data Required for Quality Measures via Provider FHIR-based APIs

The AAMC supports a long-term goal of implementing a digital and interoperable quality enterprise. Such an enterprise has great promise and could have positive and far-reaching effects of patient outcomes and experience. We also support the potential use of Fast Healthcare Interoperability Resources (FHIR), as this standard is internationally supported and easier to implement and more fluid than many other available frameworks. However, we encourage CMS to hone its approach to transforming its quality measurement enterprise by more clearly defining the goals and expectations for patients and providers, in particular considering the specific needs

and capabilities of providers across settings. Again, this is especially true for physicians, whose CEHRT requirements do not yet include FHIR-based API capabilities.

Digital Quality Measures as Self-Contained Tools

CMS seeks feedback on a list of attributes and functionalities that dQMs could and should have. These range from simpler tasks, such as the ability to generate measure score reports, to more complex areas like being "compatible with any data source," and "having the flexibility to employ current and evolving advanced analytic approaches like natural language processing." Considering the breadth of expanded flexibilities and functionality listed, the AAMC urges CMS to engage stakeholders to determine which attributes can be sequenced and scaled, and to develop a prioritization framework for what realistically may be achievable with the Agency's goal of transitioning to dQMs by 2025.

Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

The AAMC strongly supports efforts to better align quality measures across federal, state, and private payer programs. To do so with fully interoperable data is likely to require leadership from HHS, including CMS and the ONC, and a potential rethinking of its health IT certification activities. This is because health IT certification was initially designed to evaluate a product's ability to meet minimum meaningful use requirements, and not necessarily on the quality, exchange and usability of data aligned with requirements for robust quality measurement. To realize the full extent of digital quality measurement requires EHRs that improve the capture, management, and communication of clinical information and better accommodate the needs of providers and their patients. Relatedly, quality measurement development does not always require inclusion of health IT developers to complete robust testing, resulting in insufficient test cases that do not ensure actual ease and accuracy of measure reporting in addition to ensuring that measurement is clinically useful. CMS will need to partner with ONC to prioritize concurrent certification requirements that validate dQMs and improve overall EHR user experience with measure development and implementation policy. Additional opportunity for alignment could relate to the collection and use of standardized social risk factor data collection and use in measurement. CMS should investigate potential incentives for encouraging alignment with providers and other payers. The AAMC would be very interested in working with CMS to better align quality measures and believe that initial stakeholder conversations would be productive in moving this concept forward.

Closing the Health Equity Gap in CMS Clinician Quality Programs

CMS requests feedback on making the reporting of health disparities based on social risk factors more comprehensive and actionable for hospitals, clinicians, and patients. The AAMC applauds CMS for its efforts to inform future proposals to address inequities in outcomes in its hospital quality programs. As noted elsewhere in this letter, the COVID-19 pandemic laid bare the realities of longstanding inequities in our communities that must be addressed. This work is critical to building a healthier future for all, and the AAMC strongly supports efforts to move the needle and ultimately eliminate inequity. To this end, the AAMC recently launched a 10-point

strategic plan[19] to drive systemic change, including the creation of a new AAMC Center for Health Justice and an action plan dedicated to improving access to health care for all. The AAMC is helping to build academic medicine's capacity to contribute to advancing community health systems and to strengthen our sector's commitment to partnerships and policies that promote health equity and health justice.

A critical aspect of this work is the need for clarity on the role of health care quality and measurement in promoting health equity and community health. The AAMC believes that there is valuable overlap in these aims, but also that there are important distinctions that must be made when using quality measurement as a tool for improving equity. Health equity rightfully includes health care but must also evaluate and address broader community resources and needs. More and more evidence show that health care and genetics play a limited role in one's health compared to behavioral, social, and environmental risk factors.[20] Improving quality of care is only a factor within the broader health equity aim and should have the goal of evaluating and driving improvement in care delivery for all patient populations. Health equity data is more meaningful when it considers the community-level, and not just a single hospital.

To this end, when measuring equity, we must measure and shine light on the broad mix of factors at play in order to find appropriate solutions, including the role of measurement. Quality measurement of health care must measure factors which are in the control of providers and not the social factors that are outside the realm of health care delivery.[21] The role of improved risk adjustment that addresses clinical, social and functional status risk factors is crucial for ensuring accurate and fair assessment and ensuring that the safety net is not penalized by losing the very resources it needs. When paired with stratification, we can and should ensure that adjustment does not mask inequities, but rather highlights them in a way that points to appropriate intervention and guides investments needed to drive improvement. We believe that CMS can and should drive toward broader health equity in part through its value-based payment programs. CMS could use reporting of stratified measures to incent progress and demonstrate improvement in local care gaps over time. However, joining health care quality and equity with validated health equity measurement[22] must be tested as a means of driving improvement prior to adoption in the agency's hospital quality programs. In addition, we strongly oppose the use of health care quality metrics to rank hospitals on health equity. Addressing inequities in health requires collaboration and not competition. Rankings and tiers create divisions, rather than rewarding coalitions and sharing successful interventions.

Specific to the MIPS Program, the AAMC supports the proposals to incorporate health equity and anti-racism into the Improvement Activities performance category. We agree that the inclusion of a proposed improvement activity titled "create and implement an anti-racism plan" is an important activity necessary to address systemic racism as a root cause of inequity. We support the explicit link to health equity in both new proposed activities, such as implementing protocols for food insecurity and nutrition risk and trauma-informed approaches to clinical practice, and proposed modifications to existing activities in the program's current

[19] *See* A Healthier Future for All: The AAMC Strategic Plan.
[20] *See* National Quality Forum, Social Risk Trial Final Draft Report at 5 (April 19, 2021).
[21] *See* National Quality Forum Issues Quality Roadmap for Reducing Healthcare Disparities
[22] *See* US Department of Health and Human Services Assistant Secretary for Planning and Evaluation, "Developing Health Equity Measures" (May 20, 2021).

inventory, such as engaging Medicaid patients and clinical leadership in clinical trials or community-based participatory research. The AAMC encourages taking a structural measurement approach to health equity improvement as a crucial first step to addressing inequity through physician quality programs, in tandem with improving the underlying data to inform interventions.

The AAMC supports the Agency in its efforts to address health equity in part through its quality programs. We agree that this is critical work, and that CMS should pursue a thoughtful and considered approach to improve data collection in order to better measure and analyze disparities in a manner that builds an evidence-based, valid, and reliable framework towards provider accountability for health equity. As CMS reviews health equity care must be taken to determine which efforts can be addressed by providers and which require broader community efforts. Efforts should be routinely evaluated to ensure they are accomplishing intended goals.

Future Potential Stratification of Hospital Quality Measures by Race and Ethnicity

CMS seeks feedback on the potential future application of an algorithm to indirectly estimate race and ethnicity to support stratification of quality measures for *hospital-level* disparity reporting[23], building off current confidential disparity reporting provided to hospitals for readmissions measures using dual-eligibility.[24] CMS is clear that "[s]elf-reported race and ethnicity data are the gold standard for classifying an individual,"[25] but that the Agency does not currently collect such self-reported data and that data accuracy of race and ethnicity data it receives from the Social Security Administration is not accurate or comprehensive enough for such stratification efforts. In response, CMS is exploring the use of indirect estimation methods as a short-term solution to identify better race and ethnicity data while developing sustainable and consistent programs to collect and leverage data on social needs or demographic proxies for risk, including self-reported race and ethnicity data.

As CMS describes in this RFI, indirect estimation relies on a statistical imputation method that infers a missing variable or improves an imperfect administrative variable using a related set of readily available information.[26] The other data sources that may be predictive of race and ethnicity include language preference, correlation of first and last names to specific national origin groups, and the racial and ethnic composition of surrounding neighborhoods matched with an individual's address. CMS notes that while its efforts to develop indirect estimation efforts can be statistically reliable for calculating population-level results for groups of individuals, a risk remains of unintentionally introducing measurement bias.[27] The potential harm and ethical

---

[23] 86 *Fed. Reg.* at 39348, clearly noting that the comment solicitation regarding the use of an imputation algorithm is specific to "measuring hospital equity," and that CMS is not seeking feedback on the use of such a method for use in the MIPS program.

[24] While current stratification based on dual-eligibility is not the issue of discussion with this request for feedback, the AAMC would be remiss if it did not point to a recent study finding that broad differences in dual-eligible populations could mislead between-hospital comparisons using dual eligibility as a social risk factor. *See* Philip Alberti and Matthew C. Baker, "Dual eligible patients are not the same: How social risk may impact quality measurement's ability to reduce inequities," Medicine Vo. 99, Issue 38 (September 28, 2020).

[25] 86 *Fed. Reg.* at 25558.

[26] *Id.*, citing a 2009 Institute of Medicine 2009 report, "Race, Ethnicity, and Language Data Standardization for Health Care Quality Improvement."

[27] *Id*. at 25559.

risks[28] must be more thoroughly evaluated and carefully considered to ensure that use of the indirect estimation method does not unintentionally mislead improvement efforts.

The AAMC shares the goal to expand data capture and data harmonization in order to ensure providers have actionable information to inform improvement. However, efforts should be made to promote valid collection of demographic data and data capturing an individual's social needs that will best inform intervention. **Race and ethnicity are not themselves risk factors[29, 30] and reliance on immutable characteristics alone is not informative for intervention.** Furthermore, measuring a gap is not the same as measuring equity. Disparities surveillance does not tap into patient populations' perception[31] of (or the reality of) equitable opportunity for optimal care. Stratified quality measurement's ability to reduce inequities is only as good as the stratification factors used – and dual eligibility and race and ethnicity as proxies for actual community risk factors and health-related social needs likely reduces the intended impact. **The AAMC urges CMS not to use indirectly estimated race and ethnicity data in confidential reporting due to our concerns with the accuracy and actionability of such data. Instead, CMS should invest in supporting data collection improvements, including how to standardize and use the data already collected by hospitals, understand which data may be most helpful to utilize and encourage the reporting and use of actionable social risk factor data, such as a number of social determinants of health (SDOH)-related ICD-10 z codes identified as actionable, [32][33] in quality and payment programs.**

Improving Demographic Data Collection

The AAMC supports efforts to improve data collection and agrees that it should begin with the use of improved demographic data that captures gender, race, and ethnicity as an initial step in a larger process to investigate and remove inequities in health. In doing so it must be unambiguous that those factors themselves do not represent an individual's inherent risk. Rather, that such demographic factors may be critical proxies for social risk factors until it is feasible to quantify

---

[28] Megan Randall, Alena Stern, and Yipeng Su "Five Ethical Risks to Consider before Filling Missing Race and Ethnicity Data," Urban Institute (March 16, 2021).

[29] Angela King and Kim Shepard, "Race is not a health risk factor. Racism is." National Public Radio (July 21, 2020), quoting Dr. Roberto Montenegro "When people look at health inequities, and they focus on differences by race, and they argue that race is a risk factor, it clouds the numerous factors that are really behind what people are intending to capture with race."

[30] Sheets et al, "Unsupported labeling of race as a risk factor for certain diseases in a widely used medical textbook." Journal of Academic Medicine (October 2011), which found that roughly two-thirds of assertions that different risk factors exist for Black patients found in a widely used pathology textbook could not be supported by the published literature.

[31] For example, refer to the Minnesota Department of Health's Guild, "HEDA: Conducting a Health Equity Data Analysis," Version 2 (February 2018), which recommends that health equity data analysis (HEDA) requires engaging populations that experience health inequities in the assessment process, including a principle for community engagement that stakeholders must learn about the community's perceptions of those initiating the engagement activities. Additionally, the AAMC's "Principles of Trustworthiness" project builds on foundational principle that trust is crucial for equitable community partnerships.

[32] *See* CMS Infographic "Using Z Codes: The Social Determinants of Health (SDOH) Data Journey to Better Outcomes," (Revised February 2021).

[33] *See also* AAMC Washington Highlights, AAMC Submits Comments to CMS on Additional ICD-10 Codes for Social Determinants of Health (May 2019)

and capture the actual risks of bias and unjust distribution of resources and opportunity that create the social and structural conditions that heighten inequities.

Many AAMC member teaching hospitals and health systems use EHR-based social risk screening tools in data collection to be better informed about the broader unmet health-related social need in their communities. While several organizations have developed standard screening tools and core questions, [34] we have heard from members that they often modify the templates to ensure culturally appropriate dialogue with the patients and communities they serve. Addressing inequity in communities requires integrating local perspectives in partnership with health care organizations that have demonstrated trustworthiness. Dialogue and screening about social risk factors must be culturally competent and help to establish trust between patients and the providers. As this field continues to develop, **we believe that CMS should pursue a policy supporting the collection of standardized multi-sector social risk information to support improved stratification and risk adjustment, balanced with allowing local flexibility to promote community-based innovation and solutions.**

CMS should also explore whether there are ideas and solutions from the data science and research community on how best to standardize a roll-up of granular data for community use into a format for broader evaluation and analysis. This is a massive undertaking led by the GRAVITY Project[35] to advance interoperable social determinants of health data, beginning with three social needs: food security, housing stability and quality, and transportation access. CMS could partner on an effort led by the Office of the National Coordinator for Health Information Technology (ONC) to evaluate interoperability standards that roll data collected through screening tools up into social determinants of health (SDOH)-related ICD-10 z-codes to capture social risk factors and provide actionable data to inform intervention. From that, we could then evaluate which SDOH-related z-codes are best suited to incorporation in a minimum set of social risk factor data elements to require through EHR certification.

While exploring the utility of additional individual demographic and social risk factor data elements, CMS should also evaluate the use and validity of community-based factors for improving data analysis necessary to inform quality and equity improvement activities. For example, research[36] shows that community-defined social risk factors cause substantial shifts in projected performance on the Readmission Reduction Program's readmission models above and beyond individual level proxies. A clear benefit of community-based analysis compared to individual-level analysis is the reduced risk of compromising individual privacy in addition to ensuring the use of holistic approaches to broad, structural inequities. To this end, the AAMC urges CMS to evaluate the opportunity to partner with public health departments, who may already have robust data that supports neighborhood stratification. **Overall, data collection and systems for social risk factors at both the individual and community level should be used in**

[34] Examples include CMMI's Accountable Health Communities (AHC) Health-Related Social Needs (HRSN) Screening Tool, The National Association of Community Health Center's Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE), and the Health Leads Screening Toolkit.
[35] *See* Social Interventions Research & Evaluations Network (SIREN)'s The Gravity Project.
[36] Baker et al., Health Affairs Vol. 40, No. 4, "Social Determinants Matter for Hospital Readmission Policy: Insights From New York City," (April 2021).

conjunction to best identify disparities in quality and equity and guide interventions for improvement.

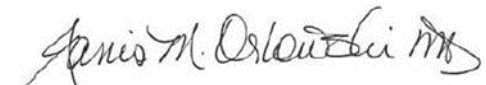
Finally, CMS should consider a variety of policy levers to improve hospital and clinician data collection. While mandating minimum data collection as a requirement may be one solution, we urge evaluation of incentives to improve data collection in part through a commitment to improving risk adjustment models for the inclusion of health-related social needs and/or for additional stratification in hospital quality programs. **The AAMC believes that patients, payers, and providers will all benefit from partnership to improve health equity. CMS should lead the effort to demonstrate the benefit of better data to inform solutions.**

CONCLUSION

The AAMC continues to appreciate the work done by CMS during the public health emergency. We are committed to work collaboratively with the Agency to improve care delivery and study the lessons to be learned from the COVID-19 experience to enhance care, improve access and to promote equity.

The AAMC appreciates your consideration of the above comments. Should you have any questions, please contact Gayle Lee at galee@aamc.org, Ki Stewart at kstewart@aamc.org or Phoebe Ramsey at pramsey@aamc.org.

Sincerely,



Janis M. Orlowski, MD, MACP
Chief Health Care Officer