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September 11, 2023

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

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

Re: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; Basic Health Program (CMS-1784-P)

Dear Administrator Brooks-LaSure:

The American Geriatrics Society (AGS) appreciates the opportunity to submit comments on the calendar year (CY) 2024 Medicare Physician Fee Schedule (PFS) proposed rule.¹ The AGS is a not-forprofit organization comprised of nearly 6,000 physician and non-physician practitioners (NPPs) who are devoted to improving the health, independence and quality of life of all older adults. The AGS provides leadership to healthcare professionals, policy makers, and the public by implementing and advocating for programs in patient care, research, professional and public education, and public policy. Our mission is to advance efforts that promote high quality of care, quality improvement, and increased payment accuracy for physicians and other professionals paid under the PFS. The AGS believes in a just society, one where we all are supported by and able to contribute to communities where ageism, ableism, classism, homophobia, racism, sexism, xenophobia, and other forms of bias and discrimination no longer impact healthcare access, quality, and outcomes for older adults and their caregivers.

The AGS appreciates that the Centers for Medicare & Medicaid Services (CMS) has taken steps in the proposed rule to ensure a smooth transition following the end of the COVID-19 public health emergency (PHE) and we share the agency's overall goals of improving patient outcomes, access, affordability, and quality of care. As CMS is aware, geriatrics professionals are disproportionately dependent upon Medicare and are already in very short supply. Consequently, CMS' payment policies are critical to ensuring access to geriatricians, given the ever increasing demands of caring for older people with multiple chronic conditions.

¹ 88 Fed. Reg. 52262 (Aug. 7, 2023).

Our recommendations are in bold text in our discussion of each section of the rule for which we are submitting comments. In particular, we want to highlight that AGS recommends that CMS:

- Finalize the proposed payment for caregiver training services;
- Finalize payment for Community Health Integration (CHI) Services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation (PIN) Services;
- Finalize the implementation of the complexity add-on code (G2211) effective January 1, 2024;
- Permanently allow the substantive portion of a split (or shared) visit to be determined based on medical decision making or time;
- Not finalize the proposal to modify the methodology used to assign beneficiaries to Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (MSSP);
- Finalize the proposal to extend the additional payment for COVID-19 vaccines furnished in the home and to expand its application to other Part B preventive vaccines; and
- Not finalize the proposals on enrollment revocation.

I. Proposed Payment Policies under the PFS

A. <u>Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection and</u> <u>Methodology (II.A.5)</u>

AGS appreciates CMS' continued engagement with the physician community as it works to update the practice expense (PE) methodology. We agree with CMS that the data used in the PE calculation should be updated and we urge CMS to ensure that the updated data accurately captures the costs involved in operating a practice. We were among the commenters that expressed concerns about the redistributive effects of implementing updated cost shares from the revised and rebased Medicare Economic Index (MEI) into the PE methodology and we noted limitations in the Census Bureau data used in the MEI update. AGS appreciates that CMS intends to continue to evaluate whether recent trends in the Census Bureau data are reflective of sustained shifts in cost structures or were temporary as a result of the COVID-19 PHE. We also support CMS' decision to propose any changes to the MEI or to use of the MEI shares in the PE methodology in future rulemaking.

We would like to reiterate our recommendations submitted in last year's rulemaking regarding the PE data and methodology:

- **CMS should conduct PE surveys not more frequently than every 5 years.** We suggest this frequency given that the surveys are time-consuming and expensive. Any shorter time frame would be administratively burdensome and may make it likely that the survey results are inaccurate or not appropriately representative of relative costs across specialties.
- CMS should refine the PE allocation methodology to reflect PE costs more appropriately for cognitive and procedural services. For example, we recommend that CMS no longer allocate indirect PE based on supplies and equipment or on physician work in the facility setting.

CMS solicits comments about the need for potential refinements to the data collected under the Physician Practice Information Survey (PPIS) conducted by the American Medical Association (AMA). Because the data from the PPIS is not yet available, we do not have recommendations for specific aggregations or other adjustments CMS should make at this time. However, we appreciate that CMS is proactively considering potential refinements to improve the PE calculation and may make additional recommendations in the future.

B. <u>Medicare Telehealth Services Proposals</u>

1. Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations (II.D.1.b)

CMS proposes to remove for 2024 frequency limitations that existed prior to the PHE for certain inpatient visit, subsequent nursing facility visit, and critical care consultation service codes.² These limitations were waived during the PHE and CMS has exercised its enforcement discretion and will not consider the limitations through December 31, 2023.

AGS applauds CMS for making this proposal. The frequency limits are arbitrary and may impede access to clinically appropriate care. We believe that the determination as to whether a patient can be seen via telehealth or in-person should be based on the individual patient's needs. The clinical appropriateness of furnishing inpatient, nursing facility, or critical care through telehealth should be determined by the physician in the same manner as other care that can be furnished through telehealth. We believe that, in general, physicians have been appropriately applying their judgement in this regard during the PHE and that they will continue to do so in the future.

A recent study confirms this understanding, finding that the number of telehealth visits to patients in skilled nursing facilities (SNFs) increased rapidly in the early days of the PHE before stabilizing at more modest levels. The cohort study of more than 4.4 million residents at roughly 15,500 SNFs found that telemedicine visits increased from 0.15% before the PHE to 15 percent of routine SNF visits and 37 percent of other outpatient visits for SNF residents in early 2020 and then stabilizing at 2 percent of routine SNF and 10 percent of outpatient visits by mid-2021.³ The other outpatient visits were focused on specialty care. The authors also found that higher telemedicine use was associated with improved access to psychiatry visits in SNFs. The Biden Administration has been working to improve access to mental health services and we believe that permanent removal of the frequency limits on telehealth visits will further support that effort. Telemedicine also allows urgent care to be provided in the nursing facility, including in many cases when the beneficiary would otherwise be referred to the emergency department.

We also note that the regulations continue to require that a physician or a NPP see nursing facility patients <u>in person</u> every 30 days⁴ for 90 days and then every 60 days thereafter. We believe that

² Subsequent inpatient CPT codes: 99231, 99232, 99232; Subsequent nursing facility visit CPT codes: 99037, 99038, 99039, 990310; and critical care consultation service HCPCS codes: G0509 and G0509

³ Ulyte A, Mehrotra A, Wilcock AD, SteelFisher GK, Grabowski DC, Barnett ML. Telemedicine Visits in US Skilled Nursing Facilities. JAMA Netw Open. 2023;6(8):e2329895. doi:10.1001/jamanetworkopen.2023.29895

⁴ 42 C.F.R 483.30(c).

this requirement provides sufficient guardrails for how care is furnished to these patients. We urge CMS to finalize the removal of the frequency limitations for 2024 and to make this removal permanent.

2. Audio-Only Services and Telephone E/M Services (II.D.2.c)

During the PHE, CMS has considered the telephone evaluation and management (E/M) services (99441 - 99443), which describe services furnished by a physician or other qualified health care professional, to be a replacement for in-person E/M services. CMS added those codes to the Medicare Telehealth Services List and paid them at the same rate as an in-person E/M service for the duration of the PHE. CMS proposes to continue to provide coverage and payment for telephone E/M services through December 31, 2024, as required by statute. CMS also proposes to continue to assign active payment status to the codes for the non-physician telephone services (98966 - 98968).

AGS believes that audio-only telephone services are important tools for caring for certain patients, particularly who are older and frailer and patients who are low income, many of whom may not have access to more advanced audio-visual technology such as smart phones or computers. We note that audio-only services are not simple phone calls directing the patient to schedule an in-person visit but are instead an episode of patient care during which the physician or other qualified health care professional furnishes an E/M or assessment and management service. We appreciate CMS' proposal to continue to pay for physician and non-physician telephone services through December 31, 2024, and urge CMS to finalize the proposed coverage and payment. AGS continues to advocate for CMS to have statutory authority to make payment for audio-only services permanent.

3. Direct Supervision via Use of Two-way Audio/Video Communications (II.D.2.a)

CMS proposes to extend through December 31, 2024, the PHE-adopted definition of "direct supervision" to allow the professional supervising the provision of a service or diagnostic test to be immediately available through a virtual presence using two-way, real-time audio/video technology, instead of requiring their physical presence. AGS shares the agency's concern about an abrupt transition to again requiring the physical presence of the supervising practitioner under direct supervision and the potential barrier to access that could result from such a transition. AGS recommends that CMS finalize the proposed extension and encourages adoption of a virtual presence policy for services that are nearly always performed entirely by auxiliary personnel (such as the Level I office visit).

C. Payment for Caregiver Training Services (II.E.4.(26))

In the proposed rule, CMS states that it believes that caregiver training services may be reasonable and necessary when they are integral to a patient's overall treatment and furnished after the treatment plan (or therapy plan of care) is established. **AGS agrees and applauds CMS' proposal to establish payment for 96202 and 96203 (caregiver behavior mgt/modification training services).** We have long maintained this viewpoint and reiterate the importance of the role of the caregiver in the patient's overall care and management as well as the importance of Medicare coverage and payment for caregiver training. We agree with the proposed definition of a caregiver as "an individual who is assisting or acting as a proxy for a patient with an illness or condition of short or long-term duration (not necessarily chronic or disabling); involved on an episodic, daily, or occasional basis in managing a patient's complex health care and assistive technology activities at home; and helping to navigate the patient's transitions between care settings."

We also support the proposal to establish payment for the new codes for caregiver training under a therapy plan established by a physical therapist, occupational therapist, or a speech language pathologist (placeholder codes 9X015, 9X016, 9X017).

D. <u>Services Addressing Health-Related Social Needs (Community Health Integration Services,</u> <u>Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)</u>

CMS proposes to create new G codes to allow physicians to report the provision of services that address health-related social needs. Specifically, CMS proposes to create codes to describe care management furnished by trained auxiliary personnel to either address a social determinant of health need (SDOH) (referred to as Community Health Integration (CHI)) or to help patients navigate the treatment plan for a serious, high-risk disease (referred to as Principal Illness Navigation (PIN)). In addition, CMS proposes to create a code to describe administration of a SDOH risk assessment.

AGS strongly supports the creation of these codes. AGS appreciates CMS' ongoing efforts to better recognize the time and resources required to perform care management and the importance of these services to patient-centered care. We are dedicated to advancing a just society where bias and discrimination no longer impact healthcare access, quality, and outcomes for older adults and their caregivers. Providing payment for services that help identify and address SDOH that can limit a patient's ability to receive needed care or achieve the full benefit of health care interventions is an important step to reduce the impact of SDOH on beneficiaries. **We urge CMS to finalize these new codes as proposed.**

We also urge CMS to monitor use of these codes and determine whether the codes, particularly the codes for CHI, are appropriately valued. In our experience, effectively addressing SDOH and helping patients identify and navigate community resources requires considerable staff time and we are concerned that the proposed valuation may be inadequate. We do not have an alternative recommendation for valuing these codes for 2024 but ask CMS to track utilization of these codes and assess whether the Medicare payment rate is sufficient to support provision of these important services.

AGS also recommends that CMS adopt policies that will avoid creating administrative barriers that could limit access to these services. For example, CMS asked whether there would be duplication between these services and services covered by Medicaid. We do not believe most state Medicaid programs cover these types of services and therefore posit that there would be no duplication of coverage or payment with Medicare. However, we encourage CMS to implement policies that facilitate payment for services furnished to dual eligible beneficiaries to account for any potential changes in state Medicaid policies around payment for these services. We agree with CMS that patient consent for CHI is not needed since there would presumably be face-to-face interaction and that requiring patient consent is an administrative burden and may create a potential barrier to receiving these services. We also recommend that CMS allow the annual wellness visit (AWV) to serve as the initiating visit for receiving CHI, although we agree with CMS that in most instances practitioners will likely report a separate E/M visit if medical problems are identified during the AWV. Finally, we ask that CMS allow practitioners flexibility to address individual patient needs and should not narrowly specify exactly who and how these services can be furnished. The type and amount of training may vary based on patient needs and how the practice is organized. CMS should leave the determination as to the length, source and content of training required to furnish these services up to the physician, absent state regulation. CMS should

reconsider that screening and assessments must be performed on the same date as the initiating visit. Assessments may be performed in advance of planned visits, or an in-person visit may not allow adequate time to fully assess the patient, even when an issue is apparent. The practitioner may ask support staff to contact the patient the next day to complete the assessment. While the assessment is expected to be 5-15 minutes, it may well be that circumstances of the moment would require a respectful assessment not be jammed into a busy schedule. The requirement for the same practitioner to do the initiating visit and bill for the CHI service may be too restrictive. For example, a covering practitioner in the same practice may provide the initiating visit while a different practitioner, the primary care continuity practitioner in the same practice group may provide the CHI service. **CMS should finalize the proposal, should not require specific consent, nor specify the training requirements of the CHI, but should allow the SDOH risk assessment to be done on a day other than the initiating visit and the CHI service.**

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

CMS proposes to implement the complexity add-on HCPCS code G2211 effective January 1, 2024 with some refinements. CMS proposes that G2211 cannot be billed with visits reported with modifier - 25 indicating that the visit is furnished on the same day as a minor procedure. CMS has also refined its understanding of how often G2211 will be reported. Under this refined understanding and with the restriction on reporting the add-on code on the same day as a minor procedure, CMS now estimates that 38 percent of all O/O E/M visits for CY24 will be billed with G2211 (down from its previous assumption of 90 percent). Implementation of G2211 under these circumstances requires a 2.00 budget neutrality adjustment, compared to a 3.20 adjustment in CY2021 rulemaking. We are uncertain whether this analysis excludes O/O E/M when performed in conjunction with Medicare Preventive Services (e.g., the Annual Wellness Visit). We believe in this circumstance the -25 modifier should not exclude use of G2211.

AGS agrees with CMS that the value of the O/O E/M office visit services does not reflect the time, intensity and PE resources involved with providing longitudinal care of complex patients. We appreciate that CMS has established the complexity add-on code to better recognize the cost of furnishing such care and AGS urges CMS to finalize implementation of G2211 effective January 1, 2024 for office-based primary care and encourage CMS to extend its use to home-based primary care services that meet the requirements of the code. However, we continue to believe that CMS should take additional steps to ensure that the payment associated with the add-on code is targeted to services that involve additional complexity and longitudinal care. We believe that such refinement will both ensure that the additional money is spent on services that actually reflect higher complexity and will reduce the impact that utilization of the add-on code has on the conversion factor.

The obligation of longitudinal care creates a greater level of work at the encounter and during the inter-encounter interval. These types of visits may be part of caring for a complex patient with multimorbidity or a patient with a single serious condition, such as diabetes, that requires complicated visits involving multiple care team members. These types of visits could occur in the office setting or in the patient's home. We do not believe that G2211 should be used for management of an acute condition (e.g., pneumonia) unless the patient is also being followed longitudinally for a chronic condition. We ask CMS to consider allowing G2211 for the Home/Residence services codes.

AGS appreciates that CMS has clarified that it does not expect the add-on code to be appended to all E/M visits and we urge CMS to finalize the proposal that G2211 cannot be billed with E/M services reported with modifier -25, unless the other services is a preventative service. We believe that CMS should further refine implementation of the add-on code to better identify and provide additional payment for services that include longitudinal care. We have recommended in previous comments that CMS consider use of the patient relationship codes to identify which practitioners should be reporting G2211. We again urge CMS to solicit comments on this approach in the final rule and gain stakeholder input on this approach. We also ask that CMS further evaluate the expected usage. We do not believe it will be applied as broadly as CMS suggests, especially if the proper usage is better defined.

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

In the proposed rule, CMS notes recommendations from some stakeholders that CMS consider a different approach to valuing services under the PFS than the specialty-specific valuation process used by the Relative Value Update Committee (RUC). These stakeholders are particularly concerned about distortions in payment for certain types of services, including E/M visits.

AGS agrees that it is critically important that E/M visits be appropriately paid but we are concerned that efforts to value those services more frequently or under a different administrative process would likely create additional burden on the physicians who furnish those services. **We recommend that CMS not pursue this approach.** We believe that the intention behind this recommendation is to improve payment for cognitive care services and better support specialties that provide primary care. We urge CMS to consider other means for achieving those goals which may be easier to implement and would provide more direct support, such as re-instating the primary care incentive program that was created under the ACA and that expired at the end of 2015.

G. Split (or Shared) Visits

In rulemaking for 2022, CMS finalized a change in how practitioners who split or share a visit determine who provides the substantive portion of the service and should therefore bill for the services. The finalized policy requires that the substantive portion of a split (or shared) visit be determined based solely on time and will not allow the substantive portion to be determined based on medical decision-making (MDM). CMS again proposes to delay implementation of this change.

AGS strongly agrees with the proposed delay and again recommends that CMS permanently reverse the policy change. As we have noted in our comments on the 2022 and 2023 rules, we believe that MDM is the most important part of any E/M visit and should be an option for determining the substantive portion of a service. Billing shared visits based on time alone will disincentivize team-based care and result in an inefficient allocation of physician and NPP resources. In almost all cases, the time-based policy would result in the reporting clinician being the NPP which is inappropriate when the physician performs the MDM. If CMS does not reverse the policy change, then we support delaying implementation until January 1, 2025, at the earliest. We also recommend that CMS adopt the policies described in the 2024 CPT E/M Guidelines to minimize confusion and align Medicare payment rules with the coding guidance.

We also continue to recommend that CMS extend its shared visit policy to certain home visits. When the nurse practitioner sees the patient in the patient's home and the physician performs the MDM, CMS should allow this service to be reported as a shared visit. "Incident to" policies do not apply to home visits and the concept of a shared home visit is identical to that of a shared facility visit. CMS also currently does not allow split (or shared) nursing facility services at the nursing facility level (as compared to skilled nursing facility level). While we understand that regulations require certain visits be performed by the physician, not all nursing facility level visits are in this category. A long-term care nursing facility resident with acute needs may well be seen by an advanced practice nurse who in conjunction with the physician determines the care i.e., performs the MDM.

We also continue to recommend that CMS will support team-based care by clarifying that O/O E/M services for new patients can be furnished on an incident-to basis. Such clarification would recognize that new patients may be managed jointly by physicians and non-physician practitioners. It would be reasonable to require that the new patient care plan being implemented "incident to" be jointly created with the physician, which could occur on the date of the encounter (i.e., it would be incident to the plan that was present, revised or created on the date of the visit).

H. <u>Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to</u> Specific Covered Services (Section II.K)

AGS appreciates CMS' ongoing efforts to carefully consider what medically necessary dental care may be covered under Part A or B of Medicare. CMS proposes to extend coverage of dental services for beneficiaries with leukemia and other hematological cancers, head and neck cancers, cancers requiring immunosuppressive chemotherapies, as well as for individuals when antiresorptive and/or antiangiogenic drug therapy is administered in conjunction with chemotherapy regimens. We agree that certain dental care may be considered inextricably linked to the clinical success of these services, and therefore, is substantially related and integral to those services. We recommend that CMS finalize the proposed expansion.

However, we remain concerned about the added strain that expanding coverage of dental services under Part B will put on the already struggling PFS. We again encourage the Biden Administration to work with Congress to ensure that funding sufficient to cover medically necessary dental care is approved in future Medicare budgets.

II. Medicare Shared Savings Program (MSSP) Proposals

A. <u>Proposed Changes to MSSP Eligibility Requirements</u>

CMS proposes to remove the exception to the shared governance requirement under existing MSSP rules at 42 C.F.R. § 425.106(c)(3), which requires that at least 75 percent control of the governing body of an Accountable Care Organization (ACO) must be held by ACO participants. CMS states that its proposal is driven by the fact that it has never granted an ACO an exception to this requirement and that this threshold is critical to ensuring that governing bodies are "participant-led and best positioned to

meet program goals, while allowing for partnership with non-Medicare enrolled entities to provide needed capital and infrastructure for ACO formation and administration."⁵

AGS urges CMS to also consider other improvements to the governance requirement to support the ability of ACOs to meet the promise of delivering high quality, coordinated care to Medicare beneficiaries. In particular, we urge CMS to include a requirement that the ACO governing body include individuals with expertise in caring for older Americans. Geriatrics professionals are the most knowledgeable about the needs of the Medicare population and how to best furnish high-quality, person-centered care to beneficiaries. A requirement that ACOs must include individuals with geriatric expertise on the governing body will improve the likelihood that the ACOs will meet CMS' goals for the MSSP.

B. <u>CMS Should Not Finalize its Proposal to Modify Step-Wise Assignment Methodology Used to</u> <u>Assign Beneficiaries to ACOs</u>

For performance years beginning on January 1, 2025, CMS proposes to add a step to the beneficiary assignment methodology under 42 C.F.R. § 425.402. This proposed step three would utilize an expanded 24-month window for assignment (the currently applicable 12-month assignment window and the preceding 12 months) to identify additional beneficiaries for assignment. CMS states its proposal would increase the number of beneficiaries included in assignable populations and those from underserved populations.

AGS does not support this proposal. We understand CMS' desire to expand the number of patients who receive the benefits of care coordination that are assumed to be part of the MSSP. However, we do not believe that expanding the assignment window will produce better coordinated care. Instead, it will increase the likelihood that an ACO will be held accountable for beneficiary care that they cannot manage because the patient no longer has a relationship with the ACO participants. For example, expanding the assignment window may result in the assignment of beneficiaries to an ACO in an area where they no longer live or based on an acute care episode that led them to seek care from a particular provider who no longer provides primary care. This is particularly problematic when considering beneficiaries that reside in multiple states (e.g., snowbirds). We urge CMS not to finalize the proposed expansion and to retain a 12-month assignment window.

C. Other Beneficiary Assignment Issues

AGS continues to be concerned about the impact of CMS' current policy regarding the taxonomy for non-physician practitioners has on assignment under the MSSP and other programs. Under this policy, advanced practice nurses and physician assistants working with physicians are often classified in a different specialty than the physician with whom they practice and generally are assumed to primary care practitioners regardless of the nature of their practice. AGS notes that this taxonomy may distort the assignment of beneficiaries under the MSSP because NPPs who work with specialty physicians appear to be primary care practitioners. As a result, an ACO may be held accountable for care furnished to a beneficiary whose care is not being coordinated by the ACO.

⁵ 88 Fed. Reg. 52488.

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We believe that policies such as erroneous assignment create significant disincentives for new entities to enter the MSSP and makes it much harder for participating ACOs to succeed. To avoid this situation, we recommend that CMS revise the taxonomy codes to provide more granularity and differentiate between NPPs who are working in primary care and those working in specialty practices.

D. <u>Medicare Clinical Quality Measure (CQM) Collection Tool</u>

The AGS is pleased that CMS has recognized the many concerns of AGS and others in the medical community around requiring ACOs to collect and report electronic clinical quality measures (eCQMs) that include all-payer/all-patient data. Data collection and processing is already burdensome -- taking time and resources that should be directed toward patient care, and the move to all-payer/all-patient eCQMs will only increase the administrative burden absent work by the U.S. Department of Health and Human Services (HHS), including the Office of the National Coordinator for Health IT (ONC) and CMS to ensure the significant data collection and processing challenges acknowledged by CMS are addressed.

We support CMS' proposal to establish the Medicare Clinical Quality Measures (CQMs) for ACOs participating in the MSSP as a new collection type within the APP measure set as an alternative to moving only to eCQMs and see this as a positive and more appropriate approach. However, we disagree with CMS' claim that this transitional policy will "help some ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient MIPS CQMs and eCQMs," because it does not address the root causes of our concerns. Currently, Health IT standards and capabilities are inadequate to efficiently collect and appropriately process all-payer/all-patient data, and as a result it is time consuming and cost-prohibitive to generate measures and data. Delays alone will not solve this problem. Rather, ONC and CMS should work in coordination to ensure that ACOs will have the technological resources to efficiently collect and process all-payor/all-patient data, including across EHR systems, prior to implementing any all-payer/all-patient eCQMs. For example, we anticipate that technological improvements, including through the use of artificial intelligence, may make this type of data gathering easier in the future -- or may make obsolete this more manual method of quality data collection altogether.

More generally, we have fundamental concerns regarding the utility of all-payor/all-patient measures as a tool to compare ACOs. Different ACOs may have vastly different patient populations. For example, some ACOs may have a large percentage of commercially insured patients while others may serve primarily Medicaid patients. Quality measures that treat these patient populations the same unfairly disadvantage the ACOs treating underserved populations and will not appropriately reflect the quality of the work they are doing. While we appreciate that CMS is proposing that, for performance years 2024 and subsequent performance years, it would apply a health equity adjustment to the quality performance score for an ACO reporting the three Medicare CQMs, or a combination of eCQMs/MIPS CQMs/Medicare CQMs, in the APP measure set, meeting the data completeness requirement for each measure, and administering the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey, we do not believe that a health equity adjustment is sufficient to address the underlying discrepancies in all-payer/all-patient measurement across vastly different patient populations.

We urge CMS to further delay the move to eCQMs until these concerns can be addressed.

III. Proposed Changes to Medicare and Medicaid Provider and Supplier Enrollment

AGS does not support finalization of the proposed changes to the enrollment processes and suggests the CMS solicit extensive feedback on the proposed changes through an RFI and "Town Halls".

CMS proposes to dramatically expand the scope of its revocation authority. We have overarching concerns about the scope of the proposals and the wide latitude CMS proposes to give itself in determining whether, for example, a misdemeanor conviction, or a small number of incorrect claims submissions, comprises an offense serious enough to warrant revocation, and, in the case of a misdemeanor conviction, retroactive revocation, of the enrollment of a provider or supplier. It is our viewpoint that revocation should only be applied in response to infractions that are severe with clear potential harm to Medicare beneficiaries or financial malfeasance. Geriatrics health professionals primarily care for Medicare beneficiaries and have longstanding multiyear relationships with their patients. As HRSA has reported, there is a maldistribution of primary care clinicians and of geriatricians.⁶ ⁷ Revoking enrollment for billing and coding infractions will not only lead to disruption in those relationships but may also leave many beneficiaries unable to find a primary care clinician. The proposed latitude could put, our most vulnerable Americans, often with multiple chronic illnesses, at risk of not having a primary care physician. Before implementing this proposed change, CMS must spell out the criteria that it will use and the level of malfeasance that would cause CMS to exercise its revocation authority. We encourage CMS to consider whether there are other mechanisms that it could deploy to penalize clinicians and suppliers who have ongoing errors in their billing and coding inclusive of a remediation period. In addition to ensuring that the criteria by which CMS will revoke authority is well defined for physicians and suppliers, CMS must have in place a mechanism that allows for rapid due process in disputing any conclusions CMS has come to so as to minimize the disruption in care for Medicare beneficiaries.

We recommend that CMS not finalize its enrollment processes proposals and instead solicit comments from interested stakeholders to better inform itself of the potential consequences of its proposals, including consequences to patient care. CMS should solicit comments in multiple ways such as through a "Request for Information" published in the Federal Register, Town Hall listening sessions, and meetings with groups of stakeholders such as physician groups, state licensing boards, and others. CMS should use the feedback it gets to inform any future rulemaking. AGS believes that CMS must develop transparent guidelines that ensure that these authorities will be applied consistently and that similarly situated providers and suppliers equally. We outline several specific concerns below.

A. <u>Misdemeanor Convictions</u>

Under 42 CFR 424.530, CMS proposes to add the ability to revoke the enrollment of, or deny enrollment to, providers or suppliers if, "the provider, supplier, or any owner, managing employee,

⁶ U.S. Department of Health and Human Services, Health Resources and Services Administration, National Center for Health Workforce Analysis. National and Regional Projections of Supply and Demand for Geriatricians: 2013-2025. Rockville, Maryland; 2017.

⁷ U.S. Department of Health and Human Services, Health Resources and Services Administration, National Center for Health Workforce Analysis. 2016. National and Regional Projections of Supply and Demand for Primary Care Practitioners: 2013-2025. Rockville, Maryland.

officer, or director of the provider or supplier" has committed a misdemeanor in the previous 10 years "that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries."

We are concerned that CMS is taking on a role that it does not have the expertise or resources to perform effectively. State boards of medicine, who are experts on the practice of medicine and issuance of medical licenses, and who have authority over physicians in their jurisdictions, are charged with adjudicating the matter of continued qualifications after a misdemeanor conviction.

B. <u>10 Year Lookback Period for Commission of a Misdemeanor or Being Subject to an FCA</u> Judgment

The ten-year lookback period CMS proposes appears arbitrary and the agency offers no rationale for the period in the proposed rule. While this may be appropriate for felony convictions, given the less severe nature and the variability of misdemeanors, this time frame seems excessive. The lookback periods should correspond to the particular action at issue. CMS also does not explain whether, if the proposals are adopted, this will apply to misdemeanors (or FCA judgments) committed before the effective date of these new authorities. Applying this 10 year lookback period to misdemeanors committed years before this requirement was established in rulemaking is inappropriate. We request that CMS clarify that the 10 year lookback period only applies to misdemeanors committed, and FCA judgments handed down, on or after January 1, 2024.

C. <u>Timeframe for reversing revocation</u>

With regard to revocations due to adverse activities (sanction, exclusion, felony) by a party,⁸ CMS proposes to revise § 424.535(e) to reduce the 30-day period time frame to 15-days for a provider or supplier to terminate, and submit proof it terminated, its business relationship with such party, in order to reverse the revocation. CMS states that a provider or supplier should not be afforded so much time given that more Medicare dollars could be paid during that time frame while the party remains affiliated. We disagree.

We believe 15-days is not sufficient and recommend that CMS retain the existing 30-day time frame. We do not believe, as CMS contends, that this would convey the false impression that maintaining such affiliates is acceptable. In many cases there are complicated contractual and organizational issues involved with terminating ownership or relationships with supervisory employees or physician partners that cannot be resolved in less than a month, irrespective of the desire of the parties. The additional time is also needed to hire and replace key personnel that have departed as a result of the termination.

D. <u>Practice pattern definition</u>

We appreciate CMS' effort to further clarify under the regulation what constitutes a "pattern or practice" for purposes of enrollment revocations. AGS is concerned, however, about the threshold number CMS proposes under the definition and recommends that CMS not finalize its proposal in order

⁸ The provider's or supplier's owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program.

to obtain more information from stakeholders on these issues. We are particularly concerned as to how CMS is going to determine whether a physician is abusive or a threat to their patients.

Specifically, CMS proposes at § 424.502, the following definition of "pattern or practice":

- For purposes of § 424.535(a)(8)(ii),⁹ at least three submitted non-compliant claims.
- For purposes of § 424.535(a)(14),¹⁰ at least three prescriptions of Part B or Part D drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.
- For purposes of § 424.535(a)(21),¹¹ at least three orders, certifications, referrals, or prescriptions of Medicare Part A or B services, items, or drugs that are abusive, represent a threat to the health and safety of Medicare beneficiaries, or otherwise fail to meet Medicare requirements.

AGS believes that CMS should identify an alternate remedy for such a pattern of non-compliant claims. We also recommend that CMS define both "non-compliant" and "abusive" and what criteria it will use to determine if services were a threat to the health and safety of a Medicare beneficiary. In our viewpoint, CMS is overstepping its authorities and potentially interfering with the provision of appropriate care that is responsive to patient-centered shared decision-making.

We appreciate that CMS states in the proposed rule that it expects "in only the rarest of circumstances" to revoke based on three claims, referrals, etc., and that these would typically involve instances of "egregious non-compliance."¹² Without a transparent framework for how "egregious non-compliance" would be determined, CMS runs the risk that the rule would not be applied equitably to similarly positioned clinicians and suppliers. We urge CMS to seek feedback from the medical community on a reasonable threshold to better reflect what would typically prompt the basis for a revocation and further explain the conduct or patterns of non-compliance that CMS would consider egregious.

IV. Medicare Part B Payment for Preventive Vaccine Administration Services

During the PHE, Medicare provided additional payment when a COVID–19 vaccine was administered in a beneficiary's home. In this rule, CMS notes that its data for in-home COVID-19 vaccinations among Medicare fee-for-service beneficiaries from June 2021 to June 2022 show the payment code was used at a disproportionately high rate for underserved populations, including persons who are dual eligible for both Medicare and Medicaid and those of advanced age (85 years or older). CMS proposes to maintain the in-home additional payment for COVID-19 vaccine administration and to extend the additional payment to the administration of the other three preventive vaccines included in the Part B preventive vaccine benefit – the pneumococcal, influenza, and hepatitis B vaccines.

⁹ Relating to abuses of billing practices and claims that do not meet Medicare requirements.

¹⁰ Relating to improper prescribing practices.

¹¹ Relating to abuses in ordering, certifying, referring or prescribing Part A and B items and services. ¹² 88 Fed. Reg. 52522.

AGS agrees with CMS that the in-home additional payment improved healthcare access to vaccines for often-underserved Medicare populations. Some of our most vulnerable patients are best able to receive care in the home setting and we applaud CMS for providing additional support to better enable practitioners to furnish such care. We believe this proposal will improve utilization of preventive vaccines which can help beneficiaries avoid serious illness. We urge CMS to finalize the proposal to extend the additional payment for COVID-19 vaccines furnished in the home and to expand its application to other Part B preventive vaccines.

V. Merit-based Incentive Payment System (MIPS)

A. General Comments

Geriatrics health professionals provide care for older adults, usually over the age of 65, with complicated medical issues and social challenges. They focus on the 5Ms of geriatrics: **M**ultimorbidity, What **M**atters, **M**edication, **M**entation, and **M**obility.¹³ Multimorbidity describes the older person who has more complex needs often due to multiple chronic conditions, frailty, and/or complex psychosocial needs. What Matters, Medication, Mentation, and Mobility describe the four main areas where geriatrics health professionals focus their clinical attention and form the basis for the age-friendly health systems framework that is focused on ensuring that all older people have access to this type of coordinated care, while also making sure personal needs, values, and preferences are at the heart of that care.¹⁴ It is crucial to identify what matters most to patients, particularly those with multiple chronic conditions, so that health professionals can tailor patients' care to align with their care **preferences**.

While we appreciate the intent of MIPS (and more recently MIPS Value Pathways (MVPs)) to improve quality of care for Medicare beneficiaries, unfortunately, it has become clear that a system of aggregated disease-specific or prevention quality measures cannot capture what matters most to older patients. In particular, the vast majority of these measures assume a unilateral approach to what it means to provide quality care that does not incentivize -- and in some cases might disincentivize -- the providing of patient-focused care that reflects patients' personal preferences and priorities.

Rather than requiring providers to expend significant administrative time and resources on measure reporting, AGS recommends that CMS focus on encouraging strategies that will reinforce care centered around the 5Ms, such as requiring ACOs to include geriatric expertise on their governing bodies or incentivizing health systems to become Age-Friendly Health Systems.¹⁵ Studies have shown that models providing coordinated and interdisciplinary geriatrics team-based care can make a critical

¹³ Adapted by the American Geriatrics Society (AGS) with permission from "The public launch of the Geriatric 5Ms" [on-line] by F. Molnar and available from the Canadian Geriatrics Society (CGS) at https://thecanadiangeriatricssociety.wildapricot.org/Geriatric5Ms/.

¹⁴ Institute for Healthcare Improvement. Age-Friendly Health Systems: Guide to Using the 4Ms in the Care of Older Adults. Published July 2020. Accessed August 21, 2023. <u>https://www.ihi.org/Engage/Initiatives/Age-Friendly-Health-Systems/Documents/IHIAgeFriendlyHealthSystems_GuidetoUsing4MsCare.pdf</u>.

¹⁵ Age-Friendly Health Systems is an initiative of <u>The John A. Hartford Foundation</u> and the Institute for Healthcare Improvement (IHI), in partnership with the <u>American Hospital Association (AHA)</u> and the <u>Catholic Health</u> <u>Association of the United States (CHA)</u>. *See* https://www.ihi.org/Engage/Initiatives/Age-Friendly-Health-Systems/Pages/default.aspx.

difference, especially for persons with multiple chronic conditions, by preventing complications and enhancing the quality and efficiency of care provided across the healthcare continuum.

To the extent CMS maintains MIPS and MVPs, we strongly recommend that CMS extend health equity adjustment to the quality score in MIPS, and not limit it to MSSP, to encourage a broader set of providers to care for underserved communities.

B. Geriatrics Specialty Measure Set

Previously Finalized Kidney Health Evaluation (Measure #488) and Depression Remission at Twelve Months (Measure #370)

The AGS continues to be concerned about the previously finalized Kidney Health Evaluation measure (Measure #488) in the Geriatrics specialty measure set. While adults over 60 years of age are more likely to develop kidney disease and more than 50 percent of adults over the age of 75 are believed to have kidney disease,¹⁶ there is strong evidence that the current definition of chronic kidney disease (CKD) leads to overdiagnosis and identifies older adults as having CKD even though they do not have an increased risk for adverse outcomes.^{17,18,19} The AGS encourages reconsidering the inclusion of the Kidney Health Evaluation measure so as not to encourage overdiagnosis, overestimation of the burden of CKD, and unnecessary interventions in older adults.

We also continue to be concerned about inclusion of the Depression Remission at Twelve Months (Measure #370) in the Geriatrics specialty set, particularly as it requires a Patient Health Questionnaire-9 (PHQ-9) score of less than five. We believe that it is unlikely that older patients would be in remission compared to an improved state considering that older adults have lower rates of remission and may have other conditions such as fragmented sleep that will result in a PHQ-9 score of 5 or higher.^{20,21} **Thus, this may not be an appropriate measure for the Medicare population.** Finally, inclusion of the Preventive Care and Screening: Screening for Depression and Follow-up Plan measure in the Geriatrics Specialty measure set is a sufficient and more appropriate measure to support proper screening and management of depression among older adults.

¹⁶ National Kidney Foundation. Aging and Kidney Disease. Accessed August 22, 2023. <u>https://www.kidney.org/news/monthly/wkd_aging</u>.

¹⁷ O'Hare AM, Rodriguez RA, Rule AD. JAMA Intern Med. 2021;181(10):1366-1368. <u>doi:10.1001/jamainternmed.2021.4823</u>

¹⁸ Liu P, Quinn RR, Lam NN, et al. Accounting for age in the definition of chronic kidney disease. JAMA Intern Med. 2021;181(10):1359-1366. <u>doi:10.1001/jamainternmed.2021.4813</u>

¹⁹ Delanaye P, Jager KJ, Bökenkamp A, et al. CKD: a call for an age-adapted definition. J Am Soc Nephrol. 2019;30(10):1785-1805. <u>doi:10.1681/ASN.2019030238</u>

²⁰ Reynolds III CF, Dew MA, Pollock BG, et al. Maintenance Treatment of Major Depression in Old Age. N Engl J Med. 2006;354:1130-1138. <u>doi:10.1056/NEJMoa052619</u>

²¹ Nelson JC, Delucchi KL, Schneider LS. Moderators of outcome in late-life depression: a patient-level metaanalysis. Am J Psychiatry. 2013;170(6):651-659. <u>doi:10.1176/appi.ajp.2012.12070927</u>

<u>Removal of Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management</u> (Measure #283)

While the Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management measure was topped out, the effectiveness of the interventions has not been examined. The AGS believes this is an opportunity to gauge what type of dementia-associated interventions and measures could replace this topped-out measure to continue to encourage evidence-based care that supports patients with dementia remaining in the community, avoiding institutionalization, and receiving appropriate palliation as their disease progresses. This would enhance the follow-up and outcomes for dementia associated behavioral and psychiatric symptoms. **Until such a measure is added to the MIPS quality measure inventory, we recommend keeping the Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management measure in the Geriatrics specialty set to maintain a baseline of care for this significantly at-risk and underserved group.**

Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood

The patient experience of feeling heard and understood is a key goal and benefit of palliative care. Patients want to be treated as an individual and have their symptoms and goals of care managed effectively, which may be challenging at times given provider time constraints. We recommend that CMS add the Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood measure to the Quality measure inventory and the Geriatrics specialty measure set to help facilitate active participation from patients in defining the outcome of their palliative care. This measure was developed by the American Academy of Hospice and Palliative Medicine (AAHPM) under a cooperative agreement with CMS and measures the percentage of patients aged 18 years and older who had an ambulatory palliative care visit, who report feeling heard and understood by their palliative care provider and team during their care in the last six months.

The AGS appreciates the opportunity to provide the above comments and recommendations. We would be pleased to answer any questions you may have. Please contact Alanna Goldstein, agoldstein@americangeriatrics.org.

Sincerely,

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Michael Harper, MD Board Chair

Nome E. America

Nancy E. Lundebjerg, MPA Chief Executive Officer