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

Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services, Department of Health and Human Services, ATTN: CMS-1751-P Mail Stop C4-26-05 7500 Security Blvd. Baltimore, MD 21244-1850

Re: [CMS-1751-P] Medicare Program: CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; et al.

Dear Administrator Brooks-LaSure:

The American Geriatrics Society ("AGS") greatly appreciates the opportunity to comment on the Physician Fee Schedule (PFS) Proposed Rule for Calendar Year (CY) 2022 (CMS-1751-P).¹ The AGS is a nationwide, not-for-profit society of geriatrics health professionals dedicated to improving the health, independence, and quality of life of older people. Our nearly 6,000 physician and non-physician practitioners (NPPs) are pioneers in advanced-illness care for older individuals, with a focus on championing interprofessional teams, eliciting personal care goals, and treating older people as whole persons. 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 advocates for policies and programs that support the health, independence, and quality of life of all of us as we age.

In particular, we urge CMS to explicitly take into consideration how changes made to payment policies and rates as well as quality programs will affect the ability of Medicare beneficiaries to access needed care.

I. <u>Recommendations</u>

The AGS recommends that CMS:

¹ 86 Fed. Reg. 39104 (July 23, 2021).

- Finalize proposals that will improve beneficiary access to care, specifically:
 - Finalize proposed work relative value units (RVUs) and direct practice expense (PE) inputs for care management codes;
 - Allow physician assistants (PAs) to be paid directly by Medicare;
 - Reduce beneficiary coinsurance for certain colorectal screening tests when those tests are performed with related services;
 - Improve payments to rural health clinics (RHCs) and federally qualified health centers (FQHCs);
- Continue to evaluate and seek stakeholder input on updates to the indirect cost PE methodology, including refinements as to how to allocate indirect costs, with a goal of developing an approach that pays appropriately for both cognitive and procedural services;
- Update the wage data used to estimate clinical labor costs as proposed and continue efforts to use standard clinical labor tasks in rate calculation where possible;
- Finalize the proposal to retain Category 3 services on the Medicare Telehealth Services List through December 31, 2023 and continue to gather data on telehealth utilization to help inform consideration of appropriate guardrails for use of telehealth;
- Finalize the proposal to make permanent the extended virtual check-in code (G2252) but revalue the code to better reflect the resources required to furnish this service;
- Continue efforts to address and recognize the importance of audio-only services;
- Finalize the following refinements to the split (or shared) visit policy:
 - Allow billing split (or shared) visits for new and initial visits;
 - Continue to allow billing to services performed "incident to";
 - Allow split (or shared) visits to be billed for critical care and certain Skilled Nursing Facility/Nursing Facility evaluation and management (E/M) visits;
 - Allow practitioners to bill for a prolonged E/M visit for a split (or shared visit);
- Work with the American Medical Association (AMA) Current Procedural Terminology (CPT) to clarify correct coding policies that intersect with payment policies in order to reduce conflict and minimize administrative burden, especially with respect to more than one E/M service on the same day;
- Revise the proposed regulations at 415.140(a)(3) to include medical decision-making (MDM) in the definition of the "substantive portion" of a split (or shared) service;
- Not finalize the use of a modifier to identify split (or shared) services;
- Revise proposed removal of National Coverage Determination (NCD) 220.6 Positron Emission Tomography (PET) Scans to include removal of NCD 220.6.20 Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease;
- Establish a separate code for chronic pain management care;
- For the Medicare Shared Savings Program (MSSP),
 - Not include the principal care management codes (CPT codes 99X21, 99X22, 99X23, 99X24, and 99X25) in the definition of primary care services for purposes of beneficiary assignment;
 - Allow sub-classification of NPPs and not identify NPPs in non-primary care specialties as primary care practitioners;
 - Continue to offer the CMS Web Interface as an optional reporting mechanism for performance year 2023; and
- For the Quality Payment Program (QPP),

- Not finalize proposals to remove measures #050 Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older and #154 Falls: Risk Assessment from the Merit-based Incentive Payment System (MIPS);
- Address the health equity gap by considering ways that quality measure data collection and public reporting could be amended to include information regarding patients' race/ethnicity and/or socioeconomic status with minimal additional data collection burden on practices;
- Finalize the proposal to continue to set the complex patient bonus at up to 10 points and make this increase permanent;
- Limit the complex patient bonus to those clinicians who have a median or higher value on risk indicators and standardize the distribution of the risk indicators to target clinicians who have a higher share of socially and/or medically complex patients;
- Carefully consider the policies related the MIPS Value Pathways (MVPs) to avoid complicating a pathway that is intended to streamline MIPS.

We describe these comments in greater detail below.

II. Support for CMS Proposals Which Will Improve Beneficiary Access to Care

CMS made several proposals that AGS believes will better encourage care coordination or improve beneficiary access to certain services. Specifically, CMS proposes to:

- Accept the work values and direct PE inputs recommended by the Relative Value System Update Committee (RUC) for the family of care management codes (CPT Codes 99490, 99439, 99491, 99X21, 99487, 99489, 99X22, 99X23, 99X24, and 99X25);
- Amend the regulations to allow PAs to bill and be paid directly for services furnished to Medicare beneficiaries, rather than requiring that payment be made to the employer of the PA;
- Reduce beneficiary coinsurance for planned screening sigmoidoscopy or colonoscopy tests when those services are furnished with another related procedure; and
- Improve payment to RHCs and FQHCs, including implementing new statutory payment limits for RHCs per visit rates and allowing RHCs and FQHCs to bill for transitional care management service (TCM) in the same service period as other care management services.

AGS supports all of these proposals and urges CMS to finalize them as proposed.

III. Determination of Practice Expense Relative Value Units (Section II. B)

A. Refining the Practice Expense Methodology

In the proposed rule, CMS solicited comments to better understand the resource costs involved in services which use innovative technologies, such as software algorithms and artificial intelligence. We agree that these are important questions, but it is too early to establish general guidelines for services that may not yet be established as benefits or generally accepted clinical practice. It is particularly challenging to value some of these services under the PFS because in many instances this new technology is used to furnish services that differ from traditional physician services in the involvement of the physician or clinical staff and the length of service. Therefore, we believe each service warrants a specific review and software, in some cases, should be allowed as a direct PE. In addition, CMS also stated that they "continue to be interested in potentially refining the PE methodology and updating the underlying data, including the PPIS data that are the data source that underpins the indirect PE allocation"² and referenced studies conducted by the RAND Corporation to support that effort. We commend CMS on reviewing the underpinning of indirect PE calculations.

AGS appreciates CMS' efforts to better understand the resources needed to furnish physician services, how those resources may or may not vary between types of services and by physician specialty, and how to most appropriately allocate indirect costs. We urge CMS to continue to explore these issues and provide an opportunity for robust public comment on any changes CMS may be considering.

We agree that CMS should obtain updated data on practice cost expense and should establish a predictable timetable for obtaining data for future updates. We recommend that CMS conduct surveys not more frequently than every 5 years and that physicians are the primary point of contact for survey participation. However, it is increasingly likely that physicians are employed by a practice group or health system rather than being in solo practice and a non-physician professional such as a practice manager may best be able to answer questions about practice operations. Therefore, the survey instrument should allow other related parties to submit the required cost information.

For the survey to help CMS appropriately understand PE costs and variations, it is critical that survey participants provide accurate and complete information. Compiling and reporting such information involves time and resources and CMS should provide financial incentives to help offset the costs of survey participation.

We also urge CMS to take into consideration the variation in site of service within a specialty when conducting PE surveys. For example, some AGS members see almost all their patients in the physician office while others almost exclusively see patients in facility settings such as hospitals or nursing facilities. The survey instrument should appropriately capture the variation between the two types of practices and allow for appropriate cost allocation between the different types of practice for physicians within the same specialty. That is, CMS should avoid averaging PE cost estimates in a way that is likely to understate the cost of services furnished primarily in the physician office.

AGS agrees that the current indirect cost allocation methodology should be refined, particularly to avoid associating a disproportionate share of indirect costs with service components that do not reflect higher utilization of indirect components. For example, CMS uses the physician work RVUs as one element for allocating indirect costs. Work RVUs capture both the time and intensity of the service and while time may be associated with greater indirect costs, it is unclear that a service that requires more intense physician effort would necessarily require additional indirect resources. CMS could limit potential distortions caused by attributing excess indirect costs to services with high physician work RVUs by capping the number of RVUs that will be used in the indirect cost allocation. CMS should also exclude indirect resources that are derived from the calculation of physician work done in the facility setting where most of the PE costs, including the indirect costs, are born by entities other than the physician or physician practice. CMS may also want to consider other refinements such as excluding facility-based add-on codes from the indirect cost allocation since the majority of the indirect costs associated with the procedure will be captured by the base code.

² 86 Fed. Reg. 39126.

We urge CMS to work to develop an indirect allocation methodology that appropriately reflects the PE cost for both cognitive and procedural services and specialties. We appreciate that CMS recognizes that medical practice is evolving and that Medicare payment policies should recognize changes in how care is delivered and resources are acquired. We also believe that the general methodology should be designed to reflect typical models of care, not unusual approaches, and recommend that CMS consider developing a unique mechanism for dealing with new services that are outliers in some elements, as CMS has done with transcranial magnetic stimulation services.

B. Clinical Labor Pricing Update

CMS proposes to update the wage data used to determine the per minute rate for clinical labor direct inputs, which were last updated in 2002. CMS proposes to update the per minute cost of clinical labor using Bureau of Labor Statistics (BLS) wage data from 2019 and use data from Salary Expert when BLS wage data is not available for a particular category.

AGS agrees that the clinical labor rates should be updated to reflect more current estimates of per hour wages. CMS should also continue to adopt standard assumptions for specific clinical labor tasks. Use of standardized tasks ensures that similar activities have similar cost estimates across services and simplifies the process of updating labor inputs. We also recommend that CMS provide more detail about the process for developing labor standards and the basis for their assumptions.

IV. <u>Telehealth and Other Services Involving Communications Technology (Section II.D)</u>

AGS believes that the COVID-19 public health emergency (PHE) has demonstrated the high value of audio-video and audio-only services. We have learned that coverage of audio-only services is essential due to challenges the beneficiary population often faces in using technology, the sporadic failure of technology, and limitations in access to the technology due to infrastructure or economic reasons. We do not believe that remote services should replace most in-person services. However, as with any medical care, the appropriate service is determined by the individual patient's health and functional status, social support factors, the goals of the visit, and the care that the healthcare professional typically provides. We recognize that both regulatory and statutory factors are at play as well as concerns about program integrity. Our comments reflect these considerations.

CMS proposes to retain all the telehealth services added to the Medicare Telehealth Services List on a Category 3 basis until the end of CY 2023 in order to permit development of more evidence that could support permanent addition of those services to the list. AGS urges CMS to finalize this proposal. We also urge CMS to continue to promote data collection on the utilization of telehealth and outcome of services furnished through telehealth and to use that data to determine what limits may be appropriate to apply to telehealth services following the end of the PHE. CMS should work to determine what services can be appropriately furnished via telehealth and those that cannot, keeping in mind that clinician judgement and encounter-specific patient needs, not just CPT/Healthcare Common Procedure Coding System (HCPCS) code, should be considered. CMS should include—as part of this analysis—an assessment of what, if any, services can be appropriately furnished under direct supervision that is provided via interactive audio/video real-time communications technology. AGS has developed clinical guidelines for our members around decision-making about the scheduling of audio/visual or face-to face services that we are happy to share with CMS. We note that audio-only telehealth services are especially important for older adults, many of whom are not comfortable with or do not have the resources (e.g., do not own a smart phone) or know-how to operate software and mobile applications. Patients with cognitive impairment and/or low vision face additional barriers that can prevent use of more advanced technology for telehealth services. The importance of telehealth during this pandemic cannot be understated and providers and patients have been utilizing these essential services. We believe that telehealth services, when appropriate, should continue to play an important role in expanding access to health care services once the COVID-19 PHE ends. Policies that require beneficiaries to use advanced technologies to access non-face-to-face services are biased to younger, more affluent, and healthier beneficiaries. **We urge CMS to allow audio-only telehealth services to continue after the PHE.**

We also ask that CMS continue to address appropriate payment for audio-only services. We appreciate that CMS provides improved payment for audio-only services during the pandemic but note that the need for these services existed before the PHE and will persist after the PHE is over. As with other telehealth services, audio-only should not broadly replace in-person E/M visits but are important tools that allow for physicians to provide timely and efficient care in certain circumstances. We urge CMS to finalize the proposal to expand access to audio-only services for treatment of mental health disorders and to maintain access to the extended virtual check in-code (G2252 Brief communication technology-based service, e.g., virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion) that was established on an interim basis for 2021.

Moreover, we ask that CMS more appropriately value G2252. CMS proposes to value G2252 by cross-walking that code to the pre-PHE valuation for the telephone E/M visit code (99442) which does not adequately reflect the resources needed to furnish the extended check-in service. (During the PHE, CMS pays for 99442 at the same level as an established patient, Level 3 office visit, which more appropriately reflects the resources of the service.) The original RVUs for 99442 are based on provision of a brief phone call and do not reflect the more extensive E/M service described by G2252. CMS should continue the cross-walk to the established patient office visits for 99441-99443 and G2252 should align with 99442 until 99241-99243 are reassessed. These codes were created in 2006 and last valued by the RUC in 2007. The structure and valuations of the CPT telephone service codes reflect a different use than is commonly in place today. For example, the code structure of both the CPT telephone services and the CMS virtual check-in services would not allow ongoing monitoring of care over a week, such as for a patient who is COVID-19 positive, treated with monoclonal antibodies, and needs daily check in regarding status. CMS has requested comment on restructuring telephone services to reflect "communication technologies," but the request is sufficiently vague as to reduce the ability to provide cogent comment. We ask CMS to work with the AMA (CPT) to address audio-only services and to provide access to those services after the end of the PHE that is not limited to mental health care.

CMS proposes to limit audio-only services to the home, citing that broadband is available in other settings. We believe clinical utility should be the primary determinant and not broadband availability. Physicians should be able to report audio-only services for services furnished to patients in their residence, with residence broadly defined to include any arrangement that is not a healthcare facility such as a hospital, skilled nursing facility, or nursing facility and should include the patient's home, assisted living facility, or other type of congregate living facility that is not a healthcare facility.

In proposing to expand telehealth services for the diagnosis, evaluation, or treatment of mental health issues to include audio-only communications, CMS proposed to require that an in-person item or service must be furnished within six months of the audio-only telehealth service. Mental health services are often provided by a care team and the in-person service should not be limited to specific CPT codes, to a specific specialty, or require an in-person service at a specified interval. **The in-person service and telehealth services furnished to the patient, including audio-only telehealth services, should be determined by the clinical judgement of the care team and patient need.**

V. Split (or Shared) Visits

CMS proposed to incorporate into regulation guidance on split (or shared) visits that was previously stated in the Medicare Claims Policy manual, with some refinements. We appreciate the recognition of team-based care in these revisions, but we are concerned that some elements of the proposed policy may conflict with current and future (CPT 2023) coding guidelines. We also note that some policy may need additional clarification. We recognize that coding is distinct from payment policies, but also strongly believe that maximizing consistency between coding guidance and payment policies will reduce administrative burden and appropriate preparation for anticipated changes will minimize confusion for physicians. For example, CMS stated policy for the services described by revised office or other outpatient E/M codes in the Final Rule for 2020, even though those revisions would not be active until 2021. This provided an opportunity for additional public comment and enabled CPT to make additional revisions to its codes and guidance. We ask CMS to consider comments that improve alignment with CPT 2023 language in specific areas. In all cases we do not believe the typical service or valuations will be affected. Specifically, CMS proposes to modify its previously existing policy for split (or shared) visits to:

- Allow billing for shared visits for new patients and initial visits;
- Limit shared visit billing to services performed in institutional settings where the concept of "incident to" does not apply;
- Allow shared visits to be billed for critical care and certain Skilled Nursing Facility/Nursing Facility E/M visits;
- Allow practitioners to bill for a prolonged E/M visit for a split (or shared) visit.

AGS supports these changes and urges CMS to finalize them with clarification regarding "incident to" services. In addition, we seek clarification or offer feedback on the following:

- Multiple E/M services on the same date;
- "Incident to" services in the office/outpatient setting for new patients or new problems;
- Substantive portion of the split (or shared) service;
- Definition of "group"; and
- Use of a modifier to identify split (or shared) services.

A. Multiple E/M Services on the Same Date

CMS addresses multiple E/M services on the same day, largely with respect to critical care services 99291-99292. We feel current CPT language in the critical care services and pediatric and neonatal critical care services should be adopted and other services should be allowed. There are specific provisions for multiple instances where this may occur. CPT 2023 intends to clarify reporting

same day critical care and emergency department (ED) services and reflect current allowed practices. We believe time can be properly tracked in all these examples because a substantial change (deterioration) in condition or change in location occurs, which requires a distinct encounter by the physician or NPP. For example, while in the ED where there is continuous oversight, the ED service is functionally complete until a clinical change occurs, and the critical service commences. Even if CMS chooses not to allow ED and critical care services on the same day, we believe there are other instances where critical care and another E/M service should both be allowed on the same day, such as when an inpatient visit is completed and then the physician must return to the unit to provide critical care services a sudden change in their condition.

CPT 2023 is expected to allow Initial Hospital Inpatient or Observation services and other E/M services on the same date. This was done largely to recognize the distinct PEs of inpatient and office care. Alternatively, if reporting of both hospital inpatient or observation and other services is not allowed, then time—including prolonged services, if applicable—would presumably be used to identify the appropriate level of service. This approach requires clarification as to which prolonged services code should be used since the time is totaled over two settings. We recommend CMS to state that it will accept CPT 2023 guidelines for these instances which should be infrequent. The more common instance is when "the group" is not a clinical practice unit at all, but part of a large entity grouped together for tax identification purposes. Allowing the reporting of both services eliminates the administrative confusion as to whether the two services are provided by a single or two distinct entities. Finally, CMS has long allowed hospital inpatient discharge services and nursing facility admission services on the same date, and this should continue.

B. "Incident to" Services and Split (or Shared) Visits

CMS proposed to allow billing of split (or shared) services only in the institutional setting (defined as a hospital or skilled nursing facility) and reporting of such services furnished to new patients. CMS indicates that in the non-institutional setting services involving a physician and NPP would be billed as "incident to services."

The "incident to" services policy is limited to established patients and, some have argued, further limited to established patients under a care plan (i.e., it may not be used for new problems). CMS may wish to allow "incident to" for new patients. However, as only direct supervision is required for "incident to," but a face-to face service is required for a split (or shared) service, it may be more appropriate to allow split (or shared) visits for new patients in the office setting. This may be a common occurrence and will facilitate greater access for the beneficiary who can be seen more quickly by the NPP working in a team practice with the physician who will also see the patient in person. Additionally, it would seem inconsistent to allow split (or shared) services for new patients in other settings, but not the office.

C. Substantive Portion of a Split (or Shared Visit)

We disagree with the proposal to define "substantive portion" as more than half of the total time spent by the physician and NPP performing the visit. The withdrawn manual provisions had provided multiple definitions of "substantive portion" that included any face-to-face portion of the service or components of the E/M visit (i.e., history of present illness, physical exam, and MDM), some of which are no longer required under the revised E/M code descriptors. Time and MDM are the remaining components that can be used to identify the appropriate level of E/M service; CMS considers

time to be a more precise factor than MDM to use as the basis for determining which practitioner performs the substantive portion of the visit. CMS stated that it believes that practitioners are increasingly likely to time their visits for purposes of level selection and therefore using time as the basis for determining split visits does not comprise a substantial new burden.

We disagree. As proposed, the distinct time provided by each practitioner would be summed to determine the total time for the visit based on the CPT E/M guidelines to identify activities that can count as time. This approach is much more complicated to track and document than the previously applied standards. The CPT code descriptors and CMS payment policy allows for selection of the E/M visit level based on the MDM required and MDM should remain an option for identifying the substantive portion of a shared service. The CPT guidelines require face-to-face services by both the physician and the NPP. Additionally, the guidelines regarding level selection by MDM require that the physician or NPP reporting the service meaningfully address the problem as noted in the guidelines "problem addressed."³ AGS recommends that CMS revise the proposed regulations at 415.140(a)(3) to read as follows (new text underlined):

"Substantive portion means more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared visit) <u>or the portion of the visit in</u> which the medical decision-making is performed."

D. Definition of a "Group"

CMS proposes to retain the requirement in the withdrawn manual provisions which requires the physician and NPP furnishing a split (or shared) visit to be in the same group. CMS asked for comment on whether it should further define "group," such as requiring the physician and NPP to be in the same clinical specialty, aligning the definition of a "physician organization" under Stark, or considering practitioners with the same billing Taxpayer Identification Number (TIN) to be in the same group.

We believe the concept of "group" applies to a clinical team and not to a TIN. CPT uses concepts in the definition of new and established patients and in 2023 the definition of initial and subsequent services will include guidance that aligns with the clinical team concept. For purposes of determining who can bill for a split (or shared) service, the physician and NPP do not necessarily need to be the same specialty but should be practicing as part of a team providing coordinated clinical care.

D. Modifier for Split (or Shared Services)

CMS proposed to create a modifier to describe split (or shared) visits and would require the modifier to be reported on Medicare claims for such visits. CMS also asked for comment on whether it needs to amend the regulations to explicitly state that Medicare does not pay for partial E/M visits.

AGS does not support the requirement to append a modifier. The modifier creates administrative complexity but because it does not affect payment, it is likely to be inconsistently

³ **Problem addressed:** A problem is addressed or managed when it is evaluated or treated at the encounter by the physician or other qualified health care professional reporting the service.

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applied. We do not believe a split (or shared) visit is an incomplete or partial service. To the extent that CMS believes it is necessary to revise the regulations to state that Medicare does not pay for partial E/M visits, split (or shared) visits should not be defined as "partial E/M services," specifically in the new section 415.40 regarding the conditions for payment for split (or shared) visits.

VI. Payment for Services of Teaching Physicians

CMS asked for comment on whether time is an accurate indicator of the complexity of the visit and how a teaching physician might select the visit level using time in the context of the primary care exception, which allows for separate payment under the PFS for services furnished by a resident without the physical presence of a teaching physician for services of lower and mid-level complexity.

We agree that time-based coding for the teaching physician is determined by the personal time of the teaching physician. We also agree that the primary care exception would not logically use time for level selection because the teaching physician is not physically present with the patient for such services. MDM should remain the basis for code level selection for services furnished under the primary care exception. Time would only be used to justify reporting a level 3 E/M service (99213) and it is difficult to imagine spending 20 minutes on a service with straightforward MDM without personally seeing the patient.

VII. <u>Removal of Selected National Coverage Determinations</u>

CMS proposes to remove NCD 220.6 PET scans which non-covers all non-oncologic uses of PET scans that are not specifically covered by another NCD. CMS is proposing to remove the broad national bar to coverage and allow local contractor discretion regarding coverage for non-oncologic uses of PET that are not subject to another NCD. CMS is not proposing to remove any other existing PET NCDs so the coverage policies and limitations applying to non-oncologic indications that are the subject of an existing NCD will remain in place, including for beta amyloid PET.

AGS urges CMS to remove NCD 220.6.20 Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease. Under this NCD, beta amyloid PET scans are currently covered only as part of a clinical trial that meets the requirements for Coverage with Evidence Development. This NCD restricts access to beta amyloid PET scans furnished to identify patients who may be candidates to receive aducanumab, an amyloid beta-directed antibody. In order to benefit from aducanumab, patients must have beta amyloid present in their brains; therefore, patients without access to amyloid PET scans may be treated with aducanumab even though there is no evidence they will benefit from the treatment. All patients in the aducanumab Phase 3 clinical trials were required to have a positive beta amyloid PET scan before entering the trial. Treating patients who do not have beta amyloid present in their brains may result in harm, since aducanumab therapy carries a risk of significant side effects. Without the ability to receive a beta amyloid PET scan, Medicare beneficiaries would need to undergo more invasive testing or receive a scan that was not part of the clinical trials for aducanumab. Without access to appropriate testing, Medicare beneficiaries would not be able to make an informed decision with their physicians about the utilization of aducanumab.

If CMS finalizes the retirement of NCD 220.6 as proposed, then the existing limitation on amyloid PET would remain in place but other uses of PET for Alzheimer's disease, such as Tau PET, could be covered at the discretion of the Medicare Administrative Contractors (MAC). To avoid this illogical

and confusing situation, we urge CMS to revise the proposed removal of NCD 220.6 to also include removal of NCD 220.6.20.

VIII. Comment Solicitation on Separate Coding and Payment for Chronic Pain Management

CMS solicited comment on whether the agency should consider creating separate coding and payment for medically necessary activities involved with chronic pain management and achieving safe and effective dose reduction of opioid medications when appropriate, or whether the resources involved in furnishing these services are appropriately recognized in current coding and payment.

AGS recommends that CMS should create a code for chronic pain management services. There is currently no CPT or HCPCS code available to describe such services and the activities that CMS identifies as being part of this service, including development and maintenance of a person-centered care plan and facilitation, crisis care, and coordination of any needed behavioral health treatment, are not wellrecognized by other codes. While in some cases, chronic pain management services may be reported using either a chronic or principal care management code, we believe it would be more appropriate for CMS to develop a specific code and specific payment for this service.

We also urge CMS to include management of the appropriate use of other medications, in addition to opioids, in any pain management code. For example, non-steroidal anti-inflammatory drugs (NSAIDs) are commonly prescribed for pain but include the risk of several adverse events, particularly in older adults.⁴ Careful evaluation of all pain management medication, including consideration of the AGS Beers Criteria[®] regarding potentially inappropriate medications for use in older adults,⁵ should be included as part of the chronic pain management service.

IX. Medicare Shared Savings Program (MSSP)

The MSSP promotes many ideals of geriatrics care and MSSP organizations often recognize the leadership of geriatrics professionals and the need for an age-friendly health system.⁶ Unfortunately, the Medicare fee schedule inadequately recognizes the value that geriatrics healthcare professionals bring to the care of Medicare beneficiaries. Below we provide comments and recommendations regarding CMS' proposals with respect to the MSSP.

Snyder R & Pelton L. Age-Friendly Health Systems. Presentation at: American Geriatrics Society 2019 Annual Scientific Meeting; May 2019; Portland, OR. Available at

https://www.americangeriatrics.org/sites/default/files/inline-files/GWEP%202019%20Age-Friendly%20Healthcare%20Systems_0.pdf .

 ⁴ Wongrakpanich S, Wongrakpanich A, Melhado K, Rangaswami J. A Comprehensive Review of Non-Steroidal Anti-Inflammatory Drug Use in The Elderly. *Aging Dis.* 2018;9(1):143-150. <u>https://doi.org/10.14336/AD.2017.0306</u>.
⁵ 2019 American Geriatrics Society Beers Criteria® Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc.* 2019;67(4):674-694. <u>https://doi.org/10.1111/jgs.15767</u>.

⁶ The 4Ms (What Matters, Medication, Mentation, and Mobility) describe four main areas where geriatrics health professionals focus their attention when caring for an older person and form the basis for the age-friendly health systems movement that is working to ensure 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.

A. Revisions to the Definition of Primary Care Services Used in MSSP Beneficiary Assignment

AGS does not believe it is appropriate to include the principal care management services codes (CPT codes 99X21, 99X22, 99X23, 99X24, and 99X25) within the definition of primary care services for purposes of beneficiary assignment. While primary care physicians and NPPs may provide these services in younger populations, in our experience, principal care management services are almost always specialist services in older populations. Thus, their inclusion in the definition of primary care services in the MSSP will lead to misattribution.

AGS has previously recommended that CMS adopt specialty designations for NPPs and commented that current NPP classifications are insufficiently granular for beneficary assignment under the MSSP and for other purposes. At a minimum, CMS should consider sub-classifications of primary care; specialty care; mental health and substance use disorder care; and obstetrics and gynecology for NPPs. If necessary, specialty care could be divided further into medicine/pediatric (i.e., non-surgical) subspecialty care and surgical specialty care. In our view, an advanced practice registered nurse (APRN) in a surgical practice should not have patients attributed to them for purposes of accountable care organization (ACO) beneficiary assignment as if they were a primary care physician or NPP. We note that the Medicare Payment Advisory Commission (MedPAC) recommended that the Secretary refine Medicare's speciality designations for APRNs and PAs in its June 2019 report.⁷

B. Quality Measure Reporting Mechanisms

AGS supports continuation of the CMS Web Interface as an optional reporting mechanism for Performance Year (PY) 2023. If properly constructed, electronic clinical quality measures (eCQMs) offer the promise of reduced reporting burden while improving population care. However, eCQMs today have a host of issues that should be addressed prior to MSSPs being required to report eCQMs through the Advanced Payment Model Performance Pathway (APP). eCQMs are constructed for individual clinicians and for use in a uniform medical record platform and not for the majority of MSSPs that bring together many practices and electronic medical record (EMR) systems. At a minimum, MSSPs will need to go through a complicated deduplication process across its EMR systems to report eCQMs.

Additionally, while the goal of evaluating and improving care across the entire population is laudable, eCQM measurement that aggregates across all patients may not accurately reflect population management. For example, all the patients of an orthopedic practice that is part of a particular MSSP will be in the denominator for MSSP measures even though those measures bear little relevance to that specialty; accordingly the patients associated with the practice will potentially fail the quality measure. The patients may be deduplicated by the ACO, but more significantly they may be appropriately attributed in another ACO based upon their primary care provider. This may disincentize MSSP entities from including procedural specialists. Instead, the goal should be to incentivize better coordinated care quality and efficiency by bringing procedural specialties into MSSP entities. One option would be to remove certain specialties from MSSP entities' quality reporting (at least with respect to certain measures) as those specialties may inappropriately and negatively skew the quality scores in a way that does not reflect actual quality of care.

⁷ MedPAC. Report to Congress: Medicare and the Health Care Delivery System at 162-64. Available at <u>http://medpac.gov/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf</u>. Published June 2019.

An even greater concern is the potential to finanially harm ACOs that have member practices that take care of disadvantaged patients. It is not a legitimate comparison of care received by the Medicare beneficiary when two ACOs have much different non-Medicare populations. Leaving aside the example of specalist participation above, consider an ACO that has a population that has 10% of their adults on Medicaid, 50% of the population commercially insured, 20% traditonal Medicare, and 20% Medicare Advantage. Now compare this to an ACO that has 10% uninsured, 20% Medicaid, 30% commercial insurance, and the same Medicare populations as the other ACO. The total populations are notably different, even if the Medicare populations are superficially similar. The performance as measured by eCQM scores has a financial impact on shared savings or losses that is very substantial as it is based on total cost of care, not payments received from Medicare.

We urge CMS to consider and address these issues prior to transitioning to the APP. CMS will not promote equitably, high-quality care if MSSP entities that seek to bring multiple practices and specialties together to provide coordinated, team-based care are disadvantaged.

X. <u>Quality Payment Program</u>

A. MIPS Quality Measures and the Geriatrics Specialty Measure Set

1. <u>Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65</u> Years and Older (Measure #050)

The AGS is concerned with CMS' proposal to remove Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Measure #050) as a quality measure from MIPS and therefore the Geriatrics Specialty Set. Removing the Plan of Care for Urinary Incontinence measure may result in mere screening of urinary incontinence without development of an appropriate plan of care. An appropriate plan of care ensures proper follow-up assessment, referrals, and treatment depending on what matters most to the patient and the impact that urinary incontinence has on the patient's overall health status. **The AGS urges CMS to retain both Measures #048 Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and older and #050.** Measures that support screening as well as care plans for a socially and materially impactful diagnosis, such as urinary incontinence, incentivize health systems and practices to improve access to quality care.

CMS states that its rationale for proposing to remove Measure #050 is that it "does not align with the Meaningful Measures Initiative as it splits a clinical process into individual quality measures." We believe that the measure does not split a single clinical process because detecting an issue (as measured by #048) is different from treating the issue (as measured by #050). There are different actions required by the two measures and denominators. Establishing an effective care plan for people with urinary incontinence is a very distinct clinical task from a screening for the presence of this condition. When an older adult screens positive for urinary incontinence, a critical next step is to address the individualized plan of care for that patient.

CMS also includes in its rationale for proposing to remove Measure #050 that "the Medicare Part B Claims Specifications collection type is at the end of the topped-out lifecycle (82 FR 53640)." Rather than supporting removal of Measure #050, we believe that would indicate the need for a more rigorous quality measure. CMS could address both of its concerns by working with the measure steward, the National Committee for Quality Assurance (NCQA), to revise Measure #048 to explicitly measure the establishment of an appropriate plan of care for patients identified through screening as having urinary incontinence so that it is an assessment as well as a plan of care measure. The plan of care can be as simple as a referral and incontinence supplies or as complex as engaging multiple specialists regarding diuretic therapies and interdisciplinary team members for additional support at home. Since urinary incontinence can result in frequent urinary infections, increased caregiving needs, social isolation, and macerated skin and wounds, the plan may include ordering covered supplies necessary for the proper care of urinary incontinence.

2. Falls: Risk Assessment (Measure #154)

The AGS disagrees with the proposal to remove Falls: Risk Assessment (Measure #154) as a quality measure from MIPS and therefore the Geriatrics Specialty Set. Given the morbidity and mortality associated with falls, as well as the costs to the health care system, removal of Measure #154 would have a detrimental impact on the geriatric population.

Falls have a significant impact on older adults on both a biopsychosocial and financial level. Onefourth of older people fall every year, and complications from falls are the leading cause of death from injury for persons 65 years and older.⁸ Of these falls, 300,000 older adults are hospitalized every year with hip fractures.⁹ These patients are at higher risk for delirium and subsequent functional decline and dementia. According to several studies, the reported one-year mortality after sustaining a hip fracture in usual care is approximately 14–58 percent, making the first year after fracture vital.¹⁰ Falls among older adults are also costly. In 2015, the cost of falls for Medicare and Medicaid was nearly \$38 billion and the total medical cost was \$50 billion.⁹ Falls remain one of the greatest harbingers of poor outcomes in older adults.

Given the importance of falls prevention, as an alternative or in addition to Measure #154, we request that CMS include Measure #318, Falls: Screening for Future Fall Risk in the Geriatrics Specialty measure set. This measure is similar to #154 but is reported through electronic health record (EHR) and CMS Web Interface reporting mechanisms. It is included in a number of other specialty measure sets and is relevant to our patient population, particularly if CMS removes Measure #154.

Moreover, should Measure #318 also become topped out, we believe this would suggest the need for a new and more informative measure, especially as fall risk continues to be a major untreated issue with significant ramifications for both quality of care and health system costs. If both measures are removed, we encourage CMS to develop and evaluate a more rigorous measure of falls risk assessment (e.g., what validated questions or maneuvers are the clinicians making to achieve compliance with this measure?) prior to omitting these measures from MIPS.

⁸ Burns E, Kakara R. Deaths from Falls Among Persons Aged ≥ 65 Years – United States, 2007-2016. *MMWR Morb Mortal Wkly Rep.* 2018;67:509-514. <u>https://doi.org/10.15585/mmwr.mm6718a1</u>.

⁹ Facts About Falls. Centers for Disease Control and Prevention (CDC) website. <u>https://www.cdc.gov/falls/facts.html</u>. August 6, 2021. Accessed August 24, 2021.

¹⁰ Based on a summary of published mortality rates in patients with hip fractures treated in usual care. Schnell S, Friedman SM, Mendelson DA, et al. The 1-Year Mortality of Patients Treated in a Hip Fracture Program for Elders. *Geriatr Orthop Surg Rehabil.* 2010;1(1):6-14. <u>https://doi.org/10.1177/2151458510378105</u>.

The AGS supports a high-quality risk assessment tool for falls. Falls risk assessment can result in active interventions to prevent a serious fall such as balance exercises and/or referral to physical therapy, ordering an assisted walking device, improving nutritional status or electrolyte imbalance, further medical and neurologic work-up, or changes in medication, including deprescribing. We believe falls risk assessment is essential to help prevent falls and the cascade of morbidity and mortality.

3. Addressing the Health Equity Gap in CMS Clinician Quality Programs

AGS was pleased to see CMS' request for information (RFI) related to ways CMS' quality programs could help address existing health disparities. In our view, collecting and publishing data that provides specific information regarding such gaps is a critical step in addressing health disparities. To that end, we recommend that CMS consider ways it could amend quality measure data collection and public reporting to include information regarding patient race/ethnicity and/or socioeconomic status. To minimize clinician reporting burden, CMS should focus on existing sources of data, such as demographic data available in EMR systems or registries or information CMS already has regarding beneficiaries' status as dual eligibles. In addition to helping identify inequities, this type of measure stratification may highlight subpopulations who are not receiving optimal care even where a related quality measure may be topped out across the overall Medicare population. For example, we suspect there is currently inequitable access to a care plan for urinary incontinence across populations. Should CMS identify a subpopulation for which a measure is not topped out, we recommend that CMS keep the measure in the MIPS measure set or amend it to specifically address the subpopulation at issue to help address that equity gap.

B. Complex Patient Bonus

1. <u>Complex Patient Bonus Points</u>

The AGS supports CMS' proposal to extend the policy of setting the complex patient bonus at up to 10 points for the 2021 performance period/2023 MIPS payment. We urge CMS to make the increase permanent and continue offering the bonus as the QPP transitions to MVPs.

First, given the early evidence of the long-term impact of COVID-19 on patients who "recover," including heart, lung, and brain damage, blood clot and blood vessel problems, and issues related to mood and fatigue,¹¹ we expect that increases in patient complexity will persist long after the PHE ends. It is likely that the risks associated with contracting COVID-19 will remain acute for our members' patient population, who are largely frail, older patients with multiple comorbidities, particularly as the virus continues to mutate into variants for which current vaccines are less effective.

Second, CMS' own analysis of 2018 MIPS data, which predates the COVID-19 PHE, found that, prior to the assignment of the complex patient bonus, clinicians who care for a higher share of complex patients have lower final scores—on average (by more than 10 points)—than other clinicians. These findings underscore the continued need for the complex patient bonus so that clinicians are not

¹¹ COVID-19 (coronavirus): Long-term effects. Mayo Clinic website. <u>https://www.mayoclinic.org/diseases-</u> <u>conditions/coronavirus/in-depth/coronavirus-long-term-effects/art-20490351</u>. Updated May 6, 2021. Accessed September 13, 2021.

incentivized to avoid caring for vulnerable, frail older patients who may naturally have less favorable outcomes and require more costly care.

2. <u>Updates to the Complex Patient Bonus</u>

Given our members' focus on caring for medically complex, frail patients, we were not surprised by CMS' data analysis that found that clinicians who have a higher share of complex patients have markedly lower final scores prior to the assignment of the complex patient bonus than other clinicians. We believe it is reasonable to amend the complex patient bonus attribution methodology to focus on such clinicians. Therefore, the AGS supports CMS' proposal to: (1) limit the bonus to clinicians who have a median or higher value for at least one of the two risk indicators (HCC and dual proportion); and (2) standardize the distribution of the two risk indicators so that the policy can target clinicians who have a higher share of socially and/or medically complex patients.

C. Subgroup Reporting Under MIPS Value Pathways (MVPs)

For the CY 2023 and 2024 MIPS performance years, CMS is proposing the term MVP Participant to include a "subgroup" defined as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's National Provider Identifier (NPI). CMS proposed that individual eligible clinicians who are part of multiple specialties could participate in multiple subgroups and report on multiple MVPs, or clinicians could join a subgroup that is most applicable to their scope of practice and report on one MVP. CMS is not planning to establish limits on the number of subgroups that a clinician can be part of. We understand, and ask CMS to confirm, that a MIPS eligible clinician that participates in MVPs via multiple subgroups would receive the highest final score that can be attributed to their TIN/NPI combination from any reporting option (traditional MIPS, APP reporting, or any MVP subgroup reporting) and participation option (as an individual, group, subgroup, or APM Entity (with the exception of virtual groups)).

While we appreciate CMS' goal of leveraging MVPs to develop comparable performance data across like entities that helps patients make informed healthcare decisions, we are concerned that subgroup reporting provides limited benefit to actually improving healthcare quality and creates significant complexity, counter to CMS' goal of reducing reporting burden. Medicare beneficiaries, particularly those with multiple chronic conditions, benefit from coordinated, team-based, population healthcare services. Subdividing multispecialty groups that are designed to advance this team-based approach for the purposes of quality measure reporting undermines these efforts. Additionally, while the proposed number of measures within a single MVP may be fewer than traditional MIPS, any future policy that either incentivizes or requires subgroup reporting could result in multispecialty groups needing to report a greater number of measures in total to address the MVP for each of its subgroups. Today, multispecialty groups are reporting population-based measures that hold every group member accountable for patient outcomes and costs regardless of specialty, which we believe more appropriately aligns with the goals of team-based care. As CMS moves toward the MVP model, the AGS urges the agency to think carefully through MVP selection, registration, reporting, attribution, and scoring rules, particularly with respect to subgroups, in order to avoid overcomplicating a pathway that is intended to streamline MIPs. For example, would groups (i.e., TINs) have to register their identified subgroups as MVP Participants or could a group of clinicians independently register themselves as MVP Participants? Conversely, could an eligible clinician be placed in a subgroup or multiple subgroups without their knowledge? In our experience, multispecialty groups collect

information for MIPS reporting on behalf of their eligible clinicians. Subgroup reporting will complicate this process, particularly if groups do not have control over the subgroups and where the same clinician may participate in multiple subgroups.

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Thank you for the opportunity to submit these comments. We would be pleased to answer any questions you may have. Please contact Alanna Goldstein, <u>agoldstein@americangeriatrics.org</u>.

Sincerely,

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