AGS | THE AMERICAN GERIATRICS SOCIETY
Geriatrics Health Professionals.
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http://www.regulations.gov

Andy Slavitt
Administrator
Centers for Medicare and Medicaid Services,
Department of Health and Human Services,
Attention: CMS-5517-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

Re: Medicare Program: Merit-Based Incentive Payment System and Alternative Payment Model Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-P)

Dear Administrator Slavitt:

The American Geriatrics Society (AGS) appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule (81 *Fed Reg* 28161) implementing the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Medicare Physician Fee Schedule (PFS), as mandated by the Medicare and CHIP Reauthorization Act of 2015 (MACRA).

The AGS is a not-for-profit 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.

In general, the AGS commends CMS for attempting to articulate the statutorily required elements under extreme time pressure. The Request for Information (RFI) released in October 2015 was a valuable opportunity for CMS to share its thinking and to get feedback from interested parties. We appreciate that CMS is emphasizing simplification, has removed all or nothing scoring and has made allowances for diverse practices (such as recognizing that physicians, including many geriatricians, may practice in multiple different nursing facilities and therefore use different electronic medical records technology in those facilities).

The AGS shares CMS's commitment to the overall goal of reforming Medicare payment structures to improve patient outcomes and the quality of care provided. However, the specifics of how those reforms are implemented are critical to the success of the program and may produce unintended and undesirable outcomes unless the programs are designed and evaluated in a careful and deliberate manner. We are concerned that many elements of the program will be implemented without a track record of how patient care and physician practice will be impacted. We feel it is critical to rapidly assess the specific impact of the proposals on clinicians by specialty, practice setting, and group size. Geriatrics professionals are disproportionately dependent upon Medicare and are already in very short supply. Unintended effects of this program could further reduce access to this specialty at a time when the aging of the population and the demands of caring for the multiple comorbidities of older patients heightens the need for geriatricians. The AGS urges CMS to fully evaluate the effects of the payment reforms and to mitigate any undue impacts on geriatrics professionals.

1. Comments on the Merit-Based Incentive Pay System

In general, we are very concerned that the proposed weighting and scoring system sets up an un-level playing field that may disadvantage geriatricians and favor other specialties. As primary care physicians, geriatrics professionals are likely to report measures in all MIPS categories. Other specialties may have few or no measures in some categories such as resource use or may have more measures on which they are evaluated or can choose to report.

The impact of CMS proposals related to resource use are particularly hard to decipher. Primary care practitioners, including geriatrics professionals, are more likely to be assessed on the total cost per capita cost measure than specialists. The other proposed resource measures -- Medicare Spending Per Beneficiary and the episode-based measures -- are most likely to apply to physicians who provide predominantly inpatient care or who specialize in certain high cost conditions or treatments. It is likely that many physicians, including entire specialties, will not be evaluated on any resource measures. At the other end of the spectrum, some specialties may be assessed based on numerous resource use measures since the proposed episode-based measures emphasize cardiovascular, musculoskeletal, and respiratory conditions.

It is unclear from the information provided in the proposed rule whether being assessed on multiple resource use measures is an advantage or disadvantage compared to being assessed on only one measure or not being measured at all. However, we note that CMS's assessment of the MIPS proposals indicates wide variations by specialty in the percentage of clinicians expected to receive positive adjustments under MIPS and the difference in the dollar amount of the negative and positive adjustments. For example, just over half of all geriatrics specialists (51.6 percent) are expected to receive a positive adjustment and the dollar value of the negative and positive adjustments for geriatrics is roughly equal ($7 million). In contrast, 62 percent of cardiologists are expected to receive positive adjustments and those positive adjustments are expected to total considerably more than the expected negative adjustments ($127 million in positive adjustments for cardiologists compared to $35 million in negative adjustments).

If many physicians successfully report quality measures, attest to clinical practice improvement activities and use certified EHRs, then resource use could be the domain that determines whether a physician or group receives a bonus or gets a penalty. We are particularly concerned about the patient attribution methodology for resource use measures because we believe that claims data is seriously flawed as a way to accurately attribute patients - especially patients who are seeing multiple physicians such as

cardiologists, and rheumatologists, in addition to primary care physicians. The proposed attribution methodology makes it impossible for a clinician to determine in advance whether or not a patient is attributed to him or her and attribution could shift from year to year if a patient sees multiple doctors.

Based on these concerns, we recommend that CMS assign a resource use score of zero for all MIPS participants until there is a better understanding of whether the proposals inappropriately favor particular specialties. CMS could obtain such understanding through extensive modeling and through analysis of CY 2016 claims data. The results of this analysis should be published in the CY 2018 proposed rule to allow all stakeholders an opportunity to comment on how the resource use category in MIPS should be implemented taking this additional information into consideration.

AGS looks forward to working with CMS on the development of future metrics based on the care episode groups, patient condition groups, and physician-patient relationship categories. We commend CMS on promoting ways to develop new, more applicable measures, but note that these development processes require substantial resources which are beyond those of a specialty society. We also note that most of the current measures are single condition focused, whereas many Medicare beneficiaries, particularly patients in a geriatrician's practice, are likely to have multiple conditions. We encourage CMS to facilitate and sponsor measure development for the very population CMS expends the most resources upon -- that is the multi-morbid patient with functional impairment who is not institutionalized. We recommend that CMS prioritize measures that specifically address care of the geriatric population.

We also hope that CMS will do more than "closely examine" the recommendations from the HHS Office of Secretary for Planning and Evaluation (ASPE) study on risk adjustment, as this issue is vitally important to the success of the MIPS. The AGS hopes that CMS will incorporate appropriate risk adjusters into the new quality and resource use metrics and the methodology for computing the composite performance score. The ability to capture patient specific factors in the EHR should also be considered in the development of a risk adjustment methodology. For example, in comparing physicians' performance on the quality measures related to diabetes management, CMS's methodology should take into account that EHRs do not have a way of capturing and reporting certain information that is likely to impact patients' cost and outcomes, such as residence in a hospice or limited life expectancy.

Below we provide additional comments on specific components of the MIPS program.

A. MIPS Program Details

Eligible Clinicians and Group Practices. The AGS supports the proposal to maintain the definition of a group practice used under the Physician Quality Reporting System (PQRS),that is that a group practice is a single Taxpayer Identification number (TIN) with two of more MIPS eligible clinicians, as identified by their National Provider Identifier (NPI), who have assigned their Medicare billing rights to the TIN. We also support CMS's proposal to not create a new MIPS eligible clinician identifier and instead use existing identifiers such as the TIN and NPI. We believe this approach will be simpler to implement and avoids the additional administrative burden on both clinicians and CMS of maintaining a new identifier.

Definition of Primary Care Services. The AGS supports CMS's proposal to modify the definition of primary care services to align with the Medicare Shared Savings Program and include the new care

coordination codes for transitional care management (TCM) (CPT codes 99495 and 99496) and the chronic care management (CCM) (CPT code 99490) in that definition.

We also support CMS's proposal to exclude nursing facility care services (CPT codes 99304 through 99318) provided in the skilled nursing facility (SNF) setting from the definition of primary care services used to attribute patients to a clinician. Patients who are in a SNF are systemically different from ambulatory patients, and those differences are reflected in comparisons of the Medicare spending per beneficiary. Most patients who are in a SNF are transient and while cared for by a generalist are not necessarily receiving continuity care from that clinician. Excluding services provided in a SNF (POS-31) will help to ensure appropriate comparisons of resource use by physicians.

B. Quality Measurement

The AGS appreciates that CMS's proposals make significant changes to the current quality reporting requirements to alleviate flaws in the PQRS program. We appreciate CMS's efforts to provide greater flexibility in measure selection and reporting and to make it easier for clinicians to identify relevant measures by expanding the use of specialty measure sets.

The AGS supports the CMS proposals to allow individual MIPS eligible clinicians and groups to determine the most meaningful quality measures for their practices and to provide flexibility in reporting those measures. We appreciate that CMS lowered the number of measures clinicians are expected to report from that are required under the PQRS and removed the requirement that the measures reported must span across multiple domains of the National Quality Strategy. We also agree that clinicians should have the flexibility to report fewer than six measures if fewer than six are applicable to their practice, and should have the option of reporting high priority measures when an appropriate outcome measure is unavailable. The AGS supports the CMS proposal to reweight the quality performance category to zero if a provider does not have at least three scored measures.

Below we make recommendations for further refinements that are needed to improve the accuracy and appropriateness of the quality data used in the MIPS program.

Specialty Measure Sets. The AGS commends CMS for responding to stakeholder feedback about the difficulty physicians have faced with navigating the PQRS program by proposing specialty-specific measure sets. The AGS recommends that CMS include in the specialty measure sets those cross-cutting measures that are most applicable to the specialty, rather than maintaining a separate list of cross-cutting measures and requiring physicians to refer to two lists. The AGS believes that this will simplify the rollout of the specialty measure sets by making them "one stop shopping."

We also recommend that CMS create a geriatric measure set. This will facilitate reporting of measures by geriatricians and encourage reporting of measures that are directly associated with improvement in care for the elderly. We recognize that these sets are not required, but facilitate understanding of the most likely appropriate measures and AGS would like to work with CMS to define a geriatric clinician set.

Several measures that are part of the General/Family Practice or Internal Medicine measure sets are also applicable to geriatric medicine. However, the AGS notes that the specifications for those measures may make them inapplicable for geriatricians, because the criteria for inclusion of beneficiaries in the measure excludes the oldest patients. For example, the following measures exclude patients above a specific age:

- Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%): Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
- Diabetes: Eye Exam: Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period.
- Diabetes: Foot Exam: Percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.

Restrictions that prevent the reporting of a measure for the most elderly patients limit the applicability of those measures to many geriatricians who may not have a sufficient number of patients within the specified age range to report the measure. Even when the measure can be reported, the results may not provide an accurate picture of the geriatrician's performance across his or her full patient population or recognize the high quality care geriatricians provide to the most senior of patients, who are often more fragile and medically complex than younger patients, as compared to others reporting the same measure.

Current quality measures may significantly disadvantage some geriatricians because very few, if any, measure outcomes of patients over the age of 85 where traditional care is often inappropriate. For example, it is not appropriate to screen healthy people for things like colon cancer or osteoporosis at that age. An alternative approach is necessary, for example one that considers beneficiary or surrogate involvement in care planning as an appropriate outcome of good care for the multi-morbid patient. The result of the paucity of measures is that geriatricians may have nothing to report for a significant portion of their patient panel. We request that CMS acknowledge this fact and provide support for the development of outcome measures in this population. Specialty societies, especially societies which represent a relatively small number of physicians, do not have the resources available to develop appropriate measures independent of CMS support.

As part of the data completeness criteria, CMS proposes that data must be reported for 90 percent of patients for most reporting mechanisms, an increase from the 50 percent required under the PQRS. CMS also proposes an expansion in the patient population for which data is to be reported to include all patients regardless of payer; under the PQRS, clinicians are only required to report on Medicare Part B fee-for-service patients. CMS indicates that it is adopting this approach because it believes that it "provides a more complete picture of each MIPS eligible clinicians scope of practice and provides more access to data about specialties and subspecialties not currently captured in PQRS."[1] While the AGS appreciates the intent behind expanding the patient population on which clinicians must report data, we are concerned that the inclusion of younger, generally healthier patients in the data set used to calculate performance thresholds may disadvantage geriatricians across all of the quality measures as MIPS is graded on a curve.

Therefore, the AGS recommends that CMS take necessary steps to minimize the impact of differences in the case mix of physicians' patient populations. CMS should analyze the quality performance data

[1] 81 Fed. Reg. 28188

looking at Medicare and non-Medicare populations separately, and should also examine whether stratifying the performance data by specialty code, site-of-service code, or both will result in more accurate measurement and fair adjustments for physicians who treat the sickest patients. We believe it will be essential for CMS to monitor results by specialty to determine if certain disciplines consistently under-perform, suggesting the process, not the clinician, is the source of low performance results. If stratifying the data by specialty type is possible, the AGS believes that comparing geriatricians who treat patients with comorbid conditions to other geriatricians who also treat patients with comorbid conditions will be more appropriate and accurate than comparing geriatricians to other primary care physicians who treat less complex cases.

The AGS supports the proposal to use the population measures from the acute (bacterial pneumonia, urinary tract infection, and dehydration) and chronic (diabetes, chronic obstructive pulmonary disease or asthma, and heart failure) composite measures of Agency for Healthcare Research and Quality (AHRQ) Prevention Quality Indicators (PQIs) with a minimum case size of 20, and urges CMS to incorporate a clinical risk adjustment as soon as feasible.

C. Resource Use

With respect to the resource use performance category, the AGS is concerned that the proposed Episode Groups do not include adequate adjustments to address patients with multiple chronic conditions. Without such risk adjustment, physicians who treat the sickest patients will be penalized. As noted above, the AGS recommends that CMS assign a resource use score of zero for all MIPS participants to allow for further analysis of the impact of the resource use measures on the MIPS adjustment and to develop appropriate measures for a wider array of physicians.

MACRA requires CMS to measure resource use taking into consideration a mandated process to engage in collaboration with physicians, practitioners and other stakeholder communities.[2] In our view, therefore, CMS should thoughtfully define new and refine old episode measures with the input of interested parties prior to moving full speed ahead with implementing episode groups as part of the resource use performance category. The episodes selected should focus on validity of the measures, not the volume of costs that are covered. While the law sets as a target for the establishment of care episode and patient condition groups that those groups account for an estimated 50 percent of expenditures under part A and B, not all of the established groups should immediately be incorporated into the MIPS determination. Priority should be placed on a small set of measures that are developed for use in physician offices, not hospitals, and that have the support of the specialties that provide the key services within the episodes.

Many of the proposed episodes are keyed to an inpatient admission, and thus place physicians' performance on the resource use measure in the control of the hospital. While CMS has publicized data comparing hospitals' costs for performing the same procedure, beneficiaries in fee-for-service Medicare may go to any hospital. The treating physician has little influence to steer patients toward the lowest-cost hospital. Rather than measuring physicians' performance based on the performance of the hospital, CMS should replace current hospital-focused measures with episodes developed in cooperation with physicians' professional societies and designed for use in the setting where the particular services are most often delivered.

[2] Social Security Act 1848(q)(2)(B)(ii).

Episodes that are keyed to the treatment of ambulatory patients will look very different from most of the episodes that CMS has proposed. Potential sources for additional episodes include recommendations from the medical specialties, state Medicaid programs, Qualified Clinical Data Registries, and specialties' alternative payment model (APM) submissions to the Center for Medicare and Medicaid Innovation (CMMI). Private payer initiatives endorsed by relevant specialties could also be considered. CMS could hold meetings similar to those that were used to develop Resource-Based Relative Value Scale practice expense units to hammer out elements of episodes.

The AGS encourages CMS to ensure far greater involvement of physicians and the professional societies that represent them in future efforts to design, evaluate, implement and re-evaluate episode groups. The AGS believes that episode groups require careful testing and consideration using experts and large databases. The AGS supports development of episodes that involve care of patients with chronic conditions. For those patients with multiple chronic conditions, we are uncertain whether CMS envisions episodes that combine commonly co-occurring conditions but would continue to treat other less common chronic condition combinations separately. Involvement of the appropriate clinicians and specialty societies will be vital in determining which conditions could be combined and how that should occur. It may be that for primary care geriatricians focused on outpatient services, total cost of care more accurately assesses resource use for persons with multiple conditions.

In addition to developing episodes specifically geared toward patients with comorbidities, the AGS recommends that CMS test the performance of other episode groups on patients with multiple chronic conditions. Unfortunately, with the information provided, the AGS is unable to determine how our members would be affected by the use of the proposed episode groups, particularly given the need to account for patients with multiple chronic conditions. Additional variables, such as presence of dementia, should be assessed.

The proposed rule indicates that CMS plans to adjust the cost data used in the total per capita cost measure to eliminate the impact of differences in payment rates (e.g. geographic variation, payments for medical education and disproportionate share hospital (DSH) payments) as well as for patient factors such as age, sex, disability status and previous diagnoses. The AGS requests that CMS make public additional data that would allow stakeholders to understand these adjustments.

The AGS is concerned that CMS proposes to set the minimum number of cases for the Medicare Spending Per Beneficiary measure at 20, rather than the 125 case minimum used under the Value Modifier. While we understand that this change is intended to ensure the resource use performance category can be applied to a greater number of MIPS eligible clinicians, we are very concerned that a physician who has only 20 cases in an episode could have average costs that are highly skewed by one or two high-cost outliers. The AGS recommends that CMS examine the distribution of cases that are attributed to physicians and make adjustments, such as removing outliers (similar to the methodology in the inpatient prospective payment system.)

As described above, the AGS is also concerned that the methodology for attributing episodes to physicians is not transparent. Unless and until CMS is able to share data with physicians about the patients who were assigned to them based on claims data and help them understand not only the cost of the care they provided individually but the cost of care provided by the other physicians in close to real time, physicians will not have the necessary tools to evaluate their resource use or to succeed in the MIPS.

Finally, the AGS supports continued use by CMS of mathematical modeling to refine its methodology. However, the AGS notes that the MIPS methodology is already extremely complicated and we urge CMS to avoid adding additional levels of complexity. Without a straightforward way for physicians to understand how their resource use measures are constructed and what changes in practice would move them up or down on resource use measures, it will be difficult for physicians to use their performance on those measure to improve the quality and value of care provided.

D. Advancing Care Information

The AGS is generally supportive of the proposed evolution of the EHR Incentive Program to the "Advancing Clinical Information" (ACI) category. The AGS supports the proposed changes that simplify the Stage 3 requirements, including requiring reporting for only six of the eight objectives and excluding the Clinical Decision Support objective and the Computerized Provider Order Entry objective from the ACI category. The AGS also supports the proposal for MIPS-eligible clinicians to report the numerator and denominator only for required measures, rather than having an all-or-nothing reporting threshold.

The AGS supports CMS's proposal to assign a weight of zero to the advancing care information performance category for hospital-based eligible clinicians, those facing a significant hardship (such as insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over the availability of certified EHR technology, and lack of face-to-face patient interaction).

The AGS understands CMS's concerns about the quality of the data reported for the PQRS. Given that EHR technology must meet federal standards and qualified clinical data registries (QCDRs) must be approved by CMS for use in data reporting, the AGS believes CMS should establish standards for data quality. The information technology industry will follow standards if CMS establishes and enforces them. The proposed rule also makes physicians accountable for interoperability and requires them to attest to the "timely, secure and trusted bi-directional exchange of structured health information." IT vendors should be required to attest to similar requirements. Physicians are not well equipped to establish such standards but will be penalized for not submitting data in a format that CMS can use. Physician societies have made substantial investments in registries and need assurance that their members can benefit from using them.

The AGS recommends that CMS require EHR vendors to capture reportable information in structured format to facilitate reporting for all of the performance categories, including the Clinical Practice Improvement Activities (CPIA) category, as described below. In the current environment, screening questionnaires (such as the Patient Health Questionnaire-9) obtained in nursing homes are not accessible to hospitals and physicians in clinics. Likewise, developing a care plan is a CPIA, but the plan, once developed, cannot be shared across settings or institutions. Achieving the goal of "advancing care information" will require addressing these issues.

E. Clinical Practice Improvement Activities

The Clinical Practice Improvement Activities (CPIA) performance category offers an opportunity for CMS to incentivize behaviors that help coordinate care across transitions and settings of care. The AGS believes that CMS should use the flexibility this category affords to identify activities that will help in the management of individuals with multiple chronic conditions. The AGS supports CMS's proposed criteria for deciding whether to include a CPIA on the CPIA inventory, particularly the criteria of achieving

improved beneficiary health outcomes, aligning with patient-centered medical homes, and choosing those that are feasible for small practices to implement.

Frailty CPIA. The AGS has reviewed the proposed CPIAs in the CPIA inventory and recommends that CMS establish a new CPIA for Frailty. Approximately 15 percent of non-nursing home Americans aged 65 years and older are frail and another 45 percent are pre-frail.[3] Frailty features can be identified in a physician's office practice, using one of several validated tools, and an assessment can be linked to interventions known to be effective in reducing risks of future disability, hospitalization, falls, institutionalization and mortality.

Frailty meets several of CMS's proposed criteria for inclusion of a CPIA, including (1) relevance to an existing CPIA subcategory (or a proposed new subcategory); (2) importance of an activity toward achieving improved beneficiary health outcomes; and (3) evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes.

Identification of frailty in practice. Prior research has identified a set of shared risk factors for common geriatric conditions that are associated with frailty, including risk of falls, cognitive impairment, urinary incontinence and immobility. These risks are often identified by geriatricians, but may also be identified by other physicians as well. Importantly, some risk factors for frailty are modifiable with specific interventions and monitoring.

Although no universal definition of frailty exists the concept has been often operationalized as a set of observable characteristics (phenotype) or an index. For example, the Cardiovascular Health Study (CHS)[4] used the five phenotypic characteristics of frailty identified in the original frailty work by Linda Fried: unintentional weight loss, exhaustion, muscle weakness, slowness while walking, and low levels of activity. Frailty items can be assessed through medical history or readily estimated during physical examination. Frailty is 3 or more of the 5 items, pre-frailty is 1-2 items and robust (non-frail) is 0 items. In prospective CHS cohort studies, the frailty score is predictive of adverse health outcomes and importantly identifies potential interventions to reverse frailty items or to prevent progression of frailty. Several other frailty measures have also been shown to be valid and predictive of future adverse health outcomes events.

Clinical interventions. Prevention of frailty through evidence-based interventions could greatly improve the quality of life of vulnerable seniors while saving billions of dollars in Medicare costs. Clinical trials involving older adults have demonstrated increased muscle strength and mass with low intensity strengthening exercises and nutritional supplements, and reduction of falls risk with multi-dimensional interventions[5] [6] (e.g., gait retraining, muscle strengthening, use of assistive devices, changes in medications) targeted to at-risk individuals.

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[3] Bandeen-Roche, K, Seplaki, CL, Huang, J, et al. Frailty in Older Adults: A Nationally Representative Profile in the United States. J Gerontol A Biol Sci Med Sci. 2015; 70(11), 1427-34. doi: 10.1093/gerona/glv133.

[4] Fried LP, Tangen, CM, Walston, J, et al. Frailty in older adults: evidence for a phenotype. *J Gerontol A Biol Sci Med Sci*. 2001;56(3):M146

[5] Tinetti ME, Baker DI, McAvay G, et al. A multifactorial intervention to reduce the risk of falling among elderly people living in the community. N Engl J Med. 1994;331:821–827.

Weighting of frailty CPIA. Geriatricians often work with interdisciplinary teams in the assessment and management of frail seniors. Physical therapy, occupational therapy, home care agencies, social services and community-based services are readily coordinated by geriatricians and provide essential services to both patients and their family caregivers. The extra time and effort needed by geriatricians for the initial assessment and subsequent coordination of patient and family needs, and the potential cost savings to Medicare, justifies a "high" weighting score for frailty.

Proposed Frailty CPIA Item

(under subcategory, Patient Safety and Practice Assessment)

Subcategory	Activity	Weighting
Patient Safety and Practice Assessment	Perform frailty assessment using a validated measure of frailty and develop a care plan to either reduce or reverse risk factors for frailty (e.g., interventions to improve patient nutrition, physical functioning, gait, balance, strength, use of community-based services); and assure delivery of essential services to support the patient and caregiver.	High

Reweighting Fall Screening and Assessment. Falls occur in over 30 percent of Americans aged 65 years and older[7], account for millions of visits to emergency departments[8], result in 700,000 admissions to hospitals for serious injuries[5] (e.g., 250,000 hip fractures annually)[9], and incur an average hospital cost of $35,000 with 78 percent of costs charged to Medicare.[10] While CMS has proposed a CPIA for fall screening and assessment, it is narrowly defined and only addresses the performance improvement activity to prevent falls. It is also weighted as only "Medium" scoring. Because of the clinical, economic and population-based importance of falls this CPIA should be weighted "High".

CPIA Requirements. The AGS supports the CMS proposal to lower the number of required CPIAs for small groups and those located in rural areas or geographic HPSAs. The AGS also appreciates that CMS would like to streamline reporting and rely on electronic reporting by third parties, although we urge CMS to rely on claims data to the maximum extent possible to eliminate the need for duplicative reporting. The AGS believes that CMS should work as quickly as possible to develop CPIA baselines for all

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[6] Close J, Ellis M, Hooper R, Glucksman E, Jackson S, Swift C. Prevention of falls in the elderly trial (PROFET): a randomised controlled trial. *Lancet*. 1999 Jan 9;353(9147):93-7.

[7] Important Facts about Falls. Home and Recreational Safety. Centers for Disease Control and Prevention Website. http://www.cdc.gov/homeandrecreationalsafety/falls/adultfalls.html. Accessed June 17, 2016.

[8] Data and Statistics (WISQARS). Injury Prevention and Control. Centers for Disease Control and Prevention Website. https://www.cdc.gov/injury/wisqars/index.html. Accessed June 17, 2016.

[9] Health Care Use and Expenditures. Health Data Interactive. National Center for Health Statistics. Centers for Disease Control and Prevention. http://www.cdc.gov/nchs/hdi/index.htm. Accessed June 17, 2016.

[10] Stevens JA, Corso PS, Finkelstein EA, Miller TR. The costs of fatal and nonfatal falls among older adults. *Inj Prev*. 2006. 12(5):290–5.

eligible clinicians and to award scores based on both performance and improvement, consistent with the MACRA law. The AGS notes that for physicians in high-performing practices, it may be difficult to demonstrate improvement; CMS should ensure that the incorporation of improvement as a factor in the scoring criteria does not inadvertently penalize physicians who are already performing many of the CPIA activities.

The AGS also recommends that CMS use the American Board of Medical Specialties (ABMS) Maintenance of Certification (MOC) Part IV, Improvement in Medical Practice, as one option for clinical practice improvement activities in the MIPS. The ABMS MOC requires that, to maintain board certification, clinicians engage in ongoing assessment and improvement activities to improve patient outcomes, and demonstrate use of evidence and best practices compared to peers and national benchmarks.[11] Eligible clinicians who have completed the required number of credit hours for their specialty board should be deemed to have met the CMS requirement for clinical practice improvement activities, and do not have to submit the same information on their activities and the credits earned to CMS.

CPIA 90-day Performance Period. The AGS is very concerned about the 90-day performance period for CPIAs included in the proposed rule. A 90-day performance period is simply inapplicable to many of the CPIAs listed by CMS and in other cases it is unclear what needs to be done for 90 days. For example, CMS identifies "Integration, facilitation, and promotion of the colocation of mental health services in primary and/or non-primary clinical care settings" as a high weight CPIA, but the action that needs to be performed for 90 days is not clear. Another example is "Consultation of Prescription Drug Monitoring Program prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription that lasts for longer than 3 days." Does this mean that the practice has to consult a drug monitoring program for 90 days or is it the establishment of a process that includes consultation when appropriate? Based on our review of the CPIAs proposed by CMS, we believe that the proposed 90-day performance period should not be finalized as it might discourage physicians from implementing these important activities because of confusion about required activities and when CPIAs can be reported. Even worse would be a scenario in which physicians are not able to report a practice improvement due to an arbitrary performance period (for example having an improvement in effect for only 89 days).

The AGS requests that CMS release further sub-regulatory guidance on how the attestation process for CPIAs will work, and on how CMS plans to approach any specified performance period, especially for CPIAs that practices began implementing prior to the start of the performance window. The time period for CPIA should be tailored to the particular activity being implemented. In some cases, positive change could occur in less than 90 days but even for activities with a longer time horizon, a practice should receive credit for the CPIA as long as it is in place for a least one quarter.

F. Reporting Requirements and Administrative Burden

The AGS appreciates CMS's efforts to reduce the administrative burden associated with reporting data for the various MIPS performance categories. Those include the proposal to use three population-based outcome measures that do not require providers to submit any data, as well as the provision permitting

[11] More information is at http://www.abms.org/board-certification/a-trusted-credential/assessed-through-a-four-part-framework/.

a qualified registry, health IT vendor, or Qualified Clinical Data Registry (QCDR) to submit data for the three performance categories that require reporting: quality, CPIA, and advancing care information.

The AGS shares CMS's concern that third party entities will not be able to implement the necessary changes to support reporting on all categories in the first year. Further, the AGS is concerned that the additional cost of creating this functionality will be passed on to physicians in the form of higher fees for using those vendors' services. The AGS urges CMS to work with vendors to ensure that vendors' products evolve as CMS's policies evolve and to ensure adequate advanced notice of upcoming changes so that physicians can trust that they will not be penalized for failing to report data their technology was not updated to collect.

G. Performance Feedback

CMS proposes that clinicians will receive performance feedback beginning July 1, 2017 on an annual basis, but may consider providing such feedback more frequently, such as on a quarterly basis, in future years as MIPS evolves. The AGS urges CMS to expedite the process so that partial-year data on performance in the first year of the MIPS is available to physicians prior to July 1, 2018 -- and preferably prior to January 1, 2018. CMS has increased the requirement for reporting quality measures from 50 percent of patients to 80 or 90 percent of patients; by July 1, providers will already have performed roughly half of the procedures they will perform in the year. There will be insufficient time available for any actions a physician takes in response to the performance feedback to affect their scores.

CMS proposes to use the Quality and Resource Use Reports (QRURs) that are currently used for the existing Physician Feedback program. As noted in the Proposed Rule, there have been problems with a lack of provider awareness of the existing PQRS Feedback Reports and QRURs and difficulties accessing them through the CMS portal. CMS should consider establishing an email list serve for physicians so that they will be notified when the QRURs are available. We encourage CMS to continue to work with stakeholders to improve the usability of the reports.

The AGS supports CMS's proposals to limit the reporting of data on the Physician Compare website to those measures that have sufficient sample size for reliable and valid measurement, and to use consumer testing to choose the measures that are most meaningful.

3. Comments on Advanced Payment Models (APMs)

A. Definition of Advanced APM

The AGS is disappointed with CMS's proposed approach to defining the financial risk criterion for Advanced APMs. We believe that CMS's interpretation of the financial risk criterion for Advanced APMs is inconsistent with the plain language of the statute and with the statutory intent to encourage proliferation of, and participation in, Advanced APMs. One of the primary goals of MACRA is to give physicians incentives to adopt APMs, but those options will be unavailable to most geriatricians given the limited geographic reach and specialization of the current Advanced APMs.

Financial Risk for Monetary Losses. Section 1833(z) of the Act, as added by section 101(e)(2) of the MACRA, requires that an incentive payment be made to Qualifying APM Participants (QPs) for participation in eligible alternative payment models, which CMS has deemed "Advanced APMs." MACRA also defines an "eligible APM entity" as an entity that participates in an APM that (1) requires

participants to use certified EHR technology, (2) provides for payment based on quality measures that are comparable to MIPS, and (3) "bears financial risk for monetary losses under the APM that are in excess of a nominal amount," or is a medical home expanded under CMMI. The statute does not define "financial risk for monetary losses" or "excess of a nominal amount."

The AGS believes that, consistent with the statute, CMS should adopt a more inclusive definition of "financial risk for monetary losses." CMS proposes to break this seemingly straightforward third criterion into two complicated multi-part standards. First, CMS extrapolates from the statutory phrase "financial risk for monetary losses" to propose a generally applicable financial risk standard, which would require an Advanced APM to include provisions that, if actual expenditures for which an APM entity is responsible under the APM structure exceed expected expenditures, CMS can (1) withhold payment for services to the APM Entity and/or the APM entity's eligible clinicians; (2) reduce payment rates to the APM Entity and/or the APM entity's eligible clinicians; or (3) require the APM entity to owe payment(s) to CMS.[12]

CMS interprets the statutory requirement to only encompass "losses" that could be incurred through either direct re-payments to CMS or reductions in payments for services. In the Preamble, CMS justifies its very narrow interpretation by arguing that it believes that the "statute supports a financial risk criterion that should be met only by those APMs that are most focused on challenging organizations, physicians, and practitioners to assume financial risk and provide high-value care."[13] The plain language of the statute, however, does not support CMS's narrow definition of financial loss and precludes many APM structures where providers are taking on "financial risk for monetary losses" as described by the statute. For instance, other APMs entities may take on financial risk by requiring significant infrastructure investments that may not be recovered or relying on payments tied to quality or value.

First, the term "financial risk for monetary losses" in MACRA, by its plain language, refers to any losses in the operations of the APM entity and is not limited to losses or increased spending in the Medicare program. The gains or losses of the APM entity are a function of both costs that the entity incurs to implement the model and the revenues it receives under the model. If an entity hires or pays for new staff to deliver services to patients under the model, acquires new or different equipment to deliver services, or incurs other kinds of expenses to implement the APM, and those expenses are not automatically or directly reimbursed by Medicare, then the entity is accepting financial risk for monetary losses.

Furthermore, under a one-sided shared savings model, an entity incurs financial risk if it incurs costs to implement programs that are designed to reduce Medicare spending, since the provider could fail to qualify for the shared savings payment needed to pay for those costs. CMS recognizes that these one-sided risk models are bearing risk of financial losses by proposing that the Medical Home Model financial risk standard could be satisfied by such reductions in bonus payments. Other APMs with financial risk associated with potential reductions in quality- or value-based payments should similarly be recognized.

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[12] 81 Fed. Reg. at 28304.

[13] 81 Fed. Reg. at 28304.

These investments can be quite significant. A 2013 survey by the National Association of ACOs found the average start-up costs for an ACO were approximately two million dollars, and described the associated risks as follows:

> Estimates in the published literature of ACO start-up costs have ranged widely, with $1.8 million estimated by CMS in the draft regulations being the most often quoted. [The American Hospital Association] estimated in 2011 that they would range from $11.6 to $26.5 million. The average actual start-up costs of the [survey] respondents in the first 12 months of operations were $2.0 million with a range from $300,000 to $6,700,000. Since savings are slow to flow as a result of data and complex reconciliation process, ACOs will have almost a second full year of operations until their cash flow can be replenished with shared savings from CMS (if any). This means that the average ACO will risk $3.5 million plus any feasibility and pre-application costs. We estimate that in total, ACOs on average will need $4 million of startup capital until there is a chance for any recoupment from savings.[14]

Second, APM entities are bearing real financial risk associated with potential reductions in "bonus payments," such as shared savings payment incentives that vary based on quality performance. Specifically, in January 2015, Secretary Burwell announced the goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016 and 90 percent by 2018.[15] When the vast majority of payments are tied to quality or value, providers are unable to sustain their practices on base payments alone and so-called "bonus payments" tied to quality become essential to a provider's business model.

In Excess of a Nominal Amount. The AGS believes that CMS's definition of "nominal amount" should better reflect the plain language and intent of the statute, and be more inclusive of APM structures. In the Preamble, CMS interprets "nominal amount" to mean "an amount that is lower than optimal but substantial enough to drive performance."[16] This standard has no foundation in the statutory language. The common dictionary definitions of nominal are: "existing as something in name only," "not actual or real" and "very small in amount."[17] There is nothing in the plain meaning of the word "nominal" to suggest that it would be appropriate to interpret nominal to mean "lower than optimal" or "substantial enough to drive performance."

CMS then proposes a strict three-part test. For an APM to meet the nominal amount standard: (1) the specific level of marginal risk must be at least 30 percent of losses in excess of expected expenditures;

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[14] National Association of ACOs, National ACO Survey, conducted November 2013, Final report January 1, 2014, at 1 (emphasis added).

[15] HHS, Press Release, Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value (January 26, 2015), available at http://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html#.

[16] 81 Fed. Reg. at 28306.

[17] Merriam-Webster (online edition), available at http://www.merriam-webster.com/dictionary/nominal.

(2) a minimum loss rate, to the extent applicable, must be no greater than 4 percent of expected expenditures; and (3) total potential risk must be at least 4 percent of expected expenditures.[18]

If Congress had wanted Advanced APM entities to accept substantial financial risk, it would have explicitly required that. Because the underlying premise for CMS's three-part test is inconsistent with the plain meaning of the statute, the test itself is similarly inconsistent with the statute and requires APM entities to bear a significant amount of risk in order to become an Advanced APM entity. The fact that the bar is too high is exemplified by the fact that so few APMs will qualify to be Advanced APMs in 2017.

In discussing the development of its proposal, it is clear that CMS recognizes the interaction between Medicare expenditures, around which CMS's test is based, and revenues. It is important to understand that even a seemingly small percentage change in Medicare spending could represent a very large percentage of a provider's revenues, particularly the revenues of a small entity, and it would represent an even larger percentage of that provider's profit margins. As CMS itself notes, this risk is especially high for smaller entities, which are just as "focused on challenging organizations, physicians, and practitioners to assume financial risk and provide high-value care"[19] as larger organizations. Physicians who are part of smaller practices want to be able to participate in the APM Incentive Payment program and meet the requirements of Qualifying APM Participant but the bar CMS proposes to set, makes this an impossibility for many physicians, including most geriatricians, other than those in the largest multi-specialty group practices, academic medical centers, and integrated health systems.

Consistent with the statutory language, we recommend that CMS both simplify the test and reduce the amount of risk required for an entity to participate in an Advanced APM.

Proposed Definition does not incentivize use of APMs. In addition to being inconsistent with the statute, CMS's interpretation of the financial risk criterion is not aligned with its policy goals to encourage development of, and participation in, APMs. In the proposed rule, CMS lays out a number of policy principles, which it states are derived from both the MACRA law and the Department's broad vision, that drive CMS's decisions in developing the overall framework for making APM Incentive Payments to QPs. These principles include the goals with regard to APMs:

- Building a portfolio of APMs that collectively allows participation for a broad range of physicians and other practitioners;
- Designing the program such that the APM Incentive Payment is attainable by increasing numbers of practitioners over time, yet remains reserved for those eligible clinicians participating in organizations that are truly engaged in care transformation;
- Maximizing participation in both Advanced APMs and other APMs; and
- Creating policies that allow for flexibility in future innovative Advanced APMs.

Given the relatively small number of APM entities and clinicians participating in such entities, CMS could better achieve these goals by developing inclusive policies regarding Advanced APMs that encourage the development of, and participation in APMs generally. CMS should be encouraging these activities not

[18] 81 Fed. Reg. at 28306.

[19] 81 Fed. Reg. at 28304.

only for large health care networks that can take on significant financial risk immediately, but for smaller organizations and a variety of provider types, who, relative to their size and structure, are taking on substantial risk in their own right. High quality, patient-centered care can come in all shapes and sizes, and CMS should not limit its ability to promote transformative care by so narrowly defining payment models that will meet the definition of Advanced APMs.

For example, an APM entity may invest in improvements that are not one-time costs but instead represent an ongoing obligation such as hiring care managers or coaches, data analysis, and information technology upgrades. In order to earn shared savings, an entity must generate costs that are lower than the benchmark by an amount that exceeds the minimum savings rate (MSR.) In all the existing programs, the MSR has been symmetrical with the minimum loss rate (MLR). CMS proposes that the maximum MLR is 4 percent. If an APM entity does not share in losses when actual expenditures exceed expected expenditures by at least 4 percent, the entity cannot share in any savings until actual expenditures are less than expected expenditures by the same 4 percent, under a symmetrical approach. One way to make participation in an APM entity more viable for physician practices is to allow two-sided arrangements that are asymmetrical, e.g., allowing the MSR to be lower than the MLR. This structure would acknowledge that the ACO has costs not accounted for by the existing approach.

CMS also proposes that the APM entity must take at least 30 percent of the downside risk. CMS does not propose any requirements for a symmetrical arrangement but we recommend that CMS clarify symmetry is not required. For example, the APM should be allowed to let a physician keep 60 percent of the upside risk and take 30 percent of the downside risk.

The fact that CMS has set the financial risk bar too high is evident by the fact that so few APMs qualify and those that do have small relative enrollment. According to the National Association of ACOs, the vast majority of ACOs participate in a one-sided risk model (and thus do not qualify as Advanced APM entities) and CMS has recognized that taking-on two-sided risk in the MSSP is not a realistic goal in the first six years of an ACO's operation for the vast majority of ACOs.[20] We encourage CMS to develop financial risk criteria that are more consistent with the statutory language and more achievable for a variety of APMs.

As both clinicians and CMS gain experience with APMs, in subsequent years, CMS could look to set forth gradually increasing financial risk criteria that would reflect the state of APMs at that time. Such an approach would allow CMS to develop appropriate criteria for identifying Advanced APMs while encouraging APMs entities to craft innovative designs that allow them to succeed through care transformation and the provision of high-value care, and maximize clinician participation in APMs.

Consistent with the statutory language, statutory intent, CMS's policy goals, and the best interests of patients, we recommend that CMS define financial risk for the 2017 performance year and beyond to include models where providers make major infrastructure investments and one-sided risk models.

[20] Comment Letter, National Association of ACOs to Andy Slavitt, Re: Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models (File Code CMS-3321-NC) (November 17, 2015).

B. Advanced APM Models

MACRA is clear in its intent to encourage physicians to join APM's. In order for physicians to participate in APM's, APM's must exist in their practice area. CMS should commit to ensuring that comparable opportunities and risks exist for physicians in all parts of the United States to participate in APMs. The AGS urges CMS to include additional ongoing projects as advanced APMs and to continue to work collaboratively with the provider community to develop new models. In particular, we advocate for inclusion of the Independence at Home Model as an advanced APM for 2017.

While the AGS is pleased that CMS will permit practices that are already participating in the Medicare Shared Savings Program to join the Comprehensive Primary Care Plus (CPC+) program, we are concerned that despite participating in the CPC+, many of the practices will not be considered to be in Advanced APMs. In a frequently-asked-questions document released after publication of the proposed rule,[21] CMS states that it will evaluate CPC+ practices based on their participation at the ACO level. Practices that are participating in MSSP Track 2 or Track 3 and the CPC+ would be eligible for the Qualifying Participant bonus. It appears that practices that participate in both Track One of the MSSP and the CPC+ will not be eligible for the Qualifying Participant bonus payments, even though the CPC+ was determined by CMS to meet the criteria for an Advanced APM. In the AGS' view, the proposal undercuts CMS's effort to bring practices into APMs via the medical home model. The AGS urges CMS to clarify in the Final Rule that any practice participating in the CPC+ program that meets the requirements to be Qualifying APM Participants would be eligible for the APM bonus.

4. Considerations for Transitioning from MIPS to APMs

Consistent with the desire to use incentives for physicians to participate in APMs, the AGS believes that the proposal to have different rules for "MIPS APMs" is inconsistent with Congress' intent to reward participation in all APMs (not just those that accept downside risk), and adds unnecessary complexity to implementation of the already complicated MIPS program. While we appreciate CMS's desire to align the incentives for APM entities and the TINs underneath them, excluding APM participants from MIPS altogether would be far simpler and consistent with the intent of Congress. There would be no need to have a separate methodology for MIPS scoring for APM participants, since qualifying participants in an APM are not eligible for MIPS, and partially qualifying participants in an APM are held harmless from MIPS payment adjustments.

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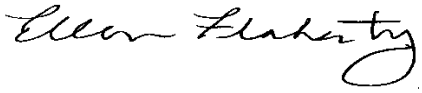
Thank you for the opportunity to submit these comments. We would be pleased to answer any questions you may have. Please contact Alanna Goldstein, agoldstein@americangeriatrics.org.

[21] Available here: https://innovation.cms.gov/Files/x/cpcplus-faqs.pdf

Sincerely,



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