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Seema Verma Administrator Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-5522-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850

Re: Medicare Program; CY 2018 Updates to the Quality Payment Program (CMS-5522-P)

Dear Administrator Verma:

The American Geriatrics Society (AGS) appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule (82 Fed. Reg. 30010) proposing CY 2018 updates to the Quality Payment Program (QPP).

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 Medicare Physician Fee Schedule (PFS).

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, and we appreciate the efforts CMS has made in this rule to reduce reporting burden and recognize the challenges faced by clinicians providing care to complex patients and in small practices and rural settings. 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. As we commented last year, we continue to be concerned that many elements of the program will be implemented without a track record of how patient care and clinician 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.

We urge CMS to adopt the following recommendations:

- CMS should provide a more meaningful weight for the complex bonus, consider certain adjustments to the scoring methodology to more accurately reflect patient complexity, and limit attribution to patients with a continuous/broad relationship with the clinician.
- AGS strongly supports CMS's proposal to weigh the Cost performance category at zero for the CY 2018 performance year. For CY 2019 and beyond, CMS should establish scoring policies that take an incremental approach to allow both CMS and clinicians to gain experience with cost measures. We also believe that primary care providers should be scored on the total cost per capita cost measure only, for the reasons discussed below.
- We encourage CMS to establish a slow and thoughtful process for removing topped out Quality measures. We urge CMS to carefully consider the potential impact of removing any measure on quality of care and particular specialties.
- We support measuring improvement in the Quality performance category, but recommend that CMS monitor improvement scores for gaming or trends showing that eligible clinicians are tending to select new measures rather than improvement on previously reported measures.
- AGS is general supportive of alternative scoring options for facility-based clinicians and urges CMS to consider this option for other site of services, such as skilled nursing facilities (SNFs). However, we do not have a clear understanding of the impact of this proposal on non-facilitybased clinicians and have outlined our questions and concerns below.
- We support the concept of virtual groups, but urge CMS to exercise caution. As there are many unknowns regarding how virtual groups will work in practice, the AGS recommends that CMS implement "beta-testing" only for the 2018 performance period and allow time for stakeholder feedback prior to full implementation.
- CMS should apply the MIPS payment adjustment only to professional services paid under the Medicare Physician Fee Schedule (PFS).
- CMS should finalize its proposed reweighting policy for the Quality, Cost, and Improvement Activities performance categories in cases of extreme and uncontrollable circumstances.
- The AGS continues to be disappointed with CMS's approach to defining the financial risk criterion for Advanced APMs and urges CMS to lower the amount of risk APM entities are required to take on and allow one-sided risk models to be Advanced APMs. We strongly support any steps that make participation in the Advanced APM pathway more tenable for clinicians, including lowering revenue-based nominal risk amount for small and rural practices; however, we believe that CMS should lower the nominal risk amount for both the revenue-based standard and the benchmark-based standard, across all clinicians.

Our specific comments are set forth in more detail below.

I. Merit-Based Incentive Payment System (MIPS)

A. Complex Patient Bonus

Our members care for the sickest and most complex Medicare beneficiaries so we greatly appreciate CMS' recognition of the need for a complex patient bonus. We also support the goals of the bonus: (1) to protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage. However, we are concerned that a maximum of three points will have an immaterial effect on eligible clinicians' CPS. Eligible clinicians caring for complex patients with multiple comorbidities face significant disadvantages in the Quality and Cost performance categories, especially given the challenges of properly risk adjusting those measures, so it's important that the bonus account for those disadvantages and adequately protect complex patients' access to care. We encourage CMS to provide a meaningful weight for the complex bonus, such as a maximum of 10 points, to better align with the goals of the bonus.

We agree with CMS that patient complexity is a complicated concept that includes not only medical complexity but socio-economic factors as well. Thus, we are concerned that a bonus derived exclusively from diagnosis-based, HCC risk scores does not accurately reflect the complexity of patients because they do not incorporate socio-economic factors or adequately predict expenditures of the frail elderly, where frailty is generally defined in terms of functional impairments.¹ The dual eligible ratio may better reflect the socio-economic aspects of patient complexity, but similarly doesn't offer a complete picture of a particular patient's complexity because its agnostic to the patient's diagnoses and functional impairment. We also agree, however, that it is important that CMS balance the limitations of a single indicator with the need for the bonus scoring methodology to be relatively straightforward. With these considerations in mind, we recommend that CMS calculate both the average HCC risk score and the dual eligible ratio for each eligible clinician or group and apply whichever calculation results in the better/higher score.

Additionally, we recommend that CMS explore ways to incorporate frailty adjustment into the scoring methodology, as it has in the Program of All-Inclusive Care for the Elderly (PACE). Expenditures for the frail elderly are considerably higher than the average beneficiary, and neither HCC risk scores nor the dual eligible ratio adequately account for the higher cost of their care. In PACE, frailty adjustment is applied in conjunction with the HCCs risk adjustment model. CMS calibrates the frailty factors by regressing the residual, or unexplained, costs from the CMS-HCC risk adjustment model on counts of activities of daily living (ADLs). CMS obtains ADLs from surveys of the general Medicare population and currently uses the Fee-For-Service (FFS) Consumer Assessment of Health Providers & Systems (CAHPS).² Including a frailty adjustment in the complex patient bonus methodology would help protect clinicians that care for the frailest patients from financial risk, ensuring that these vulnerable beneficiaries have access to the care they need.

¹ See John Kautter and Gregory C. Pope, CMS Frailty Adjustment Model, Health Care Financing Review, vol. 26, no. 2 (Winter 2004-2005), available at https://www.cms.gov/research-statistics-data-and-systems/research/healthcarefinancingreview/downloads/04-05winterpg1.pdf

² Medicare Managed Care Model, Ch. 7, § 80, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c07.pdf.

AGS further recommends that, for purposes of calculating the bonus, patients should be attributed only to clinicians who have a continuous/broad relationship with the patient. HCC risk scores are designed to predict the total cost of care, but do not necessarily correlate with the complexity of a patient from the perspective of a particular specialist addressing a limited aspect of the patient's overall care. For instance, we do not believe it would be appropriate to attribute a complex patient with COPD and congestive heart failure to a dermatologist who sees the patient for an annual skin exam. The dermatologist is not treating the complexity. HCC risk scores related to the total cost of care, which is tied to a continuous care relationship. Moreover, attributing patients for any patient relationship other than broad/continuous may result in clinicians gaming the system by documenting comorbidities unrelated to the particular patient's care.

B. <u>Cost Performance Category</u>

1. Cost Performance Category Weight and Scoring Methodology

AGS strongly supports CMS's proposal to weigh the Cost performance category at zero for the CY 2018 performance year. Additionally, because we understand that CMS is statutorily required to weigh the Cost performance category at 30 percent beginning in CY 2019, we recommend that CMS establish scoring policies, as described below, to minimize the impact of such a substantive change in weight and allow for a more gradual impact of cost measures on a clinician's overall performance.

In CY 2019, when the Cost performance category will represent 30 percent of an eligible clinician's CPS, CMS should establish a minimum floor of 3 points for Cost measures, as it did for Quality measures in Transition Year and proposes to continue for CY 2018. Additionally, all new episode-based cost measures should be assigned a score of zero for at least the first year of inclusion in the Cost performance category so that they can be beta-tested.

These policies will not only allow additional time for eligible clinicians to become more comfortable with the cost measures, but also allow CMS time to analyze clinicians' performance on the measures to better understand whether they inappropriately favor or harm particular specialties, as well as determine if certain specialties or clinician types have such insufficient numbers of attributed patients for the cost measures that they aren't being measured on costs at all. CMS could begin to obtain such understanding through extensive modeling and analysis of CY 2016 and CY 2017 claims data for at least the two measures CMS proposes to finalize for CY 2018 -- the total cost per capita measure and the Medicare spending per beneficiary measure. As CMS develops new episode-based measures, it should conduct similar analysis and maintain a zero score for each measure until CMS is confident that the measure is properly structured, with appropriate risk adjustment and attribution, so that it is not disproportionately harming particular specialties or encouraging scrimping on necessary care. The results of this analysis should be published prior to cost measures being scored for purposes of the Cost performance category percentage score to allow all stakeholders an opportunity to provide meaningful feedback. As mentioned above, a key aspect of creating sound cost measures is appropriate patient attribution. To this end, we urge CMS to move as quickly as possible to finalize patient relationship categories and codes and incorporate them into the attribution methodology for cost measures. Additionally, as cost measures are implemented and eventually scored, CMS must closely monitor their effects to prevent inappropriate reductions in services and negative consequences for patient care.

2. Measuring Costs for Primary Care Physicians

Most geriatrics clinicians identify themselves as primary care providers. We provide primary care to the sickest and most complex Medicare beneficiaries, a population characterized by the presence of multiple, co-existing chronic conditions and a high prevalence of frailty. Patients with multiple chronic diseases cannot be treated as though these conditions exist independently of one another.

A "whole patient" orientation is a core principle of geriatric primary care, indeed of all primary care. We treat patients, not diseases. It is our job to provide and/or coordinate substantially all the medical care our patients need. We aspire to deliver "person-centered care." By understanding the full picture, taking into account the complexity of multiple diseases, medications, and symptoms, as well as the patient's values and preferences, we strive to balance the benefit and burden of recommendations across the whole of an older person's well-being. Ultimately this supports patients and their families and caregivers in making informed medical decisions that are consistent with their health and life goals. The nature of our work corresponds to the "continuous/broad" patient relationship category that CMS has proposed. An approach to evaluating cost performance that looks at the cost of treating patients, rather than diseases, will align better with the mission and goals of geriatric care.

Payments to primary care providers account for only about 5 percent of the Medicare dollars, making these payments an unlikely source of significant savings. However, high quality primary care is associated with overall health care cost savings. Accordingly, episode payments to primary care would be unlikely to achieve cost goals and might adversely affect overall costs. Incentives that promote reduction in payments to primary care would result in less primary care engagement with patients and higher overall costs, and would be inconsistent with the expectations and roles of primary care in health reform.

Primary care providers have an outsize influence on overall costs through the downstream impact of their decisions. Incentives that reward good stewardship of system resources, efforts to avoid unnecessary high cost and/or low value services, and more effective chronic disease care and management would address the sphere of influence of primary care on cost. Although primary care providers do not directly control downstream costs like hospitalization, imaging, and procedures, there can be no doubt that they exert substantial influence on utilization. Most importantly, incentives are insufficient in most cases to support necessary investment in transforming primary care to best serve population management.

The diagnosis and procedure-focused model of defining episodes described is relatively well-suited to the procedural and acute medical episode types that have been the focus of the cost measure development work thus far. We believe that extending this concept to chronic disease care will be exceptionally challenging, especially when most beneficiaries have multiple chronic conditions, and often interrelated diseases. We previously shared our thoughts on these challenges with CMS in our April 24, 2017, letter regarding episode-based cost measure development so we will not reiterate them here.

The AGS believes that the measure "Total per capita Medicare Part A and B costs/year," which CMS has already finalized as a cost measure for the MIPS cost performance category, is the best initial metric for assessing the cost-effectiveness of primary care providers, including their care for patients with multiple chronic diseases. We believe this measure is the most accurate way to fulfill MACRA's mandate to evaluate a primary care provider's cost performance. This approach offers multiple advantages:

- It is consistent with the "whole patient" orientation of primary care.
- It is a measure that, if adequately risk-adjusted, reflects the influence of both the provider's clinical effectiveness and his or her stewardship of taxpayer dollars. It encourages more effective chronic care, care coordination, and prudent use of costly downstream resources.
- It covers virtually the entirety of a provider's practice and serves to ameliorate to a degree the small numbers problem.
- It avoids entirely difficult issues of attribution of costs to individual disease-specific episode groups in patients with multiple chronic diseases. It permits the application of the HCC risk adjustment system, which has proven utility in Medicare Advantage and in CMS population-based payment environments, and proven capability to provide meaningful risk adjustment.
- Similar measures of primary care cost influence have been used extensively by provider groups participating in Medicare Advantage, and enjoy widespread acceptance by providers as useful measures of performance.

With the advent of patient relationship codes, however, we recommend that the existing two-step attribution process for this measure be replaced. Specifically, a patient and his associated Part A and Part B costs should be attributed to a provider who attests to having a continuous/broad relationship through claims data. This methodology will more accurately attribute patient costs to the provider— usually a primary care provider—that has a real, ongoing relationship with a patient rather than to the provider that merely has the largest share of allowed charges for primary care services. Primary care providers that have a continuous/broad relationship to their patients are much more likely to be able to influence those patients' quality of care and the prudent stewardship of associated resources. Therefore, it is both fairer and more effective as a cost-containment approach to attribute a patient's total Part A and Part B costs to those physicians.

C. Quality Performance Category

1. Topped out Measures

CMS is proposing a 3-year process for identifying and removing topped out measures, special scoring for measures identified as topped out in the published benchmarks for two consecutive performance periods, starting with the 2018 MIPS performance period. Given the large percentage of topped out measures, especially claims measures, we advise extreme caution in removing and/or adjusting the scoring for topped out measures. We are concerned that disincentivizing the use of topped out measures by placing a ceiling on their points, and then ultimately removing them, may lower quality of care related to those measures. Given the limited resources and time available to many eligible clinicians, we believe it is naïve of CMS to assume that the practices associated with those measures will be maintained without financial incentives. Moreover, without clinicians reporting those measures, CMS will have limited ability to monitor and assess whether there have been changes in the quality of care as a result of removing the measures. We also are concerned that certain specialties, including those without a relevant registry/QCDR like geriatricians, may be disadvantaged by CMS' proposal.

Given these concerns, we appreciate CMS' proposal to begin with only six topped out measures. We believe a slow and thoughtful process for removing topped out measures, rather than a blanket policy for all topped out measures, is the appropriate approach. CMS should carefully consider the potential effects of removing a particular measure, including through soliciting feedback through notice and comment rulemaking, before identifying it for this process. CMS also needs to work with measure stewards to adopt new MIPS quality measures to replace measures being removed, especially if the

removed measures are going to disproportionately affect a particular specialty. We urge CMS to support measure development as smaller societies do not have the resources to invest in this activity.

2. Improvement Percent Score

AGS supports measuring improvement as part of the Quality performance category percent score. While we understand CMS' desire to measure improvement at the performance category level to allow eligible clinicians flexibility in choosing measures, we recommend that CMS monitor improvement scores for gaming or trends showing that eligible clinicians are tending to select new measures rather than improvement on previously reported measures.

D. Alternative Scoring Option based on Facility-Based Measurement

AGS is generally supportive of providing facility-based clinicians the option of using facility-based measures to assess their quality and cost performance because it will ease the reporting burden on clinicians. We urge CMS to consider providing this option for other sites of service, such as skilled nursing facilities (SNFs) using the SNF Quality Reporting Program, so that other clinicians may take advantage of this option.

However, it is difficult to provide meaningful feedback on the specific proposal without better understanding the impact of these policies on non-facility-based clinicians. For instance, it is unclear whether facility-based clinician's data will be included in measure benchmarks. Will facility-based clinicians' costs be included in establishing the cost measure benchmarks? To the extent these clinicians have submitted quality measures during the benchmark period, will those scores be incorporated into the benchmarks used for the MIPS quality performance achievement score? Additionally, prior to finalizing these policies, CMS should conduct modeling analysis to determine how non-facility-based clinicians' performance in the Quality and Cost performance categories changes when facility-based clinicians are removed and share that information for public comment. Similarly, once finalized, CMS should carefully monitor and assess the impact of its facility-based measurement policies on non-facilitybased clinicians to ensure that these clinicians are not disadvantaged by removing facility-based clinicians from the normal scoring methodologies.

E. Virtual Groups

In the Proposed Rule, CMS establishes policies for virtual groups as a new way for clinicians to participate in MIPS starting in performance year 2018. Generally, CMS proposes that a virtual group would consist of two or more solo practitioners or groups of 10 or fewer MIPS eligible clinicians who combine "virtually" to participate in MIPS for a given performance period. There is no limit on the number of eligible clinicians or groups that may make up a virtual group. Although AGS supports the concept of virtual groups, there are many unknowns regarding how virtual groups will work in practice. Therefore, AGS advises CMS to exercise caution when implementing the proposed policies regarding virtual groups.

AGS recommends that CMS implement virtual groups for the 2018 performance period for "betatesting" only. As evidenced by CMS' expectation that only 16 virtual groups for the 2018 performance year,³ it is apparent that most solo practitioners and groups of 10 or fewer MIPS eligible clinicians are

³ 82 Fed. Reg. at 30213.

unprepared to be part of a virtual group. AGS recommends that CMS permit clinicians, at least for the CY 2018 performance year, to sign up as a virtual group and receive feedback about their performance as a virtual group; however, their CPS would be scored as either an individual or a small group under the normal policies. This policy would encourage clinicians to elect to form virtual groups without the risk associated with participating in an untested policy. Furthermore, such a policy would encourage virtual group participation despite the limited time available to form a virtual group prior to December 1, 2017.

This policy would also give CMS the opportunity to solicit additional feedback from stakeholders before fully implementing virtual groups. There is uncertainty regarding how virtual groups will form, what types of contractual arrangements they will enter into, and how the entities that form virtual groups will interact. AGS believes that stakeholders who have entered into, or contemplated entering into, beta-tested virtual groups can offer CMS valuable insight into potential benefits and pitfalls of virtual groups. After soliciting feedback and information, CMS can more easily make clear and practical proposals related to virtual groups.

We also recommend that CMS think through the potential risks for virtual groups under the federal prohibition on physician self-referrals, known as the Stark Law,⁴ and whether a regulatory exception would be necessary to successfully implement and maximize the advantages of the virtual group option. The Stark Law prohibits a physician from referring Medicare patients to an entity for the furnishing of "designated health services" (DHS)⁵ if the physician (or one of his or her immediate family members) has a direct or indirect financial relationship with the entity, unless the relationship fits within an exception. In the proposed rule, CMS states that "qualifications as a virtual group for purposes of MIPS do not change the application of the physician self-referral law to a financial relationship between a physician and an entity furnishing designated health services, nor does it change the need for such a financial relationship to comply with the physician self-referral law."⁶ However, CMS also proposes to require virtual group members to execute formal written agreements, and as part of that, it's quite possible that virtual group members will want to enter into financial arrangements with each other to maximize the benefit of the virtual group, for instance, by paying a fair market value fee to one member of the virtual group to organize and submit all measures on behalf of the virtual group. Such an arrangement likely would result in virtual group members being unable to refer patients to one another without running afoul of the Stark Law, unless CMS established an exception for virtual groups.

F. Application of MIPS Payment Adjustment to Items Paid Separately under Part B

AGS strongly believes that CMS should apply the MIPS payment adjustment only to professional services paid under the Medicare Physician Fee Schedule (PFS). Because the statutory provision establishing the MIPS payment adjustment is part of SSA § 1848, which relates to payment under the PFS, AGS believes this provision refers only to those "items and services" paid under the PFS.⁷ If Congress had intended to

⁴ 42 U.S.C. § 1395nn(a)(2).

⁵ 42 C.F.R. § 411.351. "Designated Health Services" include clinical laboratory services, radiology and certain other imaging services, durable medical equipment and supplies, home health services, outpatient prescription drugs, and outpatient hospital services.

⁶ 82 Fed. Reg. at 30028.

⁷ SSA § 1848(q)(6)(E) (providing ""in the case of items and services furnished by a MIPS eligible professional during a year (beginning with 2019), the amount otherwise paid under this part with respect to such items and services and MIPS eligible professional for such year" shall be subject to the MIPS payment adjustment).

apply the MIPS payment adjustment to Part B drugs and other items, it could have placed the MIPS payment adjustment provisions in a different section of the Social Security Act, or specifically referenced sections 1827, establishing payment for covered outpatient drugs, or 1861(t), defining drugs and biologicals.

In the Proposed Rule, however, CMS states that "[f]or those billed Medicare Part B allowable charges relating to the purchasing and administration of Part B drugs that we are able to associate with a MIPS eligible clinician at an NPI level, such items and services furnished by the MIPS eligible clinician would be included for purposes of applying the MIPS payment adjustment or making eligibility determinations."⁸ This sentence is confusing and does not provide a clear proposal that AGS can adequately address. It is clear, however, that it would be exceedingly unfair to apply the MIPS payment adjustment to anything other than covered professional services in 2019. Neither the CY 2017 proposed or final rules indicated that CMS would apply the MIPS payment adjustment to separately reimbursable Part B drugs and supplies, and the CY 2017 performance period, on which the CY 2019 payment adjustment will be based, is already well underway. Most eligible clinicians would assume, based on prior experience with CMS programs, such as PQRS, the Medicare EHR Incentive Program, and VM, that only fees associated with covered professional services would be adjusted.

More generally, we are concerned that a policy that applies the payment adjustment to Part B drugs could negatively affect access. Given the large number of clinicians who received a negative payment adjustment under the VM program, we suspect large numbers of eligible clinicians could receive a negative MIPS payment adjustment, especially beginning in 2021 when CMS is statutorily-mandated to set the performance threshold at the mean or median of the final MIPS scores of all MIPS eligible clinicians.⁹ Eligible clinicians have more control on the overhead costs associated with the provision of services -- they can work to create efficiencies, adjust staffing, etc. while still providing the same level of care. Conversely, the cost of purchasing a drug is set and outside the control of the eligible clinician. The only way for a clinician to ensure that he or she does not experience a financial loss on Part B drugs due to a negative MIPS payment adjustment is to simply stop purchasing the drugs, resulting in their patients losing access to life-saving Part B drugs.

G. <u>Reweighting for Extreme and Uncontrollable Circumstances</u>

AGS supports CMS' proposed reweighting policy for the Quality, Cost, and Improvement Activities performance categories in cases of extreme and uncontrollable circumstances. We seek clarification that if CMS deemed that an eligible clinician had an extreme and uncontrollable circumstance that affected his ability to collect or submit information, the reweighting would be zero (rather than some other weight at CMS' discretion). Additionally, we ask that CMS provide additional guidance as to what circumstances would qualify for the Cost category to be reweighted to zero since cost measures do not require the collection or submission of data, but could nonetheless be greatly affected by extreme and uncontrollable circumstances.

⁸ 82 Fed. Reg. 30010, 30019 (June 30, 2017).

⁹ SSA § 1848(q)(6)(D)(iii) permits CMS, for the first two performance years only, to set the performance threshold to a number other than the mean or median of the final MIPS scores of all MIPS eligible clinicians.

II. Advanced Alternative Payment Models (APMs)

The AGS continues to be disappointed with CMS's approach to defining the financial risk criterion for Advanced APMs.¹⁰ 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 are unavailable to most geriatricians given the limited geographic reach and specialization of the current Advanced APMs.

MACRA 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."

In the CY2017 Quality Payment Program Final Rule (CY2017 Final Rule), CMS finalized that an APM bears financial risk in excess of a "nominal amount" if the amount the APM Entity potentially owes CMS or forgoes is equal to at least either (1) 8% of the average estimated total Medicare Part A and Part B revenue of [providers and suppliers in] participating APM Entities (the revenue-based standard), or (2) 3% of the expected expenditures for which an APM is responsible under the APM for all QP Performance Periods (the benchmark-based standard). In the Proposed Rule, CMS proposes to maintain these standards for the CY 2018 Performance Period. Additionally, CMS interprets this statutory requirement to only encompass "losses" that could be incurred through either direct re-payments to CMS or withholdings/reductions in payments for services.

The AGS believes that, consistent with the statute, CMS should adopt a more inclusive definition of "financial risk for monetary losses" -- designating as Advanced APMS, those models that take on onesided risk and otherwise meet the statutory and regulatory requirements and lowering the applicable percentage of risk required for both the revenue-based standard and the benchmark-based standard.

Financial Risk for Monetary Losses. 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.

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

¹⁰ Given that our members' patients are primarily Medicare beneficiaries, our comments focus on Medicare Only Option, but are generally applicable to the All-Payer Combination Option, as well.

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.

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.¹¹

Additionally, 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. Now that the intent is to tie payments to quality or value as much as possible, providers are unable to sustain their practices on base payments alone and "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. CMS has said that "nominal amount" means "an amount that is lower than optimal but substantial enough to drive performance."¹² 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."¹³ 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." If Congress had wanted Advanced APM entities to accept substantial financial risk, it would have explicitly required that.

APMs are still a relatively new structure paradigm and most clinicians have little experience with taking on significant financial risk. Many clinicians would be financially challenged to provide sufficient care or even remain a viable business if they were faced with the kinds of substantial disruptions in revenue that can accompany financial risk arrangements. These very real concerns, especially given the magnitude of risk CMS requires for participation in an Advanced APM, prevent many clinicians from considering participation in the limited Advanced APMs available. CMS seems to recognize these concerns in the context of Medical Home Models. CMS had previously finalized a much more

¹¹ National Association of ACOs, National ACO Survey, conducted November 2013, Final report January 1, 2014, at 1 (emphasis added).

¹² 81 Fed. Reg. at 28306.

¹³ Merriam-Webster (online edition), available at <u>http://www.merriam-webster.com/dictionary/nominal</u>.

incremental approach, using much small percentages of revenue, to establishing nominal risk for Medical Home Models. In the Proposed Rule, CMS proposes to increase the percentage of revenue at stake even more gradually. We disagree with CMS that these models have such special characteristics that this approach is appropriate only for them, but not other APMs.

AGS appreciates that CMS is considering a lower revenue-based nominal risk amount for small and rural practices. We strongly support any steps that make participation in the Advanced APM pathway more tenable for clinicians. CMS states that it believes that a different, potentially lower, revenue-based nominal amount standard "may allow for increased participation in Advanced APMs, which may help increase the quality and coordination of care beneficiaries receive as a result."¹⁴ We agree with this premise but would argue that it is equally true for clinicians in APM Entities and groups of all sizes. Consistent with the plain language of the statute and the intent to encourage APM participation, CMS should lower the nominal risk amount for both the revenue-based standard and the benchmark-based standard, across all clinicians. As currently structured, the magnitude of risk required makes participation in an Advanced APM an impossibility for many clinicians, including most geriatricians, other than those in the largest multi-specialty group practices, academic medical centers, and integrated health systems.

CMS should be encouraging APM participation not 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. 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. 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.

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,

Ala Salih

Debra Saliba, MD, MPH, AGSF President

¹⁴ 82 Fed. Reg. at 30174.

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