Sound Policy. Quality Care.

August 21, 2017

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-5522-P, Medicare Program, CY 2018 Updates to the Quality Payment Program, 42 CFR Part 414

Submitted electronically via Regulations.gov

Dear Ms. Verma,

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians from 13 specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy. For this reason, we are pleased to provide input that will inform your implementation of Year 2 of the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) under the Quality Payment Program (QPP) established as part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

General Sentiments on Year 2 Proposals for the Medicare Quality Payment Programs

We greatly appreciate the considerable flexibility and incentives for small practices CMS incorporated into its proposed policies for Year 2 of the QPP, many of which will benefit specialty physicians. Nevertheless, we continue to believe specialists will struggle with the reporting and performance requirements, primarily under the MIPS, and that patient health and outcomes will not significantly improve commensurate with the time and effort specialists will expend to engage in the program. This is particularly true now that only 37 percent of professionals billing under Medicare Part B are expected to be included in MIPS.

The fragmented nature of the MIPS performance categories, each with different reporting requirements and complex scoring mechanisms, are also a constant challenge for providers to understand. Despite our best efforts to simplify and distill the information, many are still confused about how to participate. CMS' QPP website is filled with a plethora of information, yet many practices are unable to apply it practically. Unfortunately, the QPP HelpDesk has provided incorrect interpretations of MIPS program

information, which leads to further misunderstandings and frustration. CMS must work to streamline the MIPS, integrating the performance categories into a more cohesive program, and simplify the scoring, so it is well understood by participants. More training, educational tools, and technical assistance are also needed, particularly for specialty physicians.

MIPS Program

MIPS Eligible Clinicians

We strongly disagree with CMS' policy to include Part B drugs in the calculation of MIPS payment adjustments and eligibility determinations. Finalizing this policy would be a violation of the Administrative Procedures Act (APA), and we do not believe this was Congress' intent when drafting the legislation. **CMS must reconsider its policy and exclude Part B drugs from MIPS eligibility determinations and payment adjustments. MIPS payment adjustments should only apply to covered PFS services.**

Historically, Part B drugs have been excluded from payment adjustments under CMS quality reporting programs, such as the Physician Quality Reporting System (PQRS), Value-Based Payment Modifier (VM) and Electronic Health Record (EHR) Incentive Program. In the 2017 QPP final rule, CMS deferred commenter questions as to whether Part B drugs would be included in the MIPS program, stating it would "consider this issue and provide clarification" in the future. In this proposed rule, CMS has not offered a clear proposal; rather it appears to be "clarifying" what it believes to be existing policy under MIPS but still does not provide the clarity necessary to make meaningful comments.

Under the Administrative Procedures Act (APA), a final rule must be a logical outgrowth of a proposed rule. What has been outlined in this rule is not a clear proposal, rather CMS provides a confusing "clarification" of what it suggests is existing policy under the MIPS program. Without a clear proposal for stakeholders to consider and provide comment, the logical outgrowth test cannot be met. As a result, we firmly believe CMS would violate the APA should it finalize the confusing "proposal" described in the preamble.

Furthermore, we disagree with CMS' interpretation of the statute, which led it to believe that Part B drugs are subject to the MIPS payment adjustment. CMS contends that Section 1848(q)(6)(E) requires the agency to apply the MIPS payment adjustment to services rendered under Part B. However, Section 1848 of the Social Security Act (the Act) is entitled "payment for physician services" [emphasis added] and pertains to payment under the physician fee schedule (PFS). If Congress meant for MIPS adjustments to apply to items and services outside the PFS, it would have stated that *explicitly*, or placed the MIPS adjustment provisions in a different section of the Act to make clear that they apply to items and services going beyond those paid under the PFS. As noted above, adjustments under predecessor programs applied only to PFS services, and MIPS was expressly designed to consolidate and streamline those adjustments – not expand them. Moreover, under the Advanced APM track of the QPP, Part B drugs are not included in the incentive payment. There is no reason to believe Congress meant for the MIPS adjustment to apply to more services than the Advanced APM incentive.

Low-Volume Threshold

The Alliance supports CMS' proposal to modify the low-volume threshold to exclude individual eligible clinicians or groups that have Medicare Part B allowed charges less than or equal to $90,000 OR that provide care for 200 or fewer Part B-enrolled Medicare beneficiaries. However, we believe it is important to allow those clinicians who wish to participate in MIPS the ability to opt-in beginning with performance year 2018, although they should be held harmless from any penalties if they are unsuccessful given they are not *required* to participate. In addition, clinicians that are newly eligible in MIPS, such as those who suddenly exceed the low-volume threshold or are no longer newly enrolled in Medicare should be held to lower reporting requirements and alternative scoring in their first performance year. This "on-ramp" will help new eligible clinicians transition and integrate more easily into the MIPS program.

Group Reporting

We appreciate CMS' request for comment on ways to establish group-related policies that would permit a portion of a group to participate in MIPS outside the group by reporting as a separate subgroup using a new identifier. **The Alliance fully supports this concept**, which would be particularly beneficial for many specialty physicians, such as those practicing in large multispecialty group practices. However, we are concerned about the complexity and potential administrative burden that may come with the use of a new identifier. We look forward to a robust proposal that we can respond to with more substantive comment.

Virtual Groups

CMS' proposal to implement virtual groups is incredibly complicated, leaves many questions unanswered, and will be difficult for most practices to apply under the proposed timeframes. Many groups have discussed the idea of forming a virtual group in 2018 with their practice attorney and have been cautioned on entering into any contractual relationship, given a final rule will not be published until Fall 2017. We also worry that the administrative burden of virtual groups is unknown. We believe pilot testing is necessary to see if this concept is truly feasible for practices and the agency. For most specialty physicians, the "separate subgroup" concept (i.e., group-related policies that would permit a portion of a group to participate in MIPS outside the group by reporting as a separate subgroup using a new identifier) is more appealing and in line with their needs. Finally, it is hard to imagine how many virtual groups will form absent a mechanism for disparate practices to connect with one another. To that end, **we urge CMS to delay implementation of virtual groups until 2019, which will give the agency time to resolve many of these issues and pilot test the virtual group concept.**

MIPS Performance Category Measures/Activities

Submission Mechanisms

Beginning with 2018, CMS proposes to allow individual MIPS eligible clinicians and groups to submit data on measures and activities, as applicable, via multiple data submission mechanisms for a single performance category. Despite the initial appeal, we have significant concerns with this proposal. As CMS points out, this increased flexibility may create complexity and cost burden for physicians. We believe that it *significantly* adds to the cost and administrative burden for those participating in MIPS.

We are also confused how this policy would intersect with CMS' plans to implement the new Eligible Measure Applicability (EMA) validation process. Physicians should not be held accountable to meeting more measures simply because CMS is making additional submission mechanisms available. Finally, we are concerned with CMS plans for setting benchmarks and scoring quality measures submitted through multiple mechanisms. In the rule, CMS clarifies that if an individual MIPS eligible clinician or group submits the same measure through two different mechanisms, each submission would be calculated and scored separately since CMS does not have the ability to aggregate data on the same measure across submission mechanisms. In this scenario, CMS would only count the submission that gives the clinician the higher score, thereby avoiding the double count. This scenario appears to assume that the individual or group submitted the same measure through different mechanisms across the same timeframe. However, if an individual MIPS eligible clinician submits the same measure through two different mechanisms, during different timeframes (e.g., the individual submitted data through claims for the first half of the year and through a qualified registry for the second half of the year), it is not entirely clear how the clinician would be calculated and scored. We do not believe simply calculating a score for half of the year using one submission mechanism would be fair, given the physician reported for the entire year. Challenges such as this will be particularly important to rectify as longer reporting durations are mandatory.

For the reasons listed above, **we urge CMS to thoroughly consider whether offering multiple submission mechanisms for a single performance category is necessary.**

Quality Performance Category

We oppose CMS' proposal to increase the data completeness thresholds to 60 percent for each submission mechanism beginning with the 2021 MIPS payment year (i.e., the 2019 performance year). The constant flux in reporting requirements year after year poses significant administrative challenges for physicians and their administrative staff. **The Alliance urges CMS to maintain its current data completeness threshold of 50 percent for the 2021 MIPS payment year.**

We also oppose CMS' proposed 3-year timeline for identifying and proposing to remove "topped out" measures. CMS is aware that many specialties already lack a sufficient number of measures in the MIPS program. By topping out more measures, this would leave some specialties with few quality measures on which to report, if any. At that point, some physicians will be forced to report measures that have little, if any, relevance to their clinical practice. Moreover, CMS is not taking into consideration that removing so-called "topped out" measures could lead to a performance gap in areas that were showing improvement. Measures may appear "topped out" in the context of the MIPS program, but CMS cannot determine whether performance is really at its peak when so few physicians are participating in the program. By CMS' data alone, only 37 percent of clinicians will be eligible to participate if key proposals in this rule are finalized. Quality measures undergo regular maintenance by their owners with input from physicians who use the measures to ensure they reflect the most recent clinical practices and guidelines. This regular maintenance should not be overlooked by CMS, and therefore measures should not be removed as "topped out" without a request they be withdrawn by the measure stewards or going through a transparent process allowing for comments from stakeholders. In addition, measures that have not been withdrawn by the measure steward or removed from the program through the

aforementioned process should continue to be eligible for full credit under CMS' scoring methodology. **We urge CMS to develop a transparent methodology for assessing the continued relevance of individual quality measures that incorporates feedback from the medical community and measure stewards.**

Cost Performance Category

The Alliance supports CMS proposal to change the weight of the cost performance category from 10% to 0% for the 2020 MIPS payment year. However, as MACRA requires the cost performance category to consume a greater proportion of the final score relative to other performance categories in future years (i.e., 30% in the 2021 MIPS payment year), we urge CMS to consider alternative weighting and scoring options for specialty physicians. We oppose CMS' continued reliance on the Total Per Capita Cost and Medicare Spending Per Beneficiary (MSPB) measures to capture the cost and resource use of specialty physicians. Specialists are working with CMS on the development of episode-based measures that are applicable to the conditions and services they manage. **Until episode-based measures are fully developed and available for use, CMS should reweight the cost performance category of MIPS to 0% for specialty physicians, beginning with the 2021 MIPS payment year.**

Improvement Activities Performance Category

CMS previously clarified that if one MIPS eligible clinician (NPI) in a group completed an improvement activity, the entire group (TIN) would receive credit for that activity. While CMS does not propose any changes to this policy, it requests comment on whether it should establish a minimum threshold (for example, 50%) of the clinicians (NPIs) that must complete an improvement activity in order for the entire group (TIN) to receive credit in the improvement activities performance category in future years. As noted earlier, the constant flux in reporting requirements year after year poses significant administrative challenges for physicians and their administrative staff. **The Alliance urges CMS to maintain its current policy and not move to a 50% reporting threshold.**

Advancing Care Information (ACI) Performance Category

We remain frustrated that the ACI performance category remains unintuitive and complex, even more so than its predecessor program. The "all-or-nothing" approach, which holds specialists accountable for measures that may not reflect how technology can best meet their practice needs or patient population, continues to perplex us. Many Alliance organizations have invested in the development of qualified clinical data registries, and find this health IT tool much more appropriate and applicable to how specialists deliver care and improve patient outcomes. Unfortunately, ACI scoring is not weighted toward the use of registries as we might have anticipated based on the clear emphasis toward registries in MACRA. CMS must retool the ACI category in a way that is meaningful for specialty physicians, providing a robust "menu" of ACI measures that specialty physicians can choose from to meet the requirements.

Regarding ACI scoring, CMS proposes if a MIPS eligible clinician cannot fulfill the Immunization Registry Reporting Measure, it could earn 5 percentage points in the performance score for each public health agency or clinical data registry to which the clinician reports, up to a maximum of 10 percentage points. While we appreciate CMS' intent not to penalize those without access to immunization registries, this

proposal diminishes the value of reporting to specialized and clinical data registries by only awarding 5 percentage points for reporting to such registries. **The Alliance believes MIPS eligible clinicians who do not have access to an immunization registry should be able to earn the full 10 percentage points for reporting to a single other recognized registry, such as a specialized or clinical data registry, and urges CMS to finalize this alternative policy.**

CMS proposes to accept a minimum of 90 consecutive days of data in CY 2019, as it previously finalized for CY 2017 and 2018. **We support this proposal.**

Regarding certification requirements, CMS proposes that MIPS eligible clinicians may use EHR technology certified to either the 2014 or 2015 Edition certification criteria, or a combination of the two for the 2018 performance period. CMS also proposes to offer a bonus of 10 percentage points under the ACI performance category for MIPS eligible clinicians who report the ACI Objectives and Measures for the performance period in 2018 using only 2015 Edition CEHRT. **We support both proposals, however, we encourage CMS to extend the 10 percentage point bonus for use of 2015 Edition CEHRT beyond 2018,** particularly for specialty physician practices, where 2015 Edition CEHRT products are more challenging to identify, secure, modify, and implement. **We encourage CMS to also consider offering a bonus for those practices that use a combination of 2014 and 2015 Edition CEHRT in 2018 and beyond.**

Specific to the ACI objectives and measures, CMS states in the rule that, "A MIPS eligible clinician may count a specialized registry if the MIPS eligible clinician achieved the phase of active engagement as described under "active engagement option 3: production" in the 2015 EHR Incentive Programs final rule with comment period, meaning the clinician has completed testing and validation of the electronic submission and is electronically submitting production data to the public health agency or clinical data registry." Proposing to require a production level of registry exchange based solely on the *electronic* exchange ignores the realities of registry reporting. We remind CMS that it has leveraged "end-to-end" electronic registry reporting as a prerequisite for bonuses. Specialists participating in these registries contribute heavily to national efforts in quality improvement, patient safety, and clinical research and should still be rewarded even if patient information is manually entered. **We are strongly opposed to this proposal. Instead, we urge CMS to remove the term "electronically" from the proposed requirement. Further, CMS should allow eligible clinicians to demonstrate "active engagement" using any of the three current options (i.e., completed registration to submit data; testing and validation; and production).**

In addition, CMS proposes to add new exclusions to the measures associated with the Health Information Exchange and Electronic Prescribing objectives required for the base score, which would apply beginning with the 2017 performance period. **The Alliance supports both exclusions, as proposed.**

To assist eligible clinicians that face difficult circumstances, CMS proposes to rely on new authorities granted under the 21st Century Cures Act to provide for significant hardship exceptions under the ACI performance category under MIPS. CMS also proposes not to apply the 5-year limitation to significant hardship exceptions. In addition, as authorized under the 21st Century Cures Act, CMS proposes a new

significant hardship exception for MIPS eligible clinicians who are in small practices, as well as for those who have EHR technology that has been decertified. **The Alliance fully supports these each of these exemptions, as well as the proposal not to apply the 5-year limitation to significant hardship exemption.**

Finally, **the Alliance supports CMS' proposal to modify its policy to include covered professional services furnished by MIPS eligible clinicians in an off-campus-outpatient hospital (POS 19) in the definition of hospital-based MIPS eligible clinician beginning with the performance period in 2018.**

MIPS Final Scoring Methodology

We are concerned with CMS' proposal to assess performance based only on the first 9 months of the 12-month performance period for those measures significantly impacted by ICD-10 coding updates. It is unclear how this proposal will adversely impact MIPS eligible clinicians and we urge CMS to provide more information. CMS should also consider maintaining a continuous 90-day performance period in MIPS performance year 2018 to mitigate some of these challenges.

Scoring the Quality Category

CMS notes that, because of its proposed increase to the low-volume threshold, MIPS benchmarks could be affected as fewer individual eligible clinicians and groups would meet the definition of a MIPS eligible clinician to contribute to benchmarks. The Alliance agrees that this will be a challenge, but we are concerned with including PQRS, and any data from MIPS, including voluntary reporters, to create MIPS benchmarks. For example, CMS is aware that the reporting standard under PQRS was less rigorous, given the program was geared toward reporting – not performance. As a result, the introduction of this data could skew the benchmarks inappropriately. **We urge CMS to consider other options to address the challenge with establishing benchmarks.**

Regarding stratification, the Alliance previously noted that CMS does not appropriately and adequately account for all specialties and subspecialties in scoring metrics. For example, subspecialty groups that do not have a separate specialty designation in Medicare are inappropriately compared to their "peers" in the broader specialty. Case in point, Mohs micrographic surgeons are identified in claims and other datasets as relatively low-quality and/or high-cost providers, because they are being compared to the whole of dermatology. Mohs surgeons focus their practice on skin cancer diagnosis and treatment, unlike a lot of other dermatologists who may be focused on other conditions, such as psoriasis or acne.

Individually, many of these subspecialty providers have urged CMS to use "Level III, Area of Specialization" codes from the Healthcare Provider Taxonomy code set to develop quality and cost benchmarks for these providers to at least somewhat level the playing field. **We again urge CMS to begin the process of developing appropriate benchmarks for these providers using the aforementioned "third-tier" taxonomy codes.**

We oppose CMS' proposal to revise Class 2 measures to include only measures that cannot be scored based on performance because they do not have a benchmark or do not have at least 20 cases, which would continue to receive 3 points. Similarly, **we oppose CMS' proposal to create Class 3 measures**, which are measures that do not meet the data completeness requirement, which would receive 1 point,

unless submitted by a small practice with 15 or fewer clinicians, in which case it would receive 3 points given concerns that data completeness may be harder to achieve for small practices with smaller case sizes. **CMS should maintain its current policy for Class 2 measures, and not create a new class of measures.** The constant flux in reporting requirements year after year poses significant administrative challenges for physicians and their administrative staff. We seek long-term stability in program requirements and believe the existing policy is essential during this second "transition year" of the MIPS program.

We also encourage CMS to provide incentives for clinicians to report new measures, as organizations have expended tremendous effort and expense to develop such measures. An incentive to report new measures may also help ensure that enough data are submitted to establish benchmarks needed for scoring.

Specific to scoring improvement, we appreciate that CMS proposes to score improvement at the category level, rather than the measure level. However, the Alliance is concerned that it will be difficult for many specialists to show improvement given CMS' proposals to remove so-called "topped out" measures. Some specialists won't have any measures on which to report if those polices are finalized. For others, it will be difficult to demonstrate improvement when their performance on existing measures is relatively high and there are few other relevant measures on which to report and show improvement. As there are multiple challenges, notwithstanding the aforementioned challenges with establishing benchmarks, **CMS should consider a phased approach to improvement scoring, beginning with a pilot test of a limited subset of eligible clinicians, in the initial years of MIPS.**

Scoring the Cost Category

As noted above, we are concerned with the cost measures used in MIPS, which are not applicable to specialty physicians. Given that, it is impossible for specialists to be scored on improvement if the current measures are not applicable. Again, **until episode-based measures are fully developed and available for use, CMS should reweight the cost performance category of MIPS to 0% for specialty physicians, beginning with the 2021 MIPS payment year.**

Calculating the Final Score

The Alliance remains concerned about the lack of appropriate adjustment for social risk in current cost and quality metrics. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has conducted studies on the issue of risk adjustment for sociodemographic factors on quality measures and cost, as well as other strategies for including social determinants of health status evaluation in CMS programs. CMS should offer proposals to incorporate social risk into MIPS without further delay. The ongoing lack of appropriate risk adjustment hinders clinicians' ability and willingness to care for the most vulnerable beneficiaries, as the resources they need to care for this population will deteriorate under the current scoring methodology. **CMS must work diligently with physician stakeholders to develop a robust and transparent risk-adjustment strategy that includes social determinants for the cost and quality performance categories.**

We support the small practice bonus of 5 points. We also support the complex patient bonus, but oppose CMS' limitation to 3 points, particularly given the *clinical significance* of this bonus compared to the small practice bonus. The complex patient bonus should be *at least* as high as the small practice bonus.

Last, **we urge CMS to consider physician illness and maternity leave as "extreme and uncontrollable circumstances" that would cause the MIPS eligible clinician to not be able to collect information that the clinician would submit for a performance category or to submit information that would be used to score a performance category for an extended period of time.**

MIPS Payment Adjustments

We urge CMS to finalized policies that would improve *long-term stability* in reporting requirements and scoring mechanisms. For example, CMS should maintain its *existing policy* for Class 2. CMS should also maintain its current policy that allows one MIPS eligible clinician (NPI) in a group to complete an improvement activity, and the entire group (TIN) to receive credit for that activity. Other examples are outlined elsewhere in our comments. As we have noted previously, the constant flux in reporting requirements year after year poses significant administrative challenges for physicians and their administrative staff.

Review and Correction of MIPS Final Score

Beginning July 1, 2018, CMS proposes to provide performance feedback to MIPS eligible clinicians and groups for the quality and cost performance categories for the 2017 performance period, and if technically feasible, for the improvement activities and advancing care information performance categories. CMS proposes to provide this performance feedback at least annually, and as, technically feasible, CMS would provide it more frequently, such as quarterly. **We support timely, informative and actionable feedback on measures that are relevant to specialty physicians.**

In prior years, CMS' feedback via Quality and Resource Use Reports (QRURs) has been largely incomprehensible to the vast majority of specialty physicians. Because the cost measures are irrelevant, the information provided has failed to provide a clear picture of how they have a direct impact on a patients total cost of care, or how they might improve the way they personally deliver and coordinate care in order to reduce resource use. Confusion about the attribution methodologies that hold them accountable for clinical conditions and spending outside their expertise and control has also been a challenge, particular since the attribution methodologies are not consistent across programs.

Public Reporting on Physician Compare

The Alliance remains concerned about public reporting of MIPS data, particularly given we are in a transition period. CMS has raised a significant number of issues that require resolution and on which it has sought feedback. We, too, have highlighted a number of concerns related to issues that would eventually inform the data that is populated on Physician Compare. We believe public reporting of most of the data is premature and will create more confusion than clarity. We also believe the 30-day preview period is too short. **We urge CMS to at least adopt a 45-day timeframe, consistent with the Open Payments program.**

APM Incentive

We continue to be frustrated by a lack of APM participation options available to specialty physicians, given the intent of MACRA to move physicians away from traditional fee-for-service and into payment models that better focus on cost and quality. While several Physician-Focused Payment Models (PFPMs) are being submitted for review and consideration through the appropriate channels, it is unclear whether these models will be recommended and adopted as Advanced APMs, and therefore, eligible for the APM incentive track under the QPP. **CMMI should continue to develop APMs that are appropriate for specialists, as well as offer guidance on how existing APMs could be altered to meet the "advanced" criteria.** It seems as if in many cases, it is simply a lack of quality metrics or concerted use of CEHRT that limit those models from Advanced APM status. If that is the case, we request that CMS work with the developers and participants of those models to make modifications that lead to Advanced APM designation.

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We appreciate the opportunity to provide comments on the aforementioned issues of importance to the Alliance. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society