



Sound Policy. Quality Care.

June 27, 2016

Andrew M. Slavitt
Acting Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-P
Submitted electronically via <http://www.regulations.gov>

RE: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Acting Administrator Slavitt:

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 the provisions outlined in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA); specifically, the Medicare Quality Payment Program (QPP), including the Merit-Based Incentive Payment System (MIPS) and alternative payment models (APMs).

General Sentiments on the Medicare Quality Payment Program

Member organizations of the Alliance have continuously sought out and developed robust mechanisms, including clinical decision support, clinical data registries, and other tools aimed at improving the quality and efficiency of care specialty physicians provide. In addition, Alliance member organizations have analyzed and heavily scrutinized data related to the services they provide, looking for ways to improve how they diagnose, treat, and manage some of the most complex healthcare conditions in their respective specialty areas. With those sentiments in mind, the Alliance is eager to engage in programs that would further these efforts with incentives and technical assistance.

Despite the considerable and often overwhelming effort the Alliance put into helping shape provisions in the MACRA legislation, as well as the ongoing feedback provided during the many pre-rulemaking comment and feedback opportunities, we are dismayed that several of the principles we have long supported and conveyed to the agency were largely ignored. This is particularly true when it comes to proposals associated with the use of electronic health records (EHRs), the application of socioeconomic risk factors in quality and cost metrics, and most importantly, substantial disparities in QPP

requirements that significantly disadvantage specialty care providers and the patient populations they serve.

We are grateful for the multiple occasions CMS sought the advice and counsel of medical professionals in shaping the new payment system for physicians, yet a majority of our requests did not find their way into CMS' QPP proposals. In fact, a close review of our comments on the MIPS and APMs Request for Information show that much of this feedback is not reflected in the rule nor do we see evidence that the substantive comments we provided made any difference in how CMS attempted to reshape its quality and performance improvement programs.

CMS has spent many months putting together a massive set of proposed policies that will completely overhaul how physicians are paid under Medicare for providing care to seniors and the disabled. We hope that our comments herein will move CMS to address some of the most pressing issues facing specialty medicine, removing barriers that limit meaningful specialty physician engagement, and offering all specialists and non-specialists equal opportunities to demonstrate quality in a relevant manner.

Delay of the MIPS Performance Period

Given the breadth of proposed changes to CMS' quality and performance improvement programs, we are very concerned about the timeframe in which the agency expects to begin evaluating specialty physician performance. We are sympathetic to the administrative challenges CMS faces in operationalizing the new program. However, Alliance member organizations are concerned that specialty physicians will not be able to adapt under the proposed rigorous schedule.

Even before MACRA was signed into law, specialty societies were educating their members on the anticipated changes. Unfortunately, and not unlike with other CMS programs, the challenge of educating physicians on these new programs has been difficult, to say the least. We find that many of our specialty society staff are still educating members on CMS' long-standing quality programs, including the Physician Quality Reporting System (PQRS) and Value-Based Payment Modifier (VM)/Physician Feedback Program. As you know, PQRS continues to have relatively low participation rates, and those facing adjustments under the VM do not understand exactly from where those penalties stem. As a significant portion of the MIPS is based on the PQRS, which continues to suffer from critical measure gaps in regards to specialty medicine, as well as the flawed VM and problematic Quality and Resource Use Reports (QRURs) distributed under the Physician Feedback Program, we are deeply concerned about the impact this will have on specialty physicians.

As most specialty physicians will not be ready on January 1, 2017 to begin MIPS, CMS should delay the MIPS program and provide a shorter reporting/performance period in 2017 (e.g. 6 months) (with an optional "look-back" to January 1 in 2017) if they believe it is more appropriate for their practice. CMS should maintain this shorter reporting/performance period in future years of the program (with an optional "look-back" to January 1), in addition to any year-long reporting requirements, beginning in 2018. This shorter reporting/performance period will provide a necessary "on-ramp" for many specialty physicians who will be new to the program. And, it is consistent with approaches CMS has taken previously with the Medicare EHR Incentive Program.

Provide Robust Education on MIPS

As noted above, specialty societies have been working to educate specialty physicians on the new MACRA programs since before the law was enacted. We recognize that CMS has done the same, and we appreciate how available CMS staff and officials have been in responding to as many questions as possible, both before and after the release of the rule.

We request that CMS continue providing robust education through a variety of media, using both regional and national outreach, including but not limited to:

- Webinars and audio conferences
- Easy-to-read and find FAQs
- Simple process diagrams
- Telephonic and email hotlines with hours extended beyond regular office hours
- Specialty society-level education
- Office administration education
- Use of QIOs to assist in technical assistance outreach

We recognize that travel funding has been an issue, therefore, we request that CMS discuss internally how it can maximize its existing travel budgets by partnering with national medical specialty societies, such as those in the Alliance, as well as with state and local specialty medical societies, to help address some of the nuanced issues that are difficult for specialty physicians and their staff to discern through Web and teleconference events. We request that CMS expand its educational efforts to include “Train the Trainer” sessions so that medical specialty societies can identify specialty physician “champions” willing to undergo extensive training, so they can be a conduit for CMS education on the QPP, and especially MIPS, given that arm of the program is the most likely mechanism under which physicians will have their payments adjusted under the fee schedule.

Release Funding for Quality Measure Development

Cornerstone to both programs under the QPP is quality measurement. However, as CMS is aware, funding for these activities is resource intensive. Under MACRA, funding for these activities was made available, and these funds have been appropriated and dispersed to CMS. We are frustrated that these monies have not yet been distributed, despite CMS’ awareness that measure development activities take a significant amount of time, anywhere from 18- to 36-months. Alliance member organizations have repeatedly requested that these funds be released so that important measure development can ensue, particularly for the subspecialty physicians that have few, if any, quality measures available. Given existing measurement gaps within specialty medicine, we request that CMS release the quality measure development funding immediately before even more time is lost.

Improve Engagement for Specialty Care Physicians

As we discuss in more detail below, several aspects of the MIPS program put specialty physicians at a significant disadvantage. For example, CMS has revamped what was the “Meaningful Use” program under the Advancing Care Information (ACI) performance category. While CMS touts these modifications as a departure from the previous “all-or-nothing” approach to the Medicare EHR Incentive Program, specialty physicians observe little change in how they can approach the new

requirements and be successful. This is because under CMS' base scoring proposals, they must still report on at least one patient for each of the measures in the objectives that require reporting a numerator/denominator. The measures that CMS has retained are every bit the same and even more difficult with the proposed removal of most exclusions. We see no added flexibility here to demonstrate meaningful use in innovative ways that are unique to specialty medicine.

In addition, under the Clinical Practice Improvement Activity (CPIA) category, there are very few activities that create a pathway for specialists to earn credit for their engagement in clinical practice improvement. For example, the Alliance urged CMS to include continuing medical education and specialty medical fellowships, as well as specialty-focused practice accreditation, as CPIAs. Our review of the 94 CPIAs does not include the vast majority of what we requested nor did CMS acknowledge that it had at least considered these activities for inclusion. We strongly believed these would have "made the cut" given the activities recommended are based on solid evidence that proves they improve the quality of care provided. Moreover, they were easy for CMS to verify through the entities that sponsor the activities. Sadly, this was the one category where Alliance member organizations had the most hope that their respective memberships could, once and for all, be recognized for the activities in which they are engaged that improve quality, efficiency, and clinical practice.

Other examples of specialty medicine disparities in the MIPS performance categories, as well as other aspects of the MIPS program as a whole, are outlined below.

Account for All Specialties and Subspecialties

Member organizations in the Alliance represent specialty and subspecialty organizations, however, CMS' current proposals do not recognize all of these specialties and subspecialties on their own. For example, CMS began recognizing interventional cardiology as a separate specialty in 2015, yet benchmarking data proposed for use in MIPS quality and cost metrics is based on 2014 and earlier data. As a result, interventional cardiologists would not be compared to their actual peers in the 2017 performance year. Interventional cardiologists diagnose, treat and manage the sickest patients with coronary artery disease (CAD), thus, they should be separately recognized in terms of their cost and quality.

Subspecialty groups that do not have a separate specialty designation in Medicare face similar challenges, given they are largely compared to their "peers" in the broader specialty. For example, 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 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 request that CMS begin the process for developing appropriate benchmarks for these providers using the aforementioned "third-tier" taxonomy codes.

Overall, the lack of specialty and subspecialty recognition is an important disparity in the program that severely disadvantages those providers who have furthered their education and training in a specific area in order to treat some of the most complex conditions, and it must be addressed moving forward. We request that CMS consider these concerns and recommendations and finalize policies that would ensure specialty and subspecialty physicians can meaningfully engage the MIPS performance categories and be recognized on a level playing-field for their efforts.

Regulatory Impact Analysis

We believe CMS has grossly underestimated the time and resources required to engage in its current and future quality reporting programs. As indicated in a recent study, US physician practices spend more than \$15 billion annually to report quality measures alone.¹ We are not convinced that the resources required to meet the quality and other reporting activities are sustainable. CMS must conduct a more thorough assessment of the burden imposed by these quality reporting activities, as well as ensure that new programs and policies are not adding to this already significant financial and resource-heavy burden.

MIPS Program Details

MIPS Eligible Clinician Identifier

CMS proposes to use multiple identifiers that allow MIPS eligible clinicians to be measured as an individual or collectively through a group's performance. The same identifier would be used for all four performance categories. For example, if a group is submitting information collectively, then it must be measured collectively for all four MIPS performance categories.

While CMS proposes the use of multiple identifiers for participation and performance, it proposes to use a single identifier, TIN/NPI, for applying the payment adjustment, regardless of how the clinician is assessed. Specifically, if the MIPS eligible clinician is identified for performance only using the TIN, when applying the payment adjustment, CMS proposes to use the TIN/NPI.

The aforementioned proposals are clear and understandable, however, we are confused as to how CMS intends to score individual MIPS eligible clinicians that are part of a group. Specifically, how will the score of an individual MIPS eligible clinician who is part of a group be applied in each of the four performance categories? In other words, if you are a MIPS eligible clinician, but part of a group, will your score be the group score, or is it your individual score based on your own individual performance? Nowhere in the rule is this clearly explained other than in regards to resource use, in which CMS proposes two alternative approaches that seem to reach the same end. We request that CMS specifically outline in the final rule how a group score would be calculated and how individual clinicians within a group would be assessed for each of the four performance categories and for the Composite Performance Score (CPS). Especially with respect to scoring, throughout the final rule, we request that

¹ Casalino LP, Gans D, et al. "2016 US physician practices spend more than \$15.4 billion annually to report quality measures." Health Affairs 35 (3) 1-6 March 2016

CMS provide examples of how participation in a group would differ from individual reporting. Many of our members work as part of larger multispecialty groups and will be directly impacted by these policies.

Exclusions

New Medicare-Enrolled Eligible Clinician

CMS proposes that a new Medicare-enrolled eligible clinician—defined as a professional who first becomes a Medicare-enrolled eligible clinician within Provider Enrollment, Chain and Ownership System (PECOS) during the performance period for a year and who has not previously submitted claims as a Medicare-enrolled eligible clinician either as an individual, an entity, or a part of a physician group or under a different billing number or tax identifier—not be treated as a MIPS eligible clinician until the subsequent year and the performance period for such subsequent year. In accordance with section 1848(q)(1)(C)(vi) of the Act, these individuals will not receive a MIPS adjustment factor. As discussed later in the rule, the MIPS performance period would be the calendar year (January 1 through December 31) 2 years prior to the year in which the MIPS adjustment is applied. Thus, an eligible clinician who newly enrolls in Medicare within PECOS in 2017 would not be required to participate in MIPS in 2017, and he or she would not receive a MIPS adjustment in 2019.

Under CMS' proposal, a physician who newly enrolls in Medicare in, for example, November 2017, would be required to begin participation in MIPS beginning January 1, 2018, just 2 months following their enrollment. We strongly oppose CMS' proposal. Instead, we request that CMS extend this window such that a physician who enrolls in Medicare in 2017 would not be expected to begin participation in the program until January 1, 2019.

Low-Volume Threshold

CMS proposes that the definition of a MIPS eligible clinician does not include MIPS eligible clinicians who are below the low-volume threshold selected by the Secretary for a given year. To accomplish this, CMS proposes to define those who do not exceed the low-volume threshold as an individual MIPS eligible clinician or group who, during the performance period, has Medicare billing charges less than or equal to \$10,000 AND provides care for 100 or fewer Part B-enrolled Medicare beneficiaries.

We oppose this proposal, as we believe it would *inappropriately* retain as MIPS eligible clinicians those who are treating relatively few beneficiaries, but engage in resource intensive specialties. For example, many neurosurgical patients who start out as pediatric patients with diagnoses of cerebral palsy or spinal bifida live into adulthood and are likely to be on Social Security/disability making them eligible for Medicare. Their pediatric neurosurgeons typically follow them for their lifetime, which puts the pediatric neurosurgeon in Medicare for this finite population. The few procedures rendered to these patients easily exceed the \$10,000 threshold.

We request that CMS increase the low-volume threshold for billing charges to at least \$75,000.

Virtual Groups

CMS determined that implementation of virtual groups for the 2017 performance period is infeasible. CMS will instead aim to implement a web-based registration system for 2018, which would provide the

necessary time to establish and implement an election process and requirements applicable to virtual groups. CMS assessed alternative approaches for the first year only, but believes there are limitations and potential risks for numerous errors.

In accordance with Section 1848(q)(5)(I)(iii)(I) of the Act, CMS proposes to establish an election (i.e., registration) process that would end on June 30 of a calendar year preceding the applicable performance period.

While CMS seeks comment, we are provided no details to which we can react. Given that the concept of Virtual Groups was an important provision of MACRA to better tailor reporting to measures that are more appropriate for specialty physicians, we are disappointed to find that CMS has not proposed their introduction for the initial performance year. Therefore, we request that CMS issue proposals related to Virtual Groups as quickly as possible. If CMS agrees to a July 1, 2017 start date for the initial reporting period, we believe that CMS will have ample time to issue additional proposals for Virtual Groups in advance of the commencement of the initial reporting period. Furthermore, similar to our comments above on group identifiers and group reporting, we are unable to provide much feedback until we understand how CMS intends to score individual MIPS eligible clinicians that are part of a group, as we believe some of these same policies would apply to those in future virtual groups.

We request that CMS address our aforementioned questions. We further request that CMS host listening sessions and town halls on this issue in the coming weeks so physicians have a fair and meaningful opportunity to determine their best course of action for reporting at the beginning of the performance period.

MIPS Performance Period

CMS proposes that for 2019 and subsequent years, the performance period under MIPS would be the calendar year (January 1 through December 31) 2 years prior to the year in which the MIPS adjustment is applied. Thus, the performance period for the 2019 MIPS adjustment would be the full calendar year 2017. CMS feels this approach allows for a full year of measurement and sufficient time to base adjustments on complete and accurate information.

We oppose this proposal. Most specialty physicians will not be ready on January 1, 2017 to begin MIPS. As a result, CMS should delay the MIPS program and provide a shorter reporting/performance period in 2017 (e.g. 6 months) (with an optional “look-back” to January 1 in 2017) if they believe it is more appropriate for their practice. CMS should maintain this shorter reporting/performance period in future years of the program (with an optional “look-back” to January 1), in addition to any year-long reporting requirements, beginning in 2018. This shorter reporting/performance period will provide a necessary “on-ramp” for many specialty physicians who will be new to the program. And, it is consistent with approaches CMS has taken previously with the Medicare EHR Incentive Program.

Over time, we recommend that CMS try to close the gap between the performance and payment year to ensure that data is actionable and that changes to MIPS policies can be made in a timely and impactful manner.

MIPS Category Measures and Activities

Under CMS' proposals, clinicians and groups may elect to submit information via multiple mechanisms; however, they must use the same identifier for all performance categories and they may only use one submission mechanism per category. For example, a clinician could submit quality measures via claims and CPIA data via attestation, but a MIPS eligible clinician could not use two submission mechanisms for a single category such as submitting three quality measures via claims and three quality measures via registry.

CMS also seeks comments for future rulemaking on whether it should propose *requiring* health IT vendors, QCDRs, and qualified registries to have the capability to submit data for all MIPS performance categories. We appreciate giving vendors the opportunity to report this data if they are prepared to do so, but strongly oppose making it a requirement. While we agree that allowing QCDRs and other clinical data registries to submit data for all MIPS performance categories could provide a valuable tool to Eligible Clinicians looking to meet the MIPS reporting requirements, we also noted that many have adopted a mission that is exclusively centered on addressing a specific area of healthcare quality. It would be inappropriate to require them to divert scarce resources from their core objective in order to satisfy additional requirements that may not be in sync with their primary mission. We further believe this would provide a disincentive for health IT vendors to further efforts toward interoperability with disparate systems, such as specialty society-sponsored registries, given they could address the entire spectrum of reporting with their product.

Quality Performance Category

CMS proposes to remove the requirement for measures to span across multiple domains of the National Quality Strategy (NQS). We support this proposal, agreeing with CMS that the MIPS program overall will naturally cover many elements in the NQS.

Quality Data Submission Criteria

CMS also proposes to no longer include Measures Groups as a data submission method for purposes of the quality performance category. In its place, CMS is proposing specialty-specific measure sets, which CMS believes will address confusion in the quality measure selection process. We strongly oppose the removal of Measures Groups and strongly urge that they be maintained.

Some of the specialties represented in the Alliance heavily rely on Measures Groups to meet quality reporting requirements under the current PQRS program and would appreciate the opportunity to continue meeting the quality reporting requirements under the quality performance category in the same way. By proposing to do away with this reporting mechanism, CMS is severely limiting meaningful quality reporting options available to many specialists, particularly those in small practices. Similarly, in many instances, the proposed removal of measure groups will either leave no *meaningful* measures for certain specialties and subspecialties or greatly diminish the value of the measures that CMS proposes to retain as stand-alone measures.

We believe CMS' proposed elimination of the option is counterintuitive to CMS' stated goals for overall quality improvement and specific condition and/or episode-based performance and measurement. For example, at CMS' encouragement, Alliance members in ophthalmic specialties invested significant time

and resources developing the Cataract and Diabetic Retinopathy Measure Groups to satisfy that stated goal. The Cataracts Measures Group features six outcomes measures that focus on surgical complication rates, clinical outcomes, patient-reported outcomes, and patient satisfaction. We believe these highly relevant measures are more in line with CMS' stated goals than other measures not grouped to address particular conditions or procedures.

While we recognize CMS has proposed a list of specialty measures lists in the proposed rule (Table E), the sets are merely a re-ordering of the numerical list of available measures (Table A) by specialty and are not analogous to the Measures Groups. Under the proposal, for proposed sets with more than 6 measures, a physician would be able to choose any of the measures available without any relationship between them and not specific to a particular procedure or condition. By focusing on a particular condition or episode, as in the Measures Groups, a physician could instead focus on a procedure or condition that represents the majority of his or her particular practice.

We also remind CMS that physicians reporting through the Measures Groups were already participating at a more advanced level. For example, in ophthalmology, the Cataracts Measures Group included six outcomes measures and two cross-cutting measures, and the Diabetic Retinopathy Group included one outcome measure and two cross-cutting measures, which CMS deems to be "high priority." Therefore, under CMS' proposals, physicians would not be required to submit as many clinically-relevant measures that center around a particular condition or procedure.

Given the much higher reporting thresholds for registry reporting, there is a further disincentive for physicians to report on these measures since several, such as Measure #191, Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery and Measure #192, Cataracts: Complications within 30 Days Following Surgery Requiring Additional Surgical Procedures, are only reportable through registry. If physicians opt to report via claims, they will not be able to select several of the outcome measures included in the Measures Group.

In the calendar year (CY) 2012 Medicare Physician Fee Schedule Final Rule, CMS finalized lowering the patient threshold for measures groups to 20 patients from the previously finalized threshold of 30, with the rationale that it would reduce provider burden. The measures included in the Measures Groups are work-intensive and so require a lower number of patients for providers, particularly those in small practices, to achieve. For larger groups reporting through the CMS Web Interface, CMS proposes to base the Quality score on a sample of 248 Medicare patients, which is significantly lower than the reporting requirement for individual physicians. Similarly, CMS should retain the option of reporting on 20 patients through a Measures Group. We urge CMS to continue to work toward the goal stated in this proposed rule of reducing provider burden by maintaining its previously set standards toward that goal of reduced burden.

CAHPS for MIPS

CMS proposes to allow registered groups of two or more MIPS eligible clinicians to voluntarily elect to participate in the CAHPS for MIPS survey. Groups would have to use a CMS-approved vendor and bear the cost of contracting with the vendor, as is the case under the CAHPS for PQRS survey. The CAHPS for MIPS survey would count as one cross-cutting and/or a patient experience measure, and the group

would be required to submit at least five other measures through one other data submission mechanism to complete their quality data submission.

CMS seeks feedback on whether the CAHPS for MIPS survey should be required for groups of 100 or more MIPS eligible clinicians or whether it should be voluntary. We are opposed to CMS requiring participation in CAHPS surveys. We are concerned that, if specialty groups of 100 or more MIPS eligible clinicians are required to participate in the CAHPS for MIPS, they would be forced to participate in an instrument that does not capture important patient experience of care metrics in specialty medicine. We urge CMS to make CAHPS for MIPS an option, along with other patient experience of care measures, such as the Surgical CAHPS (S-CAHPS), on the list of available MIPS measures. We would oppose any future proposal that would require groups of 2 or more MIPS eligible clinicians participate in the CAHPS for MIPS.

Data Completeness Criteria

CMS also proposes to revise its data completeness thresholds such that individual MIPS eligible clinicians submitting via Part B claims would need to report on 80 percent of his/her Medicare Part B-only patients; whereas individual MIPS eligible clinicians and groups submitting via QCDR, qualified registry, and EHR would need to report on 90 percent of their Medicare and non-Medicare patients. We very much oppose this proposal.

The Alliance is surprised that CMS would increase the reporting threshold for the QCDR submission mechanism over and above claims-based reporting mechanism, which CMS has previously described as less-desirable. MACRA requires the Secretary to emphasize the use of QCDRs, thus it stands to reason that the reporting threshold should be much lower to encourage its use. Instead, however, CMS is proposing to create a claims-based reporting data completeness threshold that is relatively lower when compared to other reporting options. This proposed policy encourages physicians to move away from QCDR reporting and towards claims-based reporting.

We request that CMS lower the reporting thresholds for all reporting mechanisms to 50 percent, which is consistent with the current PQRS reporting requirements. As an alternative, CMS could consider simply requiring reporting on 20 consecutive patients, which would be consistent with CMS' current threshold for Measures Groups under the PQRS program.

Exception for QCDR Measures

QCDR measures are considered non-MIPS measures (i.e., not a part of the MIPS quality measure set). If a QCDR wants to use a non-MIPS measure for inclusion in the MIPS program for reporting, CMS proposes that these measures go through a rigorous CMS approval process during the QCDR self-nomination period. The measure specifications will be reviewed and each measure will be analyzed for its scientific rigor, technical feasibility, duplication to current MIPS measures, clinical performance gaps, as evidenced by background and/or literature review, and relevance to specialty practice quality improvement. CMS proposes that each non-MIPS measure will be assigned a unique ID that can only be used by the QCDR that proposed it. Although non-MIPS measures are not required to be NQF-endorsed, CMS encourages the use of NQF-endorsed measures and measures that have been in use prior to implementation in MIPS.

As described in the Third Party Data Submission requirements aforementioned section, for non-MIPS measures, the QCDR must provide CMS, if available, data from years prior (for example, 2015 data for the 2017 MIPS performance period) before the start of the performance period. In addition, the QCDR must provide CMS, if available, with the entire distribution of the measure's performance broken down by deciles. As an alternative to supplying this information to CMS, the QCDR may post this information on its website prior to the start of the performance period, to the extent permitted by applicable privacy laws.

We are concerned with CMS' proposal since many QCDR measures are relatively new and will not have good benchmarking data in the initial years of MIPS. Rather than expecting QCDRs to base the benchmark on the performance year, which is confusing for clinicians since it does not provide them with a goal to work toward at the start of the performance year, we recommend that CMS recognize the reporting of first year QCDR measures but not use them to evaluate performance.

Resource Use Performance Category

Resource Use Criteria: Value Modifier Cost Measures

For the CY 2017 MIPS performance period, CMS proposes to use the following measures for the MIPS resource use performance category:

- *The Total per Capita Cost measure (from the VM)*
- *The Medicare Spending Per Beneficiary (MSPB) (from the VM); and*
- *Several new episode-based measures*

CMS is not proposing to include the VM total per capita cost measures for the four condition-specific groups (chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, and diabetes mellitus).

We are deeply concerned about the use of the VM measures in the MIPS program, particularly in the initial years. A CMS report on the result of the 2016 VM program (based on 2014 performance) showed that, for purposes of the 2016 VM payment adjustment applied to physicians in groups with 10 or more eligible professionals (EPs), physicians in 5,418 groups that failed to meet minimum reporting requirements saw a “-2.0%” decrease in their Medicare payments in 2016 and physicians in 59 groups saw a decrease in their Medicare payments based on their performance on cost and quality measures under the VM. In addition, there were 1,390 groups with at least one Physician Quality Reporting System (PQRS) informal review or Value Modifier informal review pending, at the time the report was released. Only 128 groups exceeded the program’s benchmarks in quality and cost efficiency and earned a payment incentive. Moreover, CMS notes that Medicare payments for most physician groups nationwide (8,208 groups) that met the minimum reporting requirements will remain unchanged in 2016 because of their performance on quality and cost efficiency measures or because there was insufficient data to calculate the groups’ Value Modifier, further evidence that the existing VM measures produce meaningless data and information for physicians.

Physicians that received a downward were totally blind-sided by these negative adjustments because they were not familiar with the VM program, despite CMS' and the medical societies best efforts to

educate them. We are anxious to see the results for all physicians under the 2017 VM program, which we anticipate will be relatively dismal.

It is clear that these measures are not ready for prime time, and the need to further refine and evaluate episode-based cost measures is essential. Therefore, we strongly urge CMS to use its authority under MACRA to re-weight this category to zero.

Attribution

In the VM, all cost measures are attributed to a TIN. In MIPS, however, CMS proposes to evaluate cost performance at the individual and group levels.

For the MSPB measure, CMS proposes to use attribution logic that is similar to what is used in the VM. The only difference from the VM attribution methodology would be that the MSPB measure would be assigned differently for individuals than for groups.

For the total per capita cost measure, CMS proposes to use a two-step attribution methodology that is similar to the methodology used in the 2017 and 2018 VM. CMS clarifies that the 2-step attribution for MIPS would still be different than the one used for the Shared Saving Program. For example, the MIPS method would not exclude select specialties (e.g., ophthalmology, rheumatology, etc.) from the second attribution step. CMS does not believe that many MIPS eligible clinicians or clinician groups within these specialties would be attributed enough cases to meet or exceed the case minimum. It also believes that an automatic exclusion could remove some MIPS eligible clinicians and groups that should be measured for resource use.

In addition, CMS does not incorporate required patient relationship categories and codes into its proposals, as these continue to be developed by the agency. This is unfortunate given the potential impact patient relationship categories and codes will have on specialty physicians under the resource use performance category.

As a result, we oppose this proposal. The Alliance, as well as individual members of the Alliance, weighed in heavily on the issue of attribution in the Shared Savings Program. Given the lack of developed proposals related to how CMS will incorporate patient relationship categories and patient condition codes, we request that CMS exclude the same specialties from the second attribution step as it does in the Shared Savings Program (as outlined in 80 FR 32749 through 32754). Without this, we believe that many specialty physicians will be inappropriately attributed beneficiaries under the resource use measures and be penalized unfairly under CMS' current proposal.

Reliability

While CMS proposes to use the minimum of 20 cases for the total per capita cost measure, the same case minimum that is being used for the VM, it proposes to revert to a minimum of 20 cases (from the current 125 case requirement) for the MSPB measure.

We oppose this proposal. In the CY 2016 PFS final rule, CMS finalized a policy that increased the minimum cases for the MSPB measure from 20 to 125 cases (80 FR 71295 through 71296) due to

reliability concerns with the measure including the specialty adjustment. Recognizing that this case size also may limit the ability of MIPS eligible clinicians to be scored on MSPB, CMS has been evaluating alternative strategies for that better balance participation, accuracy, and reliability. However, we do not believe it is appropriate to revert to the 20 case minimum despite CMS's desire to apply this measure more broadly given the influx of new providers into the MIPS program over the former VM. We request that CMS maintain the 125 case minimum for the MSPB, at least in the initial years of the MIPS program.

CMS also proposes to remove the specialty-adjustment from the MSPB measure's calculation.

We oppose this proposal. Despite CMS' assertion that current risk adjustment for this measure ensures that comparisons account for case-mix differences between practitioners' patient populations, we argue that costs to vary across specialties and that additional adjustment for physician specialty continues to be needed. We request that CMS continue to adjust all cost measures for each practitioner's specialty and each TIN's specialty mix to facilitate comparisons in health care costs across disparate TINs.

Resource Use Criteria: Episode-based Measures

CMS proposes to include in the resource use performance category several clinical condition and treatment episode-based measures that have been reported in Supplemental Quality and Resource Use Report (sQRUR) or were included in the list of the episode groups developed under section 1848(n)(9)(A) of the Act published on the CMS website. CMS does not propose any specialty adjustment for the episode-based measures.

We are concerned about the premature application of these cost measures, which have not been adequately vetted by specialty care providers given their limited use. Most of the cost measures are new, only recently having been put forward for comment as part of CMS' Episode Groups Request for Comment. The remaining measures may have been included in sQRURs, however, very few clinicians understood (or understand) how to access or interpret their QRURs or sQRURs. For example, the cataract surgery episode was never included in any sQRURs downloaded by cataract surgeons. In addition, most specialty physicians did not (and still do not) understand what actions they should take to improve quality and cost based on these reports. Furthermore, the patient relationship/conditions codes are not yet available which would have an impact in this category. For these reasons, and the reasons above related to the VM cost measures, we request that CMS reweight this category to zero.

Clinical Practice Improvement Activity (CPIA) Category

Contribution to Composite Performance Score (CPS)

In addition, our read of the proposed rule and associated provisions in the MACRA statute, it is clear that CPIA credit for APM participation would mean MIPS eligible clinicians or groups who are participating in an APM (as defined in section 1833(z)(3)(C) of the Act), which would include any of the following:

- *A model under section 1115A (other than a health care innovation award).*
- *The shared savings program under section 1899.*

- A demonstration under section 1866C; or
- A demonstration required by Federal law.

While the statute is clear, we request that CMS clarify that, for example, a specialty physician participating in the Comprehensive Care for Joint Replacement Demo or Bundled Payment for Care Improvement (BPCI), would receive one-half credit for his or her participation in these models, as both models fall into the aforementioned statutory definition of an APM. If this is not accurate, we request that CMS provide a rationale as to why these and other models would not award physicians credit for their participation, and the statutory authority it has for that departure from what appears to be clear in the law.

CPIA Inventory

Despite the inclusion of 94 unique activities in the CPIA inventory, the vast majority of activities are focused on activities more appropriate for primary care providers vs. specialty physicians. This is a notable disparity in the CPIA category that puts specialists at a disadvantage. The Alliance provided a robust list of potential CPIAs for specialty physicians. We urge CMS to reconsider including these activities in the proposed rule. They include:

- Attendance and participation in ACGME-accredited events, such as the specialty and subspecialty society conferences and events, including those that are web-based, that exceed certification requirements
- Attendance and participation in other CME and non-CME events that exceed certification requirements
- Fellowship training or other advanced clinical training completed during a performance year
- Participation in morbidity & mortality (M&M) conferences
- Taking Emergency Department (ED) Call as part of Expanded Practice Access
- Voluntary practice accreditation, such as accreditation achieved by the National Committee on Quality Assurance (NCQA), Accreditation Association for Ambulatory Health Care (AAAHC), The Joint Commission (TJC), or other recognized accreditation organizations
- Demonstration of incorporation of evidence-based practices and appropriate use in clinician practices, using evidence-based clinical guidelines, appropriate use criteria, Choosing Wisely recommendations, etc.
- Engagement in state and local health improvement activities, such as participation in a regional health information exchange or health information organization
- Engagement in private quality improvement initiatives, such as those sponsored by health plans, health insurers, and health systems
- Participation in other federally sponsored quality reporting and improvement programs not already affiliated or considered under the MIPS program

Regarding the list of proposed CPIAs, we seek clarity on language used to describe specific CPIAs. Specifically, CMS lists “*Use of tools that assist specialty practices in tracking specific measures that are meaningful to their practice, such as use of the Surgical Risk Calculator.*” Does CMS intend that only the Surgical Risk Calculator is an appropriate CPIA, or does CMS’ use of “such as” mean that similar tools would apply and the Surgical Risk Calculator is merely an example? For example, could a

rheumatologist earn credit under this CPIA for use of the Fracture Risk Assessment Tool (FRAX), a sophisticated risk assessment instrument developed by the University of Sheffield in association with the World Health Organization instrument, and highly-regarded in specialty? Or, could spine specialists use the North American Spine Society (NASS) Sign, Mark & X-ray (SMaX) Prevention of Wrong-Site Spinal Surgery Checklist?

In another example, CMS lists “*Participation in the Consumer Assessment of Healthcare Providers and Systems Survey or other supplemental questionnaire items (e.g., Cultural Competence or Health Information Technology supplemental item sets).*” Does CMS intend that only the examples in parenthesis are acceptable for meeting this CPIA, or could other CAHPS or supplemental questionnaire items apply here? For example, could a surgical practice use the Surgical CAHPS and earn credit under this CPIA?

For specialty physicians, these clarifications are essential to their ability to earn credit for meaningful clinical practice improvement activities in the current list of proposed CPIAs.

CPIA Policies for Future Years of the MIPS Program

CMS intends, in future performance years, to begin measuring CPIA data points for all eligible clinicians and to award scores based on performance and improvement.

We strongly oppose this proposal, particularly given there are no baseline or benchmark data available for comparison. In addition, we believe that requiring this diverts from the Congressional intent of including this proposal in the first place.

Advancing Care Information Performance Category

We are sorely disappointed in the proposals included in the Advancing Care Information performance category. The implementation of programs established under MACRA afforded CMS a unique opportunity to drastically change the direction of the meaningful use program for physicians. Since the fall, CMS promised a more flexible program in response to physician concerns heard around the country, yet its proposed approach of calculating a base and performance score for this category do not:

- *Allow physicians and other clinicians to choose to select the measures that reflect how technology best suits their day-to-day practice*
- *Simplify the process for achievement and provide multiple paths for success*
- *Simplify reporting by no longer requiring all-or-nothing EHR measurement or quality reporting*

Instead, MIPS eligible clinicians will continue to be forced to report on measures that are not meaningful to their practice and patient populations. CMS’ proposed approach also means that EHR vendor resources will be diverted to functionalities that do not make sense for specialty medicine, which is disconcerting since physicians are desperately seeking health IT solutions that would address real healthcare challenges, such as incorporating medical device data. Vendors will not address these issues through modifications to their EHR products if they have no incentive to do so. In general, the

“new” meaningful use does not shift us toward measuring end-results stemming from the use of health IT, using a more evidence-based, outcomes-driven approach, that physicians have been clamoring for since the inception of the Medicare EHR Incentive Program.

In addition, the emphasis on privacy and security is a challenge for most specialty physicians. Requiring professionals to conduct or review a security risk analysis is a reasonable metric, however, specialty physician practices, primarily those that are small, continue to face challenges in meeting this requirement, as evidenced in recent payment audits of the EHR Incentive Program. While the Office of the National Coordinator for Health Information Technology (ONC) and the Office of Civil Rights (OCR) have collaborated to provide physician practices with tools to assist with their security risk assessment, many practices do not employ information technology (IT) staff, nor do their office staff have proper training in IT security protocols.

We request that CMS collaborate with its federal agency partners to develop more robust guidance for physician offices on conducting security risk assessments; provide data on common security risk failures in physician practices, large and small; and, provide enhanced technical assistance and support on HIT security. These efforts would go along way in helping many MIPS eligible clinicians with meeting the requirements and avoiding a “0” score for the entire performance category, which would significantly impact their composite performance score.

Exclusions for the Advancing Care Information Performance Category

CMS proposes exclusions to the electronic prescribing and public health and clinical data registry reporting objectives but is not proposing to maintain any of the other measure-specific exclusions previously established under the EHR Incentive Program.

For CMS to truly depart from its “all-or-nothing” approach, it must provide exclusions from measures under this category when they do not apply. We recognize that some of the existing exclusions are specific to the thresholds that CMS is recommending to remove. However, some of the measures are not applicable to specialists or would be too challenging to implement in their current form. We urge CMS to adopt, maintain, and/or incorporate new exclusions for the advancing care information measures to account for the fact that not all measures are applicable to all clinicians. We recommend that CMS do this via sub-regulatory guidance to avoid concerns with its “logical outgrowth” requirements as outlined in the Administrative Procedures Act (APA).

Reweighting of the Advancing Care Information Performance Category for MIPS Eligible Clinicians without Sufficient Measures Applicable and Available

Under the EHR Incentive Program, hospital-based EPs and EPs facing a significant hardship were exempted from being a meaningful EHR user. CMS notes that, under MIPS, these hardship exemptions do not apply to the advancing care information performance category. As an alternative to exempting these clinicians, CMS is proposing to assign a weight of zero to the advancing care information performance category for purposes of calculating a MIPS CPS for these MIPS eligible clinicians. We appreciate and support this proposal.

MIPS Scoring Standards

MIPS Composite Performance Score Methodology

Unified Scoring System

We are deeply concerned about the scoring methodology for MIPS. Alliance member organizations have reviewed the proposals in great detail, yet we continue to find the proposals extremely complex and confusing. We recognize that, to provide flexibility, the scoring will be more difficult. However, if our most sophisticated and knowledgeable volunteer physician leaders are struggling to understand the scoring proposals, how does CMS expect the vast majority of physicians in practice to understand?

The proposed methodology also maintains the current silos of performance scoring, despite the fact that scoring is all rolled up into a composite performance score. To move toward a more value-driven healthcare system, it seems that the scoring should provide physicians with meaningful and actionable information that leads them toward that goal.

We request that CMS rethink its scoring methodology and make modifications that would standardize, streamline, and maintain consistency so that MIPS eligible clinicians are able to understand and respond appropriately.

Scoring the Quality Performance Category

If a MIPS eligible clinician fails to submit a measure required under the quality performance category criteria, then the MIPS eligible clinician would receive zero points for that measure. MIPS eligible clinicians would not receive zero points if the required measure is submitted but is unable to be scored, such as not meeting the required case minimum or a measure lacks a benchmark.

We support this proposal. This is particularly helpful, as it would eliminate concerns by specialty physicians that they would be unfairly penalized if they could not reach the case minimum or if the measure lacks benchmark data, the latter being more likely given the majority of specialty measures are too new to have such data available. This policy would also address concerns about third party vendor data submission errors that are not in the control of the clinician.

Quality Measure Benchmarks

CMS proposes the performance standard to be measure-specific benchmarks based on a baseline period that would be two years prior to the performance period for the MIPS payment year. With less than 50 percent of eligible professionals having actually participated in CMS' prior quality reporting programs, we are concerned that legacy data will be problematic and skew any benchmarking data. In addition, CMS should not hold clinicians accountable for performance until it has built a foundation of data under MIPS on which to base benchmarks. Basing MIPS benchmarks on pre-MIPS data opens the door for inaccurate and unfair evaluations since measures, reporting requirements and options, eligible professionals and incentives for participation will all be changing under MIPS. Additional transparency in benchmarking data is required, therefore, we request that CMS provide the benchmark data for all measures proposed for use under the MIPS program.

Section 1848(q)(5)(D) of the Act lays out the requirements for incorporating performance

improvement into the MIPS scoring methodology beginning with the second MIPS performance period, if data sufficient to measure improvement is available. CMS seeks feedback on specific options for measuring improvement in the future. While the Alliance does not have a specific recommendation, we do support the overall concept of ***evaluating both achievement and improvement***. Rewarding clinicians for improvement can be important for those with historically low performance or with a particularly complex patient population. At the same time, rewarding achievement will help to continue to incentivize historically high performers to maintain that level of performance without holding them to an endlessly higher standard. As noted below, we support the maintenance of topped out measures (at least for a minimum period of time) to ensure that clinicians with historically high performance are rewarded for their efforts.

Benchmarks for Each Submission Mechanism

CMS proposes to develop separate benchmarks for EHR submission options, claims submission options, Qualified Clinical Data Registries (QCDRs) and qualified registries submission options. We strongly support this proposal and urge CMS to finalize this policy.

Topped Out Measures

We are concerned with CMS' proposed policies associated with "topped out measures." In prior PQRS rulemaking, CMS identified quality measures that it considered "topped out," and therefore, no longer useful in assessing the performance. In the MIPS program, CMS is proposing to allow providers to continue reporting some "topped out" measures, but limit the maximum number of points these measures can achieve.

While we appreciate CMS' proposal to maintain topped out measures, we disagree with its methodology for deeming measures as "topped out" and its proposal to limit the number of performance points associated with these measures. If a gap in performance for a given quality measure has narrowed, it simply means that performance has improved for that cohort of reporting providers. It says nothing about the rest of the population to whom the measure may be applicable. As noted above, few physicians were actually reporting quality data in the PQRS program; in fact, even after many years of PQRS' existence, CMS' 2014 PQRS Experience Report shows that one-third of eligible professionals do not report into PQRS at all, and shows even more who are unable to successfully meet the reporting requirements. We believe there are not enough data for CMS to deem current quality measures as truly "topped out" since only the highest performers might have chosen to report on these measures. In many instances, these "topped out" measures remain valuable in assessing performance. An example is the perioperative measures, which Alliance members continue to believe are important in assessing surgical performance.

Another example is the cataract surgery measures. While cataract surgery has one of the highest success rates of all surgical services; it is also the number one surgical service provided to Medicare beneficiaries. Therefore, a small gap in performance still represents a significant number of beneficiaries. Cataract surgeons should not be penalized because they are high performers, and we must continue to allow reporting on the cataract measures to continue performance improvement efforts for the thousands of beneficiaries that fall into that small percentage of a performance gap.

The Alliance is also confused by the fact that on one hand, CMS proposes a policy to maintain topped out measures, but on the other hand, it proposes to retire select measures because they are topped out. For instance, CMS proposes to remove PQRS 22: Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-Cardiac Procedures) rather than maintain it and subject it to its proposed limited scoring methodology. While we do not support the modified scoring methodology, we believe ALL topped out measures should be maintained, at least in the initial years of MIPS. CMS decision to remove some topped out measures and not others is arbitrary and inconsistent.

Overall, to gain a true understanding of whether performance has improved over time, measures should be maintained in the program considerably longer. Many of the CMS-identified “topped out” measures were not in the program long enough for robust data to have been collected and for a fair assessment to be made on a measures’ “topped out” status. We request that CMS remove the “topped out” designation from the quality measures that will be used in MIPS, especially those that have not been used in CMS’ quality programs for more than 5 years. We further recommend that all MIPS quality measures be considered in “pilot” mode for the first two years they are included in MIPS, rigorously evaluated for validity and accuracy during this pilot mode, and maintained for at least five years following to ensure sufficient benchmark data and accommodate more robust evaluation of topped out performance.

MIPS Payment Adjustments

Payment Adjustment Identifier and CPS Used in Payment Adjustment Calculation

CMS proposes to allow MIPS eligible clinicians to measure performance as an individual, as a group defined by TIN, or as an APM Entity group using the APM scoring standard; however, for purposes of the application of the MIPS adjustment factors to payments, CMS proposes to use a single identifier, TIN/NPI, for all MIPS eligible clinicians, regardless of whether the TIN/NPI was measured as an individual, group or APM Entity group. In other words, a TIN/NPI may receive a CPS based on individual, group, or APM Entity group performance, but the payment adjustment would be applied at the TIN/NPI level.

We continue to be perplexed by this proposal. We are not clear as to how certain performance categories will yield an individual performance score if MIPS eligible clinicians are in a group. Will the group score be applied to the individual MIPS eligible clinician? Will the individual MIPS eligible clinician’s scores be averaged to create a group score? We seek the answer to these and the other questions we have posed in the various sections above.

Review and Correction of MIPS CPS

Feedback and Information to Improve Performance

Similar to the scoring methodology, we need significantly improved feedback and information that will allow specialty physicians to meaningfully improve their performance. The current QRURs remain impossible to understand, meaning physicians are unable to take action based on the information that

has been provided. If physicians cannot understand the feedback, it lacks utility, which is contrary to CMS' goal of driving physicians toward a value-driven system. As we have said in prior comments, performance feedback should be provided in real-time, where possible, but at least monthly to ensure providers have adequate time to clinical workflows and processes if there are areas where the EP may need to change direction to ensure success for the year.

Targeted Review & Review Limitation

CMS proposes to adopt a targeted review process under MIPS wherein a MIPS eligible clinician may request that CMS review the calculation of the MIPS adjustment factor and, as applicable, the calculation of the additional MIPS adjustment factor applicable to such MIPS eligible clinician for a year. While CMS proposes that a MIPS eligible clinician electing to request a targeted review may submit their request within 60 days (or a longer period specified by CMS) after the close of the data submission period, it only proposes to allow MIPS eligible clinicians 10 calendar days to respond to a request for additional information. This timeframe is unreasonable. We request that CMS adopt a more reasonable timeframe, such as 30 business days.

We are also concerned with the lack of due process, particularly in light of the impact it will have on provider payments and reputation among peers and their community. CMS notes that this is an informal review process and given the limitations on review under MACRA, decisions based on the targeted review will be final, and there will be no further review or appeal. We request that CMS reconsider this proposed policy and allow for second level appeals.

Data Validation and Auditing

We are also concerned about errors and omissions that are treated as fraud under the review process. We urge CMS to be reasonable in its auditing criteria and not penalize physicians when errors and omissions are identified. This will be particularly important if physicians utilize a third party for their quality data submissions and the third party submits erroneous information that a MIPS eligible clinician could be liable for.

Public Reporting on Physician Compare

We are concerned about CMS' proposals for a 30-day preview period, which we believe is too short. We urge CMS to adopt the same review period as is used in the Open Payments program, which is 45 days.

In addition, CMS includes on the current Physician Compare Website a disclaimer about the data and its use. As the agency is aware, many third party entities have downloaded data from the Physician Compare website, manipulating it in such a way that paints providers in a poor light.

As a reminder, "Standard of Care Protection Act", which was included in MACRA states that federal healthcare metrics shall not be determinative in a court of law as to whether or not an act of medical negligence has occurred. To that end, we request that CMS modify its disclaimer to include language referencing this language, clearly indicating to those who download these data are aware that lawsuits can not hinge on a physicians' participation in CMS' Quality Payment Program, or other CMS-sponsored quality programs, as participation is not an indication of whether a provider has met the

standard of care. Recognizing that CMS has little control over how the data are used by these entities or by other stakeholders, we encourage CMS to be more diligent in monitoring these activities and looking for ways to limit its likelihood.

Alternative Payment Models (APMs)

Specialty physicians are at a disadvantage as the proposed Advanced APMs remain primary care-focused, leaving specialty physicians with few APM participation options. Despite its RFI on Specialty Practitioner Payment Model, the Center for Medicare and Medicaid Innovation (CMMI) has not made a concerted effort to ensure specialists have a pathway toward engaging in APMs. Only two models currently cover specialty medicine – the Oncology Care Model and the Comprehensive Care for Joint Replacement Model, the latter of which CMS did not propose to qualify as an Advanced APM.

We continue to be frustrated by 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. We urge CMS to offer guidance on how APMs that did not meet the proposed Advanced APM criteria could be altered to meet the 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.

Qualifying APM Participant (QP) and Partial QP Determination

Despite our frustration about the lack of specialty-focused APMs that could lead specialists toward Qualifying Participant (QP) and Partial QP status, we are sincerely appreciative of CMS' proposed mechanism for determining QP and Partial QP status at the APM entity level. We request that CMS finalize this proposal.

Similarly, we support and appreciate that CMS proposes that if none of the Advanced APM Entities in which the eligible clinician participates meet the QP threshold, CMS will assess the eligible clinician individually using combined information for services associated with that individual's NPI and furnished through all such eligible clinician's Advanced APM Entities during the QP Performance Period. We request that CMS finalize this proposal.

Physician-Focused Payment Models (PFPM)

Proposed PFPM Criteria

While Advanced APMs offer minimal participation opportunities for specialty providers, MACRA encourages specialty-focused models under the PFPM track. We support CMS' proposed PFPM criteria related to payment incentives, care delivery, and information availability. We request that CMS allow flexibility for PFPMs to meet the criteria and encourage parity in the review process for assuring that many models are specialty-focused. We request that CMS work with the Assistant Secretary for Planning and Evaluation (ASPE) under the Department of Health and Human Services (HHS) to encourage a high degree of engagement of specialty medicine providers as its Physician-Focused Payment Model Technical Advisory Committee (PTAC) reviews PFPMs.

Facilitation and CMS Consideration of Models Recommended by the PTAC

To facilitate and potentially expedite the consideration of models for CMS testing following PTAC review and recommendation, CMS suggests “supplemental information elements” stakeholders may include in their PFPM proposals to assist agency review. CMS does not propose to require these elements as PFPM criteria and defers to the PTAC on how it may approach requesting any supplemental information beyond that required to meet the PFPM criteria.

We support the concept of “supplemental information elements,” which we understand are aimed at providing important information to CMMI as it determines whether PFPMs are ready for testing by the Innovation Center and could make their way into the Medicare program as Advanced APMs, MIPS APMs or to earn credit under CPIA. Of course, it would be most desirable to see specialty-driven PFPMs be deemed Advanced APMs so specialty-physicians would have access to increased incentives afforded under the Advanced APM track. We request that CMMI make every effort to provide necessary technical assistance so that specialty models are tested and approved for use in Medicare.

We thank CMS for agreeing that utilization of Clinical Data Registries managed by specialty societies or other groups should be included in the PFPM proposals as an aspect of CEHRT use.

Third Party Data Submission

CMS proposes that MIPS data may be submitted by third party intermediaries on behalf of a MIPS eligible clinician or group by: (1) a qualified registry; (2) a QCDR; (3) a health IT vendor; or (4) a CMS-approved survey vendor.

We support the concept of third party intermediaries as a mechanism by which MIPS eligible clinicians can meet their reporting requirements under MACRA. However, some of the criteria for these entities have raised concerns by specialty societies, particularly those who have heavily invested in developing clinical data registries, many of which have QCDR status.

We recognize that CMS must ensure a level playing field for all entities that wish to become a QCDR or submit quality data via EHR. To that end, we request that CMS hold health IT vendors to the same level of scrutiny to which specialty societies are held. We also request that CMS establish additional criteria that would require health IT vendors to be transparent in their activities, to include identification of the clinical experts they used to establish QCDRs.

We also request that CMS monitor to ensure health IT vendors are not inappropriately reducing their efforts to support interoperability now that they can offer “one-stop shopping” for MIPS eligible clinicians. Regardless of whether a health IT vendor wishes to become a QCDR or develop functionalities that would enable quality data reporting through their CEHRT, this should not detract them from their broader responsibility to continue furthering efforts that would lead to seamless communication and exchange of patient data between disparate EHR systems. As they are currently proposed, the standards do not continue the push toward interoperability, and we encourage stringent monitoring of these activities either through the addition of new criteria, through the Office of the National Coordinator for Health Information Technology (ONC) certification criteria, or by other means.

If a QCDR or other entity does not submit accurate data, then the clinicians using that reporting mechanism should not be penalized and instead should be assessed as “average” for the the impacted performance category(ies). We appreciate CMS’ proposal that if it identifies issues or circumstances that would impact the reliability or validity of a measure score, it would exclude those measures from scoring. Although not clear in the rule, we remind CMS of the importance of applying this policy to vendor-related data submission inaccuracies, as well.

Furthermore, we note the gross absence of “hold harmless” provisions that would ensure if a third party intermediary were to have *any* error rate, or withdraw from the market, that MIPS eligible clinicians would not be subject to penalties under MIPS due to these errors on the part of the vendor. We further encourage CMS to work with its colleagues in the HHS Office of Inspector General (OIG) to provide guidance that would extend safe harbors to MIPS eligible clinicians if data submitted by third parties on their behalf is later discovered to be inaccurate, as these clinicians should not be subject to civil monetary penalties (CMP) under the False Claims Act.

Prevention of Information Blocking and Surveillance Demonstration

To address concerns about efforts to prevent information and data sharing by health care providers, CMS is proposing to require eligible professionals (EPs), eligible hospitals (EHs), and critical access hospitals (CAHs) (as part of their demonstration of meaningful use under the Medicare and Medicaid EHR Incentive Programs) and MIPS eligible clinicians (under the Advancing Care Information performance category of MIPS, including eligible clinicians who report on the Advancing Care Information performance category as part of an APM Entity group under the APM Scoring Standard), to attest that they have cooperated with the surveillance of certified EHR technology under the ONC Health IT Certification Program.

We oppose this proposal. While we have heard anecdotal stories that certain health systems have intentionally limited their ability to share patient health data with other local health systems via their EHR system, we do not believe this is a likely circumstance with physicians and physician group practices. On the contrary, specialty physicians and specialty group practices have been clamoring for EHR systems that would allow them to communicate important patient data to referring providers in order to “close the referral loop”. We also note that, under the current Medicare EHR Incentive Program, eligible professionals have struggled significantly with meeting the security risk analysis that is required under the Protecting Patient Health Information objective. This is because their understanding of the technology at a level that goes beyond its use for clinical practice, is severely limited. Therefore, it is unlikely that any specialty physician or specialty group practice has the know-how to intentionally limit their ability to communicate with other care providers. We included recommendations for assistance in addressing this challenge in the preceding paragraphs.

We request that CMS limit the attestation to only the first and third statements. That is, MIPS eligible clinicians should only be required to attest that they: *“Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology,”* and *“Responded in good faith and in a timely manner to requests to retrieve or exchange*

electronic health information, including from patients, health care providers (as defined by 42 USC 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor."

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 Association of Neurological Surgeons
American Academy of Facial Plastic and Reconstructive Surgery
American College of Mohs Surgery
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association
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
Society for Cardiovascular Angiography and Interventions