The Alliance of Specialty Medicine (Alliance) is a coalition of national medical specialty societies representing more than 100,000 physicians and surgeons. We are dedicated to the development of sound health care policies that foster patient access to the highest quality specialty care. Our member societies appreciate the work that went into drafting and passing the Medicare Access and CHIP Reauthorization Act (MACRA), P.L. 114-10, and we thank the Subcommittee for holding a hearing to discuss the Center for Medicare and Medicaid’s (CMS) proposed rule on implementation of the Merit-Based Incentive Payment System (MIPS) and participation in Alternative Payment Models (APMs).

While the Alliance is pleased that CMS is taking meaningful steps to address many of the obstacles that have prevented specialists from participating meaningfully in quality reporting programs to date, we also believe that additional reforms must be made before the incentives to participate among specialists truly outweighs the disincentives.

Listed below are some of specialty medicine’s overarching principles regarding MACRA implementation, including some related questions for the Subcommittee to consider using at its hearing.

**Merit-based Incentive Payment System (MIPS)**

- **Investment in measure gaps must occur expeditiously.** For many specialties, the most significant barrier to meaningful participation in current programs is an ongoing lack of relevant measures. CMS must expeditiously support — through financial investments, technical assistance, and greater access to data — the development of high-quality, specialty-focused measures to ensure that all physicians have a fair opportunity to demonstrate quality and value for the unique conditions and populations they treat. The paucity of relevant resource use measures is especially critical. **Question:** The proposed rule, as well as CMS’s recently released Measure Development Plan, continue to offer vague details about how and when CMS plans to fulfill its mandate to spend the $75 million authorized under MACRA explicitly for measure development to fill such gaps. Why has CMS not yet released any of these funds and when does it plan to release the first $30 million that were supposed to be allocated by 2016? We would appreciate CMS providing us with additional details regarding its strategy for filling current measure gaps and to what extent that will entail partnering with specialty societies?

Another key aspect of developing meaningful, specialty-specific measures and conducting analyses that allow us to better understand physician performance is broader access to data. We are concerned that CMS has misinterpreted Section 105(b) of MACRA, which directs CMS to make Medicare claims data available to Qualified Clinical Data Registries (QCDRs) to support quality improvement and patient safety efforts. Unfortunately, through a separate rule, CMS opted not to issue new regulations addressing this aspect of MACRA, stating that QCDRs can already access Medicare claims data through existing processes (i.e., ResDAC). The Alliance believes that existing mechanisms for accessing
data are insufficient and have limitations that contradict the Congressional intent of this provision, which is greater access to Medicare data. Could CMS please comment on its rationale behind this decision?

- **Minimize administrative burden and ensure more meaningful reporting options.** One of the Alliance’s biggest concerns with the proposed rule is that rather than streamlining and simplifying reporting requirements across federal programs, its seems to make things even more complicated than under the current structure. While we appreciate the range of flexible reporting options, the scoring mechanisms and variable weights proposed for each category, as well as the overall MIPS composite score, make this an incredibly complex program to understand for practicing physicians and their administrative staff. Many practices have already had to hire additional staff simply to comply with existing mandates and MIPS will divert even more attention away from clinical care. A recent study in Health Affairs demonstrates that physicians are spending more than $15 billion each year on quality reporting. Other research published in leading journals—including the prestigious New England Journal of Medicine—has shown that the focus on the way Medicare is measuring quality is off-track and is turning physicians into meaningless information box-checkers. **Question:** What data did CMS use to calculate the estimated burden of compliance with these newly proposed requirements, which seem to vastly underestimate the burden on physician practices? For instance, the registration fees for PQRS Qualified Registries and QCDRs alone often exceed the estimated cost burden for practices without even yet taking into account eligible clinical and staff time spent on meeting the program requirements. What does CMS plan to do going forward to carefully monitor the regulatory burden of these new policies on practicing physicians to ensure that compliance does not result in meaningless engagement, wasted resources or otherwise interfere with patient access to personalized care? The MIPS program is intended to simplify quality mandates—not make them more complicated.

- **Gradual, thoughtful implementation will be the key to success.** MIPS represents a critical opportunity to press the reset button on current programs, such as the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program and the Value-Based Payment Modifier (VM). At the same time, we recognize that building a new quality infrastructure requires a thoughtful and gradual approach to ensure that the initial transition to this new system is as seamless and undisruptive to clinical practice as possible. CMS is therefore faced with the task of maintaining certain elements of current programs while abandoning the most critically flawed features and replacing them with alternative strategies that allow physicians to more meaningfully demonstrate value. While we understand the difficulty of this balancing act, we were disappointed to learn that CMS is proposing to maintain most aspects of the Value Modifier program—most notably, two of its resource use measures that specialty medicine has long criticized as not only meaningless, but flawed and inappropriate. **Question:** What work has CMS done to date to evaluate the utility of resource use measures that it is proposing to maintain in MIPS and whether holding physicians accountable for these measures has resulted in any meaningful or actionable data that is having an impact the overall value of health care? Similarly, what work has CMS done to ensure that these flawed measures are not having an adverse impact on practice patterns or discouraging treatments that best meet the needs of individual patients? To ensure that physicians are not inappropriately penalized, did CMS consider removing these measures from MIPS and re-weighting the resource use category to reflect this ongoing gap in measurement?

- **Flexibility will ensure meaningful engagement.** When developing MIPS policies, it is critical that CMS take a flexible, rather than prescriptive, one-size-fits-all approach. Ensuring that MIPS is relevant to all specialties will help to not only ease the transition to
this new system but will also foster innovation, trust and ultimately widespread stakeholder engagement. The Alliance very much appreciates that CMS proposes to abandon the all-or-nothing approach that it has historically relied on for assessing meaningful use of Health Information Technology (HIT) and that it generally proposes to apply this concept across the MIPS performance categories, giving physicians an opportunity to earn incremental points based on their level of engagement. However, the selection of metrics and activities across all four performance categories are still very primary care-focused and seem to award greater weight to actions that are only relevant and meaningful to a primary care practice. **Question:** Can CMS please explain what strategies it employed when developing this rule to ensure a fair balance between reporting opportunities available to primary care physicians versus specialists?

In regards to Clinical Practice Improvement Activities (CPIA), in particular, MACRA created this new category under MIPS to recognize physicians for engaging in quality improvement activities that do not necessarily lend themselves to traditional performance measurement, such as continuing medical education, maintenance of certification, expanded office hours and the use of clinical data registries. It is critical that CMS preserve the intent of this innovative and long sought after provision by recognizing a wide variety of activities that represent the unique needs of each specialty. As such, we were disappointed to learn that CMS is proposing a finite set of CPIAs rather than giving professional societies the authority to determine which activities should count for their specialty and how best to evaluate and score physician compliance with those activities—a policy we have long advocated for. **Question:** Could CMS please discuss its rationale behind not giving specialties the authority to determine which CPIAs should count under this category?

- **Continue to promote the value of clinical data registries.** The Alliance strongly supports CMS’s investment and promotion of qualified clinical data registries (QCDRs) to date. We support policies that continue to recognize the value of registries, that permit physicians to meet multiple components of MIPS by participating in a QCDR, that promote interoperability between registries and EHRs, and that provide registries greater access to private and payer claims data. We are pleased that CMS’s proposed inventory of Clinical Practice Improvement Activities includes 13 separate activities that rely on the use of a QCDR. However, of those 13, only one proposed activity is given the higher of two potential weights (i.e., high vs. medium). The other 12 are all designated as “medium,” which carries a lower weight and will either prevent specialists who actively engage with registries for quality improvement purposes from achieving the maximum total score for the CPIA performance category or require them to demonstrate their participation in more numerous activities than those who participate in activities with a higher weight. **Question:** Could CMS please address the logic behind its decision to largely designate participation in a registry as less valuable than other activities when, in fact, ongoing participation in a clinical data registry is one of the most meaningful quality improvement activities for specialists (not to mention, an activity that requires a substantial investment of resources and engagement)?

Furthermore, in the proposed rule’s discussion on QCDRs, CMS states that while non-MIPS measures are not required to have NQF-endorsement, the agency encourages the use of NQF-endorsed measures and measures that have been in use prior to implementation in MIPS. In addition, CMS’s Measure Development Plan states that for measures that are not consensus-endorsed, CMS will ensure that each measure is evaluated on the basis of the NQF measure evaluation criteria used in the consensus review process. While we agree that QCDR measures must be evidence-based and
held to minimum standards, we strongly believe that these proposed policies contradict the original statutory language authorizing the QCDR reporting mechanism, which explicitly carves out an exception for the testing of more innovative QCDR measures so that they are not required to go through consensus-based endorsement processes, including the NQF and the Measures Application Partnership. Question: Could CMS please address this concern?

**Alternative Payment Model (APM) Implementation**

- **Flexibility is essential for specialties and subspecialties to develop and implement APMs for their specific patient population and practice types.** CMS’s proposed rule suggests that the agency plans to focus on only a handful of existing models, most of which do not apply to our specialties. Similarly, we have heard that the few APMs developed to date by specialty societies are too narrow in focus because they are centered on a particular disease, condition or set of procedures. *Question: What is CMS doing to provide maximum flexibility in considering new models that have not previously been tested? What is CMS’s plan for releasing the resources and technical assistance to get those models off the ground?*

In addition to flexibility, policies to encourage more widespread APM participation among specialists must carry minimal administrative burden for both physicians and patients, maintain patient access to specialty care and choice of provider, and recognize patient diversity. The problems with this arise when it comes to CMS’s proposed definition of “more-than-nominal” financial risk. *Question: In the future, how does CMS plan to alter its definition to account for the fact that the financial risk for physicians comes in many forms, including investments in human capital — clinical and administrative — technological infrastructure, clinical workflows and patient case-mix?*

- **Ensure recognition of physician-focused payment models.** We have heard from many groups that specialists are concerned about the limited role of the PTAC and CMS comments that is under no obligation to recognize models recommended by the PTAC. These policies are concerning given that we included this in the legislation to broaden APM participation opportunities. If CMS is “not obligated” to test the recommendations of the PTAC, what is it that CMS is doing to provide specialists with the opportunity and incentive to participate in more transformative payment and delivery models?

- **Thoughtful consideration of APM implementation timeline to minimize physician burden and confusion.** We are very encouraged to see that CMS has aligned the reporting timelines for MIPS and the APM Incentive Payment. However, we’ve heard from a good number of groups that it is important that CMS administer the 2019 APM payment update in a way that allows physicians who are qualified APM participants to forego participation in MIPS in 2017. It appears that CMS has attempted to achieve this by structuring the programs in a way so that a MIPS qualified APM will do the MIPS quality reporting for eligible clinicians that are on the APM’s participant list. *Question: So for clarification, exactly what MIPS quality data must be submitted on behalf of APM participants, for example, in 2017? In addition, just reporting quality wouldn’t meet all of the MIPS reporting requirements. Does CMS envision that the APM would be reporting other data to ensure that the participants meet the reporting requirements in the other performance categories? Or does CMS expect that eligible clinicians participating in approved APMs would need to meet the reporting requirements for Advancing Care Information and Clinical Practice Improvement Activities even though they could eventually qualify for the Advanced APM Incentive Payment?*