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November 17, 2015

Andrew M. Slavitt

Acting Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-3321-NC

Submitted electronically via <http://www.regulations.gov>

**RE: Request for Information Regarding Implementation of the
Merit-Based Incentive Payment System, Promotion of
Alternative Payment Models, and Incentive Payments for
Participation in Eligible Alternative Payment Models**

Dear Acting Administrator Slavitt:

Established in 1943, the AAAAI is a professional organization with more than 6,700 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases.

Today, we are writing to share our thoughts on the recently released Request for Information on the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. We urge CMS to consider our comments as it implements the newly established Medicare payment and quality improvement programs under MACRA, while also considering the overall burden of Medicare's regulations on physician practices.

Merit-Based Incentive Payment System (MIPS)

AAAAI is eager to work with CMS to improve upon its existing quality reporting programs, such as the Physician Quality Reporting System (PQRS) and Value-based Payment Modifier (VM), both of which rely on provider reporting of clinical quality data and measures, as these programs are consolidated into the MIPS.

AAAAI has worked diligently to ensure there are meaningful and appropriate measures of quality available for our specialty. We continue to expand our quality measure development and stewardship activities, working closely with our clinical committees to identify areas where performance gaps or variations in care may need to be addressed. For that

and other reasons, AAAAI was also the first and only A/I organization to establish a qualified clinical data registry (QCDR). The AAAAI QCDR is a vital tool for our specialty to measure important quality indicators for our patients and the care we provide. However, these activities are resource intensive, and the support of CMS is greatly needed.

With those sentiments in mind, we urge CMS to further emphasize the development of clinical quality measures and the use of QCDRs in the MIPS program. Specifically, we urge CMS to support the development high-quality and relevant measures for A/I specialists and subspecialists, which will ensure all have a fair opportunity to demonstrate quality improvement for the conditions and populations they treat. We also urge CMS to adopt policies that promote interoperability between QCDRs and electronic health records (EHR), and permit eligible professionals to meet the quality component of MIPS by participating in a QCDR. We also urge you to ensure that use of a QCDR counts toward any meaningful use requirements related to quality reporting.

Finally, we would oppose any effort that would require endorsement of quality measures by the National Quality Forum (NQF). Measures developed by AAAAI following a rigorous, well-vetted and accepted protocol that should not require the additional time or expense of securing endorsement by the NQF.

With regard to resource use, we continue to be concerned that the available cost measures are not appropriate for our specialty and rely on questionable attribution and risk adjustments methodologies. CMS should work closely with specialty societies to develop specific and meaningful resource use measures. We also encourage CMS to incorporate socio-economic status (SES) and other demographic factors that have a clear relationship to quality of care and patient outcomes into resource use (and quality) measurement.

For clinical practice improvement activities, we reiterate our comments from the 2016 Medicare physician fee schedule proposed rule. Specifically, we urge CMS to adopt additional subcategories that give credit for enhanced professional education and training, professional and practice accreditation activities, and other clinical practice improvement activities, and include at least the following as clinical practice improvement activities:

- Physician attendance and participation in ACGME-accredited events, such as the AAAAI Annual Meeting
- Physician attendance and participation in other CME and non-CME events
- Fellowship training or other advanced clinical training completed during a performance year
- Physician practice accreditation, such as accreditation achieved by the National Committee on Quality Assurance (NQCA), Accreditation Association for Ambulatory Health Care (AAAHC), The Joint Commission (TJC), or other recognized accreditation organizations
- 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 the NIH’s USIDNET registry, or other federally sponsored quality reporting and improvement programs not already affiliated or considered under the MIPS program

It is our sense that attestation is the most appropriate mechanism for reporting these activities, and should be done on an annual basis. We believe this could be accomplished easily using a web-based reporting tool.

Finally, and in addition to our MACRA RFI specific comments, we urge CMS to consider the overall burden of CMS’ regulations on physician practices as it implements the MIPS program. A/I members feel consumed with the mounting requirements of current quality programs, and those programs beyond the quality realm. For example, the burden of Medicare’s program integrity and Medicare Advantage audits, not to mention the cumbersome evaluation and management (E/M) guidelines that, together with the quality improvement programs and the implementation of ICD-10, have lengthened the medical record to a level that makes it difficult to review by patients and healthcare professionals. In addition, we are concerned that the increased regulatory burden by the aforementioned requirements, programs, and initiatives, have contributed significantly to increased cost of medical care (e.g. ongoing monthly fees for EHR, quality reporting and additional staff time to fulfill these regulatory requirements) and have not conclusively demonstrated to improve patient outcomes, care or lower healthcare costs.

Toward that end, CMS should use the consolidation of its quality programs to also evaluate how it can reduce the complexity of participating in the Medicare program, in general. CMS should take a close look at whether the current E/M guidelines hold the same value now that providers are reporting quality data and adopting electronic health record (EHR) systems.

Alternative Payment Models (APMs)

Regarding APMs, and as we commented during the 2016 MPFS, we urge CMS to adopt a set of fundamental elements that would be core to any model “deemed” by the agency. This would provide the needed flexibility for physicians to develop APMs that make the most sense for their specialty and/or practices. At a minimum, these fundamental elements should include:

- **Quality Measurement** – Measures of clinical quality that meet minimum standards and are developed by relevant clinical experts should be a fundamental component of any APM.
- **Continuous Data Collection** –APMs should require continuous clinical data collection through the use of a qualified registry, database, or other health information technology, as appropriate.
- **Shared Decision-Making (SDM)** – Where appropriate, APMs should encourage engagement in collaborative processes that assist patients with making individualized treatment decisions by taking into account the best scientific evidence, as well as the

patient's values and preferences.

- **Care Coordination** – APMs should incentivize seamless transitions of care between providers and care settings, when appropriate, including effective communication during referrals and consultations, systematic processes for tracking follow-up tests and treatments, and patient education and support for self-management.
- **Patient Reported Outcomes (PROs) and Care Experiences** – APMs should collect data on both patient reported care experiences and patient reported health outcomes relevant to the model, using validated instruments.

APM entities should have significant flexibility in how its participants meet these elements, and we encourage CMS to avoid being overly prescriptive as specialty organizations attempt to design APMs and Physician-focused Payment Models (PFPMs). Technical assistance will be needed by specialty societies, and we encourage CMS to give priority to those APM developers whose models address important quality initiatives that have far-reaching impacts, such as antimicrobial resistance.

We appreciate the opportunity to provide comments on the aforementioned issues of importance to our members. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Lemanske, Jr.", with a stylized flourish at the end.

Robert F. Lemanske, Jr., MD, FAAAAI
AAAAI President