American Academy of
Allergy Asthma & Immunology

August 21, 2017

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

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

Submitted electronically via Regulations.gov

Dear Ms. Verma,

Established in 1943, the AAAAI is a professional organization with more than 7,000 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.

We appreciate the opportunity to provide feedback on CMS' ongoing implementation of the Quality Payment Program (QPP), primarily the Merit-Based Incentive Payment System (MIPS), as well as aspects of the Alternative Payment Model (APM) incentive, and the impact on A/I professionals and beneficiaries they serve.

Medicare's Quality Payment Program – Proposed Implementation in Year 2 and Beyond

In CMS' 2018 QPP proposed rule, the agency offers multiple proposals that would provide important flexibility and incentives, particularly for small practices, which will have a major impact on A/I professionals. There are also a number of proposals that would have a significant negative impact on A/I professionals, including the beneficiaries who rely on them, if finalized as proposed.

AAAAI supports the following proposals, offering additional recommendations to improve the ability of A/I professionals to engage in the MIPS program in the 2018 performance year and beyond.

(more)

www.aaaai.org
(414) 272-6071 • Fax: (414) 272-6070
555 E. Wells Street, Suite 1100 • Milwaukee, Wisconsin 53202-3823

- **Modify the low-volume threshold to exclude individual eligible clinicians or groups that have Medicare Part B allowed charges less than or equal to $90,000 OR that provide care for 200 or fewer Part B-enrolled Medicare beneficiaries.** We urge CMS to finalize this policy, but encourage that the agency consider extending it beyond the 2018 performance year, which would offer clinicians a level of certainty as to the likelihood that they would be expected to participate in future years. We also feel it is important to allow those clinicians who wish to participate in MIPS the ability to opt-in beginning with performance year 2018. Furthermore, for those clinicians that are newly eligible in MIPS (i.e., those who suddenly exceed the low-volume threshold or are no longer newly-enrolled in Medicare) CMS should provide an "on-ramp," allowing them to more easily integrate into the program. This may be accomplished through lower reporting requirements and alternative scoring in their first performance year.

- Reduce the weight of the cost performance category from 10% to 0% for the 2020 MIPS payment year. We urge CMS to finalize this proposal, as it will give the agency additional time to develop and test episode-based cost measures that are more appropriate for A/I professionals, which will be important once the cost category consumes a greater proportion of the MIPS final score in future years. As we stated in our comments on the development of episode-based measures, AAAAI continues to believe that A/I professionals should not be attributed patients with diagnoses that are outside the scope of their specialty, which is the case under the current cost measures that CMS relies on from its former Value-Based Payment Modifier program (i.e., the Total Per Capita Cost and Medicare Spending Per Beneficiary (MSPB) measures). We request that CMS reweight the cost performance category to 0% for our specialty, beginning with the 2021 MIPS payment year, until episode-based measures for A/I professionals are available for implementation in MIPS.

- Modify the scoring of the Public Health and Clinical Data Registry Reporting objective beginning with the performance period in 2018, given there are areas of the country where immunization registries are not available. We urge CMS to finalize this proposal with modifications. While we appreciate CMS' intent not to penalize those without access to immunization registries, we are concerned that the proposal diminishes the value of reporting to specialized and clinical data registries by only awarding 5 percentage points for reporting to such registries. We contend that A/I professionals who do not have access to an immunization registry should be able to earn the full 10 percentage points for reporting to a single other recognized registry, such as a specialized or clinical data registry. AAAAI has developed such a registry for A/I professionals to report. We urge CMS to finalize 10 points for reporting to a specialized or clinical data registry in lieu of an immunization registry.

- **Use EHR technology certified to either the 2014 or 2015 Edition certification criteria, or a combination of the two for the 2018 performance period.** We urge CMS to finalize this policy with modifications. Specifically, CMS should extend this policy beyond 2018, given there are few certified EHR technology (CEHRT) products appropriate for A/I professionals in the market or under development. We note that efforts to develop and implement robust interoperability standards and address data blocking between EHRs and clinical data registries remain a challenge, causing A/I professionals to question whether the investment is worthwhile at this juncture. We also have concerns about efforts to address the role of health IT on patient safety and in adverse events. Until these issues are resolved, CMS should not expect physicians to

continue making significant financial investments in CEHRT that do not meet their needs, or the needs of their patients. For those who have made the investment in 2015 Edition CEHRT, **we also support the 10 percentage point bonus and encourage CMS to extend it beyond 2018.**

- Accept a minimum of 90 consecutive days of data in CY 2019 for the Advancing Care Information (ACI) performance category. CMS previously finalized this policy for CY 2017 and 2018, and we appreciate that CMS proposes its continuation in CY 2019. We believe this policy offers a level of certainty and stability that A/I professionals needs in the MIPS program, particularly with overly complex and cumbersome ACI performance category.

- Add new exclusions to the measures associated with the Health Information Exchange and Electronic Prescribing objectives required for the base score, which would apply beginning with the 2017 performance period. We urge CMS to finalize these exclusions, which will be important for those who would not otherwise be able to meet the requirements.

- Rely on new authorities granted under the 21st Century Cures Act to provide a new significant hardship exception for MIPS eligible clinicians who are in small practices, as well as for those who have EHR technology that has been decertified, and not apply the 5-year limitation to significant hardship exemption. We urge CMS to finalize these policies as proposed, which bring significant relief to several small A/I practice's that continue to face challenges with the ACI performance category.

- Provide a small practice bonus and a complex patient bonus. We urge CMS to finalize the small practice bonus, but we are concerned that CMS proposes to limit the complex patient bonus to 3 points. We believe the clinical relevance of managing complex patients warrants a bonus structure that starts at least as high as the bonus for small practices. We urge CMS to correct this discrepancy by increasing the complex patient bonus to a level that is commensurate with treating truly complex patients. The lowest complex patient bonus should start at 5 points.

- Broaden the definition of Physician-Focused Payment Models (PFPM) to include payment arrangements that involve Medicaid or the Children's Health Insurance Program (CHIP) as a payer even if Medicare is not included as a payer. We agree with CMS that such a broadened definition might be more inclusive of potential PFPMs that could focus on areas not generally applicable to the Medicare population, and could engage more stakeholders in designing PFPMs, including A/I practices.

As noted above, we also have significant concerns about certain other proposals outlined in the rule. **We oppose the following proposals:**

- **Include of Part B drugs in the calculation of MIPS payment adjustments and eligibility determinations.** Not only would finalizing this policy be a violation of the Administrative Procedures Act (APA), we disagree that it was Congress' intent when drafting the legislation. The Administrative Procedures Act (APA) requires that a final rule must be a logical outgrowth of a proposed rule. What CMS has outlined in the rule is not a clear proposal; it is a confusing "clarification" of what it suggests is existing policy. Without a clear proposal for stakeholders to consider and provide comment, the logical outgrowth test cannot be met. Moreover, CMS' interpretation of the statute, which led it to believe that Part B drugs are subject to the MIPS payment adjustment, is flawed. The MIPS payment adjustment provisions are included in

Section 1848 of the Social Security Act (the Act), which is entitled "payment for physician services" [emphasis added] and pertains to payment under the Physician Fee Schedule (PFS). Under CMS' predecessor quality improvement programs (i.e., the Physician Quality Reporting System (PQRS), the Value-Based Payment Modifier (VM) and the Electronic Health Record (EHR) Incentive Program), Part B drugs were excluded from payment adjustments. And, since MIPS was expressly designed to consolidate and streamline adjustment under those program, we do not believe Congress intended for CMS to *expand* them to include Part B drugs. It should be noted that the Advanced APM track of the QPP does not include Part B drugs in the incentive payment, and we do not believe that Congress intended for the MIPS adjustment to apply to more services than the Advanced APM incentive. **CMS must reconsider its proposal and exclude Part B drugs from MIPS eligibility determinations and payment adjustments. MIPS payment adjustments should only apply to covered PFS services.**

- **Revise the A/I specialty measure set.** We strongly oppose CMS' revisions to the A/I specialty measure set, which include the removal of quality measures that are specific to the A/I specialty, and the addition of measures that are unlikely to be reported by A/I professionals. We recognize that all of the measures are still in the MIPS measure set, however, there may be implications as CMS finalizes its Eligible Measures Applicability (EMA) validation process. **We urge CMS to maintain the 2017 A/I specialty measure set in 2018.**

- **Allow individual MIPS eligible clinicians and groups to submit data on measures and activities, as applicable, via multiple data submission mechanisms for a single performance category.** We oppose this proposal for the very reason that CMS notes in the rule, that the increased flexibility may create complexity and cost burden for physicians. In fact, we are certain that the proposal would significantly add to the cost and administrative burden for those participating in MIPS. It is also unclear how this policy would intersect with CMS' plans to implement the new Eligible Measure Applicability (EMA) validation process. Would physicians now be held accountable to meeting more measures simply because CMS is making additional submission mechanisms available? It is also unclear how CMS would set benchmarks and score quality measures submitted through multiple mechanisms. CMS clarifies that if an individual MIPS eligible clinician or group submits the same measure through two different mechanisms, each submission would be calculated and scored separately, given CMS does not have the ability to aggregate data on the same measure across submission mechanisms. In this scenario, CMS would only count the submission that gives the clinician the higher score, thereby avoiding the double count. This scenario appears to assume that the individual or group submitted the same measure through different mechanisms across the same timeframe. However, if an individual MIPS eligible clinician submits the same measure through two different mechanisms, during different timeframes (e.g., the individual submitted data through claims for the first half of the year and through a qualified registry for the second half of the year), it is not entirely clear how the clinician would be calculated and scored. Calculating a score for half of the year using one submission mechanism would not be fair, given the physician reported for the entire year. CMS would have to rectify this issue, particularly as longer reporting durations are mandated.

- **Revise Class 2 measures/Add Class 3 measures.** We oppose CMS' proposal to revise Class 2 measures to include only measures that cannot be scored based on performance because they do not have a benchmark or do not have at least 20 cases, which would continue to receive 3

points. Similarly, we oppose CMS' proposal to create Class 3 measures, which are measures that do not meet the data completeness requirement, which would receive 1 point, unless submitted by a small practice with 15 or fewer clinicians, in which case it would receive 3 points given concerns that data completeness may be harder to achieve for small practices with smaller case sizes. **CMS should maintain its current policy for Class 2 measures, and not create a new class of measures.**

- **Increase the data completeness thresholds to 60 percent for each submission mechanism beginning with the 2021 MIPS payment year (i.e., the 2019 performance year).** We oppose this proposal and urge CMS to maintain its current data completeness threshold of 50 percent for the 2021 MIPS payment year. The constant flux in reporting requirements year after year poses significant administrative challenges for physicians and their administrative staff. A/I professionals seek long-term stability in program requirements, and there is no demonstrated benefit or clinical relevance for increasing the threshold beyond 50 percent.

- **Establish a minimum threshold for group reporting of improvement activities.** CMS previously clarified that if one MIPS eligible clinician (NPI) in a group completed an improvement activity, the entire group (TIN) would receive credit for that activity. While CMS does not propose any changes to this policy, it requests comment on whether it should establish a minimum threshold (for example, 50%) of the clinicians (NPIs) that must complete an improvement activity in order for the entire group (TIN) to receive credit in the improvement activities performance category in future years. We urge CMS to maintain its current policy and not establish any reporting threshold. Similar to our comments above, A/I professionals need long-term stability in program requirements. Fluctuation in these policies create unnecessary administrative challenges for practices without any proof that quality or outcomes are improved for patients when they are revised.

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We appreciate the opportunity to offer these comments, and we look forward to working with you as you implement the Medicare QPP in 2018 and future years. If you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071.

Sincerely,

David B. Peden, MD MS FAAAAI
President