American Academy of
Allergy Asthma & Immunology

September 26, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted online via regulations.gov

Re: CMS-1715-P – Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

Dear Administrator Verma:

Established in 1943, the American Academy of Allergy, Asthma & Immunology (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. We appreciate the opportunity to provide comments on the aforementioned proposed rule and the impact on A/I patients and providers.

Physician Supervision for Physician Assistant (PA) Services

AAAAI opposes CMS' proposal to revise the physician supervision

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requirement for PAs. Specifically, CMS proposes to update regulations such that:

- The statutory supervision requirement would be met when the PA performs his or her services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed.
- In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by "documentation in the medical record of the PA's approach to working with physicians in furnishing their services."

AAAAI has serious concerns with this policy, which we believe fails to meet the statutory requirement at Section 1861(s)(2)(K)(i) of the Social Security Act that requires that PA services be provided "under the supervision of a physician" – particularly with respect to those states where there is no state law governing physician supervision. We do not believe that documentation demonstrating a "PA's approach to working with physicians" sufficiently establishes a supervisory relationship, and that the current language provides a clearer standard for physician supervision across-the-board consistent with statutory requirements. AAAAI therefore recommends that CMS retain its existing physician supervision requirement for PAs rather than finalize the proposal outlined above.

Review and Verification of Medical Record Documentation

AAAAI supports CMS' proposal to "establish a general principle to allow the physician, the PA, or the advanced practice registered nurse (APRN) who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team." This proposal would significantly reduce documentation burden for services delivered under the Physician Fee Schedule and would allow physicians and other billing practitioners to focus on patient care rather than unnecessary and duplicative paperwork.

Care Management Services

CMS includes several proposals designed to improve clinicians' ability to manage the care of patients with complex health care needs, including:

- Increasing payment for transitional care management services consistent with RUC recommendations and removing certain billing restrictions;
- Revising coding for chronic care management (CCM) and complex CCM services, including establishing add on codes to account for incremental time engaged in these services and removing and revising certain billing requirements; and
- Establishing principal care management (PCM) codes that would describe care management services for a single serious chronic condition.

AAAAI supports these proposals, which we believe more appropriately recognize, value, and reimburse the services required to appropriately manage patients with complex health care needs, and we urge CMS to finalize these policies as proposed. In particular, AAAAI appreciates CMS' proposal to establish PCM codes, which we believe recognizes the role of specialty

practitioners in the diagnosis, treatment, and management of high-risk conditions. CMS specifically notes its expectation that initiation of PCM services would be "billed when a single condition is of such complexity that it could not be managed as effectively in the primary care setting, and instead requires management by another, more specialized, practitioner." Our members regularly encounter situations where patients with complex allergic and immunology diseases (e.g. severe asthma, anaphylaxis, chronic sinus disease, urticaria / angioedema, drug reaction, eosinophilia, and food allergy) where specialized expertise and intensive care management services are necessary to control patients' symptoms and to establish and implement successful treatment plans to support patients' long-term well-being. PCM codes would enable our members to be reimbursed for these services as they provide targeted and specialized care.

Comment Solicitation on Consent for Communication Technology-Based Services

CMS is seeking comment on whether a single advance beneficiary consent could be obtained for a number of the communication technology-based services CMS finalized in rulemaking last year, including virtual check-ins, remote evaluation of pre-recorded video or images, and interprofessional internet consultations. AAAAI supports a single advance beneficiary consent, through which a beneficiary could be informed of the potential communication technology-based services that could be offered and their associated cost-sharing requirements. We believe such a single advance consent covering all services and remaining in force for at least a year would significantly reduce burden for practices, while still assuring that patients are well informed about their potential cost-sharing obligations. We believe that CMS' current audit programs, along with beneficiary complaints against abusive providers, would provide sufficient protection to mitigate the risk of improper provider actions associated with these services.

Comment Solicitation on Opportunities for Bundled Payments under the PFS

CMS seeks comment on opportunities to expand the concept of bundled payments under the PFS. AAAAI has significant concerns about this proposition, particularly when CMS already experiences significant challenges with bundled payment approaches, not only under the PFS, but also under MIPS and in alternative payment models (APMs) as well. For example, it is not clear whether CMS can accurately value and pay for care within a bundle, particularly when CMS does not account for variation in care due to variation in patient risk. There is also a concern that bundled payments create incentives to stint care, but CMS has not established how risk would be mitigated through linkages to quality measures.

AAAAI recommends that these issues be more fully understood and addressed through existing bundled payment approaches and through new APMs, before CMS expands bundled payments in the PFS. Indeed, we encourage CMS to contemplate these issues through the development of APMs that would allow for greater, more meaningful participation by A/I specialists. AAAAI believes that APMs are a clear avenue for testing new payment approaches, including bundled payment, prior to their introduction into the PFS, and that a focus on A/I care is long overdue.

Payment for Evaluation and Management (E/M) Visits

CMS has proposed significant revisions to its policies regarding documentation, coding, and payment for office and outpatient E/M visits that would apply beginning in 2021, most of which adopt recommendations put forward by the CPT Editorial Panel and the American Medical Association (AMA) RUC, including:

- Adoption of the CPT Editorial Panel's recommended revisions to office/outpatient E/M coding, prefatory language, and interpretive guidance framework
- Adoption of RUC-recommend work values for all office/outpatient E/M codes, and
- Adoption of a new prolonged service code to use when billing for E/M using time, as recommended by the CPT Editorial Panel

CMS also proposes to simplify and consolidate two previously finalized add-on codes for inherent complexity into a single add-on code (GPC1X) that would be used to support complexity associated with evaluation and management that serves as the continuing focal point for health care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition.

AAAAI strongly supports these proposals, which largely reflect input and broad agreement across the medical community. AAAAI appreciates CMS' responsiveness to stakeholder input, as well as its continued commitment to reducing administrative burden associated with documentation of office and outpatient E/M visits, as demonstrated by these proposals. We also believe that these proposals more appropriately value the cognitive work that is required by many A/I professionals with high-need patient populations whose care often requires significant time and medical decision making expertise to deliver effective, high-quality care. For all these reasons, AAAAI urges CMS to finalize the above policies for office/outpatient E/M services as proposed.

Solicitation of Public Comments Regarding Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy

As a result of passage of the 21st Century Cures Act, a separate benefit was created to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously through a pump that is an item of DME in the beneficiary's home, beginning January 1, 2021. Prior to the furnishing of home infusion therapy to an individual, the law stipulates that the physician who establishes the therapy plan for the individual shall provide notification of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part. As such, CMS solicits comments regarding the appropriate form, manner and frequency that any physician must use to provide notification of the treatment options available to their patient for the furnishing of infusion therapy under Medicare Part B. CMS also invites comments on any additional interpretations of this notification requirement.

The physician needs to be sufficiently informed of the insurer's policies and payment in order to adequately counsel the patient. It will be important to document this in the patient chart, on the initial order and with subsequent changes or re-authorization.

Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm

CMS proposes to revise policies related to enrollment revocation and denial related to improper prescribing and patient harm. AAAAI has significant concerns regarding these proposals and urges CMS not to finalize these policies.

First, with respect to CMS' proposal to add improper prescribing of Part B drugs (in addition to Part D drugs) as a potential reason for enrollment revocation, AAAAI is concerned that the underlying premise of improper prescribing may inappropriately and unfairly target professionals from our specialty, who regularly prescribe high-cost Part B and Part D drugs for patients with complex A/I disorders. We are concerned that this new proposal could lead our members to improperly restrict access to drugs that are medically necessary and clinically appropriate, including in some cases off-label drugs that may be considered the standard of care (e.g., cyclosporine for management of refractory chronic urticaria). When off-label changes occur after approval, it can be difficult for prescribers to determine what constitutes a violation that could result in audit, repayment or penalties. It is of upmost importance that prescribing guidelines are up to date, effectively communicated, and also allow for physician opportunity to provide the best care for their patients, supported by appropriate documentation and when challenged by commercial payers.

Of even greater concern is CMS' proposal to add new revocation and denial reasons to regulation text to permit CMS to revoke or deny, as applicable, a physician's or other eligible professional's enrollment if he or she has been subject to prior action by oversight entities where underlying facts reflecting improper conduct that led to patient harm. AAAAI believes that this proposal reflects significant overreach on the part of CMS that would place clinicians at inappropriately high risk for enrollment revocation or denial. Many of the actions taken by these entities that CMS proposes to consider – for example required compliance appearances before state oversight board members or formal reprimands – may be based on a single complaint by an irate patient and do not necessarily reflect action leading to patient harm. CMS' proposal to rely upon these types of state actions as a potential revocation or denial reason therefore raises significant concern. Furthermore, we do not believe that CMS has established sufficiently clear standards for how it would assess the multiple factors CMS outlines (e.g. the nature of patient harm, the number and types of sanctions, the number of patients) when making a determination to revoke or deny enrollment. CMS even proposes to base its decision-making on "any other information that CMS deems relevant to its determination."

We are concerned that this policy, as proposed and without clear standards, is too vague and gives CMS overly broad authority to make negative enrollment determinations on faulty grounds that could have a devastating toll on clinicians' ability to practice their profession and earn a living. This is particularly true given that revocation of Medicare enrollment automatically results in termination from the Medicaid program and certain other federal health programs. We also caution against the unintended consequences that may occur as

implementation of this policy could reduce access to medical professionals in remote and underserved areas. As such, we urge CMS not to finalize this policy.

CY 2020 Updates to the Quality Payment Program

MIPS Value Pathways (MVP) Framework

CMS proposes to apply a new MVP framework to future MIPS proposals beginning with the 2021 MIPS performance period/2023 MIPS payment year, noting its interest in creating a more cohesive and simplified participation experience for clinicians by focusing on specific specialties or conditions that are more meaningful to clinicians' practice and including measures and activities covering all four MIPS performance categories. CMS also expresses interest in increasing the voice of the patient, increasing data and feedback to clinicians to reduce reporting burden, and facilitating movement to APMs.

AAAAI appreciates CMS' interest in improving the MIPS participation experience for eligible clinicians, including through simplification of program requirements, meaningful clinician assessment, and burden reduction, and we believe that MVPs have the potential to achieve those goals – but only if they are developed and implemented in a collaborative, deliberate, well-reasoned manner that truly connects clinician performance and assessment across the MIPS performance categories. Indeed, we have several concerns with CMS' proposed and contemplated approach to establishing MVPs, including:

- **Timing.** CMS proposes to implement MVPs starting with the 2021 MIPS performance period. AAAAI believes this proposal is overly aggressive, particularly given that no MVPs have been developed or tested to date, and that there are no data to understand what implementation of MVPs will mean for clinicians in terms of burden, quality of care, and payment impacts. CMS has expressed interest in working with stakeholders from all specialties participating in MIPS, yet such a process would require ongoing and repeat engagement and feedback, testing, education, and more. Rather than pursue implementation across the MIPS program in 2021, AAAAI urges CMS to take a more measured approach that begins with pilot testing and allows CMS to better understand how MVPs will impact quality and cost for Medicare clinicians and patients.

- **Assignment.** CMS contemplates mandatory assignment of clinicians and groups to MVPs, which AAAAI believes would be truly problematic. Preserving clinician choice to select specific MVPs or continue to rely on the existing MIPS performance categories is necessary to ensure that MVPs are clinically relevant for each individual or group, as well as to limit reporting burden.

- **Population Health Measures.** CMS indicates its intent to incorporate a set of administrative claims-based quality measures into MVPs that focus on population health. Given well documented concerns with existing claims-based measures around improper attribution, limited relevance to specialty clinicians, limited opportunities to meaningfully influence outcomes or take corrective action, and potential perverse incentives, AAAAI has significant concerns with CMS' plan to incorporate additional

population health measures. Rather than pursue additional population health measures, AAAAI recommends that CMS focus on meaningful measures that are patient-centered and targeted to clinicians' daily practice and provide actionable feedback that can be used to improve performance.

As CMS continues to refine its thinking around MVPs and how they can be most effectively integrated into MIPS, AAAAI urges CMS to work closely and collaboratively with stakeholders to address these concerns and ensure that MVPs provide a meaningful, cohesive, and less burdensome alternative to the complex and siloed program that currently exists.

MIPS Proposed Changes for Performance Year 2020

Performance Category Weights. CMS proposes to increase the weight of the cost category to 20 percent and to decrease the weight of the quality performance category to 40 percent for performance year 2020, as well as to continually adjust these category weights each year until each performance category is weighted at 30 percent, as required by law. AAAAI has concerns about these proposals given the many limitations of existing cost measures and the lack of measures that meaningfully capture the scope of care across the A/I specialty and recommends that CMS retain the current weight of the cost category for performance year 2020 at this time.

Quality Performance Category: Allergy/Immunology Specialty Measure Set. As we have previously commented, we continue to object to the inclusion of measures that are not relevant to the Allergy/Immunology specialty. Given A/I specialists do not diagnose, treat or manage HIV/AIDS, measures related to this disease do not belong in the A/I Specialty Measure Set. Therefore, we ask CMS to remove the following measures:

- Measure 338: HIV Viral Load Suppression
- Measure 340: HIV Medical Visit Frequency

At the same time, A/I specialists do diagnose, treat and frequently manage sinusitis and asthma, and therefore, we again ask that CMS include the following measures in the A/I Specialty Measure Set:

- Measure 331: Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis
- Measure 332: Adult Sinusitis: Appropriate Choice of Antibiotic
- Measure 333: Adult Sinusitis: CT for Acute Sinusitis
- Measure 398 Optimal Asthma Control
- Measure 444: Medication Management for People with Asthma

Quality Performance Category: Data Completeness Criteria. CMS proposes to increase the data completeness criteria from 60 percent to 70 percent for the 2020 performance year. We oppose this proposal and urge CMS to maintain its current data completeness threshold of 60 percent. The constant flux in reporting requirements year after year poses significant administrative challenges for physicians and their administrative staff. And while CMS suggests that individuals and groups are routinely reporting with high levels of data completeness, we note that the average data completeness rates reported by CMS reflect that there are likely still

substantial proportions of reporters – particularly individual reporters and those in small practices – who will fall below the average and likely face significant burden when striving to meet the proposed requirement.

Quality Performance Category: All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions. CMS proposes to add the Multiple Chronic Conditions measure as a second administrative claims-based population health measure to MIPS in 2021. AAAAI opposes this proposal, consistent with our comments on population health measures provided under the MVP discussion, given concerns about the applicability and actionability of claims-based measures.

Quality Performance Category: Measures without Benchmarks after Two Performance Periods. CMS proposes to remove MIPS quality measures that do not have benchmarks after inclusion in the MIPS program for two performance periods. This policy would apply to MIPS measures as well as QCDR measures. AAAAI strongly objects to this proposal, which we believe would serve as a significant barrier for new measure development and would further limit specialists' ability to participate meaningfully in MIPS. Many of the new measures under development address specialty areas where there are existing gaps in measurement. If CMS were to finalize this policy, measure developers would have a strong disincentive to dedicate the resources to develop, test, and implement new measures given the uncertainty that would exist regarding the ongoing availability of measures for use under MIPS. Furthermore, we believe that CMS' proposal is misguided as it assumes that measures without sufficient participation to establish benchmarks are not clinically meaningful. There are many reasons why measures may not have rapid adoption. For example, some QCDR measures may require more than two years to fully develop and test. Additionally, current MIPS scoring rules for the quality category also create disincentives for reporting measures without benchmarks, given the three-point scoring cap that CMS applies. AAAAI believes that CMS should instead remedy scoring policies that discourage reporting of new measures, for example by removing the scoring cap or providing bonus points for reporting new measures, instead of instituting punitive policies that place specialists at a disadvantage.

Cost Performance Category. As noted above, AAAAI opposes CMS' proposal to increase the weight of the cost category. Additionally, with respect to new and refined cost measures proposed for performance year 2020, AAAAI continues to oppose the use of the revised Total Per Capita Cost (TPCC) and the Medicare Spending per Beneficiary (MSPB) measures. AAAAI continues to believe that these measures – even with the refinements – are not appropriate for assessing performance under a clinician-level value-based purchasing program, and it remains unclear how our members can meaningfully influence outcomes for those measures.

Improvement Activities Performance Category. CMS proposes to increase the minimum number of clinicians in a group or virtual group who are required to perform an improvement activity to 50 percent beginning with the 2020 performance year and future years. This is in contrast to the current policy, under which the full group would receive credit for completing an improvement activity if one MIPS eligible clinician completes the activity. 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. As such, we urge CMS to maintain its current policy.

Qualified Clinical Data Registries (QCDRs). Below we address several of CMS' proposals related to QCDRs for performance year 2020 and future years:

- **Support of Quality, Improvement Activities, and Promoting Interoperability performance categories.** CMS proposes that, starting with 2021, QCDRs and qualified registries must be able to support all three performance categories requiring active reporting. AAAAI supports this proposal, which aligns QCDR reporting with the functionality already supported by AAAAI's QCDR. Supporting all three performance categories has been a priority for the AAAAI QCDR.

- **Activities that Will Foster Improvement in the Quality of Care.** CMS proposes that beginning with 2021, QCDRs must provide educational services and lead quality improvement initiatives, as well as provide performance feedback at least 4 times a year. AAAAI is concerned that these policies will impose new requirements and new burden without evidence to support that they will meaningfully improve quality. Furthermore, we note that feedback 4 times a year may not be helpful if clinicians do not routinely report data on an ongoing basis, so we encourage CMS to take such situations into account.

- **Measure Availability.** AAAAI **strongly** opposes CMS' proposal that it will consider the extent to which a QCDR measure is available to MIPS eligible clinicians other than those reporting through the QCDR measure owner, and that if CMS determines the measure is not available, CMS may not approve the measure. We have significant concerns about this proposal, which builds from CMS' previous efforts to take control of measures away from measure owners. Measure owners should have the autonomy to monitor who has access to their measures, including through the use of appropriate licensing requirements. Furthermore, in the case of the AAAAI QCDR, our measures were developed specifically for use by A/I specialists based on A/I practice patterns and strong recommendations from evidence-based guidelines. In most cases, these measures would be inappropriate if reported by other specialists or through other registries not specific to A/I.

- **Linking QCDR Measures to Cost Measures, Improvement Activities, OR MIPS MVPs.** CMS proposes that, beginning with the 2021 performance period, QCDRs must identify a linkage between their QCDR measures and cost measures, improvement activities, or MIPS MVPs at the time of self-nomination. It is not clear, however, if CMS intends to require linkage to one of the three items, or to all three. It is also not clear how CMS defines the requirement to "identify a linkage." We also note that there are currently no MVPs and very few cost measures with which linkages could be established. We believe

this proposal will significantly increase burden for QCDRs, while also devaluing the role that QCDR measures play in promoting the delivery of high-quality care for its own sake. As such, we urge CMS not to finalize this proposal.

- **Completion of QCDR Measure Testing.** AAAAI opposes CMS' proposals to (1) require, beginning with 2021, that all QCDR measures be fully developed and tested, with complete testing results at the clinician level, prior to self-nomination and (2) require that a QCDR collect data that must demonstrate that QCDR measures are valid and reflect important clinical concepts by which clinicians wish to be measured. Full testing and data collection, as CMS proposes, is time-consuming, expensive, and impractical, and would make it virtually impossible for QCDRs to be a tool for ongoing measure development and refinement. The flexibility to develop, test, and refine measures that are meaningful to their clinical practice was a major driver in pushing specialties to make the initial investment into establishing QCDRs. This proposal would remove that flexibility and establish new barriers that would create significant disincentives for QCDRs to develop new measures. Particularly given the ongoing lack of measures that are truly meaningful for certain specialties and subspecialties, AAAAI believes that CMS should not be creating additional barriers for the development and implementation of new measures. Further, these proposals create an unlevel playing field as MIPS measure owners would not be subject to this same requirement.

- **Multi-year Approval.** CMS proposes to allow, beginning with 2021, a two-year QCDR measure approval period for measures that meet criteria proposed by CMS. AAAAI supports CMS' proposal for two-year measure approval, which will reduce burden for QCDRs and create greater certainty for physicians who may come to rely on the use of specific measures. However, as detailed in the bullets above, we have significant objections to the criteria that CMS proposes to implement, and we do not believe that the benefits of two-year approval would outweigh the harms that would result from the accompanying proposals. We encourage CMS to provide ongoing flexibility to QCDRs as they propose and implement measures for the MIPS program.

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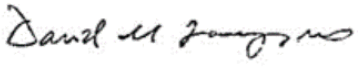
We appreciate the opportunity to provide comments on the aforementioned issues of importance to our members. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@AAAAI.org or (414) 272-6071.

Sincerely,



David M. Lang, MD FAAAAI
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