American Academy of
Allergy Asthma & Immunology

September 11, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
P.O. Box 8016
Baltimore, MD 21244-8013
Submitted electronically via Regulations.gov

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (CMS-1676-P)

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 the 2018 Medicare Physician Fee Schedule (MPFS) proposed rule and the impact on A/I professionals and beneficiaries they serve.

Evaluation and Management (E/M) Guidelines and Care Management Services

E/M Guidelines

CMS seeks input from a broad array of stakeholders, including patient advocates, on the specific changes CMS should undertake to reform the guidelines, reduce the associated burden, and better align E/M coding and documentation with the current practice of medicine.

AAAAI appreciates CMS' opening the dialogue on this important issue. We concur with stakeholders that both the 1995 and 1997 guidelines are administratively burdensome and outdated with respect to the practice of medicine, and are too complex, ambiguous, and fail to distinguish meaningful differences among code levels. AAAAI has long-advocated that CMS should take a close look at whether the current E/M guidelines hold the same value now

(more)

that providers are reporting quality data through multiple government and privately sponsored quality improvement initiatives, including Medicare's Quality Payment Program (QPP) and adopting electronic health record (EHR) systems. The burden of the current E/M guidelines, combined with voluminous quality reporting requirements, distracts from patient care. Physicians are essentially functioning as documentarians as opposed to health care providers.

While we support the direction of CMS' discussion, we have concerns that a long, multi-year process to revise the documentation guidelines will not provide the regulatory relief that we envisioned. The issues that will be raised by various stakeholders as a result of the comment solicitation will be many, and there is a strong likelihood that CMS' intended effort will be waylaid by concerns about a revaluation of the E/M services, the impact on program integrity efforts and audits by CMS' multiple contractors, among others. These are all important considerations, yet the overall result on improving the guidelines and reducing burden on practicing physicians will be severely diminished.

It is our sense that, regardless of the changes made to the E/M documentation guidelines, physicians will continue to document what is necessary to evaluate and manage the conditions they diagnose, treat and manage, and refer on for subspecialized care. These elements are necessary for a variety of medicolegal purposes and to facilitate proper care and coordination of health services. For these reasons, **we urge CMS to fully eliminate the E/M documentation guidelines rather than expend years of effort modifying the current guidelines, which will never fully satisfy all stakeholders.**

Care Management Services

CMS has sought to recognize significant changes in health care practice, especially innovations in the active management and ongoing care of chronically ill patients. This includes the development and valuation of several new codes, such as Transitional care management (TCM) services (2013) and Chronic care management services (CCM) (2015, 2017), among others. CMS solicits public comments on ways it might further reduce administrative burden for these and similar services under the PFS.

As discussed in our comments last year, AAAAI continues to support CMS' efforts to provide payment for non-face-to-face work associated with coordinating care for chronically-ill beneficiaries, such as those with conditions treated by A/I professionals. We also appreciate CMS' efforts to reduce the administrative burden and improve payment accuracy for CCM services, which we hoped would significantly increase the uptake of these codes by A/I physicians. **We encourage CMS to work with specialists to identify additional ways to reduce the administrative burden in providing these services, which may include addressing requirements associated with beneficiary consent.**

In recent months, CMS has initiated multiple awareness and education campaigns related to the provision of CCM services. However, these have been primarily directed at primary care physicians. Specialists, including A/I professionals, may also deliver these services. To ensure beneficiaries have improved access and benefit from the provision of CCM, **we encourage CMS to expand is outreach on CCM services to include specialists, such as A/I professionals. Educational tools should also be designed to assist specialists with the delivery of CCM services.**

Part B Drug Payment: Infusion Drugs Furnished through an Item of Durable Medical Equipment (DME)

CMS implemented provisions stemming from the 21st Century Cures Act, which require the agency to make payment for drugs infused through durable medical equipment (DME) at the drugs average sales price (ASP) rather than its average wholesale price (AWP), effective January 1, 2017. Prior to enactment of the law, these drugs were paid at 95% of AWP, while most other drugs covered under Part B were paid at 106% of ASP. To accomplish this, CMS updated its ASP pricing files used by Medicare Administrative Contractors (MACs) to process claims. In this rule, CMS is proposing to update its regulations to align with its statutory requirement.

AAAAI remains concerned about the impact of this policy on beneficiaries with primary immunodeficiency (PI) diseases that need access to certain life-saving therapies, such as subcutaneous immune globulin (SCIG), that are paid for under Part B and administered via DME. As you may know, the 21st Century Cures included another provision (Section 5012) to establish a new Medicare home infusion services payment that will include the cost of delivering this care – including the education, training and monitoring services needed to make sure beneficiaries are able to safely administer their treatments in the home. However, the services payment does not start until January 2021, while the reduced drug reimbursement went into effect this past January, creating a 4-year coverage gap.

A/I professionals that focus their practice on treating immune-compromised patients have indicated that the reduced payment, coupled with the 4-year delay in implementation of a new services payment, will force them to either stop taking new patients, cease prescribing these therapies in the home, or send beneficiaries to hospital outpatient departments for care, which is not only a more expensive site-of-care for the patient and Medicare program, but needlessly exposes these beneficiaries to other life threatening communicable diseases at a time when their immune system is compromised.

Our concerns are not unfounded. When Medicare Part B drug reimbursement shifted from AWP to ASP more than a decade ago, immune-compromised beneficiaries experienced serious access issues. This was highlighted in a 2007 report, *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)*, prepared under contract by the Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation (ASPE). According to the report, *"Several physicians interviewed for the study described situations in which patient health was compromised when they were shifted from a physician's office to a hospital setting for IGIV infusions and/or when patients had difficulties and delays in receiving IGIV infusions."*

While we are working with a coalition of concerned stakeholders on a legislative solution to provide a transitional payment, **we urge CMS to consider all administrative authorities it may have to address this concern and avoid any disruption to the continuity of care for this patient population. We also urge CMS to work with Congressional leaders to ensure access to medically necessary and life-saving therapies for Medicare's most vulnerable, immune-compromised beneficiaries is not further jeopardized.**

Proposed Valuation of Specific Codes

Percutaneous Allergy Skin Tests (CPT code 95004)

CPT code 95004 was reviewed by the American Medical Association's Relative Value System Update Committee (AMA RUC) as a potentially misvalued code, which recommended maintaining the work

relative value units (RVU) of 0.01. The AMA RUC also reviewed practice expense and recommended changes to supply items and the quantity of antigen used in furnishing a single skin test. The recommendations are consistent with the recommendations made by AAAAI, along with the American College of Allergy Asthma and Immunology and the American Academy of Otolaryngic Allergy. We support CMS' proposal to adopt the AMA RUC recommendations. Given the revaluation of this existing code results in a payment reduction of 20 percent or more, we anticipate a two-year phase-in of the reductions for this service, as required under applicable law and regulations.

Payment for Biosimilar Biological Products

Pursuant to the Biologics Price Competition and Innovation Act (BPCIA), enacted in 2010, the Food and Drug Administration (FDA) has the authority to approve "biosimilars," which are copies of brand-name biologic drugs. In enacting the BPCIA, Congress acknowledged that the existing regulatory approval pathway for generic, chemical drugs was not appropriate for these complex, biological products. As a result, there are two entirely different approval pathways for generics and biosimilars, as well as different patent litigation procedures and standards for similarity.

Despite these differences, CMS has decided to treat biosimilars the way it treats generics, for purposes of payment. Specifically, CMS has determined that all biosimilars sharing a reference product will share a single Healthcare Common Procedure Coding System (HCPCS) code.

The aggregating of biosimilars for purposes of payment is concerning because it implies to clinicians that all biosimilars sharing a reference product are interchangeable, when this may not be so. In fact, the BPCIA specifically delineates two levels of similarity. The threshold finding for marketing is "biosimilarity," but there is an additional, higher standard for "interchangeability." Thus far, while the FDA has approved several biosimilars, it has not yet approved a product as an interchangeable biosimilar. Grouping biosimilars and, eventually, interchangeable biosimilars for purposes of payment threatens to undermine this distinction between the two groups of products as specified by Congress and implemented by the FDA, the agency tasked with ensuring the safety of our drug supply. **We urge CMS to assign each biosimilar its own code for purposes of billing and payment**

Physician Quality Reporting System (PQRS) Criteria for Satisfactory Reporting for Reporting Individual EPs and Group Practices for the 2018 Payment Adjustment *and* Clinical Quality Measurement for Eligible Professionals Participating in the Electronic Health Record (EHR) Incentive Program for 2016

In this rule, CMS proposes to revise the previously finalized satisfactory reporting criteria for the 2016 PQRS reporting period to lower the requirement from 9 measures across 3 National Quality Strategy (NQS) domains, where applicable, to only 6 measures with no domain requirement, among other things. In addition, CMS proposes to change the EHR Incentive Program clinical quality measure (CQM) reporting criteria from 9 CQMs covering at least 3 NQS domains to 6 CQMs with no domain requirement for eligible professionals (EPs) and groups who, in 2016, chose to electronically report CQMs through the PQRS Portal for purposes of the Medicare Electronic Health Record (EHR) Incentive Program.

AAAAI strongly supports the direction of these proposals, but would request that CMS consider reducing the requirement for satisfactory reporting further. Specifically, we urge CMS to change the reporting criteria from 9 measures or CQMs covering at least 3 NQS domains, down to one measure or CQM.

A/I professionals are overwhelmed by massive changes to the Medicare physician reimbursement system that stem from passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which established the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) incentive, two programs under the framework of the new Quality Payment Program (QPP). Despite the "transition policies" that were afforded for Year 1 of the program, the multitude of requirements and ongoing program changes throughout 2017, not to mention the proposals under consideration for future years of the program, have generated a level of angst unparalleled to any other time in most A/I physicians time in medicine.

In addition, MACRA included a 0.5% update to the Medicare physician fee schedule conversion factor between 2016 – 2019, meant to serve as a "period of stability" in Medicare reimbursements while providers learned the new system. Unfortunately, other changes in law and regulation essentially overrode the intended impact of these positive updates. Thus, the promised "period of stability" was never fully realized by providers.

Given this administration's emphasis on providing regulatory relief, particularly for smaller practices, we believe CMS should use the full extent of its authority to eliminate the negative payment adjustment stemming from prior CMS quality improvement programs for as many providers as possible by reducing the reporting requirement for the 2016 aforementioned programs to one measure or CQM. By reducing the negative financial impact of its former quality improvement programs, CMS would be helping restore the "period of stability" providers were assured under MACRA.

Medicare Shared Savings Program (MSSP)

MSSP Initial Application

CMS states that it does not believe it is necessary for Medicare Accountable Care Organization (ACO) applicants to submit narratives describing how they would distribute shared savings payments; CMS instead states that it would be more useful for the ACO to state "*that it has a method and plan to receive shared savings payments and to distribute those payments to its ACO participants and ACO providers/suppliers, as required by statute.*" However, given CMS understands that it is useful for stakeholders to know how ACOs use or distribute shared savings, CMS will continue to require ACOs to publicly report information on their dedicated Web pages about their shared savings and losses (including information about proportion of shared savings investing in infrastructure, redesigned care processes, and other resources) including the proportion distributed among ACO participants.

We are disappointed in this proposal and urge CMS to reconsider. It is unclear what level of detail ACOs will provide when publicly posting the proportion of shared savings that was distributed among ACO participants, given there are no specific requirements as to how this information must be delineated. As a result, A/I professionals will have no ability to observe what proportion of shared savings their specialty earned, which *should* commensurate with their impact on improved health outcomes for the ACOs assigned population.

As you know, CMS previously finalized a requirement that would permit an MSSP ACO to take remedial action against an ACO participant and its ACO providers/suppliers *"…to address noncompliance with the requirements of the Shared Savings Program and other program integrity issue, including those identified by CMS."* Remedial action may include the denial of shared savings payments (that is, the ability of the ACO participant or ACO provider/supplier to receive a distribution of the ACO's shared savings). Unfortunately, there is no requirement that ACOs share any savings with ACO participants and ACO providers/suppliers, at all. If CMS will no longer require the ACOs to provide details about how these shared savings will be distributed at the outset via their application, how would the agency know if the ACO followed the plan it set forth? We view this as a significant problem and one that only serves to dissuade A/I professionals from joining ACOs, which is contrary to vision Congress set forth in MACRA when it established the APM Incentive.

We urge CMS to reconsider its proposal, as well as put forward new requirements such that MSSP ACOs must share some portion of their savings with ACO participants and ACO providers/suppliers that have facilitated the ACO's success. We agree that MSSP ACOs should have flexibility in determining what proportion of shared savings are appropriate for distribution among ACO participants and ACO providers/suppliers, given a proportion of the savings will likely be needed to reinvest in the ACO's infrastructure.

In addition, as we have stated in prior comments, **CMS should develop guidance to help ACOs establish a shared savings distribution model that fosters a fair and sustainable shared savings distribution process.** AAAAI supports a shared savings model that considers the contributions of each individual ACO provider/supplier and ACO participant, including their impact on outcomes and overall level of engagement with assigned beneficiaries.

Further, **we urge CMS to establish benchmarks to determine whether the ACOs shared savings distribution process is facilitating or limiting care coordination activities and access to A/I care**. We are concerned that access to A/I professionals, and the life-saving and life-improving treatments, including allergen immunotherapy (AIT) and certain biologic therapies, for multiple widespread chronic conditions, including allergies, asthma and PID, may be hindered under these models, if left unchecked.

Value-Based Payment Modifier and Physician Feedback Program

In the interest of program alignment and providing a smooth transition between the Value Modifier (VM) and MIPS, as well as aligning with the proposed changes to the PQRS, CMS proposes modifications to the VM policies for the CY 2018 payment adjustment period. Specifically, CMS proposes to reduce the automatic downward adjustment for groups and solo practitioners in Category 2 (i.e., those who do not meet the criteria to avoid the 2018 PQRS payment adjustment as individual solo practitioners, as a group practice, or groups that have at least 50% of the group's EPs meet the criteria as individuals) to 2.0% for groups with 10 or more EPs and at least one physician, and -1.0% for groups with between 2 to 9 EPs, physician solo practitioners, and for groups and solo practitioners that consist only of non-physician EPs. In addition, CMS proposes to hold all groups and solo practitioners who are in Category 1 (i.e., those who meet the criteria to avoid the 2018 PQRS payment adjustment as individual solo practitioners, as a group practice, or groups that have at least 50% of the group's EPs meet the criteria as individuals) harmless from downward payment adjustments under quality-tiering for the last year of the program. Finally, CMS proposes to reduce the maximum upward adjustment under the quality-tiering methodology to two times an adjustment factor (+2.0x) for groups with 10 or more EPs.

We urge CMS to finalize this proposal, but reiterate our request above that CMS further reduce the satisfactory reporting requirement for the 2016 PQRS program, which would expand the positive impact of this policy to even more providers.

MACRA Patient Relationship Categories and Codes

CMS proposes that Medicare claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, should include the applicable HCPCS modifiers listed below, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). To allow clinicians time to gain familiarity with using these modifiers, CMS proposes that, at least for an initial period, clinicians may voluntarily report these codes on claims. In other words, the selection of the modifiers would not be a condition of payment and claims would be paid regardless of whether and how the modifiers are included.

CMS is in the process of developing episode-based cost and resource use measures. Measures specific to A/I conditions are planned; however, the process has been slow and little information has been released for review and comment, other than the list of conditions under consideration. Once the measures are available, these patient relationship codes would be used to attribute beneficiary costs to clinicians. Unfortunately, without knowing more about the cost and resource use measures on which we may or may not be assigned costs, it is hard to contemplate how A/I professionals would begin applying these codes in less than 4 months.

Further, we continue to be concerned about the effectiveness, feasibility and utility of the patient relationship codes. We previously expressed concern that including a patient relationship code on every single claim would be a significant administrative burden, which is contrary to this administration's goals and objectives. In addition, we believe that A/I professionals will struggle with deciphering whether their care is "continuous" or "episodic" in some instances. We also suggested that CMS ensure that specialists, such as A/I professionals, would not be attributed patients with diagnoses that are outside the scope of their specialty, as was the case in the VM cost measures.

Frankly speaking, CMS is "putting the cart before the horse" and should delay this proposal until episode-based measures have been developed and vetted. Implementing these codes at this time, even voluntarily, is premature and an administrative burden on practices still trying to understand the rules and requirements of the MIPS program. **CMS should delay implementation of the patient relationship codes until episode-based measures have been developed, tested and implemented.**

Request for Information on CMS Flexibilities and Efficiencies

We appreciate the opportunity to provide ideas that would improve the Medicare program at various levels. The sixty-day comment afforded through this proposed rule is not enough time to contemplate all of the suggested improvements that A/I professionals and the beneficiaries they serve would benefit from. Toward that end, **we urge CMS to extend the comment period or provide alternate avenues to continue providing ideas to make the program for flexible and efficient.**

While we consider additional ideas, **we urge CMS to establish a A/I Resource Center web page as part of the Medicare Learning Network web site, similar to what it has done for other specialties' – including Ophthalmology and Anesthesiology – that would provide links to relevant CMS rulings,**

correct coding edits, and other important information relevant to A/I professionals. Navigating CMS' web site for information on Medicare payment and other policies is a significant issue for A/I professionals and their administrative staff. This would significant reduce the time it takes for their practices to search the CMS web site for information they routinely need to carry out day-to-day operations of serving Medicare beneficiaries. AAAAI would be happy to work with CMS' Medicare Learning Network staff to help identify and populate the site with the most appropriate information for to our specialty.

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We appreciate the opportunity to offer these comments. 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