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September 12, 2025

Mehmet Oz, MD

Administrator

Centers for Medicare and Medicaid Services

U.S. Department of Health and Human Services

200 Independence Avenue SW

Washington, DC 20201

Submitted electronically via www.regulations.gov

RE: Medicare and Medicaid Programs; CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

Dear Administrator Oz,

Established in 1943, the American Academy of Allergy, Asthma & Immunology (AAAAI) is a professional organization with more than 7000 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. In the paragraphs that follow, we provide feedback on key proposals and policies in the aforementioned rule.

Conversion Factor (CF)

AAAAI appreciates that our practices will see a modest increase in Medicare payments under the CY 2026 Medicare Physician Fee Schedule (PFS), the result of statutory updates under the *Medicare Access and CHIP Reauthorization Act (MACRA)*, a one-year update provided by Congress, and a positive budget neutrality adjustment. While the proposed conversion factor is preferable to the recurring threat of cuts, it remains temporary, is tied to a problematic policy approach, and does not resolve the underlying structural flaws of the Medicare physician payment system.

(More)

As we have shared before, most A/I practices are small, so the impact of stagnant updates that fail to keep pace with rising practice costs is felt acutely. The ongoing Medicare sequester and the threat of additional across-the-board cuts further strain practice viability, making it increasingly difficult to sustain care for our patient population. Meaningful long-term reform is essential to provide greater stability and predictability in annual payments. ***AAAAI urges CMS to work with Congress on a long-term solution that ties physician updates to the Medicare Economic Index (MEI), which would ensure payments better reflect the cost of delivering care.***

Valuation of Services Efficiency Adjustment

This year's conversion factor is improved in part due to CMS' proposal to establish an "efficiency adjustment" and the resulting positive budget neutrality adjustment. Under the proposal, CMS would apply an efficiency adjustment to work RVUs, along with corresponding updates to the intraservice portion of physician time inputs, for non-time-based services, while holding time-based services harmless. CMS' rationale is that efficiency gains occur as physicians develop expertise, reducing both the time and intensity required to perform certain services.

While we support efforts to rebalance Medicare dollars toward cognitive services to which an efficiency adjustment cannot apply, we are concerned that several allergy and immunology services would be adversely affected, including allergen immunotherapy, allergy testing, and drug administration services. Allergen immunotherapy and testing cannot realize efficiency gains in the same way certain other procedures might. Likewise, drug administration services are inherently time-based and must be performed according to FDA label instructions specifying infusion rates. The requirements associated with delivering this care mean that neither physician familiarity nor patient volume can meaningfully shorten intraservice time without jeopardizing patient safety.

We urge CMS to carefully review the services to which this policy would apply and, most importantly, exclude those services where assumed efficiencies would compromise patient safety. This includes critical allergy and immunology services, and specifically, the following services:

Allergen Immunotherapy:

95165 – Allergen Multi-dose
95144 – Allergen Single Dose
95145-95149 – Venom antigen
95170 – Whole body
95180 – Rapid Desensitization

Allergy Testing:

95004, 95017, 95018 - Puncture/Prick Tests – allergen, venom, drug
95024, 95027 95028 – Intracutaneous (intra-dermal) Tests
95044 – Patch Test

Challenge/Other Testing:

94010 – Spirometry, including graphic record, total and timed vital capacity
94060 – Bronchodilation responsiveness
95070 – Inhalation Bronchial Test
95076 and 95079 – Ingestion Challenge

Practice Expense (PE)

The AAAAI supports CMS' decision not to move forward with the AMA's Physician Practice Information (PPI) survey data for CY 2026. As previously communicated, the survey process supporting PPI data failed to reach a meaningful level of participation among our specialty. Unfortunately, the AAAAI was not aware of this until after the AMA had combined Allergy/Immunology with a group of other specialties with whom there is no other meaningful correlation related to the economics of our practices. The AMA acknowledged the insufficient data but did not give the AAAAI an opportunity to address this significant fault in the methodology, and we have been told that we cannot be given a report of the data provided by our specialists, as had been indicated when the data collection process was launched. The AAAAI asserts that if the PPI survey did not receive sufficient data to be able to report it back to us, then it was not sufficient data on which to base any PE recommendation. The rates the AMA proposed for Allergy/Immunology and others in its "Office Based Proceduralists" category would be disastrous for our practices' financial sustainability and for patient access to care. ***We sincerely appreciate that CMS has proposed increased reimbursement for allergy immunotherapy codes to reflect increased cost inputs, which will help keep our practices sustainable.***

However, we remain concerned with the impact of CMS' proposed PE methodology changes. While we welcome the significant increase of 8% to apply to office-based A/I services, unfortunately the 11% reduction for facility-based services is unacceptable. Although the office-setting is the primary location for A/I care and delivery, drastic reductions to facility-based care risks creating barriers for many patients' access; particularly those who require care services in a higher acuity setting. ***AAAAI urges CMS to ensure that practice expense allocations do not destabilize patient access across sites of care.***

More broadly, these proposals do not resolve the persistent challenge that Medicare physician payment updates have not kept pace with inflation, nor CMS' difficulty in maintaining up-to-date direct PE inputs. The recent phase-in of clinical labor pricing, for example, significantly lowered the value of key A/I services at the same time practice costs were rising. ***AAAAI supports a regular four-year update cycle for direct PE inputs to ensure payment rates reflect the real costs of care and sustain patient access across all sites of service.***

Telehealth

AAAAI appreciates and largely supports CMS' telehealth proposals outlined in the rule. We do, however, remain concerned that the statutory Medicare telehealth flexibilities that have enabled beneficiaries to receive care from their homes since the COVID-19 public health emergency are set to expire at the end of September. Without congressional action to extend these provisions, those who have come to rely on telehealth, and particularly those who are immunocompromised, will face unnecessary barriers to accessing safe and effective care. ***We urge CMS to continue working with Congress to make these flexibilities permanent, including the elimination of originating site requirements and geographic restrictions, to preserve beneficiaries' ability to access the telehealth services they need.***

With regard to direct supervision by virtual presence, AAAAI urges CMS to clarify the scope of these policies within the Medicare program, and that they do not override other guidelines or standards that may require in-person supervision. Because standards-setting organizations and other federal agencies may impose different supervision requirements for certain services, it is important that CMS emphasize the limits of its regulations. In addition, ***we continue to urge CMS to carefully monitor the use of virtual presence to ensure beneficiary safety is not compromised as a result of this policy, and recommend the***

establishment a billing modifier and/or documentation requirements so that practices may indicate virtual presence was used to meet direct supervision requirements.

The AAAAI supports CMS' proposal to include the add-on code G0545, Visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious disease consultant, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and complex antimicrobial therapy counseling and treatment, to the Medicare telehealth list. As we noted in prior comments, A/I physicians have specialized expertise in managing complex infections, particularly for patients with immunodeficiencies and other conditions requiring the complex care described by this code. Allergist/immunologists are also frequently called upon to consult with hospitals and health systems on infection control practices, including antibiotic stewardship and antimicrobial resistance efforts. This is especially important in areas where an infectious disease physician is not available. ***We therefore urge CMS to clarify that G0545 may be reported not only by infectious disease physicians but also by allergist/immunologists.***

Finally, ***AAAAI urges CMS to continue allowing physicians to report their currently enrolled practice location, rather than their home address, when providing telehealth services from home, and to make this policy permanent.*** As we shared in prior comments, this safeguard is essential to protect provider privacy and safety, as well as to minimize unnecessary administrative burden associated with frequently updating enrollment records.

Inflation Reduction Act: Average Sales Price

CMS is proposing clarifications to the Average Sales Price (ASP) methodology—specifically, that the Maximum Fair Price (MFP) for negotiated drugs will be included in ASP and new guidance regarding price concessions and bona fide service fees (BFSFs)—which CMS acknowledges may lower Medicare reimbursement for physician-administered drugs. While we appreciate the intent of these policies, the clarifications risk misaligning payments with the actual acquisition costs faced by A/I practices that provide life-saving therapies, creating added strain on small practices and potentially reducing patient access. Any policy that disconnects Medicare reimbursement from real-world acquisition costs must be approached with caution. ***AAAAI urges CMS to proceed carefully in finalizing these clarifications and emphasizes that greater transparency in drug pricing is essential.*** We also support congressional efforts to advance legislation to address broader challenges with the ASP payment methodology, including those aimed at addressing challenges with pharmacy benefit managers (PBMs), and help ensure patients' access to needed therapies is protected.

Prevention and Management of Chronic Disease – Request for Information

AAAAI appreciates CMS' request for information on strategies to enhance the uptake and usefulness of the Annual Wellness Visit (AWV). We believe there is an important opportunity to improve patient outcomes, reduce healthcare expenditures and help fight antimicrobial resistance/advance antibiotic stewardship by adding penicillin allergy verification and evaluation as a component of the AWV. Evidence shows that more than 90 percent of patients who report a penicillin allergy can safely take the medication after proper evaluation, yet the label persists in electronic health records and contributes to compromised outcomes from inappropriate antibiotic prescribing, significantly higher costs, and antimicrobial resistance. Including penicillin allergy verification within the AWV would represent a low-cost, high-impact intervention to advance public health and improve care for Medicare beneficiaries.

We anticipate the introduction of the bipartisan-supported *Penicillin Allergy Verification and Evaluation (PAVE) Act*, a bill to add penicillin allergy delabeling to the introductory and annual wellness visits for all

Medicare patients. However, CMS has the statutory authority to act without congressional intervention. Therefore, **AAAAI urges CMS to add penicillin allergy verification and evaluation as an optional element of the AWW, or as an add-on code, thereby reducing burden on clinicians while creating a pathway for widespread and routine use of this important service.** Initiating this change would help ensure that older adults, who face heightened risks from both severe infections and adverse drug reactions, have access to accurate allergy evaluation, and it would advance CMS' broader goals of prevention, chronic disease management, and antibiotic stewardship.

Quality Payment Program

CMS proposes several updates to the Merit-based Incentive Payment System (MIPS), while also emphasizing its intent to phase out traditional MIPS and transition fully to MIPS Value Pathways (MVPs). **AAAAI supports proposals that maintain program stability and offer a more reasonable approach to performance assessment, including CMS' proposals to:**

- **Maintain the MIPS performance threshold at 75 points for 2026 through 2028;**
- **Revise the benchmark methodology for administrative claims quality measures to improve scoring;**
- **Revise the Total Per Capita Cost (TPCC) measure attribution methodology to prevent inappropriate attribution; and**
- **Provide a two-year informational-only feedback period for new cost measures.**

However, we are concerned about CMS' plans to transition to mandatory MVPs. Allergist/Immunologists do not have a "home" in the MVP program. We have previously recommended that CMS work with our specialty societies to develop an MVP for Allergy/Immunology, and we continue to believe that to be the best path forward if MVPs are still to become required by 2029.

Otherwise, the measures that are applicable to our specialty are split among existing MVPs, none of which is sufficiently relevant or an appropriate fit for most A/I practices. The loss of the Allergy/Immunology Qualified Clinical Data Registry (QCDR) resulted in the loss of measures in a meaningful reporting option, as important measures such as AAAAI_17 (Asthma Control: Minimal Important Difference Improvement) and AAAAI_18 (Penicillin Allergy: Appropriate Removal or Confirmation) are no longer available. This reduction in available measures affects A/I practices participating in traditional MIPS, as well as those trying to identify a relevant MVP.

The AAAAI has previously recommended that CMS add existing measures to the Pulmonary MVP to expand the limited set of relevant measures available to A/I clinicians through MVPs [Quality ID 240: Childhood Immunization Status; Quality ID 394: Immunizations for Adolescents; and Quality ID 493: Adult Immunization Status]. These suggested changes have not been made or addressed.

Long term, **the AAAAI urges CMS to work with our specialty to develop a standalone MVP that is more directly relevant to our specialty and patient populations. We further encourage CMS to immediately deprioritize reducing the number of measures in the system overall, which directly disincentivizes existing QCDRs and reporting registries to add new measures, thus making reintroduction of A/I specialty measures in another reporting mechanism much more difficult and less likely.**

Ambulatory Specialty Model

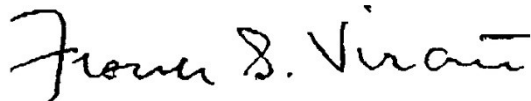
CMS proposes to implement the Ambulatory Specialty Model (ASM) as a new mandatory alternative payment model (APM) for low-back pain and heart failure. While our specialty is not directly affected, we are concerned about the precedent of mandatory models with downside risk, particularly for small

A/I practices that lack the resources to participate successfully. We are also troubled by any model that seeks to achieve program savings by further reducing already inadequate Medicare physician payments.

In addition, the ASM is designed to rely on the MIPS Value Pathways (MVP) framework, which the physician community has consistently noted is not a reliable means of assessing value. MVPs are built on misaligned quality and cost measures, flawed scoring methodologies, and siloed performance categories – just like the MIPS program. We are also disappointed that this model would not count as an Advanced APM and allow clinicians to earn Qualifying Participant (QP) status in the QPP. The lack of opportunities for specialists to qualify as QPs has been an ongoing problem that CMS has acknowledged and promised to help address, yet this model does nothing to help achieve that goal. As such, ***AAAAI opposes the ASM model as currently proposed and urges CMS to identify alternative approaches for engaging specialists in value-based care that are voluntary, clinically relevant, and developed in partnership with specialty societies.***

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 that reads "Frank S. Virant". The signature is written in a cursive, flowing style.

Frank S. Virant, MD FAAAAI
President, American Academy of Allergy, Asthma & Immunology