American Academy of
Allergy Asthma & Immunology

September 9, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1807-P
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

Submitted electronically via Regulations.gov

RE: CY 2025 Payment Policies under the Medicare Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies

Dear Administrator Brooks-LaSure,

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. In the paragraphs that follow, we provide feedback on proposals in the aforementioned proposed rule.

Conversion Factor Update

CMS anticipates reducing Medicare payments to physicians by an estimated 2.8%, driven by statutory requirements and regulatory changes discussed in this rule. This reduction comes at a time when physician practice costs have been rising, particularly for small, rural practices and those serving underserved populations. As we have shared before, the proposed updates do not adequately address the impact of inflation. Both the Medicare Payment Advisory Commission (MedPAC) and the Medicare's Trustees have highlighted that clinician costs have consistently outpaced the increases in Medicare payments, and this gap is expected to continue and could create access challenges for beneficiaries. As an example, venom immunotherapy has become a challenge for patients to receive given the financial burden on A/I practices to offer this life saving therapy.

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Given CMS's constraints in adjusting payments based on inflation, ***we urge CMS to carefully consider the impact of its coding and payment policies on the conversion factor.*** While we appreciate CMS's efforts to improve payment accuracy in specific areas, ***we strongly recommend that CMS actively seek further opportunities for meaningful positive payment adjustments, which may include adjustments in how its pays Medicare Advantage plans (e.g., increasing the coding intensity adjustment), which would produce savings to Part B and help offset a Congressional fix to the physician payment system.*** Most critically, ***CMS should work closely with Congress to develop a long-term solution that provides stable and sufficient payment updates reflecting the actual costs of physician practice.***

Practice Expense

We appreciate and support that CMS' proposal to postpone the use of alternative cost data sources in the physician payment system, awaiting the completion of the AMA's Physician Practice Information Survey (PPIS). However, we reiterate the need for CMS to adopt a consistent and regular approach to updating both direct and indirect practice expenses. The ongoing phase-in of clinical labor price updates, which is nearing completion, has created significant challenges for many specialties due to the budget-neutral nature of the practice expense component of the PFS. This has led to substantial payment reductions for critical services, including drug administration services that our practices provide.

We look forward to CMS's work with the RAND Corporation on developing alternative methods for measuring practice expenses and ***would support a four-year review cycle for these inputs to ensure they remain accurate and fair.***

Non-chemotherapy Administration

We appreciate and support CMS' proposal to amend the Medicare Claims Processing Manual, Chapter 12, section 30.5, to address the "down coding" of complex drug administration services (CPT codes 96401-96549) by Medicare Administrative Contractors (MACs). As outlined in the proposed rule, these non-chemotherapy complex drugs or biologic agents require oversight by staff with advanced practice training and competency, such as physicians or other qualified healthcare professionals, due to the potential for severe adverse reactions during infusions. CMS also acknowledges the unique considerations for the preparation, dosage, and disposal of these infusion drugs, aligning with AAAAI's previous comments. We would also add that these in-office infusions are important for physicians to monitor their patient's condition. ***AAAAI commends CMS for being responsive to our concerns and strongly urge the Agency to finalize the proposal to integrate these criteria into the Manual.***

Furthermore, in line with the recommendations put forth by a broader coalition of physician practices and infusion providers, which AAAAI has joined, ***we recommend that CMS also implement the following:***

- ***Establish clear documentation requirements that allow physicians to demonstrate in the medical record that the complex drug administration service code reported on their claims meets the revised criteria.***
- ***Develop a Medicare Learning Network (MLN) article to educate practices on the updated criteria and documentation requirements, and require MACs to post this resource on their respective websites.***
- ***Prohibit program safeguard contractors, including MACs, from initiating program integrity audits or recoupments for complex drug administration services for dates of service from August 12, 2022, until the effective date of the Manual revisions.***

By adopting these recommendations, CMS will ensure that allergy and immunology professionals, among others, can continue providing critical care without unnecessary administrative burdens.

Infectious Diseases Add-on Code, GIDXX

AAAAI supports CMS' proposal to establish HCPCS "add-on" code GIDXX, *Visit complexity inherent to hospital inpatient or observation care associated with a confirmed or suspected infectious disease by an infectious diseases consultant, including disease transmission risk assessment and mitigation, public health investigation, analysis, and testing, and complex antimicrobial therapy counseling and treatment. (add-on code, list separately in addition to hospital inpatient or observation evaluation and management visit, initial, same day discharge, or subsequent.*

Allergy and immunology (A/I) professionals, who possess specialized expertise in managing complex infections in inpatient settings, should also be eligible to report this new add-on code on Medicare claims. A/I specialists, many working in the inpatient hospital setting, often manage patients with immunodeficiencies and other conditions that require intricate infectious disease care, including risk assessments, public health investigations, and complex antimicrobial therapies. This is particularly true in areas where an infectious diseases physician is not available.

We urge CMS to clarify that this add-on code applies not only to infectious disease physicians but also to A/I professionals who are equally qualified to deliver these critical services. By allowing A/I specialists to bill for this code, CMS would ensure that patients with complex immune-related infections receive the comprehensive care they need.

Telemedicine

AAAAI strongly supports the AMA's recommendation that CMS adopt the new telemedicine code set, CPT codes 9X075-9X090, beginning with CY 2025. We agree with the AMA's analysis that CMS has the statutory authority to pay for E/M services delivered remotely via interactive remote audio/video or audio-only telecommunications systems *outside of section 1834(m) of the Act*, and that doing so would substantially mitigate concerns about the telehealth waivers set to expire on December 31, 2024. ***We further support AMA's recommendation that CMS should not apply a budget neutrality adjustment related to telehealth services utilization.***

Telehealth

AAAAI generally supports CMS' proposals to allow for direct supervision via virtual presence using audio/video real-time communications technology on a permanent basis for a subset of incident to services when:

- the service is provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision, and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; or
- the service is an office or other outpatient E/M visit for an established patient that may not require the presence of a physician or other qualified healthcare practitioner.

However, ***we urge CMS to remind physicians that its virtual presence policies are applicable only to the Medicare program, and would not supplant other guidelines and standards that may require in-person physician supervision.*** Further, CMS should carefully monitor the use of virtual presence to ensure beneficiary safety is not compromised as a result of this policy. This may necessitate the establishment a billing modifier and/or documentation requirements so that practices may indicate virtual presence was used to meet direct supervision requirements.

AAAAI also appreciates CMS' proposal to continue permitting practitioners to use their currently enrolled practice location instead of their home address when providing telehealth services from their home through 2025 and urges CMS to make this policy final.

Finally, CMS' proposal to revise its regulations to allow "audio-only" communication for a limited range of services (e.g., behavioral health) is a meaningful step toward enabling patients to access care in a way that best suits their needs. However, without Congressional intervention, this policy will not improve access for many more beneficiaries that would benefit from access to audio-only services. This is particularly important where barriers to technology exist, and particularly in underserved and rural communities. ***We urge CMS to work closely with Congress to extend and make permanent many of the flexibilities introduced during the COVID-19 PHE, including the removal of originating site requirements and geographic restrictions.***

Quality Payment Program: Merit-based Incentive Payment System (MIPS)

AAAAI appreciates and supports CMS' proposals to:

- ***maintain the MIPS performance threshold at 75 points for the CY 2025 performance period/CY 2027 payment year,***
- ***maintain the 75% data completeness threshold for two additional years,***
- ***remove the improvement activity weights and reduce the number required to report to two (versus 2-4 for non-small practices) and 1 for small practices/rural/non-patient facing for traditional MIPS and 1 for MVP participants, and***
- ***revise the cost measure scoring methodology to measure cost more appropriately after recognizing that the current methodology is having a negative impact on physician final scores.***

AAAAI also appreciates and supports CMS' proposed reweighting policy, beginning with the CY 2024 performance period/2026 MIPS payment year, where the Agency may reweight a category if it determines that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. AAAAI believes this is an important protection for physicians working with registry vendors.

Pulmonary Care MVP

CMS has stated that the intent of MVPs "is to allow some flexibility and choice to clinicians in reporting a subset of measures and activities within a proposed MVP." However, as we expressed in comments to CMS earlier in the year, the Pulmonology Care MVP does not offer sufficient reporting options for allergists. Currently, only three quality measures in the Pulmonology Care MVP are regularly utilized by allergists:

- Quality ID #128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
- Quality ID #226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention; and
- Quality ID #398: Optimal Asthma Control

Although we appreciate CMS's efforts to incentivize screening for Social Drivers of Health (SDOH), we are concerned that allergists are not as familiar with Quality ID #Q487: Screening for SDOH. Moreover, the medical practice of allergy does not typically concern advance care plans or surrogate decision makers. Conversations regarding such documents are typically handled by primary care physicians, not allergists, and it is unclear to what extent Quality ID #Q047: Advance Care Plan is being reported by allergists.

Therefore, ***we reiterate our request for CMS to include in the Pulmonology Care MVP the following additional measures:***

- ***Quality ID #130: Documentation of Current Medications in the Medical Record;***
- ***Quality ID # 331 Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse); and***
- ***Quality ID #332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)***

In addition, ***we encourage CMS to keep the following qualified clinical data registry (QCDR) measures in mind for any future allergy-specific MVP:***

- ***AAAAI_17: Asthma Control: Minimal Important Difference Improvement***
- ***AAAAI_18: Penicillin Allergy: Appropriate Removal or Confirmation***

Although these AAAAI QCDR measures will not be eligible for inclusion in any MVP in 2025, due to unforeseeable technical issues on the part of AAAAI's QCDR vendor, AAAAI is exploring efforts to secure MVP eligibility as soon as possible, and the measures are meaningful, can improve patient outcomes, and have documented gaps in care.

RFI on Building Upon the MVP Framework to Improve Ambulatory Specialty Care

CMS is soliciting feedback on the design of a potential ambulatory specialty care model that would leverage MVPs. The goal is to increase specialty engagement in value-based care and expand incentives for primary and specialty care coordination. Participants under this conceptualized model would receive, in lieu of an MIPS adjustment payment, a payment adjustment based upon a set of clinically relevant MVP measures and how they performed relative to other specialists of their same specialty type and clinical profile.

AAAAI agrees that increased engagement of specialists in value-based payment and with primary care providers is important, and appreciates the challenges related to creating narrowly defined and condition/specialty specific models. However, we are not confident that the MVP framework will produce accurate assessments of value as is the case with more robust and targeted APMs, as MVPs continue to rely on a limited inventory of misaligned MIPS quality and cost measures, flawed scoring methodologies, and siloed performance categories.

Qualifying Participants (QP) in Advanced APMs Determinations and the APM Incentive Payment

CMS proposes to expand the definition of "attribution-eligible beneficiary" for purposes of determining which services count towards the QP eligibility threshold. The revised definition would be based on covered professional services, as opposed to evaluation and management (E/M) services, to address current perverse incentives that favor primary care physicians over specialty physicians on APM Participation Lists.

AAAAI appreciates and supports this proposal since our members tell us they are either blocked from participation or dropped from APMs despite CMS' attempt to helping specialists better engage in primary care-focused population-based models, such as Accountable Care Organizations (ACOs). However, we are concerned that until CMS imposes "network adequacy" criteria on these models, which operate much like health plans, or until CMS incorporate more meaningful measures of specialty care access, many specialists will not be able to join the value-based care movement. ***CMS should consider adopting such criteria and measures in future rulemaking, and before the MACRA-mandated PFS payment update differential for QPs versus non-QPs begins in CY 2026.***

Sincerely,

Paul Williams, MD FAAAAI
President, American Academy of Allergy, Asthma & Immunology