American Academy of
Allergy Asthma & Immunology

September 6, 2022

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P
P.O. Box 8013
Baltimore, MD 21244-8016

Submitted electronically via www.regulations.gov

RE: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

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 key proposals and policies in the aforementioned rule.

Conversion Factor

We are deeply troubled by ongoing reductions to the Medicare physician fee schedule (PFS) conversion factor, which CMS anticipates will be reduced by $1.53 and result in a rate of $33.0775 for CY 2023. While CMS must implement the law as written, we are increasingly concerned about year-after-year pay cuts that negatively impact A/I practices and threaten access to care. Even more frustrating is that almost every other provider type in Medicare (e.g., acute care hospitals, hospital outpatient departments, ambulatory surgery centers) will receive a substantial increase in their base payment rate for 2023. Most egregious is that CMS estimates Medicare Advantage (MA) plans will realize an 8.5% increase in 2023.

Physicians face the same inflation increases as all of these other providers, including challenges purchasing equipment and supplies and retaining staff. We urge you to work with Congress on a long-term solution to the broken Medicare physician payment system, consistent with the principles outlined by the American Medical Association (AMA). Without a meaningful fix to Medicare physician payment, it will be impossible to modernize and reform our health care system, to include reducing health disparities.

Medicare Economic Index (MEI) and Practice Expense Data Collection

Data currently used for the MEI are outmoded and must be updated. However, CMS' proposal for rebasing and revising this index raises serious concerns. As such, we ask that you pause consideration of other sources of cost data for use in the MEI until the efforts by the AMA to collect practice cost data from physician offices is complete. Using the most current and appropriate set of data for the MEI will be even more critical should Congress consider the MEI as an inflation proxy under a revised Medicare physician payment system.

As CMS continues to improve its approach for collecting practice expense (PE) data, we also ask that CMS establish a more consistent and regular approach for direct PEs, as well as indirect PEs. Our practices that deliver physician-administered drugs in the office continue to be harmed by CMS' clinical labor pricing updates that reduced drug administration services. These cuts would not be as drastic had CMS not waited 20 years to revise the clinical labor inputs.

Telehealth

We continue to applaud CMS for its telehealth flexibilities, which has allowed many of our most vulnerable patients to seek medically necessary care from A/I providers throughout the COVID-19 public health emergency (PHE). With that in mind, we appreciate CMS' proposal to implement the *Consolidated Appropriations Act, 2022,* by allowing certain telehealth services (that would otherwise not be available via telehealth after the expiration of the public health emergency (PHE)) to remain on the Medicare Telehealth Services List for 151 days after the expiration of the PHE. AAAAI also appreciates CMS' proposals to add several codes to the Medicare Telehealth Services List on a Category 3 basis that are currently temporarily included during the PHE.

However, we are disappointed that CMS did not propose to continue separate Medicare coverage of telephone E/M services nor to keep these services on the Medicare Telehealth Services List after the 151-day post-PHE extension period, and urge CMS to reconsider this position. As we've shared in prior comments, many patients face challenges when utilizing audio-visual telecommunications technology. In the spirit of reducing inequities and expanding access to care, CMS should expand access to audio-only telehealth for the provisions of E/M services to evaluate, manage and treat a range of health conditions, beyond mental health disorders.

Finally, with regard to virtual presence, we urge CMS to proceed cautiously in allowing A/V technology to replace direct supervision, particularly for certain A/I services. For example, allergy immunotherapy (AIT), allergy testing and food challenges should ***never*** be allowed without the physical presence of a physician. Indeed, the most recent update of the practice parameters for Allergen Immunotherapy recommends AIT to be administered in physician-supervised facility that is trained, equipped, and prepared to deal with anaphylaxis, a rare but documented adverse event associated with AIT, including a screening with an allergy-trained clinician prior to administration and a recommended wait time of 30

minutes after injection to monitor for potential adverse reactions. There are serious risks to patients when AIT services are delivered, making virtual presence wholly inappropriate.

Beyond CMS' proposals in the rule, we urge CMS to continue working with Congress to remove originating site requirements and geographic restrictions on a permanent basis. Further, we urge CMS encourage states to adopt the Interstate Medical Licensure Compact (IMLC) to improve access to care across state lines. As of today, 34 states, the District of Columbia and the Territory of Guam, are participating.

Discarded Drug Rebates

CMS will require practices to report a new JZ modifier on their Part B claims if there were no discarded amounts following delivery of a physician-administered medication. This new modifier, coupled with the exiting JW modifier (that indicates when there are discarded amounts), will help CMS facilitate provisions in the *Infrastructure Investment and Jobs Act* that require manufacturers to provide a refund to CMS for discarded amounts from certain single-dose container or single-use package drugs. AAAAI welcomes the opportunity to collaborate with CMS on educational resources to ensure these modifiers are appropriately reported so that CMS can calculate the amount owed by drug manufacturers.

A/I Specialty Measure Set

We are concerned about CMS' proposals to add "*Screening for Social Drivers of Health*." First, there are no standardized screening tools for capturing social determinants of health (SDOH) in a physician's office. Even if there were such screening tools, they are not incorporated in our electronic health record (EHR) systems, which may be due to the fact there are no uniform data standards for collecting SDOH data in an electronic environment. In addition, we are anxious about the administrative burden any SDOH data collection will impose on physicians' practices, and more importantly, what responsibility physicians' office would have to act on these data. Our practices are already overly burdened by CMS' requirements and our reimbursements are too low to hire additional staff to manage this activity. Until Congress improves reimbursement to cover the costs associated with the need for social workers and other staff in our offices, we caution CMS on further tasking our practices with new requirements.

We also opposed the removal of Measure #110: Influenza Immunization. Despite the burden of reporting this measure, especially among small practices, it is one of the highest reported measures by allergy/immunology. This is not surprising given may of our patients are immunocompromised, thus vaccination against the flu is particularly important in our population. Considering the performance rate is lower than 50% (based on prior year data), there is obvious room for improvement. CMS should maintain this measure in the MIPS program, as well as our specialty set, so that practices can choose to report it should they so choose.

Qualified Clinical Data Registry (QCDR) Policies

AAAAI appreciates, supports, and urges CMS to finalize its proposal to delay the requirement for a QCDR measure to be fully developed and tested with complete testing results at the clinician level until the CY 2024 performance year. As we've shared in the past, measure testing requirements are incredibly challenging for our organization to comply with amidst all of the other new and revised requirements that CMS has imposed over the last few years and proposes for the future (e.g., support for MVPs). Importantly, the resources needed to comply with CMS' full measure testing requirements are significant, especially for a smaller professional society such as ours. Further, it can be extremely difficult

to convince already burdened practices to assist with testing efforts – particularly when there are no incentives for doing so.

While we recognize and support the need for CMS to adopt minimum standards to ensure the validity, reliability and feasibility of QCDR measures, we feel these standards can be achieved with requirements that are less onerous than what CMS envisions for full measure testing. As CMS looks to the future, we urge it to reconsider the necessity of setting such a high bar and the negative impact it could have on the availability of specialty-specific measures, particularly as we move into MVPs and sub-group reporting. If CMS resumes its testing policy in future years, it will threaten the practicality of continuing to support the only A/I-focused QCDR. We strongly urge CMS to streamline and simplify its QCDRs requirements in ways that ease the burden on specialty societies who manage them, while still ensuring the introduction of high quality measures.

Request for Information: *Third Party Intermediary Support of MVPs*

AAAAI would oppose any future requirement that its QCDR must support MIPS Value Pathways (MVPs), particularly if it had no hand in developing the MVP or disagrees with the measures that have been included. AAAAI is already overly laden with QCDR requirements, and this would create an entirely new set of challenges that would push us out of the program.

Request for Information: *National Continuing Medical Education (CME) Accreditation Organizations Submitting Improvement Activities*

AAAAI is concerned about any future policy that would allow *all* national CME accreditation organizations to submit improvement activities (IAs). You may be aware that AAAAI is an accredited CME provider, like many other specialty societies. It is not clear from the proposed rule if you are targeting CME organizations like ours, or other national CME accreditation organizations. If we assumed it is the former, we are deeply concerned about the extra burden - human and financial - it will impose on AAAAI to establish these reporting systems, in addition to other mechanisms we support for the same purpose – including our QCDR. If we assumed the latter, we are concerned about other national CME accreditation organizations reporting IAs directly to CMS, such as a diplomate's Maintenance of Certification (MOC) completion status, particularly as it is the certification boards that are responsible for making such determinations and the national accrediting organizations would receive learner data from the education providers, not the certification boards. Moreover, clinicians will be extremely confused as to who is reporting their CME activities, and if they were indeed reported, as there will be multiple organizations and mechanisms submitting this information. This proposed policy does nothing to streamline reporting and is assured to create new challenges for our organization and the members we serve. We urge CMS to reconsider this contemplated policy.

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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 A. Khan, MD, FAAAAI
President, American Academy of Allergy, Asthma & Immunology