September 14, 2026

SUBMITTED ELECTRONICALLY (https://www.regulations.gov/docket/ CMS-2026-2377)

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Re: CMS-1848-P – CY 2027 Medicare Physician Fee Schedule Proposed Rule

Dear Administrator Oz:

The undersigned organizations write to you regarding the CY 2027 Medicare Physician Fee Schedule proposed rule's request for stakeholder input regarding the definition of a "dose" for CPT code 95165. CMS identified this code as a potentially misvalued service and cited feedback from public stakeholders advocating for a new coverage definition and other changes. We agree that CMS should replace its current definition of an allergy immunotherapy dose for CPT code 95165 with the definition currently used by other allergy immunotherapy CPT codes (95115 and 95117), which defines a dose as "a single injection from a multidose vial."

Background

Allergy immunotherapy has been effectively used for more than 100 years to provide patient-specific treatment for allergic rhinitis, asthma, and eczema.[1] Allergen immunotherapy, which is administered through subcutaneous injections, is tailored to the unique needs of the patient and is described by three Current Procedural Terminology (CPT) codes. CPT codes 95115 and 95117 describe the subcutaneous administration of allergen extracts. CPT Code 95165 describes professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens, per dose.

Allergy immunotherapy is individualized for every patient based on their diagnosed allergic conditions. Patients begin immunotherapy treatment with a lower concentration of allergens and gradually "build-up" to a stronger, maintenance dose. Physicians determine the appropriate concentration, allergen mixtures, injection volume, and dosing schedule based on each patient's sensitivities, treatment phase, response to therapy, and tolerance. Many patients require multiple allergen mixtures because certain extracts cannot safely or effectively be combined in

[1] https://pubmed.ncbi.nlm.nih.gov/39503676/

the same vial. These clinical decisions are based on established medical standards—not arbitrary billing conventions.

As CMS acknowledges in the proposed rule, Medicare patients currently make up a more substantial amount of a typical allergy practice's patient mix than when Medicare first adopted its 1cc definition. With Medicare now accounting for upwards of 20% of a practice's patients, this flawed coverage policy is having an increasingly pronounced impact.

Replacing Medicare's Definition of "Dose" for CPT code 95165

Medicare currently defines a "dose" under CPT code 95165 as a one cubic centimeter (1 cc) aliquot. This definition is inconsistent with CPT coding conventions and disconnected from how physicians prepare and administer allergy immunotherapy. It also differs from the clinical framework used for the other allergy immunotherapy CPT codes.

We respectfully ask CMS to adopt a new definition of "dose" for CPT Code as **"a single injection from a multidose vial."** This definition is consistent with the Current Procedural Terminology (CPT) coding framework used for allergy immunotherapy, including CPT codes 95115 and 95117, and accurately reflects how allergy immunotherapy is furnished in clinical practice.

This change would modernize Medicare policy by aligning reimbursement with the way allergy immunotherapy has long been prepared and delivered in clinical practice. A more accurate Medicare coverage policy would allow allergy practices to better focus their resources on patient care, where it belongs.

Remove the Medically Unlikely Edit (MUE) Cap

We also encourage CMS to replace the medically unlikely edit (MUE) cap for CPT code 95165. The current limit of 30 units per claim is frequently insufficient for medically appropriate treatment, particularly for patients requiring multiple separately prepared allergen mixtures. Whether CMS substantially increases the existing MUE or ultimately adopts an annual utilization framework that better reflects the longitudinal nature of allergy immunotherapy, any utilization safeguard should recognize that utilization varies based on individualized patient needs and should permit exceptions supported by medical necessity.

Conclusion

We appreciate your consideration of our comments in support of CMS changing its definition of dose for CPT code 95165 to "a single injection from a multidose vial" and for our comments in support of removing the MUE cap of 30 units for this code. We feel these changes more accurately reflect clinical practice of care and would significantly reduce administrative burdens

on allergy practices. These improvements will help allow allergists to better focus their resources and medical training on caring for their patients.

These changes will also help to ensure that people with allergic disease can continue to access clinically appropriate, evidence-based care. Improved reimbursement accuracy supports the availability of allergen immunotherapy, which can reduce disease burden, improve quality of life, and help patients better manage their conditions over the long term.

Sincerely,

The American College of Allergy, Asthma and Immunology
The American Academy of Allergy, Asthma and Immunology
American College of Physicians
American Academy of Otolaryngic Allergy
Alliance for Patient Access
Allergy and Asthma Network
Asthma and Allergy Foundation of America
Food Allergy and Anaphylaxis Connection Team
Food Allergy Research and Education
Eastern Allergy Conference
Southeastern Allergy Asthma and Immunology Society, Inc.
Alabama Society of Allergy, Asthma and Immunology
Allergy, Asthma, and Immunology Society of South Carolina
Allergy and Asthma Society of Virginia
Louisiana Society of Allergy, Asthma and Immunology
Michigan Allergy & Asthma Society
Michigan State Medical Society
North Carolina Allergy, Asthma, and Immunology Society
Oregon Society of Allergy, Asthma, and Immunology
San Antonio Allergy, Asthma and Immunology Society
Texas Allergy Asthma & Immunology Society
Texas Medical Association