[Allergist Name, Credentials]
[Practice Name]
[Street Address]
[City, State ZIP]
[Email Address]
[Telephone Number]

[Date]

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1848-P
P.O. Box 8016
Baltimore, MD 21244-8016
CMS Online submission link

Re: CMS-1848-P—CY 2027 Medicare Physician Fee Schedule Proposed Rule; CPT Code 95165

Dear Administrator Oz:

I am a practicing allergist-immunologist writing in response to CMS's request for information concerning the definition of a "dose" for CPT code 95165, which describes the professional services associated with preparing allergenic extracts for allergen immunotherapy.

[PERSONALIZED PRACTICE INFORMATION: Describe your practice, including estimates or precise information about the number or percentage of Medicare beneficiaries you treat and examples of how Medicare's current definition affects your patients or practice.]

Background on Allergy Immunotherapy

Allergen immunotherapy is an important, disease-modifying treatment for patients with allergic rhinitis, allergic asthma, and other clinically significant allergic disease. Unlike treatments that address symptoms only while they are being taken, immunotherapy can alter the underlying allergic response and provide sustained clinical benefit. Effective immunotherapy can reduce symptoms, improve quality of life, decrease reliance on costly medications, and help prevent complications associated with poorly controlled allergic disease.

Adopt the CPT Definition of "Dose" for CPT Code 95165

I appreciate CMS's recognition that Medicare's current definition may not reflect contemporary clinical practice and may create confusion for physicians, patients, and payers. CMS currently treats a dose as a 1 cc aliquot, based on assumptions about vial preparation and use that dates back more than two decades. In the proposed rule, CMS acknowledges concerns held by

myself and many of my colleagues that this approach may produce reimbursement-driven changes in medical practice rather than policies that reflect how immunotherapy is actually furnished.

The Medicare definition is inconsistent with CPT coding conventions and disconnected from how allergists practice. **I strongly urge CMS to adopt the CPT definition and clinical understanding of a dose for CPT code 95165. CMS should specifically replace its existing definition of dose by defining dose as "a single injection from a multidose vial."** This definition is consistent with other CPT codes for allergy immunotherapy (e.g., CPT codes 95115 and 95117). Under this approach, a dose will reflect the amount of allergenic extract prepared for administration to a patient as a single injection.

This position is consistent with that held by my professional specialty societies.[1]

Emphasizing the Importance of Adopting CPT's Definition of Dose for 96165

Allergy immunotherapy doses are individualized based on the patient's sensitivities, treatment phase, prescribed concentration, number of allergen mixtures, tolerance, and response to therapy. The volume administered changes throughout the build-up, maintenance, dose adjustments, missed treatments, illness, or periods of increased allergen exposure. Medicare's definition of dose does not accurately represent the number of clinically usable doses prepared for a patient.

CMS acknowledges that Medicare beneficiaries now account for a significant portion of the allergy immunotherapy population. In my practice, Medicare beneficiaries represent approximately **[XX percent]** of patients receiving allergy immunotherapy. This is consistent with the specialty information cited by CMS indicating that Medicare beneficiaries may comprise more than 20 percent of an individual practice's immunotherapy patients, compared with fewer than 5 percent when the existing policy was developed.

As the Medicare population has grown, the consequences of maintaining an outdated and Medicare-specific definition have become substantially more significant.

Adopting the CPT definition would promote consistency, reduce billing confusion, and allow treatment decisions to be driven by patient needs rather than reimbursement rules. It would also reduce the likelihood that Medicare's unique interpretation will be adopted by Medicaid programs and commercial insurers, which compounds the harmful impact of this outdated policy. A uniform definition would make it easier for physicians to document services accurately, for contractors to adjudicate claims consistently, and for patients to receive treatment according to clinically appropriate protocols.

Eliminate or Raise the Medically Unlikely Edits (MUE) Cap

I also urge CMS to eliminate or significantly increase the medically unlikely edit limit for CPT code 95165. The current MUE of 30 units per claim is insufficient for many medically necessary

treatment plans. Patients may require multiple separate allergen mixtures because certain extracts are incompatible and cannot safely or effectively be combined in the same vial. A patient receiving injections from two or three separately prepared vials can therefore require substantially more than 30 clinically appropriate doses during a preparation cycle. The current edit does not adequately account for multiple-vial treatment, individualized build-up schedules, or the number of doses that can be prepared from a multidose vial under the CPT definition.

CMS should replace the per-claim limit with a clinically appropriate annual framework or, at minimum, substantially raise the MUE so that it does not routinely interfere with legitimate care. CMS notes that specialty societies have recommended annual limits that recognize higher utilization during the first year of therapy, including up to 160 doses during the build-up year and 130 or fewer doses during subsequent maintenance years. An annual approach would be better aligned with the longitudinal nature of immunotherapy and would allow CMS to identify unusual utilization without denying or delaying routine, medically necessary treatment.

Any utilization safeguard should also permit exceptions based on documented medical necessity. Patients differ in the number of clinically incompatible allergen mixtures they require, the duration and frequency of build-up, their tolerance of dose increases, and the adjustments needed following treatment interruptions or adverse reactions. A rigid per-claim cap cannot appropriately account for these differences.

Conclusion

For these reasons, I respectfully request that CMS:

- Replace Medicare's definition of dose for CPT code 95165 by adopting the CPT definition and clinical interpretation of a dose for CPT code 95165, based on each dose prepared for administration as a single injection rather than a fixed 1 cc aliquot.
- Eliminate or significantly increase the 30-unit MUE.
    - Consider replacing the per-claim MUE with clinically appropriate annual utilization parameters that account for build-up and maintenance therapy.
    - Establish a clear medical-necessity exception process for patients whose individualized treatment requires additional doses or multiple allergen mixtures.

Thank you for seeking input from practicing physicians and for considering changes that would align Medicare policy with current clinical practice. Updating the definition of a dose and addressing the inadequate MUE would improve coding consistency, reduce unnecessary administrative burdens, and protect Medicare beneficiaries' access to safe and effective allergy immunotherapy.

Sincerely,

[Allergist Name, Credentials]
[Title]

[Practice Name]
[City, State]