Asthma and Allergy Foundation of America

June 15, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244
Submitted via www.regulations.gov

Re: Proposed Rule: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges

Dear Administrator Oz,

On behalf of the Asthma and Allergy Foundation of America (AAFA), I am writing to provide our comments regarding the proposed rule noted above. AAFA is the leading patient organization advocating for people with asthma and allergies, and the oldest asthma and allergy patient group in the world.

We appreciate CMS's effort to identify how to streamline the prior authorization and step therapy processes through technology and data sharing, and, most importantly, address unnecessary barriers to patient health.

Asthma is one of the most common chronic diseases in the U.S., affecting nearly 28 million Americans, including about 5 million children.[1,2] Asthma leads to almost 1

[1] National Center for Health Statistics. *2024 NHIS Adult Summary Health Statistics*. Data accessed February 19, 2026. Available from https://data.cdc.gov/d/25m4-6qqq
[2] National Center for Health Statistics. *2024 NHIS Child Summary Health Statistics*. Data accessed February 19, 2026. Available from https://data.cdc.gov/d/wxz7-ekz9

million emergency department visits in the U.S. per year,[3] and causes an average of 10 deaths every day.[4]

While there is currently no cure for asthma, there are medications that can greatly reduce the burden and impact. Patients can use controller medication to prevent symptoms; quick-relief medication when an attack starts; a combination medication; or newer biologic immunomodulators for certain types of persistent asthma.

Asthma is a very heterogenous disease: triggers, symptoms, and the effectiveness of different treatments and delivery mechanisms vary tremendously among patients. For people with asthma, delays in care can lead to severe or even irreversible health outcomes, including permanent lung damage, reduced lung function, health problems during pregnancy, reduced quality of life, and worsening asthma symptoms.

Unfortunately, prior authorization and step therapy can prevent providers from getting asthma patients the treatment best suited to them, instead either creating blocks or delays, or requiring patients to cycle through potentially less effective (or entirely ineffective) medication. By limiting or delaying medication options, both doctors and patients are forced to compromise treatment decisions in a way that is potentially dangerous, time consuming and, often, more expensive in the long term.

Creating transparency and efficiency in the prior authorization and step therapy processes across federal programs is an important step toward minimizing the harm to patients.

With regard to prior authorization, AAFA urges CMS to:

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[3]Agency for Healthcare Research and Quality. (2023). *Healthcare Cost and Utilization Project 2020 Healthcare Use Data.* U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. https://www.cdc.gov/asthma/healthcare-use/2020/data.htm

[4] National Center for Health Statistics. *National Vital Statistics System: Mortality (2018-2024).* U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. https://wonder.cdc.gov/ucd-icd10-expanded.html

- Finalize the proposal to extend electronic prior authorization requirements to drugs, to reduce delay for drugs under both the medical and pharmacy benefits.
- Require clear and timely denial communications that support rapid appeals, corrections, resubmissions or exception requests.
- Assure that implementation facilitates continuity of care for patients.
- Make public reporting and metrics on prior authorization data clear and meaningful for all stakeholders.
- Ensure that PBM involvement in the drug purchasing process does not diminish compliance with patient protections and interoperability.

With regard to step therapy, AAFA urges CMS to:

- Require all health insurance plans under CMS's jurisdiction to develop clear step therapy exceptions processes. The process should require a response to exemption requests of no more than 72 hours, and 24 hours for emergency requests.
- Require recognition of a previous payer's step therapy determination. No patient should be required to stop taking an effective treatment and repeat another step therapy process simply due to a change in employment or health insurance plan.
- Standardize step therapy information and processes across payers.

These would be important first steps toward protecting patient health – but they are not the full solution. CMS should work with all stakeholders to continue to reduce the burden of prior authorization and step therapy across the healthcare system, beyond just those programs under the agency's jurisdiction. While we understand that such tools are part of a complex landscape of drug pricing, we do not believe that the answer lies in limiting patient access for nonclinical reasons. That said, the actions outlined above would constitute an important first step in reining in the most damaging impacts of prior authorization and step therapy for patients in programs under CMS's jurisdiction.

We would be happy to share any further information on asthma, AAFA's stance on prior authorization and step therapy, or related issues. Please do not hesitate to contact Jenna Riemenschneider at jennar@aafa.org.

Sincerely,

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America