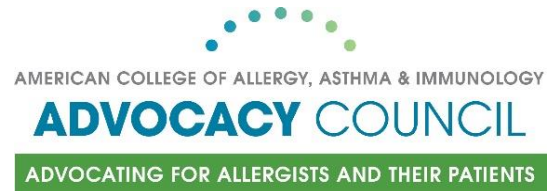




American  
**College**  
of Allergy, Asthma  
& Immunology



AMERICAN COLLEGE OF ALLERGY, ASTHMA & IMMUNOLOGY

**ADVOCACY COUNCIL**

ADVOCATING FOR ALLERGISTS AND THEIR PATIENTS

June 9, 2026

**SUBMITTED ELECTRONICALLY**

The Honorable Mehmet Oz, M.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**RE: ACAAI's Comments on the Proposed Rule Governing Electronic Prior Authorization for Drugs**

Dear Administrator Oz:

The Advocacy Council of the American College of Allergy, Asthma and Immunology (“ACAAI”)—representing the interests of more than 6,000 allergists-immunologists and allied health professionals—appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services’ (“CMS”) and the Office of the National Coordinator for Health Information Technology’s (“ONC”) proposed rule that seeks to modernize and streamline the prior authorization (“PA”) process for drugs to reduce patient and practitioner burden.<sup>1</sup>

The Advocacy Council commends CMS and ONC for proposing to improve communication between the payer and practitioner and to help patients receive the drugs they need in a timely manner. However, we respectfully urge the agencies to exercise greater oversight of the PA process, including through increased monitoring of practices employed by insurers and enforcement of PA requirements. We further encourage CMS and ONC to promote transparency through detailed public metrics. Greater visibility into insurer practices will help identify patterns of inappropriate delays in care and denials of PA requests.

**Electronic Prior Authorization for Drugs**

CMS and ONC propose to extend mandatory electronic PA (“ePA”) requirements to prescription drugs across nearly all federal healthcare programs, including Medicare Advantage plans, Medicaid and Children’s Health Insurance Program (“CHIP”) plans, and qualified health plans (“QHPs”) on a federally-facilitated exchange (“FFE”). The Advocacy Council strongly supports CMS’s proposal to include drugs in ePA systems to facilitate faster response times. Physicians

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<sup>1</sup> 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, 91 Fed. Reg. 19890 (Apr. 14, 2026).

currently spend approximately twelve hours per week managing PA requests.<sup>2</sup> Modernizing the PA process through electronic systems would help reduce the administrative burden associated with completing paper-based forms and transmitting documents via fax. In addition, ePA systems enable more timely and streamlined communication between physician offices and insurers, ultimately allowing physicians to devote more time to direct patient care.

The Advocacy Council appreciates CMS's and ONC's proposal requiring insurers to implement ePA for drugs using NCPDP SCRIPT, a standard already required for Medicare Advantage Prescription Drug Part D plans. Aligning with existing standards would minimize implementation burdens on practitioners by leveraging systems and workflows with which they are already familiar, rather than requiring integration into entirely new and unfamiliar platforms.

### **Shortened Timeframe for Prior Authorization**

Under the proposed rule, QHP issuers on the FFEs would be required to notify a requesting practitioner of their PA decision regarding drugs as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving a standard PA request and no later than 24 hours after receiving an expedited PA request. We believe that this timeframe should be shortened to 48 hours for standard requests and 24 hours for expedited requests, both for drugs and non-drugs.

Faster and more consistent turnaround times can reduce administrative delays, minimize interruptions in care, and support better continuity of treatment. For patients, timely access to medications is critical to optimize health outcomes and avoid complications, hospitalizations, and emergency room visits. This is particularly important for patients living with asthma, allergies, and other chronic conditions, where interruption in treatment can quickly escalate into serious medical events.

### **Improved Prior Authorization Transparency and Oversight**

It is critically important that insurers provide valid and detailed reasons for a PA denial. Currently, practitioners often receive incomplete or vague explanations from payers regarding the basis for a denial. As a result, practitioners are forced to spend considerable time seeking clarification or repeatedly resubmitting PA requests. These delays directly impact patients, particularly those living with chronic conditions, for whom timely access to medication is necessary to maintain health and prevent serious medical crises. In fact, according to an American Medical Association survey, one in four physicians "report that PA has led to a serious adverse event for a patient in their care."<sup>3</sup>

The Advocacy Council appreciates that, under the proposed rule, Medicaid, CHIP, and QHP issuers on the FFEs must respond to the provider with a specific reason for denying a PA

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<sup>2</sup> American Medical Association, *AMA Survey Indicates Prior Authorization Wreaks Havoc on Patient Care* (July 18, 2024), <https://www.ama-assn.org/press-center/ama-press-releases/ama-survey-indicates-prior-authorization-wreaks-havoc-patient-care>.

<sup>3</sup> AMA, *2025 AMA Prior Authorization Physician Survey*, <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>.

request for any drugs within a designated timeframe. We urge the agencies to clarify that a conclusory statement that a drug is not “medically necessary” does not satisfy the requirement to provide a specific reason for denial. Rather, impacted insurers should be required to furnish sufficient detail to enable the prescribing practitioner to meaningfully evaluate and address the basis for the denial.

Further, we strongly encourage CMS and ONC to strengthen oversight of how insurers process PA requests. Insurers need to be held accountable for improper denials of PA requests, particularly denials that do not follow established coverage criteria, are not based on clinical evidence, or are rendered by unqualified reviewers. To ensure clinically sound decision-making, insurers should be required to utilize physicians with relevant specialty training in the review of PA requests. For instance, in cases involving allergies or asthma, the PA determination should be made by a board-certified allergist. Permitting non-physician specialists to second guess the treating physician increases the likelihood that determinations will fail to reflect the current standards of care, coverage criteria, and specialty-specific best practices.

The Advocacy Council also recommends the establishment and administration of a public reporting mechanism through which patients and practitioners can report noncompliance with PA requirements. A mechanism to identify violations is critical to ensuring accountability and meaningful oversight of insurer practices. A centralized reporting platform may also help to deter improper insurer conduct.

In addition, we believe that public data could help assess insurer performance and identify opportunities for improvement in the PA process. To that end, we appreciate CMS’s and ONC’s proposal to require impacted payers to publicly post on their websites a set of metrics on PA. This public data should include greater level of detail to illuminate abusive or negligent practices that result in delayed processing of PA requests or improper denials of PA requests.

### **Step Therapy Request for Information**

The Advocacy Council appreciates CMS’s and ONC’s interest in streamlining the step therapy process through technology and data sharing. At the same time, however, we remain concerned about the application of step therapy to drugs that are typically administered by a physician. We believe that, as a general matter, this category of drugs, including Medicare Part B drugs, should not be subject to step therapy requirements. These therapies are often used to treat serious or chronic conditions for which delays in treatment or interruptions in therapy can have considerable medical consequences. Step therapy requirements can create barriers to timely access to care by forcing patients to try other therapies that may be less effective. Therefore, we urge the agencies to exempt physician administered drugs from step therapy.

Separately, if a patient is stable and responding well to a medication, it can be a significant setback when a change in insurance coverage results in a new payer refusing to honor prior step therapy determinations that the patient has already completed. Requiring patients to repeat therapies that have previously failed is not only burdensome, but clinically inappropriate, and may lead to disease exacerbations, emergency room visits, or hospitalizations.

We believe that technology, through the use of a Payer-to-Payer API, could help address these challenges by enabling the secure transfer of information about previous step therapy requirements that a patient has already undertaken. Such systems could streamline continuity of care by automatically populating previous treatment failures and relevant dates, while also transferring existing documentation between plans..

While greater automation in the step therapy process could improve efficiency, we caution against fully automating clinical decision-making without opportunities for individualized review, particularly for clinically complex cases. We also ask that CMS and ONC consider setting standardized criteria across payers for expectations that a patient must take for completing step therapy requirements so that when a patient does switch payers, the expectations remain the same.

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We appreciate your consideration of our recommendations. Please contact Susan Grupe at [SueGrupe@acaai.org](mailto:SueGrupe@acaai.org) if you have any questions.

Sincerely,



Cherie Zachary, MD, FAAAAI  
President, ACAA



J. Wesley Sublett, MD, MPH, FAAAAI  
Chair, Advocacy Council