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June 15, 2026

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

Sent electronically via regulations.gov

RE: [CMS-0062-P] 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…

Dear Administrator Oz,

The American College of Rheumatology (ACR), representing over 10,400 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to respond to the proposed rule on interoperability standards and prior authorization for drugs, which was published in the Federal Register on April 14, 2026. **The ACR commends CMS for recognizing the undue burden of prior authorization and the delays these processes impose on both patients and clinicians.**

Rheumatologists provide ongoing care for patients with complex chronic and acute conditions that require specialized expertise. Rheumatologists, rheumatology physician assistants, and nurse practitioners provide face-to-face, primarily non-procedure-based care and serve patients with conditions that can be difficult to diagnose and treat. Rheumatic disease patients are particularly affected by prior authorization. According to a 2020 patient survey conducted by the ACR, 48% of patients reported being subjected to prior authorization.

We offer suggestions on further strengthening the transparency and interoperability requirements enumerated in the proposed rule by:

1) requiring payers to provide actionable reasons for coverage denials;
2) mandating more granular public reporting of prior authorization metrics;
3) extending the requirements in the rule to plans on state-based exchanges; and
4) extending the rule's interoperability and transparency requirements to Medicare Part D plans.

Accordingly, the ACR offers comments on the rule's prior authorization decision timeframes, denial reasons, public reporting of metrics and scope.

<u>Impact of Prior Authorization on Care</u>

Prior authorization processes can cause significant delays in access to care and in some cases, may lead to patients abandoning treatment altogether. Rheumatologists treat patients with debilitating and sometimes life-threatening conditions. Timely care, especially medically appropriate pharmacologic interventions, are essential for rapidly suppressing severe inflammatory conditions, keeping these diseases in remission, and improving patients' quality of life.

A 2023 survey of physicians conducted by the American Medical Association (AMA) found that for patients whose treatments required prior authorization, 94% experienced delays in care. 78% of physicians surveyed reported that they had patients that had abandoned treatment altogether due to the delays imposed by prior authorization.[i]

These delays in care are not merely administrative and are associated with worse health outcomes. A January 2026 meta-analysis of 25 studies found that prior authorization processes were associated with disease exacerbation, preventable hospitalizations and longer hospital stays along multiple specialties.[ii] Researchers involved in the analysis said that the delayed access could be "potentially life-threatening."[iii] For time-sensitive conditions, even short interruptions in treatment can result in clinical consequences.

Furthermore, prior authorization processes consume clinician time that could be spent on patient care. A late 2024 AMA analysis found that physicians complete an average of 39 prior authorizations per week, requiring 13 hours or two full days of staff time.[iv]

Though insurers claim that the purpose of prior authorization processes is to ensure proper treatment without unnecessary costs, unduly burdensome requirements can prevent rheumatologists from making the best decisions for their patients.[v]

<u>Prior Authorization Proposals</u>

Decision Timeframes

The 2024 prior authorization and interoperability proposed rule introduced a shortened decision timeframe for prior authorization decisions for non-drug services for certain payers: specifically, 72 hours for expedited requests and 7 calendar days for standard requests, with the possibility of an extension for up to 14 days in special circumstances. The rule excluded Qualified Health Plan (QHP) issuers from this requirement, allowing them to follow existing ERISA-based guidance requiring decisions within 15 days.

The 2026 proposed rule compresses the decision timeframe for drug treatments further: to 72 hours for most requests and 24 hours for expedited requests. Furthermore, the rule applies to payers across CMS programs, including QHP issuers. **We applaud CMS for introducing this shortened minimum timeframe for drug services and for aligning decision timeframes across payers.**

Denial Reasons

The proposed rule requires all impacted payers to furnish providers with a specific reason for denying prior authorization requests for any drugs, extending a similar provision for non-drug services in the 2024 rule.

We are strongly in support of the extension of this critical requirement that will allow rheumatology professionals to determine alternative treatment options or strategize about how to appeal coverage denials However, we urge CMS to provide further detail regarding what constitutes a "specific reason" for a coverage denial. Vague denial reasons like "medical necessity not met" or "does not meet plan criteria" do not provide sufficient information.

Denials should include enough information for the clinician to either resubmit with the correct documentation or understand what therapeutic alternative the plan expects themto try first. For example, an effective denial reason might include what documentation is missing, alternative treatments or what clinical threshold the plan requires. This level of granularity in the denial would allow the practice to give their patients clear guidance about next steps and would allow the denial to be resolved quickly. We urge CMS to include more detailed information about what constitutes a "specific reason" for denial in the final rule, so that rheumatologists and patients are able to effectively appeal denials and understand why a treatment was denied.

Public Reporting of Prior Authorization Metrics

The 2024 final rule requires that impacted payers report prior authorization metrics for non-drug items and services on their public websites annually. CMS is proposing to add requirements for impacted payers to report the numeric counts in addition to percentages for certain existing metrics and adding several new metrics for non-drug services. **We commend CMS for its commitment to increased transparency in prior authorization decisions and are strongly in support of these provisions.**

However, we also urge CMS to require the reporting of more information that will allow rheumatology professionals and patients to compare payers' prior authorization behavior with their stated approval criteria. **We encourage CMS to strengthen the transparency component of this rule by requiring payers to publish their approval criteria for drugs and to mandate specialty-level disaggregation in public reporting.** We also request that CMS explore mechanisms to investigate the difference between payers' published approval criteria and behavior.

More granular public reporting of approval criteria and denial rates may also discourage payers from denying claims simply as a means of "running out the clock" on the new, shorter decision timeframes. In some states that have instituted shortened decision timeframes for prior authorization decisions, denial rates have risen, as payers work around the new regulations by denying more services, requiring providers to submit claims and delaying care. Greater transparency around denial rates and approval criteria, supplemented by the requirement that payers provide specific, actionable denial reasons, will provide a meaningful counterweight to attempts by payers to preempt the new decision timeframes by denying more claims.

Finally, the proposed rule allows Part D plans to report prior authorization metrics at the "contract level," bundling individual plans into one aggregated average. This approach makes it difficult to determine which plans are denying care at higher rates. **We urge CMS to require Part D plans to report prior authorization metrics at the plan level, so that direct comparisons between plans are possible.**

Scope

The proposed rule extends new transparency and interoperability requirements to Medicare Advantage, Medicaid, CHIP and QHP plans on the Marketplace. **However, the rule does not extend these requirements to QHP issuers on state-based exchanges.** This is a meaningful exclusion, as over 7 million American receive coverage through state-based exchanges.[vi]

Many potential levers exist for extending these requirements to QHPs on state-based exchanges. For example, for exchanges that use the HealthCare.gov platform for enrollment but handle their own QHP certification, CMS could condition continued access to the federal platform on meeting the new interoperability requirements.

Interoperability Requirements

Finally, the proposed rule requires adoption of Fast Healthcare Interoperability Resources (FHIR)-based APIs for prior authorization requests for most impacted payers, allowing clinical documentation to flow directly from clinician electronic health records to the payer's system, without requiring the practice to fax or manually upload clinical documentation. This is an important step for minimizing administrative burden.

However, the proposed rule does not extend this same API infrastructure to Medicare Part D drugs, which will continue to use the NCPDP SCRIPT standard, run through pharmacy billing systems. Practices would have to continue to fax paperwork or manually documentation to a separate portal, when requesting prior authorization for Part D drugs, thereby maintaining the administrative burden the rule intends to eliminate. **To simplify prior authorization processes further, CMS should require adoption of the same FHIR-based APIs for Part D drugs and work with health IT vendors and PBMs to build integration between the FHIR-based API and the NCPDP-based pharmacy billing systems, so that Part D drugs are integrated into the same digital pathway as other prior authorization requests.**

Please contact Sweta Haldar, MSPH, ACR Manager of Regulatory Affairs, at shaldar@rheumatology.org or (202) 807-5262 should you have any questions or if we can provide additional assistance.

Sincerely,

William F. Harvey, MD, MSc, FACR
President, American College of Rheumatology

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[i] https://www.ajmc.com/view/prior-authorizations-and-the-adverse-impact-on-continuity-of-care
[ii] https://pubmed.ncbi.nlm.nih.gov/40912445/
[iii] https://www.hopkinsmedicine.org/news/articles/2025/10/researchers-find-measurable-patient-harm-linked-to-prior-authorization
[iv] https://www.ama-assn.org/practice-management/prior-authorization/fixing-prior-auth-nearly-40-prior-authorizations-week-way

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[v] https://www.health.harvard.edu/healthy-aging-and-longevity/prior-authorization-what-is-it-when-might-you-need-it-and-how-do-you-get-it
[vi] https://www.kff.org/medicare/a-current-snapshot-of-the-medicare-part-d-prescription-drug-benefit/