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June 15, 2026

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Attn: 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, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges

Dear Administrator Oz,

On behalf of the EveryLife Foundation for Rare Diseases, we are pleased to provide comments on the proposed rule regarding interoperability standards and prior authorization for prescription drugs

The EveryLife Foundation for Rare Diseases is a 501 (c)(3) nonprofit, nonpartisan organization powered by the rare disease community to improve health outcomes by driving change through evidence-based policy, leading science-driven policy and regulatory research, activating the community to advocate for their rights and needs, and strengthening the rare disease community. Our comments reflect the insights and experiences of our diverse coalition, comprised of patient organizations, industry leaders, and other relevant stakeholders who together inform our policy efforts.

Over 30 million Americans live with one or more rare diseases, 95% of which have no approved treatment[1]. Rare disease patients and families navigate expenses from multiple inpatient and outpatient encounters, prescription therapies and medical devices, and the support services critical to their health and well-being. The National Economic Burden of Rare Disease Study in the United States estimated that the overall annual economic impact of rare disease exceeded $966 billion in 2019[2]. The 8.4 million Medicare enrollees with a rare disease accounted for 53% of the total direct costs identified in the study.[3] Medicare and Medicaid enrollees

[1] National Center for Advancing Translational Sciences. (2023, February 24). Delivering Hope for Rare Diseases. https://ncats.nih.gov/sites/default/files/NCATS_RareDiseasesFactSheet.pdf
[2] Yang G, Cintina I, Pariser A, Oehrlein E, Sullivan J, Kennedy A. The national economic burden of rare disease in the United States in 2019. Orphanet J Rare Dis. 2022 Apr 12;17(1):163. doi: 10.1186/s13023-022-02299-5.

accounted for $236.4 billion in excess direct medical costs, including $28,185 per person for Medicare and $27,573 per person for Medicaid[4].

In rare diseases, time is a precious commodity. Inappropriate use of utilization management techniques creates unnecessary hurdles to critical and time-sensitive treatment interventions, yielding irreversible disease progression and catastrophic healthcare costs. Nearly all (99%) Medicare Advantage plans require prior authorization for some services, with 97% requiring prior authorization for acute inpatient hospital stays, 94% for diagnostic procedures, labs, and tests, and 90% for home and health services.[5] Prior authorization can lead to care delays, significant negative impacts on clinical outcomes, and increased hospitalizations.[6]

The proposed rule makes much-needed improvements to address prior authorization challenges experienced by the rare disease community, building on the 2024 CMS Interoperability and Prior Authorization Final Rule (CMS-0057 F). Many of the proposed changes would improve timely access to prescription drugs for the rare disease community and align with prior authorization principles developed by our coalition of rare disease stakeholders. However, there are opportunities to improve the rule to further meet the needs of the rare disease community.

These recommendations include:

- Further strengthening response timeline requirements;
- Further defining 'urgent' requests;
- Implementation of rules to prevent repeated, unnecessary authorization requests;
- Requiring disclosure of clinical reviewer's credentials and use of AI tools;
- Increasing accountability for noncompliance;
- Clarifying how improved transparency and reporting will result in process changes; and
- Commitment to ongoing stakeholder engagement.

Further Strengthen Response Timeline Requirements

Many rare diseases are progressive and associated with limited life expectancy. Navigating a confirmed rare disease diagnosis can take, on average, more than 6 years after symptoms begin[7]. In many cases, once a patient is diagnosed, inefficient prior authorization processes can further delay their treatment. Timely reviews of prior authorization requests, information requests, and appeals can mean the difference between irreversible disease progression and interventions that alter or stabilize disease course. While a step in the right direction, the proposed response timelines in the rule fall short of the American Medical Association's recommended timeframe: 24 hours for urgent and 48 hours for non-

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[4] *Ibid*

[5] Freed, M., Biniek, J. F., Damico, A., & Neuman, T. (2026, June 5). *Medicare Advantage in 2026: Premiums, out-of-pocket limits, supplemental benefits, and prior authorization*. KFF. https://www.kff.org/medicare/medicare-advantage-in-2026-premiums-out-of-pocket-limits-supplemental-benefits-and-prior-authorization/ Inserro, A. (2022, February 28).

[6] How Prior Authorization Can Impact Patients with Rare Disease. American Journal of Managed Care. https://www.ajmc.com/view/how-prior-authorization-can-impact-patients-with-rare-disease

[7] Yang G, Cintina I, Pariser A, Oehrlein E, Sullivan J, Kennedy A. The national economic burden of rare disease in the United States in 2019. Orphanet J Rare Dis. 2022 Apr 12;17(1):163. doi: 10.1186/s13023-022-02299-5.

urgent requests[8]. The response timelines that our coalition of rare disease stakeholders felt would best meet the community's needs include:

- 24 hours for concurrent prior authorization review;
- 48 hours for urgent prior authorization requests for services and prescriptions;
- 72 hours for non-urgent prior authorization requests for services and prescriptions;
- 1-2 days for additional information for urgent requests;
- 7-12 days for additional information for non-urgent requests;
- Review of expedited appeals within 48 hours, and non-expedited appeals within 7 days.

Further Define 'Urgent' Requests

While 95% of rare diseases do not yet have an FDA-approved treatment[9], for those patients who do have an available therapy, prior authorization and step therapy requirements create hurdles in accessing the treatments they have been waiting for decades to exist. These hurdles are particularly threatening for patients with rare diseases, whose treatments often lack alternatives. CMS should provide additional guidance that defines 'urgent' requests to include treatments that have Breakthrough Designation from the FDA and those that include diseases with no other alternative medication or intervention approved by the FDA. The treatments granted Breakthrough Designation have already been shown to address life-threatening conditions and demonstrate substantial improvement over available and alternative therapies.

Implement Rules to Prevent Repeated, Unnecessary Reauthorizations

For rare disease patients, stability and continuity of care are paramount. Nearly 70% of rare diseases are genetic and, for many of these conditions, frequent reauthorizations are not clinically justified based on the expected course of disease. Frequent reauthorizations can lead to interruptions in treatment, increased stress for patients, and irreversible disease progression.[10] When authorizations are valid for longer periods, patients can focus on managing their health rather than navigating procedural hurdles. Streamlining prior authorization requirements reduces the administrative burden and saves valuable time and resources for patients and clinicians.

To ensure continuity of care, payers should be barred from reversing or rescinding approved authorizations, protecting patients from major disruptions and changes during their treatment. CMS should also establish guardrails to prevent unnecessary repeat prior authorization for medications,

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[8] American Medical Association & American Medical Association. (2024, June 11). When health plans delay and deny, they must say why. American Medical Association. https://www.ama-assn.org/practice-management/prior-authorization/when-health-plans-delay-and-deny-they must-say-why

[9] National Center for Advancing Translational Sciences. (2023, February 24). Delivering Hope for Rare Diseases. https://ncats.nih.gov/sites/default/files/NCATS_RareDiseasesFactSheet.pdf

[10] In this recent national survey of physicians, almost half of the physicians reported that prior authorization policies led to urgent or emergency care for patients, and one-third of the physicians reported that prior authorization led to a serious adverse event for a patient in their care, including hospitalization, permanent impairment, or death. *2022 AMA Prior Authorization (PA) Physician Survey, American Medical Association*

including prohibiting reauthorization for patients stable on long-term therapies, requiring approvals to remain valid for the duration of treatment, and preventing new prior authorization requirements from being imposed mid-course without continuity protections. These guardrails should also include protections for patients switching insurance companies by honoring prior authorizations to ensure continuity of care, a goal supported by proposed improvements to API reporting capabilities.

Require Disclosure of Clinical Reviewer's Credentials and Use of AI Tools

Too often, prior authorization determinations for complex rare diseases are not based on the opinions of the highly specialized medical experts who treat them. We often hear from patients with rare diseases that the reviewers of their prior authorization requests lack expertise in their condition. Given the complex nature of individual rare diseases, it is important that appropriate medical experts are involved in reviewing prior authorization requests. Public reporting of the specialist's credentials will improve transparency about who is reviewing complex rare disease cases. This information can support future policy and resource prioritization to address the limitations insurers face in identifying appropriate peer reviewers.

Artificial intelligence cannot be the sole decision-maker at any point throughout the prior authorization process. Expert decision-making must be a consultation with a human, licensed medical practitioner in the specific rare disease or medical specialty. If artificial intelligence or automation is used during prior authorization review, a human, licensed medical practitioner in the relevant specialty must be the final decision-maker. In addition, CMS should require payers to provide notice to enrollees and health care providers when artificial intelligence or automation is used to issue adverse determinations, and to include the use of AI in the list of required reporting elements.

Increase Accountability for Noncompliance

There is a dearth of available mechanisms to monitor and enforce plan compliance with prior authorization timelines, especially at the individual level, leaving patients with limited recourse when required timelines are not met. 68 % of insured adults with chronic conditions cite the prior authorization process as a major problem, and nearly 1 in 5 adults with insurance indicate that the prior authorization process has majorly impacted their mental health, physical health, and/or finances.[11] Prior authorization delays should not adversely affect patient health, particularly for those seeking an expedited review due to serious medical need. We urge CMS to consider requiring automatic approval for urgent prior authorization requests when required timelines are not met to ensure patients receive access to appropriate care in a timely manner.

[11] Kirzinger, A., Montalvo, J., & Hamel, L. (2026, February 2). *Poll: People view prior authorization as greatest burden in navigating the health system*. KFF. https://www.kff.org/public-opinion/poll-people-view-prior-authorization-as-greatest-burden-in-navigating-the-health-system/

Clarify How Improved Transparency and Reporting Will Result in Process Changes

In 2024, 92.3% of prior authorization requests were approved, but of the more than 4.1 million requests denied or partially denied, only 11.5% were appealed.[12] Of the appeals filed, there was an 80.7% success rate in full or partial overturns. [13] The high approval percentage and the low appeals rate raise the question: Are prior authorization policies needlessly disrupting care and causing clinical workforce burden?

We applaud the public reporting requirements in the proposed rule, which will provide insights on prior authorization processes across various programs. Additional data on how often prior authorizations are approved versus denied, the median time to decision, and how the process works under standard versus expedited approval can support future process improvements. However, the rule falls short of specifying how the data will be used to guide whether and what changes in policy are needed, noting only that this additional information "improves efficiencies for both payers and providers".

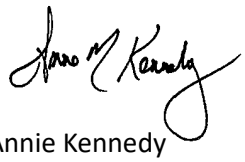
We urge CMS to identify opportunities to use the data from new reporting requirements to improve the prior authorization process.

Commit to Ongoing Stakeholder Engagement

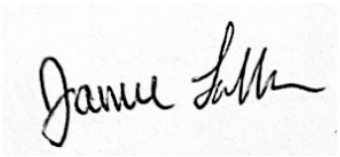
We urge you to continuously engage with stakeholders, including patients with rare diseases, chronic diseases, and disabilities, so that the final rule and its implementation reflect their lived experiences. Robust public engagement should also focus on increasing public awareness of the time rules and appeals rights. This outreach and engagement should afford CMS the opportunity to develop methodology in collaboration with stakeholders and create a feedback loop to identify any unintended barriers that may arise as new standards are implemented.

Thank you for the opportunity to provide comments. Please contact Jamie Sullivan, Senior Vice President of Policy and Advocacy at jsullivan@everylifefoundation.org if we can provide any additional information to inform your process.

Sincerely,



Annie Kennedy
Chief Mission Officer
EveryLife Foundation for Rare Diseases



Jamie Sullivan, MPH
Senior Vice President of Policy and Advocacy
EveryLife Foundation for Rare Diseases

CC: Michael Pearlmutter, Chief Executive Officer
Amy Gaviglio, Chairman, Board of Directors

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[12] Biniek, J. F., Sroczynski, N., Freed, M., & Neuman, T. (2026, January 28). *Medicare Advantage Insurers made nearly 53 million prior authorization determinations in 2024*. KFF. https://www.kff.org/medicare/medicare-advantage-insurers-made-nearly-53-million-prior-authorization-determinations-in-2024/

[13] *Ibid*