PATIENTS RISING

*A national voice for patients and the people who care for them*

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June 15, 2026

The Honorable Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-0062-P

**RE: 2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule (CMS-0062-P); Docket No. CMS-2026-1255**

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Dear Administrator Oz:

## Introduction: Who We Are and Why We Are Writing

Patients Rising is a national patient advocacy organization. For more than ten years, we have worked alongside patients and caregivers living with serious and chronic illness — across oncology, rare disease, autoimmune, neurological, and immunological conditions, among others. What distinguishes our perspective is proximity and volume: through our patient learning center and our daily work with patients across the country, we hear directly and continuously about what prior authorization does to real people — the delays, the denials, the repeated tests, and the quiet decisions to give up on care altogether. We submit these comments to bring that ground-level experience to the agency's analysis.

## Background: The Provisions We Address

This comment addresses the 2026 CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule (CMS-0062-P; Docket No. CMS-2026-1255), published in the Federal Register on April 14, 2026. We support the rule's overall direction — which, for the first time, treats prior authorization for drugs as infrastructure to be modernized rather than a permanent fact of patient life. We respond specifically to the proposed provisions on electronic prior authorization, on decision timelines and denial transparency, and on payer reporting, as well as to the rule's Requests for Information on step therapy and on prior authorization for laboratory testing. Our recommendations are organized by provision and summarized at the end.

## The Scale of the Problem, in Patients' Terms

The case for this rule is written in the data CMS already collects. In 2024, Medicare Advantage insurers made nearly 53 million prior authorization determinations and denied 4.1 million of

them — about 7.7 percent of all requests. Only 11.5 percent of those denials were appealed; but of the denials that *were* appealed, 80.7 percent were partially or fully overturned.[1]

That overturn rate is the signal CMS should weigh most heavily. When a patient or provider has the time, knowledge, and stamina to challenge a denial, the original "no" is reversed far more often than not — meaning a large share of denials block or delay care that is ultimately found appropriate. And because nearly nine in ten denials are never appealed at all, the reversals we see are only the visible portion of a much larger volume of wrongly delayed care. Most patients simply absorb the "no."

Physicians describe the human consequences plainly. In the American Medical Association's most recent national survey, 95 percent of physicians said prior authorization delays access to necessary care, 79 percent reported that patients abandon treatment because of it, 92 percent said it negatively affects clinical outcomes, and more than one in four (26 percent) reported that prior authorization had led to a serious adverse event for a patient in their care — including hospitalization, permanent impairment, or death.[2]

These are the stakes the rule's reforms address. Our recommendations aim to ensure the final rule reduces that harm rather than relocating it.

## I. Build Electronic Prior Authorization Around the Patient's Time

For a patient, a prior authorization delay is not an administrative detail. It is days or weeks without treatment while a condition advances, and it is the all-too-common moment of walking away from a pharmacy counter empty-handed. Electronic prior authorization that lets a care team check coverage rules, submit a request, and track its status in real time — inside the systems they already use — directly attacks the abandonment and delay the data above describe. We strongly support extending these requirements across both the medical and pharmacy benefit.

> **Our recommendation:** CMS should require electronic prior authorization across both the medical and pharmacy benefit, and should ensure patients can see the status and outcome of a request affecting their own care — not only their providers.

## II. Faster Decisions — and Honest Ones

We support requiring prior authorization determinations within 24 hours for all drugs, aligned across markets. But the 80.7 percent overturn rate is also a caution: a faster clock cannot be allowed to become an automatic "no." Speed without accountability simply produces wrong

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[1]KFF, "Medicare Advantage Insurers Made Nearly 53 Million Prior Authorization Determinations in 2024," Jan. 28, 2026. Figures reflect 2024 data submitted by Medicare Advantage insurers to CMS. https://www.kff.org/medicare/medicare-advantage-insurers-made-nearly-53-million-prior-authorization-determinations-in-2024/

[2]American Medical Association, 2025 Prior Authorization Physician Survey (nationwide survey of 1,000 practicing physicians). https://www.ama-assn.org/about/leadership/ama-survey-prior-authorization-reform-pledge-falls-short-physicians

answers more quickly. Expedited timelines must therefore be paired with active CMS oversight to ensure they do not drive inappropriate denials.

Just as important, the low appeal rate tells us patients cannot act on denials they do not understand. Every denial — including the very first one — should arrive with a clear, plain-language explanation of why, delivered to the patient at the same time it reaches the provider. A patient who is told the reason can appeal; a patient who is not, abandons care.

> **Our recommendation:** Require 24-hour determinations across all markets; pair expedited timelines with active CMS oversight against auto-denials; and require a detailed, plain-language denial justification — for every denial, including initial denials — delivered to both the provider and the patient.

## III. Transparency Patients Can Actually Use

Families cannot navigate a system they cannot see. Counting how often payers use a data interface tells no one whether patients are actually getting care. Those usage metrics should be paired with meaningful measures of the patient and provider experience — denial rates, appeal outcomes, and turnaround times — evaluated and summarized in an annual report that CMS publishes for the public. The KFF figures above exist only because CMS requires Medicare Advantage plans to report them; that same visibility should extend across markets and drugs.

Reporting should be public and at the plan level, broken out by brand versus generic, by therapeutic area, and including both initial denials and step therapy. Medicare Part D plans should report these metrics like everyone else. When a plan denies care, patients deserve to know how often that happens, and why.

> **Our recommendation:** Require public, plan-level prior authorization metrics — including Part D plans — broken out by brand vs. generic, by therapeutic area, and including initial denials and step therapy, paired with patient-experience data in an annual public CMS report.

## IV. Step Therapy: Do Not Make Patients Lose Ground (Response to RFI)

“Fail first” is experienced by a patient as being required to get worse before being allowed the treatment their clinician already chose. The survey data bear this out: most physicians report that step-therapy and similar protocols lead patients to start on treatments expected to be ineffective, contributing to the abandonment and poor outcomes described above. And when a patient has already worked through those required steps, switching to a new plan should not send them back to square one to prove all over again what their body has already shown.

> **Our recommendation:** CMS should not permit Medicare Advantage plans to expand step therapy for Part B drugs, and should collect and release data on its use; require plans to honor step therapy a patient has already completed when they move between plans; require step therapy to be disclosed openly rather than buried inside the prior authorization process; and ensure a robust, transparent exceptions and appeals process.

## V. Prior Authorization for Laboratory Testing (Response to RFI)

CMS's own Request for Information names the core problems precisely: poor coordination between providers and laboratories, the length of time approvals take, denials issued when a request is submitted after the specimen is collected, and the role of laboratory benefit managers. We urge CMS to act on each.

Advanced and biomarker testing is how a care team learns which treatment will work for a specific patient — especially in oncology and rare disease, where the right test can be the difference between targeted treatment and lost time. When prior authorization stands between a patient and that test, the cost is measured in repeated blood draws, delayed diagnoses, and weeks of not knowing.

The accounts our interactions with patients and families receive put a face to CMS's questions. Representative of the calls we regularly field: a patient in cancer treatment whose oncologist ordered biomarker testing to identify the targeted therapy suited to her disease. The test was denied because the authorization was still pending on the day her blood was drawn. She returned weeks later for a second draw, her treatment decision on hold the entire time, while her family absorbed the uncertainty. The clinical need never changed — only the paperwork's timing did. Allowing a test requisition form to serve as valid documentation of medical necessity, and ending these timing-based denials, would have spared her both the second needle and the delay.

> **Our recommendation:** End timing-based denials of laboratory tests; allow a test requisition form to serve as valid documentation of medical necessity; closely examine the role of laboratory benefit managers as an added layer between patients and diagnosis; and pursue laboratory prior authorization reform with the same urgency as the rule's drug provisions.

### Costs That Do Not Appear in a Spreadsheet

Finally, we ask CMS to weigh impacts that resist a dollar figure. The burdens of prior authorization do not fall evenly. They land hardest on the sickest patients — those in cancer treatment, those with rare and complex conditions — who face the most authorizations and the most at stake in every delay. They land hard on working families who must take unpaid time from their jobs for a repeat blood draw or an extra office visit that prior authorization made necessary. And they carry a cost in dignity and peace of mind — the exhaustion of fighting one's own insurer while sick — that no economic table will capture but that every patient feels. We urge CMS to treat these qualitative and distributional effects as part of the rule's justification, not as a footnote to it.

### Conclusion and Summary of Recommendations

Patients Rising supports the direction of this proposed rule. The agency's own data show a system in which millions of denials are issued, few are appealed, and most that are appealed are overturned — and in which physicians report real and sometimes irreversible harm to patients. Done well, this rule can change that. We respectfully recommend that CMS, in the final rule:

1. Require electronic prior authorization across both the medical and pharmacy benefit, and ensure patients — not only providers — can see the status and outcome of requests affecting their own care.
2. Require 24-hour determinations across all markets, paired with active CMS oversight to ensure expedited timelines do not produce inappropriate denials.
3. Require a detailed, plain-language denial justification for every denial, including initial denials, delivered to both the provider and the patient at the same time.
4. Require public, plan-level prior authorization metrics — including Part D plans — broken out by brand vs. generic and by therapeutic area, including initial denials and step therapy, paired with patient-experience data in an annual public CMS report.
5. Decline to permit Medicare Advantage plans to expand step therapy for Part B drugs; collect and release data on its use; require plans to honor step therapy a patient has already completed when switching plans; require step therapy to be disclosed openly rather than embedded in prior authorization; and ensure a transparent exceptions and appeals process.
6. End timing-based denials of laboratory tests, allow a test requisition form to serve as valid documentation of medical necessity, examine the role of laboratory benefit managers, and pursue laboratory prior authorization reform with the same urgency as the rule's drug provisions.

Patients Rising welcomes the opportunity to be a constructive partner in this work and to serve as a neutral table where patients, providers, health plans, and CMS can solve these problems together. We thank CMS for advancing reforms that put patients' time and health first, and we stand ready as a resource as the agency finalizes this rule.

Sincerely,

Terry Wilcox

**Terry Wilcox**
Co-Founder & CEO
Patients Rising