RRC
Regulatory Relief Coalition
Protecting Patients' Timely Access To Care

June 15, 2026

Submitted Electronically via www.regulations.gov

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0062-P
P.O. Box 8013
Baltimore MD 21244-8013

RE: Regulatory Relief Coalition's Comments on the Proposed Rule Governing Electronic Prior Authorization for Drugs

Dear Administrator Oz:

The undersigned members of the Regulatory Relief Coalition (RRC), representing thousands of physicians throughout the United States, appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) proposed rule on electronic prior authorization (e-PA) for drugs in federal health care programs ("Proposed Rule"). RRC is a group of national physician specialty organizations advocating for regulatory burden reduction to ensure that utilization review policies are not a barrier to timely and equitable access to care for the patients we serve.

RRC strongly supports the regulatory changes set forth in the Proposed Rule, which build on CMS's 2024 rulemaking[1] by standardizing e-PA for drugs across all services and payer types. These regulations would significantly reduce barriers to care for patients and lessen provider burden associated with payers' PA requirements.[2] Our comments focus on additional modifications and clarifications which will further aid CMS in accomplishing these goals.

[1] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes, 89 Fed. Reg. 8758 (2024) (hereinafter 2024 Final Rule).
[2] For the purposes of these comments, unless otherwise noted, the term payers will be used to refer to Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges.

Required E-Prior Authorization for Drugs

RRC strongly supports, and urges CMS to finalize, its proposal to require payers to support e-PA for drugs covered under a pharmacy benefit via National Council for Prescription Drug Programs (NCPDP) standards, as well as medical benefit drugs via Fast Healthcare Interoperability Resource (FHIR)-based APIs. Standardized use of e-PA across services and payer types will reduce administrative burdens for providers, allowing them to spend more time on patient care. Similarly, for patients, expanding e-PA to drugs is essential to ensuring that patients receive timely access to care in all areas of their medical treatment.

RRC supports the use of PA APIs for drugs. Standardized APIs can help transition PA processes from individual, payer-specific portals to processes within a provider's existing workflow, minimizing administrative burden. RRC requests that any standards for such APIs undergo robust real-world testing in a variety of clinical settings, including small, independent, and rural physician practices, and with all end users, including physicians, to ensure standards are effective, adoptable, and efficient.

Shortened Timeframes for Prior Authorization Decisions

To address PA decision timeframes, CMS proposes that impacted payers must provide notice of PA decisions no later than 72 hours for standard requests and no later than 24 hours for expedited requests. This requirement would align PA decision timeframes for drugs with those for other services finalized in the 2024 Final Rule. Clear deadlines for PA request decisions are foundational to ensuring patients receive the treatment they need within a timeframe that facilitates optimal health outcomes. Current PA delays often result in patient harm, despite physicians' best efforts to deliver high quality care to patients and ensure the best possible outcomes for those they care for.

RRC supports an expedited 24-hour timeframe for PA determinations for drugs. However, RRC urges CMS to modify the timeframe for standard determinations for both drugs and services by requiring payers to respond to a PA request within 48 hours rather than 72 hours. Unnecessary treatment delays for standard requests can compromise patient health just as much as treatment delays in more emergent situations. Advances in technology and the automation of PA determinations have made it reasonable to expect shorter turnaround times from payers. A 48-hour decision timeframe for standard requests is more than sufficient for payers to make determinations, and this timeframe has been consistently recommended by provider organizations such as the American Medical Association (AMA).[3]

[3] American Medical Association, Prior Authorization and Utilization Management Reform Principles 6, https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf.

RRC further believes that CMS should require payers to implement a mechanism for real-time PA decisions for frequently approved drugs and services, as described in the *Improving Seniors' Timely Access to Care Act* (S. 1816/H.R. 3514). Implementing such a program has the potential to virtually eliminate the delay associated with many PA requirements and facilitate seamless patient care.

Increased Payer Reporting and Transparency

RRC commends CMS for its proposals to improve transparency in the PA process. Transparency is an important first step to ensuring payer accountability in PA decisions. However, additional specificity is necessary to make the information reported by payers more meaningful and actionable for providers.

The Proposed Rule would require payers to provide a specific reason for denying a provider's PA request. RRC strongly supports this proposed requirement, as it will increase consistency in payer decision-making and give providers the necessary information to direct the next steps in a patient's care. However, in addition to denial reasons, we respectfully request that CMS also require payers to report what specific steps a provider must take, including the required medical record documentation, to successfully appeal the payer's PA denial. Clarity on these next steps will reduce providers' back-and-forth with payers and enable quicker resolutions for patients.

RRC also supports the Proposed Rule's requirement that payers publicly report on the metrics they use in PA decisions. This change will aid providers in framing their PA requests in a manner that makes requests more likely to be approved at the outset. However, under the current proposal, payers would only be required to report this information at the contract or issuer level, as was required in the 2024 Final Rule. This policy permits reporting of data on an aggregated basis, rather than on an individual service or product basis. Such aggregate data does not provide the level of detail necessary for providers to tailor PA requests to specific payer policies or for patients to understand their coverage options. RRC requests that CMS modify its policy to require payers to report these metrics on an individual service-level basis. Only individual service level reporting provides the necessary granular level detail for providers and patients.

While the Proposed Rule requires public reporting of reasons for denial, PA criteria must be supported by clinical evidence. For example, CMS's 2024 Medicare Advantage PA final rule includes numerous safeguards intended to ensure that PA criteria are reasonably supported by clinical literature and expert opinion.[4] The Medicare Advantage PA final rule requires PA criteria to be made public before it goes into effect; be accompanied by references to the clinical

[4] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 88 Fed. Reg. 22120 (April 12, 2023).

literature or other data that support them; and be reviewed and approved by a Utilization Management Committee. RRC strongly urges CMS to include in this final rule parallel requirements to the 2024 Medicare Advantage PA rule – PA criteria of payers must be supported by clinical literature, made public in advance of adoption, and be reviewed by physicians with expertise in the services involved prior to implementation.

Lack of Enforcement

While transparency is an important first step in ensuring payer accountability, it is insufficient by itself to direct payer behavior and discourage bad actors. RRC is extremely concerned that the Proposed Rule does not include a workable enforcement mechanism to ensure that PA time deadlines, reporting requirements, and technology standards are met. Like with the 2024 Final Rule, if a payer fails to comply with these requirements, it is up to the provider to follow up with the payer, appeal the payer's failure to adhere to these requirements, or convey concerns to CMS. Payers have little incentive to take these new requirements seriously if there are no tangible consequences for failure to follow them.

RRC strongly believes that failure to comply with a PA deadline should be constitute an approval of the PA request with guaranteed reimbursement. RRC opposes placing the burden of unfulfilled PA requests on the physician and patient instead of the plan that has failed to respond. We urge CMS to allow providers to treat a failure to respond within the required timeframe as a PA approval, thereby incentivizing payers to comply with PA requests as required by regulation.

Additionally, we urge CMS to develop a voluntary process through which providers and patients can report payer non-compliance with time deadlines, reporting requirements, and technology standards. The portal operated by the Office of the National Coordinator for Health Information Technology to report information blocking practices offers a blueprint for how this process can be structured. A formal avenue to report instances of non-compliance is essential for CMS to monitor and address payer noncompliance with these regulatory requirements.

Request for Information: Step Therapy

RRC is fundamentally opposed to step therapy as a utilization management technique and encourages CMS to eliminate the use of step therapy in Medicare Advantage for Part B drugs. Step therapy adds significant administrative burdens on providers, directly interferes in clinical decision-making, and is not in the best interest of patient care. Research shows substantial variation in step therapy protocols, and many step therapy restrictions are not supported by published clinical literature or practice guidelines. One study evaluating seventeen of the largest U.S. commercial health plans found that 55.6 percent of plans applied step therapy more

stringent than corresponding clinical guidelines.[5] The authors raised serious questions about potentially overly restrictive step therapy protocols, as well as concerns that variability across health plans makes protocols onerous for patients and practitioners alike.

If CMS continues to permit use of step therapy protocols, including via new technological capabilities, RRC strongly urges CMS to ensure that any new automation does not compromise clinical decision-making. While greater automation in the step therapy process could improve efficiency, individualized review is still necessary, particularly for complex clinical cases.

Further, each "step" in step therapy requirements should be subject to the time limitations discussed above. Under the timeframes established in the 2024 Final Rule and this Proposed Rule, while a payer may be required to respond to an initial medication request within specified timeframes, these deadlines do not apply to subsequent requests. After a payer denies a provider's initial request for a specific medication and requires the patient to try another medication first, there are no federal deadlines for subsequent steps for patients to receive a particular drug. This payer loophole causes significant treatment delays for patients and is antithetical to the spirit of CMS requirements to make determinations like these in a timely fashion.

Request for Information: Application to Medicare Fee-For-Service

CMS states in the Proposed Rule that it "intend[s] for the Medicare FFS program to be a market leader on electronic prior authorization and therefore, seek[s] comment throughout this proposed rule on how these proposals could apply to Medicare FFS."[6] Given serious patient and provider concerns with the WISeR model,[7] implementation of additional PA changes in the fee-for-service context are unfounded. Aggressive implementation timeframes, insufficient overview of AI-driven reviews, multiple submission portals, and lack of integration of electronic health record systems have all led to increased administrative burden on providers and questionable denials. These concerns should be thoroughly addressed before CMS considers expanding e-PA in traditional Medicare.

Payer Clawbacks Require CMS Intervention

Not contemplated by this rule is a newly observed payer practice that harms patient access to care and is not in accordance with the goals of this Proposed Rule and the 2024 Final Rule.

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[5] Kelly L. Lenahan, Donald E. Nichols, Rebecca M. Gertler & James D. Chambers, Variation In Use And Content Of Prescription Drug Step Therapy Protocols, Within And Across Health Plans, 40 Health Affs. 1749 (Nov. 2021), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2021.00822.
[6] Proposed Rule at 19898.
[7] WISeR (Wasteful and Inappropriate Service Reduction) Model, CMS (April 30, 2026), https://www.cms.gov/priorities/innovation/innovation-models/wiser.

Providers have reported instances of payers including disclaimers on PA approvals stating that PA approvals do not guarantee payment. Payers are using this tactic to later claw back their previous approvals and deny or recoup payment. This practice is deeply deceptive, places patients at risk, and imposes new administrative burdens on providers to dispute reversals. We urge CMS to instruct payers that affirmations of coverage are final, guarantee payment, and cannot be later retracted by payers.

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RRC appreciates the opportunity to provide feedback on CMS's Proposed Rule to expand its e-PA requirements to drugs across payers. E-PA is a critical step forward in ensuring medically necessary drugs and services are available to patients on a timely basis. We appreciate CMS's consideration of our additional feedback to meet CMS's goal of streamlining PA processes in a manner that reduces patient and provider burden.

Respectfully,

American Academy of Neurology
American Academy of Family Physicians
American Academy of Ophthalmology
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Cardiology
American Gastroenterological Association
American Osteopathic Association
Association for Clinical Oncology
Congress of Neurological Surgeons
Heart Rhythm Society
Medical Group Management Association
North American Spine Society
The Society for Cardiovascular Angiography and Interventions