Alliance of Specialty Medicine

Sound Policy. Quality Care.

June 15, 2026

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Thomas Keane, MD, MBA
National Coordinator for Health IT
Office of the National Coordinator for Health IT
Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

Submitted electronically via www.regulations.gov

RE: 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 (CMS-0062-P)

Dear Administrator Oz and National Coordinator Keane,

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians across 15 specialty and subspecialty societies who are committed to improving access to specialty medical care by advancing sound health policy. On behalf of the undersigned members, we appreciate the opportunity to comment on the aforementioned proposed rule to improve the electronic exchange of health care data and streamline prior authorization processes through enhanced interoperability.

The Alliance greatly appreciates that this rule builds on previous finalized regulations that we generally supported, including the 2024 CMS Interoperability and Prior Authorization final rule ("2024 final rule"), which aimed to improve the electronic exchange of health care data and streamline prior authorization by requiring impacted payers to automate prior authorization processes, accelerate decision timelines, improve data exchange through the adoption of standards, and enhance transparency by requiring payers to provide specific denial reasons and publicly report prior authorization metrics.

As we have expressed numerous times in the past, specialty physicians and their patients are often subject to prior authorizations and other utilization management tactics, which delay patient access to medically necessary care and treatments and create considerable, unnecessary administrative burdens for specialty physicians. Equally concerning, these tactics are a leading cause of physician burnout, forcing many to retire early or leave the practice of medicine.

The Alliance has repeatedly urged CMS to address egregious utilization management practices employed by payers, including prior authorization, which ignore physician clinical expertise and disrupts patient care. Some of the biggest challenges that specialty physicians face are delays in prior

authorization decisions, inconsistent payer policies, and prior authorization for routinely approved items and services. A 2025 AMA survey of physicians[1] further highlighted the ongoing burden of prior authorization on physicians and their patients:

- 98% of physicians surveyed reported care delays due to prior authorization.
- An overwhelming majority (88%) of physicians reported that prior authorization interferes with continuity of care, while three in five (61%) physicians reported that prior authorization at least sometimes destabilizes a patient whose condition was previously stabilized on a specific treatment plan.
- A majority of physicians reported that it is difficult to determine whether a prescription medication (63%) or medical service (62%) requires prior authorization, while more than one in four (27%) physicians reported that the drug prior authorization requirement information provided in their electronic health record (EHR)/e-prescribing system is rarely or never accurate.
- 94% of physicians surveyed reported that prior authorization somewhat or significantly increases physician burnout.
    - On average, practices complete 40 prior authorizations per physician, per week; spend 13 hours each week completing prior authorizations; and 40% of physicians have staff who work exclusively on prior authorization.
- 88% of physicians surveyed reported that prior authorization leads to higher overall utilization.
- More than 1 in 3 (35%) physicians reported that prior authorization criteria are rarely or never evidence-based.
- More than 1 in 4 physicians reported that prior authorization has led to a serious adverse event for a patient in their care.

These challenges are especially acute in the context of Medicare Advantage (MA) plans. A 2022 report issued by the Office of Inspector General (OIG)[2] raised concerns about beneficiary access to medically necessary care, citing widespread and persistent problems related to inappropriate delays and denials of services by MA plans even when requests met Medicare coverage rules and MA billing rules.

To address these issues, we have urged CMS to strengthen oversight of health plan utilization management practices, including data collection of denials, delays and approval rates; require transparency of these data to hold plans accountable; and standardize prior authorization processes to minimize delays in patient care. The Alliance was very pleased to see many of its requests reflected in the 2024 CMS Interoperability and Prior Authorization final rule. However, we requested at the time that HHS also extend these policies to drugs, including outpatient drugs and those administered by a physician, rather than limit them to items and services only. As such, ***the Alliance very much appreciates that CMS and ONC are proposing to extend existing and critical interoperability, timeliness, and transparency requirements to the prior authorization of drugs***. By including drugs in these policies, CMS can help to further reduce patient and provider burden and ensure safe, timely and affordable access to care for patients.

Below, we share our thoughts on more specific proposals in this latest proposed rule.

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[1] American Medical Association (2025). AMA Prior Authorization Physician Survey. Accessed at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

[2] Office of Inspector General. (2022). Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care (publication No. OEI-09-18-00260). Accessed at: https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

Electronic Prior Authorization of Drugs

The 2024 final rule requires impacted payers to implement and maintain a Prior Authorization Application Programming Interface (API) to facilitate electronic prior authorization for non-drug items and services. CMS now proposes to require impacted payers to incorporate coverage and documentation requirements into APIs that rely on FHIR standards to support the electronic prior authorization of drugs covered under a medical benefit beginning October 1, 2027.

CMS is also proposing to require that state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs support electronic prior authorization for drugs covered under a pharmacy benefit, which aligns with existing requirements for Medicare Part D sponsors. Specifically, CMS is proposing to require those impacted payers to support three National Council for Prescription Drug Programs (NCPDP) standards beginning October 1, 2027. The proposed standards allow providers to query formulary information, determine real-time coverage information, and exchange electronic prior authorization requests and decisions for drugs.

CMS' proposals would require that electronic prior authorization be available for all drugs covered by any impacted payer for which they require prior authorization, either through the Prior Authorization API or NCPDP SCRIPT standards. The Agency notes that, should these electronic prior authorization proposals be finalized, impacted payers would need to review the list of covered drugs for which they require prior authorization to determine whether they fit into the scope of the Prior Authorization API ("drugs covered under a medical benefit") or the NCPDP SCRIPT standard ("drugs covered under a pharmacy benefit").

The Alliance strongly supports expanding these requirements to drugs. We believe that aligning the technology and standards for all items, services, and drugs will result in a more streamlined experience for patients and providers, allow for real-time data exchange, and accelerate payer decision-making, all of which are critical to ensure high quality care. However, we are concerned that the proposed framework continues to reinforce the longstanding divide between the medical and pharmacy benefit. Many specialty therapies may be covered under either benefit depending on formulation, site of care, payer policies, or distribution arrangements, forcing patients and providers to navigate separate coverage and documentation requirements for the same medication. This fragmented approach creates unnecessary administrative complexity, delays treatment, and undermines continuity of care for patients with serious chronic, complex diseases.

The Alliance urges CMS and ONC to work toward a more integrated interoperability framework that provides clinicians and patients with a unified view of coverage and utilization management requirements across both benefit structures. This may require new standards development efforts capable of supporting more seamless exchange of coverage and documentation requirements across medical and pharmacy benefit systems. At a minimum, providers and patients should be able to access a consolidated, real-time view of applicable coverage policies and utilization management requirements, including prior authorization and step therapy protocols, as well as patient cost-sharing obligations, for a medication regardless of how the therapy is classified, covered, or administered by a health plan. Such alignment would reduce unnecessary administrative burden, improve continuity of care, minimize patient confusion regarding coverage and financial obligations, and support more timely access to clinically appropriate treatment.

Improving Communications and Decision Timeframes for Prior Authorizations

Proposed Requirement to Include a Specific Reason for Denial in Response to Prior Authorization Requests for All Drugs

In the 2024 final rule, CMS finalized a requirement that, beginning in 2026, impacted payers must provide a specific reason for denial in their response to a provider's prior authorization request for non-drug items and services, regardless of the method used to communicate the prior authorization request or decision. In this rule, CMS proposes the same requirements for denied prior authorizations for all drugs for impacted payers that are not already subject to such a requirement. ***The Alliance very much supports this proposal, as well as CMS' clarification that the content of the response should include a specific reason for denying a prior authorization request for drugs that helps a provider to understand why the request was denied and what actions must be taken to resubmit or appeal the decision.***

Although this rule and the 2024 rule do not directly address how prior authorization decisions are made, such as requirements for clinical decisions or other algorithms, the Alliance reminds CMS that a critical component of transparent decision-making is ensuring that prior authorization decisions are informed by peer-to-peer reviews that are conducted by physicians in the same specialty or subspecialty as the treating physician and based on the most current, evidence-based practice guidelines, consensus statements, or best practices relevant to that specific patient. The Alliance supports the *Reducing Medically Unnecessary Delays in Care Ac*t (H.R. 2433), which aims to ensure that prior authorization decisions in Medicare and Medicare Advantage are made by board-certified physicians in the same specialty as the treating physician and that plans adhere to medical necessity and clinical criteria requirements. We urge CMS to adopt requirements for the payers impacted by this rule that align with these goals.

Prior Authorization Timeframes

In the 2024 final rule, CMS also finalized requirements for MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities to make prior authorization decision requests on non-drug items and services as expeditiously as a patient's health condition requires, but no later than 7 calendar days after receiving a standard request and no later than 72 hours after receiving an expedited request, effective in 2026. In addition to these requirements for non-drug items and services, MA organizations, state Medicaid FFS programs, Medicaid managed care plans, and CHIP managed care entities have existing decision timeframe requirements for prior authorization of certain drugs, including covered outpatient drugs, which are discussed in more detail in the rule.

To ensure prompt notification and align prior authorization decision processes across different CMS programs, CMS proposes in this rule that certain payers be required to provide notice of drug-related prior authorization decisions within the following specific timeframes.

- To align patient protections and create consistent requirements across the Medicaid and CHIP programs, state Medicaid FFS programs, Medicaid managed care plans, and CHIP managed care entities would be required to make prior authorization decisions for all drugs within a timeframe

that aligns with existing decision timeframe requirements for covered outpatient drugs—which is no later than 24 hours after receiving a prior authorization request. For items and services, the timeframe would remain 7 days for standard requests, 72 hours for expedited requests. State CHIP FFS programs would be required to provide notice of a prior authorization decision no later than 24 hours after receiving a prior authorization request for any prescription drugs for which Federal Financial Participation (FFP) is available.

- QHP issuers on the FFEs would be required to provide notice of a prior authorization decision to the requesting provider as expeditiously as the enrollee's health condition requires, but no later than 72 hours after standard prior authorization requests and no later than 24 hours for expedited prior authorization requests for all drugs. For non-drug items and services, CMS proposes to align the timeframes for QHP issuers with its current policy for other impacted payers, which is 7 days for standard requests and 72 hours for expedited requests.

The Alliance appreciates that CMS is proposing more expeditious decision timeframes for drug-related prior authorization decisions. ***However, we strongly urge CMS to adopt even shorter decision timeframes to both drug and non-drug items and services***. As we expressed during rulemaking in 2024, we strongly believe that as payers transition to more standardized and automated electronic prior authorization processes, they will be able to communicate prior authorization decisions in increasingly shorter timeframes, including real-time responses. ***We, therefore, urge CMS to require impacted payers to respond within 48 hours for standard requests and within 24 hours for expedited/urgent requests related to non-drug items and services and within 24 hours for all requests related to drugs. Ideally, we would like to see plans use automated processes to render real-time approvals for routinely approved items, services, drugs, and/or more straightforward prior authorization requests (i.e., where limited information is needed to render a determination) and for plans to render a determination in less than 24 hours for more complex requests (i.e., where more detailed information may be necessary). The ultimate goal should be for payers to respond as often as possible in real-time.***

For many specialty-focused conditions, time can make a significant and sometimes life-altering difference in the patient's outcome. For example, in the case of retinal disease, the longer a patient waits to be treated, the higher they are at risk of losing vision. Similarly, patients with severe autoimmune and inflammatory diseases, including forms of systemic vasculitis, may experience irreversible organ damage, permanent disability, or other serious complications if medically necessary therapies are delayed. In other situations, if a physician could get real-time approval for a procedure or drug, the patient could be treated on the spot rather than having to make arrangements to return for another appointment. This would ensure more timely treatments, save time and resources for patients and their caregivers, and free up clinician time for other patients in need of care. Overall, more real-time response times will result in greater efficiencies across the health system and, most importantly, improve patients' timely access to care and clinical outcomes.

At the same time, ***the Alliance is very concerned that CMS has not proposed any mechanisms to enforce payer compliance with these decision timelines for both drug and non-drug requests***. In the 2024 CMS Interoperability and Prior Authorization final rule and on CMS' Interoperability website,[3] the agency notes that each CMS program oversees compliance under existing program authorities for each type of impacted payer; that oversight and compliance procedures vary among these CMS programs; and that

[3] https://www.cms.gov/priorities/burden-reduction/overview/interoperability/frequently-asked-questions/compliance-enforcement

CMS may choose from an array of possible enforcement actions, based on a payer's status in the program, previous compliance actions, and corrective action plans. CMS also stated in the 2024 rule that "[i]f a payer fails to meet the timeline for approval or other decision, providers should contact the payer to obtain the status of the request and determine if supporting documentation is needed to complete processing of the authorization or if there are other reasons for the delay in a decision."

Without an enforcement mechanism — such as a penalty for non-compliance or requiring that payers automatically provide approval for a request should they fail to meet the decision timeframe — these shortened timeframes will be ineffectual and simply serve as window dressing. It is also unacceptable to put the onus on the provider to check in with the payer on the status of a delayed response. The main goal this rule, as well as the 2024 rule, is to reduce provider burden and minimize unnecessary delays in care. However, if payers are afforded latitude regarding response times, this proposal will do little to change the status quo.

Publicly Reported Prior Authorization Metrics

The 2024 final rule requires that impacted payers annually report prior authorization metrics for non-drug items and services on their public websites. CMS proposes to add requirements for impacted payers to report the numeric counts in addition to percentages for certain existing metrics, as well as for impacted payers to publicly report additional prior authorization metrics on non-drug items and services. These proposals can be found in Table 5. The proposed requirements would begin on the effective date of the final rule.

In addition, CMS proposes to require impacted payers to annually report prior authorization metrics for drugs on their public websites that generally align with the requirements for non-drug items and services. The proposed compliance dates for reporting these new metrics are in 2028 for data from the 2027 reporting period.

Overall, the Alliance supports CMS' proposal to expand the scope and detail of publicly reported prior authorization metrics. These metrics will not only hold payers accountable for their actions, but offer valuable insight into payer practices and patterns and the effectiveness of these policies on prior authorization processes and patient access to care. By relying on more complete information, these metrics will also enable CMS to identify potential ongoing problems related to prior authorization and target areas for improvement.

While the Alliance supports CMS' proposals requiring impacted payers to publicly report prior authorization metrics related to drugs, ***we encourage CMS to require more detailed reporting for therapeutic categories that are frequently subject to intensive utilization management practices, including specialty and chronic disease therapies that often involve prior authorization, step therapy, or other coverage restrictions.*** More granular reporting could help identify patterns of excessive denials, repeated prior authorization requirements, delays associated with step therapy protocols, and other barriers that may disrupt continuity of care and timely access to treatment. These transparency efforts may become increasingly important as utilization management approaches continue to evolve across impacted payers and alternative care delivery and payment models, potentially resulting in greater variation in coverage requirements, prior authorization protocols, and step therapy policies that affect patient access and continuity of care.

Updates to Patient Access, Provider Access, and Payer-to-Payer APIs

In the 2024 CMS Interoperability and Prior Authorization final rule, CMS required impacted payers to make available certain information about prior authorizations for non-drug items and services via a Patient Access API and Provider Access API. CMS also required impacted payers to make available similar information via the Payer-to-Payer API. Additionally, impacted payers must make available via the Payer-to-Payer API both structured and unstructured administrative and clinical documentation submitted by a provider. CMS finalized compliance dates beginning in 2027 for each of these APIs.

In this rule, CMS proposes a new requirement for impacted payers to make detailed information about prior authorization requests and decisions for all drugs available through the Patient Access, Provider Access, and Payer-to-Payer APIs.

For the Patient Access and Provider Access APIs, this would include, as applicable:

- The status of the prior authorization;
- The date the prior authorization was approved or denied;
- The date or circumstance under which the authorization ends;
- The drug or drugs approved (including dosage);
- A specific reason the request was denied (if applicable); and
- Related structured administrative and clinical documentation submitted by a provider.

For the Payer-to-Payer API, the required information would include:

- The status of the prior authorization;
- The date the prior authorization was approved;
- The date or circumstance under which the authorization ends;
- The drug or drugs approved (including dosage); and
- Related structured and unstructured administrative and clinical documentation submitted by a provider, excluding denied prior authorization requests.

Impacted payers would be required to comply with this proposal beginning October 1, 2027. The requirement to make available information about prior authorization for drugs would be subject to the same timeframes established for making available prior authorization information for non-drug items and services—no later than 1 business day after the payer receives a prior authorization request and the payer must update that information no later than 1 business day after any status change. ***The Alliance supports these requirements, including the 1 business day timeframe, since they would help to ensure that patients, providers, and payers have consistent and comprehensive access to prior authorization information, improving transparency and care coordination.***

Nevertheless, ***the Alliance is concerned with the proposal to remove drug formulary information from the Provider Access and Payer-to-Payer APIs.*** Providers routinely rely on formulary, coverage, and utilization management information to support treatment decisions, coordinate care, and facilitate timely patient access to medically necessary therapies, particularly for patients with chronic, complex, or specialty conditions who may transition between payers or receive therapies covered under different benefit structures. Removing formulary information from these APIs could limit future opportunities to advance more coordinated and interoperable exchange of coverage and utilization management information across payers. While fragmentation across medical and pharmacy benefit systems remains a significant challenge today, maintaining formulary data within these interoperability frameworks could support future efforts to streamline provider workflows, reduce unnecessary administrative burden,

improve continuity of care, and promote more seamless access to coverage and utilization management information across impacted payers. Accordingly**, *the Alliance encourages CMS and ONC to retain formulary information within these APIs and continue working with stakeholders to improve the consistency, usability, and interoperability of formulary and utilization management information.***

Under the 2024 final rule, CMS also requires that impacted payers annually report certain Patient Access API usage metrics to CMS. CMS is now proposing that impacted payers also annually report certain Provider Access, Payer-to-Payer, and Prior Authorization APIs usage metrics to CMS. Please refer to the Proposed Metrics Updates document for a full list of the new metrics. CMS proposes to require impacted payers to submit these metrics beginning in 2028 with data from the 2027 reporting period.

In general, the Alliance supports this effort to further emphasize the importance of transparency and to hold payers accountable for complying with these requirements in the absence of penalties. These data will help CMS to better understand whether these APIs are being deployed effectively and efficiently, who is using them, and whether payers are providing required information in a transparent and timely manner.

Requests for Information

Step Therapy

The Alliance strongly opposes restrictive step therapy protocols employed by health insurers, which require patients to first try and fail less costly drugs before covering a physician-prescribed medication. Step therapy jeopardizes the health of patients, as well as the physician-patient relationship, by delaying access to optimal treatments, which can lead to disease progression, adverse side effects, and higher rates of emergency care, hospitalizations, and additional outpatient services. A 2018 article in the Food and Drug Law Journal[4] discusses that such policy has been shown not to save money in the long run due to patient complications. Another article published in 2021,[5] cites numerous studies showing that step therapy policies shift, rather than reduce, cost and can lead to increased long-term costs of less effective medications.

While we outright oppose step therapy policies and would ideally like to see CMS withdraw its 2018 memorandum that allow MA plans to use these protocols, we appreciate CMS' and ONC's efforts to improve step therapy processes through technology and data sharing, including through the Payer-to-Payer API. More effective interoperability across systems has the potential to reduce unnecessary administrative burden, improve continuity of care, and facilitate more seamless transitions for patients receiving ongoing treatment for serious, chronic, and complex conditions. However, meaningful improvement in step therapy processes will be difficult to achieve without more integrated access to coverage, formulary, and utilization management information across both the medical and pharmacy benefit. Importantly, step therapy policies for certain chronic specialty conditions, including autoimmune and inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, lupus, inflammatory bowel disease, Crohn's disease, and ulcerative colitis, increasingly involve therapies that may be covered under either the medical or pharmacy benefit depending on payer policy, formulation, route of administration, site-of-care requirements, or specialty pharmacy distribution arrangements,

[4] https://specialtydocs.org/wp-content/uploads/2019/06/Step-Therapy_-Legal-and-Ethical-Implications-of-a-Cost-Cutting-Measure.pdf

[5] https://www.cambridge.org/core/journals/health-economics-policy-and-law/article/do-patients-benefit-from-legislation-regulating-step-therapy/0A89759AD6ADB88E0BBF1F919D2179C4

making it difficult for providers and patients to navigate applicable coverage requirements and maintain continuity of treatment across fragmented benefit structures.

As discussed above, the Alliance encourages CMS and ONC to continue working with stakeholders to support more seamless interoperability between medical and pharmacy benefit systems so that technology can better facilitate continuity of care, recognition of prior payer determinations, and timely access to clinically appropriate treatment. CMS and ONC should also explore how interoperability tools and data exchange could help evaluate whether therapies identified by plans as "preferred" or subject to "fail first" requirements are meaningfully accessible to patients through in-network providers and existing coverage arrangements, rather than merely available "on paper" – a challenge facing beneficiaries when their physician is unable to acquire "underwater" medications, including lower-cost biosimilar drugs. Finally, while technology may help support administrative functions and access to historical treatment information, the Alliance encourages CMS and ONC to maintain appropriate guardrails around the use of automation in utilization management processes to ensure that clinical judgment and individualized patient needs remain central to treatment decision-making.

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We appreciate the opportunity to provide feedback on the Interoperability Standards and Prior Authorization for Drugs proposed rule. Should you have any questions or would like to meet with the Alliance to discuss these recommendations further, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Otolaryngology – Head and Neck Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Cataract & Refractive Surgery
American Society of Echocardiography
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society
Society of Interventional Radiology