June 15, 2026

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244
Submitted via regulations.gov

RE: CMS-0062-P -- Proposed Rule on Interoperability Standards and Prior Authorization for Drugs

Dear Administrator Oz,

The MAPRx Coalition (MAPRx) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on Interoperability Standards and Prior Authorization for Drugs released on April 10, 2026.

MAPRx is a national coalition of more than 60 beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. The coalition has championed policies in Part D that improve the affordability of medications and beneficiary access to those medications, including provisions of the Inflation Reduction Act (IRA) that establish an out-of-pocket cap in Part D and the Medicare Prescription Payment Plan. We are committed to ensuring that the implementation of these and other elements of the IRA are informed by the experiences and needs of beneficiaries living with chronic diseases and conditions.

The undersigned members of MAPRx support CMS's efforts to modernize prior authorization processes and improve interoperability across the healthcare system. The proposed rule takes important steps to reduce administrative burden for providers and expedite access to medications for patients. However, we are deeply concerned that Medicare Part D beneficiaries have been left behind in critical areas of this reform. While the proposed rule extends new protections and transparency requirements to Medicare Advantage, Medicaid, CHIP, and Marketplace plans, similar requirements for Part D sponsors are either absent or weakened, perpetuating longstanding access barriers for Part D enrollees.

MAPRx urges CMS to finalize policies that:

- Require real denial explanations, not "medical necessity not met"
- Extend public prior authorization reporting to Medicare Part D and require granular, disaggregated plan data
- Let clinical history travel when beneficiaries switch plans, particularly for previously completed step requirements
- Stop forcing providers to fax clinical documentation
- Require decisions in a time frame that matches the clinical urgency, not just the plan's convenience
- Give caregivers a way to access prior authorization status for the beneficiaries they help

1. Require Specific Denial Explanations

The proposed rule requires Medicaid and Marketplace plans to provide a specific reason to providers and beneficiaries when they deny a prior authorization request. With this new requirement, if a plan denies a prior authorization request, the provider will now know the rationale, whether it is specific lab results, step therapy requirement, or documentation of a contraindication. That clarity allows providers to resubmit or adjust the treatment plan based on what the plan will cover.

When a Part D plan denies prior authorization for a medication, beneficiaries and their providers still receive vague explanations like "medical necessity not met" or "does not meet plan criteria." These denials do not tell the provider what documentation is missing, which alternative drug to try first, or what clinical threshold the plan requires. Without that information, providers cannot give their patients clear guidance about next steps, and beneficiaries cannot understand why they were denied or what they need to do differently.

This is not a minor technical detail. It is the difference between a denial that can be resolved quickly and a denial that leads to prescription abandonment or unsafe delays in care. For someone managing diabetes, neurological disorders, heart disease, or cancer, those delays are not administrative inconveniences, they are clinical risks. And when neither the provider nor the beneficiary can get a straight answer about what the plan needs, some beneficiaries simply abandon the prescription rather than continuing to fight a system that will not tell them what it wants.

The problem is compounded by how these notices are written. Even in programs where a specific reason is required, the explanation is typically drafted for plan administrators, not for providers, patients or caregivers. A notice that says "criteria for medical necessity not satisfied under plan guidelines" tells a beneficiary nothing about what to do next. Specificity only helps if it is written in language the provider or beneficiary can use.
Furthermore, the lack of explicit denial reasons directly undermines efficiency. Providing a transparent, actionable reason is the primary mechanism that enables a rapid turnaround; without it, meeting an expedited 24-hour decision standard is structurally impossible because providers are forced to guess, appeal, and resubmit blindly.

MAPRx recommends that CMS:

- Expand the requirement for specific denial reasons to Part D sponsors. Part D sponsors are currently required to provide a reason for denial, but that requirement does not mandate the level of specificity this rule would require of Medicaid and Marketplace plans. When a Part D plan denies prior authorization for a drug, the plan should provide both the requesting provider and the beneficiary with an explanation of what specific coverage criteria were not met, what alternative drug the beneficiary must try, or what additional clinical documentation the plan requires.

- Ensure denial explanations are actionable. A specific denial reason should include enough information for the provider to either resubmit with the correct documentation or understand which therapeutic alternative the plan expects the beneficiary to try first and should give the beneficiary a clear understanding of why their medication was denied and what steps they can take. Generic references to medical necessity or plan criteria are not sufficient. Notices sent directly to beneficiaries must be written in plain language, terms a non-specialist can understand and act on, and must meet CMS language access standards.

2. Extend Public Reporting to Part D and Require Granular, Disaggregated Data

Section II.C.7 explicitly excludes Medicare Part D plans and covered Part D drugs from these public reporting mandates. CMS asserts that because Part D sponsors already submit internal data to the agency, public website reporting would result in duplicative administrative data streams.

MAPRx strongly opposes this exclusion. While Part D sponsors report performance metrics internally to CMS, this information remains entirely shielded from public view. There is no policy justification for withholding this critical information from the beneficiaries, caregivers, and healthcare professionals who must navigate these coverage barriers daily.

Furthermore, simply reporting high-level, aggregate averages is fundamentally insufficient. Aggregate-only reporting actively obscures high denial rates for critical therapies and masks the deployment of prior authorization as a tool for non-medical switching. This ultimately hides the true clinical impact of utilization management barriers on patients.

MAPRx recommends that CMS:

- Extend public reporting requirements to Medicare Part D plans: CMS should require Part D sponsors to publicly report the same standardized metrics being proposed for other impacted payers.

- Integrate prior authorization metrics into consumer tools: Prior authorization performance data should be made available on plan comparison and shopping tools, such as the Medicare Plan Finder, so patients can evaluate coverage barriers before enrollment.

- Require granular, standardized, and disaggregated public reporting: Rather than aggregate contract averages, CMS must require all impacted payers to disaggregate public prior authorization metrics by: (1) therapeutic area or drug category; (2) specific reason for

denial; (3) brand-name versus generic drug status; (4) type of utilization management applied (prior authorization vs. step therapy); (5) average length of delay created by the prior authorization process; (6) rate of treatment abandonment; and (7) whether the patient ultimately received the initially prescribed therapy or a payer-directed alternative.

- Monitor denial rates alongside timeframe compliance: CMS should actively track reported denial rates in tandem with timeframe compliance to ensure that accelerated decision windows do not simply produce faster access denials rather than genuinely improved patient access.

3. Let Clinical History Travel When Beneficiaries Switch Plans

When a Part D beneficiary switches plans, they lose credit for step therapy requirements they have already completed. Even though their provider may document that they tried Drug A and it did not work, the new plan may require them to start over. They may be required to fill Drug A again, wait for it to fail again, and only then get approval for Drug B, the drug their provider already knows they need. Some beneficiaries may even be subject to more than one step before finally getting approval for their clinically appropriate drug.

This reset is a well-documented problem; it is clinically harmful, administratively wasteful, and entirely preventable. The proposed rule establishes a Payer-to-Payer Application Programming Interface (API) specifically designed to transfer clinical information and prior authorization history between plans. When a beneficiary switches from Plan X to Plan Y, Plan Y can retrieve records showing that the beneficiary already completed step therapy, already tried the generic, or already failed first-line treatment. That should mean the beneficiary does not have to start over.

But the rule does not require Part D sponsors to use the Payer-to-Payer API this way. It simply makes the infrastructure available. Unless CMS directs Part D sponsors to accept and apply prior authorization history transmitted through the Payer-to-Payer API, beneficiaries could continue to be required to restart step therapy every January 1st, delaying access to clinically appropriate care. The clinical record that could prevent that harm will sit unused in an interoperable system.

The same clinical history problem also affects beneficiaries who never switch plans. For example, a beneficiary with multiple sclerosis stable on an infused biologic for three years should not have to re-prove medical necessity every January simply because their plan's authorization period expires. The doctor documented the need. The plan approved it. Nothing changed except the date. But the provider still submits new paperwork, the plan still reviews it, and if anything goes wrong in that cycle, the beneficiary faces a treatment gap. This is administrative friction that creates clinical risk for patients whose conditions require uninterrupted therapy.

MAPRx has documented the rapid growth of step therapy in Part D since passage of the IRA. With the implementation of the IRA's out-of-pocket cap shifting greater financial liability to plans, Part D sponsors have significantly escalated the use of restrictive step therapy protocols to manage utilization. Forcing stable patients to repeat this gauntlet every January 1st solely due to an administrative reset creates an unacceptable clinical risk.

MAPRx recommends that CMS:

- Require Part D sponsors to retrieve and apply prior authorization history through the Payer-to-Payer API when a beneficiary switches plans. If a beneficiary completed step therapy or received prior authorization approval in their prior plan, the new plan should honor that clinical record unless there is a documented change in the beneficiary's condition or treatment.

- Establish clear standards for when a plan may disregard prior authorization history from a previous plan. Plans should not be permitted to restart step therapy simply because the beneficiary changed coverage.

- Include prior authorization continuity as a reported metric. CMS should track how often Part D sponsors retrieve and apply prior authorization history when beneficiaries switch plans and publicly report those rates to identify plans that are forcing unnecessary step therapy restarts.

- In response to CMS's Request for Information on step therapy, require plans to retrieve and apply prior treatment history through the Payer-to-Payer API and EHR connections when evaluating step therapy, using the same infrastructure this proposed rule is already building.

4. Stop Requiring Providers to Fax Clinical Documentation

The proposed rule establishes modern digital pathways for providers to submit prior authorization requests for medical drugs through Fast Healthcare Interoperability Resources (FHIR)-based APIs. These APIs allow clinical documentation such as lab results, imaging reports, and physician notes to flow directly from a provider's electronic health record to the payer's system. That infrastructure eliminates the need for faxing, scanning, or manually uploading documents to separate portals. It is a meaningful step forward for reducing provider burden and expediting coverage decisions.

Part D is different. Part D sponsors are already required under 42 CFR 423.160 to use the NCPDP SCRIPT standard for electronic prior authorization of covered Part D drugs, and that electronic pathway handles the transactional elements of a PA request well. But the NCPDP SCRIPT standard runs through pharmacy billing systems that were designed for transactional data such as drug name, dosage and prescriber ID, not for transmitting clinical documentation.

Changes could be made to solve this problem. The same architecture—utilizing FHIR-based APIs to transmit clinical documentation while NCPDP systems handle the pharmacy transaction—should work for Part D drugs. Providers should be able to submit prior authorization requests for Part D drugs through their EHR, with clinical documentation flowing through a FHIR-based pathway that connects to the pharmacy billing system.

MAPRx recommends that CMS:

- Establish interoperability requirements that allow clinical documentation to flow from provider EHRs to Part D sponsors through FHIR-based APIs, even when the prior authorization transaction itself uses the NCPDP SCRIPT standard. Providers should not be required to use separate systems for clinical data and pharmacy transactions.

- Work with health IT vendors, pharmacy system developers, and PBMs to build bridges between FHIR-based clinical data exchange and NCPDP-based pharmacy transactions.

- Set a compliance timeline that aligns with the implementation dates for other interoperability requirements in the rule. Providers should not be left faxing documentation for Part D drugs while they use modern digital pathways for everything else.

5. Establish Clinical Decision Time Frames for Part D

The proposed rule asks whether a 24-hour decision standard should apply to prior authorization requests for Marketplace plans. Part D sponsors are not subject to equivalent time frame requirements. There is no clinical reason that should be the case. A beneficiary waiting on approval for a chemotherapy drug or a biologic faces the same urgency regardless of which program covers it. And as Section 1 establishes, clear denial reasons are the prerequisite for any time frame to mean anything in practice; without them, providers are forced to guess and resubmit.

MAPRx recommends that CMS:

- Extend public reporting and oversight of decision time frame compliance to Part D. Part D sponsors are already subject to existing timeframe requirements of 72 hours for standard requests and 24 hours for expedited requests under 42 CFR 423.568 and 423.572. However, extension usage and incomplete-submission findings are not publicly reported, making those requirements effectively unenforceable in practice. CMS should require the same public reporting of timeframe compliance and extension usage for Part D sponsors as it is proposing for other impacted payers.
- Require Part D sponsors to report extension usage and incomplete-submission findings publicly so CMS and beneficiaries can see whether those pathways are being used to reset the clock and avoid timely decisions.

6. Support Caregiver Access to Prior Authorization Information

Prior authorization is rarely navigated by the beneficiary alone. For many beneficiaries, a family member, spouse, or caregiver is the one making phone calls, tracking appeal deadlines, and trying to find out where a request stands.

CMS is building an interoperability framework that will make prior authorization information available through APIs to providers and plans. It should also work for authorized caregivers. Right now, a caregiver trying to check the status of a prior authorization request or understand why a drug was denied has no electronic pathway to that information. That gap undermines the practical value of the whole framework for the patients it is supposed to help.

MAPRx recommends that CMS:

- Require that prior authorization status and decision information be accessible to authorized caregivers and personal representatives through the Patient Access API, consistent with HIPAA authorization requirements. CMS should issue clear guidance on how plans must support caregiver access and extend this requirement to Part D sponsors. The beneficiaries most likely to depend on a caregiver are also among those most heavily impacted by Part D prior authorization. They should not be last in line for these protections.

Conclusion

MAPRx strongly supports CMS's efforts to modernize prior authorization and improve interoperability. The proposed rule makes meaningful progress for Medicare Advantage, Medicaid, CHIP, and Marketplace beneficiaries. But Part D beneficiaries should not be left behind. The infrastructure CMS is building can solve longstanding problems in Part D if CMS applies it consistently.

Thank you for your consideration of these comments from the undersigned members of our coalition. MAPRx welcomes continued opportunities to work with CMS to strengthen prior authorization processes and ensure that Part D beneficiaries have timely access to the medications they need.

For questions related to MAPRx or these comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or bduffy@nvgllc.com.

Sincerely,
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American Parkinson Disease Association
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Derma Care Access Network
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