June 15, 2026

Submitted via http://www.regulations.gov

Administrator Mehmet Oz
Deputy Administrator Daniel Brillman
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0062-P

Re: CMS Interoperability Standards and Prior Authorization for Drugs Proposed Rule (CMS-0062-P)

Dear Administrator Oz,

On behalf of the Medicaid Health Plans of America (MHPA), we appreciate the opportunity to comment on the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (CMS-0062-P). MHPA and its member Medicaid health plans are grateful for the opportunity to support CMS's efforts to improve the prior authorization process for patients and to further its broader initiative to promote standards for interoperability and health information exchange.

MHPA is the only national trade association with a sole focus on Medicaid, representing more than 160 Medicaid managed care organizations (MCOs) serving nearly 47 million Medicaid enrollees in 40 states, the District of Columbia and Puerto Rico. MHPA's members include both for-profit and non-profit, national, regional, as well as single-state health plans that compete in the Medicaid market. Nearly three-quarters of all Medicaid enrollees receive health care through MCOs, and MHPA provides research and advocacy services that support policy solutions to enhance the delivery and coordination of comprehensive, cost- effective, and quality health care for Medicaid enrollees.

MHPA shares CMS's commitment to improving transparency in health care and expanding patient access to health information, including prior authorization requests and decisions. MHPA has previously expressed support for data standardization among states and utilizing modern application programming interface (API) architecture to reduce tech debt for individuals and organizations who interface with State Medicaid systems[1].

While we support these goals, we note that complex health information technology (IT) system changes require time for system integration, testing, staff training, vendor coordination, and member notification. A compressed timeline increases the risk of implementation failures when systems do not have sufficient time to be adequately tested. This potentially disrupts patient care, drives up administrative costs, and erodes trust in the very systems the interoperability rules seek to improve. While we support CMS and the Office

[1] https://medicaidplans.org/wp-content/uploads/2024/08/MHPA-Technology-Educa4on-and-Ac4on-Workgroup.pdf

of the National Coordinator for Health Information Technology's (ONC) commitment to expanding patient access to health information and support the goals of these initiatives, we urge CMS to allow for sufficient lead time to support a smooth and successful implementation.

Our specific feedback on this proposed rule is as follows:

Required Standards for FHIR APIs and Implementation Guide Requirements

We are generally supportive of CMS's proposal to update the required FHIR-based standards and implementation guides (IGs) in furtherance of API implementation, including the proposal to move the Da Vinci CRD, DTR, and PAS IGs from strongly recommended to required. However, we recommend CMS provide sufficient time for vendors, payers, and providers to gain real-world experience, identify issues, and stabilize implementations before these standards are codified in regulation. This would also allow Health Level 7 (HL7) to address known gaps before finalization. We would also encourage that new standards be backwards compatible to ease system transitions and reduce implementation burden.

We note that HL7 is recommending FHIR R6 as the next formal version for U.S. adoption and encourage CMS to account for its anticipated publication before formally adopting standards under HIPAA's Administrative Simplification provisions. The 2024 CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) and associated HIPAA enforcement discretion allow for sufficient time and incentive for the adoption of the Burden Reduction APIs before they are formalized as HIPAA transaction standards. We believe allowing that process to continue will lead to a stronger and more durable final standard. We also note that pending legislation related to HIPAA standards should be closely monitored and aligned with any final rule requirements. The cautionary experience of the X12 278, which was finalized before the industry could meaningfully test and refine it in practice, underscores the importance of allowing sufficient time before formalizing new standards under HIPAA.

Modifications to HIPAA Standards Related to Prior Authorization

We support CMS's proposal to adopt the HL7 Fast Healthcare Interoperability Resources (FHIR) standard and certain IGs for prior authorization transactions. We also support adoption of the CDex IG, Version 2.1.0 - STU 2.1 as the standard for attachments accompanying prior authorization transactions. For the accompanying timeframe, we support the 24-month timeline from the effective date of the final rule.

Extending Electronic Prior Authorization Requirements to Drugs: Implementation Timeline for Updates to Patient Access, Provider Access and Payer-to-Payer APIs

While CMS proposes a compliance deadline of October 1, 2027 for most provisions of this proposed rule, including the expansion of prior authorization (PA) APIs to incorporate drugs, we believe this timeline is insufficient for successful implementation. As such, we recommend that CMS delay the compliance deadline of these provisions to January 1, 2029.

Medicaid enrollees are already navigating significant program changes taking effect on January 1, 2027, including community engagement requirements, more frequent redeterminations, and modified retroactive coverage periods. Each of these changes require notice and outreach to Medicaid enrollees. The provisions in this proposed rule would layer additional programmatic changes increasing the risk of confusion among enrollees and providers.

Further, incorporating drugs into PA APIs is highly complex to operationalize due to nuances that are specific to drugs, such as dosage considerations and step therapy. Medicaid MCOs are already focused on building out PA API capability for non-drug items and services by January 1, 2027. Adding drugs introduces a significant additional layer of administrative burden including updating API requirements to add drugs to the Patient Access APIs, removing formulary information from the Provider and Payer-to-Payer APIs, aligning denial or discontinuation policies for the Provider Directory API, and adding and updating relevant IGs. Moreover, a fourth quarter implementation deadline compounds these challenges further, as impacted payers would have minimal time to monitor implementation before needing to update formulary and PA requirements for the new plan year beginning on January 1, 2028.

To align with the implementation of these prior policy changes and to minimize burden while ensuring that APIs for non-drug items and services are working as intended, we recommend that CMS allow for a two-year phased-in period for implementation with an effective date of January 1, 2029.

Prior Authorization Requirements for Drugs Covered Under Medical & Pharmacy Benefits

We appreciate CMS providing flexibility for health plans to use their internal categorization to determine whether a drug is categorized under the medical or the pharmacy benefit. To provide further clarity, we encourage CMS to provide some examples or additional guidance on this distinction to help support consistent application across plans, particularly when determining which items are subject to prior authorization timelines, API requirements, and reporting obligations. For example, CMS could clarify whether all pharmacy items and services should be treated as drugs (e.g., should DME obtained using the pharmacy benefit be treated as a drug when applying the prior authorization timelines and implementing the prior authorization API). CMS could also provide guidance on how health plans should treat physician-administered drugs (buy-and-bill), medical equipment and supplies with drug components used outside a clinical setting, and combination products tied to drugs, to ensure consistent compliance with timeline, API, and reporting requirements.

Denial Reason Inclusion for Prior Authorizations of Drugs

MHPA supports including a denial reason and believes the October 1, 2027 deadline for including a reason for a denial of prior authorization for drugs is generally feasible. Payers should be permitted to provide contextual narrative alongside reported metrics, including identification of the top reasons for prior authorization denials, to ensure public data is accurate, complete, and not subject to misinterpretation. Without additional context there is a risk of misinterpreting data and potentially misleading cross-payer comparisons. Should CMS move forward with this approach, we recommend CMS provide additional time (e.g., January 1, 2029) for implementation.

Timeframe for Including Prior Authorization Information in the Patient Access, Provider Access, and Payer-to-Payer APIs

We are generally supportive of the proposal to retain prior authorization information for at least 1 year after the last status change.

Timeframe for Prior Authorization Decisions for Non-Covered Outpatient Drugs

While covered outpatient drugs are subject to an existing statutory 24-hour prior authorization decision requirement, CMS should not apply the 24-hour standard to non-covered outpatient drugs. Drug prior authorizations are inherently complex to operationalize, and the short turnaround time does not provide sufficient opportunity for payers to request and obtain additional clinical information that is frequently needed for determinations related to non-covered outpatient drugs. For example, a compounded drug does not meet the statutory definition of a covered outpatient drug. These drugs often require additional clinical review and documentation for medical necessity determinations and present challenges for health plan integration of that drug's information into the API within a 24-hour window. Additional challenges include health plan dependencies on pharmacy benefit managers (PBMs), vendors, and pharmacy systems to obtain and evaluate clinical information. We therefore recommend CMS refrain from applying the 24-hour timeframe to non-covered outpatient drugs and instead apply the standard 7-day timeframe for non-urgent prior authorization requests and 72-hours for expedited requests, consistent with the timeframes established for non-drug items and services.

Additionally, consistent with the 2024 CMS Interoperability final rule, we urge CMS to confirm that the timeframe begins when the payer has access to the data, control over the data, and authority to make the data available through the API.

Removing Drug Formulary Information from Provider Access and Payer-to-Payer APIs

We support CMS's proposal to remove drug formulary information from the Provider Access and Payer-to-Payer APIs. Formulary data is dynamic and subject to frequent updates, and its inclusion in these APIs risks making outdated or inaccurate information available to

providers and other payers, which could result in inappropriate prescribing or coverage decisions. Formulary information is more appropriately accessed through dedicated formulary tools and resources, such as the Patient Access API and plan formulary look-up tools, where it can be maintained and updated in real time.

Alignment of Denial and Discontinuation of Access Policies Across APIs

We support CMS's proposal to align Provider Directory API policies with the denial and discontinuation policies that apply to the other APIs. Consistent policies across APIs will reduce operational complexity, simplify compliance, and ensure a more uniform experience for providers and other users accessing plan data.

Prior Authorization Metrics- Public Reporting Data Requirements and Timeframe

For the proposed publicly reported metrics on prior authorization for drugs, including the six new metrics, we recommend that all the metrics to be reported include only percentages and not numeric counts. We believe that percentages provide the most useful context for consumers compared to raw numbers. For example, a partial denial encompasses both an approval and denial making it difficult to accurately categorize for reporting purposes and the resulting metrics would not yield meaningful data for CMS or stakeholders.

Additionally, we recommend maintaining the current public reporting requirement deadline for each calendar year (CY) of March 31st. Reporting on a calendar year basis allows health plans sufficient time to collect, validate, and reconcile data across systems before submission to help ensure the accuracy and completeness of reported metrics. This due diligence is particularly important for integrated health plans and plans operating across multiple lines of business. A March 31st deadline following the close of the prior calendar year provides a reasonable and workable window to complete this process, and we urge CMS to preserve this approach rather than introduce reporting structures that would compress timelines or require health plans to report before data can be fully validated. Given the complexities of the IT build-outs to support these reporting requirements, we recommend the reporting requirement to go into effect in CY 2029.

Provider Access, Payer-to-Payer, and Prior Authorization API Usage Metrics - Requirements

We appreciate CMS's efforts to establish usage metrics that promote transparency and accountability across APIs, but have several concerns regarding feasibility, clarity, and operational burden.

MHPA has concerns about the scope and structure of the Payer-to-Payer API. There are unresolved operational questions about PA intake routing and how it affects reporting, including whether PA intake will route through existing channels or a separate endpoint. More broadly, routine payer-to-payer sharing outside of member transitions lacks a clear use case and may introduce unnecessary risk. Such sharing also raises HIPAA concerns around

the "minimum necessary" standard, potential anti-trust issues if PA criteria are shared across payers, and provider confusion given that clinical information from one payer may not be appropriate under another's policies. We recommend CMS limit payer-to-payer exchange to active transitions of care, require explicit member authorization prior to sharing, and restrict shared data to the minimum necessary to support continuity of care. We also recommend that CMS require explicit approval from Medicaid enrollees prior to sharing prior authorization information.

Regarding the Provider Access API, we question whether separately reporting individual versus group providers is operationally feasible at this time. It remains unclear how providers will connect to these APIs and how existing workflows and vendor tools will interface with the API infrastructure. While we share certain information with providers through letters and vendor-based tools, how those touchpoints would map to API-level reporting is not yet defined. We recommend CMS refrain from finalizing separate individual and group reporting requirements until there is greater clarity on API connectivity.

Provider Access, Payer-to-Payer, and Prior Authorization API Usage Metrics – Timeframe

We urge CMS to adopt a uniform March 31st deadline across all lines of business, as the current variation creates confusion and unnecessary operational burden. If this rule is finalized late in the year, payers will have insufficient time to meet a March 31, 2027 deadline. As such, we recommend instead requiring prior authorization metric reporting to begin with CY 2028 reporting using 2027 data to be reported by March 31, 2029.

In addition, we request clarification on the metric measuring "the percent of patients who have opted in to the payer-to-payer data exchange." Specifically, we seek clarity whether this captures patients who have requested data transmission from a prior payer or those whose data has actually been sent.

API Endpoint Reporting

We recommend that CMS allow payers to report API endpoint information directly to CMS rather than requiring use of the National Directory of Healthcare Providers and Services (NDH) Implementation Guide at this time. Significant open questions remain regarding the NDH IG, including the reporting requirements for health plans with multiple brand names. We believe direct reporting to CMS would reduce operational burden and provide greater clarity for impacted payers while those questions are resolved. We also respectfully request that CMS clarify its authority to build or mandate participation in a commercial endpoint directory, as this remains an open question that should be addressed before any related requirements are finalized.

Requests for Information

RFI 1: Streamlining Step Therapy Processes Through Technology and Data Sharing

We appreciate CMS's interest in leveraging interoperability to streamline step therapy and other utilization management processes. We note that many health plans already utilize advanced tools, including automated adjudication logic and historical claims lookback, to efficiently evaluate step therapy requirements. Additionally, existing transition of care processes, including grandfathering and override mechanisms, support continuity for members on established therapies. We also note that step therapy criteria vary across payers based on differing clinical policies and formulary strategies, and automatic acceptance of another payer's step therapy determinations would not account for those differences.

We acknowledge that enhanced access to historical claims data could be beneficial for enrollees new to a health plan, where prior therapy history is not readily available, and could help reduce redundant step therapy requirements in those cases. We recommend that CMS support the targeted use of historical data to inform step therapy decisions, particularly for new enrollees, while preserving payer flexibility to apply plan-specific clinical criteria. We would caution against mandates that require automatic acceptance of step therapy determinations made by other payers.

RFI 2: Strengthening Health Care Resiliency (Cybersecurity)

We support CMS's efforts to explore strategies to strengthen cybersecurity resiliency across the health care sector. Information sharing between private entities and government agencies is one of the most effective tools for helping organizations detect and proactively respond to cyber threats. While we recognize this falls outside CMS's direct authority, we encourage CMS to support long-term reauthorization of the Cybersecurity and Infrastructure Security Agency (CISA), as lapses in legal coverage can create uncertainty for entities sharing information about active cyber threats. We also encourage CMS to work with other agencies to establish non-disclosure agreements that reduce duplicative reporting burdens on the private sector.

With respect to challenges facing smaller and rural providers, we note that the Health Sector Coordinating Council (HSCC) and its Cyber Working Groups have developed valuable publications specifically designed to help under-resourced entities improve their cybersecurity practices. We encourage CMS, alongside CISA, HHS, and other agencies, to actively amplify and promote this work rather than create duplicative or burdensome new requirements.

RFI 3: Improving Implementation of Payer API Technology

We appreciate CMS's focus on improving the implementation of payer API technology. In our experience, the most significant challenge in API testing is the availability of adequate test data. We strongly encourage CMS and ONC to support the development of an industry-wide, standardized set of test data that stakeholders could load into their systems for testing

purposes as the single most impactful step toward improving implementation outcomes across the industry.

We also recommend that CMS and ONC support the establishment of a common testing tool and sandbox environment, such as Inferno or the CDS Sandbox, that would simplify the process for payers to develop, test, and deliver API enhancements and support future upgrades. Because these APIs are implemented in alignment with standard implementation guides, a shared testing environment would promote consistency, reduce duplicative development efforts, and ultimately accelerate adoption.

Once again, thank you for the opportunity to provide comment on the Interoperability Standards and Prior Authorization for Drugs proposed rule. We appreciate the opportunity to share our perspective on addressing these challenges and look forward to continuing to work with CMS to make a meaningful difference in the lives of Medicaid enrollees.

Please feel free to reach out to me directly at sattanasio@mhpa.org with any questions or should you need any additional information.

Sincerely,

/s/

Shannon Attanasio
Senior Vice President, Government Relations, Policy and Advocacy