June 15, 2026

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

RE: CMS-0062-P: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs

Dear Administrator Oz:

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule, *Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs*.

AMIA is the professional home for more than 6,000 informatics professionals, representing frontline clinicians, researchers, public health experts, data scientists, health information technology leaders, and policy experts who bring meaning to data, manage information, and generate new knowledge across the health and healthcare enterprise.

AMIA commends CMS for continuing to address the workflow burden, care delays, and access challenges associated with prior authorization. CMS-0062-P represents an important opportunity to modernize prior authorization for drugs through FHIR-based standards, structured data exchange, payer accountability, and interoperable electronic processes. AMIA supports these goals but urges CMS to ensure that electronic prior authorization (ePA) reduces administrative burden rather than digitizing existing inefficiencies. To be successful, ePA must support clinical decision-making at the point of care, enable timely two-way communication between providers and payers, provide explicit, precise, substantiated, clinically meaningful, and machine-readable denial reasons, and reduce unnecessary documentation and payer-specific variation.

AMIA offers the following comments and recommendations.

I. CMS should provide a clear implementation roadmap and align CMS-0062-P with existing prior authorization, administrative simplification, and ONC requirements.

AMIA previously urged CMS to provide an implementation timeline and roadmap for major prior authorization reforms, given the broad administrative, infrastructure, and technical changes required for successful implementation. AMIA reiterates that recommendation here.

CMS-0062-P builds on existing CMS interoperability and prior authorization requirements while also proposing changes to HIPAA Administrative Simplification standards. This creates a complex implementation environment for payers, providers, electronic health record (EHR) developers, pharmacies, pharmacy benefit managers, clearinghouses, and other health IT stakeholders. Without a clear roadmap, stakeholders may struggle to understand how CMS-0062-P interacts with

CMS-0057-F, HIPAA transaction standards, ONC certification policies, and payer-specific implementation timelines.

AMIA recommends that CMS publish a detailed implementation roadmap that clearly identifies the sequence of technical and operational milestones, the responsibilities of impacted payers and other stakeholders, expectations for testing and conformance, timelines for subregulatory guidance, and opportunities for pilot testing and real-world validation. CMS should also clearly describe how CMS-0062-P aligns, overlaps, or conflicts with existing prior authorization and administrative simplification requirements. In prior comments, AMIA raised concern that stakeholders faced challenges understanding the relationship between administrative simplification proposals and prior authorization interoperability proposals. CMS should avoid ambiguity that forces providers, vendors, and payers to interpret overlapping federal requirements without clear guidance.

AMIA is also concerned that the October 1, 2027 compliance date for drug prior authorization requirements and FHIR-based administrative simplification changes may be challenging, especially because these requirements will follow closely after major CMS interoperability API deadlines. AMIA recommends that CMS adopt a phased and operationally realistic implementation approach, align deadlines with ONC certification updates and vendor release cycles, offer good-faith implementation flexibility where appropriate, and provide technical assistance for smaller, rural, safety-net, and under-resourced organizations.

CMS should ensure that providers are not held responsible for failures caused by payer API unavailability, poor technical documentation, vendor delays, pharmacy benefit manager (PBM) readiness gaps, or inconsistent payer implementation. Primary accountability for payer API readiness, documentation, transparency, and reporting should rest with impacted payers, and CMS should ensure that the costs of creating and maintaining payer APIs are not shifted to providers/offices/health systems used to create new barriers to participation.

II. ePA for drugs should be integrated into point-of-care workflows and support two-way payer-provider communication.

AMIA supports CMS's proposal to expand ePA requirements to include drugs covered under both medical and pharmacy benefits. This expansion has the potential to improve medication access, reduce manual processing, and support greater interoperability across payer, provider, pharmacy, and patient-facing systems.

To achieve these goals, CMS should ensure that drug ePA workflows are integrated directly into EHR prescribing workflows, e-prescribing systems, pharmacy systems, and practice management tools. Clinicians should not be required to leave the EHR, navigate payer-specific portals, or duplicate documentation across multiple systems. Where appropriate, these workflows should support cert clinical staff and delegates who help complete prior authorization tasks on behalf of ordering clinicians.

AMIA recommends that CMS require ePA systems to support decisions at the point of care. Clinicians should be able to determine whether prior authorization is required, understand applicable coverage criteria, submit necessary documentation, receive a decision, and respond to denials or requests for additional information within their normal clinical workflow. CMS should

encourage a standardized criteria-based workflow that allows providers or their delegates to indicate whether required coverage criteria are met, similar to existing prescription renewal authorization workflows.

CMS should also clarify how denial exchanges will function inside EHR-integrated workflows. FHIR-based prior authorization APIs should support two-way communication, including payer questions, provider responses, requests for additional information, escalation pathways, appeals, and reconsideration workflows. Providers should also have access to appropriate human clinical expertise when needed to resolve authorization questions, clarify clinical criteria, or address contested denials. Without this functionality, ePA may still require clinicians and staff to rely on disconnected manual follow-up processes, limiting the burden-reduction benefits of the rule.

AMIA also supports shorter and standardized prior authorization decision timelines to improve patient access and reduce care delays. However, CMS should ensure that shorter timelines do not incentivize inappropriate automated denials, superficial reviews, or increased requests for additional documentation. Faster timelines should improve access to care, not shift burden back to providers and patients.

III. CMS should require contemporary, FHIR-based standards while minimizing optionality, payer variation, and duplicative workflows.

AMIA strongly supports CMS's efforts to require contemporary, FHIR-based standards, including HL7 FHIR-based Prior Authorization APIs, updated HL7 Da Vinci implementation guides, and FHIR-based approaches under HIPAA Administrative Simplification. As AMIA has stated in prior comments, FHIR is critical to advancing automation and reducing burden when implemented consistently and aligned with real-world clinical workflows.

However, standards adoption alone will not guarantee meaningful interoperability. Excessive optionality, payer-specific implementation choices, inconsistent vocabularies, and uneven conformance testing can produce fragmented workflows that increase rather than reduce burden. AMIA recommends that CMS minimize optionality across payer implementations, require strong conformance testing before enforcement, and establish standard processes, questions, data elements, and vocabularies for prior authorization. CMS should clearly distinguish required implementation elements from optional capabilities so that payers do not implement the same standards in incompatible ways.

AMIA further recommends that CMS work closely with ONC to ensure that payer API requirements, EHR certification criteria, implementation guides, and data standards are harmonized. Providers should not be expected to bridge gaps between payer requirements and certified health IT capabilities. Alignment between CMS and ONC is especially important for drug prior authorization, where successful implementation will depend on EHRs, e-prescribing systems, pharmacy systems, payer systems, and PBM infrastructure working together.

AMIA supports CMS's proposal to adopt FHIR standards under HIPAA Administrative Simplification for eligibility and prior authorization transactions. AMIA has previously supported national electronic healthcare claims and prior authorization attachment standards when those standards are current, practical, and offer improvement over other standards in use. CMS should avoid requiring outdated standards or duplicative translation workflows that could move the industry

backward, impose undue administrative burden, or require stakeholders to invest in systems that may soon need to be replaced.

CMS should accelerate the transition toward modern FHIR-based workflows while maintaining appropriate backward compatibility during implementation. CMS should also clarify how FHIR-based standards will interact with existing X12 requirements, avoid requiring FHIR-to-X12 translation when a FHIR-native approach would better advance automation and burden reduction, and clarify whether any electronic signature or attachment requirements apply to clinical documentation submitted in support of ePA.

AMIA strongly supports moving prior authorization away from a host of manual entry formats, including fax-based, PDF-based, and other unstructured data formats toward structured, machine-readable authorization processes and data exchange. CMS should prioritize structured clinical data exchange wherever feasible and limit reliance on static attachments. When attachments are necessary, CMS should encourage structured or semi-structured exchange that supports automated review, auditability, and reuse of existing clinical data. Prior authorization reform should streamline prior authorization with data, not increase the volume of documentation requested from clinicians.

IV. CMS should strengthen transparency of ePA decisions, API reporting, and patient-facing data exchange processes.

AMIA supports CMS's proposal requiring payers to expose prior authorization data through interoperable APIs, including authorization status, denial reasons, approval dates, expiration dates, and supporting documentation. These data should be standardized, machine-readable, and accessible to both clinicians and patients.

AMIA previously supported CMS's proposal to make prior authorization information available to patients through the Patient Access API and emphasized that payers must state the complete reasons for any denial of a prior authorization request. AMIA reiterates that recommendation here. Patients should be able to access substantially the same authorization status, decision information, and next steps available to clinicians, presented in clear and understandable language.

CMS should require denial explanations to be explicit, precise, substantiated, clinically meaningful, and machine-readable. Denial responses should identify the specific coverage criterion not met, the missing documentation if applicable, whether step therapy or formulary requirements apply, and the steps needed for appeal or reconsideration. Standardized denial reason terminology would also support appeals automation, analytics, quality improvement, and oversight of payer behavior.

AMIA also recommends that CMS consider how clinical data used in prior authorization are represented. Allergies, side effects, diagnoses on the problem list, visit-specific diagnoses, medication history, and other relevant clinical data should be represented using standardized vocabularies and consistent data structures. This will improve payer-provider exchange and reduce unnecessary requests for additional information.

AMIA supports CMS's proposed public reporting requirements for prior authorization metrics, including denials, approvals, and turnaround times. Transparency is essential for accountability and will allow CMS, researchers, clinicians, and patients to better understand how prior authorization functions across payers. AMIA recommends that CMS expand public reporting to include appeal rates, appeal overturn rates, requests for additional information, number of times an API transmission failed or was rejected, patient delays in receiving prescriptions, provider and patient burden metrics, abandonment or withdrawal rates, and disparities in approval, denial, and turnaround outcomes.

AMIA also supports CMS's proposal to require reporting of API usage metrics for Provider Access, Payer-to-Payer, and Prior Authorization APIs. CMS should not evaluate success based solely on whether an API exists or receives traffic. CMS should assess whether APIs are usable, reliable, integrated into workflows, and successful in reducing burden. Relevant metrics should include successful transaction rates, failed transaction rates, error types, API downtime, response times, volume of manual fallback workflows, provider experience, and whether API outputs are incorporated into EHR or pharmacy workflows.

AMIA supports CMS's proposal requiring payers to report API endpoints and technical documentation. CMS should establish formal API testing, validation, and certification processes aligned with ONC interoperability governance frameworks. Payers should be required to maintain accurate documentation, update endpoint changes promptly, and demonstrate that their APIs conform to required implementation specifications.

Where patient permission, opt-in, or opt-out processes apply, CMS should require clear, uniform, and accessible language explaining what information will be exchanged, how it will be used, what the consequences of opting out may be, and how patients may change their preferences. Patients should be allowed to change their preferences after enrollment, and payers should provide periodic reminders about available options. Clear and uniform processes are particularly important for patients who change payers frequently, have complex medication needs, or rely on continuity of prior authorization information to avoid disruptions in care.

V. CMS should establish guardrails for automated and AI-enabled prior authorization and continue working toward reducing unnecessary prior authorization.

AMIA urges CMS to address the potential use of AI-enabled and automated systems in prior authorization. As payers face shorter decision timelines and increased transaction volume, they may increasingly rely on automation to support utilization management. When payers use algorithms or automated decision-making tools, CMS should require and receive clear documentation of the criteria, logic, and data used to support authorization decisions and should be sent to providers and patients that is language understood.

CMS should establish guardrails for AI-enabled prior authorization tools, including transparency requirements, human oversight, auditability, explainability, bias monitoring, accountability for inappropriate denials, and evaluation of inequitable impacts or unintended disparities. Automated systems should be used to streamline appropriate approvals and reduce burden, not to obscure decision logic, increase inappropriate denials, or undermine clinician and patient trust.

CMS should monitor whether accelerated timelines lead to increased automated denials, increased requests for additional information, or disparities in access to medications. AMIA also urges CMS to address the underlying prior authorization process itself. A standardized electronic process is valuable, but it should not preserve unnecessary, duplicative, or clinically low-value authorization requirements. CMS should use this rulemaking and future policymaking to streamline prior authorization with data, reduce payer-specific variation, and support clinical decision-making at the point of care.

Conclusion

AMIA supports CMS's efforts to modernize prior authorization through interoperable, standards-based, and machine-readable processes. CMS-0062-P is an important step toward reducing administrative burden, improving transparency, and supporting timely access to medications. To fully realize these goals, CMS should ensure that ePA supports point-of-care decision-making, two-way payer-provider communication, explicit and substantiated machine-readable denial reasons, strong conformance testing, and realistic implementation timelines.

AMIA continues to believe that the long-term goal should be to reduce and ultimately eliminate prior authorization requirements where they are unnecessary, duplicative, or unsupported by evidence. Until that goal is achieved, CMS should ensure that prior authorization is as streamlined, transparent, interoperable, and minimally burdensome as possible.

AMIA appreciates CMS's leadership on interoperability and administrative simplification and welcomes continued collaboration to ensure these policies improve care delivery, reduce burden, and advance a more data-driven healthcare system.

Thank you for your consideration of these comments. Please contact Tayler Williams, Senior Manager of Public Policy, at twilliams@amia.org with any questions.

Sincerely,

Eileen Koski

Eileen Koski
AMIA Public Policy Committee Chair