ConnectedHealthInitiative

June 9, 2026

The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Comments of the Connected Health Initiative, *Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs* (CMS-0062-P; RIN 0938-AV44; 91 Fed. Reg. 19890, April 14, 2026)

Dear Administrator Oz:

The Connected Health Initiative (CHI) appreciates the opportunity to comment on the proposed rule issued by the Centers for Medicare & Medicaid Services (CMS) and the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC) on interoperability standards and prior authorization for drugs.[1]

CHI is a broad multistakeholder effort that brings together patients, providers, payers, and technology innovators, including many small and medium-sized software developers, to advance a connected and interoperable health care system. Our comments focus on the proposed changes to the Medicare Promoting Interoperability (PI) Program, which fall within CHI's core interests in interoperability, patient access to health data, and the responsible use of digital health tools.

I. Introduction and Statement of Interest

CHI is a leading multistakeholder effort dedicated to realizing the full potential of connected health technologies to improve patient outcomes, lower the cost of care, and expand access. CHI's participants include patients, providers, payers, and the technology developers who build the digital health tools that patients and clinicians rely on every day. Standardized, predictable, and openly accessible health data infrastructure benefits every participant in this ecosystem.
CHI prioritizes interoperability and patient access to health data, the reduction of the burden that prior authorization imposes on patients, clinicians, and developers, and the responsible development and deployment of digital health and artificial intelligence (AI) tools. CHI has consistently urged the responsible expansion of application programming interface (API) based interoperability and the reduction of administrative burden across the health care system.

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[1] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; 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, 91 Fed. Reg. 19890 (Apr. 14, 2026) (the "Proposed Rule").

II. General Views of CHI

CHI's overarching priority, in this rulemaking and across CMS' broader regulatory agenda, is the development of a connected care continuum in which patient data, clinical workflows, and payer processes interoperate seamlessly across care settings and over the full course of a patient's care. When information follows the patient rather than remaining siloed in disconnected systems, clinicians can better coordinate care, patients can engage meaningfully in their own health, administrative friction such as prior authorization is reduced, and digital health tools, including remote patient monitoring, telehealth, and AI-enabled services, can deliver their full value. These priorities recur across CMS rulemakings, from interoperability and prior authorization, and the benefit of any individual rule is magnified when its requirements remain consistent with those of the others.

Accordingly, CHI supports a technology-neutral and standards-based approach to interoperability, robust patient and provider access to health data through Fast Healthcare Interoperability Resources (FHIR)-based APIs, the reduction of unnecessary administrative burden including prior authorization burden, symmetry and accountability between payer and provider technology, and alignment of requirements across programs so that technology can be built once and used everywhere. CHI assesses the proposals and requests for information in this proposed rule against these priorities. CHI also recognizes that realizing these priorities depends on realistic implementation timelines, careful attention to the cost and technical complexity that new requirements can impose on payers and providers alike, and a collaborative relationship between CMS and the regulated community.

III. Specific Input of CHI on Various Proposals

a. CHI supports extending electronic prior authorization to drugs and standardizing it on FHIR and the NCPDP standards

Prior authorization remains one of the most significant sources of delay to timely care and of administrative cost in the system. CHI supports CMS' proposal to require impacted payers to support electronic prior authorization for all drugs, to incorporate drugs covered under a medical benefit into the Prior Authorization API, and to support the National Council for Prescription Drug Programs (NCPDP) SCRIPT, Formulary & Benefit, and Real-Time Prescription Benefit standards for drugs covered under a pharmacy benefit.[2] Standardized, API-based prior authorization built on FHIR reduces the manual work that consumes clinician time and delays patient access to medications.

CHI encourages CMS to keep its requirements consistent across CMS programs and aligned with ASTP/ONC certification criteria so that developers can build once and deploy across settings, rather than maintaining duplicative implementations for different payers and programs.

[2] See 91 Fed. Reg. at 19892 (proposing to require impacted payers to support electronic prior authorization for all drugs, to incorporate drugs covered under a medical benefit into the Prior Authorization API, and to support the NCPDP standards for drugs covered under a pharmacy benefit).

b. CHI supports requiring the FHIR implementation guides and adopting FHIR for prior authorization transactions

CHI supports CMS' proposal to require (rather than recommend) the Health Level Seven (HL7) FHIR Da Vinci implementation guides that underpin the interoperability APIs, and to permit impacted payers to use any unexpired adopted version of a required standard.[3] Moving these implementation guides from recommended to required reduces variability and gives developers the predictability they need to build conformant products. CHI likewise supports CMS' proposal under the Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification authority to adopt the FHIR standard and associated guides for the referral certification and authorization and eligibility transactions associated with prior authorization for dental, professional, and institutional transactions.[4]

CHI urges CMS and ASTP/ONC to coordinate version adoption and expiration timelines carefully so that the transition periods are workable. Where more than one unexpired version of a standard is adopted, developers and payers benefit from a clearly communicated schedule and adequate overlap before older versions expire.

c. CHI supports the centralized directory of payer API endpoints

CHI has consistently emphasized that the full value of the interoperability APIs cannot be realized if developers, providers, and payers must locate one another's endpoints individually. CHI therefore supports CMS' proposal to require impacted payers to report their Patient Access, Provider Directory, Provider Access, Payer-to-Payer, and Prior Authorization API endpoints and related information to CMS for publication.[5] A reliable, centralized, machine-readable endpoint directory is foundational to the Payer-to-Payer use case and materially lowers the discovery burden across the ecosystem. CHI encourages CMS to publish the directory in an openly accessible, standardized, and regularly updated form, and to keep the reporting requirements themselves lightweight.

d. Payer-side and provider-side technology should be subject to comparable and consistent standards

CHI reiterates that certified technology used by providers and the corresponding technical interfaces on the payer side should be held to comparable standards so that electronic data exchange functions effectively, particularly for electronic prior authorization. Interoperability works best when payer-side and provider-side technology advance together, rather than holding one side to obligations the other does not share. CHI therefore encourages CMS to pair API expectations with appropriate conformance testing and to work collaboratively with payers and developers to define reasonable, achievable performance expectations that support near-real-time exchange. CHI recognizes that meeting such expectations involves real implementation cost and technical

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[3] See 91 Fed. Reg. at 19893 (proposing to require implementation guides previously recommended and to permit use of any unexpired adopted version of a required standard).

[4] See 91 Fed. Reg. at 19896 (proposing under HIPAA Administrative Simplification to adopt the FHIR standard and associated guides for the referral certification and authorization and eligibility for a health plan transactions associated with prior authorization).

[5] See 91 Fed. Reg. at 19896 (proposing to require impacted payers to report Patient Access, Provider Directory, Provider Access, Payer-to-Payer, and Prior Authorization API endpoints and related information to CMS).

complexity for payers, and encourages CMS to develop any performance benchmarks collaboratively and to phase them in over an adequate timeline.

e. CHI supports including small group market QHP issuers on the FF-SHOPs and aligning compliance across payers

CHI supports CMS' goal of extending comparable interoperability and prior authorization protections to small group market Qualified Health Plan (QHP) issuers on the Federally-facilitated Small Business Health Options Program (FF-SHOP) Exchanges.[6] Patients should not be disadvantaged in their data access or prior authorization protections simply because of the market in which their coverage is offered. At the same time, CHI recognizes that some affected issuers may face meaningful implementation cost and operational complexity, and encourages CMS to extend these protections through a phased and adequately resourced timeline. CHI encourages CMS to retain a narrowly tailored exception mechanism, and to consider additional flexibility, for any issuer, including genuine new entrants, that has not previously implemented the APIs.

f. RFI on Electronic Event Notifications for Value-Based Care and Care Coordination

CHI supports expanded use of electronic event notifications (commonly admission, discharge, and transfer, or ADT) as a tool for care coordination and value-based care. Timely notification of care transitions is one of the highest-value, lowest-cost interventions available for reducing avoidable readmissions and closing gaps in care.

CHI recommends that CMS and ASTP/ONC advance event notifications on a standardized, FHIR-based foundation, which will allow notifications to be generated, routed, and consumed consistently across the ecosystem. Further, because patient-generated health data and the digital tools that capture it are central to modern care coordination, CHI encourages CMS to consider whether, with appropriate patient authorization and privacy safeguards, the universe of entities able to receive notifications could extend beyond traditional treating providers to include the care management platforms, remote monitoring services, and patient-authorized applications that increasingly support care transitions, while remaining attentive to the operational burden that broader distribution may place on the organizations that generate and send notifications.

To the extent CMS considers health IT certification criteria for notification capabilities, CHI urges that any such criteria be FHIR-forward, align with the standards adopted elsewhere in this rulemaking so that developers can build once, and be supported by accessible testing tools. CHI supports encouraging more consistent delivery of notifications, and recommends that CMS favor collaborative and voluntary approaches over new enforcement obligations, calibrated so as not to impose disproportionate burden on developers, payers, and under-resourced facilities.

g. RFI on Increasing Health Care Resiliency

CHI shares CMS' concern about the escalating threat that hacking, ransomware, and other cyberattacks pose to the health care system and to electronic protected health information. CHI

[6] See 91 Fed. Reg. at 19895 (proposing to include small group market QHP issuers on the FF-SHOPs as impacted payers and to apply the existing API and prior authorization requirements to them).

supports strengthening the resiliency of the health care system through collaborative, largely voluntary measures developed together with payers, providers, and developers, and offers the following recommendations:

- First, CMS should anchor any resiliency expectations to existing, widely recognized frameworks rather than creating new and potentially conflicting requirements. The Department of Health and Human Services (HHS) Healthcare and Public Health Sector Cybersecurity Performance Goals, the National Institute of Standards and Technology (NIST) Cybersecurity Framework, the Health Industry Cybersecurity Practices developed under Section 405(d), and the Cybersecurity and Infrastructure Security Agency (CISA) Known Exploited Vulnerabilities guidance provide a coherent baseline. Aligning to these frameworks reduces compliance cost and improves security outcomes, particularly for the under-resourced and rural facilities that cannot absorb duplicative requirements.
- Second, CHI reiterates its recommendation that HHS expand cybersecurity safe harbor protections to facilitate the donation of security tools, threat monitoring, and security training to under-resourced provider organizations, including in connection with remote monitoring and connected health deployments. As connected devices proliferate, cybersecurity is increasingly inseparable from digital health deployment, and outdated fraud and abuse rules should not stand in the way of arrangements designed to protect patient data and the integrity of remote care systems.
- Third, CHI supports reasonable software transparency measures, including software bills of materials and supply-chain security attestations, as tools for improving resiliency. CHI cautions, however, that such requirements be scaled appropriately so that they strengthen security without functioning as de facto barriers to entry. Security requirements throughout should be risk-proportionate and outcome-focused.
- Finally, CHI notes that the migration away from one-off point-to-point connections toward standardized, certified FHIR APIs is itself a means of improving resiliency. CHI encourages CMS to coordinate across ASTP/ONC, the Office for Civil Rights, and CISA so that payers and developers face a single coherent set of expectations rather than overlapping and inconsistent mandates.

h. RFI on Improving Implementation of Payer Application Programming Interface Technology

CHI supports exploring how the ONC Health IT Certification Program, and comparable testing and conformance mechanisms, could help payer APIs meet the technical requirements CMS establishes. Conformance testing for payer APIs could be modeled on the approach used for certified health IT, applied in a manner appropriate to payers and developed collaboratively with them. CHI supports CMS' proposal to use automated testing tools to verify conformance[7] and encourages CMS to make those tools, along with reference implementations and openly accessible sandboxes, available to developers without the resources to build private test environments.

[7] See 91 Fed. Reg. at 19890 (proposed rule section II.A.4.c) (proposing the use of testing tools to ensure conformance with the required implementation guides); see also id. at 19896-97 (request for information on improving payer API implementation through testing and certification, including potential use of the ONC Health IT Certification Program).

CHI encourages CMS to work with payers and developers to develop reasonable, achievable expectations for API response-time and availability, so that payer APIs perform dependably in practice, and to consider appropriate and proportionate transparency around API performance. Transparency of this kind, developed collaboratively with industry, can inform CMS oversight and give the market useful information while respecting the operational realities that payers face.

CHI also encourages CMS to help ensure that the APIs this rule supports are genuinely usable in practice, so that nominal availability translates into real-world functionality for the providers, patients, and developers they are meant to serve. To that end, CHI encourages CMS to work with all stakeholders, including payers, to identify and address any practical barriers to access, including fee or contracting terms that could unintentionally limit usability, in a balanced manner that recognizes payers' legitimate operational and business interests.

i. RFI on Step Therapy

CHI supports using standardized technology and data sharing to help step therapy work more smoothly for patients, providers, and payers alike. When a patient changes payers, the voluntary transfer of relevant step therapy history through the Payer-to-Payer API can help avoid unnecessary repetition of therapies a patient has already completed, which benefits patients and payers alike by reducing duplicative review. CHI encourages CMS to work with payers and developers to standardize the data elements needed to evaluate, apply, and honor step therapy criteria, so that this information can move through the FHIR-based APIs alongside other prior authorization data and so that developers can build to a single specification.

j. RFI on Laboratory Tests and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

CHI sees value in eventually extending a standardized, API-based prior authorization approach to laboratory tests and to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Where coordination among providers, laboratories, and suppliers can be improved and approval times shortened, standardized FHIR-based prior authorization and the Provider Access and Payer-to-Payer APIs may help address those challenges.

CHI encourages CMS to consider, over an appropriate timeframe and in consultation with affected payers and suppliers, bringing laboratory and DMEPOS prior authorization within the same framework being established for drugs and non-drug items and services, so that developers can build once and so that the necessary documentation can be exchanged through standardized interfaces. CHI further encourages CMS to explore transparency and selective-exemption approaches that could reduce burden without compromising program integrity, recognizing that the design of any such approach, including any relief from repetitive requirements for consistently compliant providers, should be developed collaboratively with payers.

IV. Conclusion

CHI urges CMS to move forward consistent with the above recommendations. CHI looks forward to continued engagement as the rule is finalized and stands ready to provide additional information or to participate in any stakeholder engagement opportunities.

Sincerely,

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