June 15, 2026

Mehmet Oz, M.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201
RIN 0938-AV44

Attention: CMS-0062-P
Submitted electronically to http://www.regulations.gov

Re: 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

Dear Administrator Oz:

The Sequoia Project is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the advancing interoperability and improving prior authorization proposed rule. We appreciate CMS's demonstrated record of responding thoughtfully to the comments that it receives on such proposed rules from its many stakeholders.

The Sequoia Project is a non-profit, 501(c)(3) public-private collaborative that advances the interoperability of electronic health information for the public good. The Sequoia Project previously served as a corporate home for several independently governed health IT interoperability initiatives. The Sequoia Project currently supports the RSNA Image Share Validation Program and the Interoperability Matters Cooperative. We are also honored to have been selected by the Office of the National Coordinator for Health IT (ONC) to be the Recognized Coordinating Entity (RCE) for the Trusted Exchange Framework and Common Agreement (TEFCA).

These comments reflect our experience supporting large-scale, nationwide health information sharing initiatives, including active work with several federal government agencies. Through these efforts, we serve as an experienced, transparent, and neutral convener of public and private sector stakeholders to address and resolve practical challenges to interoperability. Our decade of experience building public-private collaborations and launching highly successful nationwide health IT initiatives provides us with a unique perspective on the proposed rule. The comments and recommendations in this letter reflect this expertise independent of our role as the TEFCA RCE.

Overview

Highlights of our comment letter include:

Interoperability Standards

- Support CMS's continued alignment with ONC-adopted standards and use of unexpired standard versions to promote consistency across federal interoperability initiatives, reduce implementation variation, and encourage adoption of current standards.

Reporting API Endpoints

- Support CMS's efforts to improve endpoint discovery and publication while encouraging alignment with existing directory standards, reporting mechanisms, and broader directory initiatives such as the National Provider Directory and FAST National Directory of Healthcare Providers & Services (NDH) Implementation Guide.
- Encourage CMS to consider the governance, validation, and lifecycle management processes necessary to maintain accurate and trustworthy endpoint information over time and provide sufficient implementation guidance as reporting requirements are finalized.

Modifications to HIPAA Standards Related to Prior Authorization

- Support the long-term transition toward FHIR-based prior authorization workflows while encouraging a practical implementation approach that accounts for implementation maturity, version management, and industry readiness.
- Encourage CMS to consider the directory, discovery, and trust infrastructure necessary to support scalable exchange between payers and providers and ensure that FHIR-based approaches can support the range of clinical information needed for prior authorization decisions.

RFI: Electronic Event Notification

- Recommend CMS use its levers to encourage and incentivize regulated providers and payers to participate in TEFCA to expand the reach of nationwide exchange and support future care coordination use cases, including electronic event notifications.

RFI: Building Health Care Resiliency

- Highlight how trusted nationwide exchange infrastructure, collaborative governance, and a network-of-networks approach can support health care resiliency and continuity of information sharing during periods of operational disruption.

Detailed Comments

Section II.A — Interoperability Standards for APIs

In summary, we request comment on our proposals in the CFR citations listed in Table 2, and specifically on the following:

- *The proposal to require impacted payers to implement and maintain API technology conformant with unexpired versions of the standards adopted by the Secretary in 45 CFR 170.215, specifically 45 CFR 170.215(a), (b)(1), and (c), (d), and (e), as applicable.*

The Sequoia Project supports CMS's continued approach to align interoperability requirements with standards adopted through the ONC Health IT Certification Program. Aligning API requirements with unexpired standards adopted by ONC and referenced in regulation can help promote consistency across the healthcare ecosystem, reduce implementation variation, and encourage adoption of current standards as older versions are retired.

In previous comments to CMS, The Sequoia Project has emphasized the importance of aligning standards implementation across federal interoperability initiatives to reduce burden and improve the effectiveness of health information exchange. **We therefore support CMS's proposal to align API requirements with applicable ONC-adopted standards and believe this approach represents an important step toward continued coordination of federal interoperability efforts**.

Section II.E — Reporting Payer API Endpoints and Associated Information for CMS To Publish

We request comment on our proposals in the CFR citations listed in Table 8, and specifically on the following:

- *The proposal to require impacted payers to report all API endpoints to CMS, in the form of an Endpoint Resource, as defined by an unexpired version of the FHIR standard adopted in 45 CFR 170.215(a), including, if multiple, appropriate use cases for each.*
- *The proposal to require impacted payers to report URLs with the required documentation for each of their interoperability APIs, as applicable:*

Implementation Considerations

The Sequoia Project appreciates CMS's efforts to improve endpoint discovery and interoperability through standardized reporting and publication of payer API information. We recognize that CMS has established analogous reporting processes through prior interoperability rulemaking and encourage the agency to align endpoint reporting and publication processes with existing directory standards and reporting mechanisms wherever feasible. We also support CMS's proposal to collect endpoint documentation, including API capability, authentication, authorization, and implementation information, and encourage CMS to collect such information in a structured and standardized manner to support automated discovery and integration.

CMS should ensure that technical specifications and operational requirements are clearly communicated prior to the compliance date. If the final requirements differ significantly from existing directory reporting approaches, CMS should consider whether additional implementation time, beyond the proposed 60 days, may be appropriate to support successful implementation. **Clear implementation guidance and sufficient implementation time will be critical to successful adoption.**

Leveraging Existing Directory Infrastructure

Through implementation of TEFCA, The Sequoia Project, acting as the Recognized Coordinating Entity (RCE), developed and operates a successful federated directory model supporting QHINs, Participants, and Subparticipants, participating in nationwide exchange. In doing so, Sequoia has established processes and infrastructure for endpoint onboarding, publication, governance, and lifecycle management at scale. These capabilities have been informed through ongoing collaboration with exchange participants, governance bodies, and other stakeholders to address real-world operational and interoperability needs.

We believe this experience is relevant as CMS considers requirements for collecting, validating, and publishing payer API endpoint information. We support CMS's consideration of the FAST National Directory of Healthcare Providers & Services (NDH) Endpoint Profile as an alternative reporting format and believe it represents a promising foundation for endpoint discovery and publication. We encourage CMS to continue aligning this proposal with broader provider directory initiatives, including the National Provider Directory and other NDH-based efforts. Greater alignment across directory-related initiatives could reduce implementation burden, promote consistency across the healthcare ecosystem, and support a more scalable approach to endpoint discovery and interoperability. **Alignment with broader directory initiatives will help maximize the long-term value and scalability of this proposal.**

Directory Governance and Maintenance

Our experience operating large-scale federated directories has demonstrated that endpoint directories are not static compliance registries. While the initial publication of endpoint information is relatively straightforward, maintaining accurate and reliable endpoint information over time presents a significantly greater operational challenge. Endpoint information evolves as organizations, technologies, and exchange relationships change over time.

Accordingly, we encourage CMS to provide additional guidance regarding the proposed annual endpoint verification requirement, including acceptable verification methodologies, the role of automated validation, evidentiary requirements, and the potential use of third-party validation services. We also believe CMS should consider the ongoing governance and operational processes necessary to support directory quality, usability, and trust over time.

More broadly, The Sequoia Project appreciates CMS's continued efforts to advance standards-based directory infrastructure. We believe the greatest long-term value of this proposal will be achieved if endpoint reporting requirements are implemented as part of a broader national directory strategy that aligns with existing directory initiatives and promotes consistency across the healthcare ecosystem. A clearly articulated long-term approach could help promote alignment across industry directory efforts, reduce duplicative implementation activities, and support a more consistent and scalable approach to endpoint discovery and interoperability.

The Sequoia Project would welcome the opportunity to share lessons learned from operating nationwide federated directories and to engage further with CMS as it evaluates approaches for endpoint discovery, validation, and directory management.

Section III.H Modifications to HIPAA Standards Related to Prior Authorization

CMS requests comment on this proposal specifically seeking input on:

- *Whether adopting the FHIR standards for prior authorization transmissions and retaining the currently adopted X12N transaction standards for other referral certification transmission use cases would increase burden on HIPAA covered entities to maintain the ability to conduct electronic transactions using two different standards?*
- *Rather than adopting the CDex IG, would it be appropriate to recommend it at this time to give the industry an opportunity to test the CDex IG in real-world applications?*

Support for FHIR-Based Prior Authorization

The Sequoia Project supports CMS's efforts to advance FHIR-based prior authorization workflows and recognizes the potential for FHIR standards and implementation guides to improve automation and interoperability across the healthcare ecosystem. We encourage CMS to continue supporting a thoughtful transition toward FHIR-based prior authorization standards while recognizing the need for a practical implementation path that accounts for implementation maturity, version management, and industry readiness. Among other considerations, it is not clear that FHIR standards can convey all the information that may be requested to support a prior authorization. **CMS should prioritize a phased and practical transition that balances innovation with implementation readiness.**

Directory Infrastructure and Trusted Exchange

As CMS evaluates the transition toward FHIR-based prior authorization transactions, we encourage consideration of the supporting infrastructure necessary to enable trusted exchange between payers and providers. The ability to discover, verify, and connect to the appropriate endpoints may be as important as the transaction standard itself. Trusted directory infrastructure can support endpoint discovery, establish trust between exchange partners, and facilitate scalable implementation of FHIR-based workflows.

Through implementation of TEFCA, The Sequoia Project has experience supporting trusted exchange frameworks and federated directory models that enable organizations to discover and connect with one another at scale. We believe these lessons may be relevant as CMS considers the infrastructure needed to support future prior authorization exchange. We also encourage CMS to maximize alignment between payer and provider directory initiatives and leverage common directory standards wherever possible. **The success of FHIR-based prior authorization will depend not only on the standards themselves, but also on the directory, discovery, and trust infrastructure that enables reliable exchange.**

Implementation Considerations

The Sequoia Project recognizes the potential for FHIR-based approaches, including the Da Vinci Clinical Data Exchange (CDex) Implementation Guide, to improve access to clinical information needed to support prior authorization decisions. At the same time, we encourage CMS to continue evaluating implementation maturity and real-world experience before requiring broad adoption.

Prior authorization workflows often require the exchange of a wide range of clinical information. As CMS advances these standards, it will be important to ensure that providers and payers can exchange all information necessary to support timely and accurate prior authorization determinations, while maintaining flexibility to accommodate evolving implementation experience and industry adoption. **CMS should ensure that FHIR-based approaches can support the full range of clinical information needed for prior authorization decisions before fully replacing existing approaches.**

Section III.A Request for Information: Electronic Event Notifications for Value-Based Care and Care Coordination

- *RFI Question: How could CMS leverage the TEFCA network to improve the quality of notifications and/or improve the likelihood that electronic event notifications shared by hospitals are able to reach authorized recipients?*

The Sequoia Project appreciates CMS's interest in exploring how TEFCA may support electronic event notifications for value-based care and care coordination. TEFCA was established to support trusted exchange at a national scale and provides governance, connectivity, and directory infrastructure that may help improve the ability of organizations to identify, discover, and exchange information with authorized recipients. **TEFCA's nationwide connectivity and trusted exchange framework provide a strong foundation for improving the reach and reliability of electronic event notifications.**

To start, the Sequoia Project recommends that CMS use its levers to encourage and incentivize regulated providers and payers to participate in TEFCA. Broad participation by major data holders will expand the reach of nationwide exchange and create opportunities to support key industry use cases that will lead to greater adoption. **Greater participation in TEFCA will strengthen the network effects necessary to support scalable care coordination and notification use cases.**

Event notifications are not within the initial enumerated use cases of TEFCA Exchange and are something that some state and regional Health Information Exchanges (HIEs) support. However, the underlying TEFCA framework includes capabilities that could support this Treatment use case and is already supported through TEFCA Message Delivery. For example, TEFCA's nationwide connectivity and directory infrastructure may help improve the ability to identify appropriate recipients, establish trust between exchange partners, and support more reliable delivery of notifications across organizational boundaries through TEFCA Message Delivery.

The Sequoia Project, in its role as the TEFCA RCE, would welcome the opportunity to work with CMS and industry stakeholders to evaluate requirements, implementation considerations, and potential pathways for supporting event notification use cases through TEFCA in the future. **CMS should consider event notifications as a potential future TEFCA exchange scenario and collaborate with the RCE, ONC, and stakeholders to evaluate requirements for implementation.**

Section III.B Request for Information: Increasing Health Care Resiliency

- *RFI Question: How could the Trusted Exchange Framework and Common Agreement (TEFCA) be used to support health care resiliency goals?*

The Sequoia Project appreciates CMS's commitment to strengthening the resilience of the nation's health care infrastructure. This objective aligns closely with the goals of TEFCA, which seeks to enable secure, appropriate, and nationwide access to health information among authorized stakeholders. **Trusted nationwide exchange infrastructure can play an important role in supporting broader health care resiliency objectives.**

As the TEFCA RCE, The Sequoia Project works collaboratively with QHINs, Participants, Subparticipants, federal partners, and stakeholders to establish and maintain a common framework for trusted exchange. Through this collaborative governance model, TEFCA promotes consistency, transparency, and coordination across a diverse ecosystem of organizations involved in the exchange of health information. **Collaborative governance and stakeholder coordination are critical components of a resilient health information exchange ecosystem.**

TEFCA can support health care resiliency by providing a trusted nationwide exchange framework that enables access to health information across organizational and geographic boundaries, including during periods of operational disruption. By connecting health care organizations through multiple Qualified Health Information Networks (QHINs), TEFCA reduces reliance on any single exchange pathway and supports continuity of information sharing. **A network-of-networks approach, when appropriately resourced, can strengthen continuity of information sharing during disruptions and other resiliency events.**

Beyond its technical infrastructure, TEFCA's governance framework provides a mechanism for stakeholders to collaborate on emerging challenges and develop coordinated approaches to strengthen health care system resilience. **As TEFCA adoption continues to expand, The Sequoia Project would welcome the opportunity to work with CMS and other stakeholders to explore how TEFCA's governance, connectivity, and trusted exchange infrastructure can further advance national health care resiliency goals.**

Conclusions

We appreciate CMS's consideration of these comments and its continued commitment to advancing nationwide interoperability. The Sequoia Project strongly supports CMS's efforts to align federal interoperability initiatives, promote standards-based exchange, and reduce burden across the health care ecosystem.

Throughout this letter, we have encouraged CMS to build upon existing interoperability investments, align related directory and exchange initiatives, and support practical implementation pathways that enable scalable and sustainable adoption. We believe these principles will help maximize the value of federal interoperability efforts while improving the ability of patients, providers, payers, and other stakeholders to securely access and exchange health information.

As CMS continues this work, we encourage ongoing collaboration with industry stakeholders and federal partners to leverage trusted exchange infrastructure, advance interoperability through coordinated policy and standards development, and support the long-term success of nationwide health information exchange. The Sequoia Project, in its role as the TEFCA RCE, remains committed to supporting secure, trusted, and nationwide health information exchange and welcomes continued collaboration to advance interoperability for the public good.