



May 28, 2024

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Submitted electronically to [inquiry.healthit.gov](mailto:inquiry.healthit.gov)

**RE: Draft 2024-2030 Federal Health IT Strategic Plan**

Dear Dr. Tripathi:

The Health IT End-Users Alliance (the Alliance) appreciates the opportunity to comment on the Office of the National Coordinator for Health IT (ONC) draft [2024-2030 Federal Health IT Strategic Plan](#) (the draft Plan), published on March 27, 2024.

The Alliance brings together health information professionals, physicians, hospitals, and other front-line healthcare providers and organizations that use health IT in the provision of care to ensure that policy and standards development activities reflect the complex web of clinical and operational challenges facing those who use technology tools for care. By working collaboratively across settings of care, the Health IT End-Users Alliance is focused on priorities for how technology can best support clinical care and operations.

The Alliance appreciates ONC's commitment to improving health experiences and outcomes for individuals, populations, and communities while also promoting opportunities for improving health equity, advancing scientific discovery and innovation, and modernizing the nation's public health infrastructure. We share many of ONC's goals for addressing the policy and technology components essential for meeting the diverse data requirements of all health IT users. While the Alliance sees great alignment in the objectives of goals two – Enhance the Delivery and Experience of Care – and four – Connect the Health System with Health Data; we see end-users playing a role in all components of the draft Plan and have identified areas of opportunity for collaboration below.

**Interoperability and Data Sharing Through Real-World Testing**

The development of new health IT standards and their adoption into regulatory requirements can bring benefits by addressing specific challenges and creating more uniformity in how health information is gathered, shared, and used. The Alliance appreciates ONC's intent to collaborate across public and private sectors on health IT standards' maturity, adoption, and use, as well as improve alignment and automation of data collection and reporting to reduce burden and costs associated with federal requirements. The Alliance also agrees with the need to develop, align, test, and implement data standards to increase interoperability.

Over the past decade, end-users have found that new and [compounding](#) regulatory requirements were not sufficiently grounded in real-world experiences and did not adequately consider the implementation pathway before mandated use.<sup>1</sup> Adequate and inclusive testing of standards should be done **before** they are included in regulation. End-user input should be part of every phase of the development, maturity, testing, and implementation of health IT standards.

We are pleased ONC references real-world performance throughout the draft Plan. We note, however, that while the real-world testing requirements included in ONC's certification rules are helpful to assess how products perform after implementation, they are not the same as real-world testing in advance of inclusion in regulation. The Alliance's [Real World Testing Consensus Statement](#) outlines several key principles to leverage the input of health IT end-users to ensure standards and policies are efficiently adopted and implemented, keep burden minimal, and accomplish the desired tasks.<sup>2</sup> Key principles include:

- End-users must be instrumental in establishing goals and priorities for setting standards.
- End-user input should be included in every phase of standards development from initial standard scoping to real-world testing.
- Standards and policies to advance standards adoption should prioritize patient care and wellness and public health.
- Real-world testing should include real-world implementations, production pilots, collection of metrics, training needs for staff, markers of success, and estimated costs and benefits.
- Standards shouldn't be considered mature, or included in regulation, until real-world testing has been completed and report outs are made public.
- Continuous monitoring of standards after deployment.
- Standards and policy should ensure equity and embrace diverse end-user involvement.

The Alliance encourages ONC to include a diverse set of end-users from various types, sizes, and settings of healthcare organizations in all phases of real-world testing. We encourage ONC to work with the Centers for Medicare & Medicaid Services (CMS), other relevant federal agencies, and the broader health IT community to identify expectations and needed elements for the successful real-world testing of standards. Again, this testing must happen in advance of inclusion in certification requirements and needs to go beyond what is included in the real-world testing requirements in the certification regulations.

### **Advancing Health IT in Clinical Workflows with the End-User Perspective**

New technologies must be integrated as seamlessly as possible into existing clinical workflows. The Alliance strongly supports ONC's objectives to promote the use of health IT and other modern technologies in clinical workflows and to provide support for healthcare professionals for easier adoption, implementation, and use of secure health IT.

We commend ONC for recognizing the need for resources and support focused on end-users. We encourage ONC to consider the needs of different clinical settings and organizations of different sizes. Information dissemination through webinars and broad implementation guides is a necessary first step, but end-users would benefit further from tailored assistance that accounts for and builds on the different capabilities of various organizations. We recommend ONC offer forums for end-users to identify needed resources and technical assistance. These feedback processes should bring end-users together with federal

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<sup>1</sup>Health IT End Users Alliance Collaborative Roadmap. Available at: <https://hitenduser.org/hit-end-users-alliance-releases-2024-2027-collaborative-roadmap/>.

<sup>2</sup>Health IT End Users Consensus Statement on Real-World Testing. Available at: [https://hitenduser.org/wp-content/uploads/2022/09/Real-world-testing-consensus-statement\\_FINAL.pdf](https://hitenduser.org/wp-content/uploads/2022/09/Real-world-testing-consensus-statement_FINAL.pdf).

agency staff, technology vendors, and other key stakeholders to outline actionable steps for streamlining and improving implementation of health IT.

Further, the Alliance supports the ONC objective to engage health IT end-users across the industry in health IT development, optimization, and usability testing so that the needs of end-users are reflected. We also support ONC's objective to investigate the impact and effectiveness of health IT on care outcomes. As referenced above, a federally supported, collaborative process to engage stakeholders in real-world testing is crucial for success. Real-world testing must be done in advance of regulatory requirements, though it should not end with implementation of technology and standards. A lifecycle approach to product monitoring will help to ensure the goal of improved patient care is being accomplished. Yet, ONC, CMS, developers, and other healthcare stakeholders should endeavor to mitigate or eliminate any monitoring burden that could be placed on providers.

The Alliance appreciates ONC's continued commitment to streamlining electronic documentation requirements to reduce burden and improve the quality of patient health records, including leveraging health IT to standardize data and processes related to [electronic prior authorization](#).<sup>3</sup> Improving the prior authorization process will require federal support of more robust real-world testing of interoperability standards and implementation guides intended to facilitate automation. Greater engagement with the health IT end-user community will help create a better understanding of the effort needed to operationalize technology solutions and business processes needed to interact with payer systems.

For example, stakeholders would benefit from understanding the scope and outcomes of pilot projects that used the Health Level Seven (HL7) DaVinci Project standards for electronic prior authorization before proposing any requirements that they be supported in certified health IT products. In April 2021, CMS approved a request from the HL7 Da Vinci Project for an "exception from use of adopted standards, as provided under 45 CFR 162.940, to test Fast Healthcare Interoperability Resources (FHIR) based standards. The goal of the test is to determine whether FHIR based standards will reduce the cost, complexity, and reduce the burden of the prior authorization transaction."<sup>4</sup> CMS required reporting of findings from the pilot not later than July 14, 2024. Before moving forward with any regulations, federal officials and end-users should evaluate those findings to understand whether the pilot was successful, how standards might need to be modified, and whether the results are scalable to other settings of care and across providers and payers of all sizes. Additional real-world testing may also be needed.

Pursuant to stakeholder concerns, CMS recently issued an enforcement discretion statement exempting the industry from the use of the HIPAA mandated prior authorization transaction.<sup>5</sup> We strongly urge that ONC continue to monitor the scalability of FHIR as it relates to prior authorization workflows and the impact of the enforcement discretion on the industry, to include implementation variations and any associated impacts on interoperability.

## **Social Determinants of Health Data Collection and Use to Address Health Inequities**

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<sup>3</sup>Health IT End Users Alliance Comments on CMS Electronic Prior Authorization Proposed Rule. Available at: <https://hitenduser.org/health-it-end-users-alliance-responds-to-cms-electronic-prior-authorization-proposed-rule/>.

<sup>4</sup>Letter from Christine Gerhardt, Director, National Standards Group, CMS to Sagraan S. Moodley, Chair, HL7 Da Vinci Project Steering Committee dated April 14, 2021.

<sup>5</sup>Statement of Enforcement Discretion for Referral Certification and Authorization Transaction Standard at 45 CFR § 162.1302 for HIPAA Covered Entities Subject to the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) that Implement an All-FHIR-Based Prior Authorization API. Available at: <https://www.cms.gov/files/document/discretion-x12-278-enforcement-guidance-letter-remediated-2024-02-28.pdf>

Achieving equity in health and healthcare is a shared priority of the healthcare field that includes the collection of needed data to identify disparities and work towards improving care delivery for better patient health outcomes. Federal health programs are increasingly incorporating policies that encourage or require screening and the collection of demographic and social determinants of health (SDOH) data. The Alliance supports SDOH programs when needed data are collected and used appropriately. However, standardization and increased uniform collection and reporting of relevant data are necessary to limit burden and ensure that only needed data are collected. This can best be accomplished with more resources for providers to offset the costs of training staff, updating systems, and developing systems to leverage these data to improve care.

Throughout all goals in the draft Plan, the Alliance is pleased to see objectives related to advancing the collection and use of standardized SDOH data; ensuring data collection involves appropriate consent for and understanding of secure sharing and use of this information; and encouraging equity, safety, and user-centered design principles in the development and use of health IT. While flexibility in screening tools and processes can allow providers to best collect these data within existing workflows and environments, the lack of standard approaches can lead to inconsistent data classifications and collection, struggles to track progress over time, and the inability to share this data across organizations and care settings to efficiently coordinate care. We stress that, without appropriate data sharing guardrails (both technical and policy-driven), patients may lose trust in data protection and may refrain from open and honest communication with their providers—impacting care and negating the usefulness of health IT.

Improved collection and use of relevant demographic and social factor data to identify and guide efforts to address disparities can positively impact healthcare delivery and operations. Collecting duplicative data for the sake of collecting data or reporting it to government programs without realistic opportunities to connect the data to care improvements only increases burden and may be seen by patients as overly intrusive. The Alliance’s [Data to Support Equity Consensus Statement](#) references several principles to guide efforts to ensure the collection of this data is used optimally and appropriately, is actionable, and remains purpose-driven:<sup>6</sup>

- Prioritize continued development of standardized and validated SDOH data elements to be collected in a consistent, comparable fashion for priority domains.
- Align selected domains across federal and state healthcare programs and reporting requirements, and by commercial health plans.
- Develop consensus on validated instruments to be used for data collection.
- Recognize the shared obligation across providers, public programs, payers, and community-based organizations to collect and appropriately share SDOH data, with appropriate compensation for data collection and management of health-related social needs, as well as ensuring the availability of data for providers to support clinical and social care delivery.
- Keep the primary focus on collecting demographic and SDOH data to meet patient needs.
- Federal, state, and local governments and health plans should actively provide funding, technical resources, and infrastructure to support training, implementation, and care coordination.
- Continue and expand research to improve SDOH data collection to optimize improved equity.

The Alliance also appreciates the objective to harmonize common data elements for improved interoperability. We support efforts to standardize and increase uniform collection and reporting of relevant data, but more needs to be done to support end-users. In addition to standardization, end-users need training in how best to collect sensitive data, the tools and workflows best equipped to collect and

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<sup>6</sup>Health IT End Users Consensus Statement on Data to Support Equity. Available at: [https://hitenduser.org/wp-content/uploads/2023/05/HIT-Template4\\_5.15.23.pdf](https://hitenduser.org/wp-content/uploads/2023/05/HIT-Template4_5.15.23.pdf).

share it effectively, and how to avoid redundant or inaccurate data collection. Federal policies must also reflect the realities end-users face, including the limitations of certified health IT to protect sensitive health information.

The Alliance recommends ONC continue working with CMS to support the development of standardized data elements, including the US Core Data for Interoperability (USCDI). Tools to collect and share SDOH data should undergo real-world testing with input from end-users to increase the likelihood that these technical approaches will succeed. Lastly, providing resources, tools, and training will widen the opportunity for end-users to be able to collect this information and work with community organizations to implement closed referral loops to monitor impacts and interventions on health disparities and health outcomes.

### **Artificial Intelligence and Decision Support Interventions**

The rapid proliferation and advancement of artificial intelligence (AI) tools in healthcare is already impacting end-users. The Alliance appreciates the draft Plan objectives on promoting education, outreach, and transparency about the development and use of AI algorithms, as well as promoting the safe and responsible use of AI tools for care delivery supported by decision support interventions (DSIs). Most end-users will be reliant on AI tool developers and their EHR vendor for integrating the tools. Including the input of end-users and providing transparency throughout the life cycle of AI innovation, technology development, implementation, and use will help contribute to the safe and appropriate use of these technologies.

Building on DSI transparency policies finalized in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) final rule, the Alliance encourages ONC to work with federal partners and industry to identify transparency requirements that provide useful and actionable information for end-users and patients. ONC and other federal agencies should actively engage end-users to identify the most appropriate list of DSI attributes to include in transparency requirements and evaluate how best to share this information with end-users for their use. This must include assessments and guidance to identify and mitigate possible bias. End-users will also need plain language descriptions from tool developers to support patient education efforts. Like electronic prior authorization, we [encourage](#) ONC to include consideration of end-users in these efforts as this landscape continues to develop, ensuring a shared responsibility across both end users and DSI developers to prioritize improved patient care while preserving safety and addressing biases.<sup>7</sup> ONC should also encourage certified health IT developers to identify common and effective approaches to presenting or displaying DSI attributes. A wide variation in DSI transparency across developers may encumber provider use of this information and undermine the goals ONC has established.

### **Conclusion**

The Alliance supports ONC's visions and focused, yet comprehensive, goals to improve the health and well-being of individuals and communities using technology and health information that is accessible when and where it matters most. We look forward to engaging with ONC and other federal partners to contribute our diverse expertise to accomplishing these goals and objectives. For further questions related to the contents of this letter, or the Alliance and our policy positions, please contact American Health Information Management Association (AHIMA) Senior Director of Regulatory and International Affairs Andrew Tomlinson at [Andrew.Tomlinson@ahima.org](mailto:Andrew.Tomlinson@ahima.org) or by phone at 443-676-7106.

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<sup>7</sup>Health IT End Users Alliance Comments on RFI on NIST's Assignments Under Executive Order Concerning Artificial Intelligence. Available at: <https://hitenduser.org/health-it-end-users-alliance-responds-to-rfi-on-nists-assignments-under-executive-order-concerning-artificial-intelligence/>.