HEALTH IT
End Users Alliance

February 27, 2026

Dr. Thomas Keane
Assistant Secretary
Assistant Secretary for Technology Policy / Office of the National Coordinator for Health Information Technology
330 C St. SW, 7th Floor
Washington, DC 20201

**RE: RIN 0955-AA09 Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity**

Dear Assistant Secretary Keane:

The Health IT End-Users Alliance (the Alliance) applauds the Assistant Secretary for Technology Policy/ Office of the National Coordinator for Health Information Technology (ASTP/ONC) for its review of the Health IT Certification Program (Certification Program) and other ASTP/ONC initiatives seeking opportunities to reduce ecosystem burden and promote innovation. The Alliance supports the intent behind many of the proposals within the *Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI-5)* proposed rule and looks forward to collaborating with ASTP/ONC to refine other proposals to ensure the rule achieves its stated regulatory goals.

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 Alliance is focused on advancing end-user perspectives in health IT policy and standards development to support clinical care and operations.

We recognize that HTI-5 as proposed is intended to reduce regulatory burden; however, we are concerned that what is proposed will result in additional burden to the end-user. In effect, this regulatory burden would continue to place end-users in the position of needing to develop or fund technology to ensure they maintain compliance with other regulatory requirements throughout HHS. This additional burden would potentially cause end-users to need to choose between maintaining regulatory compliance and focusing on new innovative solutions to improve patient outcomes.

End-users consistently struggle to find a seat at the health IT development and implementation table despite efforts to engage in these processes. Both policy and technology development often happen before the end-user is involved in the process, making it difficult for end-user pain points to be addressed prior to implementation. This existing burden on end-users increases the cost for technology development, as the developed technology often does not meet its intended goals or policy outcomes once implemented in the end-user environment. The Alliance believes many of the proposals in HTI-5 will exacerbate these ongoing problems and recommends ASTP/ONC refrain from finalizing these proposed changes until a time when end-user concerns, experiences, and needs are accounted for during technology and policy development.

For example, ASTP/ONC proposes to remove the Condition and Maintenance of Certification Real World Testing requirement from the Certification Program. While the Alliance recognizes this is a codification of previously released enforcement discretion, we recommend ASTP/ONC refrain from removing these crucial requirements from the Certification Program. Real-world testing plays a crucial role in ensuring Certified Electronic Health Record Technology (CEHRT) meets the needs of end-users once implemented. Should this requirement be removed, it may cause increased burden on the end-user due to poorly designed technology or technology that does not meet real-world workflows. Other consequences due to lack of adequate real-world testing include:

- adoption and implementation of standards that require significant workarounds by healthcare organizations;
- adoption and implementation of incomplete or immature standards;
- standards and policies that do not achieve the desired goal when deployed;
- excessive burden added to end-users;
- wasted money on failed implementations; and
- confusion from patients with respect to technological capabilities.

We urge ASTP/ONC to refrain from removing the real-world testing requirement from the Certification Program, and instead strengthen the required use of real-world testing. By working together with end-users earlier, developers and policymakers can ensure innovation is realized in health IT with fewer burdens. Ensuring real-world testing remains a robust requirement in the Maintenance and Conditions of Certification criteria is one way to realize that potential. As part of the Appendix to this letter, we have included our Real-world Testing Consensus Statement that includes further policy recommendations.

ASTP/ONC also proposes to remove the decision support intervention (DSI) transparency requirements from the Certification Program criteria. ASTP/ONC cites a lack of evidence of utility as the reasoning behind removal of the criteria, as well as the desire to reduce burden on developers as they seek compliance with the program. The Alliance recommends ASTP/ONC refrain from removing these criteria without proposing alternative transparency criteria or an alternative regulatory pathway for giving end-users access to transparency information relating to DSI technology. If the DSI transparency requirements are preserved, we recommend ASTP/ONC solicit and publish feedback from end-users on the usefulness of this information to understand the industry's needs and allow developers to prioritize DSI transparency information that is most useful for end-users.

Artificial intelligence (AI) technology continues to proliferate throughout healthcare at an ever-expanding rate. Such rapid adoption increases the need for end-users to have transparency, trust, and predictability that the technology will deploy successfully. Without trust, it will not only be difficult for end-users to identify technology suitable for adoption, but could also lead to an erosion of trust within the patient-provider relationship. The existing DSI criteria helps narrow the gap for end-users by giving them insight into the data the tools utilized and how decisions were made. It also assists them in making smart purchase decisions to ensure the technology implemented is cost effective and suitable for their environment.

Without the DSI criteria, there will be no regulatory framework in place for health IT relating to AI. If ASTP/ONC were to replace DSI with a new framework – as recommended above – we recommend ASTP/ONC prioritize creating a framework that embodies the following characteristics:

- A risk-based approach to oversight;
- aligns across federal agencies;
- exhibits shared responsibility between developers and end-users in prioritizing safety and transparency;
- ensures AI does not compromise the security of end-user IT systems and is strengthened against cyberattacks;
- reduces workflow burden of end-users;
- supports and provides robust end-user education, participation, and leadership; and
- accounts for accessibility and usability in the end-user facing technology.

The Alliance believes preserving the DSI criteria, or pursuing another AI transparency framework, within the Certification Program is important to advancing the use of AI within health IT. Without these provisions in the Certification Program, end-users will be hindered from understanding what they are purchasing and implementing, potentially leading to wasted money in the healthcare system if the implementations fail. The Appendix to this letter contains our Artificial Intelligence Consensus Statement which provides additional recommendations for how ASTP/ONC should approach maintaining an AI and DSI regulatory framework.

The Alliance would also like to commend ASTP/ONC for its work to review and update the information blocking program. Within the proposed rule, ASTP/ONC proposes changes to tighten the ability of actors to exploit exceptions to prevent the transmittal of patient data. We urge ASTP/ONC to ensure that future reviews of the information blocking exceptions account for the actors that rely on exceptions to reflect their information exchange capabilities, while also searching for opportunities to limit the ability for other actors to misuse those exceptions. These proposed changes demonstrate ASTP/ONC's focus on ensuring an environment exists where patient data flows freely to those who need it most, when they need it while also ensuring the information blocking program is suitable for all actors.

At the same time, the Alliance cautions ASTP/ONC from further altering the information blocking program and its exceptions once HTI-5 is finalized. With a continued state of change, it remains difficult for end-users to build strong compliance and education programs in preparation for future enforcement. Further changes will create additional burden and unpredictability, leading to an enforcement environment where an information blocking actor may be found non-compliant because of a confusing change made to the program. Programmatic consistency is the best way to attain high levels of compliance, and we believe this will be true for the information blocking program in the long-term.

We thank you again for the opportunity to provide our input on this important set of issues and welcome the opportunity to share more about the Alliance and discuss our work further. If you would like to schedule a follow up engagement, please contact American Healthcare Information Management Association's (AHIMA) Senior Director of Regulatory and International Affairs, Andrew Tomlinson, at Andrew.tomlinson@ahima.org. We look forward to collaborating with ASTP/ONC on issues relating to HTI-5 and other key interoperability matters.

**Appendix:**

- Document 1: Real-world Testing Consensus Statement[1]
- Document 2: Artificial Intelligence Consensus Statement[2]

[1] https://hitenduser.org/wp-content/uploads/2022/09/Real-world-testing-consensus-statement_FINAL.pdf
[2] https://hitenduser.org/wp-content/uploads/2025/04/Health-IT-End-Users-Alliance-Artificial-Intelligence-Consensus-Statement_Final-Formatted.pdf