February 27, 2025

Dr. Thomas Keane
Assistant Secretary and National Coordinator
Assistant Secretary for Technology Policy / Office of the National Coordinator for Health Information Technology
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Assistant Secretary Keane,

We represent provider organizations nationwide focused on balancing the use of standards-based electronic health record systems and trusted data to provide the best care possible to patients. Our organizations represent hospitals and providers both large and small that utilize certified health IT daily to enable the access, exchange, and use of patient health data to deliver high quality patient care. We thank the Assistant Secretary for Technology Policy / Office of the National Coordinator for Health Information Technology (ASTP/ONC) for the opportunity to respond to the proposals within the *Health, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI-5)* proposed rule. Our comments on the proposed rule are below.

Areas of Support

As providers of patient care, we share the goal of reducing burden on the frontline provider and related end-users while also seeking out new technologies to better enable that care. We applaud the efforts put forward by ASTP/ONC to reduce that burden while prioritizing the need for new innovative technologies. It is clear ASTP/ONC engaged in an overdue examination of the individual criteria within the Health IT Certification Program (Certification Program) to find areas of duplication and proposed to trim those to lower the burden of compliance.

Additionally, we applaud ASTP/ONC for doing a similar review of the information blocking program by prioritizing changes to clarify confusing requirements and cracking down on areas of the program exploited by some actors to prevent the movement of data. As ASTP/ONC engages in the robust enforcement of information blocking, we encourage ASTP/ONC to prioritize updates that control and limit exception misuse. We remain ready to collaborate with ASTP/ONC and other relevant agencies to ensure the information blocking program is implemented in the least burdensome and most comprehensive way to hold all actors accountable.

Further Recommendations

With the positive momentum spurred by many of the changes proposed in this rule, we believe there are several areas where ASTP/ONC can improve its proposals. We share ASTP/ONC's goal of modernizing the Certification Program and believe an updated program that considers our recommendations can ensure the healthcare system maintains a robust health IT landscape while also reducing burden and spurring innovation. As the final rule is developed, we encourage ASTP/ONC to consider burden for the whole of healthcare and seek ways to extend burden reduction activities, where appropriate, to all participants in the healthcare technology ecosystem.

Privacy and Security

The proposed rule makes multiple changes to the privacy and security standards included in the Certification Program. The proposed changes shift the ability for providers utilizing certified health IT to maintain the highest cybersecurity posture available to them. Removing section §170.315(d) Authentication, access control, and authorization from the Certification Program leaves providers who rely on these criteria vulnerable as it shifts responsibility for maintaining Health Insurance Portability and Accountability Act (HIPAA) compliance and safeguarding patient data on to them. We recommend ASTP/ONC preserve these criteria and instead search for ways to strengthen privacy and security requirements within the Certification Program.

The healthcare sector remains under constant threat of cyber intrusion. Patient data remains one of the most valuable commodities on the dark web for purchase. As a result, providers need all the tools available to them to protect that data. That includes a robust cybersecurity posture maintained by the technology storing the data itself. Within the proposed rule, ASTP/ONC states the certification requirements being removed are widely adopted. While this may be true, wide adoption does not guarantee these functionalities will remain part of the certified health IT product if the criteria are removed. Perhaps more concerningly, the removal of these criteria opens the door for developers to charge providers for the continued inclusion of these functionalities in these products. The assertion that developers cannot innovate due to the costs related to privacy and security mistakenly believes removal of the requirements removes the cost burden, when in reality, it shifts this burden to providers.

If these proposed changes are finalized as is, providers will be left to fend for themselves in finding and paying for appropriate privacy and security solutions. This will leave less resourced and solo practice providers at greater risk for intrusion and patient data theft, with disproportionate impacts on under resourced providers and vulnerable populations, including children and people with disabilities. While a certified health IT product is only one part of a provider's overall technology stack, ensuring the most robust portion of that

stack has basic privacy and security protections will relieve significant burden from providers, many of whom lack adequate resources to support these functions independently.

Transition from the Consolidated Clinical Document Architecture (C-CDA) to HL7 Fast Healthcare Interoperability Resources (FHIR)

Since the 21st Century Cures Act was signed into law, providers have been working with developers and policymakers to determine the best way to transition to a FHIR-based ecosystem. The fundamental principles of a FHIR-based ecosystem align with our goals as providers and end-users to be able to easily send discrete data in trusted formats with limited burden. Many of the proposed changes to the Certification Program in this rule accelerate the health system's progression to FHIR, but at the expense of ensuring a data exchange floor utilizing C-CDA is maintained.

C-CDA has been part of the bedrock of health data exchange since the advent of nationwide exchange. While document-based exchange is something all entities want to move beyond, removing the criteria from §170.315(b)(1) Transitions of Care, §170.315(b)(9) Care Plan, and other areas throughout the proposed rule that relate to C-CDA thrusts the health system into a world where systems can no longer support C-CDA-based data exchange, or are charged for access to C-CDA exchange functionality. This change would open the door for untested or immature FHIR standards being pushed into production environments with no safety net for exchange in the event those standards do not function or are not ready for use.

It is well-known that FHIR standards and exchange development have not progressed consistently. There have been problems related to Bulk Data Export and the ability for true two-way at rest exchange of patient data between organizations. Many of these challenges are still being addressed, even as new FHIR standard implementation guides for initiatives such as electronic prior authorization are being considered for finalization. With FHIR still in active development and basic questions on how it will function at scale still needing to be answered, we recommend ASTP/ONC refrain from removing C-CDA criteria from the Certification Program at this time.

Moving forward with these proposed changes exposes providers to the possibility of being charged for the continued use of C-CDA exchange technology, and exchange modalities that rely on C-CDA such as Direct Messaging. It is important to note that C-CDA is still regularly relied on by providers to exchange information when FHIR exchange is not available or not supported. Rural, less resourced providers, and providers utilizing certified health IT from smaller developers still rely on C-CDA as the primary exchange modality. If

these changes move forward as proposed, ASTP/ONC risks breaking the current data exchange landscape by excluding many provider settings from being able to exchange health data unless they pay additional fees or adopt new technologies. It is crucial that ASTP/ONC does not jeopardize existing data exchange capability via C-CDA. Instead, ASTP/ONC should preserve certification criteria that maintain the current level of interoperability while providing robust incentives for new technologies and standards to be adopted.

Long-Term ASTP/ONC Program Stability

ASTP/ONC's goal of ensuring the Certification Program remains up to date with trends in health IT and the current state of health data exchange nationally is laudable. Similarly, taking a continual look at the information blocking program to ensure it remains relevant and accomplishes its policy goals is crucial to ensuring widespread compliance. Despite these needed activities, we recommend ASTP/ONC take an approach that refrains from yearly, or more frequent, changes to these programs to foster a more predictable, consistent compliance environment.

In the past, ASTP/ONC programs have offered a more predictable regulatory environment, which allowed for all parties subject to these regulations the time to prepare and ensure they understand what is required. Similarly, it allowed organizations to ensure training and compliance materials are accurate and robust. Finally, this predictability ensured other federal programs, such as the Centers for Medicare and Medicaid Services (CMS) Promoting Interoperability program, had time to adjust compliance requirements for partner programs.

Many of the changes in the HTI-5 proposed rule upend this predictability. Several of the information blocking changes proposed reverse exceptions that were added a few years ago. Similarly, many of the changes in the Certification Program remove criteria that went into effect in recent years. Such changes create uncertainty and increase the compliance burden on organizations who must update internal policies and procedures, as well as retrain staff on new policies. Additionally, throughout the rule, it is noted that other HHS agencies will need to adjust compliance requirements to meet the updated proposed changes, without a corresponding plan for how those updates will be implemented. Lack of a predictable roadmap for how and when such updates will happen foster an unstable compliance environment and undermines effective planning, education, and or preparation for compliance activities.

As ASTP/ONC moves forward with additional rulemaking activity, we recommend the agency refrain from removing or changing existing requirements without thorough review

and public comment. The certification and information blocking programs have made progress in nationwide health data exchange and changing them without a robust plan or adequate notice threatens to disrupt future progress. Additionally, ASTP/ONC should ensure it is actively collaborating with all agencies within HHS impacted by changes to ASTP/ONC programs to ensure that further regulatory changes do not significantly impact the ability for entities subject to those programs to achieve compliance. We stand ready to assist ASTP/ONC to further outline the best path forward to creating a sustainable, predictable regulatory environment that minimizes burden for all parties.

Thank you for the opportunity to comment on the HTI-5 proposed rule. In our role as providers and end-users in healthcare we are committed to a dedicated focus on patient care and ensuring policymaking activities enhance that care by producing the best possible outcomes. We know ASTP/ONC shares the same goal of improving how patients receive care and the quality of care they receive. If you'd like to discuss our comments further or opportunities to collaborate to advance the health data exchange landscape, please contact Andrew Tomlinson, Senior Director of Regulatory and International Affairs, AHIMA at Andrew.tomlinson@ahima.org. Thank you again and we look forward to continuing these collaborations.

Sincerely,

American Academy of Family Physicians
American Academy of Pediatrics
American College of Physicians
American Health Information Management Association
College of Healthcare Information Management Executives
Medical Group Management Association
Premier Inc.