HEALTH INNOVATION ALLIANCE

October 8, 2024

Mr. Jarreau Vieira, Chief
Acquisition Rule-Making Branch
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Financial Resources
Office of Acquisition Policy
200 Independence Avenue SW
Washington, DC 20201

RE: RIN 0991-AC35

Submitted electronically via regulations.gov

Dear Mr. Vieira:

The Health Innovation Alliance (HIA) is pleased to submit comments to the 2024 proposed rule entitled *HHS Acquisition Regulation: Acquisition of Information Technology; Standards for Health Information Technology (HHSAW Case 202-001).* HIA is concerned with the implementation and impact of this rule, as well as the cost certification requirements will mean for entities that may not have adequate resources, as reflected in our comments below.

HIA is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers working together to improve health care through the commonsense use of data and technology. Founded in 2007, HIA has been a stalwart supporter of health information technology and interoperability, having worked on key legislation ranging from the HITECH Act to the 21st Century Cures Act.

This proposed rule, along with the Health Data, Technology, and Interoperability (HTI-2) proposed rule from the Assistant Secretary for Technology Policy / Office of the National Coordinator (ASTP/ONC), mark a significant shift in the Department of Health and Human Services' (HHS) treatment of health information technology standards. ASTP/ONC announced a "Health IT Alignment Policy" in 2022 to begin coordinating health IT activities across HHS.[1] That plan, along with the HTI-2 proposed rule and this acquisition regulation proposed rule, will begin to force actors across the health care system to use standards specifically adopted by the HHS Secretary. The HITECH Act passed in 2009 includes statutory language establishing the Office of the National Coordinator and its underlying duties, including setting standards and certification requirements for electronic health records (EHRs). The subsequent regulations established under these authorities set up the EHR Certification Program that was implemented as part of the Medicare and Medicaid Meaningful Use Program. HHS's use of HITECH authorities to require certification outside of electronic health records is new to this rule – 15 years after the original law passed.

HIA is concerned that HHS has underestimated the impact of this proposal. HIA also is unsure how HHS intends to implement the scope of the proposals: where do the lines of HHS funding end? Depending on how the Department implements the requirements proposed in this rule, contracts and agreements covered under

[1] *Available at:* https://www.healthit.gov/topic/hhs-health-it-alignment-policy

other HHS authorities, like those under Medicare's programs, could be implicated. HIA asks that HHS clearly delineate where the scope of this policy begins and ends so that stakeholders can determine whether they are implicated. Additionally, if the scope is left unclear, the interpretation could vary according to the political tide.

HIA urges HHS to clarify through clear guidance what contracts will be impacted by these policies and what contracts will not. A large part of the policy in this proposal applies to "health care providers, health plans, or health insurance issuers."[2] Because these three types of entities are numerous and their organization and structure vary, HHS must be very clear when and where a provider, plan, or issuer is subject to the rule. So far, the information provided has been inadequate to provide many organizations with sufficient clarity to advise their governing boards or corporate leadership. For example, HHS held a webinar on September 19, 2024, to provide more information to the public about this rule. However, the scheduled one-hour presentation contained only information verbatim from the rule, ended abruptly after 23 minutes, and did not provide the opportunity for questions from the audience.

Additionally, where HHS plans to require certified technology as part of direct federal contracting, HIA is concerned how these requirements will be implemented and whether they will pose undue burdens to those impacted. For example, many public health entities rely on grants and contracts from the Centers for Disease Control and Prevention, so technology acquired, updated, or implemented under those contracts would be covered by this new policy. However, many public health organizations are spread thin with their current resources to meet the growing demands of public health. HHS should clarify how it plans to implement requirements on these entities: does HHS expect public health organizations to reallocate resources from existing work to cover the cost of technology upgrades? HIA urges HHS to detail how and when certified technology will be required of contractors, grantees, and others covered by these proposals. We also ask that you outline a process for remediation or hardship exemption should contractors, grantees, or others not be able to afford certified technology without substantially altering the programs their contracts, grants, or other funding arrangements support.

HIA appreciates the aggressive stance HHS is taking to advance interoperability in health care. However, we are concerned that these policies are not tied to additional resources necessary to achieve success. We urge HHS to clarify the scope and extent of these policies, including where they will not apply. HIA is wary that other proposals on the Unified Agenda may be combined with this proposed rule, creating a market-wide mandate on the specific types of technology health care entities are able to acquire and use. Such requirements on the part of government have sweeping impacts on the development and availability of products in the marketplace. Should the scope of this rule be too large, many innovative technology companies may go out of business. HIA believes that government-dictated technology evolution benefits large companies at the expense of smaller ones, and we do not believe that the government operates at the speed of innovation. We urge HHS to reconsider these proposals to ensure innovative technology products may be developed and offered across the health care industry. We also ask that HHS provide guidance and clarity on the impact of these rules, including a reexamination of the finding that this proposed rule does not constitute an unfunded mandate and does not constitute a significant regulatory action.

We thank HHS for the opportunity to comment on this proposed rule, and we look forward to working with you to achieve health care interoperability while ensuring an appropriate balance of government regulation and private-sector innovation.

[2] 89 Fed. Reg. 65303, at 65305.

Sincerely,

Brett Meeks
Executive Director

CC:
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