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October 4, 2024

Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

Dear Dr. Tripathi,

Re: Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability

RIN: 0955-AA06

Submitted electronically via www.regulations.gov

Dear Dr. Tripathi,

athenahealth, Inc. ("athenahealth" or "athena") appreciates the opportunity to respond to the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule (HTI-2) by the Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health IT (ASTP).

As you are aware, athenahealth has built a network of approximately 385,000 healthcare providers in both the ambulatory and acute settings in all fifty states over the past 27 years. We provide electronic health record (EHR), practice management, care coordination, patient engagement, data analytics, revenue cycle management, and related services, such as Epocrates, to physician practices and hospitals. More than 155,000 providers utilize our single-instance, continuously updated, cloud-based platform to serve one-fourth of the US population. We also support on-premises software solutions. In both hosting paradigms, athenahealth seeks out and establishes connections with partners across the care continuum, enabling our clinicians to improve the quality of care they deliver.

athenahealth's vision is to create a thriving healthcare ecosystem that delivers accessible, high quality, and sustainable healthcare for all. We work towards this vision partially by reducing burdensome administrative tasks for providers so that they can focus on improving patient outcomes. We support ASTP's continued focus on the advancement of Certified Electronic Health Record Technology (CEHRT) utilization and improving interoperability. athenahealth is committed to a healthcare ecosystem where information exchange is the norm, not the exception. As we look forward, we must recognize that healthcare is undeniably better connected today than it was yesterday, and certainly than it was ten years ago. Ongoing policy and regulation should build on this progress through a balanced approach that ensures every stakeholder meets minimum standards while allowing those at the forefront of greater connectivity and interoperability to continue to push the envelope through innovative tools and functionality.

We would first like to offer some general comments on the HTI-2 proposed rule. athenahealth shares ASTP's vision for a strong healthcare ecosystem fueled by reliable technology and sound data. In the pursuit of this goal, we are convinced that ASTP rules must focus on the outcomes and not how technology vendors achieve them. Certification requirements should continue to be the industry floor. As technology evolves at an ever-increasing rate, we believe ASTP can be effective by continuing to allow flexibility for technology that advances beyond the floor certification criteria metrics and achieves the same result through a better process. This adaptability is important to sustaining an innovative regulatory environment and should be a focus in all ASTP regulations.

Second, as detailed in ASTP communications and strategic plan, we fully support the HHS Health IT Alignment Policy. The barriers that previously existed between CEHRT, other technology tools necessary for success in quality programs, and technology partners necessary to run a sustainable medical practice are all but gone. Clinicians and healthcare professionals rely on a multitude of technology and business tools every day. It is more important than ever for HHS to ensure all programs impacting clinicians and their technology vendors utilize mature technology standards, establish clear goals, and implement reasonable timelines. We strongly urge ASTP to proactively engage with stakeholders across the industry and government as HHS pursues better coordination in local, state, and federal agencies with private sector technology vendors.

Unnecessarily short and overlapping compliance deadlines can jeopardize the success of any policy or regulation. All of HHS must create compliance dates that account for development of new software tools, robust testing of the software, and customer implementation and adoption of the functionality. athenahealth has experience in both cloud hosted environments and on-premises solutions. While both situations need to build in time for end-user adoption, the on-premises world relies on the medical practice to perform the deployment. We ask that ASTP account for this additional process in setting compliance deadlines. This allows the entire industry time to build trustworthy technology, and the clinician end users have time to adjust to and adopt the new tools.

Third, ASTP must be part of the solution to physician burnout. In a recent Physician Sentiment Survey covering clinicians across the country using all EHRs, 93% of physicians reported that they feel burned out on a regular basis. Additionally, doctors report spending an average of 15 hours per week working outside their normal work hours.[1] The industry is on an unsustainable path. ASTP has a vital role to play to reduce this burden. Every certification criterion requires that athenahealth balance development resources for compliance requirements with customer requested functionality and opportunities to streamline low value tasks as identified by our network analysis. The certification program plays an important role in the healthcare system. The more that the criteria and implementation timelines can be aligned across HHS and made adaptable to future advances in technology and innovation, the greater impact it may have on reducing physician burnout.

In the HTI-1 Final Rule, ASTP moved away from an edition-based certification program towards a version-based model. athenahealth supports this change. ASTP detailed in the HTI-1 final rule the intent "to maintain a single set of certification criteria that have been updated to include the most recent versions of adopted standards, and to establish an incremental approach to health IT updates over time."[2] We support this goal and encourage ASTP to apply these guidelines for an appropriate cadence of rulemaking, scope of rules, and compliance timelines that account for software development, testing, and adoption. While the HTI-2 rule addresses many parts of the healthcare ecosystem, it is a complex rule with significant scope and depth and impacts stakeholders across healthcare.

It is with that context that we offer the following specific comments.

Revised Clinical Information Reconciliation and Incorporate Criterion
athenahealth supports a reasonable expansion of data for (b)(2). We believe that jumping from three data elements to more than one hundred at one time is unreasonable. As stated in our general comments, each of these measures takes technology vendors time to build, perform robust testing, and push adoption and implementation to clinician end users. Clinicians and staff have limited capacity to absorb new requirements. These requirements compete with patient time and other practice wide initiatives for limited resources. The proposal to include all USCDI v4 data elements is untenable for providers. Based on our experience with athenahealth clinicians, we strongly suggest a more iterative approach from the original data elements of problems, medications, and allergies, to also include immunizations, procedures, lab results, and clinical notes.

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[1] https://www.athenahealth.com/press-releases/us-physicians-surveyed-feel-burned-out-on-a-regular-basis
[2] HTI-1 Final Rule, Section III. ONC Health IT Certification Program Updates

Additionally, we are supportive of the automated trusted source solution. This is an example of ASTP's ability to allow for technology that supports providers by wicking away work where appropriate.

§ 170.315(f)(1) Immunization registries – Bi-directional exchange
athenahealth supports the goals in this criterion to improve information exchange with public health registries. To be successful with the measure, ASTP should create a clear road map that focuses on the value of the use cases and recognizes current industry challenges. As such, ASTP should finalize a more gradual implementation timeline to account for the broad range of resources available to public health registries.

Additionally, there are duplicative technologies incorporated into public health registry criteria. We encourage ASTP to focus on the § 170.315(g)(20) criterion that utilizes FHIR APIs. Today, EHRs typically send immunizations to registries when administered, as required by § 170.315(f)(1). The proposed criterion changes direct the public health agencies and EHR vendors to use an older technology in HL7 v-2 to support incoming immunization queries. These queries are better facilitated by FHIR. As such, we recommend the requirement for HL7 v2-based query responses for immunization data should be removed for the final rule. Consistent with our general comments regarding the need to future proof and implement mature standards, ASTP should focus on FHIR API queries in the § 170.315(g)(20) criteria in addition to the public health agency oriented § 170.315(f)(21)-(29) criteria.

New Imaging Requirements for Health IT Modules Imaging links
athenahealth supports ASTP's ongoing mission to increase electronic access to diagnostic images through CEHRT. However, we believe this proposed change is pre-mature because it could increase security vulnerabilities due to the lack of established/adopted industry standards for authentication of URLs. We suggest that ASTP remove this proposed change and revisit later with further stakeholder engagement.

Should ASTP decide to finalize this proposed requirement, we seek clarification related to HTI-1 (g)(10) API requirements in US Core 6.1 Diagnostic Report. How does this proposed requirement differ to what is already required in the media.link element, which is currently a "Must Support"?

Protecting Care Access Exemption
athenahealth fully supports the protecting care access exemption in the proposed rule. We applaud ASTP for proposing this update to adapt to the current nationwide regulatory climate and enable technology vendors and providers to confidently comply with state requirements. We urge ASTP to finalize this exemption.

We look forward to continuing to engage with your office on this important proposed rule and all health IT policy matters. Please do not hesitate to reach out directly by phone at 617-402-8516 or email gcarey@athenahealth.com.

Regards,

Greg Carey
Director, Government & Regulatory Affairs
athenahealth, Inc.