HEALTH INNOVATION ALLIANCE

June 20, 2023

The Honorable Micky Tripathi, Ph.D., M.P.P.
National Coordinator
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
7th Floor
Washington, DC 20201

Re: RIN: 0955-AA03 Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

Submitted electronically via regulations.gov

Dear Dr. Tripathi:

The Health Innovation Alliance (HIA) appreciates the opportunity to comment on the Health Data, Technology, and Interoperability (HTI-1) proposed rule.

Our comments highlight various provisions in the proposed rule and specifically recommend that prior to finalizing the proposed HTI-1 rule the Office of the National Coordinator for Health Information Technology (ONC):

- Carefully consider the timelines for transitions and implementation to USCDI Version 3 (v3);
- Work with developers to achieve the policy goals of patient privacy with the practical implications of delivering and coordinating patient care; and
- Defer regulation of technologies like artificial intelligence to the FDA and ensuring that any certification criteria do not subject EHR developers to unnecessary regulation as medical device manufacturers.

HIA is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers who support the adoption and use of technology and data to improve health outcomes and lower costs. HIA and our members have done tremendous work to improve interoperability, efficiency, and healthcare delivery while reducing burden within the healthcare system. We applaud the ongoing work by ONC to improve interoperability and update the programs that govern much of the technology used in our healthcare system. The comments and recommendations below are from HIA and do not reflect the individual views of our member organizations.

General Comments

HIA appreciates the direction of the HTI-1 rule and agrees with the goals to "advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information."[1] To

[1] Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule; 88 FR 23746; April 18, 2023.

foster an environment where interoperability can thrive, the laws and regulations governing health IT systems must remain up-to-date, prospective, and responsive to industry activity and advancements.

The U.S. Department of Health and Human Services (HHS) has proposed and finalized several rules to advance interoperability since the enactment of the 21st Century Cures Act over six years ago. With the increasing capabilities of technology deployed in this space, the ability for clinicians, payers, hospitals, patients, and others to share information continues to increase, but we still have a long way to go. In fact, a 2021 article cites ONC officials in reporting that about 70 percent of healthcare organizations use the fax machine as a primary method of communication.[2]

To better understand the interoperability needs of the healthcare system and to develop solutions to the issues faced by patients, providers, technology companies, pharmacies, and plans, HIA published our Interoperability Report including 21 specific solutions in six different policy areas. Specific to the focus of this rule, we urge you to consider policies that would:

- Allow patients to request all covered entities help find and share their health information to improve care coordination,
- Ensure clinicians have access to common-sense clinical decision support tools for care delivery and clarify software that is not subject to medical device regulation,
- Standardize public health information, including laboratory data, within the next two years, and
- Fund existing work to collect and standardize social determinants of health (SDOH) information to build toward consistent integration and use of the SDOH in clinical care.

We applaud the portions of ONC's proposal, such as including additional data classes and elements in USCDI v3, that support several of our recommendations.

Specific Comments

Transition to USCDI v3

To advance interoperability, in section III.C.1, ONC proposes to add the newly released USCDI v3 in § 170.213(b). We propose that USCDI v1 would remain in regulation and now be codified in § 170.213(a) and we propose to add USCDI v3 to § 170.213 (to be codified as § 170.213(b)). We also propose to incorporate by reference USCDI v3 in § 170.299 as of the effective date of the final rule. In addition, we propose that the USCDI v1 (July 2020 Errata) in the USCDI standard in § 170.213(a) will expire on January 1, 2025. Under this proposal, both versions would be referenced as applicable in the USCDI standard in § 170.213 for the time period up to and including December 31, 2024.[3]

USCDI v3 expands upon several existing data classes and adds 24 new data elements to USCDI v2 in areas such as health insurance information, laboratory, patient demographics, and health status. HIA agrees with the proposed expansion of USCDI to increase the availability of standardized data in the health care system, but we caution ONC to carefully consider, now and in the future, the timelines for transitions and implementation as well as the need for clarity on the specific data elements, the standards, and implementation guides to be used.

[2] *Available at* https://news.bloomberglaw.com/health-law-and-business/health-care-clings-to-faxes-as-u-s-pushes-electronic-records.
[3] *Ibid.* at 23751.

The effective date for USCDI v3 is the date of the final rule, and the current version (USCDI v1) will expire less than 18 months later. All applicable entities need adequate transition time to ensure compliance with the addition of new elements. HIA urges ONC to carefully consider the timeline requests of those entities prior to the final rule publication. For any element included, HIA encourages ONC to provide sufficient guidelines and definitions to minimize any chance for multiple interpretations of the information that could impact patient care and coordination.

Decision Support Interventions (DSIs) and Predictive Models

We propose the certification criterion, ''decision support interventions (DSI)'' in § 170.315(b)(11). The DSI criterion is a revised certification criterion as it serves as both an iterative and replacement criterion for the ''clinical decision support (CDS)'' criterion in § 170.315(a)(9). We believe that the continued evolution of decision support software, especially as it relates to AI and ML-driven predictive models, necessitates new requirements and a new name for the Program's CDS criterion.[4]

Overall, HIA supports the direction and goals of the proposed change from "Clinical Decision Support" criteria to "Decision Support Interventions," and we agree that with the technological advancements in predictive analytics and machine learning, the certification criterion needs to be updated to better reflect what is available in the market.

While we support the direction ONC is headed with this rule, there are several areas that we encourage ONC to revisit, reevaluate, and revise prior to the rule being finalized, including:

- Implementation Timeline,
- Clarification of Certain Definitions,
- Source Attribution,
- Intellectual Property,
- Innovation, and
- Coordination across the Department.

We encourage ONC to provide developers adequate time to meet the specifications for compliance. Developers will not be able to make progress toward compliance until they know the rules they will be held to in the final rule, and they should be given enough time to comply with this new proposal along with the other certification updates.

Clear definitions as to what falls inside and outside the scope of DSIs are extremely important for correct implementation and mitigation of confusion and unintended consequences. HIA urges ONC to consider the addition of qualifying language to ensure that certain technologies are not caught up in DSI and potential regulation as a device. For example, DSI's definition could specify that it is intended to capture capabilities normally associated with human intelligence or perception, such as natural language processing or visual analysis, and not back-end processes and efficiencies.

HIA agrees that transparency in source attribution is important. The end-users of the DSIs should have confidence in the integrity of the tools they are using. To maintain trust in the information provided by DSIs, users should be able to trace back the source of the predictive DSI in use or note which portions were developed by a third-party. These tools have great potential, and transparency is needed to check against potential bias and provide input for the developer to course-correct as needed.

[4] *Id.* At 23781.

While HIA believes transparency is important, ONC should take care to specify the information required by these proposals does not include confidential information such as intellectual property. Many of the technologies used for decision support are proprietary, and ONC should avoid the potential that this proposal is interpreted as mandating the sharing of intellectual property.

ONC should also consider the balance of fostering an environment of innovation in health care with its desire for transparent information related to clinical decision support. Congress acted in the Cures Act to ensure the Food and Drug Administration (FDA) does not regulate certain types of clinical decision support software, yet FDA issued a final guidance last year treating many such technologies as medical devices. ONC seems to be cataloging a list for potential FDA regulation, and HIA cautions ONC against rushing forward with a policy that, however well-intended, could lead to chilling innovation.

Finally, the FDA's authority to regulate medical devices is adapting to the rapid pace of technological advancements, and it is wise for ONC to adapt the certification program to cover the increasing sophistication of developer technology. However, close coordination across HHS is necessary to ensure that these policies are implemented and executed correctly. HIA urges ONC to defer regulation of technologies like artificial intelligence to the FDA to avoid duplicative regulation and ensure that any certification criteria do not subject EHR developers to unnecessary regulation as medical device manufacturers.

Patient Requested Privacy

HIA appreciates ONC's proposal to require developers to implement capabilities to execute the HIPAA requirement that patients can request restrictions on their disclosure of their protected health information. However, implementation of such a requirement may be difficult or impossible. HIA urges ONC to work with developers to achieve the policy goals of patient privacy with the practical implications of delivering patient care and coordinating care between providers. Congress and HHS have gone to great lengths to improve interoperability and the availability of health information to those who need it, as ONC is acutely aware. Segmenting some patient information from records will lead to incomplete information to provide care and could lead to patient harm. HHS is in the middle of implementing a change to the 42 CFR Part 2 privacy protections following an act of Congress and the pleading of the healthcare community for decades. Those changes are being made to prevent opioid deaths due to incomplete information at the site of care. HIA urges ONC to balance the need for an accurate and complete record to deliver patient care with the need to maintain patient privacy and honor the patient's wishes.

Real Time Prescription Benefit (RTPB) Request for Information

We intend to propose in future rulemaking the establishment of a real-time prescription benefit health IT certification criterion within the Program and include this criterion in the base EHR definition in § 170.102. We intend to propose a criterion that would certify health IT to enable a provider to view within the electronic prescribing workflow at the point of care patient-specific benefit, estimated cost information, and viable alternatives. We are also considering a proposal to adopt and reference the National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit (RTPB) standard version 12 as part of the potential certification criterion.[5]

Having cost information available at the point-of-prescribing is essential to provide prescribers with the information needed to make informed prescribing decisions including patient-specific cost and drug

[5] Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule; 88 FR 23848-9; April 18, 2023

utilization requirements such as prior authorization and step therapy. This information also facilitates a conversation between the patient and prescriber to help ensure medication adherence, which starts with the patient being able to afford the medication at the pharmacy counter. For these reasons, HIA has supported the CMS regulations implementing and expanding real time benefit tools (RTBTs) and the inclusion of the RTBT requirements in the 2012 Consolidated Appropriations Act.

The statute amends the definition of qualified EHRs to include the capability of RTBTs, and we support the adoption of certification criteria to that effect. We also support referencing the NCPDP RTPB standard as part of that criteria as it is the industry tested and adopted standard for provider facing RTBT. The version referenced in the HTI-1 proposal is currently in use in the industry, but we urge ONC to allow for a newer version (version 13 or later) to be adopted in the final rule or for there to be express allowance of updating newer versions in the final rule.

Thank you for your careful consideration of our comments and your continued work to improve our healthcare delivery system.

Sincerely,

Brett Meeks
Executive Director