



June 20, 2023

The Honorable Micky Tripathi
National Coordinator for Health IT
U.S. Department of Health and Human Services
Attention: Health Data, Technology, and Interoperability: Certification Program Updates,
Algorithm Transparency, and Information Sharing Proposed Rule
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

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

Comments submitted electronically via www.regulations.gov

Dear National Coordinator Tripathi:

The American Medical Informatics Association (AMIA) appreciates the opportunity to comment on the ONC Notice of Proposed Rulemaking (NPRM) on Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing. AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who bring meaning to data, manage information, and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

General Comments/Observations

We appreciate ONC taking into account our prior comments supporting enhanced harmonization of policies among agencies including the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), and the Centers for Medicare and Medicaid Services (CMS). We also strongly support the use of updated vocabulary standards as found in the most current versions of SNOMED CT, LOINC, CDC race and ethnicity standards, etc.

AMIA appreciates ONC's goal of building on the digital foundation to make interoperability easier through bolstering the use of FHIR API requirements, promoting information sharing, and ensuring appropriate use. We recognize much of this rule is geared toward developers of health information technology, and establishing an approach that will reduce burden yet spur advancements. Our concerns are primarily directed to the time and resource constraints needed for hospitals and health systems to collaborate with health information technology developers to effectively implement provisions proposed in this rule making.

We have overall concern about the ability of any stakeholder to meet the January 2025 timeline especially given that many hospitals and health systems do not have the resources to implement these rules. Hospitals and health systems will need a clear value proposition for what operational effects and improvements will result for end-user clinicians because of these certification requirements. We have further concerns about not seeing the overall picture of effort required in the near future, given that two additional ONC NPRMs are expected to be released in 2023. This makes it more difficult to submit meaningful comments on ONC's proposed overall regulatory scheme.

A central concern is the limited information to date on the impact of adding new source attributes and requirements to clinician documentation, with the unknown impact on documentation burden. There is also a critical need for information on the intended plan for measuring the impact on clinicians after implementation of these attributes with the resulting changes in workflow, including how burden may be unintentionally shifted between members of the clinical team.

Overall, the timeframe provided should integrate estimates of the amount and type of end user clinician involvement, as well as the current capacity and expense for end user engagement given the current workforce constraints our hospitals and health systems are experiencing. If the end users are not at the table, there is a risk that the implementers will move forward to meet deadlines without taking usability and workflow considerations into account – which could potentially lead to further documentation burden on clinicians (including but not limited to burden shifting within the clinical hierarchy) and potential adverse impact on patients.

Finally, we understand the desire of ONC to create a new naming convention for the ONC rules. We do, however, have concerns about renaming terms that are commonly understood among industry professionals. For example, ONC states it intends to refer to the Condition and Maintenance of Certification associated with the “EHR Reporting Program” as the “Insights” Condition and Maintenance of Certification (also referred to as the “Insights Condition”) throughout this proposed rule. The term “Insights Condition” is already causing confusion, and we urge ONC not to introduce new terminology when there is already an established body of regulation that includes reference to the EHR Reporting Program.

USCDI v3

AMIA believes USCDI serves as an important foundation for advancing interoperability, and we support efforts to establish USCDIv3 as the baseline data set. We understand that ONC is looking to keep moving forward to develop needed functionality at an appropriate cadence for industry. We also understand that ONC is looking to publish a final USCDI v4 later this summer. We are concerned that this pace is unsustainable for all stakeholders and will only increase the level of regulatory burden. We encourage parallel and coordinated development of the USCDI and FHIR Resources.

Although a move to USCDI V3 is warranted, we advocate for incremental advancement to reduce the amount of burden to all stakeholders. In the spirit of true interoperability, we believe that pre-work to understand where the V3 data elements are currently collected is critical. These V3 data elements should not be re-collected, but rather focus should be on transferring them from the original source. The additive nature of data elements without considering where it is collected already is currently causing issues with duplicative documentation and misaligned/incorrect data and leads to a greater documentation burden. Additionally, there is a risk of shifting the burden of increased reporting to the end users with the rapid turnaround time to maintain compliance. We propose a test or pilot trial to ensure that the burden of CDA reporting is not shifted further downstream when USCDI V3 is implemented. For example, if there was a case of the end user entering information that did not adhere to a standard, how would the resolution between the two be accomplished? Would that process involve increased burden on the clinician or administrative staff or others?

Decision Support Interventions (DSI)

Information overload and cognitive burden for individuals and care teams is of great concern related to documentation burden. We recommend a united approach to standardizing, capturing and sharing source attributes that doesn't rely on each organization crafting their

own documentation process. Also, this information must be strategically embedded within clinical workflows and translated to generalizable CDA reporting. Without standardization and strategic placement, providers moving across organizations will experience the added stress of learning each organization's method of addressing DSI, compounding documentation burden.

The proposed new requirements that focus on data transparency with DSI tools are critical and important. While the proposed new requirement highlights that "source attributes" be in "plain language descriptions," better guidance is needed on the level of detail required in these descriptions and specification of "plain language descriptions" for what audience, e.g., developers, clinicians, and other end-user stakeholders. Better clarity regarding source attribute reporting that includes why and how the ONC requires this documentation is suggested.

Given that many DSI tools may be created by other parties, the requirements and specifications for source attributes for the "other parties"- DSI tools used in certified health IT will require better communication and monitoring on the part of ONC for these tools. Better guidance to "other parties" that provide DSI tools in certified health IT systems edges on the boundaries for regulation of medical devices regulated by the FDA. Thus, consideration of better collaboration to determine requirements for source attribute reporting for DSI tools by "other parties" that interface with certified health IT should align with FDA guidance and regulatory standards.

The Predictive DSI definition is a good started, however given the inherent complexity of predictive modeling analytics, the ONC might consider convening a multi-stakeholder group of bioinformaticists, computational scientists (e.g., statisticians, mathematicians, computer scientists), clinicians (both non and formal informaticians), outcomes researchers, actuaries, and other experts in predictive modeling to collectively define what predictive DSI means in the context of ever-evolving analytics tools and innovations in big (and small) data analytics.

While the proposed rule text requests comments focused on attestation, the ONC should organize, support, supervise, and sponsor supervised efforts to engage the relevant predictive modeling stakeholders in defining terms and processes for predictive DSI tools in certified health IT systems. The suggested ONC-sponsored and supported stakeholder engagement can also help better define the terms "enables" and "interfaces" as on the surface they are simplistic, however not clear how they guide end-users who will use the "enabled" predictive DSI tool or developers who program and leverage certified health IT standards to "interface" with systems.

One important element of predictive DSI tools that ONC does not appear to address in the request for comments are transparency requirements for predictive DSI tools regarding their

accuracy and validity. Predictive modeling has its complexities (<https://beei.org/index.php/EEI/article/view/4373/3101>), thus while the ONC is providing rules for how these tools can be certified, the current request for comments does not explicitly indicate that the ONC has considered the complex processes in creating, validating, reporting, and interpreting predictive DSI. Thus, another suggestion for the ONC to sponsor and support engagements with multi-stakeholders to prioritize and organize relevant standards for these inherently complex tools that have the potential to both do good and harm. Other JAMIA references that discuss the complexity of predictive modeling to consider include: <https://academic.oup.com/jamiaopen/article/6/2/oad028/7150783>, <https://academic.oup.com/jamia/article/29/5/983/6511611>,

Information Blocking

ONC should more fully clarify what is meant by "Offer Health IT." It is increasingly common for hospitals and particularly health systems to extend use of their information management platforms including EHRs to community facilities and providers with whom they share patients. While such sharing clearly facilitates access to clinical information across a clinical continuum and promotes continuity of care, does such sharing subject the host facility to potential "developer" penalties?

Additionally, we encourage ONC to ensure that definitions of "Offer Health IT" and "Health IT" align across the federal government's regulatory framework. ONC should also define its reference to "certain donation and subsidized supply arrangements."

It would also be beneficial for ONC to define the term "health care provider" as referenced in the rule text: *'health care providers who self-develop certified health IT would continue to be excluded from this definition if they supply their self-developed certified health IT to others under arrangements excluded from the definition of what it means to offer health IT.'*

With regard to the *Infeasibility Exception*, what is the burden of proof on the "actor" under this exception?

Clinical Decision Support Hooks Request for Information

ONC seeks input on whether to require certified health IT systems to adopt the CDS Hooks FHIR Implementation Guide v1.0 as part of the requirements in the Program. AMIA member

feedback suggests CMS Hooks is not user friendly and is burdensome for the end user clinician to navigate. It requires substantial configuration and lacks utility and function.

Thank you for your consideration of these views. Please contact Reva Singh, JD, AMIA Vice President, Public Policy, at rsingh@amia.org, with questions or for additional information.

Sincerely,

A handwritten signature in blue ink that reads "Gretchen P Jackson". The signature is written in a cursive, flowing style.

Gretchen Purcell Jackson, MD, PhD, FACS, FACMI, FAMIA
President and Board Chair, AMIA
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