June 20, 2023

National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street, S.W., Washington, D.C. 20201

Re: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule

Submitted electronically at: http://www.regulations.gov

Dear Dr. Tripathi:

As nursing stakeholders, the Alliance for Nursing Informatics (ANI) is pleased to offer comments on the ***Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule* (hereinafter the "HTI-1").**

The Alliance for Nursing Informatics (ANI), cosponsored by AMIA & HIMSS, advances nursing informatics leadership, practice, education, policy, and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a collaboration of organizations representing more than 25,000 nurse informaticists and bringing together 29 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and collaborates with the more than 4 million nurses in practice today.

ANI has previously commented on ONC efforts related to interoperability standards and implementation specifications, including the USCDI v1, v2, v3, v4 and the Trusted Exchange Framework and Common Agreement (TEFCA).[1] We appreciate the opportunity to advance health IT standards that support high-priority target areas, including workforce burden, health equity, and underserved communities. In addition, we applaud the prioritization of the interoperability standards focused on areas referenced by the 21st Century Cures Act and in The Future of Nursing 2020-2030 report.[2]

We support the continued standardization efforts from ONC, and the majority of the proposed changes.

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[1] Alliance for Nursing Informatics Statements and Positions. (2023). https://www.allianceni.org/statements-positions

[2] Wakefield, M., Williams, D. R., & Le Menestrel, S. (2021). *The future of nursing 2020-2030: Charting a path to achieve health equity*. National Academy of Sciences. https://nap.nationalacademies.org/resource/25982/Highlights_Future%20of%20Nursing_4.30.21_final.pdf

General Comments

ANI is encouraged by the retraction of episodic timeframes in favor of establishing clear timelines associated with the specific criterion or standard to align program requirements. We are in agreement with the benefits including accelerated adoption of USCDI v3 and subsequent versioning. This measure reduces the burden and stress related to versioning mismatch providing customers with more timely technology updates. Additionally, our previous support of renaming the original "provider identifier" to "care team member identifier"[3] includes the endorsement for the inclusion of the use of the National Council of State Boards of Nursing (NCSBN) ID maintained and supported by the NCSBN, to identify nurses as members of the care team.[4] The move to annual updates and the recent NCSBN ID mapping to LOINC strengthens the adoption and incorporation of the NSCBN ID into the USCDI v4[5]

Our comments continue for the specific following sections:

DSI Proposals

ANI supports the renaming of clinical decision support (CDS) to predictive decision support intervention (DSI) to reflect contemporary and emerging functions, uses and data elements. While we applaud ONC's efforts to improve transparency on how predictive DSI is designed, developed, trained, evaluated, and should be used, we provide the following considerations:

1. Maintaining the evidence base – our membership questions whether each organization will have the capacity to maintain the evidence necessary to operationalize predicative DSI requirements independently. A central body providing oversight for research generation and translation for practice should be considered with distribution of recommendations to the vendor community and healthcare organizations.

2. Concern for clinician burden - although we agree with improved transparency, we believe that adding this functionality to the EHR may impact the cognitive load of clinicians and general EHR usability. We encourage the thoughtful design and thorough testing of any infobutton-like additions to the EHR.

3. Concern for EHR vendor burden – predictive DSI attestation will require vendors to streamline what is already provided to customers. As customers request new DSI, we would like to suggest standardized vendor templates that can be shared with customers to streamline the process. In addition, we believe there should be guidance included around customer modification of vendor-created DSI and if permissible, what process should be followed.

Insights Conditions

The insights conditions proposal introduces standardized measurement, which may support provider and health care organization evaluation and comparison of health IT capabilities. However, several proposals contained within the Insights conditions may present

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[3] Alliance for Nursing Informatics Comments. (2023, April 17). United States Core Data for Interoperability Draft Version 4. https://docs.google.com/document/d/12S6jw4dQc60KuowPPKVQ86xDQOYauoht/edit

[4] National Council of State Boards of Nursing. (2023). https://www.ncsbn.org/

[5] National Council of State Boards of Nursing (NCSBN) ID LOINC Code (2023). https://loinc.org/101114-7

implementation challenges that we recommend ONC consider.

1. The proposed timeline for reporting would have vendors collecting data in calendar year 2024 for reporting by April 2025. Given the short timeframe between rule finalization and the reporting period, combined with increasing digital measure reporting requirements from CMS in calendar year 2024, these somewhat competing efforts may limit the ability of vendors as well as implementers in health care settings to effectively meet both ONC and CMS' measurement aims effectively.

2. The proposed measurement method allows aggregation of performance results across multiple product versions. This approach would limit the utility of the performance measures for consumer use, as the mean performance across product versions could be high while the version-specific performance may be low.

Information Blocking

ANI supports ONC's modification of the definition to distinguish "health IT developer of certified health IT"[6] from health care providers who self-develop certified health IT for their own use to be excluded from the "Offer Health IT" definition. This combined with the removal for the period of time for USCDI data element representation, will support adoption of enhanced health IT solutions to improve care delivery without threat of penalty.

Impacts for Patients and Caregivers

ANI supports the accelerated adoption of USCDI v3, which includes the addition of important classes of information to support person-centered care, including sexual orientation, gender identity, health insurance information, and health related social needs. When USCDI v3 was initially proposed, we provided comment raising concerns that the included data classes both conflated and incompletely represented data needed to accurately represent intersecting identities, including SDOH data elements, and encouraged alignment with the HL7 Gender Harmony Project.[7,8] We propose adding the following data elements "Recorded Sex or Gender," "Sex for Clinical Use," "Name to Use" and "Pronouns" to the "Patient Demographics and Observations" certification criterion, in alignment with recommendations of the HL7 Gender Harmony Project.

Additionally, we believe the proposal to adopt the FHIR US Core version consistent with USCDI v3 will support interoperable collection and use of SDOH data, including SDOH observations, assessments, and responses to screening questions. US Core version 6.0.0, published in May after the release of the HTI-1 NPRM, enables exchange of findings on standardized SDOH screening instruments, consistent with the USCDI v3 data classes. However, the patient requested restrictions introduced in § 170.315(d)(14) may prevent sharing of data necessary for

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[6] Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs For Health Information Technology, Statutory Basis and Purpose, §170.100 Applicability (2010, January 13) https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170

[7] Alliance for Nursing Informatics Comments. (2022). United States Core Data for Interoperability (USCDI) v3. https://www.allianceni.org/sites/allianceni/files/ani-comments_uscdiv3.4.22.pdf

[8] HL7 Gender Harmony Project. (2022, November 16). https://confluence.hl7.org/display/VOC/The+Gender+Harmony+Project

emergent or whole-person care. A consequence requiring further exploration will be how patient flagging of data impacts the utility of exchanged data for care coordination, care transitions, and emergency care. For example missing medication or diagnosis data may impact the accuracy of CDS/DSI which could impact the quality and safety of care provided to the patient, particularly when data are shared with third-party DSI. Additionally, patient requested restrictions may significantly impact the quality of data available for secondary use of data for population health, research, and quality improvement.

In conclusion, we fully support a robust data infrastructure that includes the standardization of data elements, transparency, and data in the hands of patients and caregivers. Thank you for the opportunity to comment.

Sincerely,

Susan Hull, MSN, RN-BC, NEA-BC, FAMIA
ANI Co-chair

Nancy Beale, Ph.D., RN-BC
ANI Co-chair

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