June 10, 2024

Micky Tripathi, PhD, MPP
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue SW Washington, DC 20201

Submitted electronically to:
https://www.healthit.gov

Re: Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action

Dear National Coordinator Tripathi:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC’s Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action. We appreciate ONC’s on-going effort to support optimal, equitable whole-person care for all Americans and to drive innovation in health IT through Health Equity by Design (HEBD) and other efforts. Health equity is at the heart of a well-functioning health care system. HL7 notes the reference in the Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action regarding the critical role HL7® FHIR® standards have played in narrowing the health care digital divide through ONC adoption of a uniform standard for exchange to help address challenges created by the digital divide (HL7 FHIR Release 4) and ONC adoption of certification requirements for health IT that include FHIR-based application programming interfaces (APIs). It has been our organization’s honor to fundamentally support care and outcome improvements and to aid HHS in its health IT initiatives leveraging HL7 FHIR standards, enabling better electronic capture and exchange of clinical data. HL7 looks forward to fruitful and expanded collaboration.

As you know, HL7 is the global authority on health care interoperability and a critical leader and driver in the standards arena with more than 1,600 members from over 50 countries. As such, we stand ready to continue partnering with ONC and other U.S. federal and international leaders to make the goals outlined in the Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action a reality.

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1 Office of the National Coordinator for Health Information Technology, Advancing Health Equity by Design and Health
Below is HL7’s feedback regarding this document. It reflects the perspectives of HL7’s leadership, Policy Advisory Committee, Work Group and Accelerator communities and the HL7 AI Taskforce. Specific HL7 efforts of the Gravity Project, Gender Harmony Project and HELIOS are also highlighted.

Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and offer our assistance to ONC.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
HL7 International

Julia Skapik, MD, MPH
Board of Directors, Chair
HL7 International
HL7 Response: Advancing Health Equity by Design and Health IT

HEBD Approach: HL7 Perspectives
Below are HL7 observations and recommendations on sections outlined in the Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action.

Section I: Health Equity by Design (HEBD) for Health Information Technology

ONC HEBD Vision
“ONC envisions HEBD as a systematic approach in which health equity is considered at each phase of health IT system design and at every stage of policy and implementation to help mitigate widespread inequities in health and care systems. The use of an HEBD approach with health IT ensures that equity considerations are identified and incorporated as a core principle in the design, build, and implementation of health IT systems, and the resulting health IT products and capabilities are foundationally equity enforcing. Even if one cannot yet build and meet all needs now, through HEBD one can anticipate and consider the diversity of uses and users and not inadvertently build in inequities and significant barriers to future uses and iterations.”

ONC HEBD Objectives
- Health IT, its workflows, and accompanying policies are focused on helping eliminate disparities in health and care access and contribute to equitable health outcomes;
- Health IT systems are designed to identify and quantify disparities and can be utilized to target “upstream” causes to prevent avoidable “downstream” health care conditions such as an advanced disease state or episodic health crisis;
- Federal authorities related to interoperability, health care data standards, certification requirements for health IT, and health IT coordination improve health equity consistent with this approach.

HL7 Perspective
Overall, HL7 supports ONC’s approach to HEBD and to ONC’s Call to Action catalyzing “efforts to advance and incorporate HEBD in health IT nationwide and for private- and public-sector health stakeholders and federal partners to apply an HEBD approach and to integrate health equity as a core principle now when designing, building, and implementing health IT policies and health IT systems and uses.”

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2 Office of the National Coordinator for Health Information Technology, Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action, p. 5 (April 2024)
3 Office of the National Coordinator for Health Information Technology, Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action, p. 3 (April 2024)
health equity consistent with this approach.” HL7 will work with and inform ONC -- as appropriate -- so that our organization’s standards and projects support this goal.

HL7, its Work Groups and Accelerators touch on diverse aspects of the Advancing Health Equity by Design and Health Information Technology Roadmap and ONC’s HEBD approach. Our organization urges ONC to seek out HL7 leadership and experts as needed and by topic as it relates to its ONC’s HEBD approach and related matters. More information about specific HL7 Work Groups and Accelerators can be found at:

http://www.hl7.org/Special/committees/index.cfm?ref=nav
http://www.hl7.org/about/fhir-accelerator/

HL7 Work Groups cover a diverse stakeholder spectrum. Given the centrality of patients to the health equity by design issue, we note HL7 Work Groups on Patient Empowerment, Care and Administration. More information can be found at:

http://www.hl7.org/Special/committees/patientempowerment/index.cfm
http://www.hl7.org/Special/committees/patientcare/index.cfm
http://www.hl7.org/Special/committees/pafm/index.cfm

HL7-enabled patient access APIs underpin efforts to eliminate health care disparities and encourage bi-directional patient information flow. Our patient-focused Working Groups continue to make innovative strides in enhancing API capabilities and providing useful tools, needed resources and education. HL7 will continue to work with ONC on these issues.

Many lessons can also be learned from HEBD and Health Information Technology initiatives globally. HL7 has a robust Affiliate and international community, which can share valuable wisdom with ONC and other relevant agencies. HL7 International Council and community information can be found at:

https://www.hl7.org/Special/committees/international/overview.cfm

Section 2: Health Equity by Design Across the Nation’s Health Ecosystem

ONC Key Questions

- What ways do you design and integrate health equity in health information technology, exchange, and use, across your work in health care and delivery?
- What are the exemplars and lessons you would share with ONC in your feedback?
- What are your immediate priorities for health equity by design, and your long-term priorities?
- What are the leading barriers to health equity and health equity by design that you experience in your efforts? How do you think ONC can help?

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4 Office of the National Coordinator for Health Information Technology, Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action, p. 6 (April 2024)
HL7 Perspective
HL7 is a pro-active leader in optimizing the seamless, interoperable delivery and experience of care throughout the health care continuum. Our organization also collaborates with world-leading public and private sector organizations to make this vision a reality. HL7’s work in supporting more equitable, high-quality, and expanded care, while eliminating health disparities is particularly relevant to the Advancing Health Equity by Design and Health Information Technology Roadmap and ONC’s HEBD approach. Health equity and disparities are highly complex, sprawling and swiftly moving areas in health care. HL7 and leaders of the Gravity Project and HL7’s Gender Harmony Project stand ready to provide expert insight and perspective on this. Gravity Project and Gender Harmony Project background is on-line at:
https://www.hl7.org/gravity/
https://confluence.hl7.org/display/VOC/The+Gender+Harmony+Project

HL7 notes an example of progress and inroads on these issues: a new global initiative to categorize and standardize health related social needs information into electronic health records (EHRs), an ambitious project to integrate social needs data into clinical care to more effectively address health inequities being tackled by the Gravity Project, Logical Observation Identifiers Names and Codes (LOINC), HL7 and the Regenstrief Institute. More information can be found at: https://www.regenstrief.org/article/loinc-receives-4-million-address-health-inequities-ehrs/. HL7 looks forward to increased collaboration with HHS and other relevant agencies on these issues.

HL7 and Artificial Intelligence
It is noted in the Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action that Artificial Intelligence (AI) and machine learning holds the potential to address “the many kinds of bias that can cause health inequity”5 and that special effort should be made to design such algorithms and technologies to avoid such bias.

The rapid evolution of machine-based systems that can make predictions, recommendations, or decisions influencing real or virtual environments for a given set of human-defined objectives; and the incorporation of these technologies into health care practice, health IT tools, and individuals’ everyday lives. Below are HL7 insights and feedback on AI and concrete ideas about how ONC, HHS and HL7 can work together on this important issue.

While the latest iteration of AI methodologies, Generative AI, has succeeded in capturing both the attention of the public and policymakers – identifying how GenAI, combined with other AI methodologies developed throughout the years, will transform the future of health care services remains yet unsolved.

5 Office of the National Coordinator for Health Information Technology, Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action, p. 9 (April 2024)
Amid this background, HL7 remains committed to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services. First— with regards to the *Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action* and AI -- HL7 highlights the need for a robust framework to research, test and monitor the equity and bias of AI implementations in health care. This also acknowledges and addresses the fact that models built in one context may not be either appropriate or stable for use in other contexts.

HL7 is also committed to reducing bias and addressing equity issues in health care and this extends to AI. One of HL7’s key strengths is its focus on interoperability of health data – something that the latest zeitgeist of AI and in particular -- GenAI-- currently does not focus on, given several GenAI producers are focused more on advancing their own solutions versus interoperability with other extant and new products and services in the health care domain.

Second--with regards to *Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action* and AI -- there are multiple areas where HL7's core focus on interoperable health data standards, combined with AI (of various methods), can advance meaningful projects. These include five potential collaborative, ONC and/or HHS-funded projects which are:

1. Extending HL7’s existing standards framework to facilitate traceability on how inputs or outputs from either a set of humans or a machine may have then been taken by a separate set of humans or a machine as part of a health care services delivery flow. Such communication would need to be both machine understandable and human understandable, facilitating understanding of who (both human and machine) contributed to decisions made impacting clinical practice and the management, delivery, and evaluation of health services.

2. Extending HL7’s existing standards framework to facilitate interoperable communication of what system, what data sets, and/or what AI model was employed to produce a set of outputs by an AI system operating within a larger, interoperable health care environment. Such communication would need to be both machine understandable and human understandable, perhaps informing a brief “information card” that could be shown to health providers, clinicians, and patients. This could include identification and linking AI-powered narrations from structure data and/or clinician inputs.

3. Extending HL7’s existing standards framework to include links to a directory of Apps or Systems generating different AI outputs (to include decision support interventions, computer vision assessments of an image, etc.). This likely would not be a registry that HL7 maintains, but rather a nomenclature in which providers could facilitate registration and traceability of what systems were involved in the management, delivery, and evaluation of health services.

4. Extending HL7’s existing standards framework to facilitate interoperable data standards ranging from cryptographic watermarks to universal proofs of provenance that add a small
identifier/digest to each FHIR Resource to identify the source and source type for both traceability and fraud detection purposes, akin to attesting digitally that a data set or set of outputs were “genuinely created by this app on this date/time during health care provision in this location, and you can confirm by clicking here”.

5. Extending HL7’s existing standards framework to facilitate the GenAI-powered creation of -- as well as the compliancy to-- HL7 Implementation Guide (IG) specifications. This would include the use of GenAI to develop HL7 Reference Implementations both in computer code and human narrative form. This seeks to address an opportunity to enhance examples in IGs.

In addition to close and innovative government collaboration, these five possible collaboration projects would involve seeking out and developing working relationships with private-sector and non-profit organizations to accelerate adoption and implementation of HL7 standards for the good of effective AI development, equitable deployment in health care and HL7 standards that optimally empower global health data interoperability. The HL7 AI Taskforce would be critical in these endeavors. HL7 looks forward to working with ONC on AI as it relates to the Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action.

Section 3: Health Equity by Design Throughout ONC’s Policies and Programs

Sub-Sections

- Section A: Data Terminology Standards
- Section B: Health IT Certification
- Section C: Electronic Health Information Exchange and Interoperability
- Section D: Coordination and Public Hearings
- Section E: Measurement and Monitoring

ONC Key Questions

- What additional activities, if any, do you think ONC should undertake to implement Health Equity by Design fully and effectively?
- Are there any activities described above that you think are having unintended, adverse effects on health equity by design?

HL7 Perspective

Page six of the Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action states that, “ONC’s health IT policy development and coordination activities help turn data into actions that advance health equity nationwide. More equitable data standards (such as the SDOH, race and ethnicity, SOGI, and disability data elements in USCDI) enable more consistent data collection and greater interoperability, which can help better identify, measure, and address health inequities in traditional health and human services
settings”

6 HL7, as the global interoperability leader, has a major role to play in implementing this document’s objectives and in particular to this section’s Data Terminology Standards, Electronic Health Information Exchange and Interoperability provisions. We stand ready to do so and note additionally that the innovative work of the Gravity Project and its focus on growing a multidisciplinary community is a very important avenue to ensure diverse and implementable health equity approaches. HL7 urges ONC to maximally leverage the Gravity Project and its experts to address national health care interoperability priorities related to HEBD and social care delivery.

The importance of Sexual Orientation and Gender Identity (SOGI) and related data elements to ONC’s HEBD approach are mentioned throughout the *Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action* document. The HL7 Gender Harmony Project’s innovative approaches to modeling information (data elements, value sets, code systems) and using them to define/harmonize aspects for representing sex/gender are of critical importance here as are their cross-paradigm use cases. More information can be found at: [https://confluence.hl7.org/display/VOC/Cross+Paradigm+Use+Cases](https://confluence.hl7.org/display/VOC/Cross+Paradigm+Use+Cases)

Lastly, HL7 highlights that in dealing with health equity, one of the most overriding considerations is the access/control to information, particularly by marginal populations. HL7 has standards, tools and privacy and consent frameworks to aid in this aspect of health care. The HL7 Security Working Group and the FHIR at Scale Taskforce (FAST) are key. More information can be found at: [http://www.hl7.org/Special/committees/secure/index.cfm](http://www.hl7.org/Special/committees/secure/index.cfm) [https://www.hl7.org/fast/](https://www.hl7.org/fast/)

Effective regulatory frameworks for standards to be exchanged and consistent approaches across breadth and depth of data where patient consent is applicable must be in place and scalable, realistic and holistic. HL7 is committed to enabling Health IT to provide patients with more transparency in the health care system and a more robust and meaningful ability to access their data.

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6 Office of the National Coordinator for Health Information Technology, *Advancing Health Equity by Design and Health Information Technology: Proposed Approach, Invitation for Public Input and Call to Action*, p. 6 (April 2024)