May 28, 2024

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Secretary
U.S. Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue SW Washington, DC 20201

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Submitted electronically to:
https://www.healthit.gov/topic/draft-2024-2030-federal-health-it-strategic-plan

Re: Draft 2024 – 2030 Federal Health Information Technology (IT) Strategic Plan

Dear Secretary Becerra and National Coordinator Tripathi:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on the Draft 2024 – 2030 Federal Health Information Technology (IT) Strategic Plan (the Draft Plan). We appreciate HHS' on-going effort to drive innovation in health IT through this and other notable efforts. It has been our organization's honor to aid HHS in its health IT initiatives leveraging HL7® FHIR® standards enabling electronic capture and exchange of clinical data. HL7 applauds the broad government input into development of the Draft Plan formulated in collaboration with more than 25 federal organizations that regulate, purchase, develop, and use health IT. 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 federal and international leaders to help our nation and those around the globe, step into the future of interoperability and to create an optimal and equitable health system for all.

Below is HL7's specific feedback regarding the Draft Plan and its related goals, objectives, and strategies including that the federal government will pursue to improve health experiences and outcomes for individuals, populations, and communities while also promoting opportunities for improving health equity, advancing scientific discovery and innovation, and modernizing the nation's public health infrastructure. HHS' emphasis on using the plan to: prioritize resources, align and coordinate efforts, benchmark and assess progress and signal priorities to industry is particularly critical to in achieving these goals.

Artificial Intelligence (AI) and its rapid evolution is cited throughout the Draft Plan and additionally, as a key consideration in Appendix A. HL7 has notable efforts in this area and has provided detailed feedback in the letter

about AI issues.  Contained here is information on HL7's AI initiative and Taskforce, as well as related involvement with the larger AI and health care community.

In addition to our leadership and Policy Advisory Committee, HL7 Work Groups, Accelerators and organizational initiatives contributing to these comments include the Clinical Quality Improvement and Orders and Observation Work Groups, as well as the HL7 AI Taskforce.  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 HHS and ONC.


 Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
HL7 International

Julia Skapik, MD, MPH
Board of Directors, Chair
HL7 International

# HL7 Draft 2024-2030 Federal Health IT Strategic Plan Response

## Overarching Feedback

HL7, its Work Groups and Accelerators touch on diverse aspects of the Draft Plan. Our organization urges HHS to seek out HL7 leadership and experts as needed and by topic as it relates to Draft Plan Goals. 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/

Many lessons can also be learned from the health IT initiatives globally. HL7 has a robust Affiliate and international community, which can share valuable wisdom with HHS and other relevant agencies. HL7 International Council and community information can be found at:
https://www.hl7.org/Special/committees/international/overview.cfm

As HL7 experts reviewed the Draft Plan, a few high-level feedback points emerged:

- **Diversity and Depth of HL7 Standards** – HL7 standards have a critical role in capturing, accessing and utilizing information when and where it is needed and in standardization across the health care ecosystem. Given this, we stand ready to aid in implementation of Draft Plan goals and objectives that touch upon HL7 standards.

- **Human Service Sector and Whole-Person Care Issues** – Regarding the Draft Plan vision of better whole person care delivery via connecting human services data, it must be acknowledged that different standards are being used by human services sector. Inter-sectorial integration is needed and this issue area requires additional support, exploration, capacity and funding by HHS. Additionally, interoperable standards are also required across multiple domains to support whole person care. HL7, in partnership with HHS, is interested in extending its activities as a stakeholder convener on standards issues related to the human services sector and whole-person care.

- **Privacy and Consent Issues –** The Draft Plan purpose section notes "privacy and security considerations are critical in all aspects of health IT and EHI." Our organization concurs and emphasizes that HL7 standards enable private and secure sharing of information with consent and authorization. One of the key gaps in the Draft Plan identified by HL7 is that privacy consent management is currently inconsistent. There is a need to expand the view here beyond data segmentation standard efforts and think about helpful infrastructure that would enable better knowledge of what to share and what not to share, across the nation and state lines. The HL7 FHIR at Scale Taskforce is currently undertaking a project to address the consent at scale use case.

- **Use Cases** – Meaningful use cases highlighting Health IT policy and business driver alignment are needed in execution of the Draft Plan.


## Draft Plan Goals: HL7 Perspectives

Below are HL7 observations and recommendations outlined by the Draft 2024-2030 Federal Health IT Strategic Plan goals.


## Goal 1: Promote Health and Wellness For Individuals, Populations and Communities

### Objectives
- Individuals are empowered to manage their health
- Individuals and populations experience modern and equitable health care
- Communities are healthier and safer

### HL7 Perspective

HL7's cutting-edge standards and interoperability initiatives both support and enable the execution of groundbreaking health and wellness initiatives in the United States and around the world.  And importantly, they put ever-increasing power in the hands of patients, providers and caregivers. We note of particular importance to person-centered planning, the HL7 Multiple Chronic Condition Care Plan Implementation Guide.  More information can be found at:
https://hl7.org/fhir/us/mcc/2023Sep/ClinicalImpression-clinical-impression-example.html.


## Goal 2: Enhance the Delivery and Experience of Care for Patients, Caregivers, Health Care Providers, Public Health Professionals and Others in the Health Care Continuum

### Objectives
- Providers deliver safe, equitable, high-quality, and improved care
- Patients experience expanded access to quality care and reduced or eliminated health disparities
- Health care is improved through greater competition and transparency
- Providers experience reduced regulatory and administrative burden
- The health care workforce uses health IT with confidence

### 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 Draft Plan Goal 2. 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 and other related goals and objectives in the Draft Plan. 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.

## Goal 3: Accelerate Research and Innovation through the Collaborative Efforts of Researchers, Technology Developers and Other Health IT Users

Objectives
- Researchers and other health IT users have appropriate access to health data to drive individual and population health improvement
- Individual and population-level research and analysis are enhanced by health IT
- Researchers advance health equity by using health data that includes underrepresented groups

**HL7 Perspective**
Accelerating research and innovation through health IT is at the heart of our progressive U.S. health care system. And, researchers are increasingly advancing health equity by using health data that includes underrepresented groups. HL7 -- and in particular its FHIR standards and key Accelerators such as CodeX and Vulcan -- are critically supporting advancement on these issues. CodeX is the HL7 FHIR Accelerator working to advance the adoption of FHIR as the standard to obtain high-quality, computable data for patient care and research, including the domains of oncology, cardiovascular health, and genomics. Its community-driven use case development in key areas (such as quality measures, genomics data exchange and cancer registry reporting for example) could be particularly helpful to informing and shaping Goal 3 of the Draft Plan. A CodeX Use Case list can be accessed at: https://codex.hl7.org/uses.

The Vulcan Accelerator is dedicated to connecting clinical research and health care and includes representatives from government agencies, academia, technology companies, standards development organizations, patients, and industry consortiums. Vulcan brings together stakeholders across the translational and clinical research community in order to bridge existing gaps between clinical care and clinical research, strategically connect industry collaboratives, maximize collective resources, and deliver integrated tools and resources. Significant work is already taking place with Vulcan, CodeX and the White House Office of Science and Technology Policy (OSTP) to speed the development of standardized approaches to data exchange, with the goal of piloting faster and more inclusive data capture for multi-site clinical trials. HL7 looks forward to increased collaboration with HHS and other relevant agencies on these issues. Lastly, HL7 also highlights the impactful joint agreement between the Observational Health Data Sciences and Informatics (OHDSI) and Vulcan. Vulcan-OHSDI work has

resulted in progress on an Electronic Health Prevention Record based on HL7 FHIR and the Observational Medical Outcomes Partnership (OMOP) Common Data Model.

Lastly related to Goal 3, HL7 highlights the benefits of HL7 FHIR related to research and previously walled off data that now has a standards-based FHIR API is that small actors can connect and participate. The HL7 FHIR API represents a paradigm shift.

## Goal 4: Connect the Health System with Health Data for All Health IT Users

### Objectives
- Development and use of health IT capabilities continues to advance
- Health IT users have clear and shared expectations for data sharing
- Underserved communities and populations have access to infrastructure that supports health IT use
- Individuals' electronic health information is protected, private, and secure
- Communities are supported by modern and integrated U.S. public health data systems and infrastructure

**HL7 Perspective**

As computational, standards and interoperability capabilities continue to rapidly advance, connecting the health system with health data for all health IT users can be seen as a more practicable goal. HL7 is laying track and working with other key players across government and the health care system to achieve this vision. Below HL7 highlights its work on two Goal 4 key objectives of: (1) keeping individuals' electronic health information is protected, private, and secure; and (2) communities supported by modern and integrated U.S. public health data systems and infrastructure.

Leveraging the work of HL7's HELIOS Accelerator [jointly supported by the Centers for Disease Control and Prevention (CDC) and ONC] and the HL7 Public Health Work Group would be very valuable and germane in ensuring communities are supported by modern and integrated U.S. public health data systems and infrastructure. More information on these bodies can be found at:
https://confluence.hl7.org/display/PH
http://www.hl7.org/Special/committees/pher/index.cfm

Specifically on Goal 4, Objective E, for public health infrastructure capable of supporting high fidelity, complete, bi-directional data sharing between providers, public health, and patients/consumers, which in turn enables Public Health to improve on their mission and goals. Many steps can already be taken to improve the quality and completeness of data sharing, while other aspects of the infrastructure need substantial improvements in technology to support Public Health's mission and goals. Recognizing that the infrastructure cannot be replaced in one step given cost and effort and in light of a lack of sustained funding of the public health sector in general, HL7 recommends a focus primarily on advancing a highly integrated US Public Health data systems and infrastructure. Some of the needed integration can only be achieved with new technologies, but indicating that it be fully modernized would emphasize a one-step replacement approach is unrealistic. Many advancements can already be made by focusing on

connecting all providers, adopting industry standard vocabularies, and promoting consistency of data across jurisdiction

## Artificial Intelligence
### HL7 Perspective

Artificial Intelligence (AI) is highlighted throughout the DRAFT Plan and particularly in Appendix A of as a key consideration. 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, the Draft Plan and concrete ideas about how 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.

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. 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.

With regards to the Federal Health IT Strategic Plan, there are multiple areas where HL7's core focus on interoperable health data standards, combined with AI (of various methods), can advance meaningful projects that would achieve the four Goals of this Draft Plan. These include five potential collaborative, 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.

On the creation side, two main helpers can be the ability to create examples given a prompt and the HL7 artifact definition – as well as the ability to create ad-hoc examples extemporaneously based on a prompt, the Guide definitions, and some given data. This would represent an opportunity to accelerate how organizations employ HL7. On the compliance side, two main helpers would be the ability to automate aspects of the test-based development processes – as well as the ability to provide a descriptive report to integrators of their HL7 implementation.

This longer-term endeavor would require dedicated support to assemble the necessary talent and resources for a concerted initiative in this area. Such an effort could include some more immediate, shorter-term activities to include the use of copilot or copilot-like digital assistants to help both individuals new to HL7 as well as those experienced with HL7 ask and receive guidance to frequently asked questions as well as pointers to HL7 resources and code libraries with a unified HL7 digital assistant trained upon HL7's available resources.

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 and deployment in health care and HL7 standards that optimally empower global health data interoperability. The HL7 AI Taskforce would be critical in these endeavors.