



June 22, 2022

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Submitted electronically to:  
[NCVHSmal@cdc.gov](mailto:NCVHSmal@cdc.gov)

RE: NCVHS Subcommittee on Standards Request for Additional Feedback Regarding June 9, 2022 Listening Session on Standardization of Information for Burden Reduction and Post-Pandemic America “Convergence 2.0”

Dear NCVHS Subcommittee on Standards Co-Chairs Love and Landen:

Health Level Seven (HL7) International welcomed the opportunity to speak at the June 9 NCVHS Subcommittee on Standards listening session and values providing further written feedback with this correspondence. As you know, HL7 is the global authority on health care interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries, including 500+ corporate members representing health care consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

HL7's Chief Executive Officer (CEO) Charles Jaffe, MD, PhD emphasized three important overarching points during his June 9 remarks:

First, HL7 urges NCVHS to formally recognize HL7® FHIR® as an alternate standard to existing mandated HIPAA transaction standards, furthering the nation's journey of intersecting of clinical and administrative frameworks and related interoperability objectives. While the information requirements of health care data are extremely complex, the HL7 FHIR standard aids in removing many of the barriers to health care data exchange. FHIR itself, now 11 years old, is no longer an emerging standard but a global phenomenon and well supported by an interconnected health care ecosystem, demanding accurate, patient-centric data when and where it's needed. The time is now to make these tools more widely available starting with the prior authorization related implementation guides (IGs), including those related to: Coverage Requirements Discovery (CRD)<sup>1</sup>, Documentation Templates and Payer Rules (DTR)<sup>2</sup> and Prior Authorization Support (PAS)<sup>3</sup>. Recognizing the most current versions of these initial three IGs, supports other federal policy<sup>4</sup> to reduce burden through technology and policy-related enhancements.

Second, a critical part of the HL7 mission is to provide a comprehensive framework and related standards for electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7 and its Work Groups produce a family of standards, including FHIR, as well as Implementation Guides and Specifications, which enable both routine and cutting-edge health care functions. HL7 actively supports cross-community terminology and value set needs to further benefit data driven policy and operational needs. Our HL7 FHIR Accelerators drive groundbreaking cross-sector innovation in interoperability and bridging historical investments through partnerships to provide end-to-end capabilities needed in today's modern health care eco-system. One such example, showcased by their June 9<sup>th</sup> testimony, is the Da Vinci Project, addressing value-based care data exchange efficiencies. Other HL7 FHIR Accelerators contribute to the interoperability journey such as FAST for infrastructure and connectivity, the Gravity Project for social determinants of health, and Helios for public health.

Third, HL7 supports all five considerations below that were examined by the NCVHS Subcommittee on Standards on June 9, including:

- Consideration 1: Update relevant HIPAA policies to allow for the adoption and use of more than one standard per business function.

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<sup>1</sup> HL7 Da Vinci Project, Coverage Requirements Discovery Implementation Guide, December 2020,

<sup>2</sup> HL7 Da Vinci Project, Documentation Templates and Payer Rules Implementation Guide, December 2020, <https://confluence.hl7.org/pages/viewpage.action?pageId=21857604>

<sup>3</sup> HL7 Da Vinci Project, Prior Authorization Support Implementation Guide, December 2021, <http://hl7.org/fhir/us/davinci-pas/>

<sup>4</sup> U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria, RIN 0955-AA04; FR 2022-01309, January 24, 2022, <https://www.federalregister.gov/documents/2022/01/24/2022-01309/request-for-information-electronic-prior-authorization-standards-implementation-specifications-and>

- Consideration 2: Enable HIPAA covered entities to support multiple versions of adopted standards for business functions.
- Consideration 3: Revise the standards exception process for HIPAA covered entities who submit an application with the required justification and business case to automatically authorize them without waiting for review.
- Consideration 4: Identify options for improved integration of health information standards, including base standards plus implementation guides, more broadly than at present, and fostering relevant collaboration across HHS Agencies and Offices.
- Consideration 5: Develop and publish a guidance framework with recommended definitions, metrics, templates, and pilot test procedures. The specific areas of work include such methods for reporting on standards readiness, standards costs, results of real-world testing and metrics essential for evaluation of standards.

Complementing these points above, and contained in this letter are HL7 perspectives on key themes emerging from the June 9 listening session:

- Public-Private Sector Partnerships
- Cooperation Across Government
- Value Proposition and Incentive Alignment
- Standards Exceptions Process Revision - HIPAA Covered Entities
- Standards Transition Policy
- Standards Versioning
- Increased Standards Testing
- Standards Guidance Framework
- Sexual Orientation and Gender Identification (SOGI), Social Determinants of Health (SDOH) and Public Health Issues

Comments detailed in this letter reflect the combined perspectives of HL7's leadership, the Policy Advisory Committee and the Da Vinci Project HL7 FHIR Accelerator. Should you have any questions about the attached document, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at [cjaffe@HL7.org](mailto:cjaffe@HL7.org) or 734-677-7777. We look forward to continuing this discussion and offer our assistance to NCVHS.

Sincerely,



Charles Jaffe, MD, PhD  
Chief Executive Officer  
HL7 International



Andrew Truscott  
Board of Directors, Chair  
HL7 International

Key recurring themes expressed by stakeholders during the June 9 listening session and related, relevant HL7 comments are outlined below.

- **Public-Private Sector Partnerships** – HL7 agrees with other June 9 listening session speakers that ongoing meaningful collaboration between the public and private sectors is essential in the interoperability journey and in particular, is improved through more input from industry stakeholders and continued collaboration among Standards Setting Organizations (SSOs). When public and private sector stakeholders collaborate, challenges can be efficiently and productively solved. HL7 FHIR Accelerators are meaningful examples of this collaboration, which brings together industry and government thought leaders, to modernize thinking about technology investment in Health Information Technology (HIT). The HL7 Da Vinci Project is fundamentally re-imagining data exchange in health care is enabled, as well as accommodating existing investments in technology. The Da Vinci Project uses private industry investment, paired with our ANSI accredited standards development structure and a consensus approach, augmented with support from the federal government. The very experts implementing these exchange challenges are partnering to compete on service, differentiated offerings and establishing the best practices of data exchange among a diverse body of collaborators.
- **Cooperation Across Government** – HL7 enthusiastically supports Consideration 4 to identify options for improved integration of health information standards, including legacy technologies augmented by implementation guides, more broadly than those presently available. Furthermore, HL7 encourages strategic collaboration across U.S. Department of Health and Human Services (HHS) agencies and offices, including state, local, tribal & territorial governments. HL7's diverse project portfolio consistently enables the primary record, and supports the fundamental respect of patient preferences, as well as nurturing privacy and security policies. As the government programmatic and policy evolves, HL7 will continue to be a committed technical resource and collaborator to advance data exchange capabilities across national and international governmental partners.

HL7 is committed to the principal that collaboration and information integration is critical with non-HHS agencies and offices that impact health services, equity, and security of food, housing and transport as well as digital literacy. In fact, HL7 has partnered with the U.S. Department of Defense (DOD), Department of Veterans' Affairs, Department of Housing and Urban Development (HUD), Social Security Administration (SSA), Department of Transportation (DOT), United States Department of Agriculture (USDA) and the United States Digital Service (USDS). Lack of alignment among different agencies in both health policy and protocol is a notable burden and can adversely impact health care quality and equity. A recent JAMA Health Forum article -- *Addressing Social Determinants of Health in Federal Programs* -- sheds light on this issue. More information can be found at: <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2790811>.

Perhaps most relevant is the fundamental embrace of the global community, by which HL7 underscored in its July 2021 letter to the NCVHS Subcommittee on Standards. "as humans and diseases continue to travel globally, international coordination between jurisdictions will be increasingly important regarding electronic data such as that represented in USCDI, US Core, and specialized Implementation Guides (IGs)".

- **Value Proposition and Incentive Alignment** – HL7 recommends additional federal incentives, funding and support for testing, implementation and maturing of standards in this area. All ecosystem participants must be considered, and should benefit areas identified as HIPAA administrative, financial, and clinical frameworks which increasingly intersect. Return on investment, including societal benefits, and both accrued stakeholder value, as well as recognizing both underlying cost structures, as viewed through a holistic perspective. Several

resources to aid advancement of public-private agreed upon framework include HL7's white paper *The Case for FHIR-Based Quality Measurement and Reporting* and its outlined Value Metrics Framework. Explored elements are: expressivity, alignment, fitness, liquidity, community, extensibility, conformance, tooling, agility, re-usability, implementability, and value metrics. More information can be found at:

[http://www.hl7.org/documentcenter/private/standards/FHIR\\_GUIDE\\_QUALREPORT\\_INFORM\\_2020\\_OCT.pdf](http://www.hl7.org/documentcenter/private/standards/FHIR_GUIDE_QUALREPORT_INFORM_2020_OCT.pdf) and <https://confluence.hl7.org/display/FA/Value+Metrics>

- **Standards Exceptions Process: HIPAA Covered Entities** – HL7 strongly supports Consideration 3 to revise the standards exception process for HIPAA covered entities who submit an “application” with the required justification and business case to automatically authorize them without waiting for review. Such a modified approach should require attestation of ‘willing trading partner’ participation, improve current exception guidelines and transparency through website posting. Insights from the current exception granted to the Da Vinci Project participants supports the view of the opportunity to refresh the exception process approach, as well as to address the potentially extraneous obligation by demanding that a revised business agreement be put in place before proceeding with granting the exception. The barriers to investing in modern approaches should be minimal, in order to encourage early and meaningful testing of emerging standards while ensuring appropriate and reasonable partnering is occurring. Interoperability proving ground experiences and opportunities to access emerging standards information publicly should be considered.
- **Standards Transition Policy** – HL7 recommends adequate, additional policy be in place for more agile standards transitions involved in HIPAA administrative transactions and explicit detail about guardrails and sunsets that are a part of this process to ensure efficiency and transparency. A focus on investing, advancing and aligning both federal frameworks and tools is critical, as underscored by the *FHIR Roadmap for Trusted Exchange Framework and Common Agreement (TEFCA) Exchange*.

HL7 believes that it is critical to accelerate investment in technical tooling and education, in order to extend existing efforts to coordinate and align regulatory and sub-regulatory methods to advance health IT frameworks. This effort will more effectively support the industry in applying clinical and administrative regulations, guidances, and create clearer understanding of timing and triggers mechanism. This approach also provides a better use of resources for developing, vetting, adopting, implementing and maturing standards that support interoperability in Health IT services, products and related use by end-users.

For example:

The Standards Version Advancement Process (SVAP) methodology of adopting base standards. Allowing newer versions to be voluntarily adopted should be extended. Emerging capabilities, such as the Interoperability Standards Advisory (ISA), can be examined as a model that aids the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the US healthcare industry to address specific interoperability needs. This process should include, but not be limited to, interoperability for clinical, public health, and research purposes. The ISA already contains HIPAA administrative transactions standards and operating rules.

Moreover, a relevant concept that was included in HL7's June 9 listening session remarks emphasized that much of the health care industry is hesitant to make financial and operational investments to test or use an updated or new standard without a federal mandate. Early reporting on use, then increasingly to qualitative and increasingly quantitative measures could be a valuable strategy. In terms of global alignment, HL7 urges an examination of the Digital Square Global Goods Maturity Model, which can be accessed at:

[https://wiki.digitalsquare.io/index.php/Global\\_Goods\\_Maturity](https://wiki.digitalsquare.io/index.php/Global_Goods_Maturity)

[https://wiki.digitalsquare.io/index.php/Global\\_Goods\\_Maturity#Digital\\_Square\\_Maturity\\_Model\\_Details](https://wiki.digitalsquare.io/index.php/Global_Goods_Maturity#Digital_Square_Maturity_Model_Details).

Global Goods are the most prevalent classification and packaging of digital health tools outside of the U.S. context and particularly in Lower and Middle Income Countries (LMICS).

- **Standards Versioning** – HL7's wisdom, lessons learned and current state thinking regarding standards versioning are detailed below. We stand available for additional questions and eager to partner in finding viable ecosystem wide solutions.

Regarding standards versioning, first and foremost, a distinction must be made in standards versioning between addressing an expansion of choices where there is a nonfunctioning, lightly adopted named standard and scenarios in which there is not a named standard, but one is needed. The focus should be on optimal advancement in each scenario.

Secondly, complex interdependencies exist between standards and implementation guides (IGs) that are developed by SSOs, adopted then implemented as national standards and included in federal certification programs. There is no clear cadence for HIPAA transaction standards related upgrades. Methodologies related to healthcare operations related initiatives, as led by Office of National Coordinator, have benefited from the HIPAA experience. Today, there is a pressing need to craft a balanced, cohesive signaling and predictability approach as we move forward.

Lastly, the current process of naming required standards in regulation for every instance (tied to regulatory methods, as is done today) is not meeting nor keeping pace with societal and business demands. Upgrade approaches should leverage the Standards Version Advancement Process (SVAP) for HIPAA administrative standards. Progress involves public-private partnership(s) working to solve these challenges as well as converging frameworks.

Other relevant standards versioning comments included in HL7's June 9 listening session remarks are noted below:

As technology evolves, it is rapidly transitioning from transaction-based industry architecture to an environment that embraces modern API based standards for more real-time workflow and access to information. Our HIPAA standards need to follow this model, which has been proven to work by other industries for more than two decades. FHIR itself, now 11 years old, is no longer an emerging standard but a global phenomenon and well supported by an interconnected health care ecosystem that is demanding accurate, patient-centric data when and where it's needed in a manner that is with little to no friction.

Today there are challenges that reflect upon how standards are developed then adopted as national policy. These specifications often require a uniform versioning framework, such as the Standards Version Advancement Process. However, if the industry expects to adapt and to enhance data exchange, whether transactional or purely clinical, we must enable implementers to advance and innovate, while maintaining a floor that each component of the community can support. Extending existing efforts to coordinate and align regulatory and sub-regulatory methods to advance health IT frameworks is essential. With clear mapping and crosswalk, the use of multiple standards or versions of a standard occurs across many industries today allows for advancement of technology capabilities independent of herculean upgrade efforts. Now is the time to fully integrate the administrative and financial requirements with the clinical frameworks in order to keep pace with societal needs and expectations, as well as the power of technology.

At HL7, we recognize the complexities and the burden of supporting multiple versions of adopted standards. Such an undertaking requires the capabilities and commitment of HL7 to develop and maintain needed versions. HL7 must and will do so in partnership with key stakeholders, end-user, technology developers, government agencies and others. HL7 has been and continues to transform in response to lessons learned and the needs of its community. HL7 FHIR Accelerator Programs have already shown a very different approach to standards adoption. It is no longer an expectation that “if you build it they will come”. HL7 FHIR Accelerators have successfully demonstrated that if you provide the right environment and enable truly relevant rationale for development, innovators will coalesce around mutually beneficial deliverables, in order to build, test, implement and mature these industry-changing capabilities.

No one at HL7 believes that the complexities and burden of supporting multiple versions is an easy one. We do not expect to have answers to every problem. We recognize that our community will create solutions to problems within our sphere to address many of these obstacles. In order to become a reality, the process requires a robust governance, sound methodologies and, most importantly, the trust to enable the right people to collaborate on defining and solving those problems. This approach enables modifications based on real-world use both before and in tandem with the SSO ballot processes. This is the basis of the modern agile development process.

As a result, standards processes are able to establish their own operational guidelines and instructions with rich examples in a self-contained manner, in between formal regulatory (version) updates. In fact, HL7 FHIR does this today with supplemental Implementation Guides, at the heart of every Accelerator. In an ideal world, the implementers will be able to work with other SDOs to establish the floor and ceiling across a timeline, and any interim, supplemental guidance can be maintained, supported by the active implementer community with support of the standard owner. Ultimately, the community creating the design, and implementing and operating the standards, are best able to mature and curate them.

- **Increased Standards Testing** – HL7 agrees with the need for increased standards testing that was mentioned by multiple speakers at the listening session. Connectathons and more standards pilot testing were offered as examples. HL7 supports and can facilitate more Connectathons and standards pilot testing with adequate assistance. As HL7 stated in its July 2021 letter to the NCVHS Subcommittee on Standards, “successfully transitioning from the current state to a new state of standardized interoperability requires focused programs that involve both human and financial resources.” A few points are important to highlight here. First, there is value in increased documentation as well as increasing the transparency of tracker items emerging from the testing process. Connectathons most effectively enable the sharing of significant learnings and substantially reflect the depth and value of testing characteristics tools, participants and results. Secondly, more sandbox testing with robust proof of concept and peer-to-peer learning, as well as ideal facilitation, documentation and resource sharing, is needed and requires additional federal monies. The HL7 Gravity Project has funding from the Office of the National Coordinator for Health Information Technology (ONC) to do this within their domain. The Gravity Project’s efforts could potentially be scaled for other HL7 FHIR Accelerators.
- **Standards Guidance Framework** – HL7 supports and highlights Consideration 5 to develop and publish a standards guidance framework with recommended definitions, metrics, templates, and pilot test procedures. HL7 observes that there can be a valuable role for WEDI, HHS and others to maintain the framework, updates, and validation, but the content should emanate from the community of implementers to assure alignment. The framework should evaluate the standards and specifications, and evaluate and resolve the impediments to implementation, as well as provide a consistent library of best practices. This framework can contain examples for industry stakeholders utilize and modify in order to support a continuous learning

process around the value and importance of standards adoption and participation in the development processes.

- **SOGI, SDOH and Public Health Issues** – As was mentioned at the June 9 listening session, greater insight is needed on Sexual Orientation and Gender Identification (SOGI), Social Determinants of Health (SDOH) and public health issues in this space. Moreover, federal, state and local policy should be better aligned. HL7 emphasized in its July 2021 letter to the NCVHS Subcommittee on Standards that, “development and adoption of common data standards is foundational to identifying inequities, identifying potential interventions, coordinating interventions across agencies, measuring progress, and conducting research and evaluation. Requiring that health systems collect standardized data elements indicative of social determinants of health, and report these data, are key to improving the ability to share data that helps our society address inequities.”

HL7 Accelerators, such as the Gravity Project and Helios, and HL7 Work Group initiatives focused on Public Health and Gender Harmony, can aid significantly in lending details, knowledge and insight on these issues. We stand ready to help. We would also recommend the development of knowledge aggregation processes. One such approach would be to constitute NCVHS hearings featuring SSOs and relevant stakeholders that discuss SOGI, SDOH and public health issues. The role of standards and electronic data transport and interoperability in the area of health and disability is also an important, emerging issue.

In closing, HL7 looks forward to speaking with NCVHS and its Subcommittee on Standards regarding the issues outlined in this letter. We would be happy to offer additional information and rationale. Specifically, we are very committed to expounding on our recommendation that NCVHS formally recognize HL7 FHIR as an alternate standard to applicable, existing mandated HIPAA transaction standards. We believe that this will ultimately advance the nation’s journey of integrating clinical and administrative frameworks and related interoperability objectives.

