December 6, 2022

Jacki Monson, JD  
Chair, National Committee on Vital and Health Statistics (NCVHS)  
c/o Rebecca Hines, MHS  
Executive Secretary, NCVHS  
3311 Toledo Road  
Hyattsville, MD 20782  

Re: HL7 FHIR Standards for Electronic Attachments

Dear Ms. Monson,

Health Level Seven International (HL7®) and the HL7 Da Vinci Project, Fast Healthcare Interoperability Resources (FHIR®) Accelerator, wish to update the Committee regarding our recent advances in maturing FHIR Implementation Guides capable of supporting HIPAA mandated transactions including Prior Authorization and Electronic Attachments.

Over the past several years, NCVHS has hosted a number of presentations by HL7 and others describing the value of FHIR in advancing and modernizing capabilities underpinning interoperability objectives. Regulatory requirements such as the 21st Century Cures Act (Public Law 114–255) and CMS Patient Access API Rules have accelerated adoption of FHIR APIs by Certified Health IT vendors and the payer community. Other federal entities including the Department of Veterans Affairs, the National Institutes of Health and the Centers for Disease Control have embraced FHIR in their interoperability and technology planning. This broad adoption will enable the healthcare community to bridge to the future. Collaborations between HL7 and other Standards Development Organizations (SDOs), including X12 and NCPDP, demonstrate the ability of FHIR to support current exchange standards during this evolutionary period.

During the August 25, 2021 NCVHS Subcommittee on Standards’ Listening Session, HL7 and representatives from the Da Vinci Project highlighted efforts to develop and publish FHIR implementations guides to reduce the burdens of prior authorization processes and payer to payer data exchange. Over the past year, these Implementation Guides have undergone additional updates and balloting, with publication anticipated within the next 90 days. Notably, Da Vinci members’ Regence and MultiCare Connect ed Care announced in October 2022 their production implementation of an EHR-embedded prior authorization process based on the Da Vinci Burden Reduction Implementation Guides (IGs). This collection utilizes FHIR application programming interface standards (APIs) and includes the following Implementation Guides:

- Coverage Requirements Discovery
- Documentation Templates and Rules
- Prior Authorization Support

In June 2016, NCVHS recommended the use of the HL7 CCDA standard which was, at that point in time, the most mature HL7 standard at play for clinical data exchange. Since then, FHIR maturation and adoption has increased dramatically. In March 2022, the NCVHS recommended the publishing of the CMS Interoperability and Prior Authorization proposed rule, which includes the HL7 FHIR standard to support APIs to automate payer and provider prior authorization workflows. Additionally, NCVHS recommended
that HHS adopt a standard for Electronic Attachments, without specifying a specific standard. NCVHS recommended regulatory flexibility to allow the use of FHIR standards along with X12 HIPAA adopted standards.

In July of 2022 after deliberation of input from public hearings, NCVHS submitted to the Secretary Recommendation 1:

“In the Committee’s assessment, HHS needs to ensure that regulations allow multiple standards (i.e., one, two or three implementation guides or implementation specifications) to co-exist as they are tested and used by stakeholders to meet specific business needs and addressing gaps, while preserving ongoing use of widely used existing standards.”

The HL7 and Da Vinci community have supported this action in our previous verbal and written testimony. The industry will benefit from the use of FHIR based APIs for clinical data exchange, and believes there is ample progress to warrant the consideration of enabling FHIR alongside existing industry investments to move forward with the goal of enabling adoption of newer technologies.

We believe that these recommendations can be achieved using the Da Vinci Clinical Data Exchange FHIR Standard for Trial Use Version 2 Implementation Guide (CDex), which was balloted earlier this year. Publication of this guide is planned for Q1 2023. This guide defines a FHIR-based approach to support Electronic Attachments. The CDex guide leverages EHR based FHIR capabilities to automate the exchange of both solicited and unsolicited Claims Attachments as well as supporting requests for additional information not identified and exchanged during the initial prior authorization and quality measure exchange processes defined by other Da Vinci FHIR Implementation Guides.

HL7 is presently preparing responses to NCVHS' Request for Comment (RFC) on Proposals for Updates to X12 Transactions and New and Updated CORE Operating Rules due on December 15. Additionally, HL7 has accepted the invitation to provide oral testimony at the January NCVHS hearing. However, the Unified Agenda indicates that HHS/CMS has submitted an Attachments Notice of Proposed Rulemaking (NPRM) for review by the Office of Management and Budget (OMB). While we have no knowledge of the specifics of the NPRM, we are deeply concerned that CMS may not identify the CDex Implementation Guide as a standard for Electronic Attachments, consistent with NCVHS' recommendations noted above.

If FHIR and the CDex IG are not named in the NPRM and request for feedback on CDex is not solicited by HHS/CMS proposed rulemaking, we as an industry will miss a significant opportunity to build upon the FHIR foundations and existing investments noted above. This missed opportunity will have long lasting and costly repercussions on the patients, providers, government and commercial funders payers and the broader healthcare community.

In addition to this letter, HL7 will consult with the other members of the Designated Standards Maintenance Organizations (DSMOs) in preparing a formal recommendation to NCVHS, which would identify the CDex standard. The present DSMO processes are in need of revamping, as recognized by NCVHS's 2018 predictability roadmap and industry engagement efforts. As part of our outreach to the DSMOs regarding this matter, we will also include a request for discussion of the ongoing consultation approaches and related memorandum of understanding.

The advancements in FHIR adoption over the past 11 years have established a foundation for a dramatic transformation of healthcare using open APIs, as has been achieved by other industries including travel, commerce and finance. As we enter a renewed period of regulatory activity and the long awaited integration of clinical and administrative standards, it is imperative that we prioritize maturing these processes and ensuring all healthcare stakeholder understand the impact and how to engage across these activities. HL7’s collaboration with other SDOs demonstrates the ability for the FHIR standard to work coherently with other established standards, which offers a strategy for healthcare to transition to a FHIR-based, API infrastructure. Improved patient care, reductions in clinician burden and increased administrative efficiencies can be
achieved if HHS/CMS and the healthcare industry continue to move forward with FHIR adoption.

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.

Sincerely,

[Signatures]

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