November 9, 2020

Don Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services
Hubert Humphrey Building, Suite 729
200 Independence Avenue SW Washington, DC 20201

Submitted electronically to:
https://www.healthit.gov/isa/standards-version-advancement-process#comment-form

Re: ONC's Standards Version Advancement Process (SVAP)

Dear Dr. Rucker:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC's voluntary Standards Version Advancement Process (SVAP) and the related standards and implementation specifications that will be considered. HL7 is the global authority on healthcare 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 healthcare consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

We appreciate this collaborative process and the SVAP's potential to enable health IT developers' to incorporate newer versions of HHS Secretary-adopted standards and implementation specifications, as part of the "Real World Testing" Condition and Maintenance of Certification requirement (§ 170.405) of the *21st Century Cures Act*. HL7's feedback on the SVAP is detailed below. In addition to our leadership and Policy Advisory Committee, HL7 Work Groups contributing to these comments include Clinical Quality Information (CQI); and Structured Documents.

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   Walter G. Suarez, MD, MPH
Chief Executive Officer   Board of Directors, Chair
Health Level Seven International   Health Level Seven International

HL7 Responses to ONC's SVAP

HL7's comments on the SVAP and its related Standards and Implementation Specifications are below.

<u>Updated Implementation Guides</u> – ONC should note in reference to the SVAP, that each of these Implementation Guides (IGs) listed below have newer versions.

- "HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1 - Introductory Material, June 2015 [§ 170.205(h)(2)]"
    - o June 2015 is old, newer versions are available.
    - o 2020 Reporting: STU 5.1 with Errata.
    - o 2021 Reporting: STU 5.2 with Errata.
    - o Both are available at: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35
    - o The Certification Criteria column points to [1] and [2] which are SVAP pages, which in turn point to a ISA page [3], but there is no link to the HL7 site
        - ▪ [1] https://www.healthit.gov/isa/svap-reference-standard/ss-170315c1-clinical-quality-measures-cqms-record-and-export
        - ▪ [2] https://www.healthit.gov/isa/svap-reference-standard/ss-170315c2-clinical-quality-measures-cqms-import-and-calculate
        - ▪ [3] https://www.healthit.gov/isa/node/2191 (Vol 1)
    - o The "View/Comment" column links to ISA [3], but (for consistency and to provide a link to HL7) that column should likely link to an SVAP page, which does not exist. HL7 recommends creating an SVAP page at https://www.healthit.gov/isa/svap-standard/170205h2 , so the View/Comment column can point to it instead of an ISA page. This suggested SVAP page would point to SVAP pages for § 170.315(c)(1) and § 170.315(c)(2) at links [1] and [2], respectively; these pages point to the corresponding ISA page. To provide a link to HL7, the suggested new SVAP page https://www.healthit.gov/isa/svap-standard/170205h2 can point to http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35 in the Current Standard section.

- "HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 2 - Templates and Supporting Material, June 2015 [§ 170.205(h)(2)]"
    - o June 2015 is old, newer versions are available.
    - o 2020 Reporting: STU 5.1 with Errata.
    - o 2021 Reporting: STU 5.2 with Errata.
    - o Both available at [6].
    - o The comments above for Volume 1 also apply to Volume 2.
    - o See the Volume 1 comment above for a suggestion about a new SVAP page; the View/Comment column for Volume 2 would also point to the suggested new SVAP page at: https://www.healthit.gov/isa/svap-standard/170205h2

- "CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2019 [§ 170.205(k)(3)]"
    - o The 2019 version is old, newer versions are available for 2020 and 2021 reporting at: https://ecqi.healthit.gov/qrda

- "CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2019 [§ 170.205(h)(3)]"
    - 2019 version is old, newer versions are available for 2020 and 2021 reporting at: https://ecqi.healthit.gov/qrda

- The View/Comment column at https://www.healthit.gov/isa/standards-version-advancement-process the target of the hyperlinks is inconsistent for the four items above (and other rows). In some cases that column points to an ISA page, and in other cases it points to an SVAP page. For example, for §170.205(h)(3) the View/Comment column points to an SVAP page: https://www.healthit.gov/isa/svap-standard/170205h3 but for § 170.205(h)(2) there is no corresponding SVAP page. The View/Comment column for HL7 QRDA Category I (Vol 1) points to an ISA page https://www.healthit.gov/isa/node/2191 . Vol 2 is similar and points to a different ISA page. See suggestion above for creating a new SVAP page. HL7 notes other new SVAP pages may be needed for rows where the View/Comment column points to an ISA page.

Reference to HL7 C-CDA R1.1 - The SVAP incorrectly includes the HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012. This reference and row should be removed, with only the references to HL7 C-CDA R2.1 retained.