



May 21, 2024

Micky Tripathi, PhD, MPP  
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/topic/standards-version-advancement-process-svap>

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

Dear Dr. Tripathi:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on ONC's Standards Version Advancement Process (SVAP) permitting health information technology (IT) developers to voluntarily update health IT products certified under the ONC Health IT Certification Program (Certification Program) to newer versions of adopted standards as part of the "Real World Testing" Condition and Maintenance of Certification requirement (§ 170.405) of the 21st Century Cures Act. As you know, HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena.

We appreciate ONC's on-going effort to drive innovation through SVAP and related initiatives. HL7's specific feedback mapped to the SVAP is detailed below and includes recommendations from members of HL7's Clinical Quality Information Work Group, Policy Advisory Committee and HL7 leadership. Additionally -- as an overarching SVAP comment --HL7 observes that ideally, ONC would allow standards upversioning to link directly to the main site for the standard and not a specific version of that standard. If this scenario is not currently possible, HL7 has provided the most recent versions of the standards referenced in this response letter.

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](mailto:cjaffe@HL7.org) or 734-677-7777. We look forward to continuing this discussion and offer our assistance to ONC.

Sincerely,

A handwritten signature in black ink that reads "Charles Jaffe" with a stylized flourish at the end.

Charles Jaffe, MD, PhD  
Chief Executive Officer  
HL7 International

A handwritten signature in black ink that reads "Julia Skapik" in a cursive style.

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

## HL7 SVAP Responses

View / Comment	Current Standard / Implementation Specification listing in IBR (170.299)	Regulatory Text Citation for Standard / Implementation Specification Adopted <sup>▲</sup>	Certification Criteria(on) References Standard / Implementation Specification	National Coordinator Approved Advanced Version(s)
	HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), June 2015	§ 170.205(h)(2)	§ 170.315(c)(1) - Clinical quality measures (CQMs) — record and export  § 170.315(c)(2) - Clinical quality measures (CQMs) — import and calculate	New version available HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 5.3 with errata (US Realm), December 2022 (Available 9/11/2023)
	CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020 New version under consideration CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2024 (August 2023)	§ 170.205(h)(3)	§ 170.315(c)(3) - Clinical quality measures (CQMs) — report	New version available CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2023 (March 2023)(Available 9/11/2023) New version available CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2022 (November 2021) (Available 8/29/2022)
	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020 New version under consideration CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2024 (November 2023)	§ 170.205(k)(3)	§ 170.315(c)(3) - Clinical quality measures (CQMs) — report	New version available CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2023 (December 2022) (Available 9/11/2023) New version available CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2022 (December 2021) (Available 8/29/2022)

Regulatory Citation	Certification Reference	HL7 Comments
<b>general</b>	general	<ul style="list-style-type: none"> <li>Explain "(Available mm/dd/yyyy)" at the bottom of every standard. It does not seem to be a date used in the standard itself.</li> <li>HL7 does not know what that "Available" date should be for the new standards we want to add.</li> </ul>
<b>§ 170.205(h)(2)</b>	§ 170.315(c)(1) - Clinical quality measures (CQMs) — record  § 170.315(c)(2) - Clinical quality measures (CQMs) — import and calculate	<ul style="list-style-type: none"> <li>In the Approved Advanced Version(s) column, HL7 recommends changing "DSTU" to "STU" in the standard name.</li> </ul>

Regulatory Citation	Certification Reference	HL7 Comments
§ 170.205(h)(3)	§ 170.315(c)(3) - Clinical quality measures (CQMs) — report	<ul style="list-style-type: none"> <li>• Remove both 2022 and 2023 Implementation Guides (IGs) from the Approved Advanced Version(s) column.</li> <li>• Add the CMS Implementation Guide for Quality Reporting Document Architecture; Category I; Hospital Quality Reporting; Implementation Guide for 2024; Version 1.1; 08/31/2023 <ul style="list-style-type: none"> <li>○ This is the same as the "New version under consideration" in the "Current Standard ..." column</li> <li>○ HL7 agrees it should be added to SVAP.</li> </ul> </li> <li>• HL7 suggests to have the hyperlink point to <a href="https://ecqi.healthit.gov/qrda">https://ecqi.healthit.gov/qrda</a> instead of a specific version of the IG.</li> </ul>
§ 170.205(k)(3)	§ 170.315(c)(3) - Clinical quality measures (CQMs) — report	<ul style="list-style-type: none"> <li>• Remove both 2022 and 2023 IGs from the Approved Advanced Version(s) column.</li> <li>• Add the CMS Implementation Guide for Quality Reporting Document Architecture; Category III; Eligible Clinicians Programs; Implementation Guide for 2024; Version 1.1; 11/22/2023 <ul style="list-style-type: none"> <li>○ This is the same as the "New version under consideration" in the "Current Standard ..." column</li> <li>○ HL7 agrees it should be added to SVAP.</li> <li>○ The title of the standard does not have "and Eligible Professionals"</li> </ul> </li> <li>• HL7 suggests to have the hyperlink to point to <a href="https://ecqi.healthit.gov/qrda">https://ecqi.healthit.gov/qrda</a> instead of a specific version of the IG.</li> </ul>