May 11, 2023

Micky Tripathi, Ph.D. M.P.P.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: United States Core Data for Interoperability (USCDI) Version 4 Draft

Dear Dr. Tripathi,

Oracle Health appreciates the opportunity to submit public comment on the 2023 Standards Version Advancement Process (SVAP). As a leading supplier of clinical and management information systems and a market leader in health information interoperability, we believe our experience provides us with valuable insight in this subject area and are grateful for the ability to share that insight.

Oracle Health supports and appreciates the hard work and dedication of you and your staff behind the creation of the SVAP concept to support developers and providers in their desire to maintain better currency with the latest in interoperability standards while also maintain regulatory compliance. Oracle Health strongly supports ONC's drive for interoperability across healthcare stakeholders and recognizes the valuable role that SVAP plays in that endeavor.

If you have any questions or if we can provide any additional information, please do not hesitate to contact me at (816) 201-1924.

Sincerely.

Mike Hourigan
Sr. Director, Product Regulatory Strategy
Oracle Health

May 11, 2023

General Comments

Policy for partial implementation of new versions of standards
While the SVAP concept as a whole is very beneficial to developers and providers alike, there remains lack of clarity around guidelines for scenarios where developers may seek to partially implement a new version of a standard – whether one approved under SVAP or not.

As an example, a developer may review a new version of the U.S. Core Data for Interoperability (USCDI) and decide to pursue implementing a subset of new data elements for their FHIR APIs certified to the Standardized API criterion at 170.315(g)(10) based on an assessment of immediate value for their customers, or e.g., network or state initiatives pre-adopting targeted subsets of a later USCDI version. In this case (or others like it), our current understanding is that doing so would be acceptable under program requirements so long as the changes are additive and do not create a direct non-conformance with the version of the associated standards (HL7® FHIR® US Core IG and USCDI in this instance) that their technology currently holds a certification for. No attestation or notification should be necessary for these types of partial new standard version additions as it would not impact the version of the standard that is actively certified.

While this appears clear and obvious on the surface and seems to align with pre-SVAP policies under the program, for the avoidance of doubt we ask that ONC provide clarity on this in sub-regulatory guidance for the SVAP.

Restructuring the SVAP timeline
While we appreciate the updates that ONC made to the SVAP timelines in 2022 to better align to the cadence for standards development related to the USCDI (specifically the HL7 FHIR US Core IG and HL7 CDA® C-CDA Companion Guide), the current timelines still impose challenges for developers. Given that the new version of those referenced standards for USCDI is generally not published until May of each year, an SVAP comment period that runs from ~mid-February to ~mid-May each year does not align well. Stakeholders simply do not have suitable time to review the specifications post-publication to consider for comment.

We suggest that a better cadence would be to conduct annual SVAP comment periods from ~mid-May through ~mid-July with an approval announcement in August and a 60-day delayed effective date falling in October. This would allow for ample time to review newly published annual version of the HL7 FHIR US Core IG and HL7 CDA C-CDA Companion Guide, as well as a better runway for developers to incorporate the new standards into their technology between the SVAP cycles.

A viable, preferred alternative for needing to restructure the SVAP timeline around USCDI specification releases would be to align USCDI certification itself with recommendations that have been expressed previously by Oracle Health and the developer community at-large. This would be to fully overhaul how USCDI is cited in the program by treating it as a compendium or library of data elements from which various elements would be cited by different criteria based on specific need or purpose, instead of citing the full data set as a monolith. We recognize this is not something that can be achieved via SVAP but urge ONC to consider this change for future regulation.

Support multiple SVAP versions at a time
The current structure of the SVAP under which only one new approved version of a standard is available to exercise at a time is unnecessarily restrictive for developers and does not comport well with development cycles. The most glaring example is with USCDI where currently the specifications

necessary to support it are not formally published until May of each year, giving developers merely 3-4 months to develop and exercise under SVAP before the next versions are presumably approved and replace them.

The reality is that many developers may not find value in adopting a full version of USCDI with each annual SVAP cycle when it will be almost immediately replaced by another new version. And while such development will more than likely be necessary in the long run to satisfy various obligations (whether regulatory or otherwise), allowing developers to prioritize the elements that provide the most value to them and their customers breeds more value and enhanced interoperability for the industry at-large. Allowing multiple new approved versions of standards to be active under SVAP simultaneously would allow developers to progress at their own pace instead of a forced march that may leave certain developers behind until they are mandated by a new certification requirement to fully uplift.

Accordingly, we ask ONC to consider amending current policy to allow for the two most recent new versions of a standard approved under SVAP to be available for developers to exercise at any one time.

Web Content Accessibility Guidelines (WCAG) 2.2, January 25, 2023

While Oracle Health strongly supports the inclusion of the latest adopted versions of WCAG standards as an option for advancement in the program, the 2.2 release is currently in "candidate recommendation" status and not officially adopted as final, nor published as a W3C recommended standard.

Accordingly, we recommend withholding WCAG 2.2 from approval in the 2023 SVAP unless it is finalized and published as a W3C recommended standard prior to the June 2023 release of approved new versions of standards.

HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 5.3 with errata (US Realm), Volume 2 - Templates and Supporting Material, December 2022

Oracle Health strongly supports approval of the updated HL7 QRDA I IG in the 2023 SVAP. Since this updated version forms the basis upon which the correlated Centers for Medicare and Medicaid Services (CMS) and Joint Commission (TJC) eCQM specifications for 2023 reporting are built, developers will already be supporting it out of necessity for our customers' reporting needs. Approving this new IG version will also establish alignment between the eCQM criteria at 170.315(c)(1) and (2) that cite it with the criterion at (c)(3), which cites the CMS QRDA specifications.

HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 5.3 with errata (US Realm), Volume 1 - Introductory Material, December 2022

As noted above, Oracle Health strongly supports the approval of this new version of the HL7 QRDA I IG in the 2023 SVAP. Since each volume (1 and 2) are companions of each other both necessary for full

adoption of the specification, both must be approved. This is supported by the fact that both volumes are currently cited as the same standard at 170.205(h)(2).[1]

CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2023

Oracle Health strongly supports approval of the CMS QRDA I IG for 2023 in the 2023 SVAP. It is effectively a mandatory obligation for developers of certified health IT to uplift to each new release of this IG on an annual basis to support our customers' needs for CMS quality reporting program participation. Accordingly, we further recommend that ONC consider putting these guides on an automatic approval path with each annual SVAP.

CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2023

As with the CMS QRDA I IG for 2023 used by hospitals, Oracle Health equally supports approval of the CMS QRDA III IG for 2023 used by Eligible Clinicians and recommends an automatic approval path for future years' releases under SVAP.

United States Core Data for Interoperability (USCDI) Version 3

Oracle Health supports the approval of USCDI v3 on the condition that the associated HL7 FHIR US Core IG v6.0.0 and HL7 CDA C-CDA Companion Guide R4 releases are adopted alongside it and made binding requirements in order to exercise USCDI v3 for applicable criteria. If these new releases are not able to be approved alongside USCDI v3, then it should also not be approved.

Furthermore, we ask ONC to clearly establish conditionality for claiming USCDI v3 as part of a certification via SVAP so that the corresponding releases of the HL7 FHIR US Core IG and HL7 CDA C-CDA Companion Guide are hard dependencies for it. The HL7 FHIR US Core IG dependency would apply to claiming a new USCDI version for the API criterion at 170.315(g)(10), while the HL7 CDA C-CDA Companion Guide dependency would apply equally for C-CDA-based criteria at 170.315(b)(1), (b)(2), (e)(1), and (g)(9). This would establish appropriate guardrails for advancing to new versions of USCDI in the program and provide necessary clarity for the developer community on those expectations.

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[1] 45 CFR 170.205(h)(2)