May 2, 20223

Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

Dear Dr. Tripathi,

As the review period of the Standards Version Advancement Process (SVAP) is coming to a close on May 2, 2022, the EHR Association would like to refresh our comments submitted on October 11, 2021. In that letter we expressed support for delaying the SVAP review and publication to aim for a summer 2022 SVAP publication, so the necessary HL7® FHIR® US Core and HL7® CDA® C-CDA Companion Guide guidance could be updated to reflect the additions made to USCDI V2. We also expressed a desire to proceed with all other proposed standards, as they were ready to move forward. Specifically:

- Applicability Statement for Secure Health Transport Version 1.3, May 2021 (Direct)
- CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2022 (July 2021)
- CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2022 (May 2021)
- HL7 FHIR® US Core Implementation Guide STU 4.0.0 (June 2021)

For these standards, as well as the more recently added version below, we support inclusion in the SVAP at this time:

- HL7 FHIR® SMART Application Launch Framework Implementation Guide Release 2.0.0, November 26, 2021
- HL7 FHIR® Bulk Data Access (Flat FHIR®) (v2.0.0: STU 2), November 26, 2021

AdvancedMD	CureMD	Flatiron Health	MEDHOST	NextGen Healthcare
Allscripts	eClinicalWorks	Foothold Technology	MEDITECH, Inc.	Office Practicum
Athenahealth	eMDs	Greenway Health	Medsphere	Sevocity
BestNotes	Endosoft	Harris Healthcare Group	Modernizing Medicine	STI Computer Services
Cerner Corporation	Epic	Lumeris	Netsmart	TenEleven Group
CPSI	Experity	MatrixCare	Nextech	Varian

However, the EHR Association has concerns about including the proposed USCDI V2 standard without the necessary updates to HL7® FHIR® US Core and HL7® CDA® C-CDA Companion Guide to be able to demonstrate support of USCDI V2 in 4 out of the 5 certification criteria scoped by USCDI. These two implementation guides have not been published as of the date of this letter, and thus could not have yet appeared in the draft SVAP. With the SVAP review period ending May 2, 2022, we believe that including these without an adequate review period may prove problematic, and without them included the necessary support for USCDI V2 would not be available.

While we recognize that adoption of newer versions of SVAP is voluntary, there is a historical precedence of other programs or organizations expressing a strong desire to adopt some or all of what SVAP has to offer before they are included in a next certification edition, making them required in the industry. Our concern is that these programs/organizations may do so without understanding that HL7® FHIR® US Core and the HL7® CDA® C-CDA Companion Guide these standards have not been widely adopted as they have not yet been published.

At the same time, for organizations that wish to stay current on the latest HL7® FHIR® US Core and/or HL7® CDA® C-CDA Companion Guide, not including these yet to be published versions would delay the opportunity to adopt them while maintaining a certified solution.

With the shift in approach where data classes/elements can be included in USCDI without the necessary standards/implementation guides in place at the time of USCDI publication, rather until almost a year later, the risk increases that the necessary standards/implementation guide publications occur after the SVAP comment period is substantially, if not fully, over.

Considering these concerns and challenges, as well as that we are still on a learning curve to find the right cadence between USCDI and SVAP, we strongly recommend that *ONC revisits and recalibrates the USCDI – SVAP cadence* by either:

> Requiring that the relevant standards/implementation guides are published before USCDI is published, or
>
> Requiring that the SVAP comment period that includes the next USCDI version does not start before the relevant standards/implementation guides supporting that next USCDI version are published

In the meantime, we strongly recommend that *ONC extends the current SVAP comment period* with a new date that is 30 days after the publication of both the applicable HL7® FHIR® US Core and HL7® CDA® C-CDA Companion Guide version to allow for adequate review. This extension could be limited to just these two standards supporting USCDI V2 as the review for the other standards has been adequate. However, in the case where such an extension would push the planned SVAP publication date substantially, we recommend proceeding with the publication of all the other standards and implementation guides and have a subsequent SVAP "Update" to include USCDI V2 with the two supporting implementation guides and avoid a year delay for both USCDI V2 and these two supporting implementation guides.

 Lastly, we recommend that *ONC provides clearer announcements* when new candidates are included as it was not obvious to many that HL7 FHIR® SMART Application Launch Framework Implementation Guide Release 2.0.0, November 26, 2021, and HL7 FHIR® Bulk Data Access (Flat FHIR®) (v2.0.0: STU 2), November 26, 2021, were added after October 2021.

We believe that the combination of these two recommendations provides a way forward that recognizes the need for adequate review without a substantial delay thus enabling earlier adoption by those interested.

As always, the EHR Association stands ready to assist. Thank you for considering our input.
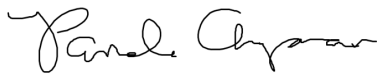
Sincerely,

Hans J. Buitendijk
Chair, EHR Association
Cerner Corporation

David J. Bucciferro
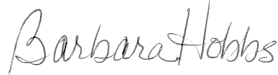Vice Chair, EHR Association
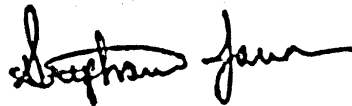Foothold Technology

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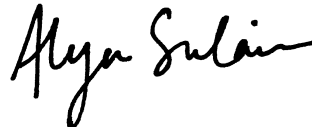
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