Health Information Technology Advisory Committee

Adopted Standards Task Force 2022 Virtual Meeting

Meeting Notes | August 16, 2022, 10:30 a.m. – 12:00 p.m. ET

Executive Summary

The focus of the Adopted Standards Task Force 2022 (AS TF) meeting was to review draft dispositions and Group 6 standards. There was one public comment submitted verbally, but there was a discussion held via the chat feature in Zoom Webinar.

Agenda

10:30 a.m.	Call to Order/Roll Call
10:35 a.m.	ONC Standards Review – Group 6, Review Draft Dispositions
11:50 a.m.	Public Comment
11:55 a.m.	Next Steps
12:00 p.m.	Adjourn

Call to Order

Mike Berry, Director, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:31 a.m. and welcomed members and the public to the meeting of the AS TF 2022.

Roll Call

MEMBERS IN ATTENDANCE

Steve (Ike) Eichner, Texas Department of State Health Services, Co-Chair
Hans Buitendijk, Oracle Cerner, Co-Chair
Jeff Danford, Altera Digital Health
Jim Jirjis, HCA Healthcare
Hung S. Luu, Children's Health
Deven McGraw, Invitae
Vassil Peytchev, Epic
Alexis Snyder, Individual
Fillipe Southerland, Yardi Systems, Inc.
Raymonde Uy, National Association of Community Health Centers (NACHC)
Debi Willis, PatientLink Enterprises, Inc.

MEMBERS NOT IN ATTENDANCE

Rajesh Godavarthi, MCG Health, part of the Hearst Health network
John Kilbourne, Department of Veterans Health Affairs (VA)
Clem McDonald, National Library of Medicine
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Samantha Pitts, Johns Hopkins University School of Medicine

Ram Sriram, National Institute of Standards and Technology

ONC STAFF

Mike Berry, Designated Federal Officer
Maggie Zeng, Subcommittee Lead
Liz Turi, Task Force Co-Lead
Scott Bohon, Task Force Co-Lead

Key Specific Points of Discussion

TOPIC: CALL TO ORDER AND CO-CHAIR REMARKS

Steve Eichner and Hans Buitendijk, AS TF 2022 co-chairs, welcomed everyone. Hans discussed the standards the TF was scheduled to review and the timeline for the TF's upcoming work. He explained that the TF has started to shift its work from the spreadsheet-based worksheet documents to a Google document as the TF's draft recommendations to the HITAC are developed. TF members were encouraged to use red-line text when editing the working document. The TF aims to complete its work by the end of August 2022, after which it will submit a report to the HITAC for its consideration and transmittal to the Office of the National Coordinator for Health IT.

TOPIC: ONC STANDARDS REVIEW – GROUP 6 AND DRAFT DISPOSITIONS

The co-chairs briefly shared the AS TF 2022 charge and related 21st Century Cures Act (the Cures Act) Requirement that the charge fulfills. These included:

- Beginning 5 years after the date of enactment [December 13, 2016] of the 21st Century Cures Act and every 3 years thereafter, the National Coordinator shall convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect to whether to-
  - (A) maintain the use of such standards and implementation specifications; or
  - (B) phase out such standards and implementation specifications.

Reference: 42 U.S. Code § 300jj–13 - Setting priorities for standards adoption

- Charge: Review the existing set of ONC adopted standards and implementation specifications and make recommendations to maintain or phase out such standards and implementation specifications, as required by 42 U.S. Code § 300jj–13 (Setting Priorities for Standards Adoption). The current set of ONC adopted standards and implementation specifications are maintained on the ONC Standards Hub.
- This charge does not seek recommendations for new standards and implementation specifications for ONC to adopt through rulemaking.

The AS TF reviewed the Group 6 standards, and a subject matter expert (SME) shared relevant information.

Steve reviewed the draft dispositions document and explained how it was created from the TF's previous working Google documents. It included an introduction (approach and summary), recommendations for all of the standards the TF reviewed (Data Scope and Vocabulary Standards, General Data Access Standards, Care Coordination Standards, Public Health Exchange Standards, Clinical Quality Measure Reporting Standards, Privacy / Security Standards, Accessibility Standards, Certification Process Standards), and Alphabetized Standards List. He explained that the TF must develop short introductions for each section and highlighted several areas that require clarification (i.e., wording of "retire" versus "phase out;" who is officially making the recommendations?). The co-chairs encouraged TF members to review the document and add changes and comments, which may be discussed at a future meeting.

TF members reviewed the document's structure and overall contents/language and agreed that the current

approach was correct; the TF did not and should not include information about the purpose, where each standard is used, or where it would be in regulation.

DISCUSSION:

- The TF reviewed the FHIR® US Core Implementation Guide (IG) STU V3.1.1 standard, and Hans explained that newer versions have been released, including version 4.0.0, June 2021 (available 8/29/2022, and version 5.0.1, June 2022 (available 8/29/2022). These support the United States Core Data for Interoperability (USCDI) versions 1 and 2. Additionally, the TF anticipates that this cadence will progress, and a newer version of the FHIR US Core IG will be released to support USCDI version 3.
  - Hans suggested that the TF consider the then most current published version that aligns with whatever version of the USCDI is to be included. Jeff supported the suggestion and emphasized the need to align the USCDI and US Core IG.
  - Deven referenced an early AS TF discussion that the version of the US Core IG should be aligned with the version of the USCDI that is going through the ONC Standards Version Advancement Process (SVAP), not the most current. Hans agreed, but he noted that the USCDI process is currently ahead of US Core; the US Core will always support a previous version of the USCDI. The TF discussed cautionary remarks that could be added to the disposition for this standard.
- The TF reviewed the HL7® FHIR® Bulk Data Access (Flat FHIR®) (V1.0.0:STU 1) standard.
  - Hans noted that a more current version was published in November 2021, and it will become available on August 29, 2022. However, there is no specific tie-in to the USCDI.
  - The TF agreed to recommend that the most current version should be considered.
- The TF reviewed the HL7® SMART Application Launch Framework Implementation Guide Release 1.0.0 standard.
  - Hans noted work is underway on Release 2.0.0, November 26, 2021, which will be available on 8/29/2022. He asked if there is another version in progress and for TF members to share feedback on a potential recommendation. Steve discussed differences in language used in the TF's recommendations, specifically the phrases "most current" and "consider adoption." Hans agreed that the TF should use "consider adopting" in its recommendations, and he discussed differences between the SVAP cycle and the release of regulation processes. Steve discussed nuances around the meaning of "current" (e.g., is the standard balloted?) and suggested that the TF provide a definition for this purpose.
- The TF reviewed the HL7® Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 standard.
  - Hans commented that there is no new release in progress and that the standard is not in SVAP. He shared TF members' comments from the working documents. Some members expressed concern that DS4P does not fully cover the privacy/consent issue.
  - Jeff agreed with Hans' comments and added that the structure of the workflow should be in place before the standard is changed. Deven supported maintaining the standard, even if it is less than ideal, though she noted that there is room for growth. Vassil asked if the standard is implemented and in use; if it is not, could it be removed and replaced with a more comprehensive standard? Hans stated that document-level tagging uses this standard, but he also asked ONC to comment on how many systems have certified to this standard. Vassil asked whether the C-CDA Documentation Guide could be used instead.
  - TF members agreed to maintain the standard. They added a comment that other things are necessary to support the full workflow and that related challenges should be highlighted.
- As an SME, Margaret Weiker, VP of Standards Development at the National Council of Prescription Drug Program (NCPDP), shared background information on the NCPDP SCRIPT Standard Implementation Guide, Version 2017071. She commented that it has been adopted under Medicare Part D, ONC has included it in certification criteria, and developers have until

the end of 2022 to certify to this version. Medicare Part D and ONC are working on Version 202211 and also on Version 2022071.

- Hans provided an overview of TF members' comments in the working documents. Alignment between all parties will drive which version of the standard is recommended for use, and Margaret agreed, noting that there will be time allotted for implementation (usually 18 months to two years). ONC will reference NCPDP's work.
- Steve asked Margaret to comment on the SCRIPT standard and the Prescription Drug Monitoring Program (PDMP) and whether the NCPDP environment is aligned with the adoption of current versions. Margaret stated that many states use the PDMP format, and there are transactions in the SCRIPT standard that support PDMP. However, other states use the ASAP format. She explained how state-level regulatory bodies drive the standards that are used and noted that it is not consistent across the United States. Hans added that additional steps must be taken to harmonize across all settings.
- TF members agreed to draft a recommendation that the older standard should be retired/phased out with the understanding of timing around work that is underway on future versions. At Steve's suggestion, they agreed to add a note that this standard must align with the existing PDMP components, as this is a secondary that is not included in regular health IT updates from vendors and is not part of regulatory maintenance for healthcare providers. This can be a substantial cost for entities to upgrade existing systems

- The TF reviewed the ISO/IEC 17025:2017(E)—General Requirements for the Competence of Testing and Calibration Laboratories, (Third Edition), November 2017 standard.
  - TF members agreed to draft a recommendation to maintain the standard, pending further versions/future work on the standard.
- The TF reviewed the ISO/IEC 17065:2012 (E)— Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services (First Edition), September 2012.
  - TF members agreed to draft a recommendation to maintain the standard, pending further versions/future work on the standard.

Action Items and Next Steps

Homework for the August 23, 2022, AS TF 2022 Meeting – due by Monday, August 22:

- Continue to refine our draft final dispositions in the Google Document.
  - Please review and provide comments or suggestions on the current wording in the Google Document. For version control, you will not be able to edit the document but can add your comments with your name.
- The TF co-chairs will merge the content into the final framework document.
- If anyone has questions, please reach out to the co-chairs or the ONC program team by email.

Public Comment

QUESTIONS AND COMMENTS RECEIVED VERBALLY

Mike Berry opened the meeting for public comments. There was one public comment received verbally:

Shelly Spiro: My name is Shelly Spiro, and I am the Executive Director of the Pharmacy HIT Collaborative. We are an active a member of the NCPDP, and I just wanted to clarify my comment in the chat of what Margaret Weiker from NCPDP stated. It's important for the SCRIPT version, which is the version Margaret had mentioned in the mention in the 2022 series. Because of Electronic Prescribing for Controlled Substances (ECPS) in the long-term post-acute care setting that handles the three-way communication between the prescriber, the facility, and the pharmacy. There was an additional functionality that was added in the newer version that isn't in the older version that would help with the adoption of the EPCS in that setting.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mike Berry (ONC): Thank you for joining the Adopted Standards Task Force. We will be starting shortly. Please remember to set your chat to “Everyone” so that everyone can see your message.

Jim Jirjis: Good morning

Fil Southerland, Yardi Systems: Agree

Shelly Spiro: The newer SCRIPT version is needed to accommodate EPCS in the LTPAC setting

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

Resources

AS TF Webpage
AS TF – August 16, 2022 Meeting Webpage
AS TF – August 16, 2022 Meeting Agenda
AS TF – August 16, 2022 Meeting Slides
HITAC Calendar Webpage

Meeting Schedule and Adjournment

Steve and Hans thanked everyone for their participation and support. The co-chairs summarized key achievements from the current meeting and shared a list of upcoming AS TF meetings. TF members will receive links to the working recommendations document from Accel staff via email. The TF will present an update to the HITAC at its August 17, 2022, meeting, and a final presentation and vote will occur at the September 14, 2022, HITAC meeting.

The next meeting of the AS TF will be held on August 23, 2022. The meeting was adjourned at 11:27 a.m. E.T.