Health Information Technology Advisory Committee
Adopted Standards Task Force 2022 Virtual Meeting

Meeting Notes | July 12, 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 begin reviewing Groups 1 and 2 of ONC's Standards. There were no public comments submitted verbally, but there was a robust 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 1 – 3
11:50 a.m.	Public Comment
11:55 a.m.	Next Steps
12:00 p.m.	Adjourn

Call to Order

Mike Berry, 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

Hans Buitendijk, Oracle Cerner, Co-Chair
Steven (Ike) Eichner, Texas Department of State Health Services, Co-Chair
Jeff Danford, Altera Digital Health
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Jim Jirjis, HCA Healthcare
John Kilbourne, Department of Veterans Health Affairs (VA)
Hung S. Luu, Children's Health
Deven McGraw, Invitae
Clem McDonald, National Library of Medicine
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Vassil Peytchev, Epic
Samantha Pitts, Johns Hopkins University School of Medicine
Alexis Snyder, Individual
Fillipe Southerland, Yardi Systems, Inc.
Ram Sriram, National Institute of Standards and Technology
Debi Willis, PatientLink Enterprises, Inc.

MEMBERS NOT IN ATTENDANCE

Raymonde Uy, National Association of Community Health Centers (NACHC)

ONC STAFF
Mike Berry, Designated Federal Officer
Josianne Charles, Task Force Co-lead
Liz Turi, Task Force Co-Lead

Key Specific Points of Discussion

TOPIC: CALL TO ORDER AND CO-CHAIR REMARKS

Steven Eichner and Hans Buitendijk, AS TF 2022 co-chairs, welcomed everyone. Steven explained that the TF would review standards included in regulations to determine if they need to be maintained or retired. 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. He added that feedback from the previous meeting of the TF was incorporated into the TF's working documents.

Hans invited new members to introduce themselves to the AS TF 2022:

- Deven McGraw is the Lead, Data Stewardship & Data Sharing, Citizen Platform at Invitae, which is a clinical genetics testing company. She previously co-founded and worked at Citizen and was the Deputy Director for Health and Information Privacy for the HHS Office of Civil Rights. Also, she served as the Acting Privacy Officer for ONC and led the tiger team on privacy and security and the predecessor to the HITAC. Her areas of expertise are in patient access, privacy, and security.
- Jeff Danford is the Solution Member for Interoperability with Altera Digital Health (formerly Allscripts). He is focused on Altera's Fast Healthcare Interoperability Resources (FHIR) specifications, application programming interface (API) development, and the full list of HL7 public and proprietary interoperability APIs.

TOPIC: ONC STANDARDS REVIEW – GROUP 1 – 3

Hans shared the AS TF 2022 charge and discussed the 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-
  - o (A) maintain the use of such standards and implementation specifications; or
  - o (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.

Hans explained that the TF would review ONC standards in Group 1 and would then move as far forward as possible into the groupings of standards during current and future meetings. He noted that the intent for TF

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members is to determine if there are new or updated standards for ONC to consider and not to provide guidance on which versions should be chosen. It is not a requirement for all AS TF members to be familiar with all the standards under review, and members may request the opportunity for the TF to learn more about standards through subject matter expert (SME) presentations.

Hans and Steven asked TF members to consider the following questions when evaluating each standard:

- Is the purpose of the still standard relevant?
- Does a better, more expanded, or newer standard exist that should be used instead?
- Will the standard be appropriately mature, keeping in mind that this process will be repeated every three years?

Hans presented AS TF's working spreadsheets containing Groups 1, 2, and 3 of the standards for review. These included columns containing the name of the standard, the corresponding last published version of the Standards Version Advancement Process (SVAP) the standard is permitted to be certified against, latest published version of the standard (if not listed in the SVAP), and the review cycle grouping number. Links were included in the spreadsheet. Hans noted that the spreadsheet does not capture if there is an alternative standard that can be used to fulfill the same purpose.

DISCUSSION:

- Vassil commented that Group 1 seems to be comprised of terminology standards and suggested that the AS TF discussed what it means to phase out a standard in favor of a newer version. He stated that it should be a given that they want the newest version.
  - o Hans thanked him for his comments and explained the way the groupings were divided based on the number of standards and code sets to be reviewed. He stated that the TF should make considerations across code sets that are referenced.
  - o Clem commented that many of the vocabulary standards have a progression built in to update when new standards are released and asked if the TF must discuss those standards. Hans answered that the TF should briefly review them as a bundle to ensure that everyone is aware of how the current process works.
- Hans and Steven reviewed the standards in Group 1, noting that they are all code systems standards that are updated frequently. Hans described how a rule/guidance was put in place as part of the certification program prior to the 21st Century Cures Act (the Cures Act) that allows certified software to take advantage of the most recently published version of a standard. He described the mechanisms that are used to set a floor. He suggested that the TF briefly discuss whether this process is working and if the rule should be kept. Steven reviewed each of the standards and invited members to comment on whether a recommendation would be appropriate that all must update to the most current floor (instead of pointing to a specific new floor because the TF will not know when the regulation comes out).
  - o TF members shared feedback. Clem commented that if the rule is working, it should be kept. Vassil commented that the rule needs to contain a safety valve for historical data to ensure that it is retained in a way that is compliant. Hans agreed that historical data should be retained.
  - o Deven explained that while vendors may adopt a standard ahead of a mandate to do so, there is no requirement to do so. The SVAP process helps to get vendors to voluntarily adopt new standards, but the TF now has an opportunity to push for standards that need to be retired. Steven agreed that the TF should create a recommendation calling for the floor to be identified and updated periodically.
  - o Hans explained the future cadence of the TF's work (meeting every three years), noting that updates to standards should at least keep pace, and discussed how updates to regulations affect the periodic raising of the floor. If the TF wants to change the cadence of its work, that is a different conversation than how quickly the floor is moved up. Steven stated that the TF should be cognizant of the related laws and processes that may vary and discussed

how ICD-10 is regularly updated and has drivers for these updates outside of standards.

o Hans asked TF members to review the draft disposition and recommendation, which could be applied uniformly across all of Group 1. He invited TF members to review the Group 1 standards to determine whether any should be replaced with a different (not updated) standard. Later groups of standards will also be reviewed to determine if they also fall under this recommendation.

o Vassil commented that the reference in the standard RFC 5646, "Tags for Identifying Languages," September 2009 should be changed and that the TF should investigate the BCP 47 reference that is absent. Hans thanked him for his comment and added that the TF would determine stated that all the standards Vassil highlighted in the Group 1 standards would be covered by a more general TF recommendation that standards would be updated as new versions are released. Clem discussed his early involvement with the development of this standard, noting that there were two standards (a shorter one and a longer one). Hans responded that the TF needs to circle back if the standard is not the same as the current.

o The TF discussed Samantha's questions about how to clarify when there are multiple versions/listings of a standard and reviewed the three standards that pertain to SNOMED (listed in Group 1). Steven noted that sometimes an implementation guide (IG) is listed first, then other documents are listed as they are developed. Hans suggested that the TF blend the references by nesting the versions of the same standard, though this could be slightly out-of-scope for the TF. Steven commented that the TF could recommend that there is a global approach to maintaining standards by using a single implementation of a standard across federal regulations.

- Steven reviewed the Group 2 standards and invited TF members to speak to the comments they left in the working document or to share feedback verbally.

o Hans highlighted comments he and Debi made on standard HL7® CDA R2 IG: C-CDA Templates for Clinical Notes. R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5). Debi commented that she would like to discuss the requirement to share CCDs with patients in R4. She was told clinical notes is in R4 but not C-CDA. A CCD is very important to patients. Was this intentional in §170.315(g)(10) Standardized API for patient and population services? Vassil asked which version of the USCDI should be considered. TF members discussed whether they should consider the most currently published version(s) based on the United States Core Data for Interoperability (USCDI) progression (i.e., USCDI cannot get ahead of supporting standards) and how regulations are updated and have interplay. Steven commented that internal compatibility should be considered. Jim asked how ONC will drive the versioning and adoption of the USCDI for certification, and Hans described ONC's SVAP process, including the use of supporting companion guides and their use/adoption. Deven added that ONC ultimately controls when and what is required but must first go through a public rulemaking process. Hans asked if the TF would be willing to wait to circle back with Debi on her CCD comment at the next TF meeting.

o The TF decided to maintain the standard HL7® Implementation Guide (IG) for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata). And its companion guide. In response to a prompt from Hans, TF members indicated that it is too early to start considering FHIR Documents due to the current level of adoption. Members recommended revisiting this recommendation by a future iteration of the AS TF in three years.

o TF members discussed the standard HL7® Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012. John commented that there is a more recent release of C-CDA. Hans commented that the TF could reference available Errata for completeness, but not an issue. Vassil commented that it should be retired for generation while processing limited to display only and use the CDA Release 2 display requirement. Steven suggested that the TF check

whether the current language is restricted to "view" or still includes "generate." Hung commented that just because this is being retired to raise the floor, the TF must consider the need to retain and support historical data as systems are updated in the future. Steven asked the TF to consider what functions the standard is being applied. He asked if this was for exchange, ingest, etc.? Hans asked if the standard could be dropped, and TF members discussed a potential recommendation to drop the old standard in favor of one stating that there is a requirement to display only for C-CDA Release 2. Hans responded to Samantha's comment, noting that a C-CDA document is meant to persist, and she asked if this discussion could be tied to the TF's earlier recommendations for Group 1. Hans suggested keeping the recommendations separate.

Action Items and Next Steps

Homework for the June 19, 2022, AS TF 2022 Meeting: -- due by Monday, July 18:

- In preparation of the next meeting, all task force members are asked to review the disposition tracking spreadsheet on Google documents. The spreadsheet was updated per the suggestions made during the first meeting. Note: Unless members have done so previously, they will need to provide their Gmail address to Accel Solutions to access this document.

Homework Assignment Instructions

- Review the instructions on the first tab of the spreadsheet and become familiar with the definitions. Reminder – There is not an expectation for one to have in-depth knowledge of every standard. Please feel free to consult others as needed to best inform your recommendation.
- Review the standards listed in Groups 2 and 5 (see "Review Cycle Grouping" in Column D):
  o Click on the link to the standard (Column A) and begin to get familiar with the standard. The AS TF will discuss each standard during our next task force meeting.
  o In Column V, please indicate with your name if any specific information is needed. For example: "Hans - Need to have a better understanding of dental codes." Please be careful to avoid overwriting other task force member comments. The co-chairs will determine if external presenters are needed to inform the task force members about a particular standard.
  o In Columns E through U, find the column with you name, and select the appropriate (tentative) disposition for each standard. If you are already familiar with a particular standard, you may be able to select "Maintain", "Phase Out_Replace/Update", etc. However, if you are not familiar with the standard, please enter "Working", and you can update your selection once the task force discusses the standard in more detail. If you are entering a final disposition, please indicate using your name in Column W if you have additional comments or rationale for your disposition. For example: "Hans – standard should be phased out/replaced with alternate standard XYZ."
  o Please indicate in Column V if you would like to lead a discussion on a particular standard. We would like all task force members to consider volunteering to present on standards where you have any level of subject matter expertise.
  o Column X will remain empty until recommendations are synthesized and finalized.
- Once you address Group 2 and 5, please feel free to work ahead to Group 3, etc. as your time allows. It would be helpful for our planning to know "Specific Information Needed" (Column V) for any standard in any group so that we can consider external presenters in advance.
- 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 were no public comments received verbally.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

John Travis: I would take great care in retiring the USCDI v1 until replaced by actual certification regulation update. SVAP already would "retire" versions of the USCDI that precede what is currently adopted that lay between USCDI v1 and what would be the then most current version of the USCDI recognized as final

John Travis: And so really little value in finalizing anything outside the SVAP process or retiring anything for the USCDI - but let regulation address that in their future certification regulation updates

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

Resources
AS TF Webpage
AS TF – July 12, 2022 Meeting Webpage
AS TF – July 12, 2022 Meeting Agenda
AS TF – July 12, 2022 Meeting Slides
HITAC Calendar Webpage

Meeting Schedule and Adjournment

Steven and Hans thanked everyone for their participation and asked TF members to focus on homework in between meetings. They invited TF members to weigh in on the method and process for reviewing standards going forward, and TF members were asked to continue to share feedback in the working Google spreadsheet document.

The co-chairs summarized key achievements from the current meeting, and they shared a list of upcoming AS TF meetings. The next meeting of the AS TF will be held on July 19, 2022. The meeting was adjourned at 11:28 a.m. E.T.