

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

Meeting Notes | July 19, 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 Groups 2 and 5 of ONC's Standards. There was one public comments submitted verbally, and there was a robust discussion held via the chat feature in Zoom Webinar.

Agenda

10:30 a.m.Call to Order/Roll Call10:35 a.m.ONC Standards Review – Group 2 & 511:50 a.m.Public Comment11:55 a.m.Next Steps12:00 p.m.Adjourn

Call to Order

Seth Pazinski, Director, Strategic Planning & Coordination Division and Acting 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 Steve (Ike) Eichner, Texas Department of State Health Services, Co-Chair John Kilbourne, Department of Veterans Health Affairs (VA) Hung S. Luu, Children's Health Clem McDonald, National Library of Medicine Deven McGraw, Invitae 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 Raymonde Uy, National Association of Community Health Centers (NACHC) Debi Willis, PatientLink Enterprises, Inc.

MEMBERS NOT IN ATTENDANCE

Jeff Danford, Altera Digital Health Rajesh Godavarthi, MCG Health, part of the Hearst Health network Jim Jirjis, HCA Healthcare



Eliel Oliveira, Dell Medical School, University of Texas at Austin

ONC STAFF

Seth Pazinski, Director, Strategic Planning & Coordination Division and Acting Designated Federal Officer Wendy Noboa, 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 and discussed the standards that the TF was scheduled to review. They explained that TF has a goal of completing 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. Hans added that feedback from the previous meeting of the TF was incorporated into the TF's working documents.

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

 Raymonde Uy is a Physician Informaticist for the National Association of Community Health Centers (NACHC) and has a background in clinical medicine. He did a postdoctoral fellowship in biomedical informatics at the National Library of Medicine (NLM)/National Institutes of Health (NIH) under Dr. Clem McDonald. He teaches clinical informatics and consults on topics across the industry, such as medical terminology at the Centers for Disease Control (CDC).

Seth reminded TF members of the process for sharing public comments and noted that they would be recorded for inclusion in the official record via meeting summaries.

TOPIC: ONC STANDARDS REVIEW – GROUPS 2 & 5

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 Groups 2 and 5 at the current meeting and briefly reviewed updates made to the Group 1 standards due to feedback shared at the previous meeting of the TF. Hans presented the 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.

TF members were invited to discuss the standards in Groups 2 and 5 and to share their expertise, comments, and/or questions.

DISCUSSION:

- Regarding the 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 invited TF members to discuss the requirement to share CCDs with patients in R4. She stated that she was told clinical notes is required to be shared with patients in R4 but not C-CDA and emphasized that a CCD is very important to patients. She explained the process and asked if this was intentional in §170.315(g)(10) Standardized API for patient and population services.
 - Hans responded that the certification still requires support for CCD, though clarification is needed as to whether they are all exposed through Fast Healthcare Interoperability Resources (FHIR) Application Programming Interfaces (APIs). He stated that determining whether a particular application does/does not support a particular capability might be outside the scope for the AS TF's work, while it is still a valid question. Debi asked who the appropriate entity would be to address this question, and Seth offered to follow up with ONC.
- Hans 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.
 - Hans reviewed the feedback AS TF members made on the standard E.123: Notation for national and international telephone numbers, e-mail addresses and web addresses, noting that the standard has not changed since it was published. The consensus of the TF was to maintain the standard; Steve added that there is no alternative identified.
 - Hans reviewed the feedback AS TF members gave on the standard E.164: The international public telecommunication numbering plan and noted that similar TF member feedback was to maintain the standard. There is no alternative identified.
 - Steve commented that the TF should document its review process and methodology to better guide future work. He suggested that the TF members should document and share where they have looked for alternative standards for future reference.
 - O Hans asked TF members to discuss The Direct Project: ONC Applicability Statement for Secure Health Transport, Version 1.2 August 2015. Vassil commented that 1.3 is an American National Standards Institute (ANSI) standard, unlike prior versions (consensusbased discussions). The AS TF agreed to draft a note to use the most current version. Plus, it is now an ANSI standard. In response to Samantha's question, Vassil also noted that one can use standard 1.3 without using standard #19 (below), but #19 is being updated to address current gaps/edge cases that address undesired variances. The new version will not replace or invalidate the older version. Vassil offered to review the specific language of the TF's recommendation to ensure clarity.
 - o The TF reviewed member feedback on the standard ONC Implementation Guide for Direct Edge Protocols, Version 1.1, June 25, 2014, and Vassil commented there is a rewrite for XDR/XDM for Direct IG (almost complete) and the Direct Edge Protocol IG (available soon). These contain many corrections, better formal definitions, and apply lessons learned from users. Hans and Vassil discussed how this is being handled by the ONC Standards Version Advancement Process (SVAP). Hung stated that he is uncomfortable recommending a standard that is not currently published. The AS TF decided to recommend updating to the most current public version of the standard, as a new version is currently in progress and expected to be published as an ANSI standard in six to 12 months. Hans noted that until that is published, the previous standard cannot be retired, and Steve discussed how to phrase the TF's recommendation to emphasize that sufficient time is needed following the



publication of a new standard to allow for implementation and adoption across the ecosystem.

- Hans reviewed the feedback AS TF members made on the standard IHE IT Infrastructure Technical Framework Volume 2b (ITI TF- 2b). John Kilbourne asked if this has been updated: <u>https://profiles.ihe.net/ITI/TF/index.html</u>. In response to a question from Clem, TF members discussed how this standard is used (e.g., widely used by the Carequality Network). TF members discussed whether HL7 or IHE should be responsible for this work. Hans explained that this standard defines the some of the fundamentals for how document exchanges occur. Vassil commented that the TF should properly reference volume 1 for the specific profiles when updating the standard, not just the individual transactions in volume 2. He offered to provide examples of the improvements and clarifications on the differences between the volumes. Steve commented that looking at justifications and costs related to implementing the newest versions of standards is important but outside the scope for the AS TF. TF members discussed using the current version, as it includes many clarifications that improve on interoperability. They determined that references to Volume 1 should be considered, as well.
- Hans reviewed the Group 5 standards and invited TF members to speak to the comments they left in the working document or to share feedback verbally.
 - O Hans reviewed the feedback AS TF members made on the standard Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2, October 8, 2014 (incorporated by reference in § 170.299). He asked if any additional information is needed regarding this standard before the TF could make a judgement and added that it is widely used for security purposes. Vassil commented that he responded, "Maintain," but he suggested that the TF request Federal guidance on whether the newest version of the standard will cause any implementation issues in the future. Steve commented that standard should be modernized for consistency for organizations. Deven supported other TF members' comments in support of upgrading to the newest version of the standard but also requested additional information around the costs related completing upgrades/migration. Steve suggested looking at regulatory impacts outside of ONC (e.g., federal audits). Deven emphasized the importance of migrating to the newest version of standards to ensure security. The TF decided to recommend using the then most current version of the standard to keep pace with any security updates.
 - Hans commented that there is no known current standard for (RFC 5905) Network Time Protocol Version 4 and explained that the overall comments from TF members supported maintaining the current status. Steve suggested adding a recommendation that any new standards must be evaluated. Vassil commented that RFC 7822 (extensions that may not be relevant), RFC 8573 (may be relevant, but unclear), and RFC 9109 (port optimization) could be considered as updates to RFC 5905. The TF determined that there is a need to follow-up on Vassil's comments before making a recommendation.
 - Hans reviewed the feedback AS TF members made on the standard ASTM E2147-18 Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems. He stated that there is a newer version from 2019 that is behind a paywall, and many TF members have commented that they could not access it. The TF decided to reach out to Raj for insight on their potential recommendation.
 - Deven highlighted Samantha's question about whether considerations around costs for updates and regulations is in-scope for the TF. Hans and Steve responded that it is not inscope for the TF because their primary focus is on what standards should be retired or replaced. The TF should not go into a full cost-benefit analysis for any or all the standards. Hans asked the ONC team if they could provide access to the standard to allow for evaluation, as there is a cost to access it; ONC will follow-up on this request.
 - Hans explained that there is nothing published in SVAP on the OpenID Connect Core 1.0 incorporating errata set 1, and there is no known latest published version/more current version. The TF will reach out to Raj for insight on his suggestion to phase this standard out



and for creating a recommendation.

- Hans explained that there is nothing published in the SVAP on the Secure Hash Standard, 180-4 (August 2015), and there are no known updates to this security standard. Steve suggested asking ONC and NIST (via Ram) whether there would be a more appropriate/current standard that would indicate replacement (e.g., SHA-1 was retired before, is anything in the works for SHA-2 replacement?). Ram offered to investigate the documents that are currently being updated across all domains, including healthcare. Steve offered to reach out to the Sequoia Project to determine whether additional work is underway related to TEFCA.
- Hans explained that the Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance standard has been recognized in the SVAP and that several members have commented that this standard should be replaced with the most current version. TF members agreed with the suggestion. Steve asked the ONC team if the TF should reach out to the Office of Civil Rights (OCR) or others in HHS for additional guidance, and Seth responded that ONC could reach out to colleagues at OCR for information on any other developments and to ensure internal consistency with other activities. There is a v2.2 in draft in progress.
- Hans reviewed the Web Content Accessibility Guidelines (WCAG) 2.0, Level AA
 Conformance, and the TF decided to take the same actions as the previous standard.
- Hans explained that the TF members' feedback ranges from wanting more information 0 about the United States Core Data for Interoperability (USCDI to voicing support for USCDI 1 to recommending updating to the latest version of the USCDI.) Hans suggested that the TF recommend considering the then most current published version. Vassil elaborated on his comments about implications of a recommendation on the US CORE and companion guide, and Hans discussed the timing of the cadence of updates to the USCDI and inherent catch-up periods during the process. TF members debated how to best frame their recommendation. Clem and Hung voiced support for a recommendation to support the newest current version of the USCDI, with Clem noting that work on it has been underway for months. Hans spoke about the "Catch 22" situation of having to support the most current version of the USCDI, while the rule that is being written does not include the most current version. How does this work in a certification environment? He cautioned the TF against adding something in that cannot work. TF members discussed the following recommendations: the then most current version. - OR - Then most current that has support of C-CDA Companion Guide and FHIR US Core in particular. - OR - A newer version and ONC to address dependencies between USCDI, C-CDA, and FHIR US Core to ensure interoperable support of adopted USCDI.
- Fil asked to make the next iteration of the AS TF aware that there is a WCAG Version 2.2. in draft form. Hans added this note to the TF's working spreadsheet.

Action Items and Next Steps

Homework for the June 26, 2022, AS TF 2022 Meeting:

 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 3 and 4 (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.

- 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.
- 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."
- 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.
- 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

Seth opened the meeting for public comments. The co-chairs shared the following public comment received during the verbal comment period by an attendee without access to the online/verbal chat function:

John Travis: My question is how does this process consider a current version of standard in current certification regulation as to questions of retirement?

John Travis: Does the process allow for reference to one version maintained and one version recommended for adoption both?

RESPONSES FROM TF MEMBERS AND ONC:

Hans: Generally, in this process, the way we would understand that is that the current rule has USCDI version 1 in play, and there is a current version and there will be an even more current version shortly. So, the recommendation that we could make is to either maintain it, as is, where there is no need to go up in the regulation any more than the current version. We have to get some more rationale as to why. Or, we could say that with a more current version and indicate which one might be or more open. Keeping in mind that it is not the task force to fully define recommendation that it must be a particular version if for these 10 versions. At that time point, when that new regulations would start to be created, there would be opportunity for review and for those more detailed and specific comments. Rather, here we are looking at an argument that is sufficient to highlight why it need not be maintained in its current form. I think that is what we are looking right now where we want to phrase, looking at a more current version. I'm getting the sense that we should move to something more current. The question is how do we phrase that idea of "more current"? Given that there is a dependency for having to implement USCDI in order to have appropriate standards that could do that, and for some programs that may be applicable and for other programs that may not be relevant for some. Which is the reason why we have it. So, looking at the reference to USCDI, it is referenced to regulations for certification, and it is referenced in regulations for information blocking until the end of October. So, regarding the other question that received from John, Seth may have more insight. It is not that we are trying to be very specific. If we feel that we should have consideration of supporting more versions, I think that we could hint at that. It is not necessarily that we are the ones that are making a firm recommendation on behalf of HITAC. That would be a future process. Is that kind of a proper representation there?

Seth: I think that is correct then I would say that there is the opportunity in the "find the rationale, information, and explanation" section to provide the additional context. That would be the place to do that, as well.

Steve: This is Steve, it is also fair say that until such time until as a regulation is changed, potentially to reference a different standard, the current standard and reference in current regulation still applies?

Seth: There is nothing binding with that coming from the HITAC recommendation, so any change as a result would be informed by the recommendations of the task force and, ultimately, the HITAC. So, any changes to the requirements would have to come through subsequent rulemakings from ONC.

Steve: And for the regular rulemaking process, is it open? Going to the comment processes, etc., and having an effective rule at some point down the line?

Seth: Correct. Any changes would go through the full rulemaking process.

Steve: Wonderful thank you for the clarification.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Hung S. Luu: I agree default user avatar

Hung S. Luu: Should we be recommending almost complete alternatives?

Hans Buitendijk: The challenge what "ready" means.

John Travis: I think you do need to state what ready means if it means removing the prior version that is currently the certification standard

John Travis: And I agree with Vassil's comment just now

Hans Buitendijk: Agreed with vassil as well.

Hans Buitendijk: We cannot have standards in rule making that are not supported by the critical standards that are not able to support that USCDI version.

John Travis: Sorry I am not on the phone - only online

John Travis: Will do

John Travis: My question is how does this process consider a current version of standard in current certification regulation as to questions of retirement?

John Travis: USCDI v1 a good example

John Travis: In the 2015 Cures Act updates

John Travis: Does the process allow for reference to one version maintained and one version recommended for adoption both?

Hung S. Luu: This WG is convened every three years. We will become an inappropriate bottleneck if we do not support the latest version and try to time the system.

Hans Buitendijk: The challenge is that USCDI on its own is not implementable using a standards based approach. That's where the rub seems to be.



QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

Resources

AS TF Webpage AS TF – July 19, 2022 Meeting Webpage AS TF – July 19, 2022 Meeting Agenda AS TF – July 19, 2022 Meeting Slides HITAC Calendar Webpage

Meeting Schedule and Adjournment

Steve and Hans thanked everyone for their participation and asked AS TF members to focus on homework in between meetings. TF members were asked to continue to share feedback in the working Google spreadsheet document.

Hans noted that he would not be able to attend the next meeting of the TF, and Steve explained that they would be focusing on standards related to public health.

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 26, 2022. The meeting was adjourned at 11:30 a.m. E.T.