Transcript

HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

GROUP 3: ONC HEALTH IT CERTIFICATION PROGRAM UPDATES – INSIGHTS CONDITION, STANDARDS UPDATES, AND RFIS

May 4, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Steven Eichner	**Texas Department of State Health Services**	**Co-Chair**
Steven Lane	**Health Gorilla**	**Co-Chair**
Hung S. Luu	**Children's Health**	**Group Lead**
Hans Buitendijk	Oracle Health	Member
Clem McDonald	National Library of Medicine	Member
Naresh Sundar Rajan	CyncHealth	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Seth Pazinski	Office of the National Coordinator for Health Information Technology	Acting Designated Federal Officer
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Michael Wittie	Office of the National Coordinator for Health Information Technology	ONC Program Co-Lead
Carmela Couderc	Office of the National Coordinator for Health Information Technology	Presenter
Kyle Cobb	Office of the National Coordinator for Health Information Technology	Presenter

Call to Order/Roll Call (00:00:00)

Seth Pazinski
Thank you, and good morning, everybody, and welcome to the HTI-1 Proposed Rule Task Force Group 3 meeting. Thanks to everybody for joining today. I am Seth Pazinski with ONC, and I will be serving as the designated federal official for today's meeting, filling in for Mike Berry. As a reminder, all the Task Force meetings are open to the public, and your feedback is welcomed. There are two ways to do that. Throughout the meeting, you can type your feedback into the Zoom feature with public comment, and we will also be pausing with about 10 minutes left in the meeting for a verbal public comment period toward the end of the meeting, so those are the two ways you can participate in today's call as the public. I will start the meeting by doing rollcall for the Task Force members, so, when I call your name, please indicate that you are present, and I will start off with our cochairs. Steven Lane?

Steven Lane
Good morning.

Seth Pazinski
Good morning. Steve Eichner?

Steven Eichner
A very good morning to you.

Seth Pazinski
Good morning. Hung Luu?

Hung S. Luu
Good morning.

Seth Pazinski
Good morning. Hans Buitendijk?

Hans Buitendijk
Good morning.

Seth Pazinski
Good morning. Jim Jirjis? Elaine Johanson? Meg Marshall? Clem McDonald? Naresh Sundar Rajan?

Naresh Sundar Rajan
Here.

Seth Pazinski
Fil Southerland? Okay. Well, thank you again, and please join me in welcoming Steven Lane, Steve Eichner, and Hung Luu for their opening remarks and getting us into the agenda.

Steven Lane

Hung, why don't you take us there?

HTI-1 Proposed Rule Task Force Charge and Timeline Update (00:02:06)

Hung S. Luu
Thank you, everyone, for attending our second meeting of Group 3. I just wanted to thank everyone for their participation so far. We have seen some significant contribution to the worksheet, and so, thank you to everyone who has contributed, and we look forward to the presentations today by our speakers to help inform our process moving forward. Steven or Ike?

Steven Lane
Yes, forge ahead.

Hung S. Luu
Back to you, Seth.

Steven Lane
ONC team, do you want to take us to the next slide here?

Seth Pazinski
Sorry, I was on mute. Bring us to the next slide, and we can get into our presentation, so I will turn it over to Carmela and Kyle.

(USCDI) v3, C-CDA, and FHIR US Core Revisions / Standardized API Updates (00:03:29)

Kyle Cobb
Okay, great. Hi, everybody. I will just put my video on, get myself off mute, and just by way of introduction, I am Kyle Cobb, a branch chief in the Certification and Testing Division, and we are going to present some proposed aspects of the rule, so let's get started on the next slide. So, for today, just before we get going, there are a couple disclaimers and public comment guidance that I need to share. The materials contained in this presentation are based on the proposals in the Health Data Technology and Interoperability Certification Program Updates, Algorithm Transparency, and Information Sharing proposed rule.

While every effort has been made to ensure the accuracy of this restatement of the proposals, this presentation is not a legal document. The official proposals are contained in the proposed rule. ONC must protect the rulemaking process and comply with the Administrative Procedure Act, also known as the APA. During the rulemaking process, the ONC can only present the information that is in the proposed rule as it is contained in the proposed rule. ONC cannot interpret that information, nor clarify or provide any further guidance. ONC cannot address any comments made by anyone attending the presentation or consider any such comments in the rulemaking process unless submitted through the formal comment submission process as specified in the *Federal Register*. This communication is produced and disseminated at U.S. taxpayer expense. Next slide, please.

So, before we dig into the details, I am just going to go over a couple of the whats that will provide some context for the rest of the presentation today. Next slide. So, what is the name? We have seen some acronyms, so let's just break this one down. We have Health Data Technology and Interoperability. That is

the prefix. The suffix is a little more definition around the certification program updates. That is Algorithm Transparency and Information Sharing. So, the acronym is HTI, and then, the numbering is 1, so the shorthand is HTI-1 proposed rule. Next slide, please.

I think the name has suggested what is in the rule, but there are a few more things that we will just look at. This is the list of topics that are covered in the proposed rule. Today's presentation will be specific to certification standard and functionality updates for G10, or standardized API for patient and population services, as well as associated standards, including USCDI, C-CDA, and US CORE. There will also be additional presentations to this group covering the other topics in the future. Next slide, please.

Finally, just a little more context setting for why the proposed rule, and I think many of you have been through this over the past decade plus, but starting on the left, even before that, we had the HITAC, but we had the 21st Century CURES Act, which set the foundation for a number of foundational technologies and programs, including API, API's Information Blocking and EHR Program, or rather, the EHR Reporting Program. Since the CURES Act, we have several very important orders from the Biden-Harris administration, including ensuring data-driven response to COVID and future high-consequence public health threats, so there have also been two other executive orders focused on advancing racial equity for underserved communities.

And then, finally, if we go all the way over, we are now in a unique position to leverage further health IT and advance interoperability through these foundations set specifically through HITAC, 21st Century CURES Act, and finally, the structures of the ONC Health IT Certification Program. So, with that, I am going to hand it over to my colleague Carmela to provide an update on USCDI and related standards.

Carmela Couderc
Thanks, Kyle. Good morning, everyone. My name is Carmela Couderc, and I am a branch chief for the Terminology, Content, and Delivery Branch, and I am in the Standards Division. So, the slides we are about to go into are standard slides. My section of this will not be going into detail about the certification criteria changes, but I will be focusing on USCDI, US CORE, and the C-CDA companion guide, and then w will switch back to Kyle, and she will go into more detail about the certification changes. Next slide, please.

So, HTI-1 contains references to standards and criteria where updates are proposed. So, we propose to update some key standards versions. No. 1, we propose to update United States Core Data for Interoperability to Version 3, so that is USCDI. We also propose to update the HL7 C-CDA companion guide to Release 3 and the HL7 FHIR US CORE IG to 5.0.1. Now, that boxed-off item you see over on the right is to acknowledge that we realize the publication cycle of the HL7 guides is such that they will be published before the final rule. Our intent is to consider adopting the updated IGs that support the data elements in USCDI Version 3, since we propose to adopt USCDI Version 3 in this rule.

Also, as we have in the past, the minimum standard code set versions have been proposed in this rule as well, so we just provide a list of some of the heavy hitters there that we are all used to seeing, such as SNOMED, RxNorm, LOINC, and NDC. This proposed rule also includes proposals to update for certification criteria and add a new one, patient-requested restrictions criteria, so Kyle will be going into more detail, as I said, about that. Next slide, please.

Just as a reminder, USCDI was established in the 2020 21st Century CURES Act final rule, and at that time, it included 16 data classes and 52 data elements, setting the minimum data set required for interoperability. The focus was also defined to be on patient access and care coordination use cases, and when USCDI Version 1 was released, ONC also established an annual update cycle that includes publication of a draft, the HITAC workgroups that look at USCDI specifically, and also public comment, and that all informs the final version. Next slide, please.

So, we fast forward to 2022, and ONC has released USCDI Version 2 the previous year, and then, Version 3 was released in July of 2022, and that resulted overall in three additional data classes from Version 1 and 94 data elements. The expansion was based on ONC priorities, feedback from the public, but the priorities that ONC was addressing are reducing disparities and inequity in healthcare, including care delivery to underserved populations and addressing public health data requirements. Next slide, please.

So, in this rule, ONC proposes to adopt USCDI Version 3 as the new baseline for certification, thus increasing the amount of data to be used and exchanged for patient care. You can see a list of criteria below that reference USCDI and where ONC proposes to update the standard reference to USCDI Version 3. Some of them are the same ones I mentioned earlier, as proposed to be updated, so the criterion itself is being updated, as well as the reference to USCDI Version 3, such as G10, standardized API for patient and population services, and B1, transitions of care, or in the case of patient-requested restrictions, it is a new proposed criterion. Next slide, please.

So, for the HL7 C-CDA companion guide, the proposed rule suggests that we adopt Release 3 starting January 1st, 2025. However, as I mentioned before, if Release 4 of the C-CDA companion guide is published before the final rule, ONC will consider adopting the updated IG. So, key updates for the proposed version are support for USCDI Version 2. We also list on this slide the criteria that are impacted by an update to the new version of the C-CDA companion guide. We have already seen some of them on other lists, such as transitions of care, care plan, and clinical information, reconciliation, and incorporation. Next slide, please.

Similar to the proposal for the updated C-CDA companion guide, ONC proposes to adopt a new version of the HL7 FHIR US CORE implementation guide, and once again, that version has support for USCDI Version 2. If the next version of the IG is published before the final rule, ONC will consider adopting the updated IG. This proposed update impacts the standardized API for patient populations and services, G10, criterion. Next slide, please.

So, among other things that I have already mentioned that we are proposing updates for, we are also proposing updates for standard code set versions. Next slide, please. So, to promote semantic interoperability, ONC proposes to update the minimum code set versions for vocabulary standards. Now, if new versions are published before the final rule, ONC plans to update to the most recent versions available at that time. Now I will hand the baton back to my colleague Kyle, who will provide more updates.

Kyle Cobb
Okay, let's go to the next slide. Over the next series of slides, I will provide more updates on the proposed updates to the G10 criterion, but here is a high level of what we are proposing, specifically, the adoption of three standards underpinning this criterion, including USCDI Version 3, US CORE Version 6.0.0, and

SMART App Launch Framework Version 2. These standard updates would support functional updates to the criterion, including identification and authorization for user scopes and token introspection leveraging SMART Version 2. In addition, these proposed revisions would expand data available through standardized APIs through the expansion of the USCDI Version 3 and corresponding implementation guides of US CORE Version 6.0.0. So, let's go to the next slide.

So, the SMART Version 2 guide would replace the currently required SMART Version 1 guide as the standard. That is the proposal. The SMART Version 2 guide iterates on the features of the SMART Version 1 guide by including new features and technical revisions based on the industry's consensus, including features that reflect security best practices. These technical enhancements improve the authentication and authorization security layer provided by the SMART V.1 guide and enable increased capabilities and functionality for individual control of EHI.

Specifically, the two major requirements for the new SMART Version 2 guide include something called Proof Key for Code Exchange, also referred to as PKCE, which makes the granting of access to health information via health apps more secure by mitigating the known vulnerability of authorization code interception attacks. This attack can be used to illegitimately obtain or access token from the authorization server, and thus obtain server data in an unauthorized manner. PKCE mitigates this vulnerability by creating cryptographically random keys for every authorization request. PKCE is an industry standard and a security extension for OAuth 2.0 to mitigate the known security vulnerabilities of authorization code interception attacks. This requirement of PKCE especially improves the security of native apps or apps that operate from an individual's phone or tablet, which were particularly vulnerable to authorization code interception attacks.

In addition, we have a revision to the syntax, or we proposed revision to the syntax and scope, to align with the FHIR interactions, specifically create, read, update, delete, search, collectively known as CRUDS. This alignment of SMART V.2 scope syntax to FHIR REST API interactions permits health IT module authorization service to provide greater specificity regarding which permissions are granted in scopes to apps and has the benefit of improved technical clarity to health IT and application developers. It also improves a patient's control over how an app accesses their health data by clarifying for a patient what specific type of API interactions are permitted to the app. For example, under this new syntax, the patient could specifically permit an app read access to a FHIR resource, but deny search access for the same FHIR resource. Next slide, please.

The next proposed update includes revising the G10 criterion to adopt several sections specified as optional in the SMART V.2 guide as required. Specifically, we propose to adopt the requirement of the following capabilities, starting with ensure better backward compatibility between SMART V.2 and SMART V.1 through scopes mapping, improve security with asymmetric client authentication, give patients greater control over their health data with the ability to select granular permissions with fine-grained FHIR resource constraints, empower individuals, clinicians, and others to deny authorization for offline access, and rather, that is for offline or online access, and finally, facilitate interoperability through a standardized process for token introspection, and I am going to cover all of these in the next few slides, so let's go to the next slide.

So, scope mapping between SMART V.1 and SMART V.2 is important for the purposes of interoperability between implementations of both guides. This proposed requirement ensures that servers advertise the

permission V.1 capability in their well-known SMART configuration discovery document, and that they return SMART V.1 scopes when a SMART V.1 scope is requested and granted and similarly process SMART V.1 scopes according to the backward compatibility mapping specified in the SMART V.2 guide. In addition, we propose to require health IT modules support something called asymmetric client authentication as an option for confidential clients during the process of authentication and authorization when granting access to patient data. This proposed requirement would align with the security practices of industry as evidenced by the SMART V.2 guides recommendation that asymmetric client authentication be used when available and improves interoperability for clients by making this API security feature consistently available across all certified G10 APIs. Next slide, please.

We also propose to require finer-grained resource constraints using search parameters, also known as granular scopes. This feature uses the FHIR REST API search parameter syntax to specify permissions more granular than the FHIR resource level. The granular scope functionality would empower patients and providers to share health data in a more granular fashion, which would improve confidence in the use of third-party apps by allowing app users to decide which specific type of EHI they share with the app. These functions would help address privacy and security concerns of third-party app access to health data and further patient empowerment by providing the ability to limit an app's access to a granular minimum set of health data, as determined by the app user. These requirements in SMART V.2 will complement search parameters for scopes developed in US CORE Version 6. Let's go to the next slide.

In the HTI-1 we propose additional requirements to standardize the process of token introspection to improve interoperability for FHIR clients and resources by defining expectations for what a health IT module authorization server returns about a token when queried by a client or resource server. This includes both scopes for requesting a refresh token and standard-based token introspection. The scopes for requesting a refresh token would empower individuals, clinicians, and other users to deny authorization for online or offline access by applications of their choice, and the standards-based token introspection would provide needed standards which would standardize a process for token introspection, which would improve interoperability for FHIR clients and resource servers by defining expectations around what information a health IT module's authorization server returns about a token when queried by a client or resource server.

You may remember that we have received feedback on the CURES Act final rule around issuance of refresh tokens to confidential applications and the storing of refresh tokens. This was further clarified in the interim final rule when we revised the language that a health IT module's authorization server must issue a refresh token to applications capable of storing a client's secret. In this current proposed update, we propose additional clarity within a standardized process through the OAuth 2.0 token introspection profile. Let's go to the next slide.

In the ONC CURES Act final rule, we established a requirement for health IT modules to be able to revoke an authorized application's access to a patient direction. This required capability is intended to enable patients to definitively revoke an application's authorization to receive their EHI until reauthorized, if ever, by the patient. Health IT developers have requested clarification regarding letting access tokens expire in lieu of immediate access token revocation for the purposes of certification testing. We also propose to revise the requirement in G10 to specify that health IT models presented for certification that allow short-lived access tokens to expire in lieu of immediate access token revocation must have such access tokens expire within one hour of request.

This revised requirement would align with industry standard practice for short-lived access tokens, would provide clarity and consistent expectations that developers revoke access or expire access privileges within one hour of a request, and would offer patients an assurance that an application's access to their data would be revoked or expired within one hour of a request. This proposal would provide clarity and create a consistent expectation that developers revoke access within one hour of a request regardless of their internal approach to fulfilling a patient's request to revoke access. This proposal would also assure patients that, once requested, an application's access to their data could be revoked within one hour. Let's go to the next slide, please.

Finally, we propose updates to revise the requirement in G10 to specify that a health IT module's authorization server must be able to revoke and must revoke an authorized application's access at a patient's direction within one hour of the request. This proposal would provide clarity and create a consistent expectation that developers revoke access within one hour of a request regardless of their internal approach to fulfilling a patient's request to revoke access. The proposal would also assure patients that, once requested, an application's access to their data would be revoked within one hour. So, we will see here that we have revised regulation text proposed that summarizes this direction of one hour, and I think we also anticipate that many or most developers would institute a process that results in revocation of access in a timeframe of much less than an hour. Investigation into industry best practices that our team has done has led us to believe that an hour is an appropriate baseline requirement to revoke.

Okay, so, that ends all of the proposal of optional requirements to become required. Let's go to the next slide, and we will look at API conditions of maintenance and certification. So, the ONC CURES Act final rule established the API conditions of maintenance and certification requirements, which contain a specific provision that, for health IT modules certified to the G10 criterion, certain service-based URLs, otherwise known as endpoints, must be publicly published for all customers in a machine-readable format at no charge. These electronic endpoints are the specific locations on the internet that make it possible for apps to access EHI at a patient's request.

Since the ONC CURES Act final rule was published, we have found that developers with publicly discoverable endpoint lists have defined their own at times bespoke publication approaches and in unique formats. There is variability across developers of certified health IT in the format they are using to publish these service-based URLs, and this also further indicates that industry has not coalesced around a common framework or approach. In addition, the inconsistent implementations of this requirement have rendered important data meant to facilitate connections to endpoints really difficult to access.

So, in summary, the benefits of this proposed requirement, in conjunction with the existing requirements for service-based URLs, would align industry approaches to publishing a common format for these standard-based URLs and improve the availability of service-based URLs for the public for patient access to their information without special effort, in addition, ensure that service-based URLs are actively monitored for errors or defects and updated as needed, and then, finally, it would support scalable endpoint directories for TEFCA and others. So, in summary, that is what we propose, but let's go to the next slide, and I am just going to dig in a little bit more on an example here.

On your left, you can look through this in the proposed rule, but these are some of the challenges that we are observing in how to map multiple unique organizations to endpoints today. So, specifically, the name of the organization associated is typically formatted as free text in a string with no unique identifier to know which organization is being supported by that service-based URL. For example, the organization name given by the endpoint, Acme Children's Hospital, could be mapped to six possible organizations, including Acme Children's Hospital Anesthesiology, or Acme Children's Hospital Urgent Care, or Acme Children's Hospital Ambulatory Care Center Pharmacy, among others, so this endpoint might map to any one of these organizations, making a definite match difficult to determine. Even more complicated is the possibility of a single endpoint representing all six of the Acme Children's Hospital organizations.

So, to address this, ONC proposes a service-based URL publication requirement that includes that service-based URLs must be formatted in a FHIR endpoint resource format according to the standard adopted in 172.15A. Additionally, we propose to require that organization details such as name, location, and provider identifiers such as NPI, the CMS certification number, CCN, or health system ID for each service-based URL must be published in the US CORE organization resource according to the implementation specifications within the organization dot endpoint element referencing the service-based URL managed by the organization. So, I think that adjourns my presentation, but we can certainly move to discussion.

Steven Lane
Hung, back to you.

Hung S. Luu
Thank you so much for that enlightening, very informative presentation. I echo Dr. Lane's point that it is really gratifying to see the thought that has been put into how to secure the patient data so that it is not easily hackable or used for illicit purposes. So, now, let's open it up to questions from the Task Force. All right, I see a hand up from Hans. You have the floor.

Hans Buitendijk
Thank you, Hung. It is not as much a question as an observation that I put in the chat and want to highlight, but first, I want to indicate that from a progression perspective, having the progression to USCDI Version 3 anticipating, not yet published, is going to be hot off the press very soon. As C-CDA and FHIR US CORE, those progressions make a lot of sense. Generally, I think we need to be aware that, as we have seen in the past, particularly around FHIR, that since these guides have not been published, there has been some connectathon-level effort, but they have not been published or implemented, and we should not be surprised that there are going to be some practical experiences that are going to show some gaps or some challenges that need to be addressed beyond errata.

We have seen that with FHIR 3.1.1 that led to a 4.0.0, so I think we need to consider that, that that is not going to be a surprise if that happens, and that we need to be able to address that, but I think a larger challenge is that USCDI is expanding, which is good, it is increasing and getting closer to covering full EHI, which is good, but it also means that increasingly, there are specialty EHRs and other HIT that would benefit from certification that are going to be hindered by being certified. Clearly, the statements from ONC are that there is no authority from an ONC perspective on the variety of HIT out there, it is a voluntary program, but if the intent is to enable HIT to be certified, having the appropriate level of granularity would enable other

HIT to be certified as well, where other programs deem that appropriate or not, so I think the current level of granularity and coarseness is not there.

The suggestion that I think we want to discuss within the HITAC and review for inclusion in recommendation is that USCDI is not being looked at as a monolithic set of data that every HIT must certify to using FHIR US CORE and C-CDA, rather that it is based on the capabilities that certain HIT has, where some of the data might be relevant to just display when a document comes in, but not necessarily need to be ingested and managed on an individual level, not managed through UI at a discrete level, but is just available from "Hey, this is what you received from elsewhere." If we do that, then, at that point in time, the HIT may not be encumbered with supporting everything at a discrete level to do that because it is not in their scope of capabilities and could not be certified. So, I think that is a topic that, as the HITAC Task Force, we want to look at a little bit further on how to address that.

Hung S. Luu
Steven, I see you made a comment in the chat. Do you want to express that verbally?

Steven Lane
Thanks. I would rather we invite others who have commented to respond. We have some good input from Ike, as well as from Fil, so I would like to invite them to speak.

Hung S. Luu
I see Fil has his hand up. Go ahead, Fil.

Fillipe Southerland
Good morning. My background is in electronic health record development for the long-term post-acute care sector, and I can say from our sector, which has 20 million plus patients, this is a major barrier, this need to conform to the entire USCDI data set, where, for example, the EHR that I represent does not include pediatric data. Though LTPAC in general has pediatric patients, because the sector is so broad, our EHR does not target that population.

So, as a result, we have very little HIT uptake within our sector, and what we have seen that that results in is a patient access issue where, because there is no certified HIT, there is very fragmented access to patient data, and interoperability remains a barrier between the electronic records in our sector. I think we have seen an emphasis by the administration on HCBS services as well, where you might have in-community meal or transportation providers, and those providers are using their software that is also very specialized that I think we would certainly benefit from including in this program as an access equity issue, but I think to the group's point or to some of the points in chat, it is a very heavy lift to encompass all of this data, particularly if it is not within the client base that you are targeting.

Steven Lane
Hans, you offered a specific proposal in your early chat message regarding the difference between being able to receive and display data that falls outside of a specialty product's needs as opposed to being able to fully ingest and manage that data. I do not know that I have seen any of our HITAC Task Forces specifically recommend that as an approach, as a way to support opening up certification to a broader population of products. Do you want to talk more about that, Hans, and what kind of discussion has been

had about that, say, within the EHR vendor association or in other venues, and whether you see that potentially evolving into a specific recommendation from the Task Force back to ONC?

Hans Buitendijk
Sure. In the EHR community, EHRA, there has been extensive discussion around the interests to focus on data that is being managed by the system rather than requiring that data that is not otherwise useful at a discrete level for the operations that it supports, for the user community that it supports, that it should not be encumbered to have to support that, where their user community and their use cases have no need for that level of detail to work with. Where there is a need, then it will expand, and once it expands, to manage that as well, then it would fall in the category of being managed, then you should be able to expose it and follow all the standards on how to do it, share it, take it in, etc. So, it is much more based on the reality of what systems actually do, and as they expand, then address the fact that they should be able to manage that at that level of granularity.

So, an example of that is if you get a discharge summary document C-CDA, you would be able to receive that as a whole and there are opportunities to display it as a whole, but do you need to ingest all the individual details for the kind of effort that you are trying to do? Similarly, you can extend that to transactions that are much more based on specific transactions and workflows. So, that is the general discussion that has been had and the variety of capabilities that make that easier. Fil highlighted a couple of those.

There are other ones that are being highlighted in a dermatology space or other specialty EHRs where some of the data may not be as relevant. If you go to the larger HIT space and you ask where EHI is being managed, and I am going to use the labs, radiology, or other systems as an example, they are the source of some of that data. They are perhaps interested to expose that, but if they wanted to be certified, if it would be helpful to be certified where there is value to enhancing that, today, from a FHIR perspective, G10 is all or nothing as opposed to how, for the data that you manage that you have responsibility for, it is a subset of that. If that can be done consistently with everybody else and there is a good argument to be made for that, we would be able to achieve that, which means that it is much more based on actual use and management of data than on having to do everything because you are a certified HIT.

Another side of it is that there has been an ongoing discussion around USCDI, and if that should aim to cover all electronic health information, if not EPHI, how far should that go? It is currently named “core data for interoperability.” At the same point in time, as we see with EEI Export and others, it is actually very helpful to have standards at some point in time for all of EHI so that we all understand how to manage that when you have that data. It would allow for the combination of USCDI and USCDI Plus or USCDI in itself to extend more than what is in the relatively arbitrary of what is core. What is core to you is not necessarily core to me, and I think the examples that we just talked about make that clear. What is core for one HIT is not core to another, but it is essential for interoperability across the spectrum and ecosystem that we are dealing with.

It would allow for that growth as well, and not be encumbered by some relatively arbitrary decision about what is core to whom. It is bound to and aiming for wanting to have standards-based exchange without special effort for all electronic health information, if not EPHI, and then, there is some other data around it that is actually extremely helpful to have as well. I think that is what the underpinning is, and within the EHRA, we have been discussing this pretty much from the start of when USCDI came about. It was not as

visible, but we already saw the signs of it happening. You see it increasingly with Versions 1, 2, 3, and 4, and we anticipate that with 5 and 6, etc., it will further expand on that, plus the examples that have been mentioned before.

Hung S. Luu
Thank you, Hans. Ike, you had your hand up.

Steven Eichner
Yes, I did. Thank you. I made a comment in the chat regarding looking at support for USCDI across a particular entity, maybe with modular support within the entity for the different components. I want to modify that a little bit based on what Hans suggested. One of my concerns is that if we look at reading support of a subset of the USCDI, how are we then supporting more universal transactions or helping providers understand the capabilities within the EHR system that they purchased in terms of things like support for public health reporting and the like. I think if we go down this route of certification across a limited set of USCDI, we also need to make sure that we address how we describe support for required exchanges for things like public health reporting and the like, and again, that gets a little bit complicated across jurisdictions. It does not mean we should not do it, it just means we need to ask how we accommodate that as well.

Hung S. Luu
Fil?

Fillipe Southerland
I would certainly support Hans's proposal, where the specialty EHR must be able to display or have that information viewable if received, but not necessarily send, and I think right now, as the Inferno test tool is built, just going through this process in my own experience, even if we do not have that data, we are unable to send a data-absent reason, so I was going to propose that as one potential technology. I believe that is available in FHIR R.4 or R.5, where you are able to send a data-absent reason with certain elements, so that might be one approach we could look at.

I also wanted to say I would hate for ONC to miss this opportunity to really address where we are going here with whole-person health, and I think finding a way to solve this is worth it from just an equity issue, and really to get the full longitudinal record captured across the system. In the graphs I have seen from ONC, we have had great success and uptake within ambulatory and acute, but you go beyond that into behavioral health, HCBS, Medicaid, and LTPAC, and it drops off a cliff. And so, with this rule change, I would just really like to see ONC take a look at that. You had mentioned earlier that there was potentially a question on if ONC has jurisdiction in these sectors, and I would like to understand that a little bit better. It seems to me that because these sectors are charging Medicaid or Medicare, we would have jurisdiction for some level of regulation.

Hung S. Luu
Thank you, Fil. I did put my hand up. For me, I want a point of clarification. When we talk about consuming and managing, I think the red line in the sand for me is transmission because I feel like there is increasing awareness that healthcare is really an ecosystem, where the data moves now from organization to organization, and these are basically nodes that transmit that data. If a health IT is truly only consuming

and displaying, then I would agree that they should still display the information in sufficient granularity, but having to manage that data to the level of the producer may not be necessary.

However, if that data is then further transmitted to other applications, institutions, or what have you, then that data needs to be managed the same way. Otherwise, there is a loss of granularity and loss of interoperability, and that would create a loophole in everything that we are trying to accomplish in terms of interoperability. So, if we are talking about subspecialty EHRs, if their endpoint is only consumption and display, then that is something different, but if they have the ability to transmit that data and pass it on to other organizations or other systems, then there has to be a given level of functionality there as well. Hans?

Hans Buitendijk
Hung, I absolutely appreciate that part of it because from maintaining high fidelity and interoperability across an ecosystem, and we do not get into the example of, as we like to usually say at times, one thing translated to another and then see where that ends up 10 translations down the road, we do not want to have something different come out at the end. I completely agree. The question, though, is that at times in these discussions, we are looking more at the organization level and saying at the hospital, clinic, or otherwise, "What is happening and what do I need to do?", while not totally recognizing that there is typically a variety of systems involved. Not every organization is a hospital that is more likely to have to cover everything versus an individual practice that only contributes part of that in their context.

You have a variety of systems, and if you want to say there is value that there is consistency, that every source exposes their EHI consistently, no matter whether they are a full, highly integrated HIT for a healthcare system large versus being just the lab or imaging service that is providing access to those images and still wanting to do it, or being in the surgery suite where they are a targeted capability, or they are an app that sits on top of things that also manages some of the data, but certainly not everything, if we want to have consistency of interoperability there and where tests and other certification mechanisms are in play, then we need to have that opportunity to do that and not have a one-size-fits-all approach. To Fil's comment, we have contemplated quite a bit in our discussions in EHRA around the authority of ONC versus CMS, and I think that is a good question, and it seems to, at times, come back to something I would really like to get more from the ONC perspective on, that there is the program that is voluntary that one needs not to certify.

For example, we do not have to certify. We know the impact that that is going to have if we are not going to get certified. Our clients, by way of CMS programs and otherwise, are not going to be very happy about that because that provides them less opportunity to participate in payment programs and provides them less certainty on how we can share data across the ecosystem, so there is tremendous value in that, but it is not ONC that enforces that, it is CMS, the providers, and our community that is enforcing that. But, I have always thought that in the role when ONC was established back in 2004, the focus was on HIT, not just on EHRs. EHRs represent a subset of HIT. So, what can be a program from an ONC perspective that enables the opportunity, not the mandate, for HIT to consistently interact with it where other programs, be it MIPS, be it CLIA, be it FDA devices, or public-private initiatives like TEFCA or Carequality, or HIEs for states, etc., that they have a mechanism by which they can validate and have assurances that if you are certified to this, then I know that you can reliably talk?

So, along the lines of Bluetooth, I know that I can click into maybe not everything immediately, based on the version that we are at, but it is getting better and better and it is predictable. I know what to get, I can do it within the scope of what is relevant in my application, and I can pass that on to the next one, where I have managed that data and I can contribute to that consistently. That seemed to have been the role that was intended for ONC to enable that capability. The way it is currently approaching it is not fully realizing that potential and that opportunity to get truly the kind of interoperability that I think Hung is talking about, that I am talking about, that Fil is talking about, and that others are talking about that we are really trying to get. That is what I am hoping for, that we can get some clarity on how the interaction between ONC and other parties can achieve it, not just ONC or not just CMS. It is a collaboration to make it happen.

Steven Lane
So, Hans, I have started to try to capture some of this discussion in the spreadsheet, and I would invite you to add some clarity to this, some specificity to capture what you are recommending. In these Task Forces, we always have to think in these Task Forces whether our recommendations are within scope, and in this case, I think that they are, and maybe the ONC team will argue with me on that, but we are being asked to comment on moving from USCDI V.1 to V.3, and I think we are all supportive of that, as well as the new version requirements for CDA, for FHIR, the code sets, etc. I certainly have not heard anyone suggesting that those are a bad idea, but I think what we are hearing is, again, looking at the downstream consequences of that change, which I think the perception is that this could make it harder for additional products to achieve and/or maintain their certification.

So, again, to my way of thinking, this is within our scope. This is a recommendation that perhaps ONC consider a new approach to certification that would allow us to continue to advance the standards and have those standards apply to any product that is managing data, but not hold every specialized product to the same build and functionality standards for data that they are not actively managing. I think that is what we are trying to get at, and Hans, I know you will phrase that better than I will.

Hans Buitendijk
I certainly will do that, and it is indeed, as you indicated and what you emphasized, that that does not mean not to adopt USCDI Version 3. I think the trick and the focus needs to be on the supporting standards and the extent to which you are required in that context to support all of USCDI. Maintain USCDI as a continuously growing library, so do not stop that. Progress it. We need that. But then, on the criteria like G10, FHIR US CORE, as an example, or on C-CDA, the standards that are being used to indicate that you are supporting it are where the focus should be, on how to enhance the granularity and ability to certify to parts of only the subset that is relevant by way of the same standards that others do. I think that is where the focus needs to be.

Steven Lane
Thank you again, if you can jump in, and Fil, as well, feel free to either craft a recommendation in Column G with or without justification in H or put… Yes, a recommendation is really what we want. That is where we are going.

Steven Eichner
Fil, I noticed your hand is up too. Is there anything you would like to add?

Fillipe Southerland
I did just want to pick up on that point that Hans made. I think it is important we clearly establish what is the population that we are targeting to exchange USCDI upon, and is that a formal EHR, or are we looking to exchange elements of USCDI with a company that may be providing dietary services or lab services that is out in the community? So, if we could clearly understand what scope ONC is targeting with USCDI so that we could shape this going forward, certainly, we want to see this standard evolve, and that is important, but just understanding exactly the sectors we are targeting, which I think is pushing more toward this whole-person care model with current administration priorities, etc., so let's clearly name where the jurisdiction is and what we are targeting this.

Steven Eichner
Right. Just to add onto that, the USCDI is focused on what is being transmitted, not necessarily on why or between whom, and those will be very relevant questions.

Steven Lane
All of our discussion has really focused on the advancement of USCDI and less on the specific topics of C-CDA, companion guide updates, standardized APIs for patient population services, FHIR US CORE, and STU Version 501, and I just want to make sure that we have the opportunity to get any feedback relevant to these other topics that we have covered today.

Steven Eichner
Steven, this is Steve. I have one other question, looking at burgeoning. Do we need to get any clarification about the interaction between regulation and SVAP, or do we need to acknowledge that SVAP is a process where developers can advance the version of USCDI they are actually still deploying within the regulatory framework? Is there any need to touch anything in that space?

Steven Lane
Well, one question that I would ask the ONC team related to that is we have seen versions come into SVAP. I presume you guys are tracking the proportion of certified vendors who are engaging in the standards version advancement process and who are certifying to the new standards. Is the general perception on the part of the ONC team that the vendors are embracing that, that vendors who certified to the prior version are stepping up and getting ready to update their certifications through the SVAP process, or do you have the sense that that has been a slow engagement, perhaps reflecting an unwillingness or unpreparedness on the part of vendors to do that work, or an inability to go to that higher standard? Carmela, you might be in a good position to comment on that. I am not sure.

Carmela Couderc
I was going to ask Kyle to answer.

Kyle Cobb
Hi, this is Kyle Cobb. I think we have not been doing this very long, so the uptake has been slow, like you said, but we have certainly seen more advancement and willingness from developers to advance to the later standards through SVAP, and like all things, I think it has been a bit of a slow start because of getting your head wrapped around and understanding what the implications are and how the cadence works, but

it certainly looks like it is picking up this year, and CHPL will certainly have all that information, and we can take a look at that as well.

Steven Eichner
Thank you for that. One of the challenges from a public health perspective is looking at the existing standard and regulation and seeing if it meets all of our needs, and if it does not, how do we evolve up, but at the same time, looking at following published guidelines that providers have implemented so that they are not facing a technology burden in customized interfaces for reporting necessary data. So, it is a little bit of a complex environment. Hans, do you have a question?

Hans Buitendijk
I have a comment responding to Steven, maybe two other topics that are not USCDI-specific. One is around the timelines for code sets when they become required as the minimum one to certify against. There is still a little bit of confusion when reading through materials around how the timelines of the standards as various elements move from addition to different line-item level staggering of criteria and enhancements. What is the general approach that is intended to be moved forward on aligning code systems? Is it the first time that a standard is meant to be in play that then that standard is supposed to use the new code set version, but if not, a standard is a little bit behind based on the timeline in its criteria, and can that still progress on the older version?

There is a bit of confusion around how code set timelines are actually aligned with the syntactical standards progression, and if there is any further insight that you already have or where to point to on how to do that, it would be great, or this might go back to an earlier question. It would be fantastic if we had a timeline of the different topics as they are being proposed, including the code set advancement. Are there any insights today or that we can look forward to shortly?

Carmela Couderc
Hi, this is Carmela. Is there a specific question there?

Hans Buitendijk
Yes. Is there clarity on the timeline of when the code systems are meant to progress and advance versions versus the underlying standards? Because things are starting to be on different timelines. The second question that was part of that is is there a summary diagram otherwise available that can clearly show that? We asked that question before because there is a lot hidden in the text and different places. We are not sure whether we are pulling it together correctly.

Carmela Couderc
So, code version system updates is a pretty standard thing I would imagine your customers are asking for. For example, they would want the most recent RxNorm so that when prescriptions are written or orders are written for meds, they have the most recent, and as we know, the code systems update on different cycles, so LOINC comes out every six months, the U.S. edition of SNOMED CT comes out on a different cycle, typically, the international edition is updated a little bit afterward, so… ONC was not planning on providing that kind of information.

Hans Buitendijk

That is actually not the question. The question is in the certification program, when we had edition, it was clear that the new baseline of a code set would go into effect across all the standards, all the code sets, and whatever the latest version was that was named in the final rule, that would be the one you needed to certify against, it was very clear, and then you could continue to pre-adopt and continue to adopt any current versions beyond that.

Carmela Couderc
So, are you asking when the certification testing tooling will be using a specific version of a code set?

Hans Buitendijk
As the certification is moving from an edition-based approach to everything together and is named all together into a more staggered approach with some things in 2025 and others in 2026 or whatever, the code set alignment with that becomes unclear when the expectation is that the minimum bar has been raised from a certification perspective. I totally understand how individual vocabulary organizations issue on different timelines. This is strictly about the certification bar that is being set and how that is orchestrated across seemingly different timelines for the standards that use them.

Carmela Couderc
Yes, and right now, Hans, I think we cannot speak to anything other than what is proposed in the HTI-1 in terms of how things are handled around dropping the versioning of the certification criteria.

Hans Buitendijk
So there is not a consolidated timeline view yet across all the components of what has been proposed?

Carmela Couderc
That is right.

Hans Buitendijk
Okay. Steven or Hung, may I have another question? Otherwise, I will hold for others. I do have one other question or thought.

Steven Lane
I would say we actually ended up using our time here. We are going to public comment in about five minutes. Clem and Naresh have not had a chance to chime in. Do you guys have anything you want to share, or should we leave it with Hans?

Clem McDonald
No, Steve. Sorry, I could not find my unmute button.

Steven Lane
Okay, you are good, Clem? Naresh **[inaudible – crosstalk] [01:13:42]**?

Naresh Sundar Rajan
[Inaudible – crosstalk]

Steven Lane
Great, okay. I just wanted to be sure we gave everyone a chance. Go ahead, Hans.

Hans Buitendijk
Another point is related to FHIR endpoints and the proposals there for HITAC, and I will put it into the spreadsheet. Consider that currently, the proposal is pointing to the base standards for organization and endpoint to be used. One of the suggestions that we are trying to figure out is whether we can point to an already emerging implementation guide and then the relevant subset within that, such as what is currently being deployed by Carequality, what TEFCA has published, and to look at that to be a little bit more specific than pointing to the FHIR R.4 standard. So, that also enabled that while it is a subset potential of what actual networks may need, we might have an opportunity to align more easily with those as well, so, this is just a heads up that that will be one of the thoughts, suggesting to align with one or the other or some other one that we are trying to figure out which one is the best.

Steven Lane
I think that is a really good point, Hans, that there is an opportunity to align this more specifically with the TEFCA work, which is obviously ONC's interest as well. You said you are prepared to put together some concrete suggestions in the spreadsheet, correct?

Hans Buitendijk
Correct.

Steven Lane
Wonderful. Hans, I just want to publicly acknowledge your willingness to do this work, not only providing concrete recommendations, but also attending every single Task Force. Thank you for that.

Hans Buitendijk
You are welcome. Thank you.

Steven Lane
Hung, do you want to take us to public comment?

Hung S. Luu
Sure. Seth?

Public Comment (01:15:58)

Seth Pazinski
We can open the meeting for public comment. If you are on Zoom and would like to make a comment, please use the raise hand feature, which is located in the Zoom toolbar towards the bottom of your screen, and if you are participating just by phone today, you can press *9 to raise your hand, and then, once called upon, you can press *6 to mute and unmute your line. I see we have Ian Sefferman teed up on the Zoom, so, Ian, go ahead.

Ian Sefferman

Thank you so much. First, I just want to say thank you to everyone here for the hard work. As an independent developer who represents patients, I think this work is really encouraging and important. For context, I am the founder of a company called Goodbill. We are a technology-based patient advocacy firm that helps patients ensure they have trust and accuracy in their hospital bills. So far, we have integrated with four of the major EHRs across greater than 2,000 hospitals with tens of thousands of patients' lives in the country, so my point of view is really the point of a developer working on behalf of a patient for the patient's benefit, and I wanted to call out the proposed update to the JSON bundles.

First, I think they are great. The JSON bundles are really useful as a developer. I think more important is the inclusion of an ID or set of IDs that allows matching between different systems. That is the No. 1 struggle. Less important is the format. Those tend to be somewhat straightforward. But I think at its core, the JSON bundle's function is to support rolling out the interoperability, and the hardest part of that is actually not in the JSON bundle itself, but rather in getting the credentials to do so. Some EHRs make this simple, as it is one credential for all endpoints, others make it one client ID and many secrets, some are different for sandbox and production, some are not, still others do not do anything and require you to find the right webpage at either a health system or the hospital, and then find a contact form that sends it into an ether, and maybe you hear back and maybe you do not.

For one of the largest for-profit systems in the nation, we have personally spent six months trying to find the right contact. We just recently found the right contact, and the actual implementation took two days, so it does not seem like the right amount of effort to find the contact to get the credentials versus the actual implementation, and I think having a consistent programmatic way to ensure that credentials, that is, the client ID and the secret, are easily accessible would make interoperability significantly easier to deploy. Thank you again for listening to my comment. I appreciate it.

Seth Pazinski
Thank you, Ian. I am not seeing anyone else on the web. Do we have anyone on the line itself?

Unknown Speaker
No more comments.

Seth Pazinski
Okay. With that, I will close the public comment period and turn it back to Steven, Steve, and Hung to take us back to any further discussion and close us out.

Steven Lane
There is one thing I would request, Seth. You pointed out the Buzz blog post from August 5 of last year regarding the alignment of ONC with other federal agencies. Do you want to comment on that and what point you were making there?

Seth Pazinski
Yes, I am happy to. In some of the earlier conversation, there were questions around the scope of things like USCDI for the purpose of just EHRs for hospitals or physician offices or for broader health IT systems, and so, I did share that blog from Micky Tripathi from about a year ago or so around HHS's management policy to look for all of the opportunities from both a policy standpoint through regulations and through HHS

investments to align around common standards, noting USCDI as an example there, so hopefully that link is in the chat, and hopefully that helps clarify some of the questions and discussion from earlier.

Steven Lane
I think the point you are making is we were focusing in on USCDI and its role in health IT certification. I think your point here, or part of it, is that by advancing to newer versions of USCDI, we are impacting many other programs in addition to health IT certification. Is that part of your point?

Seth Pazinski
Yes. I think the main point there is that the data classes and elements in USCDI have broader applicability than just for the ONC certification program.

Steven Lane
Great. We have a few more minutes, and we have some recommendations that were entered previously up in our spreadsheet in Row 2 related to insights, condition maintenance, and certification, basically, the EHR reporting program. I think, Steve and Hung, we should work towards trying to massage some of those into draft Task Force recommendations as we move forward, so we sort of do our work as we go along. I also want to acknowledge Fil.

Thank you for jumping in with some recommendations today, and we do want to point out to folks that we are going to continue meeting. We are going to be meeting again next week, again, coming back to revisit the Insights condition and maintenance and certification, the reporting program, and then this group will take… Actually, no, we are not taking a break. There is going to be a HITAC update provided on the 17th. We are going to continue to meet weekly as we move along here. I also want to just publicly thank Mr. Sefferman for taking the mic and providing public comment. We do not get nearly as many public comments as I think we might in these sessions, and it is really nice when people are willing to provide that. Hung, Ike, anything else we need to do today?

Steven Eichner
I think we are good.

Hung S. Luu
I agree.

Steven Lane
Great. Well, thank you to all for participating, thank you to the ONC team for your marvelous preparation and presentations and taking this large and complex NPRM and breaking it into bite-sized pieces so that we can understand it as well as we do. We will hopefully see many, if not all, of you next week, and enjoy five minutes back.

Hans Buitendijk
Thank you.

Adjourn (01:24:01)