

Transcript

HTI-2 PROPOSED RULE TASK FORCE 2024 MEETING

GROUP 2: STANDARDS AND CERTIFICATION

July 24, 2024, 11 AM – 12:30 PM ET

VIRTUAL



MEMBERS IN ATTENDANCE

Mark Sendak, Duke Institute for Health Innovation, Co-Chair
Hans Buitendijk, Oracle Health
Steven (Ike) Eichner, Texas Department of State Health Services
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Mary Beth Kurilo, American Immunization Registry Association (AIRA)
Hung S. Luu, Children's Health
Meg Marshall, Department of Veterans Affairs
Shantanu Nundy, Accolade
Dan Riskin, Verantos
Naresh Sundar Rajan, CyncHealth
Sheryl Turney, Elevance Health

MEMBERS NOT IN ATTENDANCE

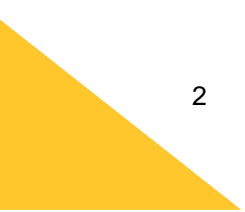
Alex Mugge, Centers for Medicare and Medicaid Services
Fillipe Southerland, Yardi Systems, Inc.

ONC STAFF

Peter Karras, Acting Designated Federal Officer
Maggie Zeng, Staff Lead
Sarah McGhee, Overall Task Force Program Lead & Group 2 Lead

PRESENTERS

Rob Anthony, ONC
Matt Rahn, ONC
Jeff Smith, ONC





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

Peter Karras

Good morning everyone and welcome to the Health Data Technology and Interoperability Patient Engagement Information Sharing and Public Health Interoperability, or HTI-2 for short, Proposed Rule Task Force Subgroup Meeting on Standards and Certification. I am a Peter Karras with ONC, and I will serve as the Designated Federal Officer for today, acting on behalf of Seth Pazinski. The meeting is open to the public. Public feedback is welcome throughout the meeting. Comments can be made via the Zoom chat feature. Also, there is scheduled time on the agenda for verbal public comments towards the end of today's meeting. We will begin the meeting with roll call, and we can start with our co-chair, Mark Sendak.

Mark Sendak

Present.

Peter Karras

Suresh Balu. Hans Buitendijk.

Hans Buitendijk

Good morning.

Peter Karras

Good morning. Steve Eichner.

Steven Eichner

Good morning.

Peter Karras

Good morning. Raj Godavarthi.

Rajesh Godavarthi

Present.

Peter Karras

Mary Beth Kurilo.

Mary Beth Kurilo

Good morning.

Peter Karras

Good morning. Hung Luu.

Hung S. Luu

Good morning.

Peter Karras





Meg Marshall.

Meg Marshall

Good morning.

Peter Karras

Good morning. Alex Mugge has indicated she will not be attending today's meeting. Shantanu Nundy? Dan Riskin?

Dan Riskin

In morning.

Peter Karras

Morning. Fil Southerland? Naresh Sundar Rajan.

Naresh Sundar Rajan

Good morning.

Peter Karras

Good morning. Sheryl Turney?

Sheryl Turney

Present

Peter Karras

Thank you. Is there anyone I missed or anyone who just joined the meeting that would like to indicate their presence? All right. Well, please join me in welcoming our co-chair, Mark Sendak, for his opening remarks and to walk us through our agenda for today's meeting and the task force charge. Mark, over to you.

Opening Remarks (00:02:18)

Mark Sendak

First off, thank you everybody for making the time to join today. I know that this is a volunteer role for folks. I know that we have several HITAC members and we also have several external subject matter experts who have been invited to contribute their expertise to this project. Over the course of the next eight weeks, we will be diving deep into different sections of HTI-2. This is my first time co-chairing a task force.

I was very much inspired to serve in this capacity from HTI-1, so really looking forward to contributing to this legislation with you all. One announcement I did want to make is that, and we can post the link here, HTI-2 did just become visible on the Federal Register. It will be published on August 5th, and there will be 60 days for public comments. While we are starting our close review and putting together recommendations, there will be opportunity for anyone to also submit public comments, also on the rule. We will be looking at those comments, but just for us to know that if there are other things that we identify here that you want to share with others, please make sure to do so.





Next slide, please. The agenda for today, I am going to be helping guide this, but I really want to thank all of the ONC staff. Today, a lot of the expertise about the rule, talking through what the proposed changes are, this is going to be things that they have prepared, so I want to thank them for all of their prep work. I know I have heard from some folks, there was not homework leading up to today because this was the first meeting. But in the future, we will be getting assignments where are going to hope that people review parts of the proposed rule in preparation for these weekly meetings.

But at least for today, really want to thank the ONC staff who have prepared things for this. Peter, I think that is my main message. Yes, the charge here is that we will evaluate, provide our own draft recommendations. This is going to be a consensus process, so, we will actually go through specific items in the proposed rule and try to agree on how we would make changes. We will actually be working in a document together that ONC staff are going support us in putting together. Both part of what I am trying to be doing is to facilitate that everyone has an opportunity to contribute, but also identify points of tension and try to resolve things as we go through the sections.

Obviously, there may be things that you see us compromise on, that if you continue to have a strong position there will be other opportunities to submit feedback as well. We are going to be looking specifically at sections of HTI-2 related to standard certification. There are three different subgroups, one is public health, the other is going to be information blocking and Trusted Exchange Framework and Common Agreement (TEFCA). As I mentioned originally, we are on a tight timeline, we are going to be doing this over the next two months. We are going to be presenting our recommendations to HITAC at a September meeting that would then go to the National Coordinator to consider for revisions of HTI-2. I think that is it. Ready to jump in.

Peter Karras

Great, thanks Mark. Yes, and this slide, it just reflects the various topics within the subgroup. What is highlighted here is what will be the focus, from an ONC perspective, on what will be provided via an overview. With that, I will turn it over to the ONC team to take us through today's discussion.

Standardized API for Patient and Population Services (00:06:52)

Rob Anthony

Thanks, Peter. This is Rob Anthony, I am the Director of the Certification and Testing Division in the Office of Technology at ONC. The Certification and Testing Division oversees and administers ONC's Health IT Certification Program. We are going to have a couple of other folks on with us on today. Jeff Smith, the Deputy in Certification and Testing. We will also have Matt Rahn, who is the Director of the Standards Division in the Office of Technology. We are going to go through, at a high level, the proposals related to standardized application programming interface (API) for patient population services. Next, slide. Actually, we can go to the next slide beyond this.

At a high level, you are going to see a large restructuring proposed for G-10, the standardized API for patient and population services. This criterion basically has an update to several standards that are included here, including an update or proposed update to United States Core Data for Interoperability Version 4 (USCDI v4), a proposed update to the Smart App Launch 2.2, where we are proposing to require support for dynamic client registration. We are also requiring support for several new standardized API workflows, so things related to workflow triggers, verifiable health cards and subscriptions.





You may have seen in some other areas that we are also looking to propose Health IT module support for multi-factor patient authentication, or patient-facing authentication. We have proposed support for imaging links in data response requirements. Finally, support for read and search API for systems applications. This primarily applies to some of the support for bulk Fast Healthcare Interoperability Resources (FHIR) API. Ultimately, I think much of these enhancements, including the proposal to support USCDI v4 ensures that patients have access to a lot more information. The inclusion of imaging information would also include some of the diagnostic imaging by imaging links, which gives them more granular control of their own data, through some of the US Core scopes.

I think dynamic client registration and some of the multi-factor authentication streamlines some of the experiences for patients with connecting apps and also, feedback and security support for things. Clinicians benefit by the expanded use of some of the standardization with some of the information in USCDI v4 related to access and exchange. We are getting down into more detailed information that Matt is going to cover for us later about behavioral health and some underserved communities.

There are also some things that we are proposing here, under the workflow capabilities for workflow triggers and subscriptions and so on that give clinicians some additional access to Clinical Decision Support (CDS) hooks and subscriptions that really help in the decision-making workflow that can be administered through health IT. Then finally, I think public health researchers and others will have additional benefit from some of the access to bulk data that we are supporting through the required support for bulk FHIR. Next slide?

These, at a very high level are the individual standards that are referenced in our proposed revisions. They are an update of existing standards for information access and for authentication authorization. Moving from USCDI v3 to a proposed v4 floor. That of course comes with moving the US Core implementation guides (IGs) from Version 6.1 to Version 7, updating the support for bulk data access from the current v1 to v2, and of course, updating the Smart App Launch from v2 to v2.2. We are adding or proposing to add a new standard for dynamic registration. This is the Health Level 7 (HL7) FHIR Unfair, Deceptive, or Abusive Acts or Practices (UDAP) Security IG v1 again. This goes to some of the security portions that we are proposing here. Then of course, vis-à-vis, standards that would be referenced under the API workflow capabilities, the CDS Hooks Release 2, the smart health cards updated framework, the smart health cards vaccination and testing IG, and then the HL7 FHIR subscriptions or FHIR IG. Next slide?

The other portion of what you will see proposed here is something of a restructuring around how G-10 works. We broadly looked across a number of APIs that we are now proposing, when we had originally structured this. We really only have the G-10 API. Now with HTI-2, we are proposing a number of different APIs, including APIs that can support public health reporting and APIs that support payer and provider information for insurance purposes. As we looked at that, we want to look at the API framework as a whole. There are many things that are incorporated today into the G-10 API regulation text.

We began to essentially pull out some of those into their own individual criteria. What we will see is a migration out of G-10 into these J criteria. The J criteria are basically things that support different aspects of the API workflow and might be applicable not just to do G-10, but also to some of the other APIs on payer and public health, things that are related to registration, things that are related to API authentication and





authorization, things that are specifically related to information access, and then things that are ultimately related to API workflow capabilities.

This is a real topline description of what we are proposing here, but as you look at the new J criteria that are proposed, that is what is behind that framework. We are pulling out a number of things from G-10 that are broadly applicable to APIs as a whole and pulling them into a more generic J framework that can be applicable to multiple different types of APIs.

Then we covered some of this I think in the earlier description, but these are the revised standards in G-10 API information access and authentication and authorization. As we said, updating that USCDI Version 3 to Version 4 is proposed. That comes with updating the US Core IG version underlying it. Then smart launch v2 gets to some of the user access brand specifications. These support how users can connect apps to specific entities in a more streamlined fashion and makes for a more seamless experience on the user side, which is why we have proposed in that area. Next slide I believe I am passing to Matt Rahn here.

Matt Rahn

Thanks, Rob. Can you hear me, everybody? Perfect, thanks. Thanks, Mark. I did want to mention, I think we were supposed to say it earlier, but I am going to say some canned language real quick even, though we already are presenting. But just wanted to mention, just for all of these slides that you see, ONC must protect the rulemaking process and comply with the Administrative Procedure Act during the rulemaking process. ONC can only present the information that is a proposed rule and is contained in the proposed rule.

We cannot interpret that information, nor clarify or provide any further guidance. We also cannot address any comments, suggestions or statements made by anyone attending a meeting or via another informal means. ONC cannot consider any such comments or suggestions in the rule writing process. We ask you please submit comments through the formal process outlined in the Federal Register. I know Sarah put links into the chat, so we do try to be as correct as we can in these slides, but please do turn to the actual regulation to confirm anything that we say.

Now that we have mentioned that, I will just have a few slides here and then I will turn it to Jeff. Again, my name is Matt Rahn, I am the Director of the Standards Division at ONC. In the regulation, we proposed to adopt USCDI Version 4 as part of the certification program and require that updates, by team module, be certified to this criteria, reference the USCDI and update and provide their customers with this technology by January 1st, 2028.

In Version 4, we added 20 new data elements. Some are relevant to behavioral health and supporting marginalized and underserved communities, specifically, around the goals and preferences, treatment intervention preference, care experience preference, data elements are in that data class. Within the health status assessment, some of the behavioral health data elements, alcohol use, substance use and physical activity data elements. The Version 4 would also support data users' ability to identify, assess and analyze gaps in care, which would in turn be informed to address inequities of healthcare through interventions and strategies. Next slide please?





This is just an overall picture of the data elements. Again, we added 20 new data elements. You can see, those in the yellow boxes are the new data classes and elements. We did reclassify a few, put social determinants of health (SDOH) assessments in the status assessments and we renamed the patient summary and plan data class. This is meant for you all to see the visual effect of what was added from Version 3 to Version 4. Next slide please?

With this, comes some of the applicable of implementation guides that Rob mentioned before. We proposed to adopt USCDI Version 4 and the US Core IG in the G-10 criterion to support the read and search API for patient and user access. Also, in G-10, to support the bulk and read, and search APIs for system access, Certified Health IT developers with Health IT modules, currently certified to G-10 must update their products to US Core V7 by December 31st, 2027.

The US Core IG helps specify which profiles must be supported at a sub-resource, or granular level scopes for read and search. This would support more granular change of specific FHIR-based data elements. For example, the patient lab results, rather than all of the patient's observations.

I will mention that we are focusing a lot on our API criteria through the slides, but we did also propose to update, to require support for Consolidated Clinical Document Architecture (C-CDA) Edition 3 Standard for Health IT modules supporting USCDI Version 4 and all the non-API related certification criteria where USCDI is listed. I believe that is my last slide. If you can go to the next slide and I am going to turn it over to Jeff Smith, so thank you all.

Jeff Smith

All right, thanks Matt. Excuse me. My name is Jeff Smith, and I am the deputy under Rob in the Certification Testing Division at ONC. We have got a number of slides here to try and unpack and provide a little more color to the high-level overview that Rob and Matt just provided. We have got a number of slides here, we are going to try and keep this though, on time and on target. That way you have got ample time for additional discussion.

But first and foremost, talking about Smart App Launch 2.2. In HTI-1, we did finalize the use of Smart App Launch 2.0. But 2.0 did not include specifications to user access brands, so there are handful of additional upgrades and improvements to 2.2. We thought it would be a good thing to try and move the floor up in this proposed rule. It does include new features and guidance that help improve standardization and interoperability. For example, the FHIR Context Launch Parameter which allows application flexibility and helps maintain backwards compatibility. I did mention the user access brands and endpoints specification and this would allow API providers to publish brands associated with the FHIR implants and hopefully help patients, and the apps of their choice, navigate the task of connecting patients to their health information via this standardized pathway.

Next slide please. Just another couple points on this. We would also require the use of essentially following the brands FHIR specification as part of the condition and maintenance of certification requirement for G-10, which is located at Code of Federal Regulations (CFR) 170.404B. We would have a compliance date of January 1st, 2028, for that. I think what you will see is a lot of bundling around that date for all of the G-10 requirements. We tried to make sure there is consistency in all of the standards we talked about updating are all targeted to January 1st, 2028, or December 31st, 2027, depending on if we are talking about





functionality, a standard or an update the condition. But everything is bundled around that time frame. Okay, next slide please?

On bulk data, obviously there is a new version of that. We think it has got some additional aspects that would be helpful, especially around the notion of a type parameter. We are proposing that module certified to G-10 which supports bulk FHIR export of groups of patients for system apps. Again, we propose that support for this be updated and provided to customers by December 31st, 2027. Next slide please.

Okay, so obviously, I think Rob's slide earlier covered this, but just to hammer home, there are new pieces of G-10 capability that we are proposing. Notably, dynamic client registration, as well as these API workflow capabilities including workflow triggers underpinned by the CDS hooks Standard Verifiable Health Records, underpinned by the SMART Health Card Standard. Specifically for vaccination and testing use cases, and then event notifications underpinned by these subscriptions, R-5 Backport Implementation guide. Next slide.

Okay, so just a few words here. We are going to go a little bit deeper on dynamic client registration protocol and our proposals around that. Looking at not just G-10, but we will preview some forthcoming sessions around payers. But generally speaking, this proposal would require several certification criteria in the program to support dynamic client registration and subsequent authentication and authorization for dynamically registered patient-facing, user-facing and system confidential applications.

We are proposing the same implementation guide that has been adopted or pointed to as part of the fast work and that is the Unified Data Access Profiles Security for scalable registration, authentication and authorization IG. The UDAP security IG v1 for short. We have amended certain API conditions and maintenance and certification requirements in 170.404. For those of you who are familiar, we have got requirements around registration timelines for apps that are registered manually. Well, if we have got dynamic client registration, we have got a new set of timelines that we expect those apps to be able to register dynamically, and in real-time. Not to give away the plot line or the ending but generally, if an app uses dynamic client registration, the idea is that that app should be able to get access to data more quickly.

Obviously, we think there are benefits to this. Not only would it facilitate timelier patient, provider and system access to health information using apps that are capable of registering dynamically, it would also create more uniform standardized and automated application registration pathways, essentially, trying to make healthcare data and access work like the rest of the internet data and access. The next slide please.

Okay, so one important dynamic about all of this to keep in mind, and I think we spend a fair amount of time opining about this in the proposed rule. But a component of dynamic client registration is this notion of trust communities. The proposal relies on this concept, so there would be an ecosystem that would enable scalable trust by establishing common policies that all participants agree to abide, reducing the need for individual agreements between organizations establishing those trusted relationships.

Participation in a trust community can be represented in a secure manner in the form of cryptographically secure digital certificates. These certificates enable an application to prove to a server that it and its developer are trusted. With the certificate as proof of its trustworthiness, UDAP user and their application registration can proceed in an automated manner without the need to perform manual and non-



standardized trust verification. This is a piece of the puzzle we would love, obviously, your thoughts on, how this could develop and how it should develop.

It is a pretty important component to the overall, but it is not something that we are proposing to require. It is not something we are proposing to stand up as a function of all of this, so we have some questions there that you are going to want to pay attention to. Next slide, please.

Okay, so obviously again, we have got requirements around publication of trust community information. This really does mirror, at least philosophically, the requirements that we have for developers to publish endpoints, what we are calling API discovery details. Specifically, we propose developers publish trust community information that is necessary to enable dynamic registration for patient-facing apps with API technology certified to G-10 and G-30. We will get to it, but G-30 is on the patient access to payer information.

We propose that trust community details such as trust community name, contact information, web address, identifying Uniform Resource Locator (URL) must be publicly published in a computable format at no charge, for each service-based URL published in accordance with B-2, which is where the G-10 API discovery details are being proposed. Essentially, again conceptually, the notion is that the trust community information needs to be publicly available, so that apps know which trust community they need to be joining or be a part of. Next slide, please.

Okay, so just a couple more here. Authentication of dynamically registered apps. We are proposing to require support for authentication of dynamically registered apps. This is going to be distinct from the Smart App Launch authentication. This proposal authentication process for dynamic registered apps would include the use of digital certificates to establish trust. For dynamically registered apps, we propose to require that the same app authentication mechanism for apps be supported in the authorization process as well. This requirement would keep the app authentication mechanism for dynamic registration and authorization of dynamically registered apps consistent.

Next slide, please. Okay, moving out of dynamic registration into workflow triggers. This is a new capability that we are proposing for G-10 certified modules. Essentially, this is CDS hooks. In trying to figure out exactly how we wanted to require, or proposed to require conformance, we landed on including support for both the patient view and order sign CDS hooks according to at least one of the versions of the implementation specifications at 215F1, and that is the CDS hook framework. We propose to support patient view and order sign because these CDS hooks are at a Maturity Level 5, according to the IG, and can be used to support a variety of workflow processes.

We propose support for this, again by the end of 2027. I think now is an important point to reiterate that certification is the floor, not the ceiling. When it comes to something like CDS hooks, we would have conformance to patient view and order sign, but I think that would demonstrate the ability of the module to support CDS hooks. However, it would be entirely logical to support more than that, if the developer and its customers wanted to support more hooks than that. That is just the minimum bar for certification requirements, but it would be entirely reasonable to think that more hooks could be supported if that was in the developer and users' interest, wants, and needs. Next slide, please.



Event notifications, otherwise known as subscriptions, is another area, another new capability that we propose support for. This would rely on FHIR subscriptions for G-10. We propose that all patient related US Core IG resources, filtered by patient identifier and code would be supported. Then as part of the exchange, the rest hook content using the HL7 FHIR resource ID. Again, representing that minimum capability that we would require for conformance to this specific piece. We do propose support for subscriptions according to the FHIR subscriptions R-5 Backport IG, Version 1.1 for FHIR resources and data elements that are specified in the J-23 criterion. I will have a few things to say about the J criteria once we get through these workflow capabilities.

We do propose subscription requirements for G-10, for patient and user access use cases, and for system access use cases. For all three of those kinds of use cases across G-10, we do propose subscriptions and we do propose subscriptions and one of the other G criteria, which is escaping me at the moment, but it is over and the health insurance and payer APIs.

All right. Next slide, please. Okay, so, on the verifiable health records, obviously our experience with COVID and the need to access vaccine information became apparent, and I think a demonstration of how quickly and importantly the standards development community can rally behind a cause and an effort to develop the smart health card specification. We are proposing that G-10 modules support the issuance of verifiable health records according to the smart health card framework. Specifically, the vaccination and testing implementation guide. We are proposing that G-10 modules supported by December 31st, 2027. I do believe we also propose smart health card support in E1. I may be mistaken or misremembering, but at any rate, the idea here is that at a basic level, trying to support vaccine and testing smart health cards. OK, next slide, please.

Okay, so take a snapshot of this picture, this is what current G-10 API criterion requirements look like. In terms of the various standards that we are requiring and the various users that would be potentially using the G-10 capabilities for different use cases. If you can go to the next slide, this is really the delta between what we have currently got and what we are proposing, which I think looks like quite a lot. But really, what we are doing here to recap, we are proposing to require support for dynamic registration and system authentication. We are requiring or we are proposing to require smart health cards, subscriptions, and CDS hooks.

We are proposing new versions of the US Core IG 7.0, as well as bulk data access. But as you can see here, I think this is going to enrich the landscape for FHIR capabilities and for potential implementation guides. If this becomes the base layer level of capability support for G-10 certified modules, then the implementation guide author community has a new set of tools to work with. We can start thinking about the exchange of FHIR, not necessarily as a reflection of what CDA exchange looks like, but really some more native FHIR capabilities that could result in more interesting, dynamic and ultimately, more efficient exchange patterns of information.

Okay, next slide. This is just another cut, another slice at what we have just already looked at. Broken into patient use access versus system and information access. A lot of this again is reflected in the new structure of the G-10 regulation text. All right. Next slide, please. Okay, so just really quickly before, Mark, we get into this. I think there was a comment by Hans made around the J criteria. We are actually going to tackle that with full force in the next work group meeting. I believe that is what we have on the agenda coming up.





But generally speaking, I think what you say there in terms of J is really representing these many IGs. I think that is true in some sense, especially for the J criteria that are related to UDAP.

It is also correct for the J criteria, what we will call the J-20 criteria that represent workflow triggers, subscriptions and smart health cards. I think what we have tried to do and again, we will get into the weeds on what the J criteria is, we are proposing to modify G-10, which has been our flagship API criterion for a number of years now. But we are also proposing G-20, which is specific to public health. We are proposing a suite of G-30 APIs. G-30 through 36, to represent different types of exchange patterns using APIs for health insurance and health coverage information. Including prior auth.

As a function of proposing to adopt all of these new J, or sorry, G criteria, we realized we might want to break out a new section of 170.315J, that would then allow us to cross-reference in almost a computable way. It does introduce a little bit of complexity in terms of how to read the regulation, but I think hopefully reflective of your comment there, once you figure out the way in which Js and Gs are related, it starts to make a little bit more sense and we can start to think about how this is more extensive of a way to get regulation text aligned with what the technology needs to do. I will leave it there. Before we get into any discussion, particularly Rob, Matt, I have got another colleague, Scott Bohan who is on the line, anything you want underscore or anything that I missed?

Matt Rahn

Nothing for me, I think you did great. Thanks.

Rob Anthony

Yes, not from my perspective either. Thanks, Jeff.

Scott Bohan

Nothing for me. Thanks, Jeff.

Jeff Smith

Okay. All right well, the mic is yours, and again, we cannot really opine or dig much deeper than what is in the preamble, but happy to be here and happy to be a resource for the discussion.

Discussion (00:40:32)

Mark Sendak

Thank you Jeff and other ONC colleagues for leading the presentation. It definitely helps break down where things stand now, what is being proposed. I do have a quick definition question and I do not know, I am not asking for expansion, but I just wanted to understand the term, image link for supporting transmission of imaging data. Can someone from ONC just describe what that means, because it is not to the image file, but I just wanted to understand what that was referencing, and I could not find a good online resource.

Rob Anthony

Yes, I think we can probably excerpt the appropriate portion of the preamble for you, but essentially the proposal, and you will see it in a couple different criteria, but simply at this point to support a hyperlink that can be used for imaging. I think, Jeff managed to pull it out really quickly.



**Jeff Smith**

Yes, we actually proposed a definition for imaging link, and also Scott Bohan who is also on the line, was one of the primary subject matter experts (SMEs). Imaging is actually sprinkled throughout various criteria, G-10 being one of them, E-1 being another one of them, and I think v1 and maybe v2. That is the definition for imaging link that we are proposed, but what Rob described is generally the idea.

Mark Sendak

Got it, and it still seems ambiguous around, you may still have to log into a system that is separate to see the image. It is not the image itself that is being transmitted, is that the right understanding?

Rob Anthony

Correct.

Mark Sendak

Cool, okay. Hans, I see your hand up, so we can start there, and then I think we will want to go through the document. Sarah, I think you may be pulling it up to discuss the different changes we want to review, so Hans.

Hans Buitendijk

Thank you, Mark. Just some a more planning and progression question that may in part be addressed later, but as the presentation went through, what is generally in standards and certification. The detail was more around G-10 and some of the general capabilities. Is the expectation that as we get into the next couple weeks that when we for example, to the payer, provider type of APIs, that we will have a more detailed overview as well, and then we jump in, which relationship question, which I did not see part of the slides beyond upcoming meetings. Roughly, what is the allocation of topics, so that where do we talk about the A's, the B's, the apps for mostly public health. Then we have the Gs and the Js. Where do they roughly fit in the progression over the next couple weeks, if that is available?

Jeff Smith

Sarah can you jump back to that slide that we had before we dunked ourselves into G-10 content?

Sarah McGhee

Yes, we should be able to go back there. Just one second.

Jeff Smith

I'm sorry. Yes, okay. Thank you. Yes, because of the intertwined, and because of tightly bound nature of a lot of the proposals across, let us see here. We yes, tried to figure it how to sequence this conversation. For those of you who are just curious, you all won the lottery because you are going to have to cover the most amount of ground in terms of trying to provide feedback and input across the various certification criteria that were updated. I think generally speaking, the hope is that next time we can talk to the J criteria, which you have got an exposure to here, so I do not think that we would have to spend the entire time. But the hope is that we would be able to get through the API capabilities certification criteria, modular API capabilities next time, and then next time dive into the patient provider and payer API's.





You can give your feedback whenever you want, Hans, but just know that I think generally we can probably spend a fairly few number of minutes on modular API capabilities and spend most of our time on the patient, provider, and payer APIs next time.

Hans Buitendijk

Yes, thank you. Yes, there was a little bit of a selfish part to the question because next week I am not convinced can make it.

Jeff Smith

Okay.

Hans Buitendijk

I have formally, PTO but you never know. But I can still make it. That is why I wanted to have an idea of when things are coming up.

Jeff Smith

Okay, well the schedule is completely within your hands, in the HITAC hands so, yes.

Mark Sendak

Are there any other questions from folks on the call about the high-level presentation? Things that are missing? Things folks would like to see potentially done differently? I know I was asking about the imaging link. I also was confirming my understanding of some other specifics related to the CDS hook, so also open to any just clarification questions people have.

Hans Buitendijk

I have another clarification question, perhaps, if I may?

Mark Sendak

Go ahead.

Hans Buitendijk

If you look at the certification criteria around the updated computerized physician order entry (CPOE), with reference to Laboratory Results Interface (LRI)-LRI there is an alignment there with public health and there is an independent piece to that because it does not necessarily need to relate to public health. A couple of the things, are they on the slide that is on the screen or part of select revised criteria and we are going to get to those little bit later? First get the, as Jeff indicated, the G-1020-ish type of things, then the payer/provider environment and then everything else, if you will? Is that the reasonable expectation?

Mark Sendak

Sarah, maybe you can help me parse this, but my understanding is what we are looking at right now is actually the plan for upcoming meetings. Next week would be modular API capabilities, next week after would be patient, provider and payer APIs. Is that correct?

Sarah McGhee

Yes.



**Mark Sendak**

Yes, and then the other thing to add is that my understanding for homework for the coming weeks is, we would get the information about the specific sections that are related to that week's topics. Is that correct Sarah?

Sarah McGhee

Yes, what I will do is send out the homework to you to review, and it would include a link to the rule, but also specify the sections. Then once we have the rule, once it is actually published in the Federal Register and we get the rule page numbers, once those are available, we will add those to the recommendation sheet as well so members, when they are looking on their recommendations, they can go straight to that section. But this page right here is how we will follow the structure for the upcoming weeks.

Hans Buitendijk

Reasonable to expect that any of the A, B, D and E criteria would be more in the select revised criteria as certification criteria, that is the bucket roughly where it will fit? **[Inaudible – crosstalk] [00:49:26]** by the sub-rules, per say.

Sarah McGhee

I believe that is correct and I will let **[inaudible – crosstalk]**.

Jeff Smith

Yes. Yes.

Sarah McGhee

But yes, and the homework should be coming out today or early tomorrow, so you should have enough, hopefully a little bit of time to look at that before next week's meeting.

Mark Sendak

Maybe just one other conceptual question for the ONC staff, making sure I understand the value of the dynamic client registration. Can you give some examples of use cases that update to the authentication and registration would enable? Or a specific pain point that was faced by the current criteria that that will solve?

Rob Anthony

I think we would have to go back and look at anything that we mentioned specifically in the preamble related to this. I would be concerned about pulling out anything separate from what we have already described here.

Mark Sendak

No worries.

Jeff Smith

If you proceed from here to some of the slides on dynamic client registration, we do try and, I do not know that we call out any specific use cases where we envision dynamic client registration to be applied. Save





for the notion that generally the context we are trying to address here is facilitating patient access to their information via G-10 and then also, G-30. We do also reference dynamic registration, I believe in a user and system access context. But the notion here is to better facilitate the registration process so that a patient can download an app of their choice and connect to their health information more seamlessly. As is the norm in the banking world.

Mark Sendak

Got it. Thank you, Jeff. Any other questions before we get into the specific recommendation part of the discussion? Okay, if not then, Sarah, maybe let us pull up the spreadsheet to start working through.

Task Force Recommendation Worksheet (00:52:19)

Sarah McGhee

Sure, give me one second and I will share my screen.

Mark Sendak

Thank you.

Sarah McGhee

Okay, can everyone see that?

Mark Sendak

Yes.

Sarah McGhee

Yes, and just direct me, guide me to where you would like me to go or if it needs to be zoomed and resumed out.

Mark Sendak

I know that this is my first time doing this, and I know for some of the others here, especially external folks. Sarah, I will try and describe my understanding of how we will work through this but then please feel free to chime in or correct anything.

This is, the document you are looking at right now is our opportunity to make specific recommendations on the different sections that we reviewed today. This is language that we will be able to actually change and write down what we would propose. As we make changes, we would try to identify language we can agree on, on this call. Once we have, and I think we are going to have a spreadsheet to go through every single week.

Once we have our recommendations set, my understanding is that this is what is what actually goes to HITAC to vote on September 12th. Is that accurate, Sarah?

Sarah McGhee

Yes, and I will also let Peter step in with the procedure side of it as well. But yes, every week we will look at this recommendation sheet. The numbers can go in, you should all have the link, so you can go in at any





time and add a recommendation. It will be displayed during the meetings, and you can work on refining the language.

What the other group is doing and is highly recommended is to put your initial before your recommendation. That is something that, you all can work through the language together during the calls. Then you can edit it up until we start putting it into a report. But what will happen, if I remember correctly last time, you will present the recommendations once there is consensus to the HITAC committee and then they will vote on the recommendations. That will go into a separate document and get submitted through the Federal Register process. Did that answer all your questions and Peter, would you want to add anything?

Peter Karras

Yes, thanks Sarah. Yes, that is correct. I think of it, within these subgroups it is folks working on a piece of the pie that will then come together is the full pie. The totality of the recommendations across sub workgroups will be put together as one transmittal package. Going through here, a consensus process, but then, will be incorporated along with the other recommendations, throughout the other sub workgroups, into one package for the full HITAC on September 12th.

Sarah McGhee

Yes, and I will just add that this document, the Google recommendation sheet, we will share it during the task force meetings, but only members of the task force will have access to the document.

Mark Sendak

Okay, wait. Sarah, I just want to make sure I understand. Are the people on this call not on the task force, so would they not have access to it? Or are you saying the access is further limited?

Sarah McGhee

No, members of the task force will have access and I believe a link was sent out to all of them. But members of the public can view the document but will not have access to the link or to make edits.

Mark Sendak

Got it. Okay, so people should have received this in their email before the meeting today?

Sarah McGhee

Yes.

Mark Sendak

Okay.

Steven Eichner

This is Steve Eichner, just to add on, more specifically I believe.

Sheryl Turney

I also had a question and I have had my hand up since the beginning of this, Steve. Sorry to jump in.

Steven Eichner





All right, sorry. I was just going to clarify the last point, members of public can see the document during task force meetings when it is displayed. Outside of meetings, it is available as a Google sheet for task force members.

Mark Sendak

Okay. Thank you, Steven and then Sheryl, we will go to you. Apologies for having you wait.

Sheryl Turney

Sarah answered most of my questions, but I also recommend that in addition to initials, you put the date in when members add recommendations, because we are going to be adding them at different times and that way it will help you know when it was put in and if it was covered or not. Typically, these recommendations have to be rewritten after, so that they, in the final report, all have one voice.

Mark Sendak

That is a good point. If folks go into the document and are making changes, please put your initials and the date that you are making that recommendation. Steven?

Steven Eichner

I just wanted to add, there are several of us that are participating in multiple groups to help cross information between the different groups and I am sure the ONC and the [inaudible] [00:58:17] staff will also help share information between the different workgroups because there are things that impact the workgroups and will impact different groups and will impact work as we go along. There are some crossover concepts that may impact different workgroups, but only appear in one workgroup's catalog, or one workgroup's spreadsheet.

Mark Sendak

Got it, thank you. Okay. Hans?

Hans Buitendijk

Yes Mark, I just put in a note in the chat for members, if we can share one of the older prior spreadsheets, where people can see how it all looked together as people had put in at recommendations, discussions. Otherwise, you can get an idea of how it is actually being managed further, rather than just looking at a blank cell.

Mark Sendak

Yes. I was just seeing some internal notes, so any task force members that are having trouble accessing this document, if you can please send your Gmail address to the Excel team, they will help get you set up with access to this. Sarah, how many of these rows are for today's content? Is it the full spreadsheet or, I just see how big the scroll is.

Sarah McGhee

Yes, so this spreadsheet includes all of the sections that we will be covering in the task force committee. I think there are four for today. No, five. It is five, excuse me. These are the five big topics that were discussing today, and here you can see this is Meeting 1. But all of the topics for the subsequent weeks are also included in the spreadsheet, as you can see here.



**Mark Sendak**

Perfect.

Steven Eichner

Just add on, the recommendation for the different work groups are on different tabs, as you can see across the bottom. Your task force members can visit any of the recommendations for any of the tabs that they can see.

Sarah McGhee

Yes.

Mark Sendak

Yes. Hans?

Hans Buitendijk

Yes, maybe two suggestions. One that was discussed you probably had yesterday as well. That having multiple lines, or a line per criteria might help. That can pull in the standards proposed for it. But there are in this, the proposal summary, there are the criteria and others are referenced inside the text. But it would be actually helpful in one of the columns A through D, somewhere in the beginning, to have the main criteria and that it is all about.

There will be some general comments where we get cross-multiple. At that same point in time, I think we will have discussions on specific criteria like G-10 specifically or smart J-23 subscriptions, specifically, etcetera, that may be helpful. It may not have to be done all immediately, but I suspect that we would like to include some extra rows to make it manageable.

Sarah McGhee

Okay. Yes, absolutely.

Hans Buitendijk

Otherwise, it will have a lot of text in the recommendation section.

Sarah McGhee

We can do that.

Mark Sendak

We have 15 minutes to try to go through at least these four topics that we have for today. I am aware that we have only heard from a small number of folks on the call. I want to make sure that we hear from folks, especially people who maybe like myself, are doing this in learning the process as we are getting started. Folks we have not heard from, is there any one of the four, if you can scroll down, Sarah, so, we can see a few of them. Any one of the four that we want to start with? We have USCDI. We have the Smart App Launch, bulk data elements and then user access brands and endpoints. Sorry, and dynamic client registration protocol.



**Hung S. Luu**

Well, I guess with the USCDI, I assumed that the scope of this task force is only to probably input on whether we should move forward with UCCDI adoption by 2028 and not to change what is in USCDI, correct?

Mark Sendak

That is a very good question that I actually had discussed with somebody. I do think, and Sarah and Peter, you can let me know how this would work. I definitely think it is important we solicit feedback on ways to improve USCDI. That may need to be routed to a different effort, especially as we look at USCDI v5. My expectation would be that we cannot change USCDI v4 or would not recommend changes to that in this. But I would still want to encourage folks to think about how can USCDI be improved, and then the question for ONC would be, what would be the right way for us to be routing those recommendations and energy to improve that data standard? Matt, I see your hand.

Matt Rahn

Yes, thanks for that question. The proposal is USCDI Version 4, as a whole, not a subset of USCDI Version 4. There is a separate process for updates to USCDI, as you said, Mark. The scope for the comments can be around whether or not to include our proposal for USCDI Version 4. There is not going to be a decrease or addition of data elements to USCDI Version 4 based on what we proposed. When it comes to USCDI Version 5, that was released last week but we are now in open comment period for Version 6. Did that help?

Mark Sendak

Yes, maybe one other question because I know that there are several USCDI v4-pluses.

Matt Rahn

Can you clarify?

Mark Sendak

Maybe I do not fully understand, but there is a plus maternal health, plus extensions?

Matt Rahn

Yes, I can clarify that.

Mark Sendak

Okay.

Matt Rahn

Yes, so those are completely separate from USCDI Version 4. USCDI+ domains and projects we have with USCDI-plus are in alignment with the other USCDI versions, right? That is our hope, but USCDI+ is for individual use cases that are above and beyond the USCDI prime needs, and are a lot of times, scoped specific to our federal partner agency needs in HHS. There might be pieces of USCDI Version 4 that are part of a maternal health data set that gets developed. But that would be called a USCDI+ Maternal Health Version 1 Data Set, right? That would not be, and it could have a superset or subset of Version 4 data elements.



**Mark Sendak**

I guess part of my question was going to be, could we make a recommendation to include any of those additional, more targeted, I am just wondering, where is there potential to include in a comment, the addition of additional data? Or is that just entirely not part of this process?

Peter Karras

Mark, this is Peter, I will step in a little bit. Just generally speaking, we like to use this term, logical outgrowth. It needs to tie back to the proposal, or at least should tie back to the proposal. There should be enough in a recommendation that you could reasonably connect it to the specific proposal language. Obviously, this is a HITAC's meeting, so technically anything could be recommended. But if it is a net new recommendation, that could be almost in a way, HITAC signaling this could be something to put into a new proposed rule. But really, cannot put anything in a final rule that was not a logical outgrowth of the proposed rule, as the public would not of had a chance to respond.

Therefore, not really introducible. Just think of it from, is there a logical outgrowth? Is there a connection? Can it be reasonably tied back to the specific language? I know I am speaking generally. I was just going through the exercise with the recommendations tracker. Of course, I mean, this is HITAC's meeting so things could be recommended. But in terms of reviewing the comments, there needs to be some logical outgrowth that ties back reasonably to the existing proposed language.

Mark Sendak

Perfect. I know this is very procedural, but I do want to go back to Hung for a second. Hung, beyond any specific data elements and what the right way to provide that input, were there concerns that you would want to express about the current language of that USCDI recommendation?

Hung S. Luu

No, not at all. I was just clarifying the scope of the task force.

Mark Sendak

Cool. Mary Beth?

Mary Beth Kurilo

Yes, thank you. I am just wondering if it is appropriate, and I really appreciate this conversation about USCDI Version 4. I am wondering if it is appropriate to provide, so for example, a comment of support in the move towards USCDI Version 4, with also a request to continue to look at the comments that have already been put in on USCDI Version 4 and Version 5, recommending the addition of data elements in future versions. I think from the immunization community, we support the move to Version 4, but we have made comments for past versions that have not yet been added. It feels a little bit incomplete to just say, "Yes, we support Version 4," without at least acknowledging that there are comments on record for future versions that have not yet been addressed, that we would love to see in future versions. Does that make sense?

Mark Sendak



Completely. Sarah and Peter, I gathered from the prep for today, that even having an affirmation as a recommendation is useful for HITAC. I do think it is worthwhile in column G, to at least put an affirmation and completely agree with you, Mary Beth. Unfortunately, I work in an innovation team, so for me it is also hard to imagine updating a data model four years from now, when we know that there are gaps. It is also, what is the next time horizon to be making these updates for v5 and v6? It sounds like a recommendation to potentially hasten the process for including updates to v4 that are reflected in v5 or v6. Is that capture what you are trying to say Mary Beth?

Mary Beth Kurilo

Yes. Absolutely, and I think hastening or providing support for revisiting addition of elements for Version 6. Yes, agreed.

Mark Sendak

Steven?

Steven Eichner

Yes. Historically, workgroups have collected comments that have been related to issues outside the scope of the charge and made reference, some referred them to things like the HITAC annual report workgroup. Or in a couple of instances, including them in recommendations, but as a separate section from the recommendations request or recommendations report. Looking at v4, v5 and what version of USCDI might be included, my personal read is that it really focused on v4 in its entirety.

Not looking under the hood and trying to manipulate or change what components might be included or modified within v4, in subsequent or in HTI-2. The recommendation for perhaps changing the pace of subsequent adoptions, or adoptions of subsequent certain versions of USCDI might be in scope, or something in that space. With leveraging ONDEC and other tools for making recommendations for future versions of USCDI, I am sure this is always a welcome opportunity and welcomed input.

Mark Sendak

I agree with you Steven and if people are thinking about these topics anyways. Hung, if you would like to go into the file and add your comments, I guess it would be Row 3, Column G, we could then try to send the recommendations to updates of USCDI to the right group.

I am mindful of time so, Hans, if you are okay with it, I would like to at least make sure we consider some of the other four?

Hans Buitendijk

It might be a general comment that is helpful as we are getting our footing on this, because the comment might come back and some other spaces as well. Using USCDI Version 4 as an example, it is really at this point in time, the only choice. A number of the other standards is that, if you look at the progression it is the only choice available. In other areas, there might be a more current version or another alternative standard that can be used and it should be suggested. But I think we have to be mindful of that, but I have a question regarding that.





Considering that USCDI Version 4 is the only published next version of USCDI that is not yet in regulation and that has standards in support of it. Version 5 is just published last week or couple days, whatever, very recent, has been published but there are no standards that support that yet, that have been recognized to do that. It would not be a candidate. But it would be a candidate for SVAP and I am just curious is that, in this context, we need to keep in mind that assuming SVAP is still around, that might also help with some of those progressions that can enable adoption more, or sooner than the next full regulation. I think all those variables, we need to keep in mind that it is really about what is published, what is available, what are alternatives, is it a step too far, too big for the timeline?

Or is it okay to do for everybody to adopt? On the latter point, with general comment that cuts across these four, and everything else, I think one of the biggest questions will be, not necessarily at each individual, is that a good thing in the context of that criterion? But the combination of everything, is it adding up for everybody involved? IT developers, payers, providers, everybody. How big is that step in light of everything else that needs to be done? I think it is also going to be a question, not only of is the standard appropriate or not? Yes, makes sense. But also, do a thing as a community, the entirety of this, is that a reasonable amount of work in the amount of time that will be available? We think then, 2028 typically. But we have to keep in mind, there is HTI-1 that is going on right now, full steam as well, and a number of other initiatives. Is it too much or is it okay?

Mark Sendak

Okay, thank you, Hans. Public comments are going to start in a minute. I know that today was the first meeting, so we are getting our footing, orienting to the process, how things will be done. I want to thank again, the ONC team. In an upcoming meeting, we will try to also build in some time to have the task force members to introduce themselves so folks can get to know each other little bit. Thank you to ONC and we are going to move into the next section.

Public Comment (01:16:42)

Peter Karras

Great, thank you Mark. All right, at this time we would like to open the meeting for public comment. If you are on Zoom and would like to make a comment, please use the raise hand function that is located on the Zoom toolbar at the bottom of your zoom screen. If you are on phone only, press star nine to raise your hand and once called upon, press star six to mute and unmute your line. We will pause for a moment to see if we have any members of the public with raised hands. Or check to see if anything is coming in through the chat from the public. Not seeing any comments at this time, and just reminder that the next subgroup meeting starts, or will be next week. Same time and place. Just a reminder that all HITAC meeting materials can be found on HealthIT.gov. I am not seeing any hands raised at this time or any comments coming in. With that, Mark, I will turn it back to you for closing remarks.

Next Steps (01:18:01)

Mark Sendak

Sorry. Unmuted now. I want to thank everybody for taking the time today for embarking on this journey. It is going to be a very productive and busy next two months, so really appreciate the time that people put in prior to the meetings, reviewing the content during the meetings, as well as after the meetings.





I know that today, maybe we did not have as much content put in the Google Doc, but feel free to continue to review and enter material afterwards. Look forward to future meetings to collaborate with you all. Thank you. Hope everyone has a good rest your day.

Adjourn (01:18:50)

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

No comments were received during public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Sara McGhee: Here's the link to the HTI-2 Proposed Rule: <https://www.federalregister.gov/public-inspection/2024-14975/health-data-technology-and-interoperability-patient-engagement-information-sharing-and-public-health>

Sara McGhee: Here's the link to the HTI-2 webpage on ONC's website: <https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-patient-engagement>

Hans Buitendijk: The J criteria seems to be "mini-IGs" providing specific guidance on what to use from certain standards. Took a little to navigate the extra layer(s), but quite helpful to understand alignment across criteria referencing J criteria. Just surprised the 170.315(d)(13) was not part of J.

Accel Solutions: onc-hitac@accelsolutionsllc.com

Hans Buitendijk: Note that 170.315(g)(20) addresses some of USCDI+ Public Health beyond USCDI v4.

Steven Eichner: USCDI v6 is in the process of being developed. Suggestions/recommendations for v6 can be submitted into ONC's ONDEC system.

Hans Buitendijk: And/or participation in the Public Health Library Profiles IG to create a next version could consider additional USCDI+ PH data to be covered.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

RESOURCES

[HTI-2 Proposed Rule Task Force 2024](#)

[HTI-2 Proposed Rule Task Force 2024 Group 2: Standards and Certification - July 24, 2024, Meeting Webpage](#)

Transcript approved by Seth Pazinski, HITAC DFO, on 9/10/24.

