Transcript

HTI-2 PROPOSED RULE TASK FORCE 2024 MEETING

GROUP 2: STANDARDS AND CERTIFICATION

July 31, 2024 11 AM – 12:30 PM ET

VIRTUAL

MEMBERS IN ATTENDANCE

Mark Sendak, Duke Institute for Health Innovation, Co-Chair
Suresh Balu, Duke Institute for Health Innovation (DIHI)
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)
Shantanu Nundy, Accolade
Dan Riskin, Verantos
Fillipe Southerland, Yardi Systems, Inc.
Naresh Sundar Rajan, CyncHealth
Sheryl Turney, Elevance Health

MEMBERS NOT IN ATTENDANCE

Hung S. Luu, Children's Health
Meg Marshall, Department of Veterans Affairs
Alex Mugge, Centers for Medicare and Medicaid Services

ONC STAFF

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

PRESENTERS

Jeff Smith, ASTP
John Bender, ASTP
Scott Bohon, ASTP

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

Peter Karras
Good morning, everyone. Welcome to the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule Task Force Group 2 Meeting. I am Peter Karras with Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT (ASTP), and I will serve as your Designated Federal Officer today acting on behalf of Seth Pazinski. This 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 for verbal comments toward the end of our agenda. Let us get started with our meeting. I will now begin with roll call of the HTI-2 Proposed Rule Task Force Group 2 members. When I call your name, please indicate that you are present. We will start with our co-chair, Mark Sendak.

Mark Sendak
Present.

Peter Karras
Suresh Balu? Hans Buitendijk? Steve Eichner?

Steve Eichner
Hello. Welcome.

Peter Karras
Good morning. Raj Godavarthi?

Raj Godavarthi
Present.

Peter Karras
Mary Beth Kurilo?

Mary Beth Kurilo
Good morning. Present.

Peter Karras
Hung Luu has indicated he will not be in attendance for today's meeting. Meg Marshall? Alex Mugge has also indicated that she will not be present at today's meeting. Shantanu Nundy?

Shantanu Nundy
Good morning.

Peter Karras
Good morning. Dan Riskin?

Dan Riskin
Good morning.

Peter Karras
Good morning. Fillipe Southerland? Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Peter Karras
Good morning. Sheryl Turney? Thank you. Is anyone I missed or anyone who just joined us that would like to indicate that they are present?

Suresh Balu
Peter, this is Suresh Balu. Good morning to everyone.

Peter Karras
Good morning, Suresh. Now, please join me in welcoming our co-chair, Mark Sendak, for opening remarks and to get us into our meeting today. Mark, over to you.

Opening Remarks (00:02:12)

Mark Sendak
Thank you, Peter. I had a chance to debrief with the team after our last meeting. Definitely, one of my priorities leading this group is going to be trying to help ensure that we get contributions from everybody. So to kick that process off, I would like to invite folks to introduce themselves to the group. So, we can use the time to do that. That way we just become familiar with each other, the perspectives we bring, and hope to solicit more input as we start going through the documents, not just today, but over the next, I think, seven weeks.

So, I am happy to call people, or we can go in an alphabetical list. Sure, let us go down that list. That would be great. So, if you are able to come off video and introduce yourself and the role that you hold within your organization, then we will move on from there. So, Suresh, it looks like you are first.

Suresh Balu
Yes. Good morning, everyone. Again, Suresh Balu. I am part of Duke University, and I am also part of Duke Institute for Health Innovation. So, we work in AI and use of electronic health certified data on a daily basis to really drive health and healthcare innovation **[inaudible] [00:03:41]**.

Mark Sendak
I know Hans said he would be late. So, if he is not on, let us go to Ike.

Steve Eichner
Good morning. My name is Steve Eichner. I am the Health IT Lead for the Texas Department of State Health Services where I have responsibility for coordinating a bunch of different activities surrounding data exchange. I also have expertise in disability issues as well as behavioral health. Thank you.

Mark Sendak

Go ahead, Rajesh.

Rajesh Godavarthi
Good morning, Rajesh from MCG Health in the clinical decision support space. I am one of the co-leaders of Health Level 7 (HL7) Da Vinci [**inaudible] [00:04:37]** prior auth space for the industry standards. So, my background is not in technology but in the clinical decision support space implementing the standards primarily in the prior auth space.

Mark Sendak
Thank you. Mary Beth?

Mary Beth Kurilo
Yes. Good morning, everybody. Mary Beth Kurilo. I am the Senior Director for Health Informatics at AIRA or the America Immunization Registry Association. So, I oversee all of the informatics programs, including the standards and analytics branch that does our measurement and standards development work. So, I am really happy to be here. Thank you, everybody.

Mark Sendak
Thank you. Hung?

Peter Karras
Hung is not present. He might join later, but I do not see him on. Currently, he is not on.

Mark Sendak
Thank you for the heads up, Peter. Meg?

Peter Karras
I do not believe Meg joined as well, and Alex is absent.

Mark Sendak
Shantanu?

Shantanu Nundy
Hey, everybody. I am Shantanu Nundy. I practice primary care in the safety net, and I am Chief Health Officer of Accolade, which is a tech-enabled population health platform for employers.

Mark Sendak
Thank you. Dan?

Dan Riskin
Good morning. My apologies for any background noise. Maya, do you want to join? I am Dan Riskin. I am a surgeon and clinical informaticist professor at Stanford and have built health AI products and companies for about two decades. That is right.

Mark Sendak

Welcome to your guest as well.

Dan Riskin
Future member of the committee.

Mark Sendak
Yes. Fillipe? He may not be on. Naresh, I saw you.

Naresh Sundar Rajan
Good morning. This is Naresh. I am Chief Data Officer with CyncHealth currently working on interoperability for health information exchanges across the states of Nebraska and Iowa. I am looking forward to this.

Mark Sendak
Thank you. Sheryl?

Sheryl Turney:
Hi. Good morning. I am Sheryl Turney from Elevance Health. I am the Interoperability Lead at Elevance Health. Prior, I have also been a member of HITAC for the first six years. Then I also am active in HL7 and on the steering committee for FHIR at Scale Taskforce (FAST).

Mark Sendak
Thank you. So, I am excited to be working with you all, and I really appreciate the time that you are spending on this with us. So, I will then hand it back to ONC for the next section of the agenda.

Shantanu Nundy
I will say, Mark, real quick, just to say I definitely appreciate how you want more contribution. I think that is a really good thing. I will say I have been quiet because, so far, there has been a fair bit of process, good process, but I just do not have a lot to contribute. Even today's discussion, when I looked at the homework, to me it seems fairly noncontroversial. I am actually excited to hear what other people have to say. But I will speak up when I feel very safe and comfortable to do so, just when I have something to day. But until then, I will be relatively quiet.

Mark Sendak
Sure. Thank you. I think in reality, too, it is going to be important to know when we want to back a recommendation. Obviously, we want to hear when there is disagreement. So, obviously there will be some folks who express concerns about the way something is currently written. When that happens, I want to make sure that if there are folks who stand behind the current wording, we hear that and if we do not have any changes we would want to make. Because even if it does not come out of this group, there will almost certainly be stakeholders at a national level who will be providing input to make changes.

So, Shantanu, at least it will help to know what you are excited about seeing. Let us put it that way, and that will apply to everybody. I may try to do this more proactively. So, as we go through them, just soliciting, it could be in the chat. It does not have to be in the video. When we are excited about the way something is worded, just give a thumbs up to keep that or make any changes. We will try to delegate things in a different way as well. I am learning from the ONC team who has done this before.

So, the next section of the agenda is going to be a discussion led by ONC around the application programming interface (API) capabilities. We will discuss any feedback from the presentation. We will then go back to the Google doc that everyone on the task force should have access to, and I want to emphasize that you can work on that before this meeting, after this meeting, and at any point leading up to the September presentation we have. Then we will do the public comments and then talk through next steps. So, thank you, and I will hand it back to Peter.

Peter Karras
Thank you, Mark. So, the next slides, Slide 6 and Slide 7, pretty much repeat. This goes over the overarching charge for the task force. Then the next slide, if you could go to that, is just the breakdown of the topic area, which we will be discussing modular API capabilities. So, with that, we can go onto the next slide. I believe, Jeff, you are up.

Modular API Capabilities Certification Criteria in § 170.315(j) + Structure of § 170.315(g)(10) (00:10:19)

Jeff Smith
Thank you, Peter. Thank you, everyone. Let me go to the next slide, and we will get this out of the way. Disclaimers: Everything that we are going to talk about here is in HTI-2 Proposed Rule preamble. So, we are going to do our best to stay as close to the terminology and the discussion that exists in the HTI-2 preamble. If you have not read it, that will be really important to read at some point very soon to keep up with a lot of the proposals that we have.

We are going to do a pretty quick flyover of the criteria today. As is the case, as has been the case, and will be the case, we really cannot address comments or concerns that are out of scope. We will do our best to try and, again, point you to specific areas in the preamble, if there are questions, where we cover those. This is your meeting to run and your recommendations to develop, not ours. We are here to try to provide clarification as needed, and I think that is it for this disclaimer. So, next slide, please.

At a really high level, I think the modular API capabilities represent a continuation of how the program has approached certification criteria for many years now, and that is that we have a very modular certification program. So, a developer can choose to get certified to one or many and different certification criteria. As we put together the proposals for HTI-2, it became clear that we needed to establish a new category of certification criteria that would define several, what we call, foundational as well as a modular API capabilities that would be necessary to support APIs across clinical public health, administrative, and other use cases.

We think that this approach enables more modularity and flexibility for health IT developers that wish to certify to more discrete functions rather than large multi-functionality and all-encompassing certification criteria. So, if you go to the next slide, our basic proposal is to add 14 new certification criteria. Eight of these new certification criteria are substantially similar to the capabilities that are currently referenced under our standardized API for patient and population-level service at (g)(10).

We call out, of course, things like the Substitutable Medical Applications Reusable Technologies (SMART) App Launch, bulk access, and some of the registration capabilities that are in (g)(10) are now standalone in (j). In addition to those similar criteria, we have proposals for capabilities that are not similar to existing (g)(10) capabilities. Those include workflow triggers for decision support interventions, verifiable health records, and subscriptions. We will go through those in some detail. Next slide, please.

So, this is really the components identified by way of what they are trying to achieve. We have (j) criteria that cover registration, other criteria that cover authentication and authorization, and then other criteria that cover API workflow capabilities. We have tried to color code this to make it easy because this is fairly complex. Essentially, you can see here the proposed capabilities that are similar to (g)(10) as well as those that would be net new and not currently in (g)(10), although we do propose some changes and updates to (g)(10), and we will cover those at the end of the session. Next slide, please.

Here is a breakdown of the (j) criteria by registration as well as authentication and authorization. These are very similar to what we have already had in (g)(10). So, we have a functional registration. We have SMART App Launch user authentication, SMART Backend Services, SMART patient access for standalone apps, and then SMART clinician access for electronic health record (EHR) launch. A lot of these are very similar to, if not the same, as the capabilities and requirements that we have in our standardized API for patient and population services today. Next slide, please.

We did spend a fair amount of time on the new capability that we are proposing related to dynamic client registration protocol using the HL7 Unfair, Deceptive, or Abusive Acts or Practices (UDAP) Security Implementation Guide. This really tries to highlight those (j) criteria that would support dynamic registration. So, we are proposing across the (j) criteria to adopt criteria that would support both registration dynamically as well as asymmetric certificate-based authentication for patient access as well as system access. We do call out a separate certification criteria at (j)(11) for certificate-based authentication for business-to-business (B2B) user access. Obviously, these are quite complex and detailed specifications, but they all tie back to the HL7 UDAP Security Implementation Guide. Next slide.

Again, we did cover these in last week's conversation around proposed updates to (g)(10). But here is where we are proposing to house these capabilities within the (j) criteria; (j)(20) and (j)(21) would speak to workflow triggers; (j)(22) would be verifiable health records; and then (j)(23) would be subscriptions. We will go into a little bit more depth on these, again, because they are new, and we did not go into quite as much depth on these proposals as we did dynamic client registration protocol last week.

So, if we go to the next slide, we will focus on (j)(20) and (j)(21). Workflow triggers for decision support interventions is our long-winded way of saying Clinical Decision Support (CDS) Hooks, and that is because we are proposing to adopt CDS Hooks Implementation Guide, V2. We are proposing to point to 170.215(f)(1) in (j)(20) and (j)(21). So, we are proposing two certification criteria to support workflow triggers from two different vantage points. So, (j)(20) would include requirements for clients participating in the API-based workflow triggers for decision support, and (j)(21) would include requirements for services providing decision support services to client.

We do note that the proposed workflow trigger criteria do not define or propose specific workflows associated with decision support, including how and when clinicians use decision support capabilities. I

think that is a rather important point to make. We are focused on the capability of the system, not necessarily when and how the system needs to be used. Rather, we propose to include standards-based interfaces to enable clinical systems to call other systems offering decision-support services in a standardized manner to support the exchange and use of the services. Next slide, please.

Verifiable health records: We have one criterion related to this. We propose to adopt the SMART Health Cards framework, Version 1.4.0, and we propose that health IT certified to (j)(22) support the issuance of verifiable health records according to the SMART Health Card standard. We also propose to adopt the SMART Health Card Vaccination & Testing Implementation Guide, Version 1.0. This implementation guide (IG) really does leverage the framework to describe a standards-based method for the issuance of verifiable health records for vaccination status and infectious disease-related laboratory testing. We do talk at some length about how COVID demonstrated a need for this kind of capability. Obviously, there are different scenarios in which verifiable health records can be verified. But for purposes of certification, we are proposing that a system be able to demonstrate conformance with the vaccination and testing IG.

Obviously, we are aware that the SMART Health Card standard is going through the ballot and publication process at HL7 over the next several months. We do say if there is a published version of the SMART Health Card standard prior to the publication of the final rule, we will consider adopting that version. So, this may be a good area for this group to monitor and incorporate into any potential recommendations regarding the adoption of the existing standard, ST1 release candidate standard, versus something that is published. I see a hand up, Rajesh?

Rajesh Godavarthi
If you can go to the previous slide, if you do not mind?

Jeff Smith
Sure.

Rajesh Godavarthi
I was just looking at your definition of client and services. As I also read, you are referring to both paid certification and provider site as well. In this context, how do you distinguish those two?

Jeff Smith
Between the client and the service?

Rajesh Godavarthi
Yes.

Jeff Smith
Yes. This would be a good point for one of my colleagues, Johnny or Scott. Did you hear the question asked?

John Bender
Yes. I am happy to take it. But, Scott, feel free to weigh in too. We are referring to clients and services as they are described in the underlying CDS Hooks Implementation Guide. Those rules are defined within

there, and clients are the requesters for CDS services. So, this would be the source of the Hooks. Then the services are the ones that are receiving the pre-fetched information and are actually doing the decision support services and then providing back the decision support results to the client.

Rajesh Godavarthi
That is very helpful. So, I hope I am not digging too far. Tell me if this is not relevant here. In the context of CDS implementation, in the next slide you guys are referring to SMART Health Cards. Are these the same as CDS cards?

John Bender
Do you want to take it? I am happy to take it too.

Jeff Smith
Sorry. There was a question. Is the SMART Health Card the same? Is that a similar functionality as CDS Hooks?

Rajesh Godavarthi
Yes, CDS Hooks.

Jeff Smith
No, this would be a different functionality. I will ask my colleagues to jump in here. Essentially, the SMART Health Cards framework is what underlies the capability of a system to provide a user with a quick response (QR) code that contains a specific set of information. So, we saw the proliferation of this technology during COVID and vaccination verification efforts. So, we are proposing that various modules that are certified to (j)(22) also be able to provide that capability, and I would say as demonstration of the capability, we have identified the vaccination and testing IG.

Rajesh Godavarthi
Good example. If you do not mind one last question, on the previous slide, are you going to refer to the types of requests, or are you going to state very generically, like service request, communication request, or medication request in terms of the triggers. We are talking about API triggers and the criteria.

John Bender
I can answer that, Jeff.

Jeff Smith
Go ahead. Thanks, Johnny.

John Bender
We proposed triggers within the certification criteria. We did not propose any triggers in the (j)(20) criterion, and the triggers that were proposed in (g)(10), which is the standardized API for patient and population services, include patient view and order signed. As described in the preamble, we proposed those because they are the most mature triggers. Then we also proposed support for CDS Hooks triggers in the prior authorization certification criterion, which is one of the payor ones. I think it is (g)(34). I am pretty sure. I

can confirm that. But we proposed a set of CDS Hooks triggers that aligned with the Coverage Requirements Discovery (CRD) Implementation Guide.

Rajesh Godavarthi
Awesome. I am amazed that you remember all of the numbers. If you do not mind, can you put that in the chat? I am struggling to reference it quickly, but thank you very much.

Jeff Smith
Definitely.

Rajesh Godavarthi
That is all I have. Thank you, guys.

Jeff Smith
Awesome. Thank you, Johnny, and thank you for the questions. Unless there are any questions on SMART Health Cards, I think we can go two slides forward.

Mark Sendak
Jeff, I was just going to say, if we want to handle Suresh's question quickly, I think the answer is yes. But, Johnny, if you want to confirm…

Jeff Smith
Sorry, let me open it up here.

Suresh Balu
The previous conversation between Rajesh and Johnny clearly addressed that. So, no questions.

Jeff Smith
Great. A good reminder for me to keep the comment box open. So, I will keep that open on my screen. We have a somewhat similar dynamic with subscriptions at (j)(23) and (j)(24). Here we proposed to adopt the HL7 FHIR Subscriptions R5 Backport Implementation Guide, Version 1.1. We do opine to at least propose a few lines, if not paragraphs, on why we are pointing to the R5 Backport Implementation Guide. If you have questions, we do cover that in the preamble. Potentially, Johnny can talk a little bit more closely to why that decision was made.

But, we have a similar dynamic insofar as the proposals in (j)(23) and (j)(24) specify constraints on the subscription's IG to ensure that Health IT that are certified to (j)(23) or (j)(24) can conform to separate but related aspects of the exchange. Similar to the proposals for CDS Hooks and workflow triggers, we propose that health IT modules certified to (j)(23) support subscriptions as a server and in health IT modules certified to ((j)(24) as support subscriptions as a client.

We reference those (j) criteria differently depending on whether we are talking about the standardized API for patient and population services or whether we are talking about one of the new payor-related APIs or public health API. Steve, I see you have a question.

Steven Eichner
One of the things I am concerned about is not necessarily the specific IG but looking at the capacity of systems in play to actually respond in a timely matter to any of these criteria and any of these interfaces. That is not in the IGs. We have not yet called any attention to that as part of certification processes. So, I have a concern about a potential disconnect where it may have the technical capability but the hardware that it is running on does not have the capacity to actually respond in a timely manner. So, do we need to address that at all? Here? Can we address it here?

Jeff Smith
I would underscore that we are presenting what we have proposed in the interim, and this seems like something that might be important for this group to voice in terms of potential concerns. So, from the ONC perspective, have at it.

Steven Eichner
The question was more directed to the workgroup members.

Jeff Smith
Great.

Mark Sendak
Ike, just so I understand, is your recommendation that we have some kind of latency requirement in terms of response to the client?

Steven Eichner
So, it is not necessarily looking at trying to delay a response. It is looking at the capacity of providers and users to respond to what volume of requests in what period of time. That is not part of the IG specification criterion. So, technology could meet the IT criterion in theory and on paper, but in implementation, it cannot. So, you could certify having an interface; but in the real world, you cannot actually perform it in a timely fashion because of the hardware or other environmental factors that are contributing to that.

The other piece that is relevant to that is also making sure that the information that is populated in these interfaces is actually accurate and complete. We noticed in the early days of things like cancer reporting, while there was certification criterion for the messages, frequently the messages were not populated properly out of the Human Resources (HR)'s source material. So, the receivers were getting a message that conformed to the standard, but the technical components of the message were not accurate and not useful. So, those are two different pieces that I think we need to potentially address in our comments.

No. 1, looking at it from a reflectional perspective, there needs to be sufficient capacity to respond to subscriptions, bulk requests, whatever. Secondly, the content that is coming out through these interfaces needs to accurately reflect these specific patient’s information and the testing criterion need to test the entire process coming out of the EHR, not solely the interface. That data use has to be negative in the EHR and tested all the way through. That matches up with the other testing requirements and certification requirements on the receiver side that are occurring elsewhere in the HTI-2.

Mark Sendak

Perfect. So, I think we can try to put these in the worksheet under the appropriate row. Jeff, you can continue, and then we will try to discuss this when we go through the worksheet.

Jeff Smith
Sounds good. So, actually, if we go to the next slide, what you are looking at here is the proposed subscriptions, including notifications and filters for notifications that were proposing. So, you will see here that there are several resources that we are proposing be supported. I would note that we really do seek public comment on the list of this US Core resources that we are proposing, and we have an alternative proposal that we would like your feedback on, which is, alternatively, we would require service to support the ability for client to subscribe to notifications filtered by any, meaning all, United States Core Data for Interoperability (USCDI) data elements and US Core profile resources for category, code, and subject where applicable.

So, this is our primary proposal that a module that is certified to (j)(23) would have to support these data elements for subscriptions. But, alternatively, we propose and would like feedback on whether we should require support of all Core resources. Suresh?

Suresh Balu
Quick question on the medication dispense that is mentioned in here. Is that medication administration? Where does medication administration fall?

Jeff Smith
Good question. Johnny, is that inclusive of or separate from medication administration?

John Bender
I would need to look at the US Core Implementation Guide, but this list is derived from US Core where the resources in the patient compartment. Mark made a comment. It looks like medication administration is in the resource. I can do a little digging if that would be helpful.

Suresh Balu
Excellent.

Jeff Smith
Thanks, John.

Mark Sendak
Thank you. Yes, Johnny, it would be helpful if we could just confirm that.

Suresh Balu
I think we need to confirm because that could be an important subscription.

Hans Buitendijk
If you are looking at the medication administration, that is not in FHIR US Core 7.0. Dispense and request there.

John Bender
Cool. Medication administration is a separate resource. Is that right, Hans?

Hans Buitendijk
Yes, it is a separate resource. It is in the patient compartment. But that does not mean it is in FHIR US Core.

John Bender
Yes, that is not part of US Core. Sweet. Cool. So, that answers your question.

Suresh Balu
So, to be included? Is that a question for this team to answer? If it is not, then we will move on.

Hans Buitendijk
That would require USCDI to be updated first.

John Bender
Yes. We are always accepting comments for USCDI.

Suresh Balu
I have it. Thank you.

Mark Sendak
Ike?

Steven Eichner
I have a similar question as I just asked regarding capacity. What capacity testing has occurred in making these recommendations to system's ability to actually respond to this complexity of **[inaudible] [00:36:57]** queries or level of service? Secondarily, do their criterion address timeliness reporting or timeframe for reporting on-demand weekly, monthly, when there is a change, and etcetera? I am concerned a little bit about what load we are asking providers and data suppliers to undertake.

Mark Sendak
Jeff or Johnny, do we have any answer for that?

Jeff Smith
No, I heard that more as a comment.

Steven Eichner
Sorry, the first part of that was a question. Thinking about the same kind of approach as we looked at for the Interoperability Standards Advisory (ISA) as whether things have been developed at concept, trialed in practice, or like the same thing we have done with USCDI adoption, what is the background in terms of testing or demonstrating the ability for this data to be exchanged successfully without breaking in production environments because of low demands? I am not suggesting at all that this information is not really useful. All I am asking is have we done any testing to see if we can actually implement it in practice for information

exchange, and what is the impact on bandwidth, etcetera? Because we are putting a pretty high hurdle here.

Jeff Smith
I would just say, again, this is likely a good comment or line of inquiry for the group to go after that is immaterial to what our proposals are at the moment.

Hans Buitendijk
Maybe I can comment on that a little bit further. Ike, I share your question and concern. There has been testing connected with ONC, things like that. But if you look at actual production use, then I think you will find very limited, if any, implementations of this at this point in time. If you look at the prior auth flow, that is where one of the subscription capabilities that is pulled in there to make that work. So there would be some experience there but also, again, very limited. So, I think you are raising a very valid question that we need to look at to determine is this too much? Is there enough to support this based on the experience and maturity from an adoption perspective that is in play?

There is another one, and this is still a back-and-forth discussion that there are different opinions around. If you look at R4, there is a particular way to deal with subscriptions. R5 Backport is done because R5 makes a substantial change from R4 to R5 in how it manages and how you work the subscriptions. R5 to R6, there is really not a change in that, but the backport is to allow for the concepts that are in R5 to actually express it more like to R4.

So, there is another question that is coming up that I think we need to dig in a little bit more with further feedback from August to say, other than limited use, like for example, prior auth, where there is some selling point with that, is this the right time to go scale? Or do you wait for R6 because then it is actually being completely done in a structure that is the target, and you would not have to restructure everything as you move forward. I am not convinced of the consensus around what the best approach is, but that would be another question to be asked and to think about. Is this the right time to go full bore on subscriptions? Or is this the right time to step into it and then from there to then with the next round have a much more solid grounding for that.

Mark Sendak
Thank you, Hans. That is something that we can maybe discuss prior to jumping into the worksheet. I think this where there is going to be having to thread a needle around the different stakeholder interests and making sure that we can make it available, that it is a moderately feasible, but we definitely want to keep forward process as well in terms of interoperability. So, thank you. Jeff, keep going.

Jeff Smith
So, next slide. You can go to the next slide, please. Just to reiterate, I did a voiceover on the previous slide. We do see public comment on the US Court resources that we listed. Alternatively, we proposed to require service to support the ability for a client to subscribe to notifications filtered by all, meaning any, USCDI/US Core resources for category, code, and subject. So, I think this is an important topic, that you have hit on too, Hans. So, thank you.

So, just a few more slides here. Based on everything that we have learned here, the notion that we will try to bring the abstract more into the concrete. So, we can go to the next slide here. Again, why did we propose a new set of criteria? Some of which are not exactly new, others of which are very new. That is really to be able to respond and extend capabilities across a suite of standardized APIs, not just for patient and population services, but also for public health in (g)(20) and also for a suite of interactions and exchanges between providers and payers from (g)(30) to (g)(36).

So what we have tried to do is follow a similar structure by referencing (j) criteria requirements for registration and authentication sections across the (g) criteria. We have now tailored information access requirements to support the criterion's use, and we have included some API workflow capabilities across these (g) criteria. So, this is the generic formula. If we go to the next slide, we will see its application to an example API criterion. If you read the regulation text related to some of the (g) criteria, this will be the illustrative (g) criteria and example where we reference once or more registration types along with different authentication or authorization requirements. We have tailored information access and then API workflow capabilities.

If you go to the next slide, we have actually broken it down by way of (g)(10). Again, to try to close the circle that we started drawing with last week's presentation, we are proposing that (g)(10) support both functional and dynamic registration. We are proposing that (g)(10) support the related SMART authentication pathways for both for manual functional registration as well as dynamic registration. But for the authentication and authorization pieces of that implementation guide, we have specific information access requirements around US Core read and search API, and then we do propose as part of the (g)(10) the ability to support both verifiable health records and the server-side of subscriptions.

So, this is really, I think, a good example. We can go through the other (g) criteria examples. In fact, we will go through the payer criteria next time. It will just be a further demonstration of how we have tried to rethink the modularity of the program and how we are trying to build the (g) criteria almost in a more computable way using these modular API criteria. So, with that, I will stop and see if any of my ONC colleagues have anything else, any other points that we have made in preamble that you want to make sure we get across before we hand the microphone back to Mark and the group for discussion.

John Bender
Just that there is the CDS Hooks piece that is missing in this slide.

Jeff Smith
Perfect. So, adding another API workflow capability in CDS Hooks. That is right. Thank you, Johnny. Again, you will see this basic formula repeated across other (g) criteria when we talk those next week. Obviously, we are talking about different implementation guides. But, again, I think what we are interested in is comments about this basic approach and the use of referencing discrete capabilities and functionalities, as opposed to establishing criteria that are all-inclusive.

Again, we did talk about that as being a philosophical difference between what we could do and what we have proposed. We could propose that a single module be able to do larger pieces of these transactions than how we have broken it up. With that, I will go ahead, stop, and welcome the discussion.

Discussion (00:47:41)

Mark Sendak
Sorry, I was muted. Thank you, Jeff. Ike, if you want to ask a question, go ahead.

Steven Eichner
It was just a general comment. One of the things we may want to recommend as a workgroup is that ONC produce some simple language to describe all the various standards. So, when things come out in the Final Rule, providers and folks that are looking to purchase the technology, how is their understanding about what each of those functions are so that they can understand what they are looking for in the marketplace.

Mark Sendak
Ike, I am only trying to think about what is the responsibility of the vendor as well in communicating the value of their products. Can you just try to clarify for me how you would think about communication? Yes, what is the problem that we think purchasers have?

Steven Eichner
What does the SMART card certification need in plain language? So, if you are a physician looking at purchasing a new EHR and you looking at this list of certifications, understanding what each of them are may very well inform what product you need to meet your particular business needs. But if there is not an explanation, you do not understand what it is that you are looking for or what it is that you are purchasing.

Mark Sendak
Yes, I think this is going to be a discussion for the group. I guess my only question would be, is it ONC's role to be defining how a company describes the value of their products?

Steven Eichner
I am not at all suggesting anything in that space. I am suggesting that there needs to be production about an explanation of what each of those criteria is. I am not trying to get anywhere close to the regulation or something of the vendor and to explain the value of their technology.

Mark Sendak
I have it.

Steven Eichner
But the plain language description of what the SMART Health Cards authentication means.

Mark Sendak
Yes, I am definitely Google searching a lot of these things as I am going through it. So, I think it would help many folks, yes. Thank you.

Steven Eichner
I have no intention of putting a burden on vendors in that space. This is just helping everybody understand what it is that they are looking at. It is like going to a car dealer and then saying, "Oh, this one has a v12

that uses 4w30 oil." Well, if you are a car aficionado, this makes sense to you. But if you are a person who is just looking for a vehicle to go to the grocery store on Saturday mornings, it does not mean much.

Mark Sendak
Ike, this kind of reminds me of last meeting. I was trying to ask for use cases. I guess this would be a question for ONC of accompanying new regulation. Are there prior instances of communicating, either in plain language or with examples, how the regulation would apply to the purchaser or the reader?

Jeff Smith
Yes, we do our best to try and produce a number of different resources, especially over the course of time. As you might understand, when we finalize a regulation and we put out explainers, for the (j) criteria fact sheet, we put out a fact sheet for these modular API capabilities, and we put a fact sheet out for a bunch of different other pieces. There is a general purpose. As it gets to the final though, we start to put out resources that are more targeted. However, having said that, the primary audience that we are educating is the regulated entities.

So, when we produce resources from the certification program perspective, for example, we are really trying to help our developer community understand exactly what their obligations and requirements are. Over in other parts of ONC that have different takes at this, they produce other resources. Generally, we do our best to try and produce educational resources and provide for examples. But even, I would say, over the course of notice and comment rule making, if we get comments that ask us to clarify or provide use case examples or something like that, then we can do our best to try and do that as a function of the final rule itself in addition to maybe an adjunct fact sheet or resource.

Mark Sendak
Yes. I know I have used your fact sheets before, and they have been very helpful. Sheryl, I see you have your hand up.

Sheryl Turney:
Thank you. Yes, I agree with Steven because I do think there is precedent for communications that are in plain language. I want to just emphasize that 30% to 40% of our providers are using what I am going to call "not in the top five EMR systems". So, those maybe smaller providers, most of them, do not have IT people. They are not developers. They are not going to understand the technical, and they are relying on their vendors to communicate to them.

So, if there was plain language that can be provided by the vendor, I think that would be of great aid to that whole population, which we all need to remember to include as part of what we are doing here and how we can help them become network compliant going forward. So, I am always going to be strongly encouraging us to remember that as we go forward, and I do believe Steve's suggestion goes there.

Mark Sendak
Jeff, Johnny, others from ONC, I know that last week we talked about how recommendations have to have…I forget what the technical term was, a logical connection to what is currently…?

Sarah McGhee

Logical outgrowth.

Mark Sendak
A logical outgrowth, yes. Can we have recommendations that are about communication and messaging? Is that logical outgrowth?

Jeff Smith
Sorry, Rob. You were going to say something?

Robert Anthony:
I was just going to say that you all are certainly welcome to give suggestions about communications in this area, and we are happy to hear them. But I would just keep in mind that within the context of the proposed rule task force, you are from a HITAC perspective pulling together specific recommendations about rule finalization. So, I would tend to err toward what comments to make about what to finalize in the rule.

Comments about how we might communicate things most clearly to folks do not have to be submitted within the context of the HITAC task force recommendations. We can take those through any varieties of submissions. So, there is not a real deadline on those. As you are prioritizing what you are doing, I would urge you to think more about the finalization recommendations versus the communications. We have a lot more leeway, I think, on the communications later down the line.

Mark Sendak
I do not know if there is a precedent for this, but maybe we have a section of the worksheet that we will open up shortly that has recommendations that are not necessarily part of the rule making but that are other pieces of feedback that this task force thinks are important that we can take them through other channels. Is that ever done as part of the worksheet. Or is that separately, folks reaching out to ONC?

Robert Anthony:
We can **[inaudible] [00:56:46]** folks. I am not sure about historically what we have done with the worksheet.

Peter Karras
I definitely want to echo Rob's sentiment about the logical outgrowth, the connection, and then just thinking through the scope of the charge for this task force is to look at the proposed rule language as its written, discuss, comment, and provide recommendations. For ONC from a consideration standpoint, we really cannot consider things that are not reasonably connected to the proposed rule language and then turn something into a final rule where the public would not have had a chance to comment on because it is a net new type of content or regulation.

HITAC members can, most certainly, submit comments individually through the public comment process. But within this context, just framing back to what Rob had indicated, the goal is to really look at this from a final rule making and connecting it back to the proposal. But it is the HITAC's meeting. So, technically, you can all recommend what you want, per se. However, ONC is going to consider that logical outgrowth connection in what we would say is reasonably connected to the proposed ruling, but there are other avenues. Members can individually comment as well, however they want.

Mark Sendak
Thank you, Peter. I am reading Han's comment. I think maybe just to allow space for people to share feedback and then individual HITAC members can follow up on these, I would like to at least have a parking lot in the document where we can gather comments. So, thank you, Sheryl and Ike. So, we are at 12:00. We will go into the worksheet now. If you can pull that up, Sarah.

Sarah McGhee
Yes. Give me one second.

Task Force Recommendation Worksheet (00:59:28)

Mark Sendak
Just to reiterate, I was trying to confirm with the ONC staff during our prior discussion if the group on this call does not agree on a recommendation from the task force, we would not send that back to HITAC. So, to what extent are information suppliers positioned to be able to respond in a timely fashion? I am just giving that as an example. Because I heard Jeff say that maybe multiple… We could specify the resources, or we could say "All USCDI." But if we discuss one of these items and there is disagreement within our group, obviously, we can present our cases. We can see if we can reach consensus, but if we are not able to reach consensus, then that will not be part of the worksheet that gets ultimately submitted to HITAC.

So we will try to have the conversation to see if we can agree. But I do not want to make that a requirement, and it cannot be. So, I just want to make sure that we are all on the same page on that. So, Sarah, I know we looked at rows from the final week, but can you just remind us which rows we are focusing on today?

Sarah McGhee
Yes. So, here are the rows from last week where we sent out the homework. It looks like people have been adding comments and recommendations, which is great. Down here, Row 9, we have the (j) criteria. I broke it out as requested by the certification criterion, and then here are the modular API capabilities. I left this as is because it is as one big bucket, but I am happy to break this up too if that would be easier for you. So, yes, here we are. I will go right back up to the top right though. Is there a particular place you would like me to go to, a cell?

Mark Sendak
One second. I am trying to dig up the link to get to the document.

Sarah McGhee
Just a note for everyone, while you are pulling that up, the proposed rule should publish next Monday. So, at that point, we will add in the links with the page numbers so that members should be able to access it more quickly once we have that available to us.

Mark Sendak
Is it in the invite? No.

Sarah McGhee
The Google Sheet? It should be in an email from Accel. Let me see here. The link went out in the homework.

Mark Sendak
Homework, okay.

Sarah McGhee
I think Hans has a question.

Hans Buitendijk
I did. I can lower my hand. I found it. I was searching for (g)(20), and I did find it in the place that I was hoping to find it.

Mark Sendak
Perfect. Accel, if it is possible to add the link to the invite for these that would be awesome. Thank you. So, I know in talking with the ONC team it sounds like the way some of these groups have worked in the past is, if there are a specific individuals who are part of the task force who want to jump into any one of the criteria that… So, let me open up with that. Does anyone want to take lead on Row 8 and its subcomponents at least for the next, let us say, five minutes? That way we can regroup, see, and discuss. The headers are eight, 23, 24, and is it 32, Sarah?

Sarah McGhee
I am sorry.

Mark Sendak
Just because now they are broken out into subcomponents. I just want to confirm that I am drawing attention to the right places.

Sarah McGhee
Yes. So, for today, the discussion, it is Row 8 through Row 23.

Mark Sendak
Eight through 23, just that one. Perfect. For any of the subcomponents, are there folks that have strong recommendations for any changes that they would like to take the lead on drafting something in Column G?

Hans Buitendijk
I am not ready immediately because we still have a couple of discussions to go for that.

Rajesh Godavarthi
I am the same. I will get back on that.

Mark Sendak
No worries.

Hans Buitendijk
A general comment though, having modular capabilities is actually quite helpful after you start getting used to how to read it. So, I really appreciate that. There, actually, as a result of going through that, there are a

couple of other places that can benefit from that approach as well. In that context, I was actually searching for and I could not find it, which is one that I am not sure whether I missed, criteria (a)(2), computerized physician order entry requirements (CPOE) with lab that references Letter of Intent (LOI) and Laboratory Results Interface (LRI). I do not think I see it in this spreadsheet. So, I am curious which one it would be in because that is where the concept of the (j) criteria might be helpful to use as well. So, I am just trying to find where (a)(2) is being addressed so that we can then bring it up there.

Jeff Smith
That is in Group 1, Hans.

Hans Buitendijk
Group 1.

Jeff Smith
Because, yes, we frame that as an adjunct to the public health certification criteria proposals. So, that is in Group 1.

Hans Buitendijk
So, it is used in public health, not for lab in general?

Jeff Smith
No, it is not scoped to public health only, but it is being presented as a proposal related to public health. So, I would not say it is scoped only to public health. It is scoped to all labs, but (a)(2) is being considered as part of the other lab-focused updates, I guess, is a better way to say it.

Hans Buitendijk
Because of the overlap, because it is scoped wider than lab and there is some correlation with the (j) modular approach, I can address at this point with Group 1. That is fine. I just wanted to put it in the right place.

Jeff Smith
Yes.

Mary Beth Kurilo
This is Mary Beth. Hans, I will just jump in and mention that we did talk a little bit on yesterday's Group 1 call about how there are some pieces in both groups, Group 1 and Group 2, that really overlap and will need to be discussed collectively. So, I think several of us are straddling both Group 1 and Group 2. I think we can definitely raise those. But I think we also might want to just make sure we have enough time when we come back together as a large group to hash through where there may be some overlapping concepts in Group 1, Group 2, and Group 3 that we want to make sure we are synchronized on and definitely get consensus on.

Hans Buitendijk
It makes sense.

Mark Sendak
So, I was going to say maybe we can at least go to 23 and 24 where I feel like, Ike, you were giving feedback on wanting to make sure that beyond just specifying the functionality of the interface, making sure that the client can provide the data in a timely fashion to the service and limiting the burden on the client. But I want to make sure. Does that capture the concern and the change that you would want?

Steven Eichner
Opacity. It is not necessarily strictly timeliness.

Mark Sendak
Is it to recommend test criteria, if you use that language of needing test criteria for that process? Is that something you would want to recommend?

Steven Eichner
I am probably amending the criterion as well as recommendation and adjusting process. I would love to hear what Hans has to say. I appreciate his viewpoint on these things.

Hans Buitendijk
I am actually going to have some discussions with folks next week to get a little bit better sense of some of the questions raised earlier across the board, not only adoption, but also the chattiness and the amount of volume that is going to go back and forth as data changes in any of these resources. What would that look like, and what value are we going to get if we go into that with everything turned on for everything versus a more gradual approach so we can more better understand and hone in on a couple of these to understand how it is actually going to be used, or are we creating something too quickly for too many and it is not going to be used?

That will be a little bit of the companion to Ike's comment on the volume. Can people respond or not? There is the other part. Are you actually going to see a pattern there? You are being been notified, and now how frequently are people going to come back to it to get the additional information? How much is already part of the reporting itself if this were for transitions of care? Are we creating a lot of traffic for not a lot of value? There are places where it is absolutely valid. Do not get me wrong. But how do we need to think about it?

So, that is where I want to get some perspectives on can we focus in some so that we can get a better sense of how it is going to be used. Prior authorization is a good example. When you have a workflow and during the workflow there is awareness needed that "Yes, we have the authorization done or whatever else. Now I am notifying the appropriate parties." So, there is a very clear correlation between the workflow and an immediate need for that.

This is written much more as a general purpose, be able to subscribe to everything. How it is going to be used? Where do we think it is going to be coming in play? Can we pick a couple to start with, etcetera, etcetera. So, that is why I am hesitating to put in a firm suggestion and recommendation for it today, but I should have more next week.

Steven Eichner

That is useful. Also, thinking about from, if it is **[inaudible] [01:12:29]** subscribe and I check the box, I might check the box and generate a bunch of unnecessary traffic. Or as the subscriber, do I have to check a box and check off that I have accepted it and received it, in which case I have created a bunch more work for me. So, there are a lot of questions, I think, that are at a deeper different level that do not address the criterion, basically, but do address the utility in how it gets used. I think that is really the two sides of the coin. 1.) Base technical function, 2.) Can it be implemented technologically, and 3.) What are the policy implications?

Mark Sendak
Maybe this is a question for ONC because I have to imagine that this tension comes up often with the load of data export placing a potential burden on the client. I am just curious. In prior rule making, how has that been balanced, whether there are limits placed on service applications, the frequency, and the amount of data that can be requested? I am just curious how has that tension been resolved in the past in the rule making?

Jeff Smith
Yes, unfortunately, that question is out of scope for our proposal. I do not think that you have identified a good tension, I think, to speak to, but we do not discuss that in the proposed rule within this context or, really any other context that I can think of. So, it is not something to which I can directly respond.

Mark Sendak
Maybe, Hans, I guess I am just trying to understand. If there is a desire to place limits, what would that recommendation actually look like, whether it is limiting the number of resources that have to be able to supply data? I know that Jeff was also saying there was consideration to have all from that list on the slide, all USCDI. So, that seems like an important topic to see if we can have consensus around. If not, then I think that we focus on other parts.

Steven Eichner
I do not think that we need to specify a specific limitation or a specific count. I think the issue is appropriate to raise. This is not included in the rule, but these three things are important factors to consider when implementing. We do not have any data around these three factors. Were they considered in the development of this rule?

Mark Sendak
So, it is more background on the rule, Ike.

Steven Eichner
No, it is not background. It is looking at successful implementation and saying, “This is the rule to implement it.” These three things need to work together. They were not addressed in the rule. This is a gap.

Mark Sendak
Yes.

Peter Karras
Just to jump in on timing to do a time check, we are scheduled to go to public comment in about one minute.

Mark Sendak
Sheryl, we will give you the last.

Sheryl Turney:
I will be short. I do agree with both Hans and Steve on this because there are things mentioned in the rule that do not have real-world application demonstration that they actually work. I know even just taking the bulk FHIR, all of the pilot activities that I have been involved have indicated that without parsing the bulk FHIR basically shuts down most electronic medical record (EMR) systems that we are working with right now. So, I do think we need to comment on the readiness of some of these certification standards and maybe recommend an on-ramp or a process for implementation. I do think that is within the realm of what we have done in the past with these types of recommendations.

Hans Buitendijk
I think that is a good example. Everybody who builds bulks certifies to it, and they use it practically not at a spot where it needs to be. So, that could have been focused elsewhere if there were that effort, not to say that bulk is not relevant in certain areas. But there is a difference between some areas and the way into it versus requiring everybody to adopt it effectively, and then it sits mostly on the shelf.

Mark Sendak
Thank you Sheryl and Hans. Peter, we will go to you for public comment.

Public Comment (01:17:58)

Peter Karras
Great. Thank you, Mark. At this time, we would like to open the meeting for public comment. If you are on Zoom and would like to make a public comment, please use the hand-raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are joining by phone only, press *9 to raise your hand. Once called upon, press *6 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.

While I do that, just a reminder that the next Group 2 meeting will be on August 7th from 11:00 to 12:30 p.m. Eastern Time and a reminder that all HITAC meeting materials can be found on healthIT.gov. I am not seeing any raised hands in the Zoom. Accel has notified me that there are no comments via phone. So, Mark, we can yield time back to the task force, and I can turn it over to you.

Next Steps (01:19:05)

Mark Sendak
Looking at Han's question, Sarah, when is our target date to send out the homework?

Sara McGhee:
I am hoping to get it out today.

Mark Sendak
Perfect, and you just answered. So, that is great.

Sara McGhee:
Patient providers and payor APIs is on deck for next week.

Mark Sendak
Perfect. Thank you, everybody, again. We are meeting next week at this same time. I want to just remind folks that the Google sheet is there. Please feel free to drop in your thoughts. Include your initials, the date in which you add your comment. We are getting our footing through the process. We just appreciate everyone's time you are spending on this. So, we are looking forward to the next meeting and progress. So, that is it on my end.

Peter Karras
Thank you, everyone.

Mark Sendak
We will adjourn. Thank you.

Adjourn (01:20:14)

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

No comments were received during public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Johnny Bender (OS/ASTP/ONC): As summary for prior CDS Hooks questions, we did not propose specific CDS Hooks in the proposed criterion at (j)(20) "Workflow triggers for decision support interventions – clients." However, we did propose to include specific CDS Hooks for the criteria that refer to the requirements in (j)(20):

> Proposed revisions at (g)(10) "Standardized API for patient and population services":

>> patient-view

>> order-sign

> Proposed new criterion at (g)(34) "Prior authorization API – provider":

>> appointment-book

>> encounter-start

>> encounter-discharge

>> order-dispatch

>> order-select

>> order-sign

Sara McGhee: Here's the Modular API Fact Sheet: https://www.healthit.gov/sites/default/files/page/2024-07/HTI-2_ProposedRule_Modular-Foundational_APIs_Factsheet_508.pdf

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

Hans Buitendijk: We have in the past put "other" comments/recommendations in the spreadsheet that we then address appropriately. They could end up in the HITAC Annual Report, or awareness notes, or otherwise. So the spreadsheet was just used for not losing those thoughts.

Hans Buitendijk: What will be the criteria on deck for August 7?

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 31, 2024, Meeting Webpage

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