Transcript

HTI-2 PROPOSED RULE TASK FORCE 2024 MEETING

GROUP 2: STANDARDS AND CERTIFICATION

August 7, 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
Meg Marshall, Department of Veterans Affairs
Dan Riskin, Verantos
Fillipe Southerland, Yardi Systems, Inc.
Naresh Sundar Rajan, CyncHealth

MEMBERS NOT IN ATTENDANCE

Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Mary Beth Kurilo, American Immunization Registry Association (AIRA)
Hung S. Luu, Children's Health
Alex Mugge, Centers for Medicare and Medicaid Services
Shantanu Nundy, Accolade
Sheryl Turney, Elevance Health

ASTP STAFF

Seth Pazinski, Designated Federal Officer
Maggie Zeng, Staff Lead
Sara McGhee, Overall Task Force Program Lead & Group 2 Lead

PRESENTERS

Jeff Smith, ASTP

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

Seth Pazinski
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 2024 Group 2 Meeting. I am Seth Pazinski with the Department of Health & Human Services (HHS) Assistant Secretary for Technology Policy, and I will be serving as your designated federal officer for today. As a reminder, this meeting is open to the public, and public feedback is welcome throughout the meeting. Comments can be made via the Zoom chat feature. Also, there is time scheduled for verbal public comments toward the end of the agenda. So, let us get started with our meeting. I want to start with a roll call beginning with our Co-Chair, Mark Sendak.

Mark Sendak
Present.

Seth Pazinski
Suresh Balu?

Suresh Balu
Present. Good morning, everyone.

Seth Pazinski
Good morning. Hans Buitendijk?

Hans Buitendijk
Good morning.

Seth Pazinski
Good morning. Steve Eichner?

Steven Eichner
Good morning.

Seth Pazinski
Good morning. Raj Godavarthi? I did get a message that Mary Beth Kurilo will not be able to join today's meeting. Hung Luu? Meg Marshall?

Mark Sendak
I see her here.

Seth Pazinski
Meg, I can see that you are here. Alex Mugge? Shantanu Nundy? Dan Riskin?

Dan Riskin
Good morning.

Seth Pazinski
Good morning. Fil Southerland? Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Seth Pazinski
Good morning. Sheryl Turney? Thank you. Is there anyone I missed or anyone who just joined us? Then I will turn it over to Mark Sendak for opening remarks.

Opening Remarks (00:01:52)

Mark Sendak
Thank you, everyone, for joining today. I did have a chance to talk to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP) group after the last meeting. We are going to spend more time in the worksheet today. One of the other things that we talked about was trying to limit questions where we are asking for educational information from the The Office of the National Coordinator for Health Information Technology (ONC) staff that is really meant to focus their remarks on the content that is in the rule. But I do want to highlight the importance of that does not mean that we cannot ask each other questions. So, I think if there is anything that people on the phone call want to ask about for more information, we just are going to be directing those questions to each other. It will be an invitation for folks to chime in if there are areas of expertise that they have to bring to the table.

That way ONC staff can focus more of their time and responses on just what is in the rule. Part of this, as I am learning, is the way that these meetings need to be conducted and that the information that we are working with cannot have anything beyond what is in the rule. So, if we are bringing new information to the table to be educating each other and raising our collective understanding, it needs to be from the task force members ourselves. So, I am looking forward to continuing to learn from everyone here.

I will go to the next slide just to go through the agenda. As I mentioned, we are going to do a shorter presentation today. So, it will just be 15 minutes led by Jeff. We will have a discussion, and then we will have 40 minutes in the worksheet. During our time in the worksheet, we are going to try to spend time on the different rows, so really trying to get us interacting more with making comments and providing feedback on the rules specifically. Then we will go to public comment and next steps. Next slide, please.

So, just to reorient everyone, the charge for our Task Force is to evaluate and provide draft recommendations to the Health Information Technology Advisory Committee (HITAC) on HTI-2. The specific charge for us is to review and provide recommendations on the proposals on public health standards and certification, information blocking, and Trusted Exchange Framework and Common Agreement (TEFCA). We specifically are the standards and certification subgroup, and our timeline is to get this submitted and presented to HITAC at the September meeting. Next slide, please.

So, today, our conversation is going to focus on patient, provider, and payer application programming interfaces (APIs). We will have a brief presentation by Jeff, and then we are going to be focusing on these

rows in the Google sheet. Everyone should have access. So, I will turn it over to Jeff for the brief presentation at this point. Thank you.

Patient, Provider, and Payer APIs (00:05:20)

Jeff Smith

Thank you, Mark. Thanks, everyone. Can we go to the next slide? I have the obligatory disclaimer here. This is the third time, I think, we have seen this. I think just to reiterate a couple things that Mark said we have to protect the rulemaking process and comply with the administrative procedures. So, that means we can really only present information that is in the proposed rule. That speaks to how we have to keep fairly tightlipped about where the ideas came from or where we think the proposals are going to go unless we speak to that into the proposed rule because we do not want to disadvantage someone who did not see this webinar or did not participate in this meeting but only has access to the Federal Register. So, at any rate, let us go to the next slide.

So, we are going to be talking about a section of our proposal that is pertinent to what we call in the proposed rule, "Patient, Provider, and Payer APIs." We proposed new certification criteria at 45 Code of Federal Regulations (CFR) 170.315(g)(30) through (g)(36). So, we are proposing six new APIs, and these certification criteria reference a set of Fast Healthcare Interoperability Resources (FHIR)-based implementation guides and specifications. We articulate where those guides are proposed to be adopted alongside a host of other API implementation guides in 45 CFR 170.215.

Some of the benefits that we articulate in the proposed rule are that these certification criteria align directly with Centers for Medicare & Medicaid Services (CMS) established API requirements and recommendations in rules that they have finalized recently. These criteria would enable implementers to ensure that APIs developed who meet the CMS regulations could adhere to the relevant interoperability standards and support other features important to the effective information sharing. We also believe that these certification criteria, if adopted, would reduce burden association with certain administrative processes, most notably prior authorization, and that it would increase patient and provider access to important healthcare data held by payers. Next slide.

So, we are going to walk through each of those six API certification criteria over the next few slides, and we are going to follow this similar path of just articulating the proposal and the benefits so that you all can get into the discussion via the worksheet and start putting together your thoughts on our proposal. So, on the patient access API, we propose to specify requirements for health IT that can be used by payers to enable patients to access health and administrative information using an application of their choice. This would include payer drug formulary information, patient clinical coverage, and claims information.

We propose to reference the Creating Access to Real-time Information Now (CARIN) Blue Button Implementation Guide as well as Da Vinci PDex, Da Vinci US Drug Formulary, and the US Core Implementation Guide. We think that this proposal would increase patient understanding of their health and healthcare as well as help patients be more informed when making decisions about their care. We, again, also believe that this proposal aligns with the CMS requirements for payers to establish patient access APIs, originally finalized in CMS Interoperability and Patient Access Final Rule. Next slide.

This is the provider access. So, we propose the provider access API client and provider access API server certification criteria at (g)(31) and (g)(32). These specify requirements for provider and payer systems, both, to support provider access to payer information. This information can include patient clinical coverage and claims information. We propose the CARIN Blue Button implementation guide (IG), the Payer Data Exchange (PDex) IG, and the US Core Implementation Guide. We also propose to include the provider access API clients in the base electronic health record (EHR) definition. So, the API client would be something that would be generally adopted by systems serving provider healthcare organizations, and the server-side would be on the payer end, generally.

The benefits here, again, would be improved provider access to data health by payers about their patients and help inform better care coordination as well as higher quality care and can support provider participation and value-based care. Again, we think this aligns nicely with the CMS requirements for payers to establish a provider access API finalized in the CMS Interoperability and Prior Authorization Final Rule. Next slide, please.

So, payer-to-payer is what it sounds like. We propose at (g)(33) to specify requirements for health IT that can be used by payers to support interoperability and data exchange between and among payers. We propose to adopt the CARIN Blue Button IG again, the Da Vinci PDex, as well as US Core. We think that this could improve exchange of patient information between payers and allow health information to follow a patient when they switch insurance plans and can enable improved coordination of care, increase patient empowerment, and reduce administrative burden. Again, this aligns with CMS requirements for payer-to-payer access APIs originally finalized in the CMS Interoperability and Patient Access Final Rule and updated in the Interoperability and Prior Authorization Final Rule. Next slide, please.

So, we have, again, a combination of certification criteria for prior authorization that is at (g)(34) and (g)(35). Again, this would support prior authorization API on the provider end as well as prior authorization on the payer end. These criteria specify requirements for providers to request coverage requirements, assemble, and submit documentation for prior authorization, while the payer criterion supports payers' ability to provide information about coverage and documentation requirements and receive prior authorization request from providers.

Here, the suite of implementation guides that we are proposing to adopt include Da Vinci Coverage Requirements Discovery IG, Da Vinci Documentation Templates, a Rules Implementation Guide, and Da Vinci Prior Authorization Support Implementation Guide. We believe that these criteria have the potential to reduce administrative burden associated with the largely manual prior authorization process and that these certification criteria adopted would streamline the electronic prior authorization process and that patients can receive more rapid information about whether treatments are approved increasing care coordination.

We, again, believe that these criteria align with CMS requirements for payers to establish prior authorization APIs and requirements for participants in promoting interoperability programs, the report on new prior authorization measures, both finalized CMS Interoperability and Prior Authorization Final Rule. Next slide, please.

Here is the last of the suite of APIs in the (g)(30)s, and this is the Provider Directory API, Health Plan Cover Certification Criterion at (g)(36). This specifies technical requirements for health IT that can be used by payers to publish information regarding providers that participate in their networks. We propose to reference the Da Vinci PDex Plan Net Implementation Guide for this certification criterion. We believe that this will provide the ability for patients to understand which providers, facilities, and pharmacies are covered by their current or future plan and that it can improve patients' ability to find the right provider and healthcare plan for their needs. I saw a comment in the chat, and then I see we have a couple of hands raised here.

Discussion (00:14:23)

Mark Sendak
So, if we want to start with Hans, since he put the comment in.

Hans Buitendijk
Sure. Then I can drop my hand because it is related. Jeff, excuse me, I appreciate the update and the summary. For the public health criteria that were new particularly focused on public health, which typically have not been included in certification, there was more clarity provided on the target dates of when they needed to be done. Do you have a chart or something, a summary like that, when looking particularly at the payer-focused components on what the target dates are for adoption?

Or are they the same as for public health, question mark, because it is not a program that would identify when somebody has to use those certification criteria. So, I want just want to have some clarity because I was trying to go through the rule and make sure I had that, and I ended up with no clarity on the dates, which I could understand. But I want to make sure, is that indeed correct, (30), (32), particularly the ones that are payer-focused. Do they not have a target date?

Jeff Smith
So, I will ask my colleagues to weigh in if I get this wrong or partially wrong. I believe the (g)(30) criteria that are included in the base Comprehensive Health Record (CHR) do have a target date. I believe that is January 1st, 2028. The other payer criteria that we proposed that are not in the base, I believe, do not have a date specific because there are currently no other programmatic hook, if you want to think about it like that, for adoption and use. Others on the team, though, please clarify if I am misremembering.

Hans Buitendijk
That is my interpretation as well. So, I appreciate that confirmation; (31) and (34) have a date because of base EHR. The other ones do not and would, and they do not apply to the provider. They need to depend on other programs. So, I think understood that and have the language correct.

Jeff Smith
Yes, I believe so.

Mark Sendak
Maybe this is more of a question for Hans. Hans, would that be a recommendation we would want to make in the document?

Hans Buitendijk

I will come back to the recommendation part, suggestions, and the alignment between ONC and CMS or lack there of after and when we go through the individual ones. It is easy to talk about it. This was just a clarification on what Jeff presented to make sure, but the suggestions will come shortly.

Mark Sendak
Perfect. Dan, do you want to go?

Dan Riskin
This is absolutely great work to increase the interoperability of administrative data. I would ask whether we are tackling who has access. For example, in a trial, would a patient be able to grant access to someone running a trial so they could access the administrative data? Or is that kind of access question not tackled in this regulation?

Jeff Smith
We do not speak necessarily to access outside of the patient access and then the provider and payer access that are part of the name in the certification criterion. I would say, generally, inside of the certification program, we have this kind of mantra of "what data," not "how data." So, we do not speak necessarily to the uses of data. We are agnostic to that, but we speak to which data need to go where. So, that is outside of the scope for the rule, and I would say somewhat outside of the scope of the certification program in most instances.

Dan Riskin
Let me ask a follow-along question. So, let us say a patient wants a proxy to be able to access the data, their parent, someone delivering care, or someone in secondary to data. In general, is that tackled in any way? Or can each payer decide whether to effectively block the patient from defining a proxy?

Jeff Smith
So, I would say, again, I do not know that we go into specifics in HTI-2 regarding a patient's authorized representative. But, certainly, that concept exists in other parts of that certification program, most notably around view, download, and transmit. Again, when we think broadly about APIs, the standardized API for patient and population-level services, for instance, we do not have specific requirements around the supportive proxies for that.

But we do have an authentication process, an authorization process that exists within the standardized API for patient and population-level services. We actually carry forward those same authorization and authentication processes and requirements across all of our (g) criteria through those aforementioned modular (j) criteria that we talked about last time. So, there exists within that framework the ability for a patient to provide an authorized representative or a proxy with credentials that would allow them to access information.

Dan Riskin
Thank you.

Mark Sendak
Ike?

Steven Eichner
Sorry, I had it on mute. One of the things I think we need to think about is looking out across all of the criterion. There are an awful lot of improvements that are recommended. That is a good thing overall, but what is the capacity of the HIT vendors to implement all of these new criterion virtually simultaneously? Are there opportunities for leveraging the development of the technology to support one of them across different dimensions? I am a little concerned. We are looking at this with such a broad spectrum that we are going to overweight or put too much pressure and too much work on too broad a set of objectives, and many things are going to slip through the cracks.

Mark Sendak
Ike, you will know better than I will, but it sounds similar to a concern raised last time where I feel like there was the beginning of a discussion with you and with Hans of, are there ways to have onramps for some of these things. I think that when we go in the worksheet, maybe it would help to specify which of these we think are most burdensome that some type of onramp could be helpful. For me too, it seems like these apply to different stakeholders. So, if there are specific stakeholders that we are most concerned about, and Hans, I see your hand just went up.

Steven Eichner
Well, the users of the different criterion are certainly different entities. The developers of the technology are not the stakeholders. The developers of the technology are the HIT vendors and the development community. What does the burden look like on implementing the technology for them and all of this diverse set of tools being implemented all at once because there is really not much staggering across the criteria.

Mark Sendak
I have it. You are right about the burden on the developer. Hans?

Hans Buitendijk
On that point, I would like a suggestion that as we go through the individual items we may want to expand that. If we look at a number of these things, everyone individually, you can argue, hey, that it is a good thing to do. But the total bolus of it is pretty large. Then it is the Health Information Technology (HIT) developers in combination with their community, be it HIT developers for payers, HIT developers for public health, or HIT developers for providers that need to do that. Some of them overlap, and some of them are still very distinct groups. But if we can along the way identify priorities and say, “Out of all these new criteria, these are really the top five or the top that really are of most interest.” Then given bandwidth challenges, you have to consider pushing some of these out.

Do not touch these five, but consider adjusting these other ones because the amount of work and the amount time is in total a challenge. I know that from an EHR perspective, we are going to certainly be looking at that over the next period of time to say, “What are we seeing for the provider community that make more sense from a priority perspective than others, purely because of the work.” There is not going to be necessarily always an argument about the intent and the goal. They are good things. But can we get it done in a timeline of everything else that is on everybody's plate? That is the bigger challenge in that regard.

Task Force Recommendation Worksheet (00:24:59)

Mark Sendak
I agree with you. For folks who have done this before, maybe, it sounds like, staggering some of these dates is an option for a type of a recommendation we can put in. So, I think Sara has already pulled up the worksheet. Sara, I will try to describe how we will go through this, but if I get anything wrong, please make sure to chime in.

So, folks, if you can pull up the Google sheet, we are going to focus on Rows 24 through 31 today. So, what Sara did, there is a column, Column B. That is the date scheduled for discussion. It is going to be today's date. Sara, I think from the emails we exchanged Row 24 is the high-level description, but then we will structure the discussion going through the individual rows between 25 and 31, is that right?

Sara McGhee
Yes, that is correct.

Mark Sendak
So we will transition to the worksheet now. Just in terms of a time check, we have until 12:20 p.m. So, we have about 50 minutes until the public comment. Let me just check. So, looking at your comments, Hans and Ike, is there something that you want to say, maybe? Ike, are there any of the individual pieces that you think are the foundation between 25 and 31? Or would you rather just go through them individually? Then we can try to see which ones build on each other.

Steven Eichner
I think it makes sense to go through all of them. I do not have a preconceived sense of which one might be more foundational than others are. I would like to look to others who have more experience on building to make some of those recommendations.

Mark Sendak
Hans?

Hans Buitendijk
There is one general comment that is more about the comments. Unfortunately, Sheryl is not here today because I would love to hear a little bit more on her perspective there. But I think a general comment would be, and we can tackle them individually as we then go through, the focus of the criteria is not always clear. In a couple of them, it is very clear. It is payer-to-payer. It is client and server, but in some of the other ones, it is not.

So the patient API in particular and the health coverage API is not as clear, No. 30 and No. 36. I think that is important because with some of the comments, as I have seen with the comments already here, is that who is really the focus? For patient API, I do not think the focus is on the EHR. It is on the payer and the patient getting access to the payer's environment that they have data about. So, therefore, for someone to come in, we may need to redirect in the context.

So, it is an overall comment that as we go through each individual one, let us be on each one very clear who is the target actor, if you will, the role that it needs to play and, therefore, the HIT that needs to support

that and that we are clear on that. If we need to split up some further, rename, or whatever, it helps. Those, I think, would be good recommendations. So, confusion around: Is the patient API going to be a requirement for EHRs? As far as we know and we read the CMS Rule, no. We have other things already that we are doing to do that. But if for some reason it is intended to be done by an EHR in support of a provider, it should be very clear. It is not in all cases.

Mark Sendak
Hans, this is a gap in my understanding. If there is a requirement for a payer to make data available to a patient through an API, does the certification criteria apply to payer IT systems that are completely separate from the EHRs? It sounds like the answer to that would be yes through this new rule.

Hans Buitendijk
Correct. That is the way I am interpreting it. So far, as much as the certification program has shifted, its focus on terminology from EHR to certified health IT, which is more than EHRs, not until this time with public health and payers, organizations in the picture, is that it becomes clearer that it is not just EHR or HIT, but it is payer HIT. It is public health HIT. Within that, we are going to see, hopefully, over time more of that clarity that in order to interoperate, both sides of the equation have to do something. What is it that we expect? We have recently put the onus on one side. Sometimes that is okay if you apply APIs for query in the source system. Well, the only way to access it is to follow with that. So, you do not have to pay attention as much to the other side.

But in these cases, we do need to start to be very clear, as to who you are expecting to. Patient API is very clear. In the EHR-focused certification criteria, we have huge download transmit. We have (g)(10) with APIs. We have a number of other things that are patient-focused. So, from that perspective, the ability for a patient to access the information by way of APIs or portals is very well addressed. It can always be enhanced further. But the core is there on the provider side. It is not for the payers. So, that is what we need to be clear. Is that the intent of patient API here? Let us be crystal about that. Jeff did clarify that in the statement on the slides. But as you read some of the actual regulatory language itself and other things around it, you could be confused and indicate that it is supposed to be done for the provider too.

Steven Eichner
Hans, this is Steve. I think you brought up an excellent point. We may want to make some comments about confusion on the patient side about where to go for information. While the technology requirements might be very appropriately on, say, the payer to make the modification, there may be a lot of confusion about the patient knowing where to go to get the different components of information. While you are at, perhaps, a single door, you are at multiple doors, and navigating to find where your information lies may be a bit of a challenge.

Mark Sendak
Do we just want to jump into the patient one, which I think it is the first one. It is Row 25. Go ahead, Sara.

Sara McGhee
Sorry, Mark. I was just going to say, if you all jump into this one, I am going to set a timer for eight minutes and then adjust the times that we discussed about earlier. But I will let you know in the chat when there is about three minutes left. Does that work?

Mark Sendak
Perfect.

Sara McGhee
Cool. You all can go ahead.

Mark Sendak
So, Hans, is this specific to 30? Sorry, (g)(30), Row 25?

Hans Buitendijk
Yes.

Mark Sendak
Cool. Go ahead.

Hans Buitendijk
In light of the prior conversations, I think we should consider a recommendation that the patient API has in its name, like it is being done for client/server, for payer/provider, and a couple of the other ones that it actually is reflected in the name as well, not just a preamble, but in the regulatory language, preferably, that it is very clear as to who is it focused at. This seems to be that it is patient API that applies to payers. They are supposed to make that available so that consumer apps can tap into the data. That is the purpose of it. That is what it seems to be. That is how I read it in the CMS Rule. So, we want to make sure the ONC Rule mimics that. So, that would be one part, to clarify that. I think that is the intent, but that just helps clarify that.

The other one is that based on the clarification, there is no target date. That makes it a little bit challenging for the actors in that as to when am I supposed to do that. In the CMS Rule, this is one of the examples where I do not believe that the ONC Rule in these sections is fully aligned with the CMS Rule. The CMS Rule has dates to functionally be able to do it, to have to do that using FHIR, but the Implementation Guides that referenced in both CMS are now here, CMS makes them recommended, not required. Here, they are required. With my EHR hat on, it is less of a problem for patient API. It does not apply to us. When we get to the next ones, it will. I will come back to that. But I think it is important that the alignment of the criteria with the programmatic requirements from CMS need to align.

So, what is possible in CMS Rule is that because it is recommended, the implementation guides, they do not have to follow them. Here to be certified you do have to follow them. That makes it hard for both parties to really work together and find the middle ground that may still be needed to adjust a little bit to make it happen. So, generally, starting with this one and with other ones as well, we would recommend that ONC follow CMS and focuses on functional requirements with a recommended use of guides, not a required use of guides based on the purity of the guides, the adoption rate right now, the maturity, etcetera, that would provide more flexibility to the parties to find the best path. Then, in the next round, that is when we are going to lock in on a version, but this seems too soon.

Mark Sendak

I have a quick question. I know that we have folks here from public health as well. I do not think Sheryl is here from Elevance. But I am just curious. Did anyone interpret this patient access API as also applying to public health health IT? Or is there consensus that this was primarily targeted to the payer health IT systems?

Hans Buitendijk
I do not want to speak on behalf of Steve, but I did not read into it, the intent on the CMS side, that it was for public health. Here could be interpreted as public health applicable as well. So, I do not think it is the intent.

Steven Eichner
This is Steve. My feel is that it was more directed at technologies like EHR, whether it is operated by private sector or public health. It might be a little bit different in the course of the payer as a substantive source of information but not necessarily looking at other public health information systems like immunization information systems. Those are addressed in different places.

Hans Buitendijk
To clarify from a provider perspective, EHR, we would not be looking at this as a primary source to get data from the payer. We would be looking at the provider API and other means but not the patient. We were looking at the patient as by the payer for the consumer, not for the provider. It does not mean that they could not take advantage of it if there is opportunity, but that is not the primary focus. It is the consumer. For provider, we would look at provider API and whatever else.

Mark Sendak
So, just to make sure I am doing this correctly. So for Row 25 in Column J, it sounds like there are two components to a recommendation. First, is to align the ONC proposal with the CMS Rule proposal in regard to functional dates. Hans?

Hans Buitendijk
Functional use. Not the dates, but the use. The dates in CMS are very clear, 2027. But for the use of the guides, the standards, basic is FHIR. But the implementation guides are recommended, which is definitely not you have to use it. But everybody is encouraged strongly to use it, and most of the industry that we are talking with is that we want to use that as our guiding principle but not necessarily that we need to be locked into it yet.

Steven Eichner
If we look at the language in Line 26, it includes “clinical” as a specific word, not just looking at coverage information. I wonder if that might be a good place to make a modification or suggest a modification to focus on payer information, not clinical information. I am not sure how much clinical information a payer might maintain in the context of it being clinical. It might be better to say looking at payer and administrative information or something in that ilk just to be more specific.

Hans Buitendijk
The question there that has come up is that in the course of submitting claims and other activities, gaps in care, care coordination otherwise, payers do have clinical information that may or may not be in the context

of specific claims. So the intent in the CMS Rule was to get patient's access to that information. A provider may not have everything on the patient. The insurance company might. You could argue that a patient could go to all the different providers that they want to. Then they have a complete picture. So, why go to the payer?

Not everybody is connected, not everything is synchronizing totally. So, having the payer as a source for clinical data as a result of the interactions and the data that they collect was actually the intent, as we understand it from CMS with their patient API. Therefore, that is why we are thinking that it is not EHR-focused. It is payer-focused with whatever they have.

Mark Sendak
Sara, can you pan a little bit to the right?

Sara McGhee
Yes. Just to let you know though, we should be moving on.

Mark Sendak
Cool. We will move on in a second. I put two lines here, first to align the ONC proposal with the CMS Rule proposal with the date and the implementation guide being recommended and then to modify language to focus on the payer API. Does that seem to accurately capture it, Hans?

Hans Buitendijk
Maybe one clarification is that on the dates I am not sure whether we can recommend that. We could, but I am not sure that ONC could act on that, per se, because it would be CMS that is going to say by which it has to be certified, not just that you are doing something functionally. So, I do not think that **[inaudible] [00:42:09]** can set dates. In the other ones, they could set dates because of where things are. I still would quibble on (31) and (34), but we can discuss that separately.

Mark Sendak
I can remove that piece. That looks good. We can move to Row 26, which is criterion (g)(31). For this, Hans, it looks as though you have similar comments.

Hans Buitendijk
Now the provider is in the picture. In another one, it would not be. So, here, it is really the concern from an EHR perspective and the maturity of the guides, the approach that CMS is taking on recommended versus in Table H3, if anybody wants to go to that rule, that it is premature for ONC to make it required. It would be part of the base EHR, and that is also why the date is being set for January 1, 2027.

So, the concern is that the flexibility that payers have to use it, not use it, adjust, etcetera, we should be able from a provider perspective to stay in sync with that. So, it is one thing to have a functional requirement to say "support FHIR API," that concept, but that we can work together with the payers. If we happened to land on the essence on exactly what the version does, okay. But they are all fairly immature in terms of adoption. They are great starting points. They are good guiding points, but we still have to learn a bit before we can scale.

So, that is why we would like to, on this one particularly, suggest that ONC actually follows CMS and aligns with their approach to have a functional requirement with a recommended implementation guide and that anything that we do is FHIR based, which effectively is already in play. The second point is for clarity. Client and server are neutral. So, what this could lead to, an interpretation, is that EHR could be a client or a server. Are we meant to do both? Or is it really that we are meant to do the provider side of this and therefore suggest not to use the term "client" but use the term "provider" to clarify that there is a provider aspect to it, and there is a payer aspect to it.

Mark Sendak
So you are saying the API being discussed in (31) and (32) is specifically to interface the payer and provider where the client is… So, that assumes that there are not other clients and servers in mind for that rule.

Hans Buitendijk
If we are looking at the implementation guide that is being referenced, PDex by Da Vinci, and considering that Da Vinci has another guide called Clinical Data Exchange (CDex), which is doing it in the opposite direction. It is looking at the payer asking for information from the provider. The provider API here looking at PDex is really focusing on the provider asking the payer for information. Another guide and another interaction would be the opposite, and it would use another guide.

So, that is why there needs to be more clarity. Given what is being specified, you really would use that from a provider asking a payer, not the other way around, or not the provider to provider. There are other means to do that already, or there should be. That is a suggestion to really not just have generic clinical and server terminology but to be specific and say it is provider and payer, as done in the Environmental Protection Agency (EPA).

Mark Sendak
So, I am drafting something in Column J. Does anyone else have any comments for this specific row for provider access API client? Hans, does this capture what you are describing in terms of aligning the ONC and CMS? Would it be different?

Hans Buitendijk
We can refine it further, but that is the essence. You have it.

Mark Sendak
The only reason I was hesitating to change client to provider versus just providing additional detail is because the client/server language is in so many other places. Do you feel strongly about removing client?

Hans Buitendijk
Somewhat. It is being used in a variety of different places in text. But in names, it is still on the EPA side, there is the use of payer and provider. If you go to public health, there is the transmitter and the receiver from a public health perspective. So, I think both techniques are used in a name. There is an understanding right now that right, wrong, or indifferent, I think it is not right, is that everything in this certification is applicable to EHRs. This is particularly demonstrating it is not, and that is really the provider side of the picture. I think it just helps educate and clarify to people that there are multiple parts to the integration, and

we are really looking at the interaction between these two parties supported by the relevant HIT to make that happen.

Mark Sendak
What you think about saying provider/client?

Hans Buitendijk
That is okay, as long as the term provider is there. If client is there as well, that is not a concern to me.

Mark Sendak
Are there any other comments on (26) before we move on? We will go to (27), so (g)(32).

Hans Buitendijk
It is the same, just a different topic of the server side. So, it is analogous.

Mark Sendak
Are there any comments on (27) for (g)(32), further recommendation?

Hans Buitendijk
No further comments from me.

Mark Sendak
So, moving onto (g)(33), Row 28. Sara, how are we on time?

Sara McGhee
We are good on time. You all actually finished that when early. So, we can give 10 minutes to this one, if would you like.

Mark Sendak
We will just see how things go. So, this is the payer-to-payer API, which for me, conceptually, is very exciting for individual patients to be able to port over data. Everyone knows that insurance churn can fragment data. Are there any proposed changes that folks would want to have?

Hans Buitendijk
I think for consistency, but it was less of a concern from our general perspective, is that the alignment that was recommended, I think, is still in play. I did not dig into it as deep because this is clearly payer-to-payer. So, I would like to hear from Sheryl or others on the payer side whether there are any concerns.

Mark Sendak
When you say alignment, do you mean alignment with the CMS?

Hans Buitendijk
Yes. Because when you go to Table H3, the guides that are being defined here, I just wanted to look it up, they are recommended as well, but I have not looked at those as precisely.

Mark Sendak
Once again, this is an educational question, so for the task force. So, can CMS require transmission of data between private payers? Or is it just if it is Medicare or Medicaid?

Hans Buitendijk
It is in defined programs on the CMS and Medicaid.

Mark Sendak
So, if I am switching from United to Elevance, then it does not apply.

Hans Buitendijk
No, Medicare, because of their programs that they both support is where the requirement comes in. It is always fuzzy to me when there are other commercial parts, private insurance. There is a general understanding and assumption, which we developed here, to follow and to be consistent. It has its limitations on what they can require.

Steven Eichner
CMS might be able to do something under Medicare regulations or folks participating in Medigap insurance. But regular everyday insurance is the same thing, potentially, with the states or Medicaid but not general insurance purposes? I do not believe there is any regulatory authority.

Mark Sendak
I feel like where this is most needed is an employer-sponsored health care that does transition at higher frequency than I would imagine, maybe Medicaid to private, if someone goes off Medicaid. But I am guessing that there is nothing we can put in the recommendation to address that because it is outside of the jurisdiction of ONC and CMS.

Hans Buitendijk
Yes. It would have to be some other program that then picks up on that criterion to say that we would like moving forward as a condition of payment, whatever, whatever, that they require the use of that certified software.

Mark Sendak
I was just looking at the list. I do not think Alex Mugge is here either from CMS. So, Hans, it sounds like from what you were saying, we can still include a line about aligning the ONC proposal with the CMS Rule proposal, it is just unclear to what extent this is explicitly mentioned in the CMS proposal.

Hans Buitendijk
I just have the CMS Final Rule up. The payer-to-payer API, the IGs that are being talked about here, are certainly directed to payer data exchange, CARIN IG, Da Vinci PDex, and the Substitutable Medical Applications and Reusable Technologies (SMART) app launch. They are all listed as recommended in the CMS Rule Table H3. So, just the same pattern there that the payers might have a thought about. They do not have a date for this particular certification criterion. So, right now, as proposed in the CMS Rule, payers would not have to support this. They would not have to be certified to this yet until CMS comes up with a rule that indicates that they have to.

Mark Sendak
Do you know if we could recommend a date for this? Or that would have to be CMS?

Hans Buitendijk
Good question. I do not think that it is ONC's purview.

Mark Sendak
Is that something that someone from ONC can answer or no?

Jeff Smith
So, generally, you all can recommend whatever you want. If it is within scope, we can take a look at it. If it were outside scope, we would just that say this comment is outside the scope. So, I do not believe that we contemplated any dates specifically for these certification criteria, the new certification criteria outside of the base EHR. But I would remind folks, historically, that ONC has not established firm dates in criterion. Historically, we have had the addition construct. In HTI-1, we went to an additional construct, which was required, which has provided the program more flexibility to say this criteria needs to be updated at a specific time, and a different criteria needs to be updated at a different time. So, if you want to recommend dates, that is within your purview.

Mark Sendak
I was originally was typing January 1st, 2028. But from what Jeff was saying, it sounds we also do not need to recommend a date. Does anyone feel strongly about that?

Hans Buitendijk
The thing is that in CMS the date is January 1, 2027. So, I was recommending 2028 would not align, per se, with this, but they have a date. But they just do not have a required use of these IGs. They have a recommended use.

Mark Sendak
So, we can just say align dates with CMS Rule recommendations.

Hans Buitendijk
If we want to say dates, we could. But it is the alignment on the recommended versus required to satisfy the criterion. That is the larger point. That is the larger challenge.

Mark Sendak
Do we want to not mention anything about dates?

Hans Buitendijk
I am not feeling strongly to have to comment on the dates here.

Mark Sendak
Cool. I do not either. Is there anybody else? We will go to (g)(34). So, this is prior authorization API for providers.

Sara McGhee
Mark, I am sorry to interrupt. This is Sara. You will have 15 minutes to discuss both Rows 29 and 30, so (g)(34) and (g)(35).

Mark Sendak
Perfect. This is the two sides of the prior authorization API, which when we were talking about sequencing and prioritizing, I know that I work in a delivery system. This is very, very burdensome. So, I think there will be a lot of eagerness to be able to get this out to support electronic prior authorization.
So, Hans, you are only one who put a recommendation here.

Hans Buitendijk
Yes. So, this is along the same lines. It is important for the other ones but more important that it aligns. The API is effectively supported by three. Depending how you count, it is actually four. But three of them are listed here to have this workflow run. In prior HITAC discussions, prior recommendations, as well as recognized that prior authorization is a very complex workflow. It does not typically involve just an EHR on the provider side. Depending on size of the organization, they have choices. They have implemented a variety of different systems. They might have a scheduling system, an EHR for the clinical documentation. They have an ADT system. They have a billing system, etcetera. So, the elements that partake or need to be involved in the workflow can rise very quickly as the organization gets bigger.

It does not mean that there are not organizations where it is one single system or maybe two, but it very rapidly can go up. That means that the interactions that are involved are actually involving multiple systems. So, flexibility is important to make sure that we can manage that across the board. The guides initially identify the interactions between a provider and a payer. Black-boxed whatever is happening on either side. But to be able to pull this off, we will over time do that, we need to be able to interact with multiple systems as well. For certain environments, it might be appropriate or best to use a SMART app or a FHIR-based app that can do some of the things that are called for in here. That is for some a strategy and an approach as well.

In the second guide referenced, the Documentation Templates and Rules (DTR), the Document Templates guide, there is accommodation for what they call a light EHR capability that can interact. That means the guides are, actually between Coverage Requirements Discovery (CRD) and DTR, reasonably able to figure out who is actually going to do what. On the last slide, the prior authorization, that guidance is not as clear yet on how you interact with that. Plus, the adoption of these guides is in its very early stage. There are some very interesting implementations that show very good promise and opportunity there, but it is very early.

So, CMS, based on the discussions that we have had, have taken effectively a functional approach that you have to support by January 2027 prior authorization. It has to be FHIR-based, and we recommend that you use these guides. Particularly here, because it is complex, is that alignment is important that if certification is going to be required by a certain date to a particular version, then, yes, there is an aspect process and otherwise. But we seem to then lock in that variation that may need to be worked out, as we are learning how to manage this workflow that there is less ability to be flexible enough to accommodate that.

So, Hans, the higher interest is to say that functional requirements recommend the guides allowing for flexibility between the payers and the providers through respective HIT working in the Da Vinci community to sort that out and learn that in this first round of making this work. Then in the next round, all of that knowledge has been applied to a next version, whenever that is. There is actually one involved right now that is about to go in **[inaudible] [01:03:36]** for the guides. But that is only addressing HTI-1, not necessarily HTI-2 and other learnings. So, that is why it is the same recommendation as the others, but there is more complexity behind this workflow that that flexibility is much more important even here then it is elsewhere. It is important everywhere, but here we have to better learn and better mature before we lock it in.

Mark Sendak
So, I tried to just add some of that detail.

Hans Buitendijk
The rationale is more expansive, but it is in essence the same recommendation. But the "why" has more behind it. This would be a good example, actually, for the provider as well in (31) and (34). They have dates to use that particular version. CMS does not. It has dates but no guarantee that they will use the guide.

Mark Sendak
So, are you saying we should mention dates or not mention dates?

Hans Buitendijk
Really, the biggest issue is the flexibility. It is not just a date. CMS has payment incentives attached to it as well in their rule. So, there is a clear need to get something done. So, incentives in that regard are starting to line up. It is the flexibility that the solution to it may not and should not have to immediately adhere here to the exact guides that are out there or even out there at the time. We need to have the flexibility to have it mature and actually deploy it enough times to say that, yes, the guides are right.

Mark Sendak
Does this recommendation look good then?

Hans Buitendijk
Yes.

Mark Sendak
I am guessing it is the same thing for the next one.

Hans Buitendijk
Yes, it is the opposite. I can add a little bit more to it on that flexibility on integrating the capabilities properly into the workflows because there are multiple touch points that we need to make sure that it all works.

Mark Sendak
We are starting to do work around prior authorization internally, but different workflows for medications or procedures will require different sets of data. So, I guess this is a question, but do we really think that a single API can cover…?

Hans Buitendijk
This is not prescriptions only. Prescriptions still go through National Council for Prescription Drug Programs (NCPDP) for prior authorization. So, there are two flows, one already in the works and being deployed for prescriptions using NCPDP standards. This is for just pretty much everything else.

Mark Sendak
Everything. I have it.

Hans Buitendijk
Touchpoints and workflows are typically different. Where you start to prescribe is not exactly the same as where you are starting an appointment, registration, an order, or something like that that multiple points could start in this context.

Mark Sendak
Any other comments for (g)(34) or (g)(35), Rows 29 and 30? So, we will then go to Row 31, (g)(36). This is the provider directory API for healthcare coverage. So, it includes publishing of information regarding the providers that participate in a payer's network.

Hans Buitendijk
I only have to clarify context. I think from CMS and other places it is pretty clear that it is payer-focused. Providers could but are intended to be the ones. It is more for the consumers in some ways, but that will be helpful to clarify.

Mark Sendak
When you say consumer-focused, you mean patient. This is patient facing.

Hans Buitendijk
Yes, where do I go for providers that in network? Not to say that a provider system might not be able to take advantage of it as part of their interactions with patients, but it is not a required capability, as we understand it on the provider side to integrate with that.

Mark Sendak
So, is there a new name we would propose, similar to what we did for some of the other criteria?

Hans Buitendijk
I think so. If you would do at the end of it, Provider Directory API Health Plan Coverage-Payer or more clear, not only of the preamble or otherwise. But I do not think it is as clearly done in the regulatory text. ONC can figure out how best to clarify that. I do not think we are changing the intent. We just want to make sure that it is always clear to everybody who is expected to do something.

Mark Sendak
How about something like that? Provider Directory API Health Plan Coverage for Patients or maybe Patient-Facing Health Plan Coverage?

Hans Buitendijk
I think the latter.

Mark Sendak
Are there any other comments for (g)(36), Row 31? So, I know, Hans, we really appreciate your input. I know that there is a lot of background content here for the different criteria, the different implementation guides, even looking at other rules from other federal agencies. So, this is complicated, and we appreciate the help from everyone. Before we move on, are there any other comments folks want to chime in on about any of the proposed rule topics and recommendations we want to make?

Hans Buitendijk
Not as much about other ones. But on these ones given that Sheryl was not able to make it and I am not sure whether she is going to be able to make it next week or the week after, from a process perspective, we may want to just see whether she has additional feedback from a payer community perspective.

Mark Sendak
So, in a future meeting where we have her, just make sure that we revisit these and get her input.

Hans Buitendijk
Yes. Make sure we do not miss anything or if there is a difference of perspective that we need to resolve.

Mark Sendak
I am just looking at the roster. I understand Sheryl from the perspective of a payer she is at Elevance. Would we also want Alex or the representative from CMS to review this?

Hans Buitendijk
I am wondering to what extent they can, even though it is not their rule.

Mark Sendak
I have it.

Hans Buitendijk
What can they weigh in other than clarify what their rule says? Is the intonation that we gave to it accurate? I think that will be good. Beyond that, I am not sure what they can say.

Mark Sendak
I have it.

Hans Buitendijk
For example, if our question would be, “When do you anticipate changing the recommended to a shell and putting in certification,” it would be an interesting question. I am not sure what the answer will be.

Mark Sendak

So, we can flag that for a future meeting. So, I will give folks one more chance. Does anyone want to chime in? Is there any other feedback on other recommendations? Then we would transition to the public comments.

Hans Buitendijk
Mark, if you are intending to open it wider, given that there was a discussion last week about subscriptions as part of (j), if you are okay to get a comment on that, I could make one.

Mark Sendak
Which row would this be?

Hans Buitendijk
Let me see. Where is subscription? It is (j)(23) thereabouts, (23) or (24). I always get confused, but it is one of those, wherever that lives.

Sara McGhee
I am looking for it. Here we go.

Mark Sendak
(21) and (22).

Hans Buitendijk
The question or the recommendations perspective that is percolating around there is currently the references where subscriptions are referenced. It is on a relatively large set of resources as well as, I think, prior authorization. There is a very specific use case where subscriptions are a part of the flow. So, there is a use case specific use of subscriptions, and then there is a large set of resources to say make subscriptions available for the set of 10, 15, whatever the exact number is. It is a challenge in that area because they are not as descriptive. What is the purpose for it? What is the kind of information that you are looking for? If you say you put it on observations, on results, or an encounter, what is it really that you are subscribing to? What is the change that you are looking for and in what context?

So, it is very wide. It is also for everybody very much a stepping into subscription space. So, the idea is can we make a recommendation? It is something to consider for followup for examples. But to focus, could we say that we have a particular use case, prior authorization. Perhaps there are one, two, or three other ones where we can say that for this purpose that may involve an encounter. It may involve observations for lab results. It may involve something else that subscriptions are being focused on.

Another approach might be that is what has happened in the past with certification around clinical decision support, early days, somebody needs to be able to demonstrate or use, in other words the CMS side, say, three, four, or five rules implemented. So, in this context, it could be of your choice in your community, your client base, your environment. Pick one, two, or three topics for a subscription that you then can then make available but not necessarily require everybody to do everything. That is **[audio cuts out] [01:15:57]** amount of work.

Mark Sendak

Sara, can you go a little bit to the right? Hans, I do not know if this captures the spirit of what you are saying, and we can come back to this in a future call. What I tried to put here, narrow down the number of resources required for subscriptions. Are we asking ONC to be more explicit about the use cases for each required resource?

Hans Buitendijk
It is more that we as part of a recommendation might indicate specific. From our collective, we think that these top three use cases are most top of mind that we are aware of. Pick those and whatever the resource is that is supporting that. So, it would be more use case driven, the applicable resource that would trigger that, but now we have to context. What are we trying to achieve? What is the user community that we are tackling with that? Are we focusing on sending a notification to public health? Are we sending it to a payer? Are we sending it to a patient? Who is that? Because if we just say "resources," we can think of many different permutations of subscriptions, what does that mean?

Mark Sendak
I know we have to switch to public comment. I moved that to Row I so that it is a discussion that we can continue to refine the recommendation.

Hans Buitendijk
That sounds good.

Mark Sendak
Thank you. Seth, we will hand it to you.

Public Comment (01:17:31)

Seth Pazinski
Thank you, Mark. We are going to open up the call now for public comments. So, if you are on Zoom and would like to make a comment, please raise your hand using the "raise hand function," which is located in the Zoom toolbar at the bottom of your screen. If you are participating by phone only today, you can press *9 to raise her hand; and once called upon press *6 to mute and unmute your line.

While we are waiting folks to queue up for public comments, just a reminder to everyone that the next Group 2 Meeting of the HITAC HTI-2 Task Force will be on August 14th from 11:00 to 12:30. Also, there is a reminder that everyone can find the materials from the HITAC meetings on healthIT.gov. So, it looks like we have no comment at this time. So, Mark, back to you to discuss next steps.

Next Steps (01:18:32)

Mark Sendak
So, we are doing a different time and date next week. So, the meeting is not going to be on Wednesday. It is going to be on Tuesday afternoon, 2:00 to 4:00 p.m. I will work with the ONC ASTP team to send out the homework shortly. Probably, similar to today, we are going to try to spend more time in our future meetings in the worksheet and less time presenting. I just encourage everyone to try to prep ahead of time. I know that this is a ton of work, a ton of learning, a lot of background reading, and I appreciate everyone's time to do this. So, that is it. Thank you!

Hans Buitendijk
Thank you.

Adjourn (01:19:18)

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

No comments were received during public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Steven Eichner: I will need to step away at the top of the hour.

Hans Buitendijk: Can you clarify target dates for the respective criteria as a number are new and payer focused where it is not clear when they are proposed to adhere to that?

Hans Buitendijk: @Dan: I believe that would need to be a recommendation for clarification in the context of Patient API as that is payer focused and where proxies/care givers are more clearly addressed elsewhere, they are not clearly applicable to payers.

Steven Eichner: Building on Hans' comments, are there some technologies for some criteria that serve as building blocks/foundational elements for others? Is there a sequencing that makes sense and is beneficial?

Jeff Smith (ASTP): Hi @Meg. We do not currently have such a resource, but could consider something along those lines as part of future educational materials

Meg Marshall: Thanks Jeff! For the record I am asking if there is a timeline matchup of API requirements and the CMS programs they are intended to support. I think that would be very helpful. Appreciate it!

Sara McGhee: 3 minutes left

Sara McGhee: 13 minutes for (g)(31) and (32)

Steven Eichner: I need to step away from

Steven Eichner: the meeting

Sara McGhee: 3 minutes left for (g)(33)

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 - August 7, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO, on 8/26/2024.