Transcript

HTI-2 PROPOSED RULE TASK FORCE 2024 MEETING

GROUP 2: STANDARDS AND CERTIFICATION

August 13, 2024, 2 – 3:30 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
Hung S. Luu, Children's Health
Dan Riskin, Verantos
Naresh Sundar Rajan, CyncHealth
Sheryl Turney, Elevance Health

MEMBERS NOT IN ATTENDANCE

Mary Beth Kurilo, American Immunization Registry Association (AIRA)
Meg Marshall, Department of Veterans Affairs
Alex Mugge, Centers for Medicare and Medicaid Services
Shantanu Nundy, Accolade
Fillipe Southerland, Yardi Systems, Inc.

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
Robert Anthony, ASTP

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

Seth Pazinski
All right. Good afternoon, everyone. Welcome to the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule Task Force meeting for Group 2. I am Seth Pazinski. I am with the United States Department of Health and Human Services (HHS) Assistant Secretary for Technology Policy (ASTP), and I will be serving as your Designated Federal Officer for today. And as a reminder, this meeting is open to the public, and public feedback is encouraged through the meeting. Comments can be made to the Zoom chat feature. There is also time scheduled at the end of our agenda for verbal public comments.

So, we are going to go ahead and get started with our meeting. And we are going to start with a roll call. And I will start with our chair, Mark Sendak.

Mark Sendak
Present.

Seth Pazinski
Suresh Balu. Hans Buitendijk.

Hans Buitendijk
Good afternoon.

Seth Pazinski
Good afternoon. Steven Eichner.

Steven Eichner
Good afternoon.

Seth Pazinski
Good afternoon. Rajesh Godavarthi.

Rajesh Godavarthi
Present.

Seth Pazinski
And I did get a message that Mary Beth Kurilo will not be able to make our call today. Next is Hung Luu?

Hung S. Luu
Good afternoon.

Seth Pazinski
Good afternoon. Meg Marshall. Alex Mugge. Shantanu Nundy. Dan Riskin.

Dan Riskin

Good afternoon.

Seth Pazinski
Afternoon. Fill Southerland. Naresh Sundar Rajan.

Naresh Sundar Rajan
Good afternoon.

Seth Pazinski
Good afternoon. And Sheryl Turney.

Sheryl Turney
Good afternoon.

Seth Pazinski
Good afternoon. All right. Thank you. Is there anyone I missed or who just joined us? Okay. And then I will turn it over to our chair, Mark Sendak, to get us into our meeting.

Opening Remarks (00:02:00)

Mark Sendak
Thank you. So, we have a lot of topics to cover today. I was excited last week to see us starting to get into the spreadsheet. We are going to continue that kind of format today, where we will have a brief presentation from our ASTP colleagues, and we will spend, it will look like 50 minutes to go through the worksheet. As always, please feel free to drop comments and work on that between these meetings. And otherwise, looking forward to jumping in today. So, we can go to the next slide to review the agenda.

So, we are going to have 10 minutes with our ASTP colleagues, 10 minutes for discussion, which if we have more to discuss, we can go over or less under. Spend most of the time today in the worksheet, have five minutes at the end for public comment, and then we will cover next steps. Next slide.

Just to make sure we are all on the same page, the charge for our task force, we are the HTI-2 Proposed Rule Task Force, where we evaluate and providing draft recommendations to HITAC on the HTI-2 proposed rule. We are reviewing and providing recommendations on proposals that are specific to standards and certifications. So, we are the subgroup.

And then our timeline is that the recommendations are due prior to the end of the day 60-day public comment period. Our presentation to HITAC, I think, is September 12th. So, we have another few weeks to finish going to the content. Next slide, please.

So, today, we have five topics that we are going to go through. As I mentioned, we are going to spend most of the time in the worksheet, where we will build out each of these bullets, spend some time going through each bullet. We are going to be using a new feature today. That is going to be a timer just to help us continue to move forward and touch on everything that we need to. Otherwise, it is going to feel similar to

the last few meetings. So, I think that is going to be it for my part. And on the next slide, I will hand over to our ASTP colleagues to start the presentation.

New Imaging Requirements for Health IT Modules, Revised Clinical Information Reconciliation and Incorporation, and Revised Security Certification Criteria (00:04:32)

Jeff Smith
All right. Thanks, Mark. This is Jeff Smith again, your friendly ASTP workgroup ticket taker. Rob Anthony is otherwise disposed at the moment. So, I am going to be stepping in for him to cover a couple of slides that really do cover, I would say, almost a potpourri of certification updates. But actually, several of the certification criteria are related to our privacy and security frameworks and speak to some advancements that we are proposing in the privacy and security space. Primarily, I would say in the security space, but not exclusively. And generally trying to … we are proposing to improve the posture of the privacy and security framework. And we are proposing to make inroads to making access to, not just imaging reports, but imaging … actual images themselves more routine and easier. And then we are also looking to … or proposing to rather update our clinical information reconciliation and incorporation certification criteria. So, let us jump right into it please. Next slide.

Ah, yes, the disclaimer. So, everything that you really need to know is in HTI-2, which was published last Monday through the Federal Register, and that is going to be the source of truth. What we are doing here is trying to present a consolidated, abbreviated, and otherwise high-level overview of our proposals. And then obviously, the preamble and associated req text for HTI-2 is where you would have wanted to spend most of your time contemplating proposals. Next slide, please.

Okay. So, on the new imaging requirements for Health IT modules. We proposed to revise a handful of certification criteria, including the transitions of care, new download transmits, and a couple of standardized application programming interface (API) criteria to include support for access, exchange, and use of diagnostic images via imaging links.

ASTP is not proposing a specific standard associated with the support of this functionality. And we note that the requirement can be met with a context-sensitive link to an external application which provides access images and their associated narratives. Excuse me. We propose that by January 1st, Health IT developers with modules certified to any of those certification criteria, that is B1, E1, G9, or G10, must update their Health IT module and provide the updated versions to their customers to maintain certification and support access to those links.

The benefits, I think, are, I think, inherently understandable. But we spell out that diagnostic images are stored in systems external to electronic health records (EHRs), such as Picture Archiving and Communication Systems, or PACS, and Vendor Neutral Archives, or VNAs. We believe that promoting access to, and the exchange of images, via these requirements would encourage more widespread adoption and integration of these already existing pathways, and reduce burdens caused by physical media exchange. And we do opine further in the proposed rule on benefits, and duplication, and reduction of waste, as well being additional benefits for this potential certification criteria update. Next slide, please.

All right. On the clinical information reconciliation and incorporation, which we call CIRI for shorthand. We have proposed two options, actually, for revising the CIRI certification criterion. Both would expand the number and types of data elements that help IT modules certified to this criterion would be required to reconcile and incorporate. Today, there are only three datatypes, meds, problems, allergies, that need to be reconciled. And we are, through our primary proposal, requiring that all United States Core Data for Interoperability (USCDI) data elements be essentially reconcilable and incorporable. If you want to think about it like that.

We are proposing that, really, every single USCDI data element, and that would be Version 4 consistent with the proposal, would be available for clinical information reconciliation and incorporation. Now, we do have an alternative proposal, which would be good place for this group to focus its energies on the pros and cons of each. And this would require CIRI an almost unlimited set of additional USCDI data elements. So, more than three, but less than the total suite of USCDI data elements.

We also propose to add a new functional requirement to enable user configuration and rules-based automatic clinical information reconciliation and incorporation. We think that the benefits of this would be support for longitudinal patient records and longitudinal patient care. It would better enable patients and stories to be consolidated and understood in a more concise fashion. And also, there are numerous patient safety benefits that would come from this. We believe, and we think that this would also have a net benefit for providers by reducing the burden of reconciliation and incorporation by having more … setting a baseline expectation that more data elements would be reconcilable and incorporable. Not just the three that are currently the baseline today. All right. Next slide, please.

Okay. So, the next, I think, three slides are going to be more … also concern our security. Privacy and security framework certification criteria. Those are generally speaking found in 170.315D. The first one is multifactorial authentication. And we propose to advise the existing multifactor multi-factor authentication (MFA) certification criterion at D13. And accordingly, update the affected criteria and privacy security certification framework in 170.550H.

This proposal would revise the MFA criterion by replacing what is currently a yes/no adaptation requirement with a specific requirement to support multifactorial authentication and configuration for three certification criteria. That is the patient portal view download transmit E1 criteria, the standardized API per patient population level services at G10 for patient facing access, and electronic prescribing at B3.

I will note here that these proposals often times get confused when understood by the general public. These will be … it would require that computers support multifactor authentication, not required at users actually implement the multifactor authentication. So, this is a capability of the technology, not a requirement for the users. Something that the users can avail themselves of, not something that they necessarily need to take advantage of.

We believe the benefits of these would essentially help improve consistency between certification program requirements and industry best practice. Particularly for important authentication use cases, such as patrons accessing their health information, prescribers using electronic prescription, as well as patient viewing, downloading, and transmitting information from one place to another. Next slide, please.

Okay. So, ASTP also proposes to revise the seven to include a new requirement that Health IT module certified to this criterion encrypt personally identifiable information stored on any user devices and server-side. Additionally, we propose to adopt the latest National Institute of Standards & Technology (NIST) Federal Information Processing Standard Publications (FIPS) National Security Agency (NSA) approved algorithms for encryption. And we reference that standard in the certification criterion. And we would propose moving it from the 2014 version of the standard to the 2021 version of the standard.

Essentially, encryption of server-side data prevents unauthorized data access in many scenarios, including those involving a server breach, theft, or improper disposal. Improved security by updating these requirements in line with the latest NIST approved encryption algorithm. So, server-side would be the additional enhancement or revision that we were requiring … or that we are proposing to the D7 criterion. Next slide, please.

Okay. So, on this one, we are proposing to revise the encrypt authentication credentials certification criterion. That is currently at D12. Similar to multifactor authentication, today, the certification program requires modules to attest yes or no to being able to encrypt authentication credentials. We are proposing that modules have this capability, no longer making it optional. We also propose to have these modules support the NIST FIPS 140-2 standard from 2021. We also propose to change the name of this criterion to Protect Stored Authentication Credentials, which would more appropriately describe the revised criterion. Again, we think of this promotes protection of stored authentication credentials according to NIST standards, and is an important defensive step to help ensure that stolen or leaked authentication credentials are useless to an attacker.

So, with that, I think those are the criteria for today's session. You can go to the next slide, please. Okay. There you have it.

Discussion & Task Force Recommendation Worksheet (00:15:11)

Mark Sendak
Thank you, Jeff. So, we have 10 minutes allocated for discussion. Once again, just to remind folks, similar message as our last meeting, is that if there are questions around just kind of general education and background required for this, we may want to try to answer those amongst the task force members rather than directing those directly to ONC. But if there is anything to kind of clarify from the ONC presentation, we can take those questions now.

So, I do not see any hands up, but I want to give folks an opportunity. Does anyone have any questions on the presentation? Okay. So, if there are no questions now, what we will do is move to the worksheet.

Sara McGhee
Okay. I will pull it up. Give me one second.

Mark Sendak
Let me confirm. I think it should be in the Google … it should be in the invite. So, folks can go to the invite and then click the link to the Google Doc, so you have that yourselves.

Sara McGhee

And can you see my screen? And does it look okay?

Mark Sendak
Yes. And Sara, can you just orient us quickly? At the top now, are you at the row that starts for today?

Sara McGhee
Yes. Row 33. The new imaging requirements. And we will have, I believe, 15 minutes for that discussion.

Mark Sendak
And how many rows in total do we have today?

Sara McGhee
Five or six.

Mark Sendak
Five. Okay.

Sara McGhee
Five. Oops.

Mark Sendak
And then I know that . Okay, there is the timer. I was just going to ask about that. So, that is what we see now in the top right? Cool.

Okay. So, this first … I can just give folks a minute to read this. And then Hans, it looks like you already put a comment. So, maybe after a minute, then we will go to you, Hans, to share any feedback.

Hans Buitendijk
Sounds good.

Mark Sendak
Okay. So, Hans, do you want to kind of provide more background or context on your comment here? Hans, you are muted.

Hans Buitendijk
Sorry, I thought that I hit the button. Sorry about that. So, well, this is a challenging criterion because on one hand, there is clear interest and need to make progress in the space and get access to the images as well. Current reality is that this remains hard. And it is hard not to get … technically, you could have a link, you could share it, and otherwise. But the systems, other than very few, would have the imaging capabilities as part of their solutions is that you have to deal with third-party image providers, PACS otherwise, that may or may not be located in the organization. And where it is within the organization, there is a lot within the provider ecosystem. Those links are very focused, tailored, and may contain information that are okay to share inside, but are not necessarily great to share with a patient externally that that needs to convey that to the other party. And the standards to be able to do that on the imaging side would have to be adopted

as well to make that work, so that we are not going to require everybody to create all kinds of individual bespoke scenarios.

So, that is a challenge. That the management of the link would be the hard part to ensure that it is secure, safe, and consistently applied to any of the reasonable image providers that are out there. So, that makes it hard to say that, are we ready? We want to be ready, but are we ready?

Mark Sendak
And so, are there kind of security … are there things that we can incorporate into a recommendation to address some of the security vulnerabilities?

Hans Buitendijk
I think we could address that and indicate that addressing those concerns are critical to making this practical and viable. And part of it is that we not only look at certified buffer, but this is also very much a great example of it needs to work on both sides. So, what will be in place on the other side, where the image is residing, that these capabilities are in place at the same point in time as well, and in a wide adoption. Or sufficiently adopted and available that that can work.

Otherwise, we are going to create effectively a one side. And either you have to bespoke it to either to the variety of image providers out there, or it is not going to be as deployable because it is not there. So, we have created capabilities not quite there.

So, there is a fair amount of work that has been going on. Argonaut, Health Level 7 (HL7) Argonaut has been working on it as well in the last year for example. So, there are so very promising, and progress being made, but it is the practical implementation and the vulnerabilities that are still raising concerns whether this is truly ready.

Mark Sendak
And just to clarify, and then I will go to you, Rajesh. It sounds like part of the concern is making sure that the imaging link is functioning as it is intended. Is there …

Hans Buitendijk
And it is secure.

Mark Sendak
Yes. So, one is secure. The other is whether it actually will work. Are there kind of tests we can reference or conformance with some procedure that would be helpful to put in a recommendation?

Hans Buitendijk
I am not sure yet whether that is there. I would have to check with some other people that have been working in the space more detailed, whether the actual tests are there. Digital Imaging and Communications in Medicine (DICOM) has been working a lot in the space as well. And so, Argonaut has been working with a number of people that also are active in DICOM. So, we would have to look there to see whether that we can point to actual tests or need to indicate that appropriate tests need to be provided. But it needs to apply to both sides of the fence. And that is the critical part.

Mark Sendak
Yes. Rajesh.

Rajesh Godavarthi
Yes. Maybe there are federal standards, Hans, on the imaging security. I know NIST and maybe others have something along those lines, but that is one thought. My couple of observations on this one is, when we use the word transmit, probably we are referring to transmitting on the wire, not necessarily transmitting things in real time. Because this may just be given based on the request, not necessarily shared synchronously right as they are coming in. So, that is Part 1 clarification.

The second is, you said the certification requirements says, “Application access all the data request”. That is a very broad term. Maybe it is good to qualify what does all data mean in this context.

Mark Sendak
So, I am trying your note. Like, I am trying to synthesize this in Column I. So, the first part of your comment is wanting to clarify the circumstances of the image link transmission?

Rajesh Godavarthi
Mm-hmm.

Mark Sendak
And then the second part was, where does it say, "all data"?

Rajesh Godavarthi
In Column E. The E1, 315 E1.

Mark Sendak
Okay. You are saying … is that the … okay. Application accesses all data requests for GE1. You are saying, is it really all data? Or is there …

Rajesh Godavarthi
Yes, what does it really mean?

Mark Sendak
And just to make sure I am reading this right, is that referencing E1 or G9?

Rajesh Godavarthi
E1.

Mark Sendak
Okay.

Rajesh Godavarthi
That is right. E1. Oh, I do not know.

Mark Sendak
Yes.

Rajesh Godavarthi
Oh, I think it is G9. You are right.

Mark Sendak
Commas are confusing me.

Rajesh Godavarthi
Yes. Oh, it is G9, yes.

Mark Sendak
Okay. Any other comments on this row? So, we are looking at Row 33, E, Column E.

Steven Eichner
I guess another issue is looking at patient access to data. And that may make the security aspects of it more complicated. Not because patients are less secure than providers, but it is a much broader audience or a much broader set of consumers. Hans, do you have any thoughts on that space?

Hans Buitendijk
Yes, it depends on the … it goes back in part. The patients that are operating outside the portal would have additional considerations that they are not operating necessarily, at that point in time, inside the provider's ecosystem, infrastructure, firewall, etcetera. So, I think there are increased considerations to make sure that remains as secure, for that patient. So, I think it depends a little bit on, in what context is the link being made available? Through an API that is done share. It is beyond or through a portal that it is clicked on right there. Which are …

Steven Eichner
Absolutely. But are the requirements in HTI-2, I think, implying that the data needs to be available to patients in API, and not just via a portal?

Hans Buitendijk
Correct. And in that context you said, I think the comments that I made about some of the vulnerability challenges that then exist on the how that URL is typically constructed currently, where you can do it inside the ecosystem, now needs to be robust enough so that it does not cause any challenges when it is used from outside. And that would be different than from a provider perspective, that is operating within their infrastructure.

Mark Sendak
Okay. So, I am incorporating that into the discussion comments. So, it sounds like specifically, if the link is shared directly to the patient through an API and not through … and just make sure I understand this correctly because we have the other row to discuss around MFA. Are we imagining that this link is made

available in a way that the multifactor authentication would not cover? Or some kind of authentication would not cover?

Hans Buitendijk
I think those would be two separate issues because it is more the content of the link then whether you, with multifactor authentication, get or do not get the link because you were not properly authenticated as the patient or whomever.

Steven Eichner
Or be able to follow it more specifically.

Hans Buitendijk
Yes. So, I think those are two separate issues.

Mark Sendak
So, you are saying the link itself could maybe not direct to the image, but could direct to some other malicious …

Hans Buitendijk
No. It could direct to the right one, but the right one, the format and the content may vary from one to the next, to the next vendor. So, it is you would have to accommodate variations. Unless they have adopted the same standard on how to construct that. Are we there yet? That is the question of more concern. And the other part is that the information, that as it is put in there, how is it constructed otherwise to ensure that it does not divulge any **[inaudible] [00:29:23]** information, etcetera.

Steven Eichner
What does the link get me? Does it get me the actual image? Does it get me a landing page? Or is the image …

Hans Buitendijk
It is meant to get to the actual image that then can be viewed or downloaded if you so desire. So, that it will open, but you get to the actual image in that context from that … that is the way we interpreted it. It is not leading to an opening page.

Steven Eichner
Well, I guess, there, even at that point, I would still think about looking at resolution, etcetera, etcetera. I mean, at least my initial thought would be, on the requesters end, to say, "Hey, do I want a low-res image to start with? Or do I want a high-res image to start with? So, I am not wasting a bunch of bandwidth on something that is not useful to me."

Mark Sendak
So, one quick question that may help with this. Its sounds like, Hans, you were saying that Argonaut is currently working on this. I do not know if it is going to be them or something else. But in Column I, should we try to reference a standard or effort to develop a standard that we would recommend aligning this with?

Hans Buitendijk
Yes. In part, Argonaut has been working on it. So, they completed an effort, I think about … I am not going to have the exact time. I am going to say six months or so, or something like that. I need to look it up exactly when they wrapped up their last effort. And there is more that has come from that. So, we could point to them, indicating that building on, things like that, we could make some comments there.

The question then is still the adoption across the boards. It is firm enough at this point in time? And that is the part that I am not convinced that it is firm enough yet to point to a published document that is adopted. And then is everybody adopting it? And can we overcome some of the challenges with the euro that are being raised? And that we need to learn a little bit more about over the next couple of weeks.

Steven Eichner
And I guess just as an aside, thinking about resolution up front. I can see big issues with not having some guidance about that or some decisions made based on what platform and what connectivity I have. Especially from a patient perspective or someone who is not thinking about what their connectivity looks like. Yes, I am walking around with my cell phone on broadband connectivity, downloading a super high-res image that just consumed a bunch of unnecessary capacity, spending money, whatever. Versus phone and Wi-Fi environments. Versus something that has a monitor or a display that can actually display the image after quality and retrieving on down the line.

Hans Buitendijk
From our perspective, we will be primarily looking at the image platform that would manage that. Whereas that if you roll the EHR, we would have to link and share it appropriately. Get the link and share it appropriately in the right places, etcetera. But that would then be not part of the certified software if it is a EHR to have those capabilities. It would be the viewer, wherever the viewer lives.

Steven Eichner
Right. But the EHR software, from my perspective, should have, as a certification criterion, support for this based on resolution. So to speak. So, the EHR is serving the right resolution for the consumer.

Hans Buitendijk
While we would not serve, necessarily, an image. It would be served by the image server. And we do not know whether the patient is going to do that now or is going to do that next month with an iPad instead of an iPhone, or an android, or whatever. So, I do not think that can be an expectation of an EHR to manage as the viewer that is being invoked. Whoever has that.

Mark Sendak
So, I think we will probably want to move on. Ike, I did try to capture your concern about kind of the format and resolution of the image in the third section, what I put in Column I. So, we can feel free to continue iterating on that, but yes, let us go to Row 34. So, once again, I will give folks maybe 30 seconds just to orient yourself. And then can we start the timer for this row? Perfect. Cool

Steven Eichner
Can you zoom in a little bit, please?

Sara McGhee
Is that better?

Steven Eichner
A bit.

Mark Sendak
So, this is the row that during Jeff's presentation, he was describing how there is kind of two potential recommendations to consider. One that looks at recommending all data elements. And then another which looks like it has six additional USCDI data classes beyond the existing three.

So, Hans, it looks like you put in something for Row G. So, do you want to give us some context for your commented there?

Hans Buitendijk
Sure. And this comment is on a particular aspect of the last bullet in the proposal, but I can also comment on the suggestion on everything or some data for data on USCDI. The comment that I wrote here is that there is one other proposal. It is that certified software support, user configurable and automated reconciliation. And those capabilities, beyond staying able to reconcile, get into aspects of the systems themselves beyond interoperability. And my question is, do we need to focus on that as part of the certification criteria? Or let that be flexible so you have to be able to reconcile? And then we can talk about how much, but you can reconcile. And then it depends on the context, the setting, the size, the volume, other elements to determine is automated reconciliation necessary to be able to support that? Perhaps for larger institutions, it is. For smaller, it is not. So, depending on the specialty of the EHR, etcetera.

So, is that really necessary for ONC criteria to be that level of detailed to specify how best to do that? So, that is where the first part comes up. The suggestion is that the criteria should not have to specify exactly the different means by which it can be done. Not to say that you could not do it, but not that it requires you to do the variety of things there. As long as you can reconcile, and then you can figure out what is best for your setting.

On the other … sorry, go ahead.

Mark Sendak
Hans, this is just, it is not directly in the line of work that I do. So, can you give us an example of automatic reconciliation for one of the three currently? Because in my mind, is this normalizing units of weight? What does this actually look like in practice?

Hans Buitendijk
What it could mean is that, let us say conditions, diagnoses, or other problems, medications. Let us pick on medications because that has units and other things. It is that from different sources, or as you put it, over time, you get new medication prescription information in. How can I recognize that? I actually already have the information about that prescription available? So, I have, from different sources, I have the same prescription effectively coming back to me. How can I identify those? And then the dupe that I am reconciling is say either, "Hey, I already got it. There is no need to reconcile." Or "No, this is new, never seen before.

Do you want to get into your records as a reconciliation?" And say, "Yes, I need to know about that." Or, "No, I do not. "

So, there are abilities that can be used to make more of that based on a variety of rules and otherwise. Depending on your volume that you have, that may be very helpful in terms of data received from other external systems. Or it may not be as critical or different users obviously may have different levels of criteria to do that. So, there is tremendous opportunity, but there is also, does everybody need to do that? So, that is where the question is coming from. Is that a required capability? Or is it just, you have to be able to reconcile? And then you may opt to provide automated capabilities for that or not. The immediate proposal is that everybody must support to be certified, you must be able to have an automated version.

Mark Sendak
And just to make sure we understand the implications. Is that if there is not automated reconciliation, for example, if I am the patient looking in my patient portal, that I may have a bunch of duplicate instances of data that were not reconciled? It just kind of shapes the quality of the data that is visible to clinicians and patients? Is that the …

Hans Buitendijk
So, today, it is the provider that reconciles, that gets somebody qualified in the organization that reconciles, that is presented with new data. And then it is presented to indicate from this new source, "I have this data. I currently have this other data already available. It overlaps. It is the same. It is new." And that makes decisions better to include that into the EHR. So, if it is done all right, then the patient, when they ultimately look at the portal or otherwise, the data has been reconciled when they look at this. That is from their perspective.

So, it all depends on how good and how fast you do the reconciliation, that you see less duplicates of data are there. Or that you see only important data that is relevant in that context. So, that is what reconciliation aims to do. So, that there is A, awareness that as the data comes in, "Hey, there are things you should consider." And B is that things that you already have, that you can say, "Yes, already got it." And you can do that manually or you can do it automatically to some extent. The question is, is the key that you can reconcile? And then depending, let the vendors and the providers determine when it is helpful to have or not have automation of that to a greater or lesser extent.

Mark Sendak
And, Hans, I also think a lot about data quality. The ability to reconcile does not necessarily mean … how do you know that that means you are reconciling correctly? And is there a log of how the data was reconciled if you want to trace back to see if there was potentially some alteration made to the data that was not correct?

Hans Buitendijk
Typically, if you have a log, then you have the ability to trace back as to what you pulled in, what you … and that you look for it. It is not necessary that the data changes. It is that you include it or exclude it from the record.

Mark Sendak

Got it. Sheryl.

Hans Buitendijk
[Inaudible] [00:42:14] typically means.

Sheryl Turney
Yes. And I want to pile onto what Hans is saying because having looked at this in the past, and currently, there is not always good updates when you are getting corrected information. So, there may be an ability in the system to do a reconciliation. But to take it from the patient portal, as you were saying, Mark, it may be that the patient is already updated, those medications are not current and there are new ones, or there are different ones. But then you go to the doctor's office, and they are asking you all the same questions. So, that may have been updated at some point in MyChart, but it does not somehow get to the doctor's office. So, when and if they are using those reconciliations, I think is part of the question. And just having the ability to have reconciliations does not fix the problem.

But along with that, we do not have a standard process still, and I think it should be noted for patient corrections. Because even with a reconciliation process, when the patient says, "Oh, this. And it happened to someone in my family, where they were diagnosed for cancer for something. That is still on their record, but that tumor was not cancerous." So, I do not know what the procedure needs to be, but there is no standard for how to fix that data. So, I think we need to at least comment from that.

Mark Sendak
So, we want to take a step back. And I know we have five minutes left for this. What I am hearing is, I think there is a lot of alignment that we want high-quality, accurate data. And that there is a need to reconcile, whether that is done manually or automatically. I think the concerns I am hearing are, is this going to actually solve the problem? Or is it going to not solve the problem, and introduce complexity? So, I guess, trying to … is there anyone here who has a strong sense that automatic reconciliation does solve an important problem for the users of the Certified Health IT systems? Sheryl.

Sheryl Turney
I believe automatic reconciliation will be more problematic because someone has to evaluate what has been reconciled. And if no one is evaluating it, then you do not know. You may get more incorrect information. So, I really feel when you are getting data from multiple sources and multiple doctors, that cannot really be automated, in my opinion, or have it be done in the background. It needs some interaction with a human.

Hans Buitendijk
Yes. And maybe to provide the other perspective on that, is that we do believe that there can be tremendous value from efficiency and still maintain good accuracy perspective. The question is, is it always necessary for oral EHR to be certified against? Which is a different question of is there value? And does it have capabilities? It definitely does. There are clearly scenarios where we can see that when you take that kind of approach, you can actually eliminate comfortably, and with a high level of confidence, you can remove a series of data coming in that you comfortably know, "I already have it." It is not new data. You do not have to look at it. So, you can look at data that is actually new, different from what you have.

Depending on volumes that you deal with, that helps substantially. Or you do not need to because the volume is not that high. The context is such that you may not need to do it. So, that is where more the question comes from. Is it something that is needed to be required? Versus, does it have value to do?

Mark Sendak
So, thinking about the recommendation we want to put forward, it seems like right now, it is required for three data elements. There are two options, to go to six, or to go to all. But are we also thinking that there should be an option to go to none? And even remove the requirement for the three that currently are …

Hans Buitendijk
There are two different questions. It is reconciliation in itself is good. We are not arguing that it should disappear.

Mark Sendak
Yes.

Hans Buitendijk
It is very clear. No. It is just a method by which you reconcile should you put particular requirements on that? That is a different parallel, but independent to the question. So, when it is looking at, should we allow for or require more data on this to be reconciled, and start to increase the bar? There, I think we answered somewhere between everything versus adding some. Not going down to zero.

Mark Sendak
Yes.

Hans Buitendijk
Not goal. Expand the list most certainly. But does it make sense to, in one jump, expand to everything? Or does it make sense to, let us say, look at specifically problems to allergies intolerance medications we already have, and immunization? But start to expand to procedures, laboratory, clinical notes, data elements around that, to say, “So, okay. That is a good next step”? Or do we say no, then you go through everything. That is just a substantial amount of work to get that down with everything else.

So, individually, you might say, “Great.” But in light of all other criteria there and the time window, you would start to say, “Let us prioritize and focus on the number. The smaller number than everything.”

Mark Sendak
Got it. So, it sounds like we are leaning towards six. Do not go to all, go to six. And then, Sheryl, I see your comment, but if you want to …

Sheryl Turney
Yes. So, I would just add, I do not disagree with Hans. But what I think we need to recommend first is that standards be developed for reconciliation, and then applied as we are suggesting. But right now, there are no standards for reconciliation, and that is part of the problem. And normally, these stamp the certification implements, a standard that already exists, and there is not one for this. So, I think we need to say, “We need to develop the standard, and it needs to be applied to XYZ.”

Mark Sendak
I was just going to ask, does this look good?

Hans Buitendijk
And sorry, Sheryl, just to make sure. It is standards on how to enable automatic reconciliation versus the number …

Sheryl Turney
Yes.

Hans Buitendijk
Of ones that can already start, whether they are automated or not?

Sheryl Turney
Yes, because I do not disagree with you, Hans. I mean, when we did large language models, we used automation, but we spit out anything that appeared to be different. And it was a standard apply to it. So, I am just saying we need that same kind of standard applied to this, and it needs to be agreed upon by everyone. Because Provider System A does it one way, Provider System B does it another way, and the standards are not even consistent that we are using. So, let us follow our own process. Develop the standard for it to automate it, and then apply it to what your …

Mark Sendak
Okay. Perfect. So, I think we are at time. Yes. It seems like those two things; we have consensus on. So, we will go to Row 35. I think we are plenty zoomed in. I will give folks 30 seconds. If we can start the timer again? And then we will open up to discussion for this one.

Okay. So, this one is about MFA and changing criteria from kind of yes or no to a requirement to support MFA. So, there is nothing in letter G, but I will give folks an opportunity. Does anyone have any specific changes they would like to propose for this?

Hans Buitendijk
Not yet. We might get a few more, but the next couple discussions still need to occur to make sure I can represent a more general perspective.

Mark Sendak
Okay. So, if there is nothing, I do not feel like … what I am hearing, Hans, is not to necessarily go ahead and call them J. Say we recommend the language as it is stated. Right? It is that this is something we may be too compact too?

Hans Buitendijk
It is the letter. Yes. I do not see right now many challenges, but I just want to confirm with said group that is talking about it shortly.

Mark Sendak

Okay.

Hans Buitendijk
Nothing jumps out at the moment.

Mark Sendak
Anything else for this row? I will just put to be determined (TBD) for Column J. If we do not have anything here, I am open to go back up to Row 34. Hans, I see your comment. Do you want to kind of speak your perspective on the concept that I think Sheryl put forward of, do we first want to recommend developing standards for how to conduct automatic reconciliation?

Hans Buitendijk
My comment is around the standards and guidance. It depends on what you are looking to try to reconcile. What are you trying to get out? And reconciliation, at least … and there might need to be some terminology. Reconciliation is not as much about extracting and ingesting the data to take out of a document, and now put it into discrete format. That is part of it obviously. But is it what you take out? Particularly from the structure to component, do you already have it, as is? So, depending on what your starting source is, that may be narrow to follow otherwise. But I am not yet sure whether that means that there are standards, or whether it will be the first to discuss the concept of guidance on what are really … what makes something that can work? Because it is a hard space to say that are there … is there a single set of rules you can apply before you can say, "Everybody can do it the same." Or it there still a fair amount of learning to be done to figure out what are some of the kinds of rules there are? How do I use Providence data? How do I use Axle data itself in the absence of Providence? Etcetera. So, there are certain things in there for, at what thresholds are you going to start to say, "I am going to toss it to a user"? As opposed to, "The user is comfortable that I have a good confidence level that I can pass it"? Are we trying to define confidence levels? So, I think that that in it itself requires a discussion as to, what is it exactly that you are looking for?

Mark Sendak
And just to make sure I am using the right terminology because I know that there are implementation guides. Is it developing implementation guidance or implementation guides?

Hans Buitendijk
It is possibly my translating if I can hear Sheryl correctly, but she can speak better to that. That it has to kind of format off an implementation guide or reconciliation implementation guide. But is that expressive of certain very specific standards? Or is it at the level of **[inaudible] [00:55:40]** just drawing a picture in there of best practices? Which is different. So, I think there might still be quite a discussion on what would that look like? But having the conversation will be interesting to do.

Mark Sendak
Yes, Sheryl.

Sheryl Turney
Yes. I agree with Hans. I mean, we do not have implementation guides for things that are not like a transport or something like that, but there are best practices. And maybe that is the right term, is to develop best practices for reconciliation. And there are some areas that have done some white papers on this process.

I know I have seen a couple of them. Let us see if I can find one that I can share a link to, but there are some recommended methods to be used. And I think that that would provide greater comfort level because at the end of the day, we do not want duplicate information that is going to add a lot of ~~bourbon~~burden. But we also want to make sure that the information that is reconciled is accurate to the extent that we can validate it to be so. So, to me, those are the two goals. And if there is a way to achieve that goal, then I think that a best practice could be referenced in terms of this particular certification requirement.

Mark Sendak
Okay. Perfect. So, I changed the language in I to say, "Recommend developing best practices or implantation guides."

Sheryl Turney
I am putting one reference in the chat right now.

Mark Sendak
Here, I can I put that link in the Google. Are folks okay with that to move forward? Okay. We will move on to, I think we are at 36 now. So, let us start the timer again, and then we will spend 30 seconds looking through this one.

So, this criterion is about encryption of the data in the Health IT systems. There are no comments right now in Column G. Does anyone want to take the opportunity to … Yes, go ahead, Rajesh.

Rajesh Godavarthi
As I read the language, instead of using the word server… Oh, sorry. I am in 36. One second. Server-side. Right? Encrypt the HHS tool server-side. I think the word server-side could lead to a misunderstanding in my view, because typically, the storage systems are now with the cloud enabled, not anymore like client and server. I think if we can leave the language on the EHS storage systems, that would be better than a server client language that we used to deal with.

Mark Sendak
So, you are saying instead of using server-side, replace with just Health IT storage?

Rajesh Godavarthi
Yes.

Mark Sendak
Okay. I can move that over to the workgroup recommendation. Any other comments for Row 36? And Hans, is this one too, where you said the next few on the prior row? Is this one too where you expect to …

Hans Buitendijk
Correct. Yes. So, as soon as I have that, I will drop in some thoughts.

Mark Sendak
Yes. Perfect. Okay. Anything else for 36? Sheryl.

Sheryl Turney
Oh, sorry. I think I was on mute. I have a question. So, when you are reading this part of it, I was assuming this was meaning anything that was PII or PHI. But are they really saying that all Health IT information, including the whole medical record, really needs to be encrypted? Or just that information that would make it attributable to a person or an organization?

Mark Sendak
So, I guess one question there is would the term Electronic Health Information (EHI), is that electronic health information? Do we know what that is?

Sheryl Turney
Yes, that is what that is.

Mark Sendak
And so, is that a question that ONC folks can clarify?

Male Speaker 1
Yes. Sorry. Can you repeat the question, Sheryl?

Mark Sendak
Sheryl, we do not hear you. I do not know if you are muted.

Sheryl Turney
Okay. So, is the intent of the encryption to be the **[inaudible] [01:01:59]** identifiable components of the EHI record? Which is obviously Protected Health Information (PHI) or Personally Identifiable Information (PII). Or is it the entire medical record that has to be encrypted?

Jeff Smith
Sorry. Sara, can you go to the left there, just so I make sure I am on the right criterion? Yes. So, essentially, what we are proposing is to apply the exact same requirements that we have for end-user devices onto servers. So, today, there are no requirements for encryption of EHI when it is stored on a server. And we do have requirements for EHI to be encrypted when it is stored on a device. And what we are looking to do is just apply pretty much the exact same requirements, so that both the server-side and the end device side are both encrypted in the same way, using the same standards.

To that question in terms of the entire record, I mean, it would be any EHI that is in the system. And I know that we talked about … and I think I have my colleague, Keith, on the phone, on the line, who might be able to shed additional details … is this the criterion that we also included or referenced PII?

Keith Carlson
Put a link to the preamble with more information on the PII definition.

Jeff Smith

Yes. Essentially, what we are looking to do is shore up the transaction. So, essentially the exact same requirements that we have got today, and looking to apply that to the server-side. Whereas today, it is just on D7, it is just on the device side.

Mark Sendak
So, I put the recommendation in Column J. We specifically define the data that is **[inaudible] [01:04:34]** definition of EHI or refer to the relevant section of the preamble. Would that address the concern, Sheryl?

Sheryl Turney
I can actually find that, so I do not need them to do it. I will look for it now that I understand what they are saying. Yes, that is fine.

Mark Sendak
No, but I mean, I guess, even if by the nature of having this call required you to … that was helpful. Do you think there is anything we should recommend in terms of helping clarify that for others?

Sheryl Turney
Let me look that up, and then I will get back to you on that, Mark.

Mark Sendak
Okay.

Sheryl Turney
I just want to see how that reference is made. And I am going to go back to the rule, but I will bring that up in the comments if I think we need to clarify it more. And I think Hans has had his hand up for a bit.

Mark Sendak
Hans.

Hans Buitendijk
Yes. So, I want to just provide the context here as well, that to date, server-side, where the data is stored, the data at rest, a variety of terms being used here. That have not been there in part because there has been, part of certification, a requirement for risk assessment. Otherwise, and depending on your data center, where is it stored? How is it done? Etcetera. That encryption may or may not be considered necessary for the risk profile at hand. Sort of a flexibility there to do it or not.

So, part of the follow and the why I do not have comments immediately, is to say is that in today's world, this has been for a while, today's world, where we are at, is that still a reasonable approach? Because encryption also, at least relatively, always comes with a cost as well from a performance perspective. So, that is why I need to follow-up a little bit more, is that we have been working under that risk assessment approach and risk management approach, where based on that, you may or may not decide to encrypt for a data address. Is that still reasonably applicable? And therefore, there is a question of why this is needed. Or is it reasonable right now to adjust based on all of the other factors that have changed over the last couple of years? So, that is the context of why you do not hear me yet, but I want to give that backdrop.

Mark Sendak
Perfect. So, I put that in the discussion Column I, and then we can come back to this. Okay. So, we have one row left. And I want to confirm with Sara, I think we have six minutes for this row, and this is our last row? Is that right?

Sara McGhee
Yes.

Mark Sendak
Okay. So, let us take 30 seconds, we will start the timer, and then we will open it up.

Okay. So, this row is about encrypting the authentication credentials. So, at least from my read of this, Hans, this is going to be lower burden compared to encrypting all data server-side. And I am anticipating that this one we will probably also want to come back to once we have more information from folks. But any initial thoughts or recommendations from members of the task force?

Rajesh Godavarthi
I think the only question I have here is, by removing the expiration **[inaudible] [01:09:06]**, if we replace with this new standard, how big is the burden for the folks to transition to this protect stored allocation credentials more in this new … for the standard? Is it a bigger of an effort then is it as good as what we have done before?

Mark Sendak
Do you have a sense of that, Hans?

Hans Buitendijk
Well, before, it was not an attestation, which really meant you do it or you do not. And then you do have … if you do it, you can do it whatever way. So, I think the other question is much more about the standard. Is that the appropriate standard? And that is the part that I need to get a little more consensus feedback to provide perspective from the EHR community.

Mark Sendak
Okay. And Hans, just to make sure that I understood. So, you are saying, it is more a question of, is this the right standard to reference for encryption?

Hans Buitendijk
That would be a question, which I do not think that it is, given the context, I do not expect that. But that is, I think, for a … that we have not really asked everybody yet, to say, “Okay, are we good with that or not **[inaudible] [01:10:26]**?” Or to get that confirmation that before I say that, I say, “Here, yes we are okay.” Or, “No, we should suggest another one.” I just want to get that confirmation.

Mark Sendak
Sounds good. So, I will put the TBD in. Any other comments from members? If not, then I think that is our last row. We have …

Sara McGhee
Yes.

Mark Sendak
Oh, go ahead?

Sara McGhee
Oh, sorry, Mark. I was going to say that if you all would like to keep discussing one of the other rows or topics, we have time. The public comment is at 3:20.

Mark Sendak
Exactly. Yes, I was just going to ask. So, yes, if we want to scroll up, I know we had a lot around of the first two. So, maybe let us scroll over to Column J, just to make sure that everyone is good with what we are recommending for those first two. Or if anyone has any thoughts, things they would want to change, feel free to raise your hand or go off of mute.

Okay. So, if these look good, then I think we are done with this part. And I think that will take us to the public comment. Can we start that early, Seth?

Public Comment (01:12:36)

Seth Pazinski
Yes, we can start the public comment, now. And then one other suggestion since we do have a few extra minutes is we are at a point kind of in the group process where we want to be transitioning from the individual comments, as we started here, into the draft recommendations from the group. So, if there is any of that, we want to circle back to, just to identify potential members of the group that will want to take a first cut at the group recommendations based on the individual comments. We could use some of the time for that as well.

But let me pivot into public comment. Accel, could you please open up our line for public comment?

So, if you are on the Zoom and would like to make a comment, please use the hand raise 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 your hand, and then once called upon, you can press *6to mute and unmute your line. And as we give folks a few seconds to raise their hands, I want to just remind everybody that the next Group 2 meeting is going to be on October 22 from 1:00 to 2:30 p.m. eastern time. And as a reminder, the materials from the meeting today and all HITAC meetings can be found on HealthIT.gov. I am not seeing any hands raised online. Accel, do we have any folks coming in?

Accel
No public comments.

Seth Pazinski
All right, thank you. Back to you, Mark. So, again, we can close out and end a little early. Or if there are additional things that the group wants to circle back on, we have a few minutes.

Next Steps (01:14:31)

Mark Sendak
Following up on your comment. Sheryl, I will come back to you in a sec. But, Hans, especially since it sounds like you are trying to get information from folks, do you think maybe the next meeting you could put content in for Rows, that will be 35, 36, 37, that we can try to follow-up on?

Hans Buitendijk
Sounds good.

Mark Sendak
Cool. So, I will just make a comment there. And then Sheryl, I saw your hand was raised.

Sheryl Turney
Yes, I had a couple comments. I guess you must have discussed it last week, but I was not here. One was Row 24, and I am trying to see where the other one was. Will we have time next time to talk about those?

Mark Sendak
So, yes, there were a handful that were related to payer. Considering we have some time; I am okay if we want to spend a few minutes now. Are other folks okay doing …

Sheryl Turney
It was seven and 24 are the two where I had written something. And I am sorry I was away last week, and I could not join. I had another call I had to take.

Mark Sendak
Sara, were you going to say something? Is it better to do that next week?

Sara McGhee
Oh, no, this week is fine. There is time. Just give me one second, and I will bring the spreadsheet back up.

Sheryl Turney
Yes. I do not think we will have time to do both of them, but if we can do one, that would be great.

Mark Sendak
Yes. So, do you want to do seven? The first one? Dynamic client registration protocol.

Sheryl Turney
Yes. So, this is the one where I was recommending that we … especially, this is important for Certified Health IT vendors and providers who, by what I am going to call, out-of-the-box solutions. Often those out-of-the-box solutions supposedly are easy to connect. And I will tell you by experience, they are not. So, what we are hoping we can recommend is that those Certified Health IT vendors, and really any Certified Health IT vendor, could offer some sort of, as part of the certification, a default network that they could register the product with. And there are multiple.

I believe both Carequality and eHealth Exchange, at a minimum, offer proving ground where you could test the process and do the connection, and then be able to offer that as an option. And I discussed at least with one of them, that this is something that perhaps we can look at for our project, which I recommended to HL7. So, we are going to try to do it as a project in the, not as Trusted Exchange Framework and Common Agreement (TEFCA), but in the … I forget what they are calling it. But the other type of proving ground that HL7 is putting together. And we are going to be talking about that in the next week or two.

But I really think this is something we need to consider for certification because it removes the burden from the provider. It actually puts it on the vendor, where it really needs to be. And that way, if they want to elect to keep the network, they can. If they do not, they can turn it off. But at least then, they know the product actually can connect to network and it works.

Today, there is certification criteria and there is testing tools, but in the end, we have found that those do not equal success in connecting to a network without a lot of burden. And most of these providers who buy those products do not have the IT people, they do not have the resources. And even with health information exchanges (HIEs) working with payers, we are unable to connect in many these situations with those products. And I do not want to call products out by name, but it is more than one.

Mark Sendak
And so, just to confirm, it seems like the particularly important part to carryover is that first sentence?

Sheryl Turney
Yes.

Mark Sendak
Okay, does anyone have … would anyone modify that sentence that I just dropped into Column J?

Hans Buitendijk
Possibly. I am not sure yet how, but I am still trying to understand. And Sheryl, maybe you can provide a little more context of what the problem that it solves. Currently certified software has to provide endpoints, directory lists for all their Fast Healthcare Interoperability Resources (FHIR) for the client. And for some, it might go through a gateway, other ones go to individual endpoints, etcetera, but they have to provide that. Having that, which network are you looking at to really be “a default”, which we know in typical situations is not going to be the one that it is going to be used in production. So, that is what I am trying to understand. What this really meant with it? Or am I not quite getting what you are trying to …

Sheryl Turney
It is really, Hans, any default network. Because at the end of the day, the problem is that even through there are requirements that they provide endpoints, etcetera, a point-to-point connection cannot even be made to those endpoints is the problem. So, the success of those. And maybe it means there needs to be better auditing of the information that is out there for some of these Certified Health IT products. And it is typically not the top-five. It is the rest of the rest of the list, which unfortunately represents about 20 to 30% or more of our smaller providers. So, from a payer’s perspective, we still want to be able to connect to these providers without burden on the provider or ourselves. And essentially today, either there is information missing, whether needs to be some sort of integration in order to make that connection happened, but it is

not documented out on the federal website where all of this information is presented, or some other problem. But we have actually worked on at least three of these other providers with not being able to connect successfully. Not only ourselves, but working with HIEs.

Hans Buitendijk
That sounds like there might need to be a or statement in there, so that if you do not do X, which some do, and it works, then at a minimum, you need to do Y. So, that we know that regardless, then it always works. Because the way I am hearing it, but I want to digest it a little bit further and share this conversation, is to that if we did it "right" with everything, you do not need this. But the certification criteria, as currently suggested to be updated, would require it. So, then we are providing double capability. That is what I am trying to see, is that what is it that when you do it right, you would not have to do this?

Sheryl Turney
Right, but the problem is, you know that there are limited capabilities to audit everything that is out there. So, then leaving it to doing it right, then the burden also goes back to the provider because the provider is the one that cannot connect. It does not go back to the vendor, who is the one responsible for implementing a solution that cannot be ... it actually does not work. So, that is where we need to do something different, Hans, here, because it needs to be more than "Yes, I have certified this works." And again, with an attestation. It needs to be a demonstration. That is what we are saying.

Hans Buitendijk
I guess I would like to see a little bit more specifics on what that would look like to understand how that would apply.

Sheryl Turney
Right. That is what we were hoping the TEFCA, if I am saying it right, that project would hopefully demonstrate.

Hans Buitendijk
Which means that, at this point in time, the guidance in what that would look like, it would still have to be developed. And by the time that we are getting to the final rule of this, that might not be in place yet. So, I am not sure what we can currently suggest beyond a suggestion to look at something, or address a problem, rather than that we have a concrete … if we just say, "You need to have a default network", I am not sure what that exactly means, if that would pop up in certification with the rest of it.

Sheryl Turney
Maybe we could come up with revised wording, but it needs to be something … something needs to be there because leaving it as is still equals not success, which will not accomplish the underlying goal of the rule.

Hans Buitendijk
I do not disagree with the … on the goal. I am trying to figure out is that how this is helping move it forward in a clear way that is not duplicating effort either.

Mark Sendak

So, Hans, I made a note in I. If you could look over this and try to propose some adaptation, that would be helpful. Hung, I see your hand also.

Hung S Luu
Just listening to the conversation. Maybe an alternative suggestion could be setting up some kind of registry, where customers who are struggling with it can provide documentation that maybe the ASTP maintains this website, so that for products that continually fail, they can be identified. And that could be a way to identify Health IT that should not be certified. Because either we need to have improved auditing or we need improved reporting of issues. Because if all it takes is saying "I am certified. My product works", and there is no way to verify that, or there is no recourse for clients who struggle with incrementing it, then I do agree, something needs to change. So, either auditing needs to be strengthened, or there needs to be a reporting system.

Mark Sendak
And so it is a registry for reporting kind of connection failures?

Hung S Luu
Implementation failures.

Sheryl Turney
Implementation failures because what is happening today is the burden is all on the provider. If the provider cannot connect, the provider is the one that is going to be held to the information blocking role, not the vendor that provided the software that they said was certified and then does not work. And the provider does not have IT people. They do not have resources to make that happen. So, essentially, I am saying something needs to be here to hold the vendor accountable for making it work and making sure that it does work. And I agree, maybe having an additional information out website, that says, “Hey, this is the trouble that different organizations are having with these vendor connections.”

But to me, it needs to go beyond that and go beyond auditing. It needs to be where the certified vendor has to demonstrate interoperability. If the big vendors are already doing that because they are a part of a network, then it would just be demonstrating certification that that is already in place. But these small vendors who are not demonstrating interoperability then would have to do something, where if you already demonstrated it, you would not have to do that, but if have not demonstrated it, you would have to do it.

Steven Eichner
This is very similar to the issues that have been faced over the years with public health reporting. That particularly in the early days of meaningful use, some of the technology might have been certified that the EHR could send the data, but it was actually not populated very well, so the data that was actually sent to public health was not really usable.

Mark Sendak
So, I want to thank everyone. This is an important discussion that we will need to continue. I have tried to capture some of the main highlights in Column I, and we will try to come back to Row 7 in a future discussion. So, thank you, everybody.

Male Speaker

Thank you.

Adjourn (01:28:20)

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

No comments were received during public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Hans Buitendijk: It will be helpful to have a discussion on automation guidance before considering any next steps, but not convinced that reconciliation standards are easy to align on. It also depends on whether one uses narrative vs. encoded/quantitative data. The focus would have to be on outcomes.

Keith Carlson: https://www.federalregister.gov/d/2024-14975/p-606

Sara McGhee: Re-sharing a link that TF member Sheryl Turney shared with the group: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6804409/

Seth Pazinski: Clarification that the next HITAC HTI-2 Proposed Rule Group 2 meeting is scheduled for August 22 from 1-2:30pm ET.

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 13, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO, on 9/30/24.