Health Information Technology Advisory Committee

HTI-2 Proposed Rule Task Force 2024 Virtual Meeting

Group 2: Standards and Certification

Transcript | August 22, 2024, 1 – 2:30 PM ET

Attendance

Members

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

Members Not in Attendance

Alex Mugge, Centers for Medicare and Medicaid Services
Shantanu Nundy, Accolade
Dan Riskin, Verantos
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

Alex Baker, ASTP

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

Seth Pazinski
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 for Group 2. I'm Seth Pazinski with the United States Department of Health and Human Services (HHS) Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP), and I will be serving as your Designated Federal Officer for today.

As a reminder, this meeting is open to the public and we encourage public feedback through the meeting, and comments can be made via the Zoom chat feature. Also, we have time scheduled for verbal public comments toward the end of our agenda for today.

We are going to kick things off with a roll call, and when I call your name, if you could please indicate that you are present. I will start with our Co-Chair, Mark Sendak.

Mark Sendak
Present.

Seth Pazinski
Suresh Balu. Hans Buitendijk?

Hans Buitendijk
Good afternoon.

Seth Pazinski
Good afternoon. Steve Eichner.

Steven Eichner
Good afternoon.

Seth Pazinski
Good afternoon. Raj Godavarthi. Mary Beth Kurilo.

Mary Beth Kurilo
Good afternoon, everyone.

Seth Pazinski
Good afternoon. Hung Luu?

Hung Luu
Good afternoon.

Seth Pazinski
Good afternoon. Meg Marshall.

Meg Marshall
Hi, good afternoon.

Seth Pazinski
Hello. Alex Mugge. Shantanu Nundy. Dan Riskin. Fil Southerland. Naresh Sundar Rajan.

Naresh Sundar Rajan
Good afternoon.

Seth Pazinski
Good afternoon. And Sheryl Turney.

Sheryl Turney
Good afternoon.

Seth Pazinski
Good afternoon. Is there anyone I missed or who just joined us that would like to announce themselves? Okay. Well, I am going to turn things over to our co-chair, Mark Sendak, for his opening remarks.

Opening Remarks (00:02:03)

Mark Sendak
Thank you, everyone. We are getting close to the end. I know that today is our second-to-last meeting, where we are going to be going through specific recommendations in the worksheet.

One thing that we will try to do as well, if we have time, is to go back and fill out some of the initial ones that we did not get to in our first few meetings. Hopefully between this meeting and the meeting we have next week, we can at least compile recommendations for as many of the proposed rule changes as we can. I appreciate everyone's time.

We will go to the next slide just to reorient on the task force charge. The overarching charge for the task force is to evaluate and provide draft recommendations to the HTI-2 specific charge. Once again, we are the certification subgroup. Our charge is to provide recommendations on the proposals for the certification content. We are on a schedule to meet this week and next week, try to finish going through all of the recommendations at that point, and then present to HITAC in early September.

Next slide.

Today we have fewer topics than we have had in some of our prior meetings. That is why we are going to try to do these two for electronic prescribing real-time prescription benefit certification, and then if we have time, try to revisit some of the items from earlier in the course of our meetings.

Next slide, thank you.

Seth Pazinski
We will now turn it over to Alex Baker, who is going to give us a brief presentation on the revised e-prescribing and real-time prescription benefit certification criteria. Alex, over to you.

Revised Electronic Prescribing Certification Criterion and Real-Time Prescription Benefit Certification Criterion (00:04:12)

Alex Baker
Great, thanks Seth. My name is Alex Baker. I am Deputy Director of the Federal and State, Tribal, Local, and Territorial division in the Office of Policy for ASTP, and I will just give a quick teeing up of these two proposal areas in HTI-2. Next slide.

First, we have a revision to the electronic prescribing certification criterion that is in § 170.315(b), which has, of course, been in the certification program for some time. This proposed update to the criterion incorporates National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011 into the criterion. So, we are updating from the SCRIPT standard version 2017071, which was finalized in the Cures Act final rule.

The timing of this update is that developers would be able to be certified to the version of the criterion using 2017071, or the new version of the criterion using 2023011, up until December 31, 2027. As of January 1st, 2028, the only certification that would be available would be that referencing the new SCRIPT standard, version 2023011.

In addition to the update in the standard, there are a number of other proposed updates to the transactions in the electronic prescribing criterion. I would note that perhaps the most significant set of proposals is around removing transactions that are currently identified as optional for the criterion. The proposed rule discusses that there has

been minimal uptake among developers for these transactions that were identified as optional, and so we have proposed to remove those optional transactions from the criterion and request comment on those proposals.

We will also just note that among the other proposals related to the transactions and the criterion, we have proposed to make a set of transactions in the SCRIPT standard around electronic prior authorization required. Those were previously optional after the final policy and the Cures Act final rule. We are proposing to require certification to those transactions as part of certification to this criterion.

We also propose to include the electronic prescribing criterion in the base definition, and that is related to the next proposal, so I will hold on that for a moment to talk about that on the next slide.

But, in general, of the benefits of these proposals, e-prescribing continues to be a core functionality for certified Health IT. We are doing these revisions in tandem with the Part D program that also adopted SCRIPT standard version 2023011 for Part D plans in a final rule that was just recently released. So, as we have done in previous years, we are working in tandem with Part D to ensure that updates to the SCRIPT standard are done in both of our programs at the same time. Next slide.

The other new proposal here is for a new certification criterion that is the real-time prescription benefit certification criterion, which we proposed to add in § 170.315(b)(4). This would enable exchange of patient eligibility, product coverage, and benefit financials for a chosen project and pharmacy, and to identify coverage restrictions and alternatives when they exist.

We will just note that the background for this criterion was motivated by a provision in the Consolidated Appropriations Act of 2021, which amended the qualified electronic health record (EHR) definition. This is an important statutory provision for the certification program and serves as the basis for what we now refer to as the base EHR definition, to add to that qualified EHR definition this functionality around real-time benefit tools in tandem, again, with requirements for the Part D program that were included in that law. And so this proposal to adopt this criterion is motivated both by wanting to support this useful functionality across developers, as well as supporting functionality in the Part D program from the provider side. This is also a statutory requirement that we are implementing through this proposed criterion.

Let me share some of the specifics here. We are proposing to reference NCPDP's Real-Time Prescription Benefit Standard Version 13 as the standard that is the basis for this criterion. That is again in tandem with the Part D requirements that have been finalized by Centers for Medicare & Medicaid Services (CMS) for their requirements for Part D plans to stand up real-time benefit tools to use for prescribers.

As I noted, the statutory provision that is important here was an amendment to the qualified EHR definition, which is the basis for what is now referred to in our regulations as the Base EHR Definition. So, this certification criteria needs to be added to the Base EHR Definition as we are reading what we need to do to implement the law here.

Because we added this to the Base EHR Definition, we have also proposed to add the electronic prescribing criterion to the Base EHR Definition that has previously not been included in the Base EHR Definition, and the proposed rule talks about doing that based on how intertwined these capabilities are for certified Health IT. We believed it would make sense to include e-prescribing functionality if we were also including this real-time prescription benefit functionality that is based on prescribing workflow. But there are questions in the proposed rule, as well, about that proposal, and we are inviting comment on whether the linking of those to criteria in the Base EHR Definition is appropriate.

What are the broader benefits here? We believe that this proposed criterion can enable prescribers to assist patients with understanding the financial impacts associated with different prescriptions, and that the ability to understand this information at the point of care can ensure patients receive the right medication and address affordability issues when a medication is prescribed.

That is just the very high-level introduction of these two proposals, and I am happy to point folks to elements in the proposed rule as necessary.

Discussion (00:14:03)

Mark Sendak
Does anyone have any questions on the slides? Hans?

Hans Buitendijk
Thank you. I have a question around the prior auth enhancements as part of one of the criteria. That is currently focusing on the provider side, but seems not to focus on the payer pharmacy side, as well, where the workflow would be involved. Is that understanding of the reading correct? And if so, what plans are there to extend it, if you can address that, that that side would be addressed as well? We are seeing within the prior auth for nonprescription that there is a payer and a provider side. We see in public health there is a provider and a public health side. We see that that is getting ingrained more into the approach, but it is not in this particular case. So, I am trying to understand a little bit of the background, and making sure that I am not missing anything there.

Alex Baker
I will just note that the Part D program does require, for Part D plans, that they support those e-prior auth transactions in the SCRIPT standard. That is a final rule from 2022, or something like that. I can add that citation in. But while this certification criterion is focused more on the prescriber side, there is a corresponding piece in the Part D program related to this, just for folks' awareness.

Hans Buitendijk
That is both payers and pharmacies?

Mark Sendak
Alex?

Alex Baker
Yes, it applies to Part D plan sponsors, which is what they regulate. Let me just take a look at that rule again. But feel free to move on.

Hans Buitendijk
That is clarity enough for now, Mark. I am good with that for the moment.

Task Force Recommendation Worksheet (00:16:56)

Mark Sendak
Sounds good. Any other questions from any other task force members? Okay. If not, I think the next step is for us to go back to the workbook.

Sara McGhee
Okay, I will bring it up. Just give me one second. Can everyone see my screen?

Mark Sendak
Yes.

Sara McGhee
Thanks. I am going to ask Accel to set the timer for 15 minutes.

Mark Sendak
Sara, is that for one of the rows? I just want to make sure we are oriented, too. We are on rows 38, 39, and 40 for today?

Sara McGhee
Yes, it will be 15 minutes for each topic, and we can start with either one. They are kind of reversed from how the presentation was given.

Mark Sendak
Let us maybe start with 40.

Sara McGhee

Okay. All right.

Mark Sendak
Okay. So, let me see. I do not see anything in row G for this, but are there any task force member-proposed changes?

Hans Buitendijk
Let me raise my hand.

Mark Sendak
Yes, go ahead, Hans.

Hans Buitendijk
I am not sure what I am looking at, the exact idea of front prescribing, but relative to the point before, I think one of the things that we should consider recommending is that, as in other criteria, there has been this two-sided pairing of criteria that are established for the provider and for the other side, the payer, the public health, whatever. That would be helpful in this instance as well, particularly as we are expanding to prior auth, and it would be good practice across the board. We could perhaps separate that, and have clear payer side responsibility clarity as well.

Mark Sendak
Just to make sure I understand, it is to have similar sets of recommendations for the payer and for the provider?

Hans Buitendijk
Yes. So, we have here the provider side requirements, and it would be helpful to extend the practice that is starting to also have criteria for the other side of the equation of the workflow, and then clearly other programs might have the appropriate level that they can enforce or not. But it would progress the approach that ONC started to introduce.

Mark Sendak
Yes.

Steven Eichner
Are you thinking in terms of potentially making a suggestion that the language might be amended to sending and receiving rather than just sending?

Hans Buitendijk
Not in the same criteria, other than having the responsibilities in the workflow on what is on the provider side and what is on the payer side, akin to, for example, G3435. It is that prior auth from the provider perspective, and it is a prior auth from the payer perspective, so they have responsibilities on either side. It is a start to make that more clear, and then enforcement, and the use of it, and the reference of it. That is clearly a lot of programs. But it would create a common practice to make that clear and also be able to address consistency there.

Steven Eichner
I am in support of the concept. I was just thinking about it from an implementation side because it is similar to the public health perception side. But I was also thinking about whether there was a need to support exchange between healthcare providers for this information. Because here again, looking at some of the prescription orders, it would seem that pharmacists would want to be able to receive the information as well.

Hans Buitendijk
That is a great point. I would agree. Is that when you say pharmacy or pharmacist, what is their role in the exchange of this flow as well? Do they receive it or do they send anything or do they do otherwise? I think as we progress, just having role-specific criteria for the same capability, in essence it would help clarify at least an understanding of A, what is my responsibility, and B, for other programs to use that to get more systems consistently adopting that.

Steven Eichner
It may have been an incorrect thought on my part, but that is why I was thinking it might have been both send and receive in this particular criterion because the certified Health Information Technology (HIT) modules might be used both by an entity ordering prescriptions, as well as the entity receiving the prescription order.

Hans Buitendijk
I would agree with that, but one of the challenges is that with using the more client/server send/receive terminology, that might mean that at times there is an implication that the same role needs to support both. Versus if you do it role-based, then at that point in time, if a system happens to support multiple roles, they would support multiple capabilities and perspectives. And that seems to be easier for HIT to understand, if I am supporting an ordering provider versus a pharmacy versus a payer. How many do I support? That is what I need to look at.

Mark Sendak
Sheryl, I know you have your hand raised.

Sheryl Turney
Yes, actually my hand was raised because I am trying to see clearly, Hans, what the workflow would be of what you are suggesting. If it is send and receive, the order would go out to the pharmacy. The pharmacy would then receive the order. Hopefully the patient then picks up the order, and what you would receive back from the payer would be a claim because that is all the payer is going to have. And if the order has never been picked up, you will not get anything from the payer.

It is a little different than the prior auth because the prior auth is dealing with information passing between the provider and the payer. This is really more of a three-pronged branch instead of the two-prong. Not that the patient has no role in a prior auth, but in a prior auth, the request is going to go to the payer, and then there is going to be information exchanged, and then there will be a response in terms of approval. Is that what you are thinking here?

Hans Buitendijk
It depends on which flow we are talking about. If we are talking about prior auth, there is clearly the ordering provider. They need to get authorization for that. There is the payer who grants that. The question is, as part of the communication to the pharmacy that is going to fill, is it ever going to arrive there? Or when it arrives, it needs to have the appropriate authorization information in there. There are three parties involved, but not to the same extent, necessarily.

I think we do not need to figure out exactly what fits where, but rather that if we recognize that a workflow has two or three or whatever number it is (but in this case, two or three key participants in there), then having a criterion focused from each one of those capabilities, as it is being done in that prior auth in G3435 and as it is done in F1 through 29, that concept would be very helpful to apply here as well.

Sheryl Turney
Okay, I am getting it now, thank you. I was just having a little trouble visualizing it, so I appreciate that expanded conversation.

Mark Sendak
Margaret, I see you put a comment in the chat. Was there anything you wanted to add to that? If not, then we will go to Ike, who has his hand raised.

Steven Eichner
I think two pieces are true. One, looking at any return from when the prescription has been picked up, there should also be feedback to the ordering provider so that the provider is aware that it has been picked up.

Secondly, while I am not familiar with prior auth in medications, from a patient perspective, it seems a little weird, to be honest, that the prior auth would come from the pharmacy to the payer, not from the ordering provider to the payer. Because then if there needs to be a substitute medication, it seems that would be an extra two steps to get a useful prescription actually fulfilled. I know that is out of scope, I am just making that as an observation. It may be out of scope for this rule.

Mark Sendak
Sheryl?

Sheryl Turney

I think, Steve, that is where I was stuck here because typically that is the way I saw it. That prior auth would go between the payer and the provider. But when the prior auth is approved, that is when the prescription goes to the prescribing pharmacy. I did not see it as a separate entity, I guess.

And I do agree that if, Hans, what you are saying is the same workflow application that we are looking at for overall prior auths should be applied to prescriptions, that makes sense. Because when you were first talking, I thought you were thinking of something different. Please correct me if I am wrong, but it sounds like you are talking about really kind of applying the same logic to the real-time benefit check.

Hans Buitendijk
We can do that there. We can do it to prior auth in any one where there is actually not just a simple submission and you are done, or a simple query and you are done, but where there is interaction back and forth, in particular.

But even if there is a submission, as we have seen with public health, there is the ability to submit or report, and there is the ability to receive, and it has certain responsibilities. I think what we are looking at is to take the workflow, look at the size of it. If it is two, it is two. If it is three, based on the flow, it is three, or whatever it is. Take the same approach of splitting up the criteria in both parts so you can more clearly articulate upon sending by that party or upon receipt by that other party what they are supposed to support and what is the standard, or are there are other requirements in play, and we can be more specific at that time.

Mark Sendak
Okay, just to make sure I am following. I am changing the wording here. It is to take this recommendation and split it like it already was, in rows 29 and 30. Can you scroll up, Sara? I think rows 29 and 30 showed two different rows for the two different roles of provider and payer. So, Hans, is that the gist of the recommendation?

Hans Buitendijk
I think so, yes. And then details about, okay, what is it exactly. I am not convinced we need to discuss those here, but that can then be part.

Mark Sendak
Does that splitting of the recommendation to both sides apply to both 39 and 40?

Hans Buitendijk
I generally would say yes, but the more complex the workflow is, the more important it is. When we see that there are multiple important parties like public health and the provider, and we see that we have a couple other ones as well, we have the provider application programming interface (API) and the payers, where it is quote-unquote a “simple query” but it is also split up, I think it is a general good practice. I think it is a great direction that ASB started with, and it would be helpful to apply it wherever we can.

Mark Sendak
Maybe from my own learning from task force members, I am learning from the chat, Margaret, it looks like there are cases where Medicaid will allow a pharmacy to submit the prior auth. Does a pharmacy fall under the notion of a provider, or do we need to call something out separately for pharmacies? Or are pharmacies totally out of scope for certification of Health IT? Does anyone know?

Hans Buitendijk
I have a response or reaction to that. There has been an effort within HITAC to address pharmacy and pharmacists on how they fill. That was last year. Among the variety of comments were some that included the interests for certification in that space, as well. It is my understanding that ONC could identify the criteria, but other programs would identify who actually needs to adhere to that or not. Like CMS, with their programs to incent providers to adopt certified software, and that is how it has been done. That would have to be defined as well. We have, similarly, with interaction of payers with public health.

But the steps are being taken here, that there is recognition of two sides of the equation, or three sides. If there was a pharmacist recognized as a kind of provider, are they the ordering provider in this sense? Can they be that? And they would take on that role. Is it something where they receive a script from an ordering provider, and then they are the one actually submitting the authorization and not the ordering provider? They would have that role as some **[inaudible] [00:32:49]**. I think that is what we are trying to tease out and have clarity around, that then a

pharmacist needs to be able to support as a pharmacist. But when are they an ordering provider? That is a good question. But this kind of approach would help with that because the system might just cover both.

Mark Sendak
That was the timer for row 40. Other than splitting the recommendation, are there other things we want to incorporate into changes? If not, then we can go to row 39, and Sara, we can start another timer for this one. But I am not too worried about time because I think they are related.

Sara McGhee
I agree. I think we have 20 minutes for this one, and then the remaining 20 minutes, so if it goes over, that is okay, too.

Mark Sendak
Okay. Row 39 is the prescription benefit. Any recommendations from folks? Obviously, I just pulled over the concept of splitting the recommendation to the payer and provider, but anything else for this one?

Hans Buitendijk
Similar question on the real-time benefits. Yes, the splitting. In the prior auth, there was clarification that there is Part B that is already requiring that. Is there something similar for real-time benefits as well? Or is this a new territory for everybody, from a clarification perspective?

Mark Sendak
Does anyone have the answer to that?

Alex Baker
The question is, is there a corresponding requirement on the payer side?

Hans Buitendijk
Correct.

Alex Baker
Yes. CMS has had a requirement for Part D plans in regulation since 2019, that they need to establish real-time benefit tools that can be used by prescribers. They separately have a requirement about real-time benefit tools that can be used by patients as part of the legislation that I mentioned in 2021. It specified that they needed to name a standard for that, and so now they have added to that regulatory requirement that Part D plans, as they are establishing these real-time benefit tools, need to comply with the NCPDP standard adopted here. So, that exists on the Part D side.

Hans Buitendijk
Thank you. So, that would then also, here, provide that same balance by splitting these up as we did for prior auth. There is the CMS interoperability, and that prior authorization rule that requires payers to do something in that space. This would then provide the underpinning, from a certification perspective, to enable a lot of programs to pick that up, whenever they are ready for that. So, it seems like good symmetry to have there.

Mark Sendak
Is that captured in the comment I added in G, Hans?

Hans Buitendijk
Yes, I think that is analogous, yes.

Mark Sendak
Any other recommendations we want to make to the proposal in row 39? Okay. I will put that in the workgroup recommendation. Sara, I think that if we are done with 39 and 40, we will want to use some time to go back over.

Sara McGhee
Yes. Are there any ones in particular? I think there was one that Sheryl wanted to discuss, if I remember correctly, that she was not able to get to last week.

Sheryl Turney

Yes, that is correct. There are two things. Hans and I talked offline about the one that I did talk about, and I did amend the wording in there, which hopefully will be more palatable for the group.

But here is what the second one was about. I have to look at it. Is this is the one recommended? Hold on. Okay, this is the one we did talk about, the one you are showing right now. This is the one that we did not talk about, and this is the one where we amended the wording over on the right. Yes. The one we did not talk about is in a lower row. It was row 24. Yes, row 24.

Mark Sendak
Yes.

Sheryl Turney
And this was the one that was talking about a need. I guess this goes beyond the rule, according to my conversation with Hans, but I feel we should comment anyway on it because at the end of the day we have, in many forms, talked about issues with patients, A, being able to correct their records, and B, adding to their records with data from other providers, which would need to be supported electronically. Today there is no way of doing that.

And I guess one read that I took of the patient access API is that yes, it primarily was targeted at payers, but to me there is no reason why payers should be the only ones that have to provide data when the patient knows there is data that providers have. Why can they not use the same type of transaction to request that providers share their data with them, and then they can share it back to another provider?

And this happens a lot when you have individuals who have chronic conditions and also sometimes rare conditions. They are primarily getting care at one setting, which might be closer to where they live, and then they have to go get care in another setting that is farther away.

Getting those records shared and trying to put all of that stuff in place, yes, implementing some of the things we have talked about overall with HTI-2 will help. But at the end of the day, there is no opportunity with the software for the patient to be the ones to say, “This is the information that needs to go from provider A to provider B because I just had a whole host of tests there.”

For instance, if a patient went to somewhere like the Mayo Clinic, where they go for a week and they get all these comprehensive things, and now they want to share it back with a local provider, there is no way for them to do that electronically, and there should be. They should not be forced to use a third-party app to do that if they do not want to. There should be a way in their patient portal, or something, like the patient app that is provided, for them to say, “We need to get this data and move it over.”

And that is all I am saying. If we are looking at interoperability and satisfying the goals that we have in the patient access rule as well as this rule, and the additional new rules with prior authorization, they all speak around it, but they don't speak to a specific process to accomplish it. And today, there is no way for a patient to do that. That is the problem.

Mark Sendak
Hans?

Hans Buitendijk
I guess, Mark, there actually are some, but we can certainly discuss whether they are sufficient or not. But as part of the certification, there is the view-down transmit criterion that enables the patient to send it to somebody else. That could be that other provider.

Sheryl Turney
That may be there, Hans, but in multiple software patient portals, there is no request, there is no process for the patient to actually make that work. It may be part of the certified Health IT software, but there is no requirement that says it has to be made available to the patient. That is the problem. And I do not know the right way to say it, maybe I am saying it wrong, but that is the issue. It may be present in the software, but it is not available to the patient.

Steven Eichner

This is Steve again. To add on to that, there is no way of doing it remotely. In other words, you the patient have to go to whatever portal the data actually exists in to request it to be pushed, not looking at a request. I cannot go to my Primary Care Physician (PCP) and say, “Hey, there is data over there. Go grab it.” Or go to my PCPs portal and say, “Go grab it over there.” I have to go chase around to all of the different places it exists and tell them to push it over.

And this means I have to spend more time, rather than going to a single hub and enabling requesting data from all the other places where I know it is.

Hans Buitendijk
And Mark, if I may add some additional thoughts from earlier. There is some capability, but as I indicated, we can certainly address that it might not be sufficient, and you gave some good examples of that. Some of that we need to look at and ask, is that part of certification? Or are there other places where that needs to sit? Because we are now looking also at the implementation provider perspective. So, we want to have a couple other thoughts there.

The use of the patient API and the ability there would not necessarily seem to be the right place because the intent there, as I understand it, and has been also in the CMS rule, as described, is query access, and that is what it is mimicking. So, perhaps there needs to be recommendation, which may not be attainable in HTI-2, to identify capabilities that further enhance the ability of a patient to initiate the transfer of data from one provider to the next, where there is interest in it. They may not be connected by a single network, so we would have to think through what work would be needed to address the concept. This is not the same, I think, as the impression of some of the comments might have been, as that a patient can write into the EHR. It is actually asking or requesting that provider A is sharing information with a specific provider B in an appropriate form.

And at that point in time, it would flow in a similar fashion as currently transitions of care are actually done, and it is another form of how to initiate a transition of care. Should that be limited to providers only to do that, or should that be expanded to patients being able to initiate that, where they feel that certain data is not yet shared?

Mark Sendak
Sheryl, before I come back to you, though, I want to ask a naïve question because I think the ideal way that this would work is that you can automatically push data between systems to update patient records to be more comprehensive. But I guess at a very basic level, do we even have identifiers in place to accurately do record linkage?

Hans Buitendijk
There is data being used when data is being shared to help in the matching process. The process is not necessarily always 100 percent accurate, based on the available information. It is probabilistic over a variety of levels that are being used, but there is not a single or unique identifier that everybody shares. But there is matching, and as a result, ability to share data and associate with not a record, but it has its shortfalls.

Mark Sendak
But Hans, just to give a concrete example, I am at Duke. University of North Carolina at Chapel Hill (UNC) is a few miles down the road. If there are records for Mark Sendak at both, I understand that it may be tedious for me to go get them from one place and give them to a provider at the other place to update my records. But I guess I am just trying to understand, do we have the linkages to automatically combine them if I have authorized both systems to do that?

Hans Buitendijk
I see a show of hands, so I do not want to jump in. But to respond directly to that, that is what the health information exchange (HIE), the networks, are all focusing on. Mostly right now it is query-based, where there is an interest from a provider to get information for other providers, where they pull it in. And then there is good discussion to be had about how does the push model work, and how does the patient-initiated push fit into that. But they all are based on using methods to match patients across networks or across providers using the networks to make that happen better. Because if we just do it between the two, the medical record numbers are clearly not in sync between those two, and they have to do it on the demographic data that is available. That is what networks are really keenly focusing on, to improve upon that.

So, is there information to use with matching? Yes. Is it perfect matching? No. But there are abilities to exchange in a variety of different forms, such as direct messaging and network-based queries. Direct messaging you can do

directly and send it to the other party. It includes the information on the patient. Can the direct message be initiated by the patients? Verbally perhaps, but if you have another form, as Sheryl described, not necessarily.

I think those are the areas we would need to look at and see whether they fit. Personally, I am not convinced it is part of patient API based on the current definition. But it is a capability that HITAC can recommend, and I would support the notion that we need to look at that and see what other ways there are to enhance that ability. What do we have and what else needs to be added to make that better? But there is not nothing.

Mark Sendak
Sheryl, go ahead.

Sheryl Turney
Yes, so I just wanted to clarify, and thank you, Hans, for having that extended conversation because I think that did help. Often what patients find, and I know this for sure with examples that I have seen, is that they will share data electronically with their providers, between one system and another, even uploading it to the portal through messages, etcetera, but that data never makes it into the EHI.

So, to me, I was not looking for direct messaging, but there needs to be an electronic way that patients can request data be shared from one provider to another, and then also there needs to be something in the rule that requires that data that the patient has shared at least be evaluated to become part of their EHI. Because in both cases, that is not happening, and it may be that there are capabilities, but they are not being utilized that way.

And maybe that is part of the reconciliation function we talked about a couple weeks ago? I do not know. Because this is where I am beyond my knowledge of what happens in an EMR system. But I know in this rule and the prior auth rule, part of the rule was to require that not only payers share data, but they actually use the data that they get in order to make it part of the patient's EHI.

To me, this is the same. It needs to have the same standard applied.

Mark Sendak
Hans?

Hans Buitendijk
Yes, it would seem as if there are a couple different places we need to look. What is the scope of reconciliation? Because once you receive it, how do you ingest it? In this context, we need to recognize the difference between "I receive a data center document"; "I have it, but I am not going to parse it apart"; "I keep it as a document, and I make it available for viewing purposes"; versus "I am taking data out of it as well," and integrate that further into the record. That is the reconciliation part, where you can look at it and say the document contains five allergies. Some of those are new, some of those you already know about. The reconciliation is about picking up the new things that are relevant and putting them into the record. Those capabilities are there, but the reconciliation criteria, to expand that, would look at additional data for which you would have to do that.

But that does not mean that the document that was sent is then gone. It can be there for viewing as a document, but not necessarily data individually, discretely. And there are other parts of how you initiate the data. Currently we have query capabilities from one provider to another, but what is the role of a patient-requested sharing of the data, whatever format we might land at?

I think there are different places to look at to see the ability for a patient to share, and to what extent is it integrated into the target EHR. We would need to understand what it is that needs to be added to each form of those.

Mark Sendak
I am trying to figure it out. This is a pretty high-level conversation in terms of the types of functionality that we are trying to advance. Is row 24 the best place for this recommendation? Where is the best place to tie this to? And Sheryl, given that you were the first one to kind of point us here, were you going to say something?

Steven Eichner
Sorry.

Mark Sendak

Sheryl, I was going to ask you, do you think?

Sheryl Turney
I have to open the spreadsheet, but I think I aligned it to this particular section because it pertains to, essentially, the patients, and what I aligned it to was the patient APIs. I guess it could be aligned to reconciliation, it could be aligned to another area, but again, I do not know if I am the best one to say what area. What I did try to do was go through all this rule, the patient access rule, and the prior auth rule to identify where it was supported, and I tried to include that in my justification for the recommendation. But the recommendation itself is really only the first paragraph.

But I do think, based on what Steve was saying, and I do not want to be using this to solutionize, but there are individual access services that will be offered through Trusted Exchange Framework and Common Agreement (TEFCA). Maybe the magic is certified Health IT needs to provide an electronic way to access those so the patient can initiate that request for the data to be shared. I do not know. But to me, this is the most important aspect of what the patient needs from these rules. Because what they are thinking is that we are implementing interoperability, which means that they have access to their data where they need it, when they need it, and how they need it. And today, what I am saying is in reality, maybe those capabilities exist, but they are not always accessible by the patient. And I am working hard to try to figure out what are the gaps and how we can fill them.

Mark Sendak
I really appreciate that, so I think definitely we are going to try to figure it out. My sense is if we include this in one place and ONC wants to incorporate it somewhere else, I think that is fine. Hans?

Hans Buitendijk
Perhaps a location suggestion, given that at least our read-off of the patient API aligned with the CMS patient API is payer-focused. It is the payer-consumer interaction, it is not provider-focused. So, from an EHR perspective, we are not looking at how we would provide a patient API. We are looking at other ones, like G10, G20, the A series, etcetera. That is where we are looking at the capabilities between the provider and the patient.

Some of the ones to consider where it could tie to, there are the A criteria around coordination of care and transitions of care. Granted, they are day-to-day, focused on the provider, but that would be a place we could suggest. Whether it lands there or not is a different story. But the progression of that care coordination, this is patient-initiated care coordination that needs for the patient to identify, “I would like you to share it with provider X.” Then it starts to flow through, and it arrives there, and then there is reconciliation that occurs. That that is where the question comes up, is all the data that is relevant being ingested and reconciled? Which means this great data is being pulled out and integrated into the records. Is that happening to the extent that is appropriate or of interest?

I think that is more the focus where, from the side of the patient relationship, where we see the criteria that touch upon that, not the patient API that is payer-focused. It does not mean that perhaps there is an opportunity or a need that a patient can ask the payer who has the data to please share it with provide X. I am not saying that. And if there is that interest, then that might be another place to focus on the payer’s capabilities to support that.

So, I think it is not necessarily one at this point in time. It might not necessarily end up extending those criteria, but creating new criteria to really hone in on that aspect. But those seem to be some of the hooks to link it to.

Mark Sendak
Hans, would that be row seven?

Hans Buitendijk
Can we jump to row seven to be able to read that? Row seven is around dynamic. No, that would not be it. That is a very technical app.

Mark Sendak
You said G20, which is where I landed.

Hans Buitendijk
G10, but that is not the dynamic. The client registration protocol is actually J, what is it, 15? I do not recall the numbers. But that is part of G10. G10 has its own. G10 could perhaps be looked at because that is patient access. I would say it is less. It would not resonate with me as much if we did it in care coordination. It is B2 and B3.

Mark Sendak
B2 and B3. So let us figure it out.

Hans Buitendijk
B3 is the creation and the transition of care, where the patient may want to be the one that initiates it in particular things. The reconciliation is the receipt of that, and that is a little more Clinical Document Architecture (CDA)-focused at this point in time. But that is where currently that kind of transfer would occur. There are other ones as well.

Mark Sendak
How about row six? That is B2. Sara, can you scroll up a little bit and to the left?

Hans Buitendijk
Row six?

Mark Sendak
User access, maybe?

Hans Buitendijk
Maybe I am looking at the wrong row. Row six? Because I am seeing end-user brands and endpoints. That would be a technical thing. It would be criteria B1 and 2, wherever they are in the spreadsheet.

Mark Sendak
Is it at 30?

Sheryl Turney
It looks more like 14, from what he is telling me, if I am understanding it.

Hans Buitendijk
14? No, that is a J. It would be wherever B is. There are updates to B1 and B2 to use more current.

Mark Sendak
So, 34 is B2, and that is the clinical recommendation conciliation.

Hans Buitendijk
Yes, and then there is the other one, where it is about new imaging requirements that is against B1.

Mark Sendak
Interesting.

Hans Buitendijk
It is not specific to new imaging.

Sheryl Turney
Sorry, that is 33 and 34. I misread it. I need better glasses.

Hans Buitendijk
Yes. But those two relate back to B1 and B2, and B1 and B2 for the intent of the patient initiating the sharing of information. My initial reaction would be that is probably the closest criteria to hook into, recognizing that what is being suggested might not really fit totally inside those two. I actually would suspect it does not. But it is still in the space of care coordination. “I want my data to be shared with somebody else.”

Mark Sendak
Just to pause for a moment, I want to get some folks from ONC. I do not know if, Seth, this is something you can speak to? I know there is an interoperability subgroup. Do you feel like this is something that that group is kind of addressing?

Seth Pazinski

Yes, the interoperability standards workgroup primarily focuses on the United States Core Data for Interoperability (USCDI) versioning but does do some additional standards work. But from a requirements standpoint, in the rule, it would be in this group.

Mark Sendak
Okay. So, then let us try to put something at least in 34. And Sheryl, I know that you said it was like the first paragraph, from what you had written in seven.

Sheryl Turney
Yes. I can move it down and rewrite it based on what we have discussed today. I will do that after this meeting.

Mark Sendak
That would be fabulous. I will make note in the row and say, “For Sheryl.” Okay.

Sheryl Turney
Thank you, Mark.

Mark Sendak
No problem. Was there another one you wanted to look at from last time?

Sheryl Turney
Well, I did rewrite the other one, which was the first one you put up, based on the network discussion that we had, and I think we modified it to the degree that I think hopefully will be something that can be accomplished. But let me tell you what row it is, so I can find it myself. Okay, so it is row seven.

Mark Sendak
Yes.

Sheryl Turney
All right. If you go over, I guess what I modified was in G. All right, so basically what we updated was recommend that ONC add a requirement that requires certified Health IT vendors to demonstrate a successful data exchange with a network, either local HIE or national, and it just listed examples: EHX, TEFCA or CareQuality, for example, in alignment with data exchange, privacy, and security. “The certification step will ensure efficient data exchange and support interoperability goals across the healthcare ecosystem.” I have to fix my misspellings.

“And enable even smaller providers that purchase certified Health IT products to achieve data interoperability goals with minimal burden. The revised regulations related to information blocking in the finalized step edition of Offer Health IT aligns to establishing a successful demonstration of network data exchange to prevent conditions that hinder interoperability.” And then, “Currently, major EMR vendors already demonstrate the successful ability to complete network data exchange based on their participation in HIEs and national networks, but many of the more out-of-the-box vendors do not demonstrate this capability, and it hinders smaller providers to complete connections as they do not have the technical expertise or resources to perform these connections and support from” – and I will fix that – “certified Health IT vendors. In many cases, it is limited or nonexistent.”

“Also, we need to include greater” – and I will fix this, again misspelled – “reporting at the certified Health IT website for organizations to report issues with certified Health IT products related to data exchange connectivity. I would also recommend that ASTP increase their audit capabilities with certified Health IT to ensure certified Health IT products are prepared for audit when necessary.”

Because actually, you know that if you look at it and people are worried that you are going to look at it, then they are going to be sure to do it versus certifying something that does not happen.

The other thing is, with the certification criteria that exist today, when they do a demonstration of a network connection, typically they have to explain how they did the process. That documentation would be very helpful for a provider who wants to work with an HIE or TEFCA, even, to connect, and they cannot get support from the vendor to understand what hurdles they had to overcome to make that connection.

Today, I understand that on the certified Health IT website, you have to say if third-party software or some integration software was required, but it is limited in terms of whether there are other things that need to be done in

order to make that data connection work. And where we see this falling apart, from a payer's perspective, we have actually been working with HIEs and others to try to enable some of these smaller providers to get the information they need from the vendor. And today, all the pressure is on the provider for information blocking, etcetera. There is no pressure on the vendor who sold them the product to actually support that product and ensure that they can make a connection.

And again, it is not the top ones. It is the other ones where we are seeing this happen.

Steven Eichner
Sheryl, can you say the first eight words again?

Sheryl Turney
The first eight words? Yes.

Steven Eichner
Yes, or 10 words.

Sheryl Turney
I am sorry, they are there. Can you see them now?

Steven Eichner
It is really, really small on my screen.

Sheryl Turney
Okay. It is, "Recommend that ONC add a requirement for certified Health IT," and again, I have to fix this, "to require certified Health IT vendors to demonstrate a successful data exchange with a network."

Steven Eichner
Okay. Per the amendment, right in front, I think you want to include that as a recommendation as far as what the certification criterion might be, rather than adding a requirement. Because we need to stay within the context of the rule in our comments. So, if you are looking at trying to modify the rule to have a new requirement, that might be out of scope because they cannot include things that were not included in the rule.

However, if the recommendation were to be something about the inclusion of a factor in the certification criterion that comes into effect underneath the rule, that might be in scope. Does that make sense?

Sheryl Turney
Yes, that makes sense, and I will update the recommendations, Steven, thank you for that.

Steven Eichner
Sorry, Hans.

Hans Buitendijk
No worries. Along those lines, I think that that same comment actually goes to the patient-initiated coordination of care transition of data. We may want to look at that as well and see where there is another, better spot because that is more likely currently not to fit otherwise clearly into what is there.

But I put in the column next to it, just a small suggestion on the first paragraph that otherwise reads very clearly, and I appreciate the updates there. The suggestion is that since TEFCA care quality are frameworks, not actual networks, and that local state HIEs, e-health exchange, and there are number of other ones there, are actual networks that you actually physically connect to, my suggestion is to look at those examples and any other network under care quality or TEFCA because there are many other ones that they could demonstrate it with.

Mark Sendak
One question also for Seth. If we have a recommendation, but if it does not cleanly fit into a row in the workbook, how do we handle it?

Seth Pazinski

Yes, just add a row at the bottom and have an overall recommendation. You just add an additional row, and then we can work on it. It could just be an overall recommendation, if there is not a specific provision it is connecting to.

Mark Sendak
Just to recap your comment, Steven, it sounds like we would adapt this to not add a requirement but update a certification criteria to require that the Health IT vendor can demonstrate the successful data exchange. Is that correct?

Steven Eichner
Right, or including in certification criterion, "Under the rule XYZ."

Mark Sendak
Okay. Sheryl, do you want to also take the lead on updating this, including the language from Hans?

Sheryl Turney
Yes, I will do both, and then I will update the language of the other one based on that advice as well. I think that is a good direction, thank you.

Steven Eichner
Sheryl, if there is anything I can do to help, please feel free to reach out. I am happy to do so, but I do not want to interfere with your excellent thought, either.

Sheryl Turney
No worries. Thank you, Steven, I appreciate it.

Mark Sendak
Sheryl, just move it to the bottom. Do not try to jerry-rig where it fits.

Sheryl Turney
Okay.

Mark Sendak
Hung?

Hung Luu
In that same vein, what I have been thinking about is giving clients a way to provide feedback on the actual performance or functionality of the certified IT. If you think about it, the United States Food and Drug Administration (FDA) has a mechanism whereby you can report issues with devices and drugs, and there is not a similar mechanism currently for the ONC to collect or to be able to evaluate these and weigh them as part of certification.

In the same vein, could I then add that as a certification criterion? To collect and provide feedback from clients on the performance of their software, as part of the certification requirement?

Mark Sendak
Let me use more FDA language. Maybe, Hans, I know you work a lot with the EHR Association. Is their post-market performance monitoring for EHRs, where there is any reporting, whether it is to ONC elsewhere, to give some public visibility?

Hans Buitendijk
There are insights to the part of the rule where there are certain measures that need to be reported on. Is it at the same level of post-market as FDA does? I do not think so, but there is certainly that, and there is real-world testing. I would defer to ONC, what level of public insights there would be. I am not personally as familiar with what is publicly shared versus what we are required to report and do post-certification. So, insights and real-world testing are two key examples there.

Mark Sendak
Hung, I compare it to post-market because it is like even after you are certified, you want to see how things work. So, if you can, add that to the bottom as well. I think we would have to confirm with ONC, Seth, and I know we just

have like 40 seconds, but is that something we could frame as in-scope for this feedback? Or would it be determined as out-of-scope?

Seth Pazinski
To be in-scope, it would have to connect to some overarching proposal. As a task force and as the HITAC, you can put forward any recommendations you see fit. But from a logical outgrowth standpoint of being addressed in the final rule, it would have to connect to some proposal. It is really up to you how that task force and the committee wants to move forward on that.

Hans Buitendijk
Row 42 has insights, and I am looking for real world, so I thought there were changes to that as well. Real world has a dash or not? We will find out if there is a dash in there. I think there is a row for that as well, somewhere. I believe there were some changes there. Maybe that did not change because things move into that at that point in time. There is a real direction.

Mark Sendak
I know we are at the public comments, so we will get to 42 next week. It looks like next week we may be able to work that in, Hung. Thank you, everybody.

Public Comment (01:16:44)

Seth Pazinski
All right, thank you. We are going to move to public comment. If you are on the Zoom and would like to make a comment, please use the raised hand function, which is located on your 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, press *6 to mute and unmute your line.

And so while we pause to allow folks to queue up, I just want to give the reminder that the next and final Group 2 meeting for the HTI-2 Proposed Rule Task Force is going to be next Wednesday on August 28th from 11:00 to 12:30 Eastern time, and then after that we will be transitioning to full task force meetings for the week of Labor Day, with meetings scheduled on September 3rd, 4th, and 5th.

So, I will check, any folks on the line? No folks on the line. Let me just check if anyone is on Zoom. No. No public comments at this time, so Mark, back to you for next steps and to close us out.

Next Steps (01:18:07)

Mark Sendak
Sorry, I was muted. Thank you, everybody, for the discussion today. We will meet next week on the 28th, so it will be on Wednesday at our normal time, 11:00 to 12:30. We will go through the last section and try to fill some gaps from other sections of the proposed rule. I appreciate everyone's time. I think we will adjourn.

Adjourn (01:18:38)

Questions and Comments Received Via Zoom Webinar Chat

Meg Marshall: Apologies - I need to leave the meeting early. I will follow up on any action items after the meeting. Thank you

Margaret Weiker: Pharmacies receives information regarding the PA in the other SCRIPT transactions such as NewRX

Margaret Weiker: If the prescription has been picked up, there is a separate SCRIPT transaction.

Margaret Weiker: There are some instances where a pharmacy can submit a PA. A few Medicaids allow a pharmacy to obtain a PA.

Margaret Weiker: Pharmacy initiated PAs are covered under HIPAA and use the Telecommunication Standard.

Steven Eichner: I would think, ideally, the order should also be forwarded to any entity the patient desires.

Margaret Weiker: Under HIPAA they do. Out of scope

Margaret Weiker: pharmacies do not receive incentives

Margaret Weiker: CMS Medicare Part D is requiring it

Steven Eichner: Patients should also be able to contribute data to their provider's EHR, including uploading images. While I can send a text message to my provider through the patient portal, I can't upload an image of my wound.

Sheryl Turney: Steven yes that is exactly the issue and any data a patient does share does not make it into the EHI for the patient.

Steven Eichner: TEFCA's IAS and the IHE framework are designed explicitly to search and retrieve data. It should be perfectly "doable" to use FHIR subscription services initiated by a patient to regularly retrieve data from multiple providers.

Steven Eichner: IAS= Individual Access Services

Steven Eichner: The patient should be able to initiate the request from either a requesting system OR a sending system.

Sheryl Turney: Perhaps the link is that the Certified Health IT needs to provide an electronic method for the patient to initiate and IAS within TEFCA if so desired

Hung S. Luu: Thank you, Sheryl.

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 22, 2024, Meeting Webpage

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