Transcript

HTI-2 PROPOSED RULE TASK FORCE 2024 MEETING

GROUP 1: PUBLIC HEALTH

August 6, 2024, 11 AM – 1 PM ET

VIRTUAL

MEMBERS IN ATTENDANCE

Bryant Thomas Karras, Washington State Department of Health, Co-Chair
Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Steven (Ike) Eichner, Texas Department of State Health Services
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Gillian Haney, Council of State and Territorial Epidemiologists (CSTE)
Joel Hartsell, Association of Public Health Laboratories (APHL)
Erin Holt Coyne, Tennessee Department of Health, Office of Informatics and Analytics
Mary Beth Kurilo, American Immunization Registry Association (AIRA)
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, CyncHealth
Thomas M. Wilkinson, U.S. Department of Homeland Security

MEMBERS NOT IN ATTENDANCE

Steven Hester, Norton Healthcare
Jim Jirjis, Centers for Disease Control and Prevention
Kikelomo Oshunkentan, Pegasystems

ASTP STAFF

Seth Pazinski, Designated Federal Officer
Maggie Zeng, Staff Lead
Molly Prieto, Group 1 Co-Lead
Rachel Abbey, Group 1 Co-Lead
Sarah McGhee, Overall Task Force Program Lead & Group 2 Lead

PRESENTERS/ DISCUSSANTS

Lynn Gibbs-Scharf, CDC/NCIRD/ISD
Kafayat Adeniyi-Inniss, CDC/NCIRD/ISD
Jennifer Junkins, CDC/NCIRD/ISD
Chrissy Miner, CDC/NCIRD/ISD
Laura A. Conn, CDC/IOD/OPHDST
Jessica Diamond, CDC/NCCDPHP/DCPC
Sean Porter, CDC/NCCDPHP/DCPC
Rebecca McNall, CDC/IOD/OLSS/CLSR
Jason Hall, Deloitte
Riki Merrick, APHL

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

Seth Pazinski
All right. Good morning, everyone. Welcome to the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) proposed rule task force Group 1 meeting. I am Seth Pazinski with Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP). And I will be serving as your designated federal officer today. This meeting is open to the public and public feedback is welcome throughout the meeting. Comments can be made in the Zoom chat feature during the meeting and there is time schedule towards the end of our agenda for verbal public comments for those that are interested. Let us get started with our meeting. I am going to start with roll call. Starting with our co-chair, Bryant Thomas Karras.

Bryant Thomas Karras
Present.

Seth Pazinski
Shila Blend? Hans Buitendijk?

Hans Buitendijk
Good morning.

Seth Pazinski
Steve Eicher?

Steven Eichner
Good morning.

Seth Pazinski
Lee Fleisher?

Lee Fleisher
Good morning.

Seth Pazinski
Raj Godavarthi?

Rajesh Godavarthi
Present.

Seth Pazinski
Gillian Haney?

Gillian Haney
Present.

Seth Pazinski
Joel Hartsell?

Joel Hartsell
Present.

Seth Pazinski
Steven Hester? Erin Holt Coyne?

Erin Holt Coyne
Good morning.

Seth Pazinski
Jim Jirjis? Mary Beth Kurilo?

Mary Beth Kurilo
Good morning.

Seth Pazinski
Kikelomo Oshunkentan? Zeynep Sumer-King?

Zeynep Sumer-King
Present.

Seth Pazinski
Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Seth Pazinski
And Thomas Wilkinson?

Thomas Wilkinson
Good morning.

Seth Pazinski
Thank you. Is there anyone I missed or anyone who just joined? With that, please welcome our co-chair, Bryant Thomas Karras for opening remarks and to get into our meeting. Bryant, over to you.

Opening Remarks (00:02:11)

Bryant Thomas Karras
I am going to keep opening remarks really brief today as we have a packed agenda. We are going to try to get through as many of these proposed rule criteria as we can. I hope the logic will be obvious to everybody.

Instead of going through all of the lower number (f) criteria and all the 20 number (f) criteria, we have tried to pair the actual standard criteria and then the measure or certification criteria together in bundles so we could minimize the burden on Centers for Disease Control and Prevention (CDC) program area staff that have to come back for multiple sessions. Apologies in advance if we do not get to the sessions that were on deck. And a big thanks to the immunization folks who came back for a continued discussion that we did not have time to complete in our last session.

Without further ado and five minutes ahead of schedule, which I am sure we will use up during the course of the day, let us jump into the first item on the agenda. Can we advance to the next slide please? All right. There is a reminder of the charge. Then, go to the next slide. But I think we are going to end up going to the spreadsheet right away. Then, one late breaking change, we may end up adjusting and moving the prescription drug monitoring program back a day for the discussion because of scheduling conflicts with CDC program area staff. Is that correct, Rachel?

Rachel Abbey
Yes. We are still discussing that but I think we are going to have to shift some topics around for next week and for the following week on the 20th. But more to come shortly.

Bryant Thomas Karras
All right. Next slide. All right.

Rachel Abbey
Aaliyah, do you want to bring up the spreadsheet?

Aaliyah Parker
Yes. There we go. Perfect.

Bryant Thomas Karras
Who is going to be the time master?

Rachel Abbey
I may have to do that so I am going to interrupt. We thought we had a clock but I guess not. I will definitely keep you guys on task and let you know when you have five minutes left.

Review Existing and New Public Health Data Exchange (00:05:31)

Bryant Thomas Karras
All right. Here is what we would like to do is go through each of the criteria, just open things up for discussion and kind of review what people have chimed in on in the recommendations. And for this first one, we have 10 minutes. Is that correct? Wait. Or are we not at the right one?

Rachel Abbey
I think also, Bryant, we have to address some of the discussion from last week first, which is just that the (f)(1) criteria. Then, we will move into the (f)(21).

Bryant Thomas Karras

Great. Immunization folks, perhaps Mary Beth, do you want to read the proposed rule summary? You covered it last week.

Mary Beth Kurilo
Absolutely. The proposed rule summary is to revise the transmission to immunization registry certification criteria at 170.315(f)(1), revised transmission requirements via updated standards, Health Level 7 (HL7) Version 251 implementation guide for immunization messaging, Release 1.5 published October 2018. Update vocabulary standard, CVX (vaccine administered) and National Drug Code (NDC). Expire existing standards on January 1, 2027. Change name to immunization registries bidirectional exchange. And then, the new component is receive incoming patient level immunization specific query or request from external systems. Bryant, do you want me to jump in with some of our comments on this?

Bryant Thomas Karras
Yes. Well, first the consistency of the "change the name" seems a little bit different than the other ones that we did. But I think we can resolve that in editing. Why don't you jump in, Mary Beth, on substantial comments you guys have?

Steven Eichner
Just to be safe, you may want to zoom in a little bit.

Mary Beth Kurilo
That could not hurt. Thank you, Steve. I want to call out there is a note in the chat that representatives from National Center for Immunization and Respiratory Diseases (NCIRD) are also on the call and we can also make space to hear from them as well. But just to pick up your note on the changing of the name, immunization registries to bidirectional exchange, on the AIRA side and certainly across our membership, we are supportive of that, as it does represent the more dynamic exchange going on between electronic health record (EHR) and Immunization Information Systems (IIS). But we do think there could be better definition there. In a lot of ways, sending Unsolicited Vaccine Update (VXU) and receiving back an acknowledgment (ACK) is in itself bidirectional. I think the rule could be a little bit more explicit on defining bidirectional just to make sure it is clear that folks understand that that really means that updates or queries could go in either direction. I see some hands up. Bryant, I do not know if you want to defer to Hans and Steven.

Bryant Thomas Karras
I do not have my usual two screen set up, so I am having difficulty seeing hands raised. Hans, or whoever is first in the queue.

Mary Beth Kurilo
Hans and then, Steve.

Hans Buitendijk
Thank you. I think having improved names is helpful. I am not sure whether bidirectional in this particular case is helpful because we also have (f)(21), which is looking at the public health side. We have (g)(20) that is also a query. One of the confusing components that I made a comment about is a provider as a result supposed to be responding to an immunization query? And is that appropriate to use the VXU, or is

it better to use the (g)(10) and Fast Healthcare Interoperability Resources (FHIR) approach? I think what we have seen in a couple of other places, we start to see client server. I have seen payer provider in the name. Can we start having the criteria along the lines of immunization recording provided? Immunization reporting Periodic Health Assessment (PHA) or IIS. And then, identify in each of these what is the provider responsibility and what is the IIS responsibility? I would agree that ACK is probably not worthy of having a separate statement around that. But that we have clarity around that a little bit better. And then, we can also make more clear that a provider's query response is actually probably better suited in (g)(10) by making the FHIR immunization resource available.

Is that sufficient or is it something else? But it is not clear from the current one. Bidirectional is very confusing because it now is putting the same party on both sides.

Bryant Thomas Karras
I had some of the same concerns. In some of the other criteria, it is clearly labeled reporting to public health. And in this, it is not even explicit that that immunization registry is housed at public health. Do we have another hand or do the program area folks from CDC who are with us or folks from AIRA want to weigh in on this comment?

Rachel Abbey
Steve has his hand up. And just to clarify that CDC staff is on just to clarify any programmatic related questions and they cannot opine on any of the rules stuff. Only restating anything it is already in the proposed rule. And so, Steve has his hand raised.

Bryant Thomas Karras
Steve?

Steven Eichner
Thank you. I do not think bidirectional is necessarily the best label here for a couple reasons. One, we have not provided clarity about what bidirectional means, whether it means just an acknowledgment message, which is bidirectional, as well as looking at more substantive content. There also is the issue where there are a number of providers that may not be interested in sending any information or may not meet the requirements for sending information in some jurisdictions. If they do not have data to send, they may not be participating in an IIS on the setting side but may only be receiving. I am a little concerned about what the implications a bidirectional label means and what does that mean at the end of the day for people understanding what they can do within the parameters of the law?

Bryant Karras Thomas
We are down to three minutes. Let us go back, Mary Beth. Are there any other comments down below?

Mary Beth Kurilo
We may want to consider, and I just put this in chat, calling this immunization exchange submission and/or query to try to better define what we mean by bidirectional because I do appreciate that this looks a bit different than other areas of public health reporting. And I think it is important to call out but there may be a more specific way to call that out that is more clear and does not muddy the waters. I know we are down to three minutes and there are a million things to talk about. But the other piece that may be helpful to discuss

is the piece about EHRs supporting Query by Parameter (QBP)/Response to Query by Parameter (RSP) as a receiver of the QBP and producer of the RSP. We have some concerns that IIS my not leverage this. We do not want to put a bunch of work on our EHR partners on something that may not be used. And also just to call out there is no specification right now IIS to query under an immunization specific use case. It is really focused on the patient use case that includes immunization. I think that the language could be cleaned up a little bit around that as well,

Bryant Thomas Karras
Be careful what you wish for Mary Beth. I would love to assign you as a task force member to assemble these comments and Hans's concerns from the EHR side and do a new proposed draft language maybe putting it into the discussion section so that it is cleanly identified as the replacement language that we recommend Office of the National Coordinator for Health Information Technology (ONC) adopt rather than what is in the proposed rule adding in some of those nuance terminologies, addressing the potential flip-flop of the actors in that bidirectional exchange. I think to Hans's point, we want to be really clear who is the sender and who is the receiver in each half of the bidirectional exchange so that it is not misinterpreted. I feel like in the past we have had, this may be in the measure category, we have separate criteria. One for the immunization administration reporting and then, a separate whole transaction measure for the querying and forecasting receipt rather than bundling them together into one (f)(1). I think it becomes a bit concatenated. We are running low on time here. Are there any hands up?

Rachel Abbey
No hands up. I would just encourage people to continue to include their comments in the member recommendations in addition to that. We are going to move to (f)(21) now.

Bryant Thomas Karras
Are you okay with having Mary Beth put her so it does not get lumped in with the recommendations putting it into the next cell over?

Rachel Abbey
Yes. That is great.

Bryant Thomas Karras.
So (f)(21), can we have somebody from the CDC program area read it or should it be a task force member, Rachel?

Rachel Abbey
I do not think it matters. Anyone can read from the summary.

Bryant Thomas Karras
Does anybody volunteer to read the proposed rule summary for (f)(21)?

Chrissy Miner
This is Chrissy Miner from the CDC. I can read the proposed rule summary.

Bryant Thomas Karras

Great. And you are not opining if you are reading what is there.

Chrissy Miner
Yes. Unless you sneak some language in there that I have not read yet. "The immunization information receive, validate, parse, filter, exchange that would support enabling a user to receive, validate, parse, and filter electronic immunization information according to the updated HL7 251 implementation guide. Respond to incoming patient level queries from external systems, including providing immunization information and structured data. Functional requirement."

Bryant Thomas Karras
My interpretation and I think, Hans, back to your point, is that this is the criteria for the public health IIS to have the function as opposed to the EHR. Mary Beth, you and Hans both have comments here. Do either of you want to jump in or is there a hand up?

Hans Buitendijk
I will put my hand up to start with. I may reference that, too. A couple of things is that the naming I think we already talked about so we can sort through that and that it nicely aligns with (f)(1). It makes it more clear. In the content itself, a couple of thoughts. One is the first comment I made there is having both data supports so that a provider can support both data queries for immunizations is a helpful tool. And by having it more clearly on the IIS side, it would not obligate that a provider has to use the bulk data because depending on what they do, the context of the volumes of what they are trying to do. And not every provider needs to support bulk data. I think it is a proper one for (f)(21) to support as the source of the data to have it available. But as the "client" of it, not every provider should be required to do it. If you have a practice, are they really going to have a high volume that you need to do it? It may not be necessary to use that. They can just do a multiple individual patient HL7 Version 2 based.

So, I think we want to be very careful about that. And that was not clear in the current description in (f)(1) and (f)(21) combined. The other comment is around, and it is a more clarifying question, there is a reference to the Integrating the Healthcare Enterprise (IHE) standard and I just want to make sure I understood the intent of that more clearly. That is a question just for clarity. What was the intent of the reference to the IHE/ITE infrastructure technical framework Volume 2, which seems to be in (f)(21)? It references 172.05P1. Is there a need for that on the IIS side or not? What would it do? We already have the Version 2 response to a query and we have a bulk data query response. What else would we need?

Bryant Thomas Karras
Mary Beth, do you have any guesses on that or are there any other staff from AIRA?

Hans Buitendijk
Or did I misread it? That is possible, too.

Mary Beth Kurilo
I might have to take that question back, Hans, because I am not sure about that and I do not know that we jumped into the part of the rule but I would be happy to take that question back.

Molly Prieto

Mary Beth, just for context, too, that would be some of the detailed regulatory language. It is not within the preamble section. It is pointing to some of the technical capabilities available as optional receipt.

Mary Beth Kurilo
Okay, thanks, Molly.

Hans Buitendijk
That would be helpful to understand because it is optional so it is helpful from an IIS perspective. What would then be the expected counter side be on the provider side because all mindsets were VHUs, etc., Version 2 and possibly FHIR-based.

Bryant Thomas Karras
How much time do we have left on this? A few more minutes?

Mary Beth Kurilo
I see Steve has his hand up, too.

Rachel Abbey
We are on time. We have about nine minutes.

Bryant Thomas Karras
Okay, good. I will call on you in a second, Steve. On the bulk FHIR, Hans, in terms of this certification of public health's functional capabilities, it is making me a bit nervous that we can get commercially available and open source IISs up to speed on that capability between now and the delivery date, especially not knowing whether or not and how many providers are going to actually want to take advantage of that. I think there is probably some open discussion we can have on bulk FHIR, specifically in this IIS certification process but thinking about how its applicability to other potential use cases as well.

Hans Buitendijk
I was not trying to say that the IIS should do it. But if bulk data is addressed, I was looking at the other side of that the provider should not be required to be able to query bulk data if that is not necessary in the context. I have a separate question on the concern, generally, on al of the sides is that is the volume of the requirements that is upon us, is that reasonable for the time window provided? That is a separate question there. And I can understand absolutely we have seen it ourselves as well that is everybody ready for something?

Bryant Thomas Karras
Okay, Steve?

Steven Eichner
I will echo the same kind of thing. In thinking about the pace at which items have been introduced and included in the United States Core Data for Interoperability (USCDI) or read as a regulating measured pace and keep thinking. As we are looking at bulk FHIR in particular, we are looking at a very advanced rate of adoption where we have really not done much work in this space in the real world at a small level either on the public health side or on the provider side. And I am a little concerned here. We are not just talking about

a functional message based capacity. We are actually talking about a cycle based capacity both on the provider and on the public health end. And we do not have a lot of experience on that. What does it mean to scale that up in a rapid pace? What are the cost impacts for everybody? What becomes the potential response parameters for bulk FHIR? If I have 15,000 providers, for example, in the state of Texas, and they all query for their entire patient population on a daily basis, how fast can I respond? How fast can I be expected to respond?

We have not really contemplated that from a regulatory standpoint or a service standpoint. And I think those are some of the impacts we need to think about and they are outside of the scope of HTI-2 but those are necessary functions that we have to have in place for this to be operationalized.

Bryant Thomas Karras
Yes. Other thoughts.

Mary Beth Kurilo
I will just jump into our experience with the Helios bulk FHIR query work. I think community is conceptually in support of it. We have seen very slow adoption in part because there is not a dedicated funding stream and in part because there does not seem to be a demand to date on the part of health payers or large provider organizations or the groups that we thought would really be interested in this functionality. We do have some concerns about the timeline, as you said Bryant, and there is also not a current specification written yet to date. I think that would need to come first and it makes me a little nervous to think about moving forward with this being in the proposed rule if there is not a bulk FHIR/ query specification out there that has really been tested and vetted.

Bryant Thomas Karras
We might want to put some stepwise recommendations that further pilot testing or with the term that ONC used for its advanced practice site, some real-world tests before we incorporate criteria into the public health certification. We need to make sure that there has been some vetting of what exactly is that we are asking people to be ready to do. We have less than five minutes left, Mary Beth. I am extremely passionate about smart health cards and smart health links. Can you talk a little bit about your thoughts on the mention of those capabilities in this and are we seeing at least in the US, a large number of IISs supporting that going beyond the covid vaccines to other vaccines?

Mary Beth Kurilo
I think we saw it heavily supported during corona virus disease (COVID), specifically for COVID vaccines. At that point, we had somewhere between one half and two thirds of IIS who were building in the smart health card framework to respond to consumer needs. However, where we are struggling a bit is thinking about the full lifespan record using the smart health card framework, which is fairly limited just in terms of the sheer size of the quick response (QR) code and how many immunizations you can really represent. I think it is easier to think about this in terms of patient receiving a QR code for immunizations they received on that visit that day. But it is harder to think about the full lifespan record actually being transmitted through a smart health card QR code. We have done some work around smart health links and we would like to see that explored as an alternative to smart health cards, as they do have just more room and more flexible, scalable technology to incorporate the full lifespan record, which I think typically is what both patients and parents are going to be looking for in terms of consumer access piece.

Bryant Thomas Karras
I think we could provide some alternative language back that includes that transition from smart health card to smart health link. There is a ballot in September going forward, which will be too late. It might be just too late for inclusion. But timing wise, maybe it would be able to be referenced for the smart health card, smart health link standard instead of just smart health card. I think it is being moved forward as a joint HL7 standard. I also think there is an opportunity for us to utilize the immunization component in the international patient summary and use perhaps if we get all public health agencies across the country to be supportive of International Patient Summary (IPS). It really signals that immunization practices part of a global initiative to prevent disease. That is language I did not see in the rule that I was kind of hoping for. All right. We are at time. Marybeth, do you have your homework in terms of the (f)(1)? And I can work together with you on the smart health card, and smart health link language for (f)(21). Hans, do you want to –

Hans Buitendijk
I am happy to help out if we go back and forth by email or a quick call. I did put **[inaudible] [00:32:40]** on bulk data, as well indicating that the threshold is having an Implementation Guide (IG). Until that point in time, it is premature.

Bryant Thomas Karras
I like that. It punts or kicks the can down the road. Yes, Steve?

Steven Eichner
I think using smart cards on the IIS side does need to be optional because different IISs are at different levels of development in the surrounding supports for it to work, not necessarily on the technical level but on personal identification information. It may or may not be in place in different jurisdictions and that may require some substantive investment.

Rachel Abbey
Bryant, we need to move onto cancer.

Bryant Thomas Karras
I do agree. Let us move on to cancer. Steve, I recognize that and I agree. I think there is some problem in the public health certification with some of these advances not necessarily being prioritized or funded by either CDC block program funding or states being able to raise the resources to make those changes. We will have to examine the timeline. Maybe we make that a super optional component as opposed to what we see as core capabilities. All right. Let us scroll down to the cancer section. All right.

Rachel Abbey
I think we need (f)(4) first. We have to do the existing criteria first.

Bryant Thomas Karras
On to our next pair. Are there folks from CDC's cancer program that would like to read through?

Chrissy Miner

Yes, we are available. Sean, would you like to read through the rule and I can kind of talk about our involvement?

Sean Porter
Sure. “Revise transmission to public health agencies, cancer registry reporting, certification criteria 170.315(f)(4), revise transmission requirements via updated standards, HL7 CDA Release 2 implementation guide. Reporting to public health cancer registries from ambulatory healthcare providers Release 1 Draft Standard for Trial Use (DSTU) Release 1.1, US realm or the cancer FHIR reporting bundle and accompanying profiles according to the HL7 FHIR Central Cancer Registry reporting content IG 1.00 Standard for Trail Use (STU1) and 170.205 I3, with the requirement that all data elements indicated as mandatory and must support and the IG must be supported. Expire existing standards on January 1, 2028. New, include cancer pathology reporting according to the HL7 FHIR cancer pathology data sharing 1.0.0 STU1. Change name to cancer registry reporting– transmission to public health agencies.”

Bryant Thomas Karras
Before you scroll over –

Rachel Abbey
Hans has his hand raised, just so you know, Bryant.

Bryant Thomas Karras
I just wanted to, without opining, try to understand the "or" means it is one or the other so we are not asking providers to report both in Clinical Document Architecture (CDA) and FHIR. They pick the standard they are most ready for. But public health has to be able to receive both, presumably.

Chrissy Miner
Yes.

Bryant Thomas Karras
Then the expiration of existing standards, which existing standards? The two that were just mentioned or the legacy ones that predated this new edition?

Chrissy Miner
The legacy ones that predate the updated ones.

Bryant Thomas Karras
At that point in time, we would need to presumably, public health, when we get to the (f)(23) has to be able to do both the legacy ones and these two new ones. It is going to be a busy time for the next three years. All right, whose hand is up?

Hans Buitendijk
I think that is me, Hans. I had the same question as you had at first and I wanted to be sure that the choice is between the CDA standard and the cancer FHIR reporting bundle. But separately, the cancer pathology reporting that is separate and that will be FHIR if it is done as proposal. There still would be a FHIR component in that criteria, correct?

Chrissy Miner
That is correct.

Hans Buitendijk
I thought I read that correctly. I just want to be sure. There is a small detail in that we do not need to resolve now. But I am trying to figure out whether we are supposed to point to 2C or 1C, but that can be addressed separately as a quick follow up as pointing in the right direction as intended. We do not need to talk about it today.

Bryant Thomas Karras
Great. Without asking you to opine, could the cancer program state factually what your involvement is? And if I could ask a follow up question, specifically are the Surveillance, Epidemiology, and End Results (SEER) academic cancer research registries and state-based registries that CDC, the cancer plus suite, are able to receive all the three standards that we have talked about here, the pathology, the FHIR, and the CDA updated?

Chrissy Miner
Sure. I can talk to our involvement, then I will leave it to Sean to kind of answer the question about the SEER registries. CDC, Net Collection Rate (NCR), we worked on the current project for about 2.5 years and provided the reference to the CAP checklist, IGs for the pathology, and the EHR reporting, the FHIR central registry reporting IG for the ambulatory reporting, and we also proposed the use of the FHIR IG for cancer pathology data sharing. CDC developed both FHIR IGs within the community. And then, we tested them at HL7 Connectathons. It was also demonstrated at Healthcare Information and Management Systems Society (HIMSS). And then, CDC is also leading the work in updating the CDA IG as well. And then Sean, I am not sure if you have additional information regarding the SEER question?

Sean Porter
One last aspect of that is we are actively working on developing the FHIR standards in our registry plus suite software. We have tested those and we have piloted the FHIR standards with a couple of different registries. So, by the time this goes into effect, we will have the ability to handle all three within the software that National Program of Cancer Registries (NPCR) develops for state cancer registries. Regarding where SEER is at, we have been in meetings with them. And to be honest, I cannot answer where they stand on that. I can get back to you with that information. But I do not know that as of right now.

Bryant Thomas Karras
This is an ONC rule, but the impact is on both CDC registries and National Cancer Institute (NCI) supported registries. We want to try to keep things well coordinated between those two, I would presume.

Sean Porter
Absolutely.

Bryant Thomas Karras

But it is good to hear there is already development in the works in the schedule to make sure the registry plus suites are updated. Will there be implementation funding that accompanies states needing to upgrade from one system to the other?

Chrissy Miner
Bryant, we cannot answer that. We are not going to necessarily opine on what could be or how we would finance it in this panel. We appreciate the suggestions of this panel for what it means for programs and for ONC's policy, but we are not in a position to speculate.

Bryant Thomas Karras
We will have to look carefully at the impact assessment and whether or not the appropriate cost estimates for what the impact for state agencies to migrate their systems. Obviously, the CDC providing free software is a great step towards that but there are still implementation costs to upgrade. Two minutes left. Are there any other hands?

Rachel Abbey
We are actually on one minute.

Hans Buitendijk
I have my hand up. Just a brief note and more to follow. In the cancer registry, a couple of concerns we are going to be talking about from the EHR perspective that having a choice of CDA versus FHIR is helpful on the provider side. Most will likely go to CDA around given current adoption and rollout. But we are working on the refinement to some of the thoughts. But on the cancer pathology, there is a concern that the guide is not very firm yet. Adoption is not there. There is work in progress with Version 2. The conversation is going to be focusing on should it actually be permitted then to focus on V2 adoption and progress the efforts on getting that more widespread given that the FHIR guidance is not quite at the level it needs to be at the point in time. There are a number of concerns around requiring and jumping too quickly into the FHIR cancer pathology spec.

Bryant Thomas Karras
And Connectathon testing is one thing. Real-world use is another. We are out of time. Abbey, I do want to push back a little bit. I am not asking you to opine or speculate on future funding. But can you talk a little bit about have cancer programs to date gotten any modernization funds? It feels like it mostly went to COVID and infectious disease areas within state infrastructure enhancements.

Chrissy Miner
For us to talk about what is the state of play right now is reasonable, and I would turn it to Sean and Jessica. We can talk about what does the landscape look like. We just do not want to speculate on what it will look like. So Sean, Jessica, I will refer to you both.

Jessica Diamond
Without going into specifics, there are several states where funds have been allocated right now for several data monetization projects. One of them being our Cloud pilot. There are definitely monetary proposals for these things. Sean, I am not sure if you have anything else to add for that but there are several projects right now that are ongoing. I do believe there are funds involved with those.

Sean Porter
I think you covered it. The one thing I did want to state is we have the on premises registry suite products. And we have a big push to move most of those to the Cloud. And what that will mean for registries in the future is that they will no longer have to have local servers or local machines specific to run these local applications. It will be in the Cloud, so it will be able to free up some of their resources. So, while there may not be additional funding, the funding they are getting will be freed up for other aspects.

Bryant Thomas Karras
We need to move on to (f)(24) to talk about that it is apropos that we are talking about resources to state public health agencies to migrate those on premises servers running the registry plus software to a Cloud enabled version. The standardization of that Cloud enabled version would presumably make it easier for states to pass a certification, more consistency begets easier certification and standardization. One closing thought on the financial impact. Scaling it to all states, not just the pilot states that you have worked with and then, thinking about a downside to Cloud migration is that Cloud server costs have to be paid or the Cloud goes away. An on premises server, once it is paid for, at a nominal charge, you can run it in the back room, even if there is a delay in federal funding to come down so you can pay your monthly Cloud server bill. We have to be careful with this modernization and advancement, we do not get ourselves in a precarious situation.

Molly Prieto
This is Molly. You mentioned it would be states going through certification. I just wanted to clarify that the requirements would be for the systems themselves.

Bryant Thomas Karras
Correct.

Molly Prieto
Also, Steve has his hand up.

Steven Eichner
Really fast, I think it is important to distinguish between something hosted in the Cloud and operated by each individual jurisdiction versus an Application Service Provider (ASP) model where CDC or another entity may be hosting the application with different data channels for the different jurisdictions. The challenges later, of course, is looking at customization that may be needed by the particular jurisdiction. So, that is a trade-off that needs to be well understood if we are going down that path. Obviously, if we are in a shared ASP model, certification may be become much easier at the cost of customization.

Bryant Thomas Karras
That application as a service you are suggesting that CDC might run it centrally in a Cloud as a service model that states could take advantage of?

Steven Eichner
I do not know if that is our example. I think it is important to distinguish when we talk about Cloud hosting what is indeed met. And that can be a challenge for different jurisdictions. We in Texas have constraints

about what we can use as a Cloud hosted service and what certifications are required to use a Cloud hosted service.

Bryant Thomas Karras
It is probably going to have a very different feel in different jurisdictions. We had a law passed that we have to use a state run Cloud environment, unless there was a compelling reason to use one of the commercial Clouds or government Cloud infrastructures. But can we get somebody from the program area to read the proposed rule summary for the certification of the systems? And thank you for the correction earlier, Molly. It is the systems that are being certified, not the jurisdictions. Could somebody read the (f)(24)?

Sean Porter
Sure. I will do that. "New, establish new certification criterion at 170.315(f)(24) cancer of pathology reporting – receive, validate, parse, and filter that would support enable a user to receive, validate, parse, and filter cancer pathology information according to either the HL7 FHIR cancer pathology data sharing IG." And it seems like there should be more to that.

Bryant Thomas Karras
Is there cutting and pasting here? There is the continuation in the next row. I believe you just scroll down a little bit more.

Molly Prieto
(f)(24) is just for the pathology. That is correct.

Bryant Thomas Karras
But the sentence structure to either and then, there is only one thing listed.

Molly Prieto
I think that is a copy and paste error on my end. It would be according to the cancer pathology sharing IG. Apologies.

Hans Buitendijk
So, it would only be for the pathology, not for the cancer CDA or FHIR?

Molly Prieto
Correct.

Sean Porter
There is no CDA for pathology.

Jessica Diamond
Right. It is just the FHIR.

Bryant Thomas Karras
And there is no proposed certification of the systems to the existing registry functionality, only to the addition of the pathology?

Molly Prieto
That is correct. That was always in the proposed rule.

Jessica Diamond
Yes. Certification for the FHIR.

Hans Buitendijk
I am not sure whether this is a fair question or an appropriate question that can be answered, but was there a particular rationale why only the pathology component of (f)(4) was picked up to the Periodic Health Assessment (PHA) side and not either of the CDA or FHIR options for the cancer reporting? I am trying to understand the rationale of why that was not mimicked on the receiver side.

Jessica Diamond
As of right now, CDA is pretty much primarily used for ambulatory reporting. It is not something that is customarily used for pathology reporting. To date, there is no certification criteria for pathology reporting so moving forward that is why it has been developed to have something standardized, the first standard of its own to certify pathology reporting using the HL7 FHIR.

Bryant Thomas Karras
Right. But I guess what folks in the chat and Hans and I are wondering is why is there not a certification criteria for the core functionality of the registry, the reporting of the cases themselves, either by CDA or FHIR.

Chrissy Miner
We are not allow to opine on that particular component but that could be something that you all decide to include as a comment if that is a shared recommendation.

Bryant Thomas Karras
We are probably almost at time. But I am wondering if we need to make recommendations that the first pass certification for (f)(24) should be with something more well-established if we are going to get it up to speed in two to three years and do it at the CDA 1.1 or 1.3 that involves CDA criteria for testing of the systems as opposed to something that is still relatively fresh and not well implemented across the country.

Hans Buitendijk
And maybe, Bryant, addressing the principle that we are starting to go here, which is a good principle, whatever is on the provider side that they need to be able to send and certify to, wherever that lands, that there is the companion receipt capability that can then be certified to ensure that the receiver can handle that same one as well. We are starting to see that in all the (f)(1) through (9) and (21) through (29), and we are seeing it with payer and provider. And it is a helpful thing because there are two sides of the interoperability. What is the responsibility of the provider to do this and then, what is the responsibility of the receiver to work with that or vice versa?

Bryant Thomas Karras
The (f)(24) is the receiver capability.

Hans Buitendijk
That is only for one component of (f)(4).

Bryant Thomas Karras
Right. I feel like we can make a recommendation that maybe we start with one component but they may have picked the more ambitious one to start with. And we should have started with the lower hanging fruit for the first pass certification. We are at time. Are there any volunteers from the task force itself that could help craft proposed language in the spreadsheet? Do not all jump forward at once.

Hans Buitendijk
It will be a little bit later but you can definitely put me in there if nobody else was interested.

Bryant Thomas Karras
I should probably make sure there is somebody from the state perspective. I am hinting to Erin, Steve, or myself to volunteer and come forward. Is there anybody else who has had a background in cancer registry systems?

Hans Buitendijk
I am happy to work with Erin on that list.

Erin Holt Coyne
I am happy to get it started.

Bryant Thomas Karras
Thanks, Erin. Most states are using the CDC supplied registry plus software.

Erin Holt Coyne
Board certification criteria with the report as opposed to the pathology?

Bryant Thomas Karras
Yes. It is a relatively new capability for the software to receive the pathology FHIR components. If we only certify it once or do we need to certify it in every state with real-world testing is kind of an open question for me.

Steven Eichner
I think with any deviation from the norm, you would want to recertify, otherwise you are stepping away from the guarantee. That goes across the board for anything, not just for cancer reporting.

Bryant Thomas Karras
My phone is blowing up in another meeting that I am not attending. All right. We need to move back up to electronic case reporting (eCR) to (f)(5). All right. Can we get a volunteer?

Joel Hartsell
I can read it. “Revise transmission to public health agencies electronic case reporting certification criterion at (f)(5). Revise transmission requirements via updated standard, HL7 FHIR existing electronic initial case report (eICR) IG. Expire existing standards on January 1, 2028. And change name to electronic case reporting transmission to public health agencies.”

Bryant Thomas Karras
Joel, you do have comments in here, but I will start with this one jumped out and struck me as ambitious that we are migrating from the existing CDA based to FHIR IG at a relatively rapid pace. And 2028 is not as far away as we imagine considering how long it took for us to get to our eICR capabilities in this country. Go ahead, Joel.

Joel Hartsell
I would echo that as well, particularly when you consider HTI in January 1, 2026. Of the EHRs that we are working with, most have started or many have started already with kind of indicating they are moving towards 3.1 and have suggested that they will not pivot on that in the short term because development is either started or too far down the line. I will let EHR representatives chime in on that. But with HTI-1 allowing CDA or FHIR, that is likely going to impact their trajectory pretty dramatically. We have only had one EHR indicate any interest in moving towards FHIR at this time. Not that it cannot be done on EHR, but it suggests a delay in the timeline to when FHIR would be implemented. And this kind of trends towards F25 but likely will indicate that that transition to FHIR right around January 1, 2028, which does not give public health much time to kind of prepare and see real-world data in an effective manner. And so, I can spend more time on that.

Another thing I wanted to call out in here is, and I know this is not a proposed change but it does reference the RCTC and I think it is important to note that the RCTC is Reportable Condition Trigger Codes for those that do not know. What it should be pointing to is the Electronic Reporting and Surveillance Distribution (eRSD), which includes the trigger codes but also the trigger timing parameters and metadata that is critical for the triggering process to ensure all the data gets to public health in a timely but complete manner without overburdening the public health agencies. And so, worth calling that out as well to potentially correct that language.

Bryant Thomas Karras
Yes. Laura, I would like to ask, from the program area perspective, can you talk about the current states? How many EHR vendors does it feel like are using the EHR or Electronic Initial Case Report (eICR) now FHIR implementation versus a more classic CDA implementation?

Laura A. Conn
Thanks, Bryant. We are working with between 50 and 60 vendors in an ongoing way. About 60% of those are implementing the eCR now FHIR app. The FHIR app currently I think, as most folks know, it uses FHIR interface with the EHR in the healthcare organization setting, but it produces CDA currently 1.1 will be advancing to 3.1 according to HTI-1 requirements but does also have capability to produce the FHIR eCR. It has not produced it yet because of the capability in public health agencies to receive CDA and not FHIR. But we do have a path forward for that trajectory to support the sending of FHIR through the intermediary

and to public health agencies. But again, as Joel has said, the capability on the public health agency side does not exist yet either or is very nascent for the most part.

Hans Buitendijk
And that is an important point because in the discussion is that where you have that app capability, the app can either be CDA to FHIR. I think the comments that perhaps there is only a small portion that is working with FHIR needs to take into context that you can switch over to FHIR and you do not need to change anything on your EHR side. And so, there is a bit of a discussion that would indicate those that do not use that would have to switch over. And is that a reasonable time window to do that? That is a very fair question. There is at least a common element that PHA should be able to, not only for certified software but for other ones, be able to continue to support the CDA variety. But that does not necessarily mean that FHIR, therefore, is not an appropriate alternative for PHAs to start to look at because of the capability. And Laura indicated it is actually a switch to go from one to the other. It is not that everybody needs to build that back into their EHR.

So, there is a bigger picture that we need to look at there as well. You will get different kinds of feedback, are we ready or not, and in part that depends on if you are using the app or not because it makes life a lot easier to switch over to FHIR than if you have to do it inside of your capabilities. Both are valid. I am not arguing that. It provides different options and readiness of jumping over and there are advantages of this. Everything is moving FHIR based expressions to get that consistency. There is advantage to CDA because that is already well-established in our areas. I think this is not going to be an easy it is one or the other. It is probably for the receiver need to get to I can accept both. And it is a typical thing that we see on the EHR side. All parties can use multiple formats. And we need to handle them all. This is one of those examples where PHAs may be in the same environment needing to be able to support CDA and FHIR together for some period of time before everybody is ready to switch over to FHIR.

Bryant Thomas Karras
I am going to put Joel back in the hot seat for a second. We are not certifying jurisdictions here. We are certifying capabilities or systems. And I wonder if APHL's infrastructure goes through that certification process and has the capability on the behalf of jurisdictions. That might potentially be an easy button path to get states up to speed by the proposed timeline.

Joel Hartsell
This is where I am less concerned about the transition on the healthcare organization side. We are implementing FHIR to CDA, CDA to FHIR transforms on the platform, which would enable jurisdictions to opt to receive CDA or FHIR as they scale their capabilities at the jurisdiction. So, regardless of what the healthcare organization was sending, there would be a manner to kind of assist jurisdictions and receiving one or the other based on their current capabilities or progressing capabilities.

Bryant Thomas Karras
We are at time, unfortunately. But, can you close this out with jumping back to your comment that only one EHR vendor inquired about the new FHIR IG. Is it they are waiting for it to go into rule?

Joel Hartsell

In my discussions with the EHRs, and a lot of this was with EHRs that have vendor developed solutions not using the app, it was a much greater lift for them to transition to FHIR. I think were hesitancy on that front, which is why they were pursuing the transition to 3.1 from 1.1 rather than the transition to FHIR. I have not had in depth conversations with app users. It is a functionality of the eCR and now FHIR app to enable sending out FHIR. And so, it should be a lower lift for those using the app.

Bryant Thomas Karras
We need to move into the public health or the receiving side discussion, (f)(25). But I think some of this creates a dependency. If EHRs are not ready to do FHIR natively and we are only seeing traction in the use of eCR now app, are we ready? Let us scroll down to (f)(25). All right.

Joel Hartsell
Do you want me to read again?

Bryant Thomas Karras
Sure, unless Laura or someone on your team wants to.

Laura A. Conn
I can do it and then, we will let him do that. “Establish new certification criteria at 170.315(f)(25), electronic case reporting, receive, validate, parse, filter, electronic initial case reports and reportability responses and create and transmit reportability responses that would support enable a user to receive, validate, parse, and filter electronic case reports according to the identified HL7 eCR FHIR IG.

Bryant Thomas Karras
We are making the leap to FHIR. Scroll down to the next row. That is the end. Unlike the other sections that had an expiration date of previous existing standards, here we are just mentioning FHIR and not any of the CDA capability.

Aaliyah Parker
This is filtered for today's information. There could be more after those but it is filtered right now.

Bryant Thomas Karras
Hands or should we go through the comments that are in the recommendations starting with Hans?

Rachel Abbey
Steve had his hand up.

Bryant Thomas Karras
Steve?

Steven Eichner
Sorry. Move on.

Bryant Thomas Karras
Hans Buitendijk.

Hans Buitendijk
The comment I made is in line with the prior comment that I made. It is always important that where a center has options that the receiver is able to support both. I understand that we have the other argument as well, in the discussion point, but where we would land that the provider could do either one then, we have to find a way that the receiver, either themselves or through an intermediary, has the ability to then receive either one or the other and accommodate that. And that is a principle we have used in a variety of places. I think that should logically happen here. Notwithstanding the other comments and considerations, are we ready for it or not? What does it mean? But somewhere in the path, it needs the ability to accept either of the options.

Bryant Thomas Karras
I am going to push back a little bit, Hans. Since we are looking at the PHA receiving side, I do understand or appreciate if we are trying to get people to move towards FHIR that putting the certification process squarely on the FHIR side of things signals longevity or a destination to be ready for that. And it is painful to put resources into a receipt capability for something that you know is eventually we hope going to be phased out.

Hans Buitendijk
That is a mutual feeling that is always in play.

Bryant Thomas Karras
And I will turn to Joel in a second. If our intermediary, the APHL, can handle the transition period for us then, we can have the receipt and the receipt parsing and incorporating be managed with a single standard rather than having to support multiple standards. But Joel, you have lots of comments here.

Joel Hartsell
I think a lot of my comments are centered around the timing of the certification. Timing and around the utility of the data that is coming from the eCR. The first is around public health infrastructure investments. PHAs have spent significant resources and effort to build infrastructure to do everything that is called out in there, process, validate, parse, ingest the content filter, the content of eCR data into their surveillance system. This has all been around CDA. But they are not just augmenting their surveillance systems. They are implementing new systems for the processing and adaptation of the clinical data that is originating in the eCR for public health specific use. So, this is kind of a unique use case for public health reporting. However, only a small percentage of the jurisdictions are really processing the data into their surveillance systems. Many are starting to get over the hump of using this data effectively but requiring FHIR certification on this timeline.

And I know it is optional, but that push would necessitate a shift in focus for FHIR preparation rather than continuing to build the infrastructure and augment the infrastructure to fully utilize the content of the eICR. And so, what I see likely happening is we progress on the FHIR front but causing delays and significant rework of not just the surveillance system but those intermediary processes that are really distilling the benefits of eCR. It is likely going to impact the ability for healthcare organizations to turn off manual reporting. If they are having to focus towards this, they are not addressing data equality. They are not addressing that grouping and filtering of the content within the eICR. Similarly, going down this line, there

is significant variation in public health agency capacity and infrastructure, which is why on the platform, we are implementing those transforms. Some jurisdictions may be ready for FHIR earlier than others, but there are others that that is to be a much bigger lift.

I would strongly recommend staggering healthcare organization and public health certification requirements to a greater timeline to enable progression and utility of the content and really see the benefit of the eCR before pushing on just the transition to FHIR. Adding to these challenges, funding limitations still remain. And so, this new requirement requires new expertise, new focus across all of these use cases. A lot of times within jurisdictions, it is similar resources that are working on it. So, there are new standards across these various public health use cases that are going to require augmentation of their system, of their processes. There is going to be a funding need to scale expertise and augment infrastructure. And similarly, I am saying that certification, I know it is optional but historically, we have seen things like this get tied to funding for public health agencies reading the tea leaves here a little bit. But if it does, it is going to delay their ability to continue adding value to eCR by building out the infrastructure needed to use it to its fullest extent. I can stop there and do the last one in a second.

Bryant Thomas Karras
I will come back to the last one. I assume that was on the Reportable Conditions Knowledge Management System (RCKMS)? Let us come back to that because that is a complexity. Where does that RCKMS persist? They did not name a single infrastructure in this rule so there is some clarity needed there. But can we scroll back to the language itself? Receive, parse, filter. It is create and transmit portability response. But receive, validate, parse and filter. Here is the challenge that I think we have, Joel, is that APHL can help with the receive and potentially translate from FHIR into something that agencies are already able to receive and can handle that last bit, the reportability, create and read, and send the reportability response. But that parse, filter and presumably incorporate into our case management systems is a lift that is going to require the vendors and/or homegrown systems to improve its ability to handle this data in whatever format it is in, XML or FHIR. Erin, you made a comment in the chat. Do you want to turn your microphone on?

Erin Holt Coyne
For the surveillance systems? Which comment, sorry?

Bryant Thomas Karras
The surveillance system. You made a new comment, not the double-edged sword one but the surveillance system. You are a Net Space System state. We are a Maven state. Both of our respective suppliers would have to increase their capability to be ready for FHIR.

Erin Holt Coyne
Yes. If we are thinking about, from my perspective and I might be a bit idealistic here, but if we are thinking but practical application, practical implementation, at the end of the day, if the public health jurisdictions are not able to use their systems to actually use the data as opposed to just viewing an image on Glass, to me this certainly helps get us piecemealed information. But it does not necessarily help us leverage the data that we are actually receiving and supporting computable semantic interoperability. That is kind of our whole point is to be able to use this data. And as long as our surveillance systems are not held to those standards to be able to support the receipt, validation, parsing, or at least a portion of that, we are not going to be able

to mine that rich information that we are receiving from our clinical care partners. That is going to be problematic. To me, that is missing the practical application point of this. And do I think that will be a problem? Probably.

A hard pill to swallow? Yes. But that is our goal. That is where we are wanting to go. Maybe we change the date, we bump it back. Maybe we take another look at the standards and submit comments accordingly into the STE process for some these things to make them more palatable and more implementable. But I think just simply relying on intermediary to solve all of the problems, unless there is a clear path forward beyond that.

Joel Hartsell
I do not think the intermediary cab solve the validate and filter, unless they are talking about RCKMS. But you need more moving and filtering functionality at the jurisdiction level in order for this to be useful. So, I agree those need to be defined. They certified at FHIR. That is big enough that the utility may not be there as well in that timeframe, which will lead to jurisdictions needing to develop their own infrastructure to do that, a middleware solution to be able to do that.

Gillian Haney
Can there not be shared services at least be able to filter as I am defining filter? Can those not be deployed to support public health agencies?

Joel Hartsell
We are doing that. APHL is doing that for jurisdictions and developing solutions for jurisdictions to do a lot of this functionality that would be implemented in the PHA environment. Right now, it is all CDA focused. We are intending to augment for FHIR as well for jurisdictions that intend to use this. Again, it is a matter of resources and functionality for jurisdictions to take it and implemented within their infrastructure.

Bryant Thomas Karras
Joel, we are at time on this one. Can I ask you to take your discussion and put it into the next cell over a draft rewording that maybe addresses some of these incremental capabilities? And I propose friendly amendment that we reorder and do the filtering that APHL can do to only send the reportable conditions onto the jurisdictions happens before the parsing and incorporating into our electronic case management, case investigation systems. And that like meaningful use and the EHR systems from the HITAC bill, they had to walk before they could run. And Phase 1 of meaningful use was installing the systems. Phase 2 was receiving and transmitting the data. And Phase 3 was actually, to Erin's point, doing something meaningful, having the impact of utilizing. Maybe we need to set a less ambitious goal that by 2028, we are able to receive these in FHIR and by 2029 or 2030, we are able to fully incorporate them into the Net Space System, Maven, Epi Tracks, and Home Grounds. That is going to take the developers of those systems some time to get ready.

Joel Hartsell
I think the goal is to delay to ensure that we are not walking until 2028 but hopefully running by 2028.

Bryant Thomas Karras

Yes. And my intent is not to slow walk the whole thing but to try to be appreciative that the work plan for each of these systems, we cannot make these changes overnight, unless we just do it superficially and that does not feel like what the intent is here.

Rachel Abbey
Bryant, I hate to be the bearer of bad news but we should move forward because we need to tackle ELR and we budgeted time for 30 minutes. Unfortunately, I think we are a little bit behind so we are going to end quickly at 12:50 to take public comment. Then, we can continue this discussion and if needed, we will have to push some into the next meeting.

Bryant Thomas Karras
The good news is that ELR is more well-established. The bad news is they are adding new complexity to the standard.

Gillian Haney
I can do it, Bryant.

Bryant Thomas Karras
I was going to say I see Jason Hall, an old familiar voice for ELR but go ahead, Gillian.

Gillian Haney
Establish new certification criteria –

Rachel Abbey
Actually, sorry, Gillian. We need to go to the existing criteria, (f)(3) first. Sorry about that.

Bryant Thomas Karras
Scroll up to the first part of the pair.

Rachel Abbey
Sorry about that.

Gillian Haney
"1.) Update electronic lab reporting certification criteria in 170.315(f)(3) as reportable laboratory results transmission to public health agencies and laboratory orders receive and validate. Revise transmission requirements by updated standards HL7 Version 2.5.1 implementation guide laboratory results interface (LRI), Release 1, STU Release 4 US realm. New receive and validate requirements by a new standard HL7 Version 2.5.1 implementation guide laboratory orders interface LRI from EHR, Release 1, STU Release 4 US realm."

Bryant Thomas Karras
All right. Hans, you have got a novel written here.

Hans Buitendijk

I was trying to follow Joel on the other topic. I think there is an interesting topic because we need to look at (f)(3), (23), and (a)(2). And I started to look at it from the perspective of the introduction of effectively Letter of Intent (LOI) and LRI where ELR is part of the LRI guide at this point in time based on the proposed versions. Where the question becomes it is not now only (f)(3) and (f)(23). What is applicable as you communicate the lab orders to include some or all of those guides, depending on whether they are going to be involving public health are not, and with (a)(2) because it is meant to not be limited to public health. I think before I go too far, I want to make sure how do we want to tackle the fact they all have a common grouping of LOI and LRI requirements. But depending on the context, public health or general lab if you will, it may not require everything that LOI and LRI has to offer based on the factors that so many or effectively just about all the end phases out there are using Version 2, but not necessarily all in the same.

They might be using 2.3, 2.3.1, 2.5, 2.5.1. How do we want to tackle this before I go too far?

Bryant Thomas Karras
Well, in the interest of time, I like and appreciate your suggestion. Why do we not scroll down and read the (23) and (a)(2) proposed rule and then, try to discuss all of them at once rather than artificially breaking them up into three different discussions?

Rachel Abbey
Hans, for some clarification to appreciate the committee's feedback on this, we did propose the public health profile for the LRI implementation guide and did ask for feedback on public's thoughts on whether there should be additional profiles referenced as well.

Hans Buitendijk
I think in (a)(2), it is a bit more wider open. There is a framework that I would like to just share as a draft thought and say would something along those lines across all three be helpful? We will get there when we get there.

Bryant Thomas Karras
Would someone want to volunteer to read (a)(2)?

Gillian Haney
Sure. I can do that again. "1.) Current criterion at (a)(2) states enable user to record change in access laboratory orders. 2.) New requirements for health IT module certified to (a)(2) would enable a user to record, change, and access laboratory orders. New, create and transmit laboratory orders electronically according to the LOI IG. New, receive and validate laboratory results according to the LRI IG."

Bryant Thomas Karras
Let us go on to the last section and read it. I see your point, Hans, that the actors here is pointing more at the EHR system or the Laboratory Information Management (LIM) system probably more accurately. Gillian, can you read the last section here, the (f)(23)?

Gillian Haney

"1.) New, establish new certification criteria at 170.315(f)(23). Reportable laboratory test values and results, receive, validate, parse, and filter that would support, create, transmit, receive, and validate functionality test using ELR and/or LRI IG."

Bryant Thomas Karras
It does not have the detail here by I am presuming that the ELR IG is still the 2.5.1 HL7 IG.

Rachel Abbey
It would be the same that I referenced in Act 3, exactly.

Bryant Thomas Karras
There is a lot here. We probably spent the whole session on e-case reporting and ELR reporting. Let us go back up to Hans's comment in his novel section. Novel meaning a whole lot of words, not novel meaning new.

Hans Buitendijk
Too many words, we will find out. A couple of thoughts. One is that I think here, what we talked about earlier with clarity on responsibility, is it the provider? Is it the lab? But now, we have the additional challenge of you have a provider that may work with an internal lab, it may be a provider that works with an external commercial lab. It may be a lab that references another lab. And it may be a public health lab that is involved. And if you look at the different variations in which orders and test results can flow, who has reporting requirements to public health for sure and who may? Providers do not always have the reporting requirements but laboratories typically do. But if the laboratory is doing it on behalf of another laboratory, it is actually the referencing lab, not the performing lab that has it. So, depending on what is happening there, more or less of the LOI guides would be applicable or relevant or desired to put in play.

It is almost like you are dealing with if I am working with an internal lab, hospital is a good example, shifting to LOI or LRI wholesale is not necessarily appropriate and is not clear from F3 or A2 that it is included or excluded. It is generally lab orders. But if they are internal, the information is kept in other systems, it is flowing differently. And you do not need to load the order with everything that you need to do that the LRI would enable you to do. It seems in that area, requiring LOI and LRI to be in play is not quite appropriate because the balancing act is done differently. But that scope is not clearly constrained to keep that outside. So, that is more important. You then get to a part where the lab may be the one that is going to do it that you order from, but they are going to outsource it to another lab. At that point in time, again, more but not necessarily as much, would have to be communicated with them because they do not have the reportability response necessarily.

So, you are building up. You would like to get more of LOI and maybe LRI in but not everything based on the way it is communicated. It is still fairly internal, but it is not totally external. You go to the one you would go to the commercial lab, they have that so I need to load more public health relevant data if that result may become reportable so that the lab has that. And lastly, if you are communicating with the public health lab, it might have additional requirements at around new blood or dried blood screening, etc., that you have in play there. It seems like we are looking at nothing but rather than depending on how you are communicating, elements of LOI and LRI are important so that the path of transition from currently people are using 2.3,

2.3.1, 2.5, whatever that there is better path to start to adopt the pieces and insert them into existing transactions rather than requiring everything to swap over everything.

And that is a general concern that is in place. Can we do this with a better migration path rather than jumping to all LOI, LRI, which is then going to end up for a vast majority of the transactions swapping formats and some other things but really not solving the problems we are trying to solve.

Bryant Thomas Karras
I am going to cut you off there, Hans. We are running short on time. We have got a few minutes before we need to open to public comment. Gillian, you have your hand up but I also want to queue up and check if Riki is on.

Riki Merrick
I am here.

Bryant Thomas Karras
I want to make sure you are queued up to opine. Go ahead, Gillian.

Gillian Haney
I want to clarify, Hans, when you are talking about public health specific data elements, what you are referring to. One of the challenges that public health agencies have is when the data are sent over to public health, we cannot interpret what is coming in if standards are not being utilized.

Hans Buitendijk
Just to clarify, it is when orders are sent to the lab, and assuming there is no public health reporting requirements, really the focus is on the data that is necessary to perform the tests, nothing more. And if you are internally in a lab, Admit / Discharge / Transfer (ADT) information, as an example, that may be relevant or needs to be known is typically sent through separate ADT transactions. It need not be at all in the order message so you would only have the identifying information and that is it. If you are then sourcing it out –

Gillian Haney
The challenge is though is that public health cannot do anything with just a name and date of birth. We need all of the additional information along with it.

Hans Buitendijk
I am not saying that it would not be, but inside the hospital, the transactions that you initially have and how it would be assembled to then, if it needs to be sent to public health as well works differently than if you communicate with a commercial lab externally. It is just a different flow of the data and how it is being shared that demographic data need not go to the Laboratory Information System (LIS), but it does not mean the hospital has a reporting obligation and can include because they have access to the data. It just need not be to its full extent on the LAS workflow flowing there differently, not on the order. You do not want to encumber it on the order to communicate it. They have already got it another way. And that is the reality of how complex this works.

Bryant Thomas Karras
Yes. I think there are some opportunities by going a little bit further upstream instead of just waiting for the results. Communicating at the time of order, there is an ability perhaps for public health to start to put questions on order entry and make sure that those are being included for conditions of public health significance.

Hans Buitendijk
We are not arguing that. In certain flows, the place where you get the data from –

Bryant Thomas Karras
Is not the LIMs.

Hans Buitendijk
Yes. When you actually communicate to the lab or to public health, you would have access to the data. Just not in the way that you otherwise are thinking.

Bryant Thomas Karras
Are there anymore hands? We have five minutes remaining. Riki, you and I had extensive discussions about LOI, LRI in the path that we have to get ready for it.

Riki Merrick
Yes. For LOI, I have the same question leading LOI in (f)(3) criterion because (f)(3) was traditionally a report to public health. So, how do the laboratory orders fit in there? That would need to have a substantial clarification. If, for example, we meant need to include data elements within the LOI public health profile for orders that may be reportable later, if that is what was intended here with the addition of LOI or if the addition of LOI was here for orders going to public health labs, that is the other question.

Bryant Thomas Karras
That is a simpler interpretation and the reference to blood spot newborn screening makes a lot more sense in that situation. Carry on.

Riki Merrick
On the new criteria to receive lab orders, I have the same question as Hans. Who would be the receiver? I am assuming this is from the view of the EHR, so unless you consider the EHR to be also the LIS or the lab that is getting orders. But then, how does public health fit into that? That was my question there. In terms of ELR being represented as the public health profile like a component of LRI, that is true. And as Hans had pointed out, LRI does have multiple different profiles that can be pre-adopted into existing things like the HHS reporting profile so that certain things that public health needs are clearly defined in that profile. But the whole message does not necessarily have to be the entire LRI profile. And then, just one other question of note is that R1S4 is really the name of this thing, that is not the latest version. The newest version Edition 5 for both LOI and LRI so I am wondering if we wanted to go there.

Bryant Thomas Karras
And that is well adopted or just valid?

Riki Merrick
No, it is not adopted. It has been published, validated and published. I do not know that S1R4 is adopted either. But certainly some components of it are adopted like that HHS profile. And I know the **NDBS [01:48:06]** profile of the R1S4 is being used in several jurisdictions.

Bryant Thomas Karras
We as a task force, and then hopefully other communities, ELR community can weigh in and echo that we should be referencing the most current validated standard, especially if it incorporates errors or fixes that were identified in the previous version. Erin, you have your hand up and I am about to assign you some homework.

Erin Holt Coyne
Great. Going back to Hans's comment, your description of the complicated ecosystem is an important one. And we have had situations where laboratories might say, "Well yeah, we did not send you all of the patient demographic information, for example, because our result messages are coming from X part of our system and that information is actually in our billing system." So, that data is not available to pull into these outbound result messages. I personally have heard that numerous times from different partners that we have worked with. So, I do not know if there should be more concrete expectations articulated that set the expectation that you are pulling it from whichever system you are collecting it in. If you have that information in the form of data, you pull it from wherever you need to pull it in order to send it and conform to the outbound communication.

Hans Buitendijk
That sounds like it is appropriate because you have, as an organization, a reporting requirement that you need to pull data whatever the systems are –

Bryant Thomas Karras
I have to cut you off, Hans. We need to comply with opening up and seeing if we have any audience members that have been waiting to chime in or make comments.

Public Comment (01:50:30)

Seth Pazinski
We are going to move into public comment. So, if you are on Zoom and would like to make a comment, please use the raise hand function, which is located in the Zoom toolbar at the bottom of your screen. If you are participating by phone only today, you can press star nine to raise your hand. And then once called upon, press star six to mute and unmute your line. And we will give folks a few seconds to queue up. A couple of reminders, the next HTI-2 task force Group 1 meeting is going to be on August 13 from 11:00 a.m. to 1:00 p.m. And a reminder that all HITAC meeting materials are available on health IT.gov. I see that we have no comments at this time so I will turn it back over to Bryant to continue the conversation.

Next Steps (01:51:31)

Bryant Thomas Karras

Hans, if I did not disrupt your thoughts too much, if you could carry on. And in our last remaining minutes here, I am feeling unsettled on what we have. We have got the full conclusion on both ELR, LOI, LRI, and eCR, I feel like could stand a little bit more discussion in my humble opinion. But we will try to look at the upcoming agendas and find a spot for them. But if people could work on their homework assignment to draft more concrete proposed word changes or recommendations that we would put forward in a transmittal. Eric, if you can help and maybe pull in Riki and others' expertise to draft those for the ELR section. Hans, you are happy to chip in. And then, Joel, you could work on the eCR and pull in assistance from other committee members or subject matter experts?

Joel Hartsell
That sounds great.

Bryant Thomas Karras
Hans, your continued thoughts?

Hans Buitendijk
Actually, I was just responding to Erin. I have completed the top thoughts.

Bryant Thomas Karras
Good. Erin, I really appreciate what you were saying about and have had the same experience here that people talk about their LIM system not having access to the patient demographic or even the peak clinical information that is needed to be transmitted in the ELR message let alone the ask and order entry components. But is this our opportunity, especially in the criteria to the EHR systems to not make it just the EHR systems that ONC is looking at but perhaps the LIMs systems themselves need to be better certified?

Molly Prieto
I will just say that the way these criteria over internet are meant to be pointed at specific systems. ONC defines those criteria to look at functions.

Bryant Thomas Karras
So, it is whatever the clinical agency, whether it is ambulatory or hospital, is using to attest to these. And if they are using their billing system for a part of it and their LIM system for part of it and their EHR system for part of it, it is all applicable?

Steven Eichner
Certification is applicable to the system separated out from other regulations that say what they have to use to report.

Hans Buitendijk
That creates challenges when you have workflows and data distributed across multiple systems and users as to which is certified to what because you may certify an EHR to it but if the lab does not support the other end of it, the LIS and then, it does not necessarily mean that the subsequent reporting is going to happen. So, this is just getting into a very complex area where the question is if you take a Computerized physician order entry (CPOE), it has clinician in the name so you would not think that it would be picked up by an LIS. If you have more criteria that defines around roles and then, a single system might cover multiple

roles or a single role but it has the roles, it might further help as it is starting to be done in some of the public health with the sender and the receiver, the provider and the PHA or the IIS, and the payer, etc., that that can help to understand because if you see in (a)(2) that there is a need to be able to receive an LOI and that looks very odd from a provider perspective, the clinician.

But it is very understandable if you are on an LIS side. That is what the LIS needs to be able to do. If it is one integrated system, okay. But not everybody has that. That is why think it is still important to break some of those criteria into different parts to say this is the criteria for the role of and that can help more clarify so it is not as an organization, I need to be able to have software that can combine the combination in order to satisfy CMS. It gets more complicated as we get beyond simple, one directional queries or one directional messages into multiple parties that are involved. I think that is just the nature of the beast that we are getting into as we progress in certification criteria.

Steven Eichner
You have to use certified technology to actually send a message, which creates the problem here of getting all the data about demographics into the LIMs could be incorporated in a message when a lot of the demographic information may not be needed by the lab to actually process the sample. That is a data integration issue for them as well, but it is a complex environment.

Hans Buitendijk
And if they are the one that is directly reporting, particularly as we see with commercial external labs, if they are reporting directly to public health then, at that point in time, it is much more reasonable to say I am sending it along. If you are more internally then, it depends how you architect and figure with your systems from one integrated system or are they multiples?

Bryant Thomas Karras
It is a downside to modular certification. And in this case, it is micro modular. So, we are at time. Just one last check if there is any public comment and then, we should wrap things up.

Seth Pazinski
Nothing on the public comment side. We can proceed to wrap things up.

Bryant Thomas Karras
I am so glad we extended discussion by half an hour and I cannot believe how much we got through and that we are already at the end. That two hours went really quickly. Thank you everybody for all of the weighing in that folks did. How do people feel about my proposal to come back to these after we have some revised language in the spreadsheet to have a little bit more discussion?

Gillian Haney
I would support that.

Hans Buitendijk
Agreed.

Bryant Thomas Karras

Gillian, you are on the hook to help with that writing.

Rachel Abbey
I think we will probably push the discussion to 8/27 because there are also some other outstanding issues. We will leave that as our outstanding issue for this meeting.

Bryant Thomas Karras
It gives you a little bit more time to craft and do wordsmithing. We will do the housekeeping on the 27th. Be sure to do your homework for the next session and get comments into the spreadsheet. For those in the public chat who are not having access to that spreadsheet, be sure to reach out to your colleagues who are officially on the task force and channel your thoughts through them. Are there any other closing housekeeping activity? We are over time. I apologize.

Seth Pazinski
We are good to adjourn.

Bryant Thomas Karras
All right, everybody. Thank you so much. I really appreciate working with you all.

Adjourn (02:00:36)

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

No comments were received during public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Rachel Abbey: FIVE MINUTES On this!

Rachel Abbey: THREE MIN On f1 criteria!

Hans Buitendijk: Perhaps f1 Immunization Reporting/Query - Provider? and f21 Immunization Reporting/Query - IIS?

Rachel Abbey: WE ARE AT TIME, let's move to F21

Hans Buitendijk: Then f1 would focus on Hl7 v2 submission and query, while g10 would address immunization queries to a provider, not here. f21 would focus on receipt of HL7 v2, support for HL7 v2 query and FHIR bulk query.

Noam Arzt: Can you please slide over the spreadsheet?

Noam Arzt: Thx!

Rachel Abbey: FIVE Minutes remain!

Rachel Abbey: TWO MIN remain!

Noam Arzt: SMART Health Links have more "room" but a different model than SMART Health Cards

Noam Arzt: Not that that's bad...

Steven Eichner: The ISA is a tool that reflects the maturity of standards. It's been used historically to inform regulatory development. The incorporation of FHIR bulk services is a significant change from what's now in the ISA, especially when considering what has been broadly adopted.

Hans Buitendijk: On the prior topic, bulk data, perhaps suggest that recommend that until a Bulk Data Immunization Query IG has been published that it is premature to adopt this capability in f21.

Rachel Abbey: We are at time we need to move to Cancer F(4) updates for 10 min

Gillian Haney: I am assuming the comments in the chat are being recorded- yes?

Rachel Abbey: yes

Gillian Haney: thanks!

Rachel Abbey: Five MIN REMAIN!

Rachel Abbey: THREE MIN REMAIN!

Steven Eichner: Funding and the volume of changes can be a challenge.

Rachel Abbey: Time! NEED To move to f24 new criteria!

Rachel Abbey: I"M STARTING THE CLOCK FOR F24, we have 8 min

Susan Clark: A bit tangential but one thought on funding is the occasional crossovers for Medicaid Technology funding where state PHAs collaborate with SMAs. Perhaps another area CMS can bring into their rules/guidance.

Rachel Abbey: Technology being certified

Noam Arzt: Has there been a broader discussion on what "receive, validate, parse and filter" mean exactly that I missed?

Riki Merrick: Noam - I was wondering the same

Rachel Abbey: Three MIN REMAIN!

Rachel Abbey: We are at time, we need to move to f5 eCR and updates!

Erin Holt Coyne: Can we need to find some time to specifically discuss 'receive, validate, parse, and filter'.

Mary Beth Kurilo: I support Erin's request for setting aside time to discuss/define 'receive, validate, parse and filter'.

Rachel Abbey: we have 10 min for eCR f5.

Gillian Haney: I also agree that we need to discuss receive, validate, parse and filter please

Rachel Abbey: MB and others we can add the definitions to the end or maybe next week

Erin Holt Coyne: Thanks Rachel.

Sean Porter: I also have to drop for another call.

Mary Beth Kurilo: Thank you, Rachel.

Riki Merrick: Do we have definitions of what types of data are included in cancer pathology reporting - would that cover genetic testing and clinical lab results, too?

Molly Prieto: The details for receive, validate, parse, and filter are in the regulatory text in the published rule. f25, for example, is here: https://www.federalregister.gov/d/2024-14975/p-3491

Noam Arzt: Thx. Did not catch those definitions

Rachel Abbey: Little less than 5 min remain!

Rachel Abbey: Two minutes remain!

Mary Beth Kurilo: Thanks, Molly, but I do think there is still room for clarification on some terms. For example, for immunizations, here is the definition for 'parse and filter': Enable a user to parse and filter immunization information received and validated in accordance with paragraph (f)(21)(ii) of this section according to the standard specified in § 170.207(e)(5) or (6).

Rachel Abbey: TIME! We need to move to F25 the eCR NEW Criteria

Rachel Abbey: We have 15 minutes for discussion on F25

Erin Holt Coyne: I do see this as an opportunity to pressure PH surveillance system vendors to more completely parse case reports.... instead of just displaying a human readable image.

Hans Buitendijk: At the same time, having an intermediary translate a FHIR eICR into CDA eICR would not put the onus on the PHA until ready. Also considering the comment that the certification is on the software, not the organization.

Rachel Abbey: FIVE Minutes Remain

Erin Holt Coyne: I think the 'certification is on the software, not the organization' will be a double edged sword if we are concerned with real world implementation

Gillian Haney: agree Erin.

Mary Beth Kurilo: Agree with Gillian and Erin. This could also unintentionally advantage new vendor software that can meet the regulation but may not meet all the other functions needed by public health.

Gillian Haney: Significant resources are needed for PH to be able to filter the data...

Rachel Abbey: TWo Minutes remain!

Rachel Abbey: TIME!

Hans Buitendijk: Agreed there is a challenge that certification without incentives/funding to adopt those capabilities can lead to capabilities being developed not being used and we do not want a check-the-box criterion either. This is a balancing of where we insert the capabilities while keeping it affordable/achievable for the organization using the capabilities.

Gillian Haney: YES Bryant and common validation protocols for PHAs would also be advantageous.

Noam Arzt: "Filtering" may be about filtering cases as Bryant is suggesting, but it may also mean filtering *data* within a case report. That is up to the PHA.

Riki Merrick: we need clarification about how LOI is expected to be used in f3 and f23

Erin Holt Coyne: I assume change would mean cancel and update an order. Is that correct?

Rachel Abbey: 10 minutes before we need to break for public comment

Erin Holt Coyne: Based on our implementation of LOI/LRI its been challenging to conform to the PH Profile of the LRI IG without the LOI PH Profile. Quality of the result can be impacted by the quality of the order, or data collected within the ordering process. For example, not including details about the specimen in the order may present challenges with ensuring specimen details are available for inclusion the LRI PH profile result.

Erin Holt Coyne: Need to also specifically address vocabulary adoption.

Molly Prieto: F3, 23, and a2 also include vocabulary standards (LOINC and SNOMED, as appropriate)

Bryant Thomas Karras: Laura C Jason H or Riki M… are you able to address LOI? Is that what we want PHA to be ready for?

Erin Holt Coyne: Thanks Molly. We need to make sure to take a good look at those.

Rachel Abbey: Five Minutes Remain until we need to break for public comment

Noam Arzt: I know this was discussed earlier, but I will say again that access to a read-only version of this working spreadsheet before each meeting would greatly increase the transparency of these proceedings to the public.

Gillian Haney: Interested to hear about LOINC and SNOMED as well - this is critical for PHA.

Rachel Abbey: 1 minute remaining!

Rachel Abbey: Time!

Bryant Thomas Karras: Hold that thought Hans

Bryant Thomas Karras: Will come back to you if time

Rachel Abbey: Thank you all the volunteers!

Riki Merrick: f(3), a(2) and f(23) sections need clear definition of the actors (roles) for each of the transactions to be certified

Erin Holt Coyne: then add on the fact that the IG may appropriately list the conformance verbs as required but may be empty or conditional or optional, then not sending 99.999% of the time conforms.

Gillian Haney: agree

Gillian Haney: ^^Erin's comment

Bryant Thomas Karras: Any hands in public chat yet?

Rachel Abbey: We are almost at time!

Rachel Abbey: Great job everyone!

Molly Prieto: Kudos!!

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 1: Public Health - August 6, 2024, Meeting Webpage

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