Transcript

HTI-2 PROPOSED RULE TASK FORCE 2024 MEETING

GROUP 1: PUBLIC HEALTH

July 30, 2024, 11 AM – 12:30 PM ET

VIRTUAL

MEMBERS IN ATTENDANCE

Bryant Thomas Karras, Washington State Department of Health, Co-Chair
Shila Blend, North Dakota Health Information Network
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)
Jim Jirjis, Centers for Disease Control and Prevention
Mary Beth Kurilo, American Immunization Registry Association (AIRA)
Kikelomo Oshunkentan, Pegasystems
Zeynep Sumer-King, New York-Presbyterian
Naresh Sundar Rajan, CyncHealth
Thomas M. Wilkinson, U.S. Department of Homeland Security

MEMBERS NOT IN ATTENDANCE

Hans Buitendijk, Oracle Health
Steven Hester, Norton Healthcare
Erin Holt Coyne, Tennessee Department of Health, Office of Informatics and Analytics

ONC STAFF

Peter Karras, Acting 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
Laura A. Conn, CDC/IOD/OPHDST
Karl Soetebier, CDC/IOD/OPHDST
Daniel Kurowski, CDC/IOD/OPHDST
Andrea L Benin, CDC/NCEZID/DHQP/SB
Hsiu Wu, CDC/DDID/NCEZID
Amy Webb, CDC/NCEZID/DHQP/SB
Prachi D Mehta, CDC/CGH/DGHT
Jessica Diamond, CDC/NCCDPHP/DCPC
Sean Porter, CDC/NCCDPHP/DCPC

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

Peter Karras
Good morning, everyone. Welcome to the HTI-2 Proposed Rule Task Force Group 1 meeting. I am Peter Karras with the Office of the Assistant Secretary for Technology Policy and I will serve as your Designated Federal Officer today acting on behalf of Seth Pazinski. This meeting is open to the public. Public feedback is welcome throughout the meeting. Comments can be made via the Zoom chat feature. Just a reminder that we do have scheduled time for verbal public comments towards the end of our agenda today. We will get started with our meeting and I will begin with roll call of the HTI-2 Proposed Rule Task Force Group 1 members. When I call your name, please indicate you are present. Bryant Thomas Karras.

Bryant Thomas Karras
Present.

Peter Karras
Shila Blend.

Shila Blend
Present. Good morning.

Peter Karras
Good morning. Hans Buitendijk. Steve Eichner.

Steven Eichner
Good morning.

Peter Karras
Good morning. Lee Fleisher. Raj Godavarthi.

Rajesh Godavarthi
Present.

Peter Karras
Gillian Haney.

Gillian Haney
Present.

Peter Karras
Joel Hartsell.

Joel Hartsell
Present.

Peter Karras

Steven Hester. Erin Holt Coyne. Jim Jirjis.

Jim Jirjis
Present.

Peter Karras
Mary Beth Kurilo.

Mary Beth Kurilo
Present.

Peter Karras
Kikelomo Oshunkentan.

Kikelomo Oshunkentan
Good morning. I am present. Thank you.

Peter Karras
Good morning. Zeynep Sumer-King.

Zeynep Sumer-King
Present.

Peter Karras
Naresh Sundar Rajan.

Naresh Sundar Rajan
Good morning.

Peter Karras
Good morning. And Thomas Wilkinson has indicated that he will not be in attendance for today's meeting. Thank you, everyone. Is there anyone I missed or anyone who just joined that would like to indicate their presence?

Hsiu Wu
Hsiu Wu from CDC is here.

Peter Karras
Welcome. I will turn it over to Bryant, our co-chair, for opening remarks to get us into our meeting. Bryant, over to you.

Opening Remarks (00:02:32)

Bryant Thomas Karras
I am uncharacteristically going to keep my remarks exceedingly brief today because we have a lot to cover today and a lot of guests in attendance just in case we need to do deep dives on any of the F criteria that

we are seeking to get through today. Today's agenda is fairly packed, and we will be plowing through as quickly as possible. Not to dissuade people from comment, but knowing we are going to need potential time for discussion, we wanted to go through and check off ones that, to our quick assessment, seemed to be easier or no brainers. Easy acceptance of, yes, we should have been using the updated implementation guide years ago, so let us check this one off. I am hoping that we can get through as many of those as possible and have deeper discussions on those that are not controversial but a little more weedy. We have invited guests from the respective program areas at the CDC to be in attendance, whether or not we thought there would be discussions because one cannot predict.

Those who are on, we apologize if you are here and there is no need for discussion. We may move on. You will still be able to comment or provide any detail that you feel needs to be shared. Thank you again for being here and take it as a compliment. If we do not need to do much in that area, it must mean the criteria made sense to us. With one exception, we did move the Electronic Laboratory Reporting (ELR) potentially to be out of sequence. In fact, we are doing a lot out of sequence today, so do not be thrown off with us bouncing around within the numbers of the F criteria. Next slide, please. I went over this last time, but I guess just for Gillian who was 20,000 feet in the air during our first kickoff session, this is our charge. And as you remember, we have to stay within our scope but we have got a fairly permissive scope here. Next slide. This is our sequence. As I said, we are moving the ELR criteria for discussion within the section. It is addressing the physician order, entry order, computerized order entry, which is the next session.

Molly Prieto
Yes, next Tuesday. Already August.

Bryant Thomas Karras
Wow. Next slide unless anybody from the ONC wanted to comment on the previous. We will have one housekeeping or cleanup session on the 27th, but that one we will be needing to be getting our final comments probably moved from the spreadsheet into a Word document so it can be combined when we reassemble as a task force as a whole, the three subcommittees reassembling on September 3. Any questions on the process, schedule, and what we are trying to get through today? An unusually quiet group today. Did anyone have difficulty getting onto the Google sheet?

Joel Hartsell
I did, but I have access now.

Bryant Thomas Karras
Great. I was going to say we can help you live and watch you type your password into the screen on a public Zoom. Anything else? Let me refer over to Rachel and Molly, anything else we need to cover or should we jump right into it?

Molly Prieto
Nothing from my end. I think we are good to get into the meat of it.

Bryant Thomas Karras
Rachel, how is your voice today? Not hearing, Rachel, so let us move on.

Rachel Abbey
Sorry, trying to get off of mute. Thanks, guys. Let us charge head. Go for it, Bryant.

Existing Public Health Certification Criteria in § 170.315(f)(1)-(f) (7) (excluding ELR) Discussion (00:09:13)

Bryant Thomas Karras
So, as I said, we are going to jump through the early F criteria that we know and love. We have moved ELR so it could be inclusive in the discussion with other laboratory-based and we also moved electronic case reporting (eCR) to the very end of the sequence going a little bit out of order. So, do not be thrown by that. If we do get through all of these early number F criteria today, we could launch into some preliminary discussion on other topics. We will see how it goes. Next slide. So, I wanted to acknowledge our guests. I apologize. In the interest of time, we are not going to do our traditional Zoom introductions, so that you know who you are speaking to and we know who you all are. Many of you can go with no introduction needed because you have been affiliated with your program for so long that your name is synonymous with your CDC program area. I thank you for your service and I thank you for being on here today. We may or may not need you to weigh in on criteria depending on how the discussion goes.

Next slide. I think we are jumping into it. Next slide. Again, as I said, going a little bit out of order. We are starting with lucky number seven. Let us see. Can I get a volunteer from the committee to read through the charge here so you do not have to hear my voice all morning long? Do not all jump first. Perhaps our CDC guests related to hospital health care surveys.

Prachi D. Mehta
No comments. This is Prachi Mehta.

Rachel Abbey
Bryant, do you want me to go ahead and read through it for folks?

Bryant Thomas Karras
That would be fabulous, Rachel.

Rachel Abbey
We are talking about F7 here. This is the health care surveys, transmission to public health agencies. We have proposed an update to health IT module certification to F7 to support the Health Level 7 (HL7) Clinical Document Architecture (CDA) R2 Implementation Guide NASH4 National Healthcare Surveys NHCS, R1, STU, Release 3.1-US Realm by January 1, 2027. We also have a request for comment on use of the FHIR-based health care surveys content implementation guide. In particular, should ONC consider modifying the certification criteria to require a health IT module to support creation and submission using at least the CDA or Fast Healthcare Interoperability Resources (FHIR) versions of the standard? And we proposed to change name to be "health care surveys-transmission to public health agencies." So, we request comment on these areas.

Bryant Thomas Karras

Any comment? I just put one what I believe is the first comment into the Google sheet. Can we jump over to the Google sheet and put that on the screen?

Aaliyah
I am sharing now. One second.

Gillian Haney
Bryant, are you looking for discussion?

Bryant Thomas Karras
Yes. How do the task force members feel about this one?

Task Force Recommendation Worksheet (00:14:25)

Molly Prieto
For additional context, and Prachi can jump in as well, the implementation guide that we proposed in the HL7 CDA R2 implementation guide is the most of recent version at the time of authoring this proposed rule. Imagine if folks have comments on that, certainly open to discussion. But like Bryant put in that comment there, very open to the discussion regarding the requests from comment within the proposed rule regarding the FHIR implementation guide and readiness there. I imagine there is not likely a huge amount to say about the CDA implementation guide.

Gillian Haney
I will make a motion to support. I do not know if Bryant can see my hand.

Bryant Thomas Karras
Sorry. And Steve is up next. Go ahead, Gillian.

Gillian Haney
Motion to be in support of naming the standard, updating the standard.

Bryant Thomas Karras
Before I get a second, can I make a friendly amendment? You are supporting just the reference to the CDA-R2 standard? You are not commenting on the sections where they are requesting comment. We should not leave that blank as a committee if ONC is requesting comment.

Gillian Haney
Right. I was just trying to get that first part out of the way.

Bryant Thomas Karras
Perfect. Thank you. Steve.

Steven Eichner
Thank you. I have a more general comment that relates to all of the standards and that is making sure we have continuity and clarity about what standard is actually enforced on the books and resolved against the Standards Version Advancement Process (SVAP) process. I question whether it should be included in

regulation because alignment with what might be subsequently adopted through SVAP so there is a commonly understood reference for all parties about what is in play at the end of this.

Bryant Thomas Karras
Thank you, Ike because we do have two Steves. Can I ask for some clarification from the ONC team? Is there a mechanism by which we can make a comment to reference a particular standard, but unlike the lock in time that we got with the 2019 criteria, can we make this standard or any subsequent updates as adopted by SVAP and –

Molly Prieto
I think the team can weigh in on this in more detail than I can but because of APA regulations, we do have to reference an explicit standard. We cannot propose a "most recent standard," which was part of the genesis behind the use of SVAP. So, we do need to reference a specific standard in a proposed and final rule.

Steven Eichner
Just to clarify, my concern is that previous regulation opened up the door for adding more variable standards. And I want to make sure we are setting a stage where there is clarity in what is in play so we are not in the position where folks can be looking at regulation that says this version but SVAP adopted something else and what is enforced and what is the correct reference. Comments that say there needs to be a pointer to an officially adopted standard in place might be a suggestion as modifying text, so that regulation includes a pointer to a source of truth.

Bryant Thomas Karras
Are you suggesting the Release 3.1 is not sufficiently published and in place? You said this is more of a general criteria.

Steven Eichner
I am suggesting for any of the standards, if the regulation is put in place by regulation but something else is adopted through SVAP then there is confusion about what is actually enforced in the marketplace. So, having a pointer to put is actually the most current standard and what is enforced would be really helpful.

Molly Prieto
Just a note that SVAP is all a voluntary process. In terms of what the certification program is enforcing would be whatever would be finalized in a final rule, not what is in SVAP. SVAP is an optional program to participate in.

Steven Eichner
But use of certified technology is also a voluntary program.

Bryant Thomas Karras
I think what Ike is trying to get to, Molly, in many of the cases, updates in SVAP may be errata or fixing something that has been discussed or newer criteria that is reverse compatible with previous published ones. Adoption of a newer version would not necessarily be out of certification or out of alignment with the voluntary certification. It would still pass the as published rule reference.

Steven Eichner
The difficulty for public health reporting and surveillance, everybody needs to be using compatible standards or the data cannot be appropriately received and utilized. So, things get out of sync and if there is something adopted through SVAP, it might be more modern but is not backwards compatible, that creates a real issue.

Kathleen Tully
One quick note, for SVAP, we can only SVAP based off of an updated version to the standard. For instance, if there is an updated version of an immunization Implementation Guide (IG) but it is using FHIR, that is something that would not be eligible for SVAP. I do think in terms of how SVAP works today, that backwards compatibility is already baked into the process because, basically, we are only encouraging updates to that specific IG that is referencing reg. If there are large deviations that would be a new IG that would not be eligible for SVAP.

Steven Eichner
Thank you. That clarification helps. Thanks.

Bryant Thomas Karras
Rajesh.

Rajesh Godavarthi
Looking at the question, should ONC consider modifying the criteria to some using Cumulative Dosage (CDO) where it says FHIR, I think it is probably good to continue to review both options for a period of time as FHIR is the de facto standard with many other standards slowly maturing. One question I have is I do not know the 3.1 maturity level in terms of the FHIR-based healthcare surveys. I do not know how many implementations they have seen. Is there enough confidence that it is in a good place to introduce? By the time they write the standards and by the time they come out, sometimes you will have a good six months. Maybe there is enough done.

Bryant Thomas Karras
We may have an answer from the program area, Rajesh.

Prachi D. Mehta
I can answer that. Currently, our providers are using mainly CDA 1.2. Some are transitioning to 3.1. As it relates to FHIR, we are in the process of piloting with three sites and we hope to have results from that pilot by the end of this year, which will also inform our future implementations.

Rajesh Godavarthi
That makes sense. I think that was my comment as well.

Bryant Thomas Karras
Just for a scale that is three sites out of more than three thousand?

Prachi D. Mehta

Yes.

Bryant Thomas Karras
It is fairly early in the adoption curve of FHIR. Since it was 2015 the last time the reg was updated to point to things, hopefully, it will not take us that long to transition. But I agree with the earlier comment that we are going to need to, Rajesh, as you said, support both.

Rajesh Godavarthi
Yes.

Bryant Thomas Karras
So, because so many institutions will not be able to make the transition as timely as we might. Back to the program area.

Prachi D. Mehta
I just wanted to second that at least for healthcare surveys, there will need to be transition time built in, so allowing both CDA and FHIR will be very important. Thanks.

Bryant Thomas Karras
Is there a release for trial use reference for the FHIR implementation for the pilot test?

Prachi D. Mehta
For the pilot, we are using the published version. We have a published FHIR implementation guide.

Bryant Thomas Karras
Can you put the exact published reference, HL7 STU or is it not in STU?

Prachi D. Mehta
Yes. Let me put it in the chat.

Bryant Thomas Karras
While she is putting it in the chat, let us get a motion on the first section that is referencing the CDA R2 implementation guide. We have a motion from Gillian, do I hear a second?

Rajesh Godavarthi
Second.

Bryant Thomas Karras
All in favor of the task force being in support of updating to the new CDA release 3.1 as the certification criteria standard say aye.

Group
Aye.

Bryant Thomas Karras

Any opposed? Great. I am not seeing anything in the chat yet. Once you finish that, I have a question for you. You mentioned some hospitals or some providers are still submitting under the previous released CDA.

Prachi D. Mehta
Yes. Most of them are submitting version 1.2 CDA. And the new ones we are onboarding, we are asking them to use 3.1.

Bryant Thomas Karras
So, does the program want those that have implemented it under the earlier release to upgrade to the 3.1?

Prachi D. Mehta
We are not pushing them to do that because our preference is to move from CDA 1.2 to FHIR depending on what the results are from this pilot.

Bryant Thomas Karras
That complicates things because if we put into regulation, 3.1 then, they have to update to 3.1.

Prachi D. Mehta
And then, they would do FHIR after that.

Bryant Thomas Karras
Which hospitals will not be happy about a two-step upgrade process. Gillian, thoughts on that? Do we reference the older standard first to keep people in compliance? Do you have any modifications to your motion?

Gillian Haney
Can anybody comment? Is there any subject matter expert (SME) that can comment on how that has previously worked by referencing the older standard? Katie or Molly?

Molly Prieto
I cannot comment on that specifically. What I can say is what we requested comment on in the proposed rule was similar to what we finalized in HTI-1 for electronic case reporting, which was the certified health IT module would need to be able to transmit using either the CDA implementation guide or the FHIR implementation guide. That is what we requested comment on there if this was a criteria that made sense to propose a similar either/or situation.

Prachi D. Mehta
That would be our strong preference as well. Sorry.

Bryant Thomas Karras
I think what we should do is make a slight modification to we are supportive of adoption of 3.1 or the new FHIR implementation that is referenced and you gave us the link.

Prachi D. Mehta

Hold on. It is right here. I am putting it in the chat.

Bryant Thomas Karras
It has been active since 2023. It has been out for a while.

Steven Eichner
I would suspect we would want to do an "and/or" for clarity sake.

Prachi D. Mehta
We can do 1.2, 3.1, FHIR.

Bryant Thomas Karras
So, we would be referencing two different CDA versions.

Prachi D. Mehta
Yes.

Bryant Thomas Karras
Is that going to get people to move if people are already on the 1.2 version? Or maybe put a time limit on that 1.2 until 2026 or 2027.

Molly Prieto
Right now, that is the proposal that would expire in 2027.

Bryant Thomas Karras
Perfect. Let us do that. And we will be in support of that with a friendly amendment of adding the reference to the new 1.0.1 IG.

Steven Eichner
As an option.

Bryant Thomas Karras
As an optional early adoption criteria that would not put people out of compliance. Of course, that is likely to be modified. The pilot is likely to find something wrong and fix, but we will give those pilot sites a pathway where their effort is not –

Steven Eichner
Let us be careful about that language, so we are not tying hands. We just went through this with HL7 and other discussions about Draft Standard for Trial Use (DSTUs) and versions and subversions and numbering versions, so let us be cautious about our language.

Bryant Thomas Karras
Yes.

Steven Eichner

So, we are not recommending something that is effectively out of date.

Bryant Thomas Karras
All right. We are falling behind schedule. I like that. Let us make it an or CDA or the new referenced FHIR IG. There is usually letters behind it if it is released for trial use. We need to get the exact reference from HL7 to which build that is.

Rachel Abbey
We will make sure. We can include it in the spreadsheet.

Bryant Thomas Karras
Perfect. We can keep going back to make sure we have the right one. Next slide or we can stay on the spreadsheet. We should read the proposed language if we can flip back to the slides for a second. Thank you. Now, we are jumping to the next one in our assessment that we thought would be a slam dunk. I am queuing up folks from the CDC program to help us out here. Would somebody like to read the proposed language? Do not all volunteer at once.

Rachel Abbey
Do folks just see the spreadsheet? I am seeing the spreadsheet.

Bryant Thomas Karras
I am seeing the spreadsheet on one screen and the slide deck on the other.

Rachel Abbey
There we go. So, criteria and thank you, Aaliyah. I appreciate you transitioning back and forth. Antimicrobial use and resistance reporting. This is transmission to public health agencies. We propose to create antimicrobial use and resistance reporting information for electronic transmission in accordance with the following sections of the HL7 CDA R2 implementation guide. Healthcare associated infection reports, HAI report Release 3-U.S. realms. There are these three components, HAI, antimicrobial use and resistance, AUR, antimicrobial resistance option, ARO, report, numerator. Antimicrobial resistance option, ARO, summary report, denominator, and the antimicrobial use AUP summary report, which is the numerator and denominator. We are proposing to change the name to "antimicrobial use and resistance reporting-transmission to public health agencies." We are looking forward to comment.

Bryant Thomas Karras
I want to acknowledge that we had a couple of people join after the roll call. Tom, can you state that you are present?

Thomas Wilkinson
I am present.

Bryant Thomas Karras
All right. Did anybody else join?

Lee Fleisher

Yeah, Lee Fleisher.

Andrea Benin
This is Andrea Benin. I joined as well.

Bryant Thomas Karras
Great, thank you. Perfect timing, Andrea. So, let us open up the discussion on this criteria.

Andrea Benin
At the risk of sounding uninformed here, what was the previous name? Sorry.

Bryant Thomas Karras
Molly.

Andrea Benin
Molly, was the name change of significance that I should be checking, too?

Rachel Abbey
No, it is not significant.

Molly Prieto
We were being consistent with where we were putting the dashes and the upper and lower cases. There should be almost nothing to change from a name perspective. And for folks who are not as embroiled in this implementation guide, this is the most recent one at the time of publication for this particular information. Of significance, too, was we removed the page numbers. There used to be page numbers, which made it challenging based on updates, so there are no more page numbers referencing the section names.

Andrea Benin
I will defer to Hsiu Wu on our team who will know more about the details and can comment.

Rachel Abbey
And I just wanted to let you know, Andrea, this is essentially reversing it. The current name is transmission to public health agencies – antimicrobial use and resistance reporting. We are switching it around so it is all uniform.

Andrea Benin
I just wanted to make sure. Thanks.

Bryant Thomas Karras
Let us start. Members of the committee, we will start with Wu.

Hsiu Wu
I want to give this group a heads up that we are going to have a new version of IG in about a month, so the newer version will be bringing both to the same version of IG, which is L43.

Bryant Thomas Karras
Will it be voted in at HL7 in September, which will be too late? When will it become publicly released?

Hsiu Wu
I do not have a timeline yet. Amy, do you know when it is likely to be?

Amy Webb
I think they are working on resolving all of the comments right now and plan to have it finalized in the next month. We plan to implement it for the January 2025 data moving forward.

Bryant Thomas Karras
So, 2027 would slow you down. Actually, these were supposed to be the easy ones. Lee, go ahead and we will come back to that.

Lee Fleisher
Nice to see you, Andrea. I just want to make sure Centers for Medicare & Medicaid Services (CMS) proposed changing the quality measure and I want to make sure it is aligned. They are separating the way they report it.

Andrea Benin
Right. For interoperability, they have been separated. Antimicrobial use and resistance have been separated into two separate things. I think this accounts for that if I am understanding correctly. Sorry, I have a smaller screen and I cannot read what is on here.

Bryant Thomas Karras
Let me zoom in on the proposed rule summary.

Kathleen Tully
Just a comment on this. It was broken out according to those two. And that is why we point to the specific profiles within the IG as well is to account for that, and just to say, as Abbey commented, CMS reviewed this as part of clearance as CDC did. So, I do think it is aligned.

Bryant Thomas Karras
Lee, this was an issue where the denominators needed to be pulled out and reported in a way that could create that measure. We have ARO and AUP separately reported. They are still part of the same IG, correct?

Amy Webb
Yes. That is the plan. They were already the same IG version.

Bryant Thomas Karras
It is not that the measure is separated into two separate IGs. It is that there are specific call outs to variables within that IG?

Molly Prieto

Exactly.

Bryant Thomas Karras
They needed to be reported in order to meet the CMS criteria. All right. I am stymied a little bit. Can we get any more detail on the timing of the release date of that updated guide that the program is planning to implement by 2025?

Molly Prieto
From an ONC perspective, again, based on other federal regulations like APA, we cannot reference standards that are not published at the time, and we cannot reference future standards in the rule just to put that out there as a statement. Again, this would be something that certified health IT modules will need to be able to do.

Bryant Thomas Karras
We could though adjust the timeline instead of keeping this currently referenced one active until 2027. We could sunset it at 2026 or 2025?

Molly Prieto
The proposal as it is written now is sunsetting the current standard that is out there, which would make this proposal active after that date. This one would be the –

Bryant Thomas Karras
So, we would be then referencing a standard that is more than three years out of date and have been replaced months after we published. That feels bad.

Andrea Benin
Is there a way to do it where it is somehow inclusive?

Bryant Thomas Karras
No, you missed that at the start. We cannot reference vapor wear.

Rachel Abbey
I will point to the fact that ONC has a process called SVAP that could assist in certain circumstances such as this.

Bryant Thomas Karras
As long as it is reverse compatible. Do we know if the soon to be published one breaks any of the components in the previous one or are they just additions of new variables or new survey data?

Amy Webb
It is new variables but essentially, vendors will only be able to use the new version come January 2025 and forward. They can use R3 for reporting 2024 data. Come January 2025, they have to use the R4 or the files will not be accepted.

Bryant Thomas Karras

If this rule goes into place, Amy, they will have to do this referenced one to stay in compliance. So, we may want to say we do not support this if you are definitely wanting to move.

Johnny Bender
I was going to add that SVAP does not require standards to be backwards compatible. If a health IT developer were to certify to using a newer standard but they were certifying to an older version of the standard then, it would need to be backwards compatible in order to pass a testing tool. But that is a unique circumstance. I think the only time that backwards compatibility matters is for certification program. In general, I hope that did not confuse anyone. In general for SVAP, backwards compatibility is not a consideration.

Bryant Thomas Karras
Thank you for that, Johnny. Gillian.

Gillian Haney
Your comment about abstaining for right now, would that mean there could be no update to Notice of Proposed Rulemaking (NPRM)? If we abstain from commenting on this now, could we then comment later or do you have to wait for a brand-new NPRM to be released? Could there be an amendment or something like that?

Steven Eichner
There has to be something to comment on as an open comment period to make a comment, whether it is NPRM, whether it is United States Core Data for Interoperability (USCDI), whether it is an ONDEC, whether it is ISA or some of the more common public comment periods but it is the NPRM that is the regulation. Commenting on ONDEC or USCDI or USCDI-plus is going to help or HL7 is going to change the standard but it will not change what is in regulation.

Gillian Haney
So, there could be no amendment to this that could then update appropriately.

Bryant Thomas Karras
Well, I mean, I am trying to go back in time. This is our chance to amend it during this 60-day window if we wanted to make some changes. But once it is locked in that will stand until the next time a proposed rule comes forward.

Steven Eichner
This was part of the process from prior rules about what they were looking at changing when they moved away from looking at certification additions to more flexible criteria. And that was one of the aspects of moving away from the 2015 edition was to provide more flexibility in evolving standards.

Bryant Thomas Karras
I feel like I have heard two different things, Johnny versus Rachel and Molly. Can we reference SVAP and say whatever newer edition referenced in SVAP could substitute in lieu of this release?

Molly Prieto

We cannot.

Rachel Abbey
No, not in the rule.

Bryant Thomas Karras
So, it is not as flexible as we hoped.

Molly Prieto
SVAP can be used by vendors but we cannot reference it in the rule as the referenced standard. We would need to reference an explicit standard.

Rachel Abbey
It needs an actual standard, exactly.

Bryant Thomas Karras
We can reference trial use standards though. Is there a trial use for the one that is being proposed to be updated within the month? Back to Amy and Andrea.

Hsiu Wu
We do not typically have any trial use.

Bryant Thomas Karras
So, there is nobody piloting the one.

Rachel Abbey
Bryant, just to clarify, ONC cannot finalize something that we did not propose in the first place. If we did not propose the current standard then we cannot put it in our final regulation. It still needs to go through the whole reg process again.

Bryant Thomas Karras
Right. But if we know what it is going to be named when it is released, we can put it as an "or" in this that will support this one, the Release 3 or the Release 3.1 for trial use.

Jeffrey Smith
This is Jeff Smith from certification and testing. One of the things we did in HTI-1 for electronic case reporting, we established an at least paradigm, where we required developers to certify using at least CDA or the FHIR version of the specification. There is a possibility that that could be, but we kind of proposed it that way and we sought feedback on both standards and the pros and cons between requiring developers to use one or the other. So, we are constricted by the Administrative Procedures Act, but remember ONC certification is the floor. SVAP allows developers to certify using newer versions of adopted standards but that does not negate the floor that has been established in regulation text. The developer could certify using the adopted version reg text and choose not to certify using the SVAP version. And those are the requirements for certification.

Now, there may be other requirements that are levied from different agencies that incentivize use for certification to use SVAP using those standards. But as far as the certification program is concerned, what we put in the reg text is bare minimum and for certification purposes, we cannot compel developers to use more than the bare minimum.

Bryant Thomas Karras
Thank you, Jeff. That is super-helpful. Back to the program area at CDC, this is an impact on you all. Hearing that there is a strong likelihood that many developers will continue to send this reference R2 Release 3 criteria for many years to come, and even though you are about to release a new guidance, are you willing to continue to support that because you will have to?

Andrea Benin
I have to defer to Hsiu on this because I am not up on the history of how this works. My understanding is we have had this problem for quite some time. Our requirements are more stringent than these requirements so, facilities, if they want to submit to us, they need to adhere to the more stringent requirements because we cannot have every data element that is necessary be bogged down by some of these processes in order to evolve in the way that is needed. So, I am not actually understanding well enough the ramifications and how the ramifications may be different from a situation we have been in for a long time. I am just coming back from being out for a couple of days. I may not have looped up with Hsiu adequately. I need you to help me understand the ramifications of that because I do not know if this is different from than it has been for quite some time if I understand correctly. I apologize if I am not entirely tracking what will manifest here.

Kathleen Tully
One thing just given what we can say during the NPRM period, maybe Andrea, it may be good to talk to you separately from this forum to talk through that. And we are happy to include others as well, given what we can comment on, but some of that gets into stuff we cannot say in this forum.

Andrea Benin
Okay.

Bryant Thomas Karras
I will make a broad comment that I think this is a great indicator of why it is so important that updates and proposed changes to HL7 criteria happen in the public and ISO process of the HL7 organization, so we can see these changes coming as standards for trial use in advance of their implementation by program areas. That way, federal regulations can be pointing to things that are coming down the pike. So, I am encouraging you all to work within the standards bodies to make sure we do not end up, again, with a timing situation like this where we are about to be locked into a standard that you guys are about to move past. I am open to suggestions. How do we want to phrase this? And, Johnny, is the text that you put in there referencing –

Johnny Bender
You requested the language that was used in HTI-1 for F5, so I provided the link.

Bryant Thomas Karras

Thank you. Does anyone want to propose a suggestion on how to put that "at least" language referenced in HTI-1 into this in particular so that we can get around locking into a particular standard and, hopefully, allow the program area to evolve in a timely way?

Rachel Abbey
Bryant, we can come back to this towards the end, which we may have a resolution to propose or additional information.

Bryant Thomas Karras
Great. Again, it will be the scale that we are dealing with. Andrea, we are talking about thousands of providers who are under the current release and how many of them are you expecting would actually implement the soon to be release during that timeframe? Are you hoping it is 100%?

Andrea Benin
From what I am understanding that is the expectation. And I can group up with the team. There is a necessary additional data element that as antimicrobial testing evolves and changes, there are things that have to be updated. And so, there is an additional data element that needs to be put in there and is probably already delayed in getting into there, right, so it is important.

Bryant Thomas Karras
Right. This may have impacts on what the cost assessment is. But we will come back to it. All right, let us jump back to the slide screen and move on to the next criteria. And I saw Karl bounce onto the screen. Karl, would you mind reading the proposed language revision that impacts your program area?

Karl Soetebier
That is not a problem. Syndromic surveillance transmission to public health agencies, revised transmission to public health agencies, syndromic surveillance certification criteria. Revised transmission requirements via updated standards, HL7 version 2.5.1 implementation guide, syndromic surveillance, Release 1, U.S. realm standard for trial use. Expired existing standards on January 1, 2027. Change name to syndromic surveillance transmission to public health agencies.

Bryant Thomas Karras
Great. As we discovered in the last section, the proposed name change is the reversal of what is on the other side of the dash to stay consistent with the other rules.

Karl Soetebier
Correct.

Bryant Thomas Karras
Are there any comments from folks? Let us dive back into the spreadsheet and swap screens, so it is a little bit bigger. Thank you. It looks like we have comments from Hans. Hans are you on today or is today one of the days he could not be?

Molly Prieto
I think today is when Hans is on vacation.

Bryant Thomas Karras
Molly, would you read his comment for the record? You have to do it in an Austrian accent.

Molly Prieto
That I cannot do. Hans stated that syndromic surveillance has unique challenges in that it uses HL7 V2 Admit / Discharge / Transfer (ADT) messages yet, the clinical payload is increasing while identifiable data is being shared based on state specific requirements. The question becomes whether it is worth upgrading in this time window or starting to consider a switch to FHIR-based approach that could be analogous to electronic initial case report (eICR) on FHIR yet, have its own trigger events content, can contain identified or de-identified data, and it is not subsumed by ACR provider models after ACR yielding substantial consistency and opportunity for alignment where appropriate.

Bryant Thomas Karras
All right. He is pointing out heavy issues there. And one that impacts the state of Washington is our implementation guide here in Washington for syndromic surveillance, as an example, does require some identifiers so that we can link back to notifiable conditions, for example. And then, we strip those identifiers before transmitting on to the National Syndromic Surveillance Program (NSSP). What is going on? All right, Steve. Ike.

Steven Eichner
The related issue thinking about adoption date and how that ties in with promoting interoperability and starts of reporting periods. If we are expiring something on January 1, that would be the first day of a reporting period and that can create all kinds of havoc.

Bryant Thomas Karras
Are you proposing expiring December 31?

Steven Eichner
I would think so if you want to have a replacement standard being in place then on January 1. That would create better alignment with reporting periods both for providers and data receivers.

Bryant Thomas Karras
And CDC Week.

Steven Eichner
Yes. Otherwise, we have an issue with having to receive standards inconsistently for that calendar year. I have not looked to see if that is a Sunday-Monday day of the week piece, but it seems odd to be expiring on the first.

Bryant Thomas Karras
Karl and team, do you have any comment on the CDC Week or the roll ups that are used in NSSP? Do they occur on the first of the month or the calendar week or the CDC –

Karl Soetebier

I do not think that is relevant. Steve is right that the date should be consistent with how it is measured under promoting interoperability more so than the data itself.

Bryant Thomas Karras
All right.

Steven Eichner
January 1, 2027, is a Monday.

Bryant Thomas Karras
So, Lee, can I ask you to put your old CMS hat on for a second? Or if there is folks on. I do not think we have our CMS official in the subcommittee. Did Lee drop?

Steven Eichner
The same issue would hold true for anything with adoption dates. It is not solely syndromic.

Bryant Thomas Karras
Yes. We should probably go back to the previous sessions.

Rachel Abbey
This is probably more of a general comment that could be added in the general section.

Steven Eichner
Or repeated throughout. I have no particular preference.

Bryant Thomas Karras
Is it just a wording of expiring on January 1 or going into effect January 1, which would imply that on December 31, the others expire? I will let the ONC staff mull over that. And maybe we will come back to some general comments.

Steven Eichner
In general, the comment would be absolute clarity on the date of last use for transmission and whatever that date is should align with other calendars such as promoting interoperability.

Bryant Thomas Karras
With a three-year lead time, hopefully, they will not wait until the last minute. Let us go back to rather than the general. Does anybody else have comments?

Steven Eichner
Right. That is the other aspect. We, as public health receivers, want to make sure we are using the right stance. We do want to look at commented option dates, unless things are also backward compatible because if people get too far advanced and we have not yet modified our systems to receive the more advanced standard, we have the problem on the other end. You also need to consider a minimum necessary if somebody has gotten further advanced than what you can catch, is that a violation of minimum necessary?

Bryant Thomas Karras
Yes.

Molly Prieto
I will just say here that minimum necessary would be outside of the scope of this particular discussion but agree with what Rachel said about if there is a comment regarding December 31 versus January 1, it can be an overarching comment versus within each specific criteria.

Steven Eichner
Well, the minimum necessary is relevant. But if more information is being disclosed than being received, that could be perceived as being in violation of minimum necessary disclosure.

Molly Prieto
Understood but that is outside of the scope for this particular discussion for this.

Steven Eichner
In terms of the date, yes. Actually, no, it is not because if public health is modified, the receiving end of it to take a more sophisticated standard that has more data then, there is no violation of minimum necessary because public health has the capacity to receive all of the data. The issue of the minimum necessary is that public health has not yet positioned itself to receive all of the data should you disclose something that public health does not have the capacity to receive.

Bryant Thomas Karras
Let me dig into that for a second. Karl, if you have any of your other team on that wants to comment. Can you scroll over to the reference of the IG on the table, please? Does the current IG allow for the optional reporting of the data elements that Karl is referencing like identifiers in the IG that is referenced here?

Karl Soetebier
So, the way the IG is specified right now, the data are to be anonymized in the sense that the identifying elements of name, address, city, state and so forth are supposed to be suppressed. That is the way the IG is crafted.

Bryant Thomas Karras
Was there not something in the previous section?

Karl Soetebier
There might be something in there. I would have to go back and check to see if there is language that says it gives you an option to do it differently.

Bryant Thomas Karras
I would like to know what has happened. I have not been in the community of practice to know what evolution has taken place, but previous implementation guide did have optional elements that individual states could exercise. So, there were optional but requirable by a given jurisdiction if that jurisdiction passed a rule or law or local law that applied and made those elements not optional in that jurisdiction. But they

were optional in the overall national guide, so they would be visible to implementers and electronic health record (EHR) vendors.

Karl Soetebier
Understood. I would have to go and research that. I would assume the language was carried over from the current version to the new proposed version but I would have to go back and confirm that. I can do that. It is an important point. We can do that. I do not know offhand.

Bryant Thomas Karras
Great. If you can do some homework or have the team dig in on that, Gillian, thinking to CSTE's community of practice, maybe that is a question that CSTE can dig in on and make sure they provide us with language or if this is a potential issue that we may be impacting jurisdictions. There are a number of jurisdictions, especially during COVID times that enacted rules permitting the identifiers to flow through the syndromic programs and linkages between syndromic and notifiable conditions.

Gillian Haney
That is only going to increase. Karl, if you could get me the question specifically that we would pose, I can carry that forward to the community of practice.

Molly Prieto
I think the community of practice is a great place to have that discussion. I will say from an NPRM perspective just to keep us very narrowly focused, the way the NPRM brings it is that we only reference the ability for implementation guide to do required data elements. If there are optional elements required at the state level that is not something NPRM explicitly would cover.

Bryant Thomas Karras
That is not true, Molly. It does mention local rules still apply.

Molly Prieto
Certainly, but from a certification perspective when going through the conformance testing, the NPRM is only required to cover the required elements.

Bryant Thomas Karras
We have gone back and forth with this. HL7 has considered creating a separate criteria where it is optional but it is not optional. So, it is required for testing and implementation that it has to be able to be supported but it may or may not be exercised. It is kind of a nuance of who is requiring it. And we have oftentimes lamented that the National Institute of Standards & Technology (NIST) was only going through and doing the required only and not the ones that are oftentimes exercised by more than half of jurisdictions. It really should be in there as a required for certification.

Gillian Haney
Can we get a clarification on how we are defining required?

Molly Prieto

For the purposes of the NPRM, it would be within the implementation guide where the data elements are listed as required, recommended, or operational.

Gillian Haney
Thanks.

Bryant Thomas Karras
It is required, but empty is permitted and optional.

Gillian Haney
We do get into trouble with this quite often in terms of the required versus required when available or required when empty because public health does not want the message to fail. And so, there are very few actually required fields that would make that fail. So, it is a very tricky situation for public health.

Peter Karras
I wanted to jump in and do a time check. We have three minutes until public comment starts.

Bryant Thomas Karras
I thought we had changed the timeline to be the end of the hour.

Peter Karras
That is starting August 6.

Rachel Abbey
Next week, Bryant, because everyone wanted to have time to make their calendar changes. No worries.

Bryant Thomas Karras
Shoot. I was going off of the wrong clock. So, Karl has got his homework. Gillian, if you can defer this discussion to the community of practice, and I have a feeling that we will need to make some general comments about required and what public health deems as required, since public health jurisdictions or public health agencies are, in many, especially home rule states, the local or state level that have the power to make required elements. We need to make sure that our vendors are supporting the ability to comply without undue expense. We need to make sure the language gets in there appropriately, so developers are not inadvertently making it harder than it needs to be.

Karl Soetebier
Agreed. Bryant, if you can have someone from Washington point me to what you were referencing in the previous guide, I can quickly ensure that the language is in the newer guide or answer that question.

Bryant Thomas Karras
It is not just Washington. There are other jurisdictions.

Karl Soetebier
I know. Illinois is doing it and Mississippi. There is a group of folks that have that situation for sure.

Bryant Thomas Karras
Thank you. I did not want to make myself feel like I was putting my thumb on a scale. Katie.

Kathleen Tully
One really quick note on the previous discussion. Just wanted to quickly clarify just the difference between what would typically be required within an IG versus what is required through our program and we point to what is within an IG and basing our requirements around that, unless it is a functional criteria. If there are data elements that need to be required for being transmitted that are not today then, that would be something I encourage goes through the HL7 process. It is not something we control through certification.

Bryant Thomas Karras
Yes. And this is where Interaction Status Detail Segment (ISDS) had a document with rules of the road documented in terms of how the guide should be interpreted. And when ISDS was defunded, we lost a lot of that explanatory guidance on how to interpret the HL7 guide appropriately. We will try to figure out a place to resurface that maybe explicitly in HL7 going forward. We are at the public comment time. Is that correct, Peter?

Peter Karras
That is correct.

Bryant Thomas Karras
Go back to the slide deck. We did a terrible job of getting through our criteria.

Public Comment (01:19:07)

Peter Karras
We will have extended time starting with the next Group 1 meeting next week. At this time, we would like to open the meeting for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press star nine to raise your hand and once called upon, press star six to mute and un-mute your line. We will pause for a moment to see if there are any members of the public with raised hands. And while we wait, again, a reminder that the next Group 1 meeting will be on August 6 from 11:00 a.m. to 1:00 p.m. Eastern, extended for half an hour. All of the HITAC materials can be found on healthit.gov. I am not seeing any raised hands at the moment. There are no members online by phone with any questions or comments. So, at this time, I will turn it back over to Bryant for closing remarks. Bryant, you are on mute.

Next Steps (01:20:36)

Bryant Thomas Karras
Rather than losing eight minutes, can we go back to the slide deck? What is next in our list? Can we cue that up? Immunization, great. If we can get opening comments and we will need to extend the discussion into the next session. So, apologies to folks from the immunization program who are on today. You may have to come back next week. Any comments from folks on this one? I am hoping immunization is such a tried and true early adopter, Mary Beth, that we are 100% in support of this. Any comments?

Mary Beth Kurilo

Yes. Thank you, Bryant. We are for the most part in support of all of this, particularly moving towards the 2018 updated version of the IG. So, we do plan to comment in support. We did think there was room for conversation about some of the pieces that are in the updated 2018 IG. And you mentioned Hans is not on today, but I am sure he has thoughts about part of what is Appendix C, which pulls forward standards around ERR5, which is more specific error messaging. We think it is a good thing because it will make the error messages and acknowledgement messages more specific, but it will be a lift for EHRs to incorporate that. We were hoping to have a conversation about that piece and maybe we can carry that over to next week.

Bryant Thomas Karras
When Hans is present. Perfect. It is going to make our session –

Steven Eichner
Just to add on to that piece, one of the other aspects of the error conditions are tie-ins to the insight conditions for ONC about what HIT vendors are going to be required.

Bryant Thomas Karras
Our numerator/denominator issue.

Steven Eichner
It is an important discussion.

Bryant Thomas Karras
Yes, absolutely. If I remember those insight, it is transmission errors have to be at a minimal level below a couple of percentage points. To be able to document and receive those error messages back will be critical to –

Steven Eichner
And one of the issues, especially for states that have opt-in versus opt out is if you return a message that says this person has not opted in, that is typically reported as what folks might interpret as an error message. It is not really an error message in terms of sending a complete message. It is an accurate message, but a response that the IAS cannot incorporate the data. If that is not clarified in the error reporting and included to work with the insight condition, it can report erroneous information. So, that is another fallout of the discussion.

Bryant Thomas Karras
Are there other comments from folks?

Mary Beth Kurilo
I think the other piece that may be helpful for us to discuss is the requirement under F1 for EHRs to receive incoming patient level immunization specific queries because it would be helpful. And I do not know if ONC can comment on it, but it would be helpful to hear ONC's intent on that one. IISR developing the ability to query but under IZ Gateway and some of the work they are doing with IZ Gateway, but it does flip the script on the expectations of which direction the queries go. That may need more discussion as well.

Bryant Thomas Karras
Yes. That is one that both for this bidirectional capability and for the prescription drug monitoring program capability, there seems to be some language potential flipping around that our ONC colleagues may be restrained from commenting. But perhaps our CDC colleagues could explain the intent there. Are there folks on –

Molly Prieto
CDC is covered by the same terms of interpretation. But I believe because we include it in preamble, we can comment that the intention here is to ensure the ability to do the query is on both ends of the spectrum. We did not cover F21 today but we will in a future conversation. But just to ensure that that function is mirrored between both of the systems in the event there is information in one system that may not be in the other. I think we do discuss that in preamble, so it gives us more wiggle room in terms of the conversation.

Bryant Thomas Karras
Are there folks from the CDC immunization program on?

Kafayat Adeniyi-Inniss
Yes. This is Kafayat Adeniyi-Inniss. I also have my colleague, Jenny Junkins on.

Bryant Thomas Karras
Great. Any thoughts on those error messages and messages going back about patients opting out, so not truly being an error.

Kafayat Adeniyi-Inniss
At this particular point, we do not have anything to add at this particular point beyond the comments that Mary Beth mentioned. And I believe there is an opportunity for further discussion around the error messaging. So, there is no additional thoughts to add on that.

Mary Beth Kurilo
To that end, Bryant, I think the insight conditions will be under Subcommittee 2. So, I am wondering if we want to plan a Group 1 and Group 2 meet up to think about how F1, F21, and the insight conditions all play together.

Bryant Thomas Karras
And not wait until the final three days to have that crossover, that is a great suggestion.

Mary Beth Kurilo
If possible.

Bryant Thomas Karras
The schedule is going to be tricky in terms of permitting that. I encourage you all as task force members, you are allowed to attend those other meetings, so be sure, Mary Beth, and look at their agenda and schedule and join in for those discussions. And they can promote you to being a panelist since you are an official task force member.

Mary Beth Kurilo
Yes. Absolutely.

Bryant Thomas Karras
Ike, I cut you off.

Steven Eichner
There are several of us participating in multiples.

Bryant Thomas Karras
Excellent. We are at time, but I want to be respectful. Peter, anything we need to do to wrap things up here?

Peter Karras
We are all good. We can adjourn the meeting.

Bryant Thomas Karras
All right. Thank you, everybody. That was a whirlwind. We almost got through what we hoped to, but not quite. So, we will have some housekeeping catch up and homework to report back on for our next session. Take care.

Adjourn (01:29:21)

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT
No comments were received during public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT
Gillian Haney: Agree with Steve - AND OR

Bryant thomas Karras: OR

Jim Jirjis: ONC can answer this process question

Bryant thomas Karras: can we get that at least language?

Johnny Bender (ONC): https://www.ecfr.gov/current/title-45/part-170/subpart-C#p-170.315(f)(5)

Gillian Haney: how are we defining "required"?

Watkins, Greg: Thank you, Chairman! Thanks all.

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 - July 30, 2024, Meeting Webpage

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