HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

August 15, 2024, 10 AM – 1:45 PM ET

VIRTUAL

MEMBERS IN ATTENDANCE

Medell Briggs-Malonson, UCLA Health, Co-Chair
Sarah DeSilvey, Gravity Project, Co-Chair
Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Michael F. Chiang, National Institutes of Health
Derek De Young, Epic
Steven (Ike) Eichner, Texas Department of State Health Services
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Hannah Galvin, Cambridge Health Alliance
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Steven Hester, Norton Healthcare
Bryant Thomas Karras, Washington State Department of Health
Hung S. Luu, Children's Health
Trudi Matthews, UK HealthCare
Anna McCollister, Individual
Deven McGraw, Ciitizen
Aaron Neinstein, Notable
Katrina Miller Parrish, Patient.com
Eliel Oliveira, Harvard Medical School & Harvard Pilgrim Health Care Institute
Kikelomo Oshunkentan, Pegasystems
Randa Perkins, H. Lee Moffitt Cancer Center & Research Institute
Rochelle Prosser, Orchid Healthcare Solutions
Dan Riskin, Verantos
Fillipe Southerland, Yardi Systems, Inc.
Naresh Sundar Rajan, CyncHealth

MEMBERS NOT IN ATTENDANCE

Mark Sendak, Duke Institute for Health Innovation
Zeynep Sumer-King, NewYork-Presbyterian

FEDERAL REPRESENTATIVES

Keith E. Campbell, Food and Drug Administration
Jim Jirjis, Centers for Disease Control and Prevention
Meg Marshall, Department of Veterans Affairs *(Absent)*
Alex Mugge, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology

ASTP STAFF

Elise Sweeney Anthony, Executive Director, Office of Policy
Avinash Shanbhag, Executive Director, Office of Technology
Seth Pazinski, Designated Federal Officer

PRESENTERS

Al Taylor, ASTP
Francheska Geegbae, ASTP
Elisabeth Myers, ASTP (Discussant)
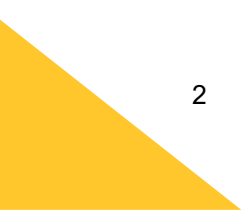
Call to Order/Roll Call (00:00:00)

Seth Pazinski
All right, good morning, everyone and welcome to our August 2024, Health Information Technology (IT) Advisory Committee Meeting. I am Seth Pazinski with the United States Department of Health and Human Services (HHS), Assistant Secretary for Technology Policy, or ASTP. I will be serving as your Designated Federal Officer today. As a reminder to everyone, this is a meeting that is open to the public, and we encourage public feedback throughout the meeting via the Zoom chat feature. There will also be a time towards the end of our agenda to make verbal comments, if you are interested in doing so.
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So I am going to get started. I would first like to welcome our ONC executive leadership to the meeting, With us, today, is Elise Sweeney Anthony, our Executive Director of the Office of Policy, and Avinash Shanbhag, the executive director of the Office of Standards, Certification, and Analysis. Now I will begin a roll call of the HITAC members. So, if you could please indicate when you are present when I call your name. I will start with our co-chairs, Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning, everyone.

Seth Pazinski
Sarah DeSilvey?

Sarah DeSilvey
Good morning, everybody.

Seth Pazinski
Good morning. Shila Blend?

Shila Blend
Good morning.

Seth Pazinski
Good morning. Hans Buitendijk?

Hans Buitendijk
Good morning.

Seth Pazinski
Good morning. Derek De Young?

Derek De Young
Good morning.

Seth Pazinski
Michael Chiang

Michael F. Chiang
Good morning.

Seth Pazinski
Good morning. Steve Eichner?

Steven (Ike) Eichner
Good morning.

Seth Pazinski
Good morning. Lee Fleisher? Hannah Galvin?

Hannah Galvin
Good morning.

Seth Pazinski
Good morning. Raj Godavarthi?

Rajesh Godavarthi
Present

Seth Pazinski
Steven Hester?

Steven Hester
Good morning.

Seth Pazinski
Good morning. Bryant Thomas Karras?

Bryant Thomas Karras
Present

Seth Pazinski
Hung Luu?

Hung S. Luu
Good morning.

Seth Pazinski
Good morning. Trudy Matthews? Anna McCollister? Deven McGraw?

Deven McGraw
Good morning, everyone.

Anna McCollister
Hi there, Anna is here. I was just on mute. Sorry.

Seth Pazinski
Thank you, Anna. Katrina Miller Parrish?

Katrina Miller Parrish
Good morning.

Seth Pazinski
Good morning. Aaron Neinstein?

Aaron Neinstein
Hi, good morning.

Seth Pazinski
Good morning. Eliel Oliveria?

Eliel Oliveira
I am here. Good morning.

Seth Pazinski
Good morning. Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning, I am here.

Seth Pazinski
Good morning. Rhonda Perkins?

Rhonda Perkins
Good morning.

Seth Pazinski
Good morning. Rochelle Prosser?

Rochelle Prosser
Good morning.

Seth Pazinski
Good morning. Dan Riskin?

Dan Riskin
Good morning.

Seth Pazinski
Good morning. Mark Sendak will not be able to join us today. Phil Sutherland? Zeynep Sumer-King? Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Seth Pazinski
Good morning. Now I will go through our federal representatives on HITAC. Keith Campbell?

Keith E. Campbell
Good morning.

Seth Pazinski
Good morning. Jim Jirjis?

Jim Jirjis
Good morning.

Seth Pazinski
Good morning. Meg Marshall? Alex Mugge? Ram Sriram?

Ram Sriram
Good morning.

Seth Pazinski
Good morning. Thank you, is there anyone I missed or anyone who just joined us that would like to announce themselves?

Lee Fleisher
Lee Fleisher joined. Thank you.

Seth Pazinski
Hi Lee. Thank you. Well, please join me in welcoming Elise Sweeney Anthony for her welcome remarks. Elise, over to you.

Welcome Remarks (00:03:55)

Elise Sweeney Anthony
Good morning, everyone, it is a pleasure to be here today, as always, with our amazing HITAC.
The work that is underway, in the summer no less, and I appreciate everyone's time during the summer to work through a range of work groups and engagements around health IT, particularly the work on most recently released rule that is underway, I am really, really excited about the contributions that HITAC is adding to that rule through their recommendations to come. I am here today to give a couple of updates from ASTP, to introduce myself, the Executive Director of the Office of Policy at the HHS Assistant Secretary

for Technology Policy, and ONC. So, that gives my first update that I wanted to give is an introduction to ASTP. ASTP is the Assistant Secretary for Technology Policy and that is our new name. We are now being renamed the Assistant Secretary for Technology Policy. We are also still the Office of the National Coordinator for Health Information Technology, long title, you can refer to us as ASTP.

We are really excited to continue the work that we have been doing around health IT, and also adding in new aspects to our portfolio including HHS's oversight over technology, thinking about data, Artificial Intelligence (AI) policy and strategy. Those components have also moved to ASTP as part of this work. So, we are led by our Assistant Secretary for Technology Policy, Micky Tripathi. The wonderful work he has been doing will continue. Now added to this portfolio is this work around AI and data and we are really excited about that. Many folks might have seen that there are several HHS wide roles, the chief technology officer, the chief data officer, and the chief AI officer; and we have launched a search for those positions, as well.

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There are some links that we can drop in the chat around the press release, and the buzz blog around the announcement to ASTP, but really, we are just looking forward to continuing the work that we have been doing with the HITAC and expanding our work overall at ASTP to include these areas. We are really excited about this, as you can see, as you can tell by my wonderful new Zoom background. So, many thanks to all the work you have done over the years and all the work to come as well. It has been a pleasure, as we continue to work with HITAC and the recommendations you have provided. Your recommendations will, of course, go to Micky as well.

So, other news, Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. So, we released HTI-2 Proposed Rule. We have gotten a number of questions over the last several months around the timing for HTI-2, when it was going to drop, and we are excited to say it has dropped. It has been published in the federal register. There is a 60-day comment period, and that is going to end on October 4th, 2024. So, please, please, do spread the word. As always, the comments we receive are so critical to us developing the final policy and the final regulation. I always say, but it is important to say, that we want to know, where we are hitting the right marks, where we are hitting the right notes on health IT and our proposals, and also where we're not, where there may be areas where we need to address, or where you think that some updates or improvement or changes would be helpful. But it is also helpful to know where we are in the right spot. Both of those things are important to us.

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And for everyone on the call, including the public, I do want to note all are helpful, so whether it is one sentence, or ten pages or more, we read all of the comments. It is really important, I think, that we hear what you're thinking, and if that's one sentence, that's okay too. If it is ten pages, 100 pages, no matter what it is, we read it, but I know folks have day jobs as well, and not just reviewing regulations. So, I always want to encourage folks to just tell us what you think, and even if that is a short statement that is still helpful as well.

So other things to note: For the HITAC, the plan is for the recommendations to be completed by the September 12th HITAC meeting. So, that is a very fast timeline. It is really critical to us kind of moving things forward. The HITAC recommendations must be voted on and approved during a HITAC meeting, so during the full meeting. The September 12th HITAC meeting is the last full committee meeting within the

public comment period, so that is why that is noted that way. A couple of other things to note is, as always, ASTP, we will be hosting and continuing to host information sessions on HTI-2 Proposed Rule you can find the ones that we have done already on healthIT.gov. I really encourage folks to check them out and listen to those sessions. It includes an overview session and a public health session, and an information blocking session. Our next informational session is scheduled after the HITAC meeting today at 2:00, so if you did not get enough of ASTP this morning, then join us at 2:00 p.m. eastern time, and we will be talking about patient payer, and provider application programming interface (API) proposals. There are also several HTI-2 proposal fact sheets located on healthIT.gov, please do check those out as well.

And then other great news the United States Core Data for Interoperability (USCDI)+ Cancer Initiative, so ASTP welcomes public feedback on the USCDI+ Cancer Registry draft data element list. We are asking for feedback about the importance and ease of collection of the data elements and the possible burden of sharing them electronically. Public feedback is due, by September 23rd, 2024, using the comment feature on the USCDI + site. A user account is needed to submit feedback, and we will include the links in the chat. Also, TEFCA, so Trusted Exchange Framework and Common Agreement, new standard operating procedures (SOPs) and updated resources. So, the Sequoia project, who is the TEFCA recognized coordinating entity, or RCE, released a new bundle of new standard operating procedures. These SOPs are immediately available for adoption and implementation by TEFCA Qualified Health Information Networks (QHINs) or qualified health information networks participants and sub participants. The TEFCA RCE will review these new SOPs during the TEFCA monthly informational call, and that is going to be on August 20th. from 12 to 1:30 p.m. eastern time.

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Also, lots of work happening around health IT alignment policy. Later today, Francheska from the team will be presenting on our work around the health IT alignment policy and our most recent work with Assistant Secretary for Financial Resources (ASFR) and their release of their new Proposed Rule. So, really excited about the advancement of health IT policy, and we will talk more about that later today, as well. Thank you, again, for all of the work that you're doing, and that you continue to do, it is truly appreciated at ASTP. It really informs the work that we do overall. With that, it is my pleasure to turn it over to Medell and Sarah for their opening remarks.

Opening Remarks and Review of the Agenda (00:11:24)

Medell Briggs-Malonson

Well, thank you so much, Elise, for all of those amazing updates. I do want to say, congratulations to the new assistant secretary, Tripathi, and the entire ASTP leadership team and overall team. This entire new restructuring really highlights just the impact and the success that ONC has had, to the point that now we get some broadened scope. So we are very, very privileged and very honored to continue to work alongside ASTP.

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So, welcome everyone. We are so excited to be here at our August HITAC meeting. It is always a pleasure to share the same space with all of you. So, we are just going to jump right on into the meeting as well. But before we do so, just want to give a friendly reminder about some of the various, different items that will be coming up. So as a reminder, the new Health Equity by Design Task Force will officially launch next month in September. So, if you are interested in serving on this task force, please make sure to let Seth know as soon as possible. The task force will be meeting biweekly because there is a fair amount of work to get done prior to the end of the calendar year. But if you are interested, please let Seth know in the ASTP

Team, because what they are also trying to do is identify all of the various different co-chairs for this task force. So, with that, I am going to turn it on over to my wonderful co-chair, Sarah.

Sarah DeSilvey

Thank you, so much, Medell. Next slide, please. We are going to go through the agenda. Welcome all to the meeting again. I want to echo, and just congratulations to the ASTP team. This slide has not been updated yet, they are going to be updated very shortly. My apologies if I got the acronym wrong. It is always amazing to see the work of this division and just to be a part of it and grateful you all are here, I want to note something that's really important and was mentioned in an email that Seth sent out, and it was just mentioned by Elise, but this is our time to pay attention to really critical elements on the agenda as we go through the work today. So, we are going to review HTI-2, from the HTI-2 Proposed Rule Task Force. Bryant and Rochelle are going to present on this. This is your moment in time to ask questions and lean in and take it in.

As Elise noted, we are going to be voting when we come back next month, so please lean into this. Make sure you review materials and ask critical questions because when we come back next month it will be time, to express our opinions. Then we are going to go through a near and dear topic of mine, overview of the USCDI Version 5, our colleague Al Taylor. We will then take a short break and then go into the annual report work group, crosswalk discussion, and then we will go into an overview of the HHS health IT alignment policy, which focus aligning HHS adopted standards across the department. We will then have public comment and close at 2:00, Eastern Standard Time, after we have final remarks and adjourn. There is a lot to talk about today, and, again, specifically, when we think about going into the next item on the agenda, please bring your whole minds to that topic and all your various ideas as we listen to our HTI-2 Proposed Rule Task Force co-chairs presenting the critical work of that committee because, again, this is our moment to ask questions, next slide. Now it is my honor to pass the –

Medell Briggs-Malonson

Sorry, Sarah to interrupt, before we go into introducing HTI-2, we do see Anna's hand.

Sarah DeSilvey

My apologies. Anna?

Medell Briggs-Malonson

That is okay. Anna, did you have a question?

Anna McCollister

Well, actually, it was more for Elise, but I can is ask the two of you as well. I am just wondering, since the ASTP remit is much broader than ONC, I am just wondering how that impacts the role of HITAC.
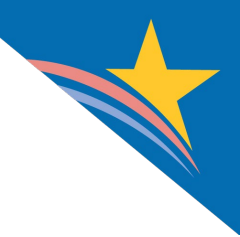
Sarah DeSilvey

That is a good question. That is definitely an Elise Question.

Elise Sweeney Anthony

I am here, Hi, everyone So, we have not lost our ONC piece of our puzzle. We are still the Office of National Coordinator for Health Information Technology. We are now also the Assistant Secretary for Technology

Policy. So, in terms of the work that the HITAC does, through our work over the years when we were ONC, that work is still going to continue. Some of the areas that we have added into our portfolio are very much in that space where I think, there is a health IT piece. There are some aspects of AI, for example, that we have already talked about through hearings and such around health IT. So, we do not anticipate that there would be an impact on HITAC. The recommendations that you are providing would still go to Micky. He serves as the Assistant Secretary for Technology Policy and the national coordinator for health IT. So, we do not expect that there would be an impact.

We will be updating, as Seth noted, we will provide new Zoom backgrounds and such and things like that that bring in ASTP as well. But, yes, we do not expect that there will be a major impact. Seth if you had anything to add please do, let me know if I left anything out.

Seth Pazinski
No, I think you covered it, Elise. I think the AI example is a good one, where while we are adding chief AI officer, the HITAC has been and anticipated continue to be those types of topics. So, for the most part, kind of continuing on as HITAC has.

Anna McCollister
Thank you.

Sarah DeSilvey
Anna, thank you so much. You always ask such good questions. My apologies for not noting your hand. Now we are transitioning to the HTI-2 Proposed Rule Task Force update from our two co-chairs, Bryant and Rochelle. Thank you so much for coming. Again, this is our moment in time so looking forward to the presentation and the conversation that follows. Bryant and Rochelle?

HTI-2 Proposed Rule Task Force 2024 Update (00:17:22)

Bryant Thomas Karras
Great. Well, thanks so much, thanks to all the ASTP staff. It is going to take me a while to not automatically say ONC. It is Rochelle and my honor to present to you all an update today. I will go first, presenting our Group 1 work, lead into the Group 2 work. Then Rochelle will finish up Group 2 and lead into Group 3 work that she has been leading. Thank you so much. Next slide, please. Is there a next slide? Thank you.

So, we will go through the membership, which is a very diverse group of both HITAC full members, as well as subject matter experts that have been invited in to be a part of the task force to round out our expertise. We will talk about the charge and then update on the progress that each of the groups has made. Next slide.

So, here is the membership. I will leave it on the screen for people to pursue and read. I am not going to read each person's name, but you will see lots of familiar names from the HITAC itself, as well as past recognizable names from people who have testified to the HITAC or have been part of prior task forces and were asked to return to serve in the review of HTI-2. We really thank everyone for their service. It has been an incredible amount of work that has been divided up amongst the three groups, running simultaneously roughly on Tuesdays, Wednesdays, and Thursdays each week, which is keeping the staff at ASTP quite busy. Next slide, unless any of the staff wanted to review anything from this slide?

Seth Pazinski
We can keep going Bryant.

Bryant Thomas Karras
So, our overarching charge, the obvious reviewing of the HTI-2 Proposed Rule, going into detail, making sure that the recommendations of the rule were clear, making suggestions for how it could potentially be improved in each of the areas of public health, technology interoperability, patient engagement, information sharing. It is a lot, as everyone on the committee knows and the public who are watching, over 1,000 pages. We have been making great progress. I am jumping ahead in each of the committees and hope to have a transmittal draft ready to circulate to the committee members for review before the meeting on the 12th. As was mentioned earlier, the push is since the 60-day comment period will end before our October meeting of the HITAC, we needed to get it completed in time for the September meeting, which has put quite a clock ticking away. Next slide.

So, into my passion, my bread and butter, the public health work. Next slide, please. So, we have checked off, you can see the yellow highlighted are areas where we had deep discussions on – apologies, we could not fit onto the slide all of the topical names that are covered within those F criteria, but I will just remind people that what we are talking about here in the F criteria are the public health standards that are the basis for the engagement between the clinical world and the public health world. The key factors, the F-1 criteria, which are immunizations. It is not, as Micky likes to say, the catcher's mitt side of the pitcher's criteria. We have added F-21 for what requirements are on the public health side. F-2 are the syndromic surveillance criteria. We have F-22 on the public health side. F-3 are the electronic laboratory reporting of notifiable or reportable conditions. F-23 on the public health side. F-4 is the cancer reporting, and F-24 on the public health registry side. F-5, relatively new, but has been in existence for a beat, are the electronic case reporting (eCR) criteria, and F-25 on the public health side.

F-6 is the antibiotic use, or antimicrobial use and antimicrobial resistance reporting. F-7, the healthcare surveys reporting. Again, another pair, F-8, which is a new criteria, birth reporting, and F-28, the birth reporting on the public health side. Not yet covered, which I will go into, are the F-9 and F-29 criteria for prescription drug monitoring. Those will be covered next week. The G criteria, you will see G, which is outside the F, is listed there. Those familiar with the G-10 API, which is covered by a different group, Group 2, there is a public health component, G-20, which we have been discussing and trying to figure out the overlap. We will continue that discussion in the next coming weeks. Next slide.

So, for each of these discussions, we have brought in subject matter experts from the relevant program area at Centers for Disease Control and Prevention (CDC) to help answer questions, to provide clarity on what exists currently, so that we can make sure that we are understanding the context and challenges. I just truly want to thank all of the federal members who have taken their time to assist us in helping us dig into the HTI-2 rule. More on the next page, next slide. Next slide.

So, this is our upcoming topics. We are continuing our discussion of G-20, and we will be digging into the prescription drug monitoring criteria, our opioid registry as it was sometimes called. Then we will be doing some housekeeping in our last session and reconvening as all three groups together. I think we now transition to Group 2. Next slide.

Great. Rochelle, I will start and then you can jump in when my voice starts to crack.

Rochelle Prosser
Sure, absolutely.

Bryant Thomas Karras
Next slide please. As you can see, Mark has been leading HTI-2 discussion on these topics, the API, principally. He has made great progress. All the yellow highlighted sections are the ones they have already discussed. The updated criteria for USCDI-4, the smart app 2.2, user access, bulk data enhancements. Then moving on to the modular capabilities, as I mentioned there is some overlap between G-10 and G-20, so we have had some public health folks from our Group 1 attending discussions in Group 2. Also, some exciting new improvements towards the pair APIs and bringing that insurance perspective or role into the certification regulation. There is some new criteria around imaging and multifactor authentication criterium, as well as encryption and protection of the data, which with everything that is in the news is well welcomed and a fabulous, I think, thing to be focusing on these days. As you can see, two more sections to go. Next slide I think talks about the schedule?

These are the ones that have been covered so far. Next slide. Rochelle, you want to take over for the upcoming?

Rochelle Prosser
Sure. So, for the upcoming on Mark's, he actually has two areas left. On the 22nd, the electronics prescribing and real-time prescription benefit criteria. For those of us on the HITAC who are very interested in the pharmacy benefit aspect or the pharmacy information or well in the pharmacy, I would strongly recommend you to just sit in on this conversation. It is going to be very interesting. Some of the people that sit on Mark's committee also sit on my committee on the information blocking and the TEFCA. So, there has been some very robust discussions as we looked at how the APIs would affect interoperability and patient access, as well as control and understanding in terms of permissions and permission stake as Bryant has mentioned, there has been a lot of talk about in the news. We are very happy to help path this means, the United States Office of Special Counsel (OSC) and ASTP here on both of our committees. Finally, on the 28th, they will discuss the condition and maintenance of certification. That is going to be interesting, for sure. I would really like an opportunity to listen to that, but I have my own one going on. So, I really look forward to hearing the committee and the HITAC's committee's comments now as we move into the interoperability slide. Just remember that this is your time to ask us the questions. Next slide, please.

So, we will begin about Group 3. I am the co-chair for the Information Blocking and TEFCA. It has been a pleasure serving on this team. Next slide, please. So, these are the areas that we have gone over thus far. We basically have two left, which is to go heavily into the trusted exchange framework and common agreement. We actually started a little bit of it yesterday. It was rather interesting to see how QHINS and Fast Healthcare Interoperability Resources (FHIR) actually overlap in areas of public health, as well as our Native American areas where we talk about Indian health services. What I decided to do on my committee was bring those voices that are not always represented right into the committee, instead of having them as subject matter experts (SMEs) where they can actually put their feedback and actually have that in the record, so that if we identify any gaps, we can bring it here to the higher committee here under HITAC, and

have them addressed in a more impactful way. And so, that has allowed us to really dig in and talk about the protected care access and requester preferences exception with extra fervor and have a real understanding of why we need to align ourselves with the higher areas so that there is no misunderstanding of what these definitions are and what we are trying to do.

I think that as we look at how information is used or not used or misjudged or repurposed and repackaged, we have to have an understanding that there are going to be entities out there that are not going to be able to comply based on their age, length of practice, or small-size level of development, etc. So, we need to allow for that lack of transparency. I live in Florida. Acts of God happens all the time here. For those that live in California, it could be a fire. So, those are the times when we do not want to penalize people for not having that level of transparency, even in the sense of it is a natural occurrence and we need this record, but it is flooded under 10-feet of water. Some will say we should prepare for all instances of this. I would say global warming has showed us that there is no planning when a 100-year and a 1000-year flood comes every year. So, these are some of the discussion that we had. I really think all the committee members and the HITAC committee members that have been here, that I have asked to come and serve with me, it has been very transformative. Next slide, please.

These are the dates and what we have covered. I did actually circle back and allow more time to ensure that the SMEs and those that were asked to serve on the committee, because they were serving for the first time, to ensure that they had a full understanding and the ability to be able to comment. Next slide, please.

On the 22nd, we have moved so fast, we will be combining the 29th meeting with the 22nd meeting, so that we can have a robust and full accounting of our rule and the purpose of information blocking and TEFCA on the 29th, so that we can actually finish and complete our task. We have really moved forward at a wonderful pace. I just want to thank the ONC and ASTP and the Accel team in ensuring that we had excellent homework content, as well as being able to help direct and guide the team until the HTI-2 document was actually released. I also want to thank the members of the public. Your comments that I have read, your comments that I have reviewed, good, bad, and the other side, they do make a difference. It helps to craft and move forward on our task. Accel, next slide, please.

So, now we will be talking about the full task force meeting topics. So, September 3rd and 4th, all three co-chairs and their taskforce will come together and combine their topics together to update and finalize recommendations and deliver those to the HITAC committee on the 12th for your review and voting. For those that are waiting to comment, for those of us on the HITAC who feel there is a dissent, I can be a dissenter at times too, myself, if you have a recommendation that you are dissenting on or want to change, we recommend and strongly urge you to bring your comment in writing so that we can address it right there and look at how you would craft what you have said so that we can vote. As Bryant has mentioned, October 4, very quickly, the public comment will end. We want to be able to provide a full account to the general public and allow them an opportunity to review, comment, and share our work. Accel, next slide.

So, we will turn it back over to discussion with the higher HITAC team. I did see in the chat there were a lot of comments. So, I am going to ask Seth to help me with the comments. Those that wish to raise their hand and share with us publicly, if you could do so now.

Medell Briggs-Malonson

Yes, so Rochelle, as well as Bryant, thank you so much. We are going to jump right on into discussion.
It seems like all of the various different subgroups have been doing amazing work in order to provide recommendations directly back on the HTI-2. Just so that we are all in the same page, because we are on a very accelerated timeline right now, and we do want the whole HITAC Committee to be able to see all of the amazing recommendations that you-all are formulating, and to be able to also weigh in, as you were just mentioning. So what would be the very first question, Bryant and Rochelle, is there a way,
since our next meeting is going to be the meeting where the full Committee of HITAC is going to review and approve the final recommendations from the HTI-2 Task Force, what would you think is the best way for the HITAC committee to start to see some of those different recommendations prior hand? And can give feedback?

Bryant Thomas Karras

Actually, it sounded like Seth was going to chime in. I will say for Group 1, we are on the cusp of having a document that is assembling our draft recommendations from the spreadsheet into a Google document, which I think will be easier for the non-task force members to digest. Seth?

Seth Pazinski

Yes, I was going to jump in. Across the three groups, so there are three groups, one focused on public health, one focused on standards and certifications, and then a third focused on information blocking ant TEFCA. So, the three individual groups are aiming to complete their draft recommendations by the end of the month, so over the next two weeks. Then at that point, we would have a full compilation of the draft recommendations that we can share with the committee members that are not participating on the taskforce. We have three full taskforce meetings scheduled the week of September 2 where the three individual groups will come together to consider and then finalize those recommendations for HITAC. So, we could share as the groups pull their recommendations together, we could share those with the HITAC members. That would be an opportunity to weigh in on the specific language before we get to that final set of recommendations and vote on September 12.

Medell Briggs-Malonson

Thank you so much Seth for that clarification. So HITAC, this is our time, also. So, it sounds like we will be able to see those recommendations before September 12th directly. As Sarah mentioned, it is so incredibly important for all of us to lean into this, because this is such an important role, just like HTI-1 was. Thank you Seth for that clarification. Now is our time to ask our co-chairs, Bryant and Rochelle, any questions that you have, any additional clarification. This is our time to ask them right now. Then we will be able to receive the recommendations at a later time. So, any questions for our co-chairs? Well, I am sure people are formulating –

Bryant Thomas Karras

Although, ask all the hard questions of Mark who is not here.

Medell Briggs-Malonson

That is right. We are going to give it all to the second group since Mark is not here. Well, I think what it is it seems like you all are proceeding the discussion of each of the topics wonderfully. I think once those recommendations are put before the full HITAC committee, I am sure that there will be some thoughts and

robust discussions. So, if there are no additional questions or comments right now from HITAC, what we can do, again, is we can wait until you all finalize your recommendations. Then we will, as a full committee of HITAC, will be able to give some thoughts about it in advance. Of course, making sure that we know our next HITAC meeting will be reviewing and approving what the task force puts before us. So, once again co-chairs, amazing job. We know that it is a large amount of work that you all have put in, and even more work to come. We are very grateful for all that you are doing. Thank you today for giving us this presentation.

Rochelle Prosser
Thank you. Such a pleasure.

Medell Briggs-Malonson
Thank you both. We are going to continue to go on into the next topic at hand, that is directly from Al Taylor, who is going to be giving us an overview of the United States Core Data for Interoperability Version 5 update. So, Al, I will turn it on over to you.

Overview of the United States Core Data for Interoperability (USCDI) Version 5 (00:42:52)

Al Taylor
Thank you Medell and thank you for the invite and the chance to address the full HITAC. Next slide, please. In July of last year – Sorry, first speech of the day. July 18, we published USCDI v5 along with the standards bulletin, which give a lot of additional detail about the rational for the things that we did add, things we did not add, and laying a little bit of the groundwork for the way forward. We will talk about the highlights of USCDI v5, that way forward with the opening of the submission and comment process for new data elements for v6. Then, I am going to touch briefly on the Notice of Proposed Rulemaking (NPRM) because Elise had already covered it, just touching on the fact that the HITAC subgroup will address the USCDI components of the NPRM. Next slide.

This is a familiar slide for everybody, why USCDI is, to define the core set of data for everybody, what should be exchanged in health IT. It is also used as a reference point for other uses besides certification and health data exchange through certified health IT. To continue to describe the process in which we expand USCDI in a way that everybody gets to participate and impact. Next slide.

USCDI was created through the Cures Act as a replacement for the common clinical data set. As we have seen, HTI-1 established a new requirement to use the content in USCDI v3 to define the set of data that much be exchanged through various certification criteria. As was mentioned, I think mentioned when we talked about HTI-2, but HT-2, NPRM proposes to update that baseline from v3, which now has a requirement date of January 2023, to USCDI v4, and a proposed date for adopting v4, should that be adopted intact – Sorry, Tina, the answer to that question is the notice of Proposed Rulemaking. It is how we announce our Proposed Rule. So, to update the baseline with USCDI v4 with a compliance date of January of 2028, that is the proposed date and the USCDI v4 is proposed new baseline.

USCDI, as I mentioned, is also used and referenced by a number of different programs, including the Centers for Medicare & Medicaid Services (CMS) patient access and payer to payer API requirement, TEFCA, as well as some states, including the California Data Exchange Framework. Next slide.

How USCDI is adopted, depending on the version, includes conforming to existing certification requirements. In this case, the requirement for V1 passed a couple of years ago. The new requirement date for adopting v3 is in January of 2026. But the standard version advancement process allows more progress, allows health IT developers to voluntarily update their programs to more recent versions of USCDI. We saw some work of developers to adopt USCDI Version 2, not last year, but starting the year before when V2 was available for update. That enabled the adoption of social determinants of health (SDOH) and sexual orientation and gender identity (SOGI) criteria, SOGI data, that was the version that California adopted as a requirement for their exchange. Now USCDI v4 is available through Standards Version Advancement Process (SVAP). So, again v4 is systems can adopt v4 as of this month. It will be available for update. Along with those newer versions that support the – along with USCDI v4, the supporting exchange standards, the consolidated Clinical Document Architecture (CDA) and US Core implementation guides (IGs), are also available to update. That enables the actual adoption and exchange of USCDI v4 data. That period of availability started just recently. Next slide please.

So, this is a very high-level review of how we have progressed through. I think people are familiar with the progress we have made. This just highlights some of the key additions to each version. As we went through, we mentioned – We will talk about the new additions to v5, but this is just an overview of some key additions. This is to demonstrate the sort of steady drumbeat of progress that I think most people can expect, have come to expect. We expect that to continue, again, all based on public input, including a lot of really solid HITAC recommendations for changes. Next slide. One more. There is an error on that slide.

So, this is just a really high-level summary. For the v5 period, this is talking about the public input, we received quite a few recommendations for new data elements for USCDI v5. These are the top 10 of the data classes in which these recommendations were made. Next slide. We also fielded over 300 questions on existing – sorry, field over 300 comments on existing – Sorry, thank you – comments on previously submitted ailments that were not added to USCDI. So, we looked at both parts, the part that added data elements as well as the ones that were recommended. There are data elements that we have adopted that were submitted two or three years ago. We have, either through ongoing maturity or through further consideration, we have added those to newer versions of USCDI. Next slide.

Here we go. So, this is just that we added 16 new data elements to USCDI, including two new data classes. Some, I think, key additions, they are all key additions. There are only 16 data elements added. It includes new clinical note types, beginning to introduce the concept of an observation class, and specific observations including advance directive observation, and sex parameter for clinical use. We also added an entire data class of orders, which are different than the values and the tests and objects – or the care that is requested. It is the fact that something was requested or the intent of the provider to provide those services, that intent is captured through these orders data elements. We also added additional patient demographic information as seen here, included an interpreter needed, and pronouns and in-views. Also, added the provenance data elements of author and author role to better communicate the sources of data, and also to indicate that the source of the data may have very well been a patient. That was a specific request of this group, of the HITAC over the last two years. So, we did decide to add that this year on that request. So, next slide.

I am not going to go through the whole thing. This is the entirety of USCDI v5, published on our website, available as a Portable Document Format (PDF) document as well as the website. In the standards

document itself, which you can download and read, it includes a change log, which shows all of the changes that we made between USCDI v4 and USCDI v5, as well as changes that we made after we published draft v5 in January. Next slide. I have somehow managed to jumble these slides up.

I am not going to read each one of these slides as far as the content of each data element, but this is additional information about each of the data elements. Next slide please. This is a more complete description of the clinical notes that we did add. I wanted to note a couple of things about these. Not only did we add these two data elements to identify specific aspects of care around emergency department (ED) and surgical care, but we intentionally highlighted the fact that the content of these data elements is, at a minimum, the narrative components that are not normally represented using structured data, things like low-end codes, Systematized Nomenclature of Medicine–Clinical Terminology (SNOMED CT) codes and the like that are structured components of any given record. We also clarified that this data element called clinical note is not to be confused or thought to be the same as these defined clinical note documents that are defined by the consolidated clinical document architecture implementation guides or templates, or the Consolidated Clinical Document Architecture (C-CDA) templates. These are, at a minimum, just the part that cannot already be captured using structured data. We wanted to highlight that because we continue to get those questions about do we mean narrative, do we mean structured, doc, do we need the whole C-CDA? This is our intent. Next slide.

Lot number is just simply an additional piece of information related to immunizations, super important in recall safety monitoring. So, we added it as a result of – we adopted it after we published in Draft v5 in January. Next slide. Medication, route of administration was kind of long overdue for addition. It is an aspect of the dose. We just simply split out that data element into two different ones, that being dose and route. Next slide. The two new observation data elements that we added are fairly different. I mean, they are very different. Advanced Directive Observation, which is the data element directly related to advanced directives that we have added. Although, last year with the addition of treatment intervention preference and care experience preference, that started to fill in some blanks as far as what a patient might desire for their care. But the advanced directive observation is a type – you can think of it as a metadata element about the advance directive. It is not the document itself. It is just information that is helpful for providers to dig into the advance directive.

And then sex parameter for clinical use is an observation that may affect the ordering of a test, may affect the test results, test or the procedure results. It adds that context to use of various aspects of clinical care. Next slide. In Draft v5, we published a single orders data element. We had a lot of feedback on that decision, that it was so broad, and it led to a lot of uncertainty about what we really meant and how do we intend to enforce such a generic data element. So, as a result, what we did is we adopted several specific data elements that it is a little more clear as to what should be included in a particular order data element, the values associated with these five areas. These five areas are not the only places where orders can be done and have that information be valuable to the downstream recipient of the order. But it is a start. There are other orders that were considered, but we decided to do this as sort of an 80% solution to the types of orders that people might like to see that have been placed. Next slide.

These three patient demographic information data elements, fairly self-explanatory. Just an ongoing addressing of specific patient centered needs. So, we added these to the demographics data elements. Next slide. These last two that were added were the providence data elements, again to provide additional

information about the source of information that is included. We specifically wanted to make sure we could communicate the fact that the patient is the original source of this information, whether it is a preference, a goal, a symptom, possibly even a reported past procedure that is not imported from a medical record, but actually just provided by the patient for history. These are some of the reasons why we added these data elements to be able to communicate that. Next slide. Next slide.

I am not going to go into details about this. We made some technical corrections, some edits, just to provide some more clear information about the content of the data elements and how it needs to be represented and exchanged. All of this information is included in the Standards Bulletin, as well as the change log. Next slide. Next slide. Hopefully this is a familiar cycle for everybody. USCDI never sleeps, never stops. We publish one, we start working on the next one. We start working on the next one before we publish one. We just published v5. We are now in the public submission and comment period for v6. Once that period ends, once that comment and submission period ends, we start building Draft v6 and the communications around that, which we expect to publish in January, followed by feedback on v6, which that was the period of time when the HITAC, and particularly the Interoperability Standards Workgroup (IS WG) subgroup met and prepares recommendations to ONC on Draft v6 to inform the final USCDI v6, which we expect to publish next July. Next slide.

So, July 18th obviously has passed, but one thing I did want to mention about one of the things that we accomplished when we published, at the same time we published v6 in the Standards book. In the spring we went through a comprehensive review of all of our leveling decisions. So, a submission comes in, we evaluate it for maturity. We evaluate it for how broadly it applies to multiple care settings, and we give them a level. Grade 2 being the highest maturity and the broadest of applicability. Level 0 is the ones where it is a narrower use case, less technically developed, or those data elements represent just a subset of one of the other existing data elements. So, that resulted in a lot of releveling. Actually, quite a few of the Level 2 data elements that were previously considered to be Level 2, after we reevaluated it based on our recently clarified criteria, we moved them down to Level 1 and Level 0. We are in the process of notifying. We are almost complete with notifying all of the affected members of the community that did those submissions. But we publish the result of those decisions in the individual element pages on USCDI.

So, I did want to note some people on this call and elsewhere have received those notifications. So, we welcome follow-up discussions on those decisions. So, we are in the USCDI submission and comment period. On deck is open, as well as the commenting. The system is open for registered users. We are open to any recommendation for additional new data elements, as well as any modifications or further recommendations or support for past data elements that we have not – we received but have not added to USCDI. As I mentioned, in January we will begin again starting with the Draft v6 publication. Next slide. I think the next slide is the end –

This is just a reminder. This is one of the things that goes into our decision-making process about which of the many, many mature data elements, the Level 2 data elements that we decide to put into USCDI, we include some specific policy priorities, mostly here at the top, along with technical standards. We also are given some scheduled work that we are doing around patient ID and patient matching. We are also looking for data elements that specifically address that concern. These could be demographic data elements. They can be other ones that are related to matching. So, we will be on the lookout for previously submitted and new data elements that address this particular area and new priority for us. Next slide.

Again, just briefly – Next slide. This is by no means a comprehensive review of HTI-2, but the Proposed Rule was published. It is now open for comment through for September. The HITAC Proposed Rule task force is well underway, as we heard earlier. That, I think, is all.

Sarah DeSilvey

Thank you so much, Al. Thank you so much for the presentation. I want to be grateful just because this is one of my favorite topics, of course. I love discussing USCDI and associated data elements. Lee, I believe you had your hand up for some time. Do you have a question?

Lee Fleisher

Yes. Thank you so much. I think this is great. But I did see that a consortium of I think 30 some groups sent a letter talking about burden and asking to adopt 4 rather than Version 5. I realize this is a public meeting, I do not know if they will comment, but anything about the burden assessment and how the ONC is thinking about that.

Al Taylor

Lee, was this a question about the Proposed Rule?

Lee Fleisher

This was, I think, one of the responses to the Proposed Rule, if I remember correctly. I think it was inside health policy or one of the – said there was a consortium that talked about burden. I just wondered how you thought about burden and whether you have – recognizing that you are not going to comment on comment letters.

Al Taylor

Yes, correct, we are not. I will say we look at – we are in the process of reviewing every comment that comes in on the Proposed Rule. If the comment were about we should adopt 3 versus 4 versus 5, we will look into that, take into consideration what that burden would be. I will say that we intentionally try to estimate what the burden of a particular version of USCDI is. We actually reduce the number of data elements that we added to this version to v5 because there was a pending HTI-1 rule with a conformance day. People are scrambling, if you will – maybe not scrambling, but people are beginning to work hard on conforming to v3. So, with that in mind, we added fewer data elements than we normally have added in the past. I cannot comment on a current Proposed Rule comment. But we look at every single one of them and we have a lot of eyes on ONC, ASTP, ONC eyes on every comment.

Al Taylor

Thank you. Just to say fully supportive of going to 5. But it is great to hear publicly that you considered burden and the ability to actually implement this. So, thank you very much.

Matt Rahn

Thank you Lee. Sorry, do you mind if I provide some clarification?

Sarah DeSilvey

No. Thank you, Matt.

Matt Rahn

Okay, thank you. Hi, I am Matt Rahn, I am the director of Standards Division at ASTP, Office of Standards Certification and Analysis. Just to clarify, so USCDI Version 5 is not currently under comment period. USCDI Version 4 was proposed in HTI-2, so that is currently under comment. What is open for comment right now would be USCDI Version 6 Draft. So, right now you could comment on that. So, Version 5 is not in any sort of – it is not part of the standards version advancement process. But as of August 19, vendors could update their product for USCDI Version 4 and the associated applicable implementation guides. When it comes to USCDI Version 5, the standards development community has just started to update the C-CDA and FHIR US Core Standards to accommodate the additional data elements that were added in Version 5 with, I think, an intention on going to ballot in January and publishing in the April/May time period. I just wanted to provide that clarification for folks. Thank you.

Sarah DeSilvey

Thank you so much, Matt. Going on with questions, Anna?

Anna McCollister

Thank you Sarah. I have an array of questions. I am not even sure where to start. I guess, again, the role that I play on this committee is as a patient. I am always frustrated with the fact that the burden on vendors and hospital systems is always considered as a policy priority, but not the burden on patients. I still, after all of these years, how many billions of dollars of investment, when I go from one doctor to another I have to manually download all of my data and provide bullet points and summaries. I am involved with HITAC, etc. I guess part of my when – when it comes to USCDI, it sort of challenges my attention deficit disorder (ADD) in terms of following the process. That is on me. It looks very methodical, etc., but it is very difficult for me to understand what is in place, what is going to be in place, what the timeline is, why on earth are we looking at data elements that do not even get incorporated into USCDI without some sort of FHIR standard there, and they are not going to be in place until 2028. I mean, that is a really long timeline for me to understand.

I frequently, because the role I play on here and the work group I am leading for the Sequoia project, people come to me, patients come to me and ask me questions like, "When is my lab value going to move from one doctor to another? How much longer do I have to keep doing this?" I cannot answer that question. So, I guess part of what I am asking is is there a process, is there a way, or is there somebody who could help me put together a flow chart of what data elements are there in a visual circle to read thing that does not require all of the clickthroughs that are on the ONC website, which are great if you are a developer. But if you are a patient who is just get their head around what is what and when it can be expected, I think that is something that is needed.

Again, if there is somebody who can help me do it, great, I will do that. But it is needed because it is impossible for people to really understand in a reasonable amount of time what is there, what has been done already, and what to expect when. Secondly, it is hard for me to understand, given that it is difficult for me to go other patient data advocates or patient advocacy groups and say, "Hey, it is time to give – it is open comment period for USCDI v6," if they understand what USCDI is. What exactly are the data elements that are already in place? Because those are not going to be a reality for patients for quite some time. Where do we actually give input? Is it with USCDI? Is it with Health Level Seven (HL7)? How does this

process work because the process for getting input from the patient community is very opaque. Sure, there is an NPRM, but what exactly is it that we are commenting on and at what point in the process are the things that we need, that are creating burdens for us, actually going to be there?

Again, I understand that the role of ONC is to regulate the industry and the systems that our set up are incredibly well organized for that. Kudos to you for doing it. It is very methodical. There is a reason why I am not a health IT engineer. I am a patient advocate. But there has to be a reasonable way to present this and to – if you are serious about getting input from the patient community, we need to do a bit more work in making it more approachable and understandable and accessible if you genuinely want input from the pubic and not just the industry.

Al Taylor

Anna, thank you for that. I appreciate, I know that I am very familiar with your continued advocacy for the patient perspective. I have come to expect it, and I appreciate it. So, we actually are currently undergoing kind of – there are a lot of questions about USCDI that are not answerable by going to the USCDI website. I think that is clear. We are redoing some information. You can find it through digging in the various different other website, web pages on our website, but by going to USCDI you cannot always get those questions. We are trying to address that.

Anna McCollister

I go to Chat generative pre-trained transformer (GPT), honestly.

Al Taylor

So, we are doing a revision of some of the information and how we present it in USCDI, we hope, that will make a difference to make it more understandable in various different ways from various different viewpoints. I am going to probably reach out to you, and have you do some user testing on the website as it comes out. So, just to make sure, because that is obviously a different perspective, not some IT engineer, somebody who has a different view of it. So, we are looking to that. As far as engagement to the public, I think maybe helping the general public understand what USCDI is, how it happens, that will help with the public's understanding of how comments are made and the impact of those comments. We absolutely are interested in getting public feedback and not just federal agency and not just an IT developer. We put out information about the comment period and the submission period through our e-blast, which goes out to 120,000 registered recipients. I am assuming quite a few of those would fall into the category of sort of the regular, if you will, the members of the public, the non-technical members of the public.

We definitely do want public input. When we look at burden of – You are right, the scope of USCDI and certification is on the industry. We recognize that the impact of that does trickle down to the patient and how usable those systems are.

Sarah DeSilvey

Al, if it is okay, I am just going to try to respond to Anna a little bit as well. This reminds me, Anna, of some of the education we did for ourselves, again clinical here, before we stepped into the work of IS WG this year. So, there was really a level-setting of the intersection between USCDI and regulation and how each of those different layers assisted towards eventual implementation. So, I want to support you in saying it is

not just patients who need that view, understanding how USCDI feeds into incoming regulation, and therefore use. So, just applauding ASTP for leaning into that. Also, just noting we in the IS WG work group needed the same thing before we kicked off our work on commenting on this. So, appreciate your comments there. Rochelle, shall we keep on going through comments?

Rochelle Prosser
Yes, thank you Sarah, thank you Anna. My comment leads off of what Anna has mentioned, but in a different aspect, looking at health equity and focusing on what we are doing that you mentioned as we move to ChatGPT. I want to make sure that I am **[inaudible] [01:18:30].**

Seth Pazinski
Did we lose here?

Rochelle Prosser
Yes, my mute is doing its own thing. Can everyone hear me? I just want to make sure everyone can hear me. So, recently a study was done between Microsoft and Epic. They talked about using, and they now use ChatGPT for part of their machine learning and natural language processing. So, as we are moving and sort of converging into looking at patient aspects and how it impacts the patient, I want us to – This is more of a comment. We already have algorithms here. As we use AI tools, AI has the level of discernment that the general public, healthcare provider, the human aspect will not look at. We have some inherent things within our society that we choose to gloss over and not bring to the fourfold. But using AI technology, those nuances of disparity come right up to the front. It is learning it itself. It is learning it itself.

So, as we crate these rules, as we create these languages and teach the AI tools to work and search and help us in all aspects of professional and private life, we must be mindful of what is written in the margins that we, the human aspect, do not see, that AI will pick up immediately and use that through learning on processes that we will not talk or bring to the forefront. AI will bring that right up. I worry that as we start using ChatGPT and other AI aspects and these tools, no matter what we do to write out these codes, what works in one community or one side of the country does not work in another facility or another side of the country, unless we are intentional on what the parameters and characteristics that are in there, as we look towards demographics, as we look towards identification, as we look towards ensuring that we are all part and inclusive.

So, basically there was this rule that just looked at x-rays. Just looking at the x-rays, we are not putting demographic information on there, but the AI tool can see exactly who this person is. It is spot on without error more than 80% of the time. So, there are influences and biases that even in our common language and speak that we bring to the table that we are not even aware of. So, I caution, yes I agree that AI and technology and ChatGPT and that natural language processing and all of these things should be here, but who is writing the code? Also, what is in the metadata, what is in the ACS, what is in those characteristics that we normally would not look for? It is there in AI, and they can find it. So, I want us to be mindful or at least have that top of mind as we move forward through the comment periods of health equity and patient access. Thank you.

Sarah DeSilvey

Thank you so much, Rochelle. I want to just echo that many of these things will likely be focused in the health equity work group that we are kicking off. I just want to note and pull forward themes from our AI panels that we had this spring when we were in person together in DC. So, thank you for elevating that. Any comments on the USCDI v5 proposal? Michael?

Michael F. Chiang

Yes, Sarah. No. 1, I really appreciated Rochelle and Anna's comments. I have a couple comments that I think are going to be more relevant later in this meeting. Al, just a very specific comment and question. I think the author field is a really important field. What I have always seen in clinical practice is the author is really a lot of different people. Sometimes a technician or medical assistant or resident will enter things, or sometimes things will be pulled in from templates or copy and pasted from other parts of the chart, and you end up with extremely long notes that are actually multi authored. There is one final person who clicks the sign button who is defined as the author who is usually the most senior person, but who is often not the one who really entered the information. In my assessment, the fact that these are multi-authored often explains some of the complexity and the length of these notes. My comment is just that I think that is one important thing in authorship, just sort of the audit trail component of it. I guess my question is did you – I am guessing author really refers to one person, the senior person who signed off on it. I just wondered your thoughts about authorship from that perspective.

Al Taylor

Certainly there are multi-authored everything. So, clearly there is. We did not try and solve that whole problem by adding that. We did not say it must be the senior author, it must be the most number of words typed into a field. We did not go that deep. We simply said there needs to be a way to represent the person or a person that was responsible for that information. So, in particular, there is not a good way to say the patient said this. Obviously, a lot of stuff originates with the patient, obviously, because whether it is their blood values or their opinions or their history. But in some cases, we need to be able to find a way to say this is patient reported. It could be a patient device, it is really device reported. We did not try to solve that entire problem, only to provide a better opportunity to be able to capture the idea of who is responsible for the information. There could be multiple authors. There obviously are multiple authors in a lot of cases. The author role is sort of a companion. I almost think of the two as inseparable because you can describe it as did it come from a patient, or did it come from a device? I do not necessarily need Michael Chang's name on it, but if Michael Chang is coming in for care, I want to be able to say, "Oh, he said it," not, "He brought in his record from another hospital."

Michael F. Chiang

Thank you, Al. I guess a quick follow-up is people are taught in medical school that notes are objective. I have just gotten more and more – I think we have all gotten more and more appreciation that they are really not totally objective. They are somebody who observes something and then puts them into the record. So, thank you for your thoughts on that.

Al Taylor

Sure.

Sarah DeSilvey

Thank you. Hung?

Hung S. Luu

Yes, thank you. I would like to ask Al if he could provide more clarity on the process for leveling? Because right now it is a black box. It is a little dispiriting when we see elements that have been in the past up for consideration for inclusion in future drafts all of a sudden relegated to categories that are, for lack of a better word, untouchable. Basically, we cannot even discuss them because they are basically considered out of the purview of HITAC input. So, I think it would really boost confidence in the process if you could elucidate the criteria for how levels are determined and what the thought process is behind that and what are the evidence or data points that are used in that determination?

Al Taylor

Sure. A couple of things. I understand the frustration and it is probably shared by a number of other people that were affected by this most recent releveling effort. When we published last year, in 2023, we also updated – we tried to make the criteria not more objective, we tried to represent it more clearly and to say there are four specific components of the leveling decision. As a composite, we come up with a final leveling. If it is Level 2, it is generally considered for another version of USCDI. So, one of the problems with that is it is a combination of technical maturity and applicability. So, we have to come up with a way to filter among the hundreds of suggestions for data elements to determine do they fit into a broader bucket so that they can be considered. We have to draw the line somewhere as far as what we can add to USCDI, for a lot of different reasons we have to say that.

So, the process is the staff at ONC, the staff go through every comment. First of all, we go through every data element as it comes in. We are going to do that again this time and try our best using our expertise in various areas to evaluate the information that is provided in the submission, plus whatever else we know. It happens that people submit something with incomplete information, but we can fill in the blanks because of our knowledge, our experience, and our judgement as to whether or not maybe it is more mature than you think or what is presented does not represent a certain level of maturity. So, we do our best. I would not call it black box. It is during a period when it is not public input, but we take those published criteria with the published data element and information contained in that submission and do our work on it to come up with the most reasonable level decision.

It has in the past been less objective than it was these last two times. We are trying to correct that. By publishing the level, publishing the individual criteria that we use to determine it, and the results of those criteria, along with a composite, we even add, especially to the ones that we releveled, we add a composite narrative as to why it was – it was releveled because it was determined to be just a narrow subset or only applies to a certain narrower use case. So, those are the reasons why. As part of the notification process we have done – we are doing, rather, in the releveling is there are ways of addressing that. We welcome further conversation on it, whether it is an email, meetings, you can also enter your comment into that data element page and say whether I want to appeal it or I think that is wrong or I think that is right, whatever you feel like is important to communicate. There are lots of different ways of advancing that feedback.

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Sarah DeSilvey

Thank you, Al. I see a couple comments in the chat of HITAC members wanting to understand the divergence between what we recommended and what is final. I know that the rational and everything is

complex, but you can find that in an analysis for the difference, but that might be something that is helpful to present back to HITAC. I know it is part of our yearly, or at least we did it this year, our kickoff for IS WG, we build off of what – in the past, this year we built off of what was carried over from the year prior and looked into whether we wanted to reelevate that. So, I just wanted to appreciate members of IS WG, I see you commenting on there, and the divergence between the full recommendation that came out of IS WG and HITAC, and USCDI v5 final as noted.

Anything has a chance of being put back in. So, any member of IS WG-2025 will be able to reelevate things into USCDI v6. That is part of the process we do. Or you can comment now. Al can comment on it a lot better than I can. Bryant, any other final comments?

Bryant Thomas Karras
I actually have two depending on how much time we have, Sarah.

Sarah DeSilvey
We have a little bit of time. We are going to go to break after this.

Bryant Thomas Karras
So, I will ask my question first and then a comment, which is a little bit rhetorical. My question is, so truly appreciate the addition of lot number from a public health perspective so that we can ensure that we have all the information we need transmitted to immunization registries so that if something turns out to be ineffective or for safety reasons, that information is critical. So, it is phenomenal that that has been added in v5. My question is it makes reference in v5 to the CVX (code of vaccine) standard as of June 12, 2024. Obviously, with the speed at which pandemics, as we have all learned, evolve, and the speed at which we need to respond with new vaccines, my hope would be that we come up with a way or an expectation from the certified vendor community that they are over exceeding the minimum requirements of updating standards as of a point in time 2024, and we can evolve to an adoption of new vaccine codes within X number of weeks or months from their issuance from CDC. Is that an unrealistic expectation that there would be, rather than having to wait for the USCDI timeframe to come back around?

Al Taylor
So, let me answer the question and you can tell me if I actually answered the question. When we publish a new version of USCDI, which eventually has some regulatory impact, may have some regulatory impact down the road as far as requirement, we take the most recent information and the most recent as of middle of July, the most recent update to the CVX file was June 12. There had not been any new CVX codes added since June 12, as of middle of last month. So, maybe that has changed. When COVID hit, it was every day there was something new. There was a new lab test, test kit every day. So, it is really impossible to keep up with – It is just impossible to keep up with, especially in anything with, I will say regulatory impact, but USCDI is not always a regulatory impact. It sits there as a standard to be met or not. But that does not work. For the most part, for many of the more political, the clinical terminologies, electronic health records are able to advance to a newer version than regulation, this thing called minimum standards version. There is a collection of those more specifically clinical SNOMED low link and the like. I do not know if CVX is on that list, but I think it might be.

So, electronic health records (EHRs) can update to something that is not in regulation, even though they are certified in that older version. Obviously, it is in everybody's interest to do that. We just cannot regulate it on a week-to-week or day-to-day basis.

Bryant Thomas Karras

So, my caveat, I super appreciate that. Our partnership with the electronic health record (EHR) community, they do exceed their regulatory requirements. So, just something that we can in public documents like the release of v5, add those wiggle words of, "At a minimum through June 20, 2024," so that our partners do not feel that they have to only comply with this and not exceed that expectation. I really appreciate that partnership. I think, as you said, things move fast, and we have to work on this together.

Al Taylor

Thank you.

Bryant Thomas Karras

My last comment is on the minimization of the number of data elements that are added in a given update. I appreciate that for burden purposes you do not want to overwhelm the community, but I do think that sometimes we focus more on the number instead of on the actual implementation. Things like, for example, advanced directives, the addition of only data element instead of multiple that might actually be needed to effectively implement it in an electronically meaningful way, as opposed to just a yes, no, there's a paper document out there that you need to go find and read, as opposed to having that granular, nuanced information readily available through USCDI data element. So, sometimes the number of data elements added is not reflective of the burden, the implementation is. So, I would like us to think about that as we move forward with v6.

Al Taylor

I appreciate that. It is not just about the number. It is not just about the number. There are some ones that are relatively easy to adopt because those data elements are already exchangeable by the normal exchange mechanisms like US Core and C-CDA. So, those are things that are in there. There are things in US Core and C-CDA that are not in USCDI. If you conform to US Core, you can already exchange it. All you have to do is capture it and make it available. The orders data element, data classes is a good example. We had one generic one that was harder to implement because of the specificity required than adopting five specific ones. In some cases, so the complexity involved in what the standards developers consider to be an advanced directive is really quite significant. For us to say we want the entire specification of advance directives in a single one, meaning the changes that would be required to the US Core IG, to the C-CDA documents, they may be different depending on the standards.

A good example is in Version 2, SDOH assessments was added. It two years to develop the spec for that in US Core and C-CDA. You would not think that, we did not think that, but sometimes the burden is a lot more than we estimate. So, we are mindful of that, and it is not just about the number. It is about the aggregate. If we added a certain amount of burden just to add a comprehensive advance directive to USCDI, there is no aggregate burden development left for all the other parts that we need to add. So, we take incremental steps. Advance directive observations is not the first advance directive element. We did add it previously.

Bryant Thomas Karras

There are treatment preferences in there as well. So, there are ways we can get to the goal. I totally appreciate the optics, and we do not want to overwhelm as we march towards better and better. We will take every move that we can.

Al Taylor

One other thing that I want to just be clear on is that we want people to adopt newer versions of USCDI, we just cannot require it every year. So, by making a modest step in the right direction, should encourage developers to bite off that piece of the apple this year, and then next year maybe another bite.

Bryant Thomas Karras

Thank you.

Sarah DeSilvey

Thank you, Al and Bryant. I also want to note that, again, looking forward to continuing these discussions, specific elements and nuances in IS WG-2025. Any final comments? Deep thanks for Al. Al, thank you for your presentation and all of the questions you answered. Any final questions or comments for Al before we head into our break? Thank you all, thank you HITAC for the thoughtful conversation. Again, this is a really good example of the diverse thoughts and perspectives and expertise on HITAC that are gathered to reflect on the charge. Al, thank you for the presentation. So, we are going to go into a break. So, we are going to stop the recording. We will reconvene at 12 noon EST. See you in a bit.

Seth Pazinski

Thank you everyone and welcome back to the HITAC meeting. We are going to turn it over to Medell and Eliel to take us into our next agenda item.

Annual Report Workgroup: FY 2024 Crosswalk Discussion (01:43:31)

Medell Briggs-Malonson

Excellent. Thank you so much, Seth. Welcome back HITAC. Just for a little bit of housekeeping, we do have two additional topics that we are going to discuss. There may be a fair amount of discussion, so just as a friendly reminder to all of our HITAC committee members, we love your input, and we love the diversity of perspectives. But in order to allow everyone to ask the questions or provide the comments that they may need to, we are asking everyone to go back to our housekeeping rules that we always have of trying to limit your questions or your discussions to two minutes or less, so that we can ensure that everyone has the time to speak. If we still have time, we will circle back on to your question or your comment as well. So, we just want to make sure that we allow for everyone to actually speak up and actually have their voice heard and their questions answered, not only just audibly, but also, of course, you can always put all your questions and comments in the chat as well.

So, we are going to directly transition into the amazing, always so interesting Annual Report Workgroup work. During this time, what we are going to present to HITAC is the draft crosswalk of topics, as well as recommendations that we would really love to hear HITAC's comments on because these items are going to go directly into the annual report for Fiscal Year 2024. So, I will now turn it over to Eliel, who will walk us through the administrative aspects, then we will dive into the crosswalk.

Eliel Oliveira

Thank you Medell. Great to be with you today. We are excited to share the progress here. It is steady, there is still a bit of work to do, but I think we are doing great this year with the work group. So, I would like to advance to the next slide and describe to you all what we are going to cover today. One, we are going to go over the membership, so you recognize the members of the group today. We have a large group. Again, as a reminder, this is a standing work group. Every year we work on building the annual report that goes to the secretary, to congress. So, it is a very important work group for HITAC itself. Then we are going to go over the meeting schedules and next steps, so everybody is on the same page. Then we are going to deep dive on the crosswalk today for a little bit in preparation for the 2024 report. So, with that said, let us move on to the next slide.

I want to take a pause here for a second for the members to be recognized and thank all of you for your participation. Again, it is a very different year. We have a lot more participation in the work group than previous years, at the same time that we have a shorter time frame because we are now trying to adjust the annual report to be submitted by the end of the year, in December. So, just keep that in mind. So, thank you so much for everybody that has been working very hard to get where we are today. I think we are in great shape with the work group and the tasks ahead. With that said, next slide, please.

Okay, the meeting schedule is the next step. So, let us go to the next one. So, we are here today, August 15. So, as you can see, we have been working on developing the list of topics, developing the crosswalk. We still have one last meeting on the crosswalk topics. I think we are close. We are on schedule. Things are looking great. Then, as you are going to see, when we finish on August 25, on September 9 we develop that draft. We are going to come back to the next HITAC meeting in September ready to show the draft report to all of you. Then we are going to finalize that in September, get a ready draft for the report in October. Make-up dates based on your feedback, and I think we will be ready then to put together the final report for transmittal in November and December. Next slide will help a little more, so if you go to next.

So, here we are, today is August 15. We are going to discuss a little bit about the crosswalk in a second. Then, like you saw in a previous slide, at a September 12 meeting, we are going to at that point have the crosswalk finalized and have a first-draft report to share with all of you. We will review again in October to make adjustment, and finally bring for approval for the November 7 meeting. If all goes well, we are on schedule to deliver the report in December. Next.

So, in summary of what I just said, we will continue to develop the crosswalk of topics, draft the report at the work group meetings during the late summer and early fall. We will provide you with a progress update in a September 12 meeting. We present a draft report for discussion at the HITAC in October. Then we present the revised report for discussion in the November meeting in 2024. We should be wrapping up that that point. With that, I think Mendell, I am going to turn back to you to walk us through some of the crosswalk points that we have at this point, and we will go from there. Thank you everyone.

Medell Briggs-Malonson

Thank you Eliel. Thank you for walking us through that. So, now we are going to jump into the discussion of the draft crosswalk of topics. We do have several new members of HITAC on this year. So, if we go to the next slide, what this draft crosswalk does of all the topics is as we are preparing the annual report for Fiscal Year 2024, what we tend to do as the annual report work group is develop this crosswalk to document

the gaps, the challenges, the opportunities, and recommended HITAC activities for each of the key topics across the five primary target areas that we are charged with. Those five primary target areas, just as a reminder, are design and use of technologies that advance health equity, use of technology that support public health, interoperability, privacy and security, and last but definitely not lease, patient access to information.

Now, as we go over the topics right now in this crosswalk you are going to see some new things. One, you are going to see that artificial intelligence is actually in multiple different topics. It is kind of just woven into many of the topics as well as many of the target areas. You will also observe very similar findings with our data quality because data quality has really been something that is near and dear to HITAC's voice and recommendations. You will see a lot about data quality and relevance also throughout the various different topics and the various different target groups. So, as we go through this crosswalk, we want you all to really dive into this, see if we are missing any key areas, or if there any additional recommendations that you have. At the end of the presentation we will open that up for everyone. Next slide.

So, let us start off with the first target area, which is design and use of technologies that advance health equity. So, the first topic that the work group came up with, and these are also not only items from the work group, but it is directly from conversations during our HITAC meetings, as well as information directly from some of the other task forces. So, the first topic of use of artificial intelligence in health and health care. The gap that has been observed is that AI holds significant promise in solving healthcare challenges, yet research and regulations are necessary to ensure that AI is implemented in a safe and non-bias way. So, while there are various AI governance standards and approaches that are being developed, there is still a lack of evidence regarding which approaches are best suited to different use cases. So, the recommended HITAC activities are explore steps that ASTP could take, especially given its new role, in collaboration with other agencies to establish criteria for what constitutes data quality related to AI models, including both inputs and outputs. This effort should consider the usability and relevance of outputs at the individual level across the spectrum of diverse populations.

The second recommended activity is to explore steps that ASTP could take to establish additional AI governance standards, including appropriate and ethical uses of AI in healthcare, or ways to leverage industry developed approaches. Last but not least, explore steps ASTP and other agencies could take to develop evidence generation in support of AI product lifecycle management approaches for different types of AI systems in varying context to mitigate bias an inequities. Some of the variation of the systems include, of course, our clinical use cases, our research use cases, as well as more of what we call our administrative or operational cases. Next slide.

The second topic is implementing health equity by design. The gap that was observed here is that many health IT systems and initiatives do not include health equity principles in their design, build, and implementation, resulting in worsening health inequities. The recommended activities from HITAC include recommendations that ASTP consider developing an actionable toolkit that gives healthcare providers and health IT developers a step-by-step guide for how to start implementing health equity principles intentionally into their work. Also, this toolkit should include case examples from different care settings and also include steps to safeguard patients and engage patients in its development. Number two, explore the promotion of policies and standards that could be implemented to improve support for health equity by design. Number three, recommend that the health equity by design taskforce 2024 include in its work a discussion of a

framework that includes health equity principles in the development of standards and health IT infrastructures. Next slide.

Now, in terms of public health, there are several different topics also focused on public health. The first topic, optimizing public health data exchange and infrastructure. The gap that has been identified is that there is a need for improved public health data systems and collaboration among federal, as well as state, tribal, local, and territorial authorities. The recommended HITAC activities should be, 1.) invite the TEFCA RCE to provide periodic updates to the HITAC and have a focused discussion on the data quality improvements required to support public health use cases in TEFCA. 2.) Identify best practices and challenges from State, Tribal, Local, and Territorial (STLT) public health authorities experiences with onboarding healthcare providers who obtain and report high quality data in support of public health use cases. 3.) Review existing STLT public health authorities data systems to identify those that contain information that could be shared with health care providers who support continuity of care and patient health. Next slide.

I think Eliel, I will turn it back over to you to take us through interoperability all the way through the rest of crosswalk.

Eliel Oliveira

Sounds great, Medell. So, this is another topic area of the report, and one that is standing. Every year we talk about interoperability. We have identified quite a few topics here to discuss and advance. The first one is supporting interoperability standards for laboratories and pharmacies. The gap that we have identified so far is the consistent use of standards by pharmacies and by commercial and public health laboratories creates a barrier for interoperability. Pharmacists lack of integration into the existing data exchange infrastructure that is widely deployed and bidirectional. We have come up with a few recommendations. The first was to hold a listening session to identify adoption levers that could be used to incentivize laboratories to support increased use of standards, in addition to what is finalized in the HTI-2 rule. Second, receive an update from ASTP and HHS multi agent effort to improve the laboratory interoperability. So, a very important topic.

The next one, support image interoperability is another piece that we highlighted as very important. We see that the gap that the interoperable access to radiological images is essential in medical care. But there is still a significant need to improve electronic access and the storage of radiological images to reduce duplicate testing and better support clinical decision making. So, we identified three recommended activities. The first one is to expand upon the recommendations identified by the HITAC Interoperability Standards Work group pertaining to radiological images. The second one is to hold a listening session to identify adoption levers that could be used to support interoperable access to image data in addition to what is finalized in HTI-2. Finally, recommend a study to evaluate the benefits and costs of different levels of image sharing among various clinical use cases, including pediatric care population, patient population to determine what approach will have the biggest impact nationally. Next slide.

Continuing here on the interoperability topic area, the other point that we identified that is quite important is improving long term and post-acute care interoperability. The gap that we see is the interoperability needs to be increased across the broader care continuum to include the Long-Term and Post-Acute Care (LTPAC) providers. So, we recommended that we should explore additional certification needs for LTPAC providers,
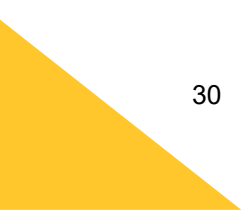
health IT systems to support bidirectional exchange with acute and ambulatory providers that have already adopted certified health IT modules. Priority setting for this initiative could include the home health and durable medical equipment providers. So, to highlight here, many of you are aware that LTPAC were not part of the adoption of certified EHRs when we first did that with meaningful use. I think we noticed that big gap, especially during the pandemic.

The next one is related, it is for behavioral health interoperability, same challenge. The gap is the health IT adoption among behavioral health providers currently lags behind that of other providers. We recommended that we should explore additional certification needs of behavioral health providers, health IT systems to support the bidirectional exchange with acute and ambulatory providers that have already adopted certified health IT modules. Next.

So, continuing on interoperability. The other topic that we identified was further improvement of data quality and sharing. The gap that we see is data continues to be crucial to clinical care, research, population health, and patient engagement. Therefore, there is a need to evaluate data quality and ease of sharing across the healthcare continuum. We have three recommendations here that we believe are important. You saw in a lot of sections how we are talking about AI being used for data quality, which I think will advance things quite a bit. Our first recommendation is we encourage ASTP to conduct an analysis of existing practices over national networks to define best practices and minimum standards for the various use cases related to the time period of data retrieved, so the last visit, the **[inaudible] [02:00:56]** days, and date of relevance. So, this has to a lot to do with the exchange of data and how that data is packaged on C-CDAs and what is shared between organizations.

The second recommendation is that we should recommend the ASTP develop expectations for the baseline amount of data, how far back in time that is expected to be included to a TEFCA data request. Additionally, consider requirements that allow for the requestor of information to indicate that different time period compared to the default baseline, or consider adopting different baselines for TEFCA purposes of use code. Finally, the last recommendation, explore opportunities to leverage AI to monitor data quality in health IT systems, like I mentioned. Next.

In interoperability still, supporting data standards for diverse abilities, that is something that we identified as a key gap. There is a lack of standards that support the interoperable exchange of information about patients with diverse abilities that we should pay attention to. The recommendations we had were two. First, evaluate the current landscape of patient disability and accessibility needs data. Then identifying information in IT systems sharing necessary to standardize and support patient accessibility needs. Then hold a listening session to identify health IT related challenges faced by patients with diverse ability and how to optimize health IT for their providers in caring for them.

The next topic we have in interoperability is provide a use of AI in health and healthcare. As you see, AI capabilities continue to grow. There is a lack of best practice of where to use AI, the use of AI is clinically appropriate or not. That is the biggest gap we see in the marketplace. So, we recommend to HITAC activities, the first one to coordinate and strategize with ASTP on a framework for AI use in healthcare and other purposes, request ASTP to identify what AI is and is not in healthcare to help frame future HITAC related work, explore steps ASTP in collaboration with other agencies could take to establish best practices for appropriate use in healthcare. Areas for best practice could include decision support, administrative and

operational use, and patient education and engagement. Finally, explore the need of AI surveillance program similar to the existing surveillance program for drugs to identify safety and equity concerns over time with AI in healthcare. Next slide.

That moves into privacy and security, the next topic. So, as you can see privacy and sensitive health data in general is a topic we wanted to address. The gap we see is there is a variability in privacy and security requirements across the country and how these requirements are interpreted and implemented, included protections for sensitive data and accommodated patients and provider's preference about how this data is used. So, we provided three recommendations in this specific line. One is first to evaluate the current models and suggest stats towards terminology value set for sensitive health data elements that could widely be adopted. The second is explore additional certification needs for health IT systems to support the privacy and security of sensitive data with acute and ambulatory providers that have already adopted certified health IT modules, including the needs of behavioral health providers given the sensitivity of data that they have. Finally, explore what additional foundational infrastructure needs to be implemented to support the interoperable exchange of consent information within and across jurisdictions. Next slide.

As you can see, there is quite a bit on this report. The next two topics here under privacy and security is the lack of disclosure accountability. Patients have limited transparency into how their health data are shared. I think we all know that and are familiar with that. We recommended a few activities here. First, propose an initial foundation for implementing accounting of disclosures. Second, recommend a simplified model of accounting of disclosures that is concise, involve patients in its development, and consider health literacy levels, which is quite relevant as well. The second other topic on the screen is transparency in the use of deidentified data, so related we felt different, deidentified data. The gap we found is patients have limited understanding and transparency into how their deidentified health data are shared. So, we proposed a few recommendations here to explore patient preferences for disclosure about the sharing of deidentified health data and explore opportunities to encourage healthcare organizations to regularly provide increased transparency into how they use deidentified data in their practices. Next slide.

I think this is where we are. Our work group is addressing the last topic area, which is patient access to information. As you can see here, the recommendations are not listed yet because that is what we are working on in the next meeting. We will share that with you later. There are two key areas that we have identified. One is patient generated health data (PGHD). It is a topic area. The gap we see is accessing PGHD requires a special effort for providers and patients, including challenges to uploading in EHRs and controlling and directing personal data. If you are familiar with PGHD use, it is a lot of data and very hard to manage that within that EHR. The second gap that we see is PGHD devices, consumer and medical, and software developers are not subject to health IT certification, but play a crucial role in the ecosystem, and that is another gap that we need to address. We are going to look into recommendations for those.

The other topic is reducing the patient burden. What we see as a gap here is patients continue to face issues in obtaining and using their health information to manage their healthcare. We see the lack of interoperability between healthcare providers increases patients' workload in being a part of their care. So, again, we have not defined recommended activities just yet here. But that is where we are. I think this is the last slide we have. With that, I think we are turning back for discussion at this point. Thank you everyone.

Medell Briggs-Malonson
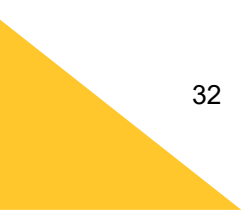
Thank you everyone. Sarah, we will let you lead us through the discussion.

Sarah DeSilvey

Thank you so much Eliel and Medell and the work group. I want to just first, before we get into discussion, just note how evident it is the work group listened to the comments and themes in prior in meetings, things that were mentioned that would be good topics for the annual report work group. I see in there in, so I just want to note the degree to which work groups are reflecting themes from our conversations we have here is noted and appreciated. Katrina?

Katrina Miller Parrish

Sorry about that. Yes, I just want to echo, man, what an amazing amount of great work and, again, building on what has been done before to really refine and focus and specify what still needs to be done. I am trying to find it. Oh, here we go. At least on my Slide 13, but I think you guys had your slides in the 70s, it was the slide with the laboratories and pharmacies topic, if you want to go back to it, if you do not, that is fine. I just noted that maybe the topic was a standing topic from previous, and thus it included pharmacies. But I was not sure how the gap and the HITAC activities reflected pharmacies. Are these specific for labs that are done through pharmacies?

Medell Briggs-Malonson

So, Katrina, we are going to go back to that right now so that we are all on the same page. So, let us know –

Katrina Miller Parrish

There you go, right there. So, it is the top row there. I was not sure how to read that because I did not see any sort of focus on the pharmacies in the HITAC activities, and I was not sure if I was supposed to read this as a pharmacy-based lab process that was being addressed.

Medell Briggs-Malonson

So, that is an excellent question. There are actually two totally different topics, but just talking about interoperability of pharmaceutical data in general, because there was a large amount of conversation about how there is so much data that is collected from pharmacies that cannot be exchanged with other clinical settings and providers. Then there is the laboratory data, which is completely different. Eliel, please, if I got that wrong, let me know. Yes, they are combined, but they are actually two different approaches.

Katrina Miller Parrish

So, I think I would recommend just adding in the pharmacy piece into the recommended HITAC activities. Sorry Eliel.

Eliel Oliveira

Yes, that is okay. I think just to give an example here, a couple of examples, I think there is a challenge where pharmacy providers do not have access to clinical data. Sometimes that becomes critical for them to be able to help their patients. So, that is one aspect that needs to be resolved. The second one and major one here related to labs, and it is not very specific here, but I think large lab organizations, they are already using Logical Observation Identifiers Names and Codes (LOINC®) standards. That is fine when we tap into those large. But that does not mean that local labs and small organization, especially hospital lab

following standards. It is very problematic to then link what an internal hospital lab is doing with the standards out there. I would say the toughest part of this that is going to be to how to go backwards in time and fix that problem. I have seen hospital systems that have thousands and thousands of labs, sometimes with a lot of duplication, they are all the same thing, with different metrics. Even within their own lab, it is pretty messy. To fix that, it is quite a heavy lift. So, I hope that helps a little bit on how the separation between the labs and pharmacy. We still have a lot of challenges getting data from pharmacies directly in the medical record and vice versa to get pharmacies to get the clinical records.

Katrina Miller Parrish
Yes, totally. So, I would **[inaudible – crosstalk] [02:13:22]** community pharmacies, maybe you can sort of mention them in some way. But maybe for the recommended HITAC activities, you add something in focused on pharmacy data.

Medell Briggs-Malonson
Absolutely. That is what I was going to say, Katrina. Your point is very well taken because now looking at this we are like oh yes, a discrete activity for pharmacy. So, that is why we bring it back HITAC because we are so in the weeds we need your voices and observations. So, thank you so much for that.

Katrina Miller Parrish
Thank you.

Sarah DeSilvey
Thank you so much for the conversation. Off to Michael with your question.

Michael F. Chiang
Yes, Sarah, Medell, Eliel, awesome work and presentation. Just a couple comments. One of them involving the imaging interoperability that is up here. I just wanted to make a plug that, of course, it is not just radiological images. There are images from so many other specialties. I happen to work in ophthalmology, but it is dermatology, cardiac. Just a plug to expand the scope of this beyond radiological images in the future because I think all that stuff now is not making it into the EHR at all. There are huge problems with interoperability because vendors define their own standards. My second comment deals with provider use of AI in healthcare. It was a couple slides from now. I think that is extremely important, obviously, but also extremely complicated. Here I will speak from my perspective at the National Institutes of Health (NIH). I think one challenge is that we have to define exactly where AI needs to be used and what it is supposed to do. It is supposed to screen at the home or Consumer Value Store (CVS) to identify who needs to see the doctor? Or is it supposed to help the doctor make a better decision in the office? Because I think the validation and design of those studies referred to here is completely different for those scenarios.

I think what we see now, in my view, in the AI research field is it is very scattered. People are just doing studies that are good to do and to publish papers, but I have some concerns that unless these studies are targeted for real indication for use that years from now we could still not be implementing it because we have not validated what we really need to validate for the real world. That is just a plug. I think it would be awesome if we could develop some framework for different options of where AI could be used, different realistic indications for use into the healthcare data ecosystem and what performance targets would be required for each of those. Then people looking for research studies could figure where am I going to do a

research study to answer this question. I think that would be an awesome collaboration between ASTP, NIH, and The United States Food and Drug Administration (FDA). That could really help advance the field. I love this. Thank you very much.

Medell Briggs-Malonson

Thank you so much Michael for those incredible comments. Yes, you are absolutely right in terms of radiological imaging, it may be more appropriate to call it clinical imaging because it is more encompassing. Thank you for that. Also for the provider use of AI in health and healthcare, you really tapped into the spirit of what we were trying to communicate, especially in No. 1 and No. 2. This is to you, but it is also to all of HITAC, if there is any wording here that you all feel need to be stronger or clearer, please make sure to submit your comments directly to Set, as well as Michelle, and we will be able to take a look at them and incorporate them. We have extensive discussions, and we try to make it clear, but if you think there is a better way to work it and make it stronger and more impactful, we welcome all of those revisions. Again, this is our report as a committee. So, thank you for that.

Sarah DeSilvey

Eliel, do you want to say anything?

Eliel Oliveira

I was just going to say on Michael's point there on the framework that I love that term for what we intended here for Recommendation No. 3, which is we need to first categorize what are the AI aspects that we need to have some sort of oversight. Some of them we may not have to, administrative operational uses as an example. Data is one, quality is another one, decision support, education, as you can see here. I think that is where we did not – it is not the job of the committee to do that, but we identified the ASTP along with the other federal agencies, define that framework, like you said Michael, is going to be very helpful because then we can focus on how are we going to optimize and make advancements on each one of those data areas.

I think we mentioned surveillance at the end. I think it is an interesting example on how the FDA already performs that surveillance and patrols certain things for devices, as you know, for drugs. We do not have to basically box in that way. There could be areas here, I think education and engagement as soon as it is validated that can be done. The National Libraries of Medicine have a ton of great resources that are underutilized in terms of educating patients about their healthcare. That is a huge opportunity. But still, who validates that the AI is doing what it is supposed to do and that the source data is valid enough to be used for that AI. I love the framework there. Thank you, that was my comment.

Sarah DeSilvey

Thank you so much, Eliel. Then Anna? I hope you hear and see your thoughts in there.

Anna McCollister

Yes. I am a member of the Annual Report Workgroup. But I think I may have missed the meeting when we were talking about pharmacy. One of the things I wanted to clarify, and perhaps I need to add this to the crosswalk document, is for the pharmacy data, one of the things we discussed previously and we just discussed pretty extensively in the pharmacy work group that we did last year, is the fact that there is a lot of pharmacy data that has nothing to do with interoperability related clinical lab results or whatever. In terms

of reducing the burden on patients and facilitating better informational exchange, getting the data that is related to supply inventories, distribution process, etc., would be incredibly helpful for physicians and for patients because the process of getting access to medication has become far too complicated and incredibly difficult and opaque in recent years.

One of the biggest issues is drug supply issues, drug shortage issues, access to pharmacy, getting accurate information from your pharmacy about when drugs are going to be available. The number of times I have – I am on 20 different medications. The number of times that I have had to wait on hold for up to six hours to try to speak to a pharmacist, I cannot even count the number of times. The other option is to go in and speak to somebody, but even then they do not have any information about when the drug that was supposed to be in last week is actually going to arrive. So, not only do patients have a lack of information, but the pharmacies. The local office has no information. The clinician has no information. So, in the case of controlled substances, which I take ADD medications as we have discussed in previous elements of this conversations, I have ADD, getting access to a controlled medication is really challenging because you have to actually identify which pharmacy has that medication with specific National Drug Code (NDC) that your insurance company will pay for in a specific denomination. Because the doctor has to write for that specific pharmacy and that specific NDC code.

The level of effort that it takes, particularly as I learned this year during finals week, when it is impossible to get access to ADD medication, is just absurd. It is calling pharmacies, literally waiting on hold for hours, driving from one pharmacy to another, asking the doctor to send a medication in. It goes to the pharmacy, the pharmacy is already sold out of that medication, so you have to identify a different pharmacy, have the doctor call that in. All this information is in a structured format that could be accessed and shared, and it is not. So, just because it is not specific to clinical information, it is absolutely essential to clinical care. The lack of access to this data, which again is already being exchanged via APIs and structured format, the lack of access to it causes significant disruptions in care and significant additional burden on both physicians and patients. So, it is not currently within – I chatted with Micky about this at one point, it is like that is not within ONC's jurisdiction. But as a committee, we are making recommendations to Congress about what should be in ONC's jurisdiction, I think that squarely should be within the scope. That is my soapbox on this issue for today.

Medell Briggs-Malonson

Thank you Anna. All points well taken. I think that is an incredibly important piece that we have had some amazing work already come out of the pharmacy interoperability task force. So, it may be great to actually add some of that, just like we are saying for HTI-1, 2 and some of these other task forces to expand and add upon the great work that is already been done. So, I think that is a wonderful addition to the recommended HITAC activities because we do not need to recreate the wheel. We need to reemphasize what HITAC has already mentioned as a priority.

Anna McCollister

Thank you.

Eliel Oliveira

I was going to add here one thought that is coming up with this is the discussion we had already about the API, the claims API interoperability work, this could be a good use case. Because a lot of this, as you know,

has to do with the insurance companies and what they are authorizing and not. If you are asking generic or brand name drug that you would like to utilize, who is paying for it, sometimes you get entangled in the process. But now that CMS has enforced the claims be API based, then I think there is an opportunity here to then test and pilot solutions that allow this to be streamlined as opposed to this phone tag and painful work of getting approvals from clinicians, from the payers, then get the pharmacy to deliver what you need at a time that you need. I have seen some of that and it is painful. Sometimes you are basically in a situation where you cannot be without a drug, but you are entangled in a mess between all these players, and you are running out. You have two pills left or you have one left. So, it just adds such a level of stress in people's lives that should not have to exist anymore. Thank you for your thoughts.

Sarah DeSilvey
Thank you Anna, Medell, and Eliel. Of course, my family practice hat elevates that comment specifically, Anna, because the numbers of pharmacies I am allowed to list in the record are not sufficient for the number of pharmacies I often need to try to send a medication to in order to get it filled. So, thank you for elevating that. Any other questions or comments on the amazing group of the Annual Report work group before cycling into the next topic?

Medell Briggs-Malonson
Just as another plug for comments and revisions, this will be the last time that we can present the crosswalk because then we are going to move into the report development. So, yes, we welcome all comments, all additions, all revisions so that we do incorporate all the voice of HITAC. If you do not feel like speaking and unmuting right now, please do at least send your written comments because we really do want your expertise in here.

Sarah DeSilvey
Katrina?

Katrina Miller Parrish
Sorry, one more question on the patient-generated health data then. Is there a way we could see what the recommendations will be before the final draft? Or should we just wait for the final draft for that?

Medell Briggs-Malonson
So, you will absolutely see what some of the recommendations are of the patient generated health data. What I meant was that our next meeting in September, we are going to give just a status update on the report being developed. And then in October, you are going to see the entire draft of the report. So, I believe, and I am looking, I am thinking of Michelle and the rest of the ASTP team, and Seth, but likely for September you will receive that final of all the different recommendations, because we will definitely move past and be able to cover PGHD and reducing patient burden. Then for October, you are going to see the first draft of the entire report. So, there will be more time to actually respond to it. But we are going to be moving pretty quickly into starting to develop the draft because we are on a tight timeframe of having everything wrapped up before the end of the calendar year. Did that answer it, Katrina?

Katrina Miller Parrish
Yes, I think I will watch for the PGHD stuff coming out around September and just make sure I can get some comments in there in case necessary. I am sure it will be awesome.

Medell Briggs-Malonson

No, please do because we know not only you, but also others like Aaron Neinstein are very much engaged in PGHD and we want to hear your feedback for sure.

Katrina Miller Parrish

Great, thanks.

Sarah DeSilvey

Rochelle, it looks like we have another question?

Rochelle Prosser

Yes, it is very, very quick. When we were looking at the digital image sharing, I did not see it in there, and Eliel, thank you for hearing me about the pediatric thing, thank you, the adolescent and young adult, can we have it, "Pediatric, adolescent, and young adult?" Because in certain sectors, a pediatric patient becomes an adolescent, which can control their care and control the sharing of the information at a certain age, it is usually between 10 and 14. Then they end up being in the adult sphere. Because there are those Health Insurance Portability and Accountability Act (HIPAA) laws that are pushed down upon them younger, the parents cannot share the data as they need to when they move on to the next provider. So, I think we said it was looking at pediatrics, or Eliel, you commented on pediatrics. But can we include adolescents and young adults? Yes, right there, including pediatric patient population, "Pediatric, adolescent, and young adult population." Thank you.

Sarah DeSilvey

Thank you so much, Rochelle.

Eliel Oliveira

Yes, great addition, Rochelle. I agree with you. There is a group that between adolescents and young adults that basically fall through the cracks because they are understood to be adults and take care of themselves, and not yet. So, there are lots of efforts out there that try to address that gap. We should note that here too. Thank you.

Sarah DeSilvey

Any other final comments? Thank you so much Medell, Eliel, and the work group. Huge amount of work. Very, very grateful to see you all weaving in so many thoughts and important comments we have had over the course of our year so far. I believe we are cycling now into the presentation of the overview of HHS Health IT Policy. Francesca, welcome. I think you are with us.

Overview of the HHS Health IT Alignment Policy: Aligning HHS-Adopted Standards Across the Department (02:30:56)

Francheska Geegbae

Yes, hello everyone, good afternoon. Beth, are you here?

Elisabeth Myers

I am. Hi there. Yes, so I am going to pass to Francheska in just a moment, but I wanted to address a few questions that we have been receiving through many channels related to the ASFR proposed regulation that was published on the Federal Register on Friday August, I believe it was the 9th, yes I got that date correct. Because we received a lot of questions that are on a specific set of themes, I was asked to quickly frame that up for you so there is not a lot of distraction worrying about those particular questions and we can all focus on Francheska's presentation, which will be updating on the entire scope of the Health IT Alignment policy that we have presented to you on in the past as well.

So, for the ASFR regulation, very quickly, just to make it very clear that that regulation's goal is to advance interoperability across intersecting health IT systems, that regulation is under Title 48 of the Code of the Federal Register for what are called the HHSARs, the HHS Acquisition Regulations, which is a specific authority for a specific set of contracts. The rule itself does not propose to require HHS contractors to use certified health IT. That has been a question that has been floating around quite a bit. I just want to clarify it does not do that. There is a reference to certified health IT in the regulation. That reference does not establish new requirements for the use of certified health IT. Instead, what that reference does is identify that if the contract actions for a contract under the HHSAR involves healthcare providers who are already required by some other statute, in particular the HITAC act, to use certified EHR technology or to use certified health IT, and the activity that the contract is covering can be done by them using that certified health IT, then in those cases the activities should use the certified health IT for that purpose.

Essentially, this prevents there from being a duplicative requirement on providers to use a different system when their certified system, they are already required by HHS to use could meet that activity. So, that is where this scope of this reference to certified health IT, there is not another new requirement in that Proposed Rule for the use of certified health IT. Instead, what the rule focuses on is using aligned standard where that standard has already been adopted by HHS under the 3004 process, which you all should know very well because it is the process that you are literally weighing on right now for our HTI-2 Proposed Rule. So, where this is a standard that has already been adopted by HHS that can support the activity under a contract governed by the HHSAR regulations, the rule proposes that the HHS activity under that contract should use aligned standards where applicable if that activity is leveraging health IT. The rule proposes that where there is a standard adopted by HHS under the Public Health Service Act 3004 process that can support activity for that contract, that the health IT should also use that standard in alignment with others who may be using that standard, and not where there is not a standard or not where it is inappropriate.

So, it is really scoped to a standard that is applicable, a standard that is feasible for an activity for standards that have already been adopted. Just for everyone's awareness, you all are probably aware because we have presented to you in the past, but the rule is implementing policies that are already in place. It is proposing to codify in regulation the existing HHSAR class deviation memo which was published in December of 2022, and which we presented to you all in January of 2023. That is in turn implementing the Health IT Policy Management directive, which was signed by the secretary in August of 2022 when we presented to you on it at that point in time as well. That in turn is going way back and establishing policies that relate to the HITAC Act Sections 13-111 and 13-112. So, again, that is some of the framing for the rule for better understanding. Again, it is a Proposed Rule. So, our general rules about how many questions we answer on it still apply. It is an ASFR regulation as well, which is a really important thing to note. It is under Title 48 of the Code of the Federal Register, not under ONC regulatory scope.

The goal is, again, to advance interoperability across intersecting health IT systems. It is part of an overarching HHS effort to align technology standards across different programs, and in particular this is using the HHS Acquisition Regulation (HHSAR) for that purpose so that activities under those types of contracts would use the same standards already in use by hospitals and healthcare providers across the country where such alignment is feasible. So, hopefully that is helpful and helps to lay some of those top line questions that we have been hearing across the board, and a couple of misunderstandings about the actual scope of this Proposed Rule. With that, I will pass to Francheska who is going to cover the entire scope of where we are and provide an update on health IT alignment as a policy as whole. Thank you.

Francheska Geegbae

Thank you Beth for the conversation. I really appreciate it. Good afternoon everyone. My name is Francheska Geegbae. I serve as a policy health analyst in the federal and state, local, and territorial division. On behalf of ASTP, I would like to thank the HITAC committee and co-chairs Medell and Sarah for providing us with an opportunity to share an overview of the policy. So, now we will go into a little bit of the background on policy. So, we have noticed that HHS spending has grown in recent years and billions of dollars have been allocated for health IT activities. Recent public health emergencies have demonstrated the importance of interoperable data to inform response, identify and address disparities in care as anticipated health IT activities have played a prominent role across the department. So, both the secretary and national coordinator are committed to aligning these efforts to eliminate data silos and avoid industry confusion.

So, we are seeking to establish a unified approach by promoting widespread use of the standard across the department. So, the process to ensure consistent HHS wide approach with the HHS Health IT Alignment policy. So, we are authorized as ASTP to do this per the HITAC act and in addition to our expertise as being the principle agency responsible for coordinating health IT across the country. Next slide please.

This slides speaks to the specifics in the HITAC Act from Sections 13-111 and 13-112. Both sections focus on federal agency use of standards adopted pursuant to Section 3004 of the public health service act, when implementing, acquiring, or updating health IT systems used for the direct exchange of individually identifiable health information between agencies and with no federal entities and requiring contracts or grants and cooperative agreements with healthcare providers, health plans, or health insurance issuers that are implementing, acquiring, or upgrading health IT systems for the use of health IT that meets such standards. Next slide.

The policy was developed to promote greater alignment of health IT activities, leverage investments, and maintain situational awareness of all health IT related programs and activities that the department is funding or is involved in. Next slide.

So, what do we mean when we say health IT related activities? Health IT related activities are any activities and/or programs that involve health IT systems or adoption, health IT standards, or any activities that promote interoperability. We also define health IT in Section 3000 of the Public Health Service Act. Next slide.

On this slide we have a high-level process diagram on the policy for both Level 1 and Level 2 activities. Level 1 speaks to the inclusion of standard health IT language. So, the Office of the Assistant Secretary for Financial Resources released medical guidance, which includes standard language that can be used in
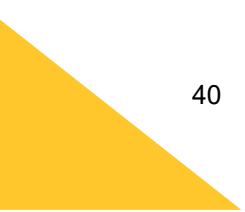
grants and cooperative agreements that began in FY23 and has since been updated in FY24. ASFR develops standard language for applicable contracts. The language primarily focuses on standard alignments and activities in applicable grants, cooperative agreements, or contracts to implement, acquire, or upgrade health IT systems, more specifically for the use of health information technology that meets standards and implementation specifications adopted under Section 3004 of the Public Health Service Act (PHSA). For health care providers eligible for previous HHS programs incentivizing adoption of certified health IT, the use of health IT certified to standards and implementation specifications adopted under Section 3004 of the PHSA, and where there are no applicable adopted standards, recommended use of technology that meets nonproprietary standards and implementation specifications that are developed by consensus based standard organizations.

Level 2 speaks to major activities review and the development of the activity inventory. This involves if an activity is a contract, grant, cooperative agreement, or if there is rule making activity or guidance. This also includes spending over 20 million annually, or 100 million over five years. Economically significant rule making at 100 million or a significant guidance at 100 million. This relates to or impacts the following substantive areas such as health IT systems adoptions or use, health IT standards, and health IT interoperability. So, once we as ASTP have determined we will take the following actions by conducting review to understand the specific opportunity for alignment, collaborate with agency staff to provide technical assistance on specific requirements related to the use of health IT standards, and determine if standard language is adequate, and if so, there will be no further action needed. Next slide.

Just to highlight a few examples of technical assistance and provide a distinction between Level 1 and Level 2 activities, ASTP's consistent provision of guidance on standard language for inclusion in contracts, grants, and cooperative agreement is categorized as a Level 1 activity. To date we have engaged in several Level 2 activities. These include partnering with CDC to draft public health IT guidance and CMS to incorporate language supporting the policy and to new initiatives, including the maternal health innovation model. Next slide.

On this slide we will go through updates on the milestones that we have completed thus far. Starting in July of 2022, the policy was instituted. The Secretary memo which notified our business staff divisions about the policy was released and ASFR released a memo and **[inaudible] [02:42:31]** guidance. In October we identified key points of contacts known as agency liaisons from across the department to support the policy implementation process within every staff bid. In November we launched an HHS wide activity inventory data call. In December ASFR released a class deviation memo, also known as a HSR class deviation. This memo outlines the standard contract language to be included in applicable contracts beginning in FY23. We also released education materials and process documentation regarding the standard language. In 2023, our policy implementation began, and we developed educational resource materials such as trainings, blogs to support our implementation efforts. We also partnered with ASFR on the HHS HSR and PRN, which the acquisition regulation of information technology, standards for health information technology notice of Proposed Rulemaking.

Since the beginning of 2024, ASTP has launched educational resource materials and developed an internet page dedicated solely to HHS **[inaudible] [02:43:40]**. To date, our team has been focused on implementation, communication strategies, and technical assistance support for the policy. Next slide.
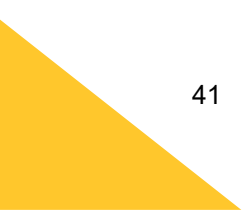
This slide speaks to our work in progress and implementation efforts. We have been working to develop a technical resource center as a mechanism for technical access (TA) provision and access to standard technical assistance resources for general support on implementation for this policy. We are in the early inception process of this development, and it has not been finalized. Recently, we have been working in partnership with ASFR on the HHS, HHSAR, and NPRM. The Proposed Rule amends and updates the HHSAR to implement requirements, to procure health IT that meets standards and implementation specifications adopted by ASTP on behalf of HHS. The rule proposes that when there is a standard adopted by HHS under the PHSA 3004 Section that can support an activity, Health IT can be used under the contract for that activity so that they should use this standard.

ASFR is requesting public comment on the Proposed Rule through October 8, 2024. We encourage you all to submit comments. If you do have questions about the rule, please visit the Federal Registry, which is linked in the presentation for more specific contact information for ASFR. Next slide.

Here are some resources that may be helpful to learn more about the policy. So, we have the HHS Health IT Alignment Policy public webpage where you can find general FAQs, a summary overview of adopted standards, and an overview presentation of the policy. We also have two blogs that speak to our development efforts on the policy. Lastly, we have a resource mailbox where you can submit questions to our team. Next slide.

This concludes the presentation. Again, I would like to thank everyone for their time. My team and I are happy to take any questions that you all may have.

Medell Briggs-Malonson

Thank you so much Beth and Francheska for providing this wonderful overview. The chat is on fire with lots of various different questions and comments. I encourage the HITAC committee members, please feel free to ask your questions right now live, also, while we have Beth and Francheska. So, any comments or questions first? Then we can also go to the chat as well. Any questions or comments from the committee? No? No one is raising their hand? Okay.

Bryant Thomas Karras

I wanted to let others voice their questions first. So, I will stay in the shadows until – I would just bring to a verbal discussion to some conversation that Keith Campbell initiated in the chat. I super appreciated this. It is amazing work to see that memo going into rule. Thank you, thank you, thank you. I have said this before, and it impacts us in the states, HHS is not the only federal department that interacts with us in the healthcare space. Especially at the states, we need to interact with the Department of Defense, bases, Veterans Affairs (VA) that are present in every single state. Then other potential crossovers into health IT, Department of Justice funds a lot of the prescription drug monitoring program work that is now in the HTI-2 rule. There is, of course, potential impacts with Department of Homeland Security and the health centers or operations that they run at the borders. How does ASTP see its scope or its authority? Is it solely limited to HHS? Or is there the potential that there is influence on other departmental level agencies?

Elisabeth Myers

So, that is a really good question. I think the first thing that might be helpful for some context is to actually go way back and visit the original statute that defines this and puts this in place. So, in the HITAC Act –

sorry, I have been speaking half the day today, so I am a little rough. In the HITAC Act in 2009, there is a provision, Section 13-111 and Section 13-112, both of which reference the process established in Title 30, so the 3004, for adoption of standards. It places the burden across the federal government. So, there is in that a reference essentially identifying that the administration is responsible for making this happen across the federal government. Going back to that time, there was a huge challenge. First off, there were not standards adopted under 3004. But there were also, as we all know and have been working for the past 15 years to advance, very little readiness for that to happen. So, piece by piece that work happened in individual instances. So, things like working with VA so that their **[Inaudible] [02:49:21]** systems are aligned with what CMS is requiring under their cert definitions, which aligns to the standards that ONC has under our certification program.

The 2022 memo by the department was an HHS move to sort of make a statement that instead of doing these catch as catch can piecemeal, the department was going to begin doing them wholesale. There could be similar approaches that look across the entire federal government. We have been thinking about that and having lots of different conversations about that. Going back to I believe 2017 there was some United States Office of Management and Budget (OMB) directed interest in identifying the types of – which agencies this would be a good plan for, including all of those that you have mentioned in that laundry list, as well as thinking about Federal Trade Commission (FTC) and telecommunications and some of these different areas. So, there has been conversation and there is thought behind what this could look like if we did this is a federal government, whole government sort of way.

I think that what ASTP is trying to accomplish right now is really ramping up how HHS is working through this together as an agency, and taking our coordination role in our partnerships with VA, in our partnerships with United States Department of Defense (DOD) through conversations like TEFCA and how that can advance standards together, and trying to do that to the extant we are able to through our coordination role, while some of that continued work needs to happen for it to be a federal approach to doing it across the department. So, if you sort of look at the pieces, there is the scope within the statute that could be applied in that particular manner. It would not necessarily be a direct authority of the ASTP, but it does reference that HHS authority to adopt healthcare standards. So, there are a lot of questions still on how that could be implemented, but we are looking at it from a coordination role to see how we can continue to advance this and really demonstrate that this can work on behalf of HHS.

Medell Briggs-Malonson
Awesome, thank you so much. Thank you Bryant for the question. Also, Keith, thank you for starting all of the chat. Beth, thank you for that amazing answer. I see Hannah's hand is up.

Hannah Galvin
Medell and Beth, thank you for all what you have provided so far, and for leading this, and actually all of ASTP. I know there has been sort of drive towards this for many years. This is so exciting to see this starting to come to fruition. I know there is a lot of work left to be done, but this is really very exciting. I am thrilled to see this coming together. I am interested, not to discount the large effort of the coordination across federal agencies, but even in the longer, longer, longer term vision of once there is that coordination, do you guys have a vision for bringing commercial payers, states, others into this alignment? What is your vision there?
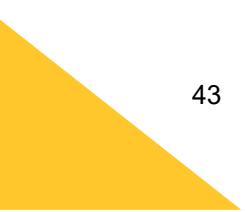
Elisabeth Myers

So, we are trying to demonstrate the success that we want to see in the world. It is an excellent question. That is actually a huge goal. It is on our vision list when we are looking at this. We want to be able to ensure that states are, first off, leveraging things like what we tried to do with the **[Inaudible] [02:53:00]** and working with CMS to make sure that those health IT plans that get Federal Medical Assistance Percentage (FMAP) funding, that they know they can put these type of things in to help support that. So, there have been some specific and deliberate efforts that you will see. Most recently, there were some guidelines about behavioral health. That is in fact American Telemedicine Association (ATA) package that we did with CMS on behavioral health under the health IT alignment policy. So, it is actually this policy in action to make that happen for those matching funds.

We are hoping that continuing to show how this can work, how this can connect points that were not previously connected, how this can optimize that our spending in HHS is supporting an actual nationwide interoperable network. Again, demonstrating what we want to see in the world. We do have goals of communicating it with states and meeting with states. We have been doing that in context with CDC, as mentioned with CMS and behavioral health. So, we have been picking high priority areas that we know states are interested in to help explain how it is relevant in that manner. We are hoping that continues as well. It is a great question because it is quite literally on my white board over here, which you cannot see. On my white board is where are we helping states to figure this out as well. They are obviously welcome to reference it at any time they want to, but we want to help them understand what is the best way to do that, what might work for them, and how can we align on these things to really increase the impact.

Hannah Galvin

Awesome, Thank you.

Medell Briggs-Malonson

Thank you, thank you. Wonderful question, wonderful answer. Any other comments or questions for Beth or Francheska? Or observations from the committee? Ike, was that something? Okay. Well, if there are no other questions or comments from the committee, again, thank you both for this amazing presentation providing us insight into this alignment process. We know that this is just going to accelerate, once again, all of the work that we are doing in a coordinated manner. So, we really do appreciate the time that you spent with us to present that to the HITAC. So, thank you so much.

At this moment, I think we are at the end of our agenda. So, Seth, I think it is time for public comment.

Public Comment (02:55:24)

Seth Pazinski

Thank you Medell. So, we will now open the line for public comments. So, if you are on the Zoom today and a member of the public, you can use the raise hand feature, which is located on the Zoom toolbar at the bottom of your screen. You can also raise your hand if you are participating by phone only today by pressing *9 to raise your hand and pressing *6 to mute and unmute your lines. While we wait for folks to raise their hands, just a reminder to everyone that the next HITAC meeting will be held virtually on September 12. That will include a presentation of the final recommendations on HTI-2, and a vote on those recommendations as well. So, just a reminder on that. As always, all the HITAC materials, including

materials from today's meeting can be found on HealthIT.gov. So, I am going to check in now with Accel, do we have any public comments on the line?

Accel
No comments.

Seth Pazinski
Okay. I do see we have one individual on the Zoom. Michael Peters, could you please go ahead and make your public comment?

Michael Peters
Sure. This is Mike Peters, American College of Radiology. In commenting on HITAC's annual report plans with respect to imaging, I would encourage HITAC to include in its plan collaboration with relevant imaging experts, stakeholders, that includes my organization and others who have long advocated for what we call our Ditch the Disk campaign. There has been widespread support throughout the radiology provider community for diskless exchange functionality in radiology IT. For AI, I would also encourage collaboration outside the immediate EHR stakeholder community to also leverage groundbreaking work of radiology initiatives. That includes American College of Radiology (ACR)'s data science institute and its AR quality insurance program. While most clinical radiology AI issues are the purview of FDA, lessons learned in those environments can potentially be transferable to non-device and unregulated AI, as well. Thank you.

Seth Pazinski
Thank you for that public comment. I am not seeing any additional hands raised on the Zoom feature. Just want to check in again, Accel, if we have anyone else on the line?

Accel
No comments.

Seth Pazinski
Okay, thank you. Then I am going to transition it back to our co-chairs, Medell and Sarah for their final remarks and to adjourn the meeting.

Final Remarks and Adjourn (02:58:22)

Medell Briggs-Malonson
Thank you, Seth, and thank you to everyone, all of our presenters, of course, all of our amazing HITAC committee members with all of your thoughts, insights, revisions, and recommendations. Thank you so much to our public for providing really important salient remarks for us to consider, especially including into our annual report. We always appreciate when the public directly comes forward and gives us some of their thoughts and recommendations. So, thank you all. We are looking forward to seeing everyone again in September. Sarah?

Sarah DeSilvey
I just want to again thank everybody as well. I also want to make sure that everyone looks for that hot off the press HTI-2 report summary we might be seeing shortly in anticipation of the vote next month. Again, it is our job to come into that meeting ready, having reviewed the guidance from the work group so that we
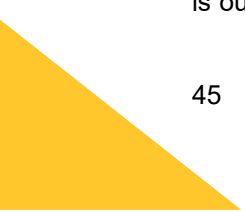
can get to a vote. I look forward to seeing you all then. Have a lovely rest of your summer. Thank you so much ASTP friends.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Maggie Zeng: Federal Register Notice: https://www.federalregister.gov/d/2024-16571

Maggie Zeng: Press Release: https://www.hhs.gov/about/news/2024/07/25/hhs-reorganizes-technology-cybersecurity-data-artificial-intelligence-strategy-policy-functions.html

Maggie Zeng: Health IT Blog-ONC Next Chapter: https://www.healthit.gov/buzz-blog/health-it/oncs-next-chapter

Maggie Zeng: HTI-2 Proposed Rule Federal Register: https://www.federalregister.gov/d/2024-14975

Susan Clark: DirectTrust will be commenting! :)

Maggie Zeng: September 12 HITAC Meeting: https://www.healthit.gov/hitac/events/health-it-advisory-committee-72

Maggie Zeng: HTI-2 Proposed Rule Information Sessions: https://www.healthit.gov/news/events/hti-2-proposed-rule-information-sessions

Maggie Zeng: Fact Sheets on the Proposed Rule: https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-patient-engagement

Maggie Zeng: USCDI+: https://www.healthit.gov/topic/interoperability/uscdi-plus

Maggie Zeng: USCDI+ Cancer Registry Data Element List: https://uscdiplus.healthit.gov/uscdi?id=uscdi_record&table=x_g_sshh_uscdi_sub_domain&sys_id=05a081bc1baf861049edc957624bcb6c&view=sp

Maggie Zeng: USCDI+ Site: https://uscdiplus.healthit.gov/uscdi

Maggie Zeng: New TEFCA SOPs and Updated Resources Released: https://sequoiaproject.org/new-tefca-sops-and-resources-released/

Maggie Zeng: 2024 TEFCA RCE Monthly Informational Call: https://sequoiaproject.org/event/2022-tefca-rce-monthly-informational-call-2/2024-08-20/

Deven McGraw: Plus the Health IT Advisory Committee's priorities are set in statute (Cures Act), right? Not sure that changes with the elevation of ONC to ASTP.

Sarah DeSilvey: No questions but gratefulness for the cochairs and TF members! Such immense and important work.

Rochelle Prosser: Thank - you Sarah
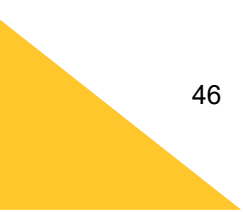
Tina Shah: What is NPRM?

Tina Shah: TY!

Anna McCollister: Why just lab orders? Why not lab values?

Sarah DeSilvey: Thank you to all of the ISWG members and HITAC for the informed review and recommendations toward USCDI. Incredibly grateful for the work of the HL7 Gender Harmony Project that assisted with a base of evidenced for the SPCU, pronoun, and name to use elements.

Matthew Rahn: Link to USCDI v5 https://www.healthit.gov/isp/sites/isp/files/2024-07/USCDI-Version-5-July-2024-Final.pdf

Matthew Rahn: Link to USCDI Main Page https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi

Rochelle Prosser: I saw Lab Values on the larger header and sub header slide @Anna

Tina Shah: Appreciate the opportunity for public feedback, I'm confused though - is there an open comment period for both USCDI4 (just cancer related elements) and USCDIv5?

Matthew Rahn: The proposed rule published in the Federal Register on August 5, 2024 and is available for public comment until October 4, 2024.

Katrina Miller Parrish: Sorry if I missed this point, but was there anything deferred that we reviewed for V5?

Mark Savage: Could there be several authors with different author roles for an piece of data, e.g. patient for patient-reported data item, plus doctor for entry in EHR?

Rochelle Prosser: Mark.+1

Sarah DeSilvey: Katrina, not all of the ISWG and HITAC recommendations for USCDI were included in the final version.

Sarah DeSilvey: And many of these nuances and elements seem excellent topics for ISWG 2025!

Mark Savage: @Katrina, yes, care plan data element, for example, was not included despite unanimous recommendation from ISWG and HITAC.

Rochelle Prosser: Is there a way to bring Care plan data element back to the table again @Mark

Rochelle Prosser: Thank - you Sarah

Mark Savage: @Rochelle, there has to be, because care plan data element/class continues to be essential for better care coordination and outcomes. We had four SMEs from CMS, AHRQ, NIH, and EMI all recommending, then ISWG and HITAC.

Rochelle Prosser: Mark +1
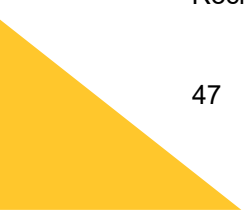
Hans Buitendijk: We have to also consider that implementation of USCDI is more specifically defined for certified HIT by CDA C-CDA and FHIR US Core, which resolve further questions, ambiguities that may be in USCDI itself.

Mark Savage: On PGHD, just remembering that HIPAA has required systems for patients to correct and supplement their medical records, for 20+ years. This is a major type of PGHD already required and in place and used for 20 years. So perhaps the gap is not so much technology-based?

Rochelle Prosser: Yes there are systems there for correction but it is extremely complicated and difficult to implement and have the record corrected. When it is corrected it is again not correct.

Lee Fleisher: I think it would be important to define which AI functions are administrative and which are clinical care and therefore how they should/should not be regulated

Eliel Oliveira: +1 Lee

Sarah DeSilvey: +1 Lee

Pooja Babbrah: +1 Anna. Based on the HITAC recommendations from our pharmacy interop task force, we are moving forward on some initiatives through NCPDP on this front and developing some standards around medication availability work

Medell K. Briggs-Malonson: Agree, +1 to Anna and Pooja to add onto past Pharmacy Interop work

Rochelle Prosser: +1 Anna and Pooja

Pooja Babbrah: we have also been sharing updates on this project with ONC

Eliel Oliveira: +1 Anna! Pricing, generic or brand drugs, approval from insurance, etc. all could be optimized. It is painful to anyone dealing with it. If you aren't already stressed with having to deck meds, you have to deal with the dysfunctional system.

Rochelle Prosser: +1 Sarah

Katrina Miller Parrish: Great point to include all ages!

Medell K. Briggs-Malonson: Thank you for all of the comments and suggestions!

Elisabeth Myers: Keith - the HITECH Act includes the whole federal government, but the HHS management directive is specific to HHS as is the ASFR proposed HHS Aquisition Regulation. We work with VA and DoD on standards alignment, but they are not under this policy or the HHSAR

Elisabeth Myers: Steven, the proposed rule does not require certification. Instead, the rule focuses on using aligned standards where standards that have already been adopted by HHS can support the activity under a contract under the HHSAR.

Bryant thomas Karras: Love putting the memo into rule coordinating between CMS and CDC... agree with Keith the ISO standards coordination scope should go beyond HHS to include other exec departments such as DOD VA but also DOJ and DHS that have footprints in Health IT?

Hannah K. Galvin: I also agree this will be very helpful. Will there be further work to ask states and commercial payers to align with these standards?

Sarah DeSilvey: So many good questions here in the chat. Beth has already offered a few excellent answers! Please raise your hand to ask your questions if you are able.

Bryant thomas Karras: love that the new assist Secretary's P role and not just the C role

Rochelle Prosser: Well said and absolutely agree

Rochelle Prosser: Thank you for your comments Michael Peters

Francheska Geegbae: Thank you everyone!

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL
No comments were received via email.

RESOURCES
HITAC Webpage
HITAC - August 15, 2024, Meeting Webpage

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