Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

August 17, 2023 11 AM – 12:15 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Medell Briggs-Malonson	**UCLA Health**	**Co-Chair**
Aaron Miri	**Baptist Health**	**Co-Chair**
Shila Blend	North Dakota Health Information Network	Member
Hans Buitendijk	Oracle Health	Member
Sarah DeSilvey	Gravity Project; Larner College of Medicine at the University of Vermont	Member
Steven Eichner	Texas Department of State Health Services	Member
Cynthia A. Fisher	Patient Rights Advocate	Member
Lisa Frey	St. Elizabeth Healthcare	Member
Hannah Galvin	Cambridge Health Alliance	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Valerie Grey	State University of New York	Member
Steven Hester	Norton Healthcare	Member
Jim Jirjis	HCA Healthcare	Member
Bryant Thomas Karras	Washington State Department of Health	Member
Kensaku Kawamoto	University of Utah Health	Member
Steven Lane	Health Gorilla	Member
Hung S. Luu	Children's Health	Member
Arien Malec	Individual	Member
Anna McCollister	Individual	Member
Clem McDonald	National Library of Medicine	Member
Deven McGraw	Invitae Corporation	Member
Aaron Neinstein	Notable	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Kikelomo Oshunkentan	Pegasystems	Member
Naresh Sundar Rajan	CyncHealth	Member
Alexis Snyder	Individual	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
Thomas Cantilina	Department of Defense	Federal Representative

Name	Organization	Role
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
Ram Iyer	Food and Drug Administration	Federal Representative
Meg Marshall	Department of Veterans Health Affairs	Federal Representative
Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Micky Tripathi	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Sweeney Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Seth Pazinski	Office of the National Coordinator for Health Information Technology	Director, Strategic Planning and Coordination Division
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Shelly Spiro	Pharmacy Health Information Technology Collaborative	Presenter
Al Taylor	Office of the National Coordinator for Health Information Technology	Presenter

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

Mike Berry
And good morning, everyone and welcome to the August HITAC meeting. I'm Mike Berry with ONC and we are glad that you can join us today. This meeting is open to the public and your feedback is always welcome, which can be typed in the Zoom chat feature throughout the meeting or could be made verbally during the public comment period that is scheduled around noon or so Eastern Time. Before we get started with our meeting, I'd like to welcome ONC's executive leadership team. And with us today is Steve Posnack, the deputy national coordinator, Elise Sweeney Anthony, the executive director of the Office of Policy, and Avinash Shanbhag, the executive director of the Office of Technology. I'd like to begin roll call of our HITAC members. When I call your name, please indicate if you are here. And I will start with our co-chairs. Aaron Miri.

Aaron Miri
Good morning.

Mike Berry
Medell Briggs-Malonson.

Medell Briggs Malonson
Good morning, everyone.

Mike Berry
Shila Blend. Hans Buitendijk.

Hans Buitendijk
Good morning.

Mike Berry
Sarah DeSilvey. Steve Eichner.

Steven Eichner
Good morning.

Mike Berry
Cynthia Fisher. Lisa Frey.

Lisa Frey
Good morning.

Mike Berry
Hannah Galvin.

Hannah Galvin
Good morning.

Mike Berry
Raj Godavarthi.

Rajesh Godavarthi
Good morning.

Mike Berry
Valerie Grey. Steven Hester.

Steven Hester
Good morning.

Mike Berry
Jim Jirjis.

Jim Jirjis
Good morning.

Mike Berry
Bryant Thomas Karras. Ken Kawamoto.

Ken Kawamoto
Good morning.

Mike Berry
Steven Lane.

Steven Lane
Good morning.

Mike Berry
Hung Luu.

Hung S. Luu
Good morning.

Mike Berry
Arien Malec.

Arien Malec
Good morning.

Mike Berry
Anna McCollister.

Anna McCollister
Good morning.

Mike Berry
Clem McDonald.

Clem McDonald
Good morning.

Mike Berry
Deven McGraw.

Deven McGraw
Here. Good morning.

Mike Berry
Aaron Neinstein.

Aaron Neinstein
Good morning.

Mike Berry
Eilel Oliveira.

Eilel Oliveira
I am present. Good morning.

Mike Berry
Kikelomo Adedayo Oshunkentan. Naresh Sundar Rajan.

Naresh Sundar Rajan
Good morning.

Mike Berry
Alexis Snyder.

Alexis Snyder
Good morning.

Mike Berry
Phil Southerland.

Fillipe Southerland
Good morning.

Mike Berry
And Sheryl Turney.

Sheryl Turney
Good morning.

Mike Berry
Good morning. And now, for our federal representatives of the HITAC. Adi Gundlapalli. Meg Marshall.

Meg Marshall
Good morning.

Mike Berry
Alexandra Mugge.

Alexandra Mugge
Good morning.

Mike Berry
And Ram Sriram.

Ram Sriram
Good morning.

Mike Berry
I would like to turn it over to Aaron Neinstein who would like to make a brief announcement.

Aaron Neinstein
Yes. Hi. I just want to update everyone that I have made a move from my position at University of California San Francisco to Notable where I am now chief medical officer as of last month. Thank you, Mike.

Mike Berry
Great. Thanks, Aaron. And now, Hung Luu would also like to make a brief announcement.

Hung S. Luu
I wanted to announce that I have joined the clinical advisory committee for Health Gorilla. Thank you.

Mike Berry
Thank you, Aaron and Hung. We appreciate it. And now, please join me in welcoming Steve Posnack for his opening remarks. Steve?

Welcome Remarks (00:03:50)

Steve Posnack
Thanks, Mike. Still good morning to everybody based on either coast. Thank you for joining. It will be a relatively short HITAC meeting as HITAC meetings go. First, I want to thank Hans and Shelly, our

colleagues leading the Pharmacy and Operability and Emerging Therapeutics Task Force for their efforts over the summer. They have, fortunately, run one of the summer camps for HITAC this year and all of the rest of the members of that task force as well. We are looking forward to hearing what they have been up to today and how they have been making progress. Before we get into the agenda for today, I did want to give a few brief ONC updates. The first is that the annual comment period for the Interoperability Standards Advisory is open until October 6. This is an opportunity to provide comments as usual, suggest revisions, and propose additions to the ISA before we publish, if you can believe it, the 10th annual reference edition in January 2024. You can go to healthit.gov/isa for more information on that web page.

Also, to note that we recently published the approved standards for 2023 as part of the standards version advancement process, SVAP as we like to call it. Starting September 11 in the next few weeks, health IT developers participating in the ONC health IT certification program will be able to voluntarily incorporate these new versions as for the SVAP processes. Later today, you will hear about the United States Core Data for Interoperability, USCIV4 that was released in early July. And also, along with its release, we are taking submissions for new data elements and other types of revisions for USCIV5. And that comment period is open through September 20. Lastly, in terms of the four year awareness aspect of things, for those of you who have been keeping an eye on the advancement of information blocking, related policy, and regulatory efforts, just a note that our HHS Office of Inspector General published its final rule related to the civil monetary penalties that would be applicable to the development of certified health IT and any health information networks and health information exchanges.

You can find more information about that rule making, certainly, on the OIT website as well as Federalregister.gov, too. ONC events, we have a few events coming up. I know the tail end of a year is always jam packed full of events. The centerpiece from an ONC perspective is the ONC Annual Meeting 2023, which will be held in Washington DC on December 14 and 15. If I have done my math correctly, this is our first in person annual meeting in at least three years. We look forward to having everybody join us for some information rich sessions that we have planned as well. Those will cover everything from public health, policy making, technology, a variety of different keynotes, main stage and breakout, and education sessions as well. You can go to our events page on HealthIT.gov as well as the ONCAnnualMeeting.com website for registration, too. Definitely keep that in mind for your winter travel. And then, the ONC tech forum, our branded, tech focused events will have two events coming up. One is tomorrow, which is Lighting the Way for FHIR API Implementation.

That will be a discussion about proposals and the recent HTI-1 Proposed Rule that may impact the endpoint publication for FHIR endpoint and see what is next for the Lantern Project, which I think many of you have been briefed on in past meetings. The second upcoming event under the tech forum banner is a two day workshop entitled Modernizing Public Health Data Exchange: Lessons Learned and Tools for the Road Ahead. That will be September 21 and 22. The workshop will highlight the current state of public health data exchange across the US and ONC and CDC's joint efforts to improve public health data infrastructure. Definitely keep an eye on the September dates. We have one more event, which is coming up in October, that is on our dance card. The registration is now open for Enabling Patient Access to Health Data for Actionable Results and that will be a joint ONC/CMS workshop all day event on October 18 for virtual. And we are going to be bringing together patients, providers, payers, health IT developers to discuss how HHS policies are working in practice and how to maximize the impact of these policies.

Again, for all of the event information that we have got going on, you can go to HealthIT.gov/events and check out that type of event information. Sorry. Wrong URL. Thank you, Seth. I am sure we have a vanity URL that the team is working on right now to correct my misstatement. But you can go there to register and get more information about upcoming events throughout the year. With that, thank you all for joining in today's succinct HITAC meeting. And I will turn it over to Aaron and Medell to go through their opening remarks and the usual opening related business. Thanks.

Opening Remarks, Review of the Agenda and June 15, 2023, Meeting Notes – HITAC Vote (00:09:46)

Aaron Miri
Thanks, Steve. We appreciate the remarks. And hello, everybody at HITAC. Happy August. I cannot believe it is August 17. That surprises me even as I say that. This year is flying by. It, literally, feels like we were just together at the in person HITAC meeting but that has been a hot minute now. This year is flying on by. Lots of good work that has happened this year. Truly a banner year for HITAC thanks to all of your hard work and really focus there. The subcommittees that are meeting, we had our annual report work group yesterday, which we will do a little update about today. Really good discussion there. I am guilty of going over by two minutes because we were knee deep in conversation about some good interoperability business. That is the kind of business that is coming out from the subcommittees. And we cannot be more proud of you. Welcome to today's edition. And we are going to have a really fun agenda. Medell?

Medell Briggs Malonson
Thank you so much, Aaron. I just want to echo all of the sentiments that you mentioned. I hope everyone has been enjoying their summer so far. We absolutely did miss meeting last month but we know that everyone needed a break and continued to be productive in all of the work groups. Today will be a bit of a concise day but also with very impactful information. Aaron, why do we not go ahead and jump on in and review the agenda?

Aaron Miri
Let us do it. All right. Today, obviously, we have got the Pharmacy Interoperability Emerging Therapeutics Task Force. Say that five times fast. And then, we are going to go over the overview of the USCDI Core Data for Interoperability Version 4 as Steve was talking about. We will go to public around lunchtime, 12:05 and then, adjourn by about 12:15. To the point, succinct as we gear up for even more work ahead in the near future. Medell?

Medell Briggs Malonson
Thank you, Aaron. To our first order of business for the morning is the approval of our meeting notes from our June 15 meeting. Do I have a motion to approve the June 15 meeting notes?

Sarah DeSilvey
Sarah DeSilvey with a motion.

Jim Jirjis
Jim Jirjis, I second.

Medell Briggs Malonson
Excellent. The motion has been appropriately seconded. Is there any discussion? Seeing none and hearing none, I will go ahead and call for the vote. All in favor of approving the June 15 meeting notes as written say aye.

Group
Aye.

Medell Briggs Malonson
All opposed? Any abstentions? Wonderful. The motion carries and the June 15 meeting minute notes are all approved. Thank you. Now, we are going to go onto our very first presentation. I would like to introduce Shelly Spiro as well as Hans Buitendijk who is going to go over our Pharmacy Interoperability and Emerging Therapeutics Task Force update.

Pharmacy Interoperability and Emerging Therapeutics Task Force Update (00:12:32)

Shelly Spiro
Thank you. I am Shelly Spiro. I am the executive director of the Pharmacy HIT Collaborative. And I am pleased to co-chair along with Hans the Pharmacy Interoperability and Emerging Therapeutics Task Force that has been taking place this summer as Steve had mentioned. You can go to the next slide. Here is our agenda. We will be going through the task force charges, talk about the task force membership and the task force progress that we have done so far, and a little bit of what we will be doing as we move forward to the recommendations to the HITAC. You can go to the next slide. I would like to thank all of the members of the ONC team and thank you, Steve, for your kind comments about the work of this particular task force. I would also like to thank the Accel team, Tricia Lee Rolle, for her help in getting this moving and all of her help in making this a reality. To Hans for putting up with us and helping us through, especially with the recommendations. Maggie, Mike Berry. Thank you, Mike for all of your help. And also, to the Accel team for their efforts in getting this working.

Our overarching charge is to identify recommendations to support interoperability between pharmacy constituents and exchange of information necessary for medication management, patient safety, and consumer engagement. Our recommendations are due in person on November 9. And these are our specific charges. The first charge is related to public health, emergency use authorization, and prescribing authorities. We have broken up our charges into short term and long term goals. Our first short term goal under public health was to identify critical standards and data needs for pharmacists and interested parties to participate in emergency use interventions and other actions ONC can take to enable data exchange in support of public health emergency use cases. For example, pharmacists are highly involved and were highly involved during the pandemic for tests to treat and COVID-19 treatment prescribing via emergency use authorizations.

Our long term is recommendations to better integrate pharmacy systems and data for public health, surveillance, reporting, and public health interventions. You can go to the next slide. We have broken it out into four topics. Our second topic is to identify opportunities and recommendations to improve interoperability between pharmacy constituents, a long list, also, for pharmacy based clinical services and care coordination. We are very interested in how can ONC help facilitate adoption of these standards to support data exchange for pharmacy based clinical services, which priority pharmacy based clinical use

cases should ONC focus on in the short term and long term and what technology gaps exist in pharmacies to participate in value based care. And what can ONC do to address drug inventory transparency for prescribers and consumers. These are really hot topics right now. And I think our group is doing really well on getting through these topics and making recommendations.

Our third topic is to identify standards needs to support prescribing and management of emerging therapies, including but not limited to specialty medications, digital therapeutics, and gene therapies. All of these are emerging types of actions that are happening within the pharmacy community. What standards gap exists for prescribing and management of specialty medications, digital therapeutics, and gene therapies. And our fourth topic, which will take place later on in the fall, identify policies and technology needs and considerations to direct consumer medication services. You can go to the next slide. This is our list of our task force members. As you can see, we have many task force members who are part of the HITAC. And we really appreciate their expertise. They have been a great help in moving this initiative forward and have come up with some excellent recommendations moving forward.

We have some subject matter experts from the pharmacy community. All are bringing great discussions and moving things forward. We have had quite a bit of participation from the public on each of our calls. This is a high interest for the pharmacy community. You can go to the next slide. Our progress moving forward, I think, is this you, Hans taking over?

Hans Buitendijk
I think you were going to do the completed and now, we are going to go to features.

Shelly Spiro
Thank you. I am sorry. I was looking at the number of slides and we were off because of our beginning slides on this. We began our first meeting on June 21 and got off to a great start. For one, I would like to thank Hans and Tricia Lee Rolle for all of their work in putting together a spreadsheet where we re capturing a huge amount of information and recommendations. We have had a large amount of comments coming through the chat that we are capturing by the Accel team. They are doing a great job. Mike Berry is leading us very well through this process also. As being my first co-chair responsibility for a task force, I am very pleased and happy that they are able to help us. Our first topic we identified critical standards and data needs for pharmacists and interested parties to participate in emergency interventions. And the action items take to enable exchange to support public health emergency use cases. We have captured most of the recommendations through this process. Our June 28 meeting, we discussed the short term public health emergency use cases.

And we have had several subject matter experts come and present. We have Retired Rear Admiral Pam Schweitzer on the public health side, Lisa Schwartz who is the senior professional affairs from the National Community Pharmacists Association, Darren Townzen from Walmart, Chad Worz who is executive director of the American Society of Consultant Pharmacists. We have brought in the LTPAC **[00:20:38]** setting into these discussions because pharmacy plays a very important role in that setting. Also, a couple of folks from STC Health. You can go to the next slide. We then met on July 12 and started our long term public health use authorizations. We did take a break for the July 4 holiday. And we have had the team from CDC come and talk to us from the US Public Health Services on some of these public health issues. July 19 we continued our long term goals in relationship to public health.

And we have had more folks from the CDC talk about electronic case reporting and what pharmacists can do to really help in that particular area and others from the CDC to further help us with immunization information, as I said, electronic case reporting and other areas that pharmacy can play a very important role in public health. You can go to the next slide. We took a break. We did not take a break yet. We went to July 26, which started our Topic 2 discussion on identifying opportunities and recommendations to improve interoperability more related to the clinical services and care coordination. Pharmacists play a very important role in many practice settings for care coordination. And we had some speakers. We had Kim Boyd who is very active within NCPDP. We also had Steve Mullinex and Rick Sage from NCPDP and Josh Howland is senior vice president of clinical strategies with RedSail Technologies, which is a national vendor for Community Pharmacy that is a nationwide vendor.

I think they service about 4,500 pharmacies across the United States as a vendor. We took a break in the first part of August for that week as some folks were on vacation. Part of the problem of having summer meetings. And then, we went on August 9 and continued our Topic 2 discussions on clinical services and care coordination. And we heard from Jake Galdo who is with Community Pharmacy enhanced service network and talked with dealings especially with health equity as part of what pharmacists are doing in relationship to social determinants of health and some of the quality initiatives that the pharmacy profession is working on. And if you can go to the next slide, I believe we had our meeting yesterday, which was August 16 and we continued to work on our spreadsheet and recommendations in relationship to care coordination and clinical services. But this was more focused on value based care. And I think that has caught us up. And I will now turn it over to Hans.

Hans Buitendijk
Thank you, Shelly. Thank you for everybody who is participating, providing input on the chat otherwise in these discussions. And I echo all of Shelly's comments about all of the support that we have to make it happen. And that got us kind of through what I think Steve Posnack considers summer camp. And we are working our way into the fall where we have a couple of upcoming meetings. August 23, we are going to progress with Task No. 2, the last component of that to understand a little bit more about some of the inventory transparency topics and what ONC could do there. Some of that conversation, actually, already started yesterday with some of the perspectives on some of the challenges in that space that we have and what can we do about I, what can ONC do about it. And we will probably have some suggestions where ONC can collaborate perhaps with other organizations to address some of these questions as well. Some of these are fairly complex as we go through it.

August 30, we are going to then start with Topic 3 and go through the respective areas of focus. First on specialty medications on August 30. We are going to take another little break around Labor Day. That is why there is a skip to September 13 where we continue with the digital therapeutics aspect of that. Can you go to the next slide? On September 20 then, we are going to go to Topic 3, Standards Gaps for Gene Therapies. September 27, we are going to go to any remaining emerging therapeutic areas that the task force has identified or that we may discuss at that point in time. In October, we are going to go to the final step of Task 4 identifying policies and technology needs. October 11 will get us to further discussion on that. And if you go to the next slide, the remainder of October and into November to bring us to November 9 in Washington DC where we are going to be finalizing the recommendations, go back to all of the materials, make sure we have it all well organized and ready for HITAC to review and make final recommendations to ONC.

As you can see, we still have a fair amount of work in terms of meetings, in terms of presentations. We are identifying additional speakers to provide insight into what we need to discuss. And the next slide, if you can move there, is providing a little bit of an insight on some of the major themes that have been discussed so far. We need to caveat that, obviously, with discussions are in progress. As we talk through it, we are clarifying earlier points as well as we discover some new areas. Do not take this as the list from Task 1 and Task 2 as they will end up but they, certainly, are indicative of where we are heading, where we are diving deeper. Around Task 1, the Public Health Emergency Use Authorization and Prescribing Authorities. There is quite a variety of topics that we are getting deeper into. What kind of standards and data exchange challenges can we address?

There is a good amount of discussion that we have had around pharmacist/physician collaboration, clinical data sharing, not only about the data to be shared, what is relevant but, actually, go through the discussions around tests to treatment in a number of areas increasingly or in emergency use scenario where there is increased inclusion of pharmacists in those processes as well. What data needs to be shared but also how long term and otherwise do we address the challenges in that space. Is there good awareness of what the role of the pharmacist is, authorizations that they have to get access to data, clarifications that need to be in play, etc. That in itself is already providing some good topics where we are diving deeper. We also explored in that regard pharmacists of public health, specifically, the data capture that occurs in the pharmacy. And that is of interest to others as well. And then, pharmacists through special settings like long term care, population level, and other data sharing that needs to occur.

Challenges were raised around the sharing of information and sometimes, the challenge of getting to the information whether that is a technical issue, whether there might be agreements in that space, whether there might be other considerations that may make that challenging. We identified that there is an area where we need to provide some insights and potential recommendations as well. Variations that we see in a variety of different areas also visible in this space jurisdictionally across jurisdictions where there is a variety of standards and rules that need to be utilized and the challenges that that providers, particularly in emergency situations. Resources, funding, privacy, and consent are the other ones that came out. A rich set of topics, as Shelly indicated, we have a set of spreadsheets that in a number of work groups we are starting to get used to how we are using it to capture our thoughts. Also, we are going on follow ups in flight to fine tune some of the thoughts that we have there. For Task 2, some of the things that are starting to bubble up and this was for 2A and B, not yet getting into the **[inaudible] [00:30:58]**.

Slides were not able to be updated by that time but I will give a little bit of a thought around that. There we are looking from a technology perspective very much at aspects of data queries or push messaging. How can we go back and forth? What are the opportunities to take advantage of existing networks? What are some of the challenges with that? Patient matching. It is a challenge that is not only in other areas where we have heard at HITAC about that but in the pharmacy space as well. USCDI linings. There is a set of data that is evolving and advancing, expanding. There is a subset of that data that is relevant, particularly in the communication between pharmacists and providers. What is the set that is relevant? How can we take advantage of that? What are some opportunities there and talking through that? Use cases starts to also go in Task 2C that we talked about yesterday in the task force meeting where we are trying to identify a number of key areas that can help us also better understand what are the needs in these areas.

And in that context, combining a little bit of Task 1 and 2 as some of the governance challenges the prioritization, the funding, agreements, challenges, and opportunities that exist there are then able to come back to those use cases as well. So, we had a good and robust discussion yesterday of some of the ones that are particularly coming to mind that provide some indications. Perhaps these are ones to look at. As you look at these, these are the things to then start to address long term/short term. And then, first steps. That goes back to the short term/long term part. What can we do now? The rules of discovery are the things that need to happen regardless of use cases. They are just fundamental that are in play. If you are going to the next slide then, we are really talking about how to enable use of existing technology standards and networks. What are barriers to adoption? There is already a lot out there but for one reason or another, they may not be deployed as much in that interaction between providers and pharmacies and pharmacists.

So, what are those barriers? That is what we are honing in on to give a little bit more insight to what are our next steps to help remove those. Components in there are not only about the existing technologies but also education, awareness, what can be done, contractual arrangements, funding and incentives, and the role of USCDI. So, those are the topic areas that we have identified so far that we are working around. And as we progress, surely we will find some more and organize it a little bit deeper in there. But that is rounding out where we are out today and what we are building up for the four meetings that are coming up. With that, I think unless, Shelly, you have any additional comments to round that out, I think we are ready for discussion.

Shelly Spiro
No. I have no other comments. Thank you, Hans. You did a great job.

Hans Buitendijk
Thank you. Aaron and Medell, however you would like to organize the discussion, we are ready for that.

Aaron Miri
All right. Let us go for it. Show a raise of hands. That was an excellent presentation by the way. Thank you for that. If any of the HITAC members have comments or questions, please signify by raising your hands and I will look for you in the Zoom box here. Any discussion? All right. Hannah Galvin.

Hannah Galvin
Thank you. This is outstanding work. I really applaud the work group. You mentioned that specialty pharmacy work is included in the scope. And I am just wondering about DME pharmacy and whether that is being included. Some of the real challenges that I have seen are around prescribing oxygen, prescribing nebulizers, and communicating with DME pharmacies. And I am wondering if that is in scope or if that is, potentially, in a parking lot for another phase.

Shelly Spiro
I can take that, Hans, if you would like. Thank you, Hannah. We really look at it from all practice settings. We have not heard from specific DME but there are pharmacists out there who have been part of our subject matter experts that are dealing in this area. It has not come up yet but we are open to those discussions on any type of topic related to the exchange of information, including from pharmacies that are providing DME services. If you have any suggestions for us of subject matter experts, we would be glad to take them. You can send them to Tricia Lee Rolle or Mike Berry.

Aaron Miri
Wonderful. Good question, Hannah. Steven Lane.

Steven Lane
Thank you so much and thank you to the task force co-chairs. You guys have been doing a wonderful job over the summer herding the cats and bringing some really good ideas to the table. I really want to applaud ONC also for sponsoring this task force. It is such an important topic and we had such an opportunity to leverage the tremendous resource of community pharmacists who are out there to contribute to the care of our population and ourselves. And we have really been unearthing a number of real challenges that pharmacists have in doing this effectively and having full access to the clinical data that is necessary to inform decision making and having access to the interoperability frameworks that we're building that allow them to contribute back to other members of the care team, to payers, public health, etc., about the care that is being provided. Really thanks to all who are involved in bringing this forward. And I really do think that there are going to be some excellent recommendations that come of this.

But I think the bottom line in my mind as a primary care physician is our patients need all of the help they can get but they need to have that help be informed by full access to data and to be supported by full integration into the sharing of clinical data downstream from the care. Hopefully, that is going to be there outcome and look forward to working through the rest of this with the task force. Thank you.

Medell Briggs Malonson
Thank you, Steven.

Aaron Miri
Great point, Steven. Other comments or questions from HITAC members? Going once, going twice. With that then, thanks, again, co-chairs. Really appreciate your hard work at this and as was articulated by Hannah and Steven, a really critical topic for the industry and one that is desperately needed. Thank you for the hard work here and lifting up your sleeves and making it happen for us. Thank you for that.

Shelly Spiro
Thank you.

Aaron Miri
Up next, we will go into USCDI Version 4, Al Taylor, you are up.

Overview of United States Core Data for Interoperability (USCDI) Version 4 (00:38:59)

Al Taylor
Thanks, Aaron. I am glad to be here to provide the HITAC with an update. Next slide please. I am going to talk not only about the recently released USCDI Version 4 but also some changes that we have implemented to the ONDEC submission system, which will help facilitate the USCDI Version 5 submission cycle. I am also going to go over the HITAC recommendations from the transmittal from April and talk about at a fairly high level ONC's responses to those recommendations to provide some feedback to the HITAC about what we are doing with those recommendations. Next slide. In July, we published the final version of USCDI Version 4, which added new data class facility information, made significant expansion of data

elements in a couple of different areas. One is health data assessments and laboratory data. And we also added data elements in some kind of new areas. One is in the goals and preferences data class, goals previously known as the goals data class.

We added two data elements related to the advanced care planning process and being able to capture our patients' preference on particular topics, especially those around interventions such as CPR innovation, IV fluids and then, also one around patients' more general healthcare experience so that we added those two data elements in the goals and preferences data class. And in the medication data class, we also, I think, took a big step forward in being able to capture more accurate and detailed information about the actual medications that a patient is taking by adding two new data elements. One is the medication instructions, which is the way that a patient understands their medication should be taken and then, a corresponding medication adherence data element, which says the extent to which a patient is taking those medications, whether they be over the counter, prescription, herbal supplements, whatever, if they are being taken according to those medication instructions.

Those two things put together go quite a ways towards capturing a fuller picture. In the past, we had data elements just about the intended dose, the intended medication, and these get much closer to the actual truth about the medication. And so, we feel like that is a really strong addition to the medications data class. And two other ones, performance time, which is one related to the timing element of a procedure or anything that is performed on or for a patient. And then, any vital sign, which has long been awaited, the average blood pressure vital sign. Those are the highlights for the additions. You will see that in Version 4. And the next slide shows USCDI Version 4 as a whole. I believe we have 120 data elements. I could be off by a couple but it is now 120 data elements across 19 data classes. Next slide. This is a high level summary of some changes that happened over the various versions of USCDI.

And it points to the iterative process but also we have tried to follow a predictable process but also collaborative where we really try to engage a great number of users, interested parties to add new things to USCDI. I feel like it has been very successful. We have had tremendous participation. Each round, whether it is a draft version or a final version, we have had many hundreds of comments or submissions about additions to USCDI. CLIArly, there is an interest in expanding but also better defining this core data set. We feel good about the progress that we have made and look forward to continuing to do that with Version 5 and beyond. Next slide. I mentioned several hundred comments and submissions for new data elements ONC has to prioritize and get prioritized. Amongst the most mature, most feasible data elements, we continue to do that addressing both technical priorities, those that are most ready, most feasible, lowest burden to implement but also those that address particular policy goals of ONC and HHS.

And that is related to adding data elements to address healthcare disparities, underserved communities, behavioral health integration and the primary care along with a number of different public health reporting requirements. And this continues. We had made some changes. We made one change to the priorities for Version 4 and we are going forward with Version 5 with the same set of priorities that are listed here. And so, we will continue to do that to look at the many data elements and use these priorities to help select the next round of additions to USCDI. Next slide. We also made some changes to the ONDEC system to help facilitate the submission, increase the transparency for users and for submitters so that they have a better expectation about what they are going to get. If they submit a data element, they should know the intent is that these changes will let them know what they should expect as far as leveling and the possibility of being

considered for USCDI the next version as they are submitting these as opposed to waiting for a week or two for ONC to do a full processing of the submission.

We feel like these changes will go a long way towards providing transparency and expectations for the submitters. Next slide. For the most part, there is one major change that we made when we published V4 is that not only did we try and clarify the criteria for each level, we actually renamed the lowest level or the lowest level of feasibility and maturity for a data element that is submitted and that is called Level 0. It used to be called comment level. There was some confusion as to whether or not things that were listed in comment levels were just comments or they were actual data elements. And so, being Level 0 does mean it has got no value or no potential but it is just a renaming of the entry level of the elements. We also published a leveling criteria page so that a submitter can review what the criteria are. And that is on the next slide please. It is sorted by different levels. Data elements that are in the Level 2 meet all of the criteria that are listed in the first row and so on through the levels.

There is one that I wanted to point out that I think would also add some clarity. In Level 0, quite a few data elements get leveled as Level 0, not because they are immature but because they are not well represented. They are not exchanged but that they represent a very small subset or a specialization of other more general data elements. And that may not sit well with some submitters but because the US core data for interoperability is a core set and it has to apply to a broader community of users' data. When a data element is so highly specialized that it is only applicable to a very narrow use case or very narrow care setting, we assign it this Level 0. And this is an alternative to what we have done in the past, which is to merge one of these specialty data elements into one of the more general data elements. And this is an improvement because everybody can see that data element. If it is merged into another data element, it, basically, disappears from the public view.

But anybody who goes to the website can see that there was a data element that was submitted that is described as a specialization of another data element. And so, they have a better understanding about why it did not make a higher level or did not make USCDI. Next slide please. Those same criteria are listed on each of the level tabs on USCDI web page. This is the Level 2 criteria. Data elements that are listed on Level 2 meet all of these criteria. If they do not meet all of them, they get relegated to a lower level. The next two slides are Level 1 and Level 2 all respectively. And that is just, again, as people review USCDI, in general, they can review what is in Level 2 and see how we determine these. I will say that if you are reviewing these levels, we continue to go back and review our evaluations of data elements in the past. And you may see a shift in the level assignment for some data elements because we have gone back and reviewed them and realized that they are either more or less broadly applicable and so may get releveled over the next couple of months as we some more CLIAn up on the website. Next slide.

I am going to move on to the submission timelines. It is a pretty basic review. Next slide. As everybody knows, we published V4 in July, which opened up the USCDI V5 cycle. As Steve mentioned in the very beginning, this submission cycle goes through September 20 midnight Eastern on September 20 after which time we complete the processing and evaluation of all of the submissions along with all of the comments on previously submitted data elements, all Level 2 data elements in the past that some people think ought to be reconsidered for Version 5. And then, we take the time to go through the process of evaluating and selecting a new set of data elements for Version 5 and then, a planned release of a draft of V5 in January of next year and then, the cycle repeats. Next slide. Now, we get to the fun part. We are

going to go through the April transmittal letter from the HITAC to ONC. And I am going to talk at a fairly high level about the recommendations and what has happened since those recommendations were made.

We published V4 in the interim and some of the recommendations were incorporated into V4 and some were not. Many are still under consideration, however, for future work. And this recommendation letter was broken down into three parts. One is recommendations and comments on the elements that were added to draft V4. And then, the second part is recommendations for Level 2 data elements that did not make draft V4 and whether or not those should be changed or even reconsidered for addition to USCDI Version 4. For those who did not already notice, we did not add any new data elements to draft V4 when we published V4 final. But those Level 2 data elements still remain in consideration for future versions pending reconsideration or additional information about more broadly applicable or aligning them more with some of our additional priorities for selection. And so, none of those data elements were added to USCDI but definitely, we have added the HITAC recommendations to the other comments that were received on these data elements and we will continue to consider them for future versions.

And then, we did receive one recommendation from the HITAC about areas where ONC might want to focus in the future. We will go through those. There are, I think, two recommendations that will look out of order. Some of the recommendations are kind of rolled up into other recommendations. We did not ignore those recommendations. We just considered them elsewhere. Let us get started on the next slide. And you can follow along in the recommendations. Transmittal of the link is in the slide deck. And you probably already know where it lands but you can follow along as we go through. Again, this is a high level summary of the recommendation and the response. And so, there may be some detail that is not in the slides. Next slide. As I said, we adopted all of the data elements in draft V4 with the Exception 2 that we had named. And I will go over those. Focusing on the health status assessment, there was a recommendation to address specific LOINC codes for the health status assessment data element that we did add. The way that we did that is by adding specific examples that the examples are represented by specific LOINC codes.

Rather than acquiring specific LOINC codes, we added these examples because we still want to allow flexibility in how data is collected and shared. We provided those specific LOINC codes as examples. And two of the recommendations were about development of appropriate vocabulary and standards in the related facilities. There is not currently a broad consensus about which ought to be used for facility data. That work will continue in the broader community and we look forward to seeing what might develop. We would love to be able to provide some specificity to help developers and implementers complete this work. And so, we look forward to seeing what shapes up. Next slide. Again, the same as with health status assessments. We added some specific examples to the average blood pressure. One of the recommendations for laboratory, result interpretation in particular, was to add an applicable vocabulary standard that relates to an HL7 specific code system.

Most of the time, we have relied on the more broader vocabulary standards like SNOMED, LOINC, CPT, ICD-10 and in this case, we did adopt the HL7 observation interpretation as an applicable standard for result interpretation. It is currently listed as optional but we did accept that. A lot of the other lab data elements, including one for that, are specifically required by CLIA. And the recommendation from the HITAC was to cite that specific requirement. While we did not adopt that because we have stayed away from citing specific recommendations, specific requirements because there, generally, are more than one. And even beyond requirements, there is a broader need for it. Though we did not cite the CLIA requirement that still

stands as another justification for adding it to USCDI. And the first recommendation that we accepted for a name change, although we named it something different than the HITAC recommended was the specimen condition and disposition data element. And we renamed it specimen condition acceptability data element. I think it is a subtle change but it is an important change to really add some clarity about what the meaning of that data element is. Next slide. The second renamed procedure is we renamed the time of procedure to performance time, although that is not reflected in the slide. And there was the recommendation that it not apply to labs. And the way we adopted that recommendation is to remove the laboratory related timing elements from the examples. We appreciate the comment and accommodated it as such. There were recommendations to change the definition of the medication related data elements. We did that with the exception of the requiring reason for non-adherence for the medication adherence.

And we really feel like that is a separate data element. And we did get that. We have a process to let folks know that what their comment was represented a new submission and, therefore, it had to be submitted through the ONDEC system for full consideration. I see some potential in that data element. And it remains to be seen whether that will be considered and added to Version 5. But it is a separate data element so we could not adopt that recommendation for a new data element but instead went into this more normal process. And then, the recommendation to change to the name of the data classes I mentioned before was accepted. Moving on to Part 2, which was the data elements that were Level 2 but not included in USCDI. As I had mentioned before, we did not adopt any of these data elements. But they are all still under consideration for next round based on policy priorities that I mentioned that is on our previous slide. And these will be reconsidered this time around, particularly if there are specific comments that are added as to why they should be reconsidered for the next version of USCDI. Next slide.

The same goes for these data elements. I think I might have a repeat on the first set of data elements. The two at the bottom on Recommendation No. 22 adding metadata or requiring a source and method for the data collection for extra clinical use and recorded sex or gender, we did not adopt either the data elements or those additional metadata elements. But that is aligned with how we have done this in the past where we do not require that a data element be sourced by a particular source but allows for it to be sourced by the patient, by provider, by machine. It is still a candidate for reconsideration. And we will take another look in this next round. Next slide. These are additional data elements that were recommended for the four that were not adopted. I wanted to talk a little bit about the Recommendation 27, which mentioned a number of different data elements that were recommended to be added. Again, not previously submitted. It would need to be resubmitted through ONDEC. Also, the data elements, specifically, allow a patient source or patient generated source for the data element.

And this goes back to what I just said about we have not specified that a data element has to be sourced by a patient or not by a patient. But it, certainly, is allowed. It is allowed in the data element. And so, we did not feel like it was necessary to specify these. It is okay for data to be sourced by the patient because, in many cases, the ultimate origination of the data is the patient in any case. We did not specify that but it certainly is allowed for many data elements. Next slide. The diagnostic imaging data elements that we did consider, we spent a lot of time in the HITAC and IS WG developing these recommendations. And while we recognize the value and enhancing the interoperability of diagnostic imaging data is a really important topic. The feedback that we got from a variety of different stakeholders was that the data is not ready for widespread collection/exchange. There are methods that are out there but they cannot be broadly applied

in many cases. More work needs to be done. And we have, actually, called for some of that work when we published the standards bulletin.

We hope that more work is done and some more clarity is brought to the topic so that, hopefully, this could be mature enough, broadly applicable enough to consider for new versions. And the other data elements here were considered but not adopted as additional data elements throughout facility and medication. Next slide. The last three, the health status assessment, the recommendations in Recommendation 33 were to add specific requirements to the data elements. And we did not adopt those. But that is still something to be considered to redefine them to require the responses to the questions and not just the questions. Next slide. Two slides forward please. And then, the final recommendation is to advance one of the data elements. And we did not adopt that but when additional information is provided, we certainly would consider it. I am over. I apologize for that. We can open it up for questions. I see one or two in the chat from when I started.

Medell Briggs Malonson
Thank you, Al, so much for this critical information that we all need to know. And we are close to our public comments but we are going to allow three minutes for discussion. Please HITAC members, keep your questions very concise so that Al can answer them and we can get to public comment. Great. The first hand that I see is Ike's hand.

Steven Eichner
Thank you so much. That was a wonderful presentation and wonderful overview. Two questions really straight forward. For those things that were not included in this last iteration, should comments be submitted while ONDEC is open for inclusion for the next iteration for things that are in Level 2? Or will things that are in Level 2 automatically be reviewed for consideration in Version 5? The second question is can you talk just for a moment about aligning things like the laboratory data with public health reporting? I think one thing that is a goal is to help ensure that things that are requirements for public health reporting are included in the USCDI. And there were a number of those laboratory elements that are directly related to public health reporting as well as general health reporting or general health exchange. Thanks.

Al Taylor
Two things. One is yes, we welcome comments on Level 2 data elements that did not make it this time around. And that is not only the specific ones that were recommended but all of the other ones that did not rise to the very top. Rather than submitting new data elements, repeating the new data elements that were not accepted at Level 2, adding comments to add to the case for considering those Level 2 data elements for V5. We fully expect that. We did that last time. During the draft period, we expected it and we encourage it this time around as well. As far as adding data elements that align to public health reporting or any other, one of the primary reasons that we did add the laboratory elements that we did is because they align. We adopted them in a way that would align as best as possible to the public health reporting requirements. And so, we might, actually, try and shape a data element that is almost well aligned with a specific requirement like public health reporting so that it would be so that we do not have to adopt two different kinds of the same data element to meet more than one use case.

Medell Briggs Malonson

Thank you so much for that answer, Al. Steven Lane, I recognize your hand. We are going to go to public comment right now first. And, hopefully, we will have some time for your question. If not, please do send your question to Al and the rest of the ONC team. Mike, I will turn it over to you for public comment.

Public Comment (01:08:54)

Mike Berry
All right. Great. Thank you, Medell. We are going to open up our meeting for verbal public comment. If you would like to make a comment, please use the hand raise function located on the Zoom tool bar at the bottom of your screen. If you happen to be on the phone only, press star 9 to raise your hand. And when it is called upon, press star 6 to mute and unmute your line. Let us pause for one moment to see if any members of the public raise their hand. And I see Mari Savickis. Sorry if I am mispronouncing your name. Please go ahead. You have three minutes.

Mari Savickis
I will be really short. It is Mari with CHIME. Thanks for taking my comment and great presentation on the medication pieces and the pharmacy pieces. I just heard the piece about the patient identification and I just want to reiterate that. Our members continue to express significant concerns around that and that continues to be one of the chief barriers to the ubiquitous interoperability and sharing of information across the healthcare system. It is an issue and we applaud you for pointing that out. And anything we can do to work with the administration given that there is still the ban in congress, we would welcome that opportunity. Thank you.

Mike Berry
Thank you, Mari. And I see someone with a 617 area code if you could state your name and provide your comment. You have three minutes. And you are on mute. If you hit star 6, you should be able to unmute your line.

Cynthia Fisher
Yes, hi. This is Cynthia Fisher. I am on the committee. I will just add a high level of consideration. From the patient aspect of pricing and receipt of payment at point of sale, it has been noticeable that patients have not been given access to the total price and receipt at pharmacy. In sum, they just receive their copay amount. And in law for years, it has been in play that the patients have the right to the past, present, and future payment information. And we are at a time where patients should be able to receive a digital provenance of both their out of pocket costs or their copay as well as the total price for the said pharmacy or the drug or the laboratory. Especially when you have a diabetic or you have a disease where you iteratively get labs or drugs to be able to see the run rate or the comparative rate on your plan and to prevent any overcharges for accountability. I just think as we look at this whole accessibility and moving to the patients having digital provenance but more importantly, having access to the actual pricing and coding and the drug **[inaudible] [01:12:11]** itself with what the plan pay is as well as the out of pocket.

I think having the complete picture is truly important, otherwise, we do not have accountability. We have overcharging and we do not have an apples to apples comparative pricing across the industry and across points of access to purchasing such modalities of care. Thank you.

Mike Berry
Thank you, Cynthia. That is Cynthia Fisher, one of our current HITAC members. Thank you, Cynthia, for your comment. We just want to remind everybody that the next HITAC meeting is scheduled for September 14 and that all of our HITAC materials whether for this meeting or any of our subcommittees can be found on HealthIT.gov. I am not seeing any other hands raised so I will turn it back to Aaron and Medell to close us out.

Final Remarks and Adjourn (01:13:02)

Medell Briggs Malonson
Thank you so much, Mike. And as always, time always flies here on HITAC. I just want to extend a sincere thank you to all of our presenters today and, of course, to our HITAC members for all of your engagement and to the public for joining us. Aaron, any other last thoughts?

Aaron Miri
No. I just want to echo what you said and thank you all for a great, fun, very engaging conversation. Great job, again, to our panelists and our co-chairs as well as to all of you. Great job and we will see you soon. Have a great one.

Medell Briggs Malonson
Take care everyone. Enjoy summer.