Transcript

HTI-2 PROPOSED RULE TASK FORCE 2024 MEETING

July 19, 2024, 2 – 3:30 PM ET

VIRTUAL

MEMBERS IN ATTENDANCE

Bryant Thomas Karras, Washington State Department of Health, Co-Chair
Rochelle Prosser, Orchid Healthcare Solutions, Co-Chair
Mark Sendak, Duke Institute for Health Innovation, Co-Chair
Hans Buitendijk, Oracle Health
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
Gillian Haney, Council of State and Territorial Epidemiologists (CSTE)
Joel Hartsell, Association of Public Health Laboratories (APHL)
Erin Holt Coyne, Tennessee Department of Health, Office of Informatics and Analytics
Jim Jirjis, Centers for Disease Control and Prevention
Mary Beth Kurilo, American Immunization Registry Association (AIRA)
Hung S. Luu, Children's Health
Anna McCollister, Individual
Alex Mugge, Centers for Medicare and Medicaid Services
Shantanu Nundy, Accolade
Eliel Oliveira, Harvard Medical School & Harvard Pilgrim Health Care Institute
Kikelomo Oshunkentan, Pegasystems
Randa Perkins, H. Lee Moffitt Cancer Center & Research Institute
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, CyncHealth
Sheryl Turney, Elevance Health
Thomas Wilkinson, U.S. Department of Homeland Security

MEMBERS NOT IN ATTENDANCE

Shila Blend, North Dakota Health Information Network
Derek De Young, Epic
Steven Hester, Norton Healthcare
Dominic Mack, Morehouse School of Medicine
Meg Marshall, Department of Veterans Affairs
Katrina Miller Parrish, Patient.com
Dan Riskin, Verantos
Fillipe Southerland, Yardi Systems, Inc.

ONC STAFF

Seth Pazinski, Designated Federal Officer
Maggie Zeng, Staff Lead
Molly Prieto, Group 1 Co-Lead
Rachel Abbey, Group 1 Co-Lead
Sarah McGhee, Overall Task Force Program Lead & Group 2 Lead
Cassie Weaver, Group 3 Lead

PRESENTERS

Steven Posnack, Deputy National Coordinator for Health IT, ONC
Beth Myers, ONC (Discussant)

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

Seth Pazinski
Good morning, everyone, and welcome to the HTI-2 Proposed Rule Task Force for 2024. This is our kickoff meeting. I am Seth Pazinski with ONC, and I will serve as your Designated Federal Officer for today. This meeting is open to the public, and public feedback is welcome throughout the meeting. Comments can be made in the Zoom chat feature throughout the meeting, and there is also time scheduled towards the end of our agenda for verbal public comments. So, we are going to go ahead and get started with our meeting, and I will start with a rollcall of the Task Force members, so when I call your name, please indicate that you are present. I will start with the co-chairs. Bryant Thomas Karras?

Bryant Thomas Karras
Present.

Seth Pazinski
Rochelle Prosser?

Rochelle Prosser
Present.

Seth Pazinski
Mark Sendak?

Mark Sendak
Present.

Seth Pazinski
Shila Blend? Hans Buitendijk? Derek De Young? Steven Eichner?

Steven Eichner
Good afternoon.

Seth Pazinski
Hello. Lee Fleisher?

Lee Fleisher
Since we could not do any operations because of the IT problem, I am here.

Seth Pazinski
Welcome. Hannah Galvin?

Hannah Galvin
Here, thank you.

Seth Pazinski

Raj Godavarthi?

Rajesh Godavarthi
Present.

Seth Pazinski
Thank you. Gillian Haney?

Gillian Haney
Present.

Seth Pazinski
Joel Hartsell? I did get a message that Steven Hester would not be able to make it today. Erin Holt Coyne?

Erin Holt Coyne
Present.

Seth Pazinski
Jim Jirjis?

Jim Jirjis
Present.

Seth Pazinski
Mary Beth Kurilo?

Mary Beth Kurilo
Present, thanks.

Seth Pazinski
Thank you. Hung Luu?

Hung S. Luu
Good afternoon.

Seth Pazinski
Thank you. Dominic Mack? Meg Marshall? Anna McCollister?

Anna McCollister
I am here, good morning.

Seth Pazinski
Thank you, good morning. I did get a message that Katrina Miller Parrish would not be able to make today's call. Alex Mugge? Shantanu Nundy?

Shantanu Nundy
Hi, good afternoon, everybody.

Seth Pazinski
Hi. Eliel Oliveira? Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Present.

Seth Pazinski
Thank you. Randa Perkins?

Randa Perkins
Present.

Seth Pazinski
I did get a message that Dan Riskin would not be able to make it today. Fil Southerland? I got a message that Zeynep Sumer-King would be joining late. Naresh Sundar Rajan?

Naresh Sundar Rajan
Present.

Seth Pazinski
Thank you. Sheryl Turney?

Sheryl Turney
Present.

Seth Pazinski
Thomas Wilkinson?

Thomas Wilkinson
Good afternoon. I am here.

Seth Pazinski
Thank you. Is there anyone I missed or anyone who just joined us?

Hans Buitendijk
I just joined. This is Hans.

Seth Pazinski
Oh, thank you, Hans. So, please join me in welcoming our co-chairs for opening remarks, and I will turn it over to Bryant to get us started.

Opening Remarks (00:03:38)

Bryant Thomas Karras
Great. Thank you, everybody. I am Bryant Thomas Karras. As many of you know, I am a physician and public health professional. I have dedicated my career and my life to public health IT and the expansion of informatics skills across the country, so I am honored to co-chair this Task Force. I have to thank the people who came before us for the many public health activities highlighted in the notice of proposed rulemaking, the co-chairs of past Public Health Data Systems Task Forces from 2022 and 2021, Janet Hamilton and Carolyn Petersen, and then, Gillian Haney and Arien Malec. We would not be where we are today if not for the hard work of past committees, so I am honored to take on that charge and will do so with the spirit and energy that public health always brings to things, so I am looking forward to this.

Seth Pazinski
All right, thank you, Bryant. Rochelle?

Rochelle Prosser
Good morning and afternoon, everyone across the country. Thank you. My name is Rochelle Prosser. I am in the public sector and am the owner of Orchid Healthcare Solutions. However, I am a 30-year neurotrauma ICU nurse, as well as an informatics nursing analyst, and the opportunity to stand here and reflect the public in terms of information blocking and patient access to information is very important to me. Like Bryant, I too share the accolades to those that have come before me here on the panel. I appreciate what they are doing, what they have done, where we have come from, and where we plan to go. Thank you very much.

Seth Pazinski
All right, thank you, Rochelle. Mark?

Mark Sendak
Welcome, everybody. I want to thank the other co-chairs. I think it will be a busy two months for us all, and I want to thank everyone who has volunteered to help serve on the Task Force. For me, it was HTI-1 that inspired me to try to join HITAC, so I am excited to build on the work from last year. I think today's events with the outage clearly emphasize the role of health IT in maintaining critical infrastructure in the US and pushing forward the way that we deliver healthcare, so I am excited to work with everybody here and excited about what we can accomplish over the next two months. I am going to do a few slides, and then I am going to hand it back to Seth. Next slide, please.

Here is the agenda for today. We are wrapping up the opening remarks right now. I am going to hand it back to Seth, who is then going to take us through the Task Force charge and the workplan. We are going to look at the sections of HTI-2. It is a thousand-page document, so we should all feel motivated that we do not have to dissect the whole thing. We are going to be divvying up into subgroups, and then subgroups are going to work on designated sections of the proposed rule. We are going to have a public comment session and then break after 90 minutes at 3:30. Next slide.

We do have a big group working on this, so there are three subgroups. In total, we have about 30 people, and over the next few slides, we are going to show how folks are allocated to the different subgroups. On this slide, I just want to emphasize the diversity of types of people and types of perspectives that we have

today. Even amongst the co-chairs, we have public health, nursing, and myself in a delivery system setting here at Duke. We have folks from state health agencies, we have folks from industry, folks who work on the employer side with health plans, many advocacy groups, as well as individual patient representatives who are going to help make sure that everything we get out of this also benefits patient care. So, I am really excited to work with you all. I think I will be working with one of the subgroups, but we will also be convening as a full team. Welcome, and thank you. I will hand it back to Seth.

HTI-2 Proposed Rule Task Force Charge and Work Plan & Breakdown of HTI-2 Proposed Rule by Task Force Subgroups (00:08:33)

Seth Pazinski
All right. Thank you, Bryant, Rochelle, and Mark. I appreciate the framing of remarks for the group. We can go to the next slide. Again, I am Seth Pazinski, the Designated Federal Officer for the Health IT Advisory Committee, and I want to start by going over the charge for this Task Force. We can go to the next slide. I do not know if it is just hung up on my end or not. There we go. And so, the charge for the HTI-2 Proposed Rule Task Force is basically to review the rule, and the specific sections of the proposed rule related to public health, standards of certification, and information blocking and Trusted Exchange Framework and Common Agreement (TEFCA). You will see that we have organized three subgroups around those areas.

The other thing I will mention on this is that we do have a hard deadline for the work of this Task Force because we need to have the final recommendations within the 60-day public comment period for the proposed rule. Speaking on behalf of ONC, I just want to start off by stating that we know that serving on this Task Force is a time commitment for all of you, and I want to just give our thanks and appreciation for you volunteering both your time and your expertise to help inform ONC's rulemaking efforts. We really do greatly appreciate your time, your expertise, and your input into this rulemaking process. We can go to the next slide. Sorry, go back one, please. I think it is getting hung up on my end, my apologies. Can we go to the action item slide, please?

So, similar to the approach we took for the HTI-1 Proposed Rule, we are splitting this Task Force into three subgroups to help us efficiently work through the thousand-page rule, as Mark highlighted, so we will have a public health subgroup, a standards and certification subgroup, and an information blocking and TEFCA subgroup. And so, the slides shared for today have the members that we have heard back from as far as which subgroups they want to be on. You can serve on one or multiple. It is up to you and your availability and interest. We do ask if you could let us know and send to Maggie Zeng and our HITAC logistics support contract, whose emails are on the slide for today, which of the subgroups you are interested in working on, and we will get that added and make sure you get the meeting invites and start to receive the materials for those as we move into subgroup meetings next week.

I want to emphasize that, as far as today's meeting goes, the aim is to establish an understanding across all the Task Force members and provide you with an opportunity to ask questions, and that can be about what the charge is or what we are asking the Task Force to do, how the Task Force is going to operate, as well as how you individually can contribute to the Task Force or the subgroups, and also, in a subsequent presentation, you will hear from Steve Posnack, our Deputy National Coordinator for health IT, and Sarah McGhee, who is a policy analyst with ONC, and will be serving as the overall ONC contact that will be

supporting the work of this Task Force. We will go into how the specific sections of the HTI-2 Proposed Rule are split out across the three workgroups.

So, as we transition and go into the content of the rule, as we break up into subgroups next week, I want to just make sure that everyone is prepared and ready to jump in on the content and understands how to contribute. So, we do have time built in for discussion and questions today, both after this presentation and after the subsequent presentation on the breakdown of the rule by the different subgroups.

So, these are three actions we ask that each of you complete, and many thanks to those of you who have already responded to these items, but first, again, I will give a reminder to email Maggie Zeng and our HITAC logistics support contractor by the end of the day today if you have not indicated which subgroups you want to be a part of. Again, that is up to you. It could be one or multiple. The second item is if you have not otherwise provided your Gmail address to the HITAC logistics support contractor, please do that. We will be using a Google doc to capture recommendations and serve as a working document across the workgroup to compile recommendations, and my colleague Sarah McGhee is going to go over that document and that process in her presentation.

The third item here is ONC presented, through a public webinar, a comprehensive overview of the HTI-2 Proposed Rule on Wednesday. That recording is now available. We will put the link to that in the chat, so if you were not able to attend that public webinar, please take the time to listen to that recording so you have that background context heading into the subgroup meetings that start next week. We can go to the next slide.

So, those of you on the HITAC are likely familiar with this, but just to remind everyone and to make folks aware who may be joining the HITAC activities through this Task Force for the first time, all Task Force meetings and subgroup meetings are open to the public, so the public comment can occur in the chat throughout the meeting, and public comment time is included towards the end of each agenda for the Task Force and/or group meetings. The link provided on the slide has the calendar of all the HITAC meetings. That is also where you can find the meeting materials, and information on how the public can participate is all available through that calendar on HealthIT.gov.

Also, following the meetings, recordings and transcripts of the meetings are made available. I will note that, because of the volume of meetings that we have scheduled for this HTI-2 Task Force, it is likely we will experience some delays in getting the transcripts posted to HealthIT.gov, but if you as Task Force members want an early copy of that to reference for your work, please just reach out, and we will be happy to provide a draft transcript upon your request. We can go to the next slide.

So, this gets into our schedule, and again, Sarah McGhee will cover the breakdown of what substance each of the subgroups is going to tackle. I just want to make sure folks are aware of the meeting dates and times, so I will not go over these slides in detail, but each slide captures the specific dates and times of the meetings as well as which topics within the proposed rule will be discussed at each of those meetings. Skip to the next slide, please.

So, each subgroup will meet once per week over the next six weeks, and the Task Force topics are listed on how the rule will be discussed at each meeting. As you look through these slides, you will notice that

each week progresses to a next set of proposed rule sections, so I am highlighting that just to emphasize that, for each individual topic, there is a limited window to deliberate on that topic, so I would just encourage folks to please anticipate the need to come prepared with your feedback or questions ready on each topic as you come into that meeting. Also, Sarah will cover some tips on the types of recommendations that are most helpful, so we can also get into that later in this meeting. Can we skip down to the slide for Week 8 of the workplan, please?

So, the subgroups are going to conclude their recommendations in the last week of August. Then, the full Task Force, the group today, will reconvene to review and finalize the draft recommendations that first week in September, and I just want to emphasize that September 5th is a hard deadline, so whatever the Task Force has approved for recommendations at that point is what will go on and move forward to the full Health IT Advisory Committee for consideration and for a vote. If there are things that have been discussed but the Task Force has not come to consensus on the recommendations, those would need to be left out at that point. Go to the next slide, please.

On behalf of the Task Force, the Task Force co-chairs will present the recommendations at the full HITAC meeting on September 12th, and then the HITAC will discuss the recommendations and ultimately hold a vote on whether or not to approve the recommendations for transmission to ONC. I think that is my last slide. On that, we will transition and open it up for any discussion folks have, so if you have questions about what the Task Force is charged to do, how the Task Force operates, or how you can contribute, please raise those questions now, and again, I want to thank everyone for lending their time and expertise, and I am looking forward to the discussions on the proposed rule. Any questions or discussions at this point? Okay. Seeing none, we will transition to our next presentation. I am going to turn it over to Steve Posnack, our Deputy National Coordinator.

Steven Posnack
All right, thanks, Seth. Happy Friday, everybody. Welcome to the beginning of your ultramarathon sprint. I also want to echo my thanks on behalf of Micky and the whole of ONC. It takes a dedicated person to volunteer to be part of the advisory committee process, and a doubly dedicated person to be on one of these Task Forces for regulatory review and recommendation. I was invited to do a full reading of the thousand pages for you, so we are going to cut over to the video recording, put it on 10x speed, and be done in 30 minutes.

All kidding aside, I just wanted to set a bit of overall context for all of you to keep in mind, as you have already been exposed to the breakouts for the subgroups, and Sarah and Seth will take on a bit more of that detail there, but to give you a sense, we published a rule about 10 days ago, it still has not been formally published in the *Federal Register*, so we are still tracking toward the formal comment period, but as Seth mentioned, that 60-day window is going to come at us quickly in terms of getting all the work done. The proposed rule is really one of the most substantive and deep policy proposals that we have included from an ONC perspective in a rulemaking in quite some time, and it is really because we have had a cumulative growth in the regulatory responsibilities that we have had over time as well.

So, you see that the rule, which is really four rulemaking authorities altogether, includes proposals related to the standards and certification criteria, proposals related to our certification program, proposals related to the information-blocking regulations, and newly has proposals related to TEFCA as well from the 21st

Century Cures Act, so we really have a blending of the HITECH Act authorities you know and love as well as 21st Century Cures Act authorities that are all blended together now in the proposed rule.

Three themes to echo across are the expansion of the horizon of our interoperability viewpoint, and as Bryant mentioned at the beginning, for the first time, you really see a slate of proposals for health IT for public health and health IT for the payer community as well. Those are two new areas where I would say the rule spends considerable real estate from a page perspective tackling in addition to continuing to set future predictable schedules for updates, and USCDI Version 4 would be one of those, to give more detail and more clarity to industry as a whole for the future direction we are looking to go in. This really builds on and has been a multiyear effort as regulatory sequencing and planning for HTI-1. Obviously, you all know that we have this new naming convention, and we have enumerated or numbered sequences for our rules, with this one to follow, but this has been in the works for the past two to three years, since the beginning of Micky's tenure.

We have really been working, and hopefully, you see some of the feedback that you all have provided from a HITAC perspective in this rulemaking as well. I know some of you were looking for some of these things in HTI-1, but they already been planned to be included in HTI-2 as we were going forward. So, we propose to advance certain health IT from a nationwide infrastructure perspective, we are looking at areas where we can reduce certain pain points and friction areas across the health IT ecosystem, and even though today was not necessarily a cybersecurity incident, we know there are growth opportunities from a cybersecurity and good-cyber-hygiene perspective too, and I think you see that built into some of the standards and certification criteria proposals that we have included as well.

Just in terms of the information-blocking regulations, obviously, there are a few new exceptions that we have proposed as part of the rulemaking. One is an added related emphasis around what we call request or preferences exceptions to cover practices that involve adhering to requests or preferences for limiting or delaying access to electronic health information (EHI). Again, I would just emphasize that, with respect to everything in the information-blocking space, this is a continued-evolution, iterative approach. As the industry gains more insight into how the information-blocking regulations are interpreted, applied, and practiced, we get that feedback, and we have to turn that around into regulatory proposals in cases where we either need to modify any existing exceptions or, as you see in this rulemaking, create new exceptions for particular certainty or detail for the regulating community.

The section exception that we propose is around protecting care access, which would permit an actor to limit EHI sharing in order to reduce a risk of potentially exposing someone to legal actions based on whether they sought, obtained, provided, or facilitated lawful reproductive healthcare. We have other changes to the privacy and infeasibility exceptions, and there is another thing I want to point out. As many of you have tracked our budget proposals, we have included in the President's budgets a request for advisory opinion authority. Short of that, going through the rulemaking process is the most formal way for us to include changes to our regulatory paradigm and add more clarity and certainty from a regulatory perspective.

This rulemaking, I would point out, in Part 171, Section 104, includes a new section that is practices that are likely to be interferences from an information-blocking perspective. And so, we are putting down a number of things that have been brought to our attention in black and white and building them into this rulemaking in order to give additional guidance, detail, specificity, and certainty to the regulating community.

Lastly, for the most part, we have a new part in the Code Federal Regulations relating to our responsibilities associated with TEFCA and certain areas around TEFCA governance. So, there is a lot going on in the rules, there is a lot that you will have an opportunity to provide feedback on, and I know Sarah and Seth are going to give you the dos and don'ts and best practices associated with you getting your comments in. I would definitely encourage you all to stay focused on the proposals and giving input to those first because, with rulemaking, we need to stay largely in the scope of what we have proposed and what we are able to extend from a logical outgrowth perspective, as we normally say in government-speak.

That is generally what I wanted to cover with you all, aside from thanking you again for your service and your participation. Your input among all the other public comments will directly influence and be considered as part of the final rule proceedings. This is a priority for us to turn around, and it will definitely guide us. I think you can see significant changes across the entire proposed rule in our health IT ecosystem for the better. So, with that, I will turn it over to Sarah to start narrating through the subgroups and everything else you have going on. Thanks.

Sarah McGhee
Thanks, Steve. Hi, I am Sarah McGhee, and I am a policy analyst in the Office of Policy at ONC. Could we go to the next slide, please? So, for this Task Force, I will be the program lead and the Subgroup 2 lead, and again, I just wanted to thank everyone for volunteering your time and your expertise. This slide shows the overall structure for each subgroup, grouped by the themes within the rule. So, the first subgroup will review proposals specific to public health, the second will review proposals specific to the standards and certification program, and the third will be responsible for information blocking and the TEFCA proposals, and we will go over each topic in subsequent slides.

So, each week, members of each subgroup will receive homework from the co-chairs on the proposal topics that we will be discussing the following week, so you should expect to receive some homework next week, and that will come from the co-chairs. We ask that you do this to help prepare for the discussions that week to make it a robust discussion. Now, as you can see, we have the three subgroups, and occasionally, there will be topics that will be of interest to multiple subgroups, so that is where the program lead will come in. I will be responsible for that coordination across the subgroups. The program staff leads will sync up offline as needed. We also plan to have debrief meetings with the co-chairs where we will identify questions or points that the subgroup might need to address for another subgroup, and then, at the end, all of the subgroups will merge back together into the full Task Force, so that should also help with some of the coordination across the three subgroups. Next slide, please.

Subgroup 1 will be covering public health proposals. The lead for this subgroup program leads are going to be Rachel Abbey and Molly Prieto, and the chair is Bryant Thomas Karras, as you have heard from him. This lists all the standards and certification criteria that group will review. Next slide, please. Subgroup 2, which is the standards and certification that are mostly non-public health, will review Application Programming Interfaces (APIs) for patient and population services proposals, any revised and new certification criteria, as well as the patient and payer APIs and modular API capabilities. Next slide, please. Subgroup 3, which will be led by Cassie Weaver, will review the information-blocking enhancement proposals, TEFCA, the Trusted Exchange Framework and Common Agreement, proposals, and then some administrative updates as well, just corrections and things like that. Next slide, please.

So, here, as we looked at earlier, are the topics that each group will discuss for next week. Like I mentioned, every week, you will receive homework from the Task Force co-chairs to help prepare for the discussions, and we ask that you review these sections of the rule and be prepared to come and discuss, make recommendations, and things like that. To help accomplish that, we have prepared a draft recommendation Excel sheet, and I am going to share that right now. This is a document that the Task Force will use to draft recommendations. Give me one minute. Hopefully, you all can see this. So, we have this document. We will post it on Google so everyone can collaborate with it, as Seth mentioned earlier. We have these tabs by group, so we have Group 1 recommendations, Group 2, Group 3, and also the meeting topics. Here, we have provided a summary of each section of the rule, and once the rule is published and on the *Federal Register*'s website, we will add a link so you will be able to click and go to that page number without having to search around for it.

And then, here is where you would write your recommendations as we go through the process. So, some of the things to think about when writing a recommendation are comments. We ask that they are as constructive and as detailed as possible because that helps us the most. We welcome positive and negative comments, so if you all agree with a proposed action, your comments are helpful to show what the public wants or needs, and then, if you disagree with a proposed action, we like it when you suggest an alternative, and that can include no regulation at all. When you suggest an alternative, we like it when you include an explanation of how the alternative might work or meet the same objectives that we are trying to address. Also, if you have any evidence-based information that you are basing your comment on, if you can provide that as well, that is really helpful for us.

Another great way to contribute is if you have subject matter expertise in a certain area, if you volunteer to draft a specific recommendation, oftentimes, members will meet in small groups with that subject matter expertise, and they will draft a recommendation and bring it to the subgroup to consider. Let's see. What else? I think that is about it. Do you all have any questions about this document?

Bryant Thomas Karras
Sarah, from past Task Force experience, for the sake of illustration, could you just type into the member recommendation section a proposed format? I recall that people would put their initials and then their comment so that you could keep track of who had made what comments, and then, if people had changes to make, they would not make them by striking out or deleting other people's comments, but by creating their new initials and a section in that same cell.

Sarah McGhee
Yes, exactly, and if you want to highlight your text in red or something, that can distinguish it as well. An example would be here, and then, here, you would just type in the next name and all of that. What I can do is send around an example from the last Task Force, if that would be helpful for everyone.

Bryant Thomas Karras
I think people will figure it out pretty quickly, but for people who are new to the HITAC or Task Force, I want them to get off on the right foot.

Sarah McGhee

I appreciate that. If you all have any questions, that is what we are here for. I just have one other reminder. We appreciate all of you for volunteering, but you do not necessarily need to volunteer for a subgroup specifically because if you do not participate in a subgroup, you are part of the Task Force, and you will have an opportunity to contribute the recommendations at the end as well, so you can still contribute to this document and all of that. I think that is it. So, I will just give a reminder that I put the link to the chat in the website for our rule, and that also has the recording from earlier this week where we went over the big proposal overview, so I recommend listening to that, and if you all have any other questions, feel free to reach out, and I look forward to working with you. Let me just stop sharing.

Seth Pazinski
Are there any questions for Sarah? Okay. Well, we are running ahead of schedule, so we welcome any questions that folks have that would be helpful as we start to get into the substance of the rule at the subgroup meetings next week. I am also happy to end early, and if you have not had a chance to listen in to the public webinar on the overview of the rule, maybe that gives you some time to do so, but I will open it up to the group. Anna, do you want to go first?

Anna McCollister
Sure, thank you. Admittedly, I have not had a chance to listen to the webinar overview yet, so I will throw that caveat out there and commit to doing that over the weekend. One of the things I am struggling with a bit as I look at the fact sheets about the rule and I look at the way that it is described in the subgroups, broken out, and sent out in documents is trying to figure out exactly what the stuff means within the context of patients and consumers. For instance, when I first took a look at it when it came out and I just skimmed it, I could not quite figure out exactly how certain aspects of it were specific to consumer concerns or pain points, but then, when Micky described it during our HITAC meeting last week, there were several things that jumped out that would have spoken very specifically toward some of the key pain points for consumers and patients as they interact with the health system through health IT and health data.

So, I am just wondering if there is any way to get a little bit more insight into how these specific standards and elements within the rule will play out as it concerns specific issues and problem areas for patients, or how it might smooth out some of those problems that we have been experiencing. I do not know if I am asking you to give me a tutorial on all things patients as it relates to HTI-2, but I am trying to find a cheat sheet, perhaps, or a way of zeroing in on which of these subgroups or sub Task Forces I should be participating in and which ones I should be bringing to other patient advocates and patient data advocates in different groups and different organizations to make sure that they are aware that this is an opportunity for them.

Seth Pazinski
Great questions. I will just pick up on the last point, and then, our Deputy Director for the Office of Policy, Beth Myers, is on, so I will also turn it over to her to give some direction on points of focus from a patient perspective in the rule. I have two things in response to you, Anna. Those are great questions, and that is what we are hoping to get into today, if there are questions on which subgroup or where to focus your energies to get into those questions today so you know where to plug into for the subgroups as they kick off next week. Hopefully, Beth can point to some areas and help focus your attention. The other piece is that this is out for public comment, so we encourage folks to share the rule with your professional networks so members of the public can comment on the rule, and they can also provide public feedback through the

meetings themselves, whether by participating in the chat or participating to share public comments. I will turn it over to Beth to see if she can answer the patient perspective question.

Beth Myers
Sure, and I think the short answer on which Task Force is all of them. That is probably the most helpful way, so I will actually focus a little bit. I think the patient's perspective is a specific thing that each Task Force should be talking through and thinking about, and in fact, there is a patient perspective relationship in policy areas that are falling into each of the Task Forces. There are a couple of key areas to take a look at because I think they are particularly relevant. One is the adoption of USCDI Version 4. There are specific data elements within that that are designed to support a broader, sweeping sense of health equity, and there is an interplay between the USCDI and things like exchange provisions that need to think about health disparities, that need to think about health equity, but also have privacy considerations, so we always couch each of those proposals in recognition of privacy considerations that go along with the continued expansion of USCDI. So, USCDI conversation relates there.

Another area that I think might be of particular interest from a patient perspective is thinking about the standards and technology criteria around the payer API suite, the sort of set there. One of those IGs specifically is the PDex IG that is specifically looking at payers sharing data with patients, so you think about some of those Centers for Medicare & Medicaid Services (CMS) provisions that are giving patients access to that information, things for patients that might be changing their coverage, and how that coverage and access is impacted by the ability to exchange that information between payers at those key points of enrollment or enrollment changes, but also for the patients to be empowered by having that themselves, so that set of things would be particularly relevant from a patient perspective of trying to add to what you currently get in your patient portal by having those key pieces. I think the prior auth thing should cause a lot less pain for patients, but from the patient perspective, that is a workflow that is pretty opaque.

So, understanding how that should empower providers to help patients would be an interesting perspective there, but I do think that some of those other things that are going directly into patient hands would be an interesting thing to take a look at. I think the information-blocking things are pretty big for patients. I will say when you do watch the overview, you will see that we already have got some pretty strong public feedback on the protecting care access provision, so I would think that in particular is one that should ensure that that patient perspective and the patient outlook is considered when you are looking at that one for putting comments on and considering what that really means.

Finally, I would say that there are tiny pieces that sort of run throughout, and one of the things that would be an interesting way to take a look at it is, for example, in talking about standards and certification, you have little things throughout that may seem like they are little things in that they only take up a page or two in the rule, but they should do big things for patients. One of those is having imaging access links. That is a thing that seems like a no-brainer. You should not have to run around with a CD-ROM. I do not have a CD-ROM reader. So, being able to have that tiny little piece be part of what is being exchanged and part of what might be available on a portal, we would love to hear how much impact you think that could really have.

So, there are some small things like that that go throughout, so I suspect that you will start to hear conversations about patient perspective and about patient impact in each Task Force, but those in particular

are key areas that I think are worth taking a look at as you are reading through or looking through the fact sheets because I think those particular areas, again, USCDI Version 4, the Cures Act, the information-blocking things, and those payer APIs that include that patient exchange and getting that new data to them, are going to be some really big ones.

Anna McCollister
Thank you very much for that. I really do appreciate it. It is really helpful, and again, I do not know that I really have the bandwidth to participate in each of the sub Task Force groups, nor do I necessarily think my perspective is the only one in this Task Force that is relevant to patient perspective, so I part of what I am trying to do is figure out where to devote my time in the context of this Task Force. Secondly, I am leading an effort and interact a lot with different consumers and patients. I am leading a workgroup with different patient data advocates with the Sequoia Project. I would love to develop either group comments or get others engaged on it, but it is just a really heavy lift, and I am just wondering if there is any kind of stakeholder-focused fact sheet or something. Maybe it makes sense, Beth, for you and I to do a one-off discussion and spare everybody else the time, but I think this is a really important rule, and a lot of the importance of it does not really come through all that readily in some of the fact sheets, which are understandably written for developers and hospital systems.

Beth Myers
It is a fair point, because we have a fundamental requirement to make sure that we are being very, very clear in our proposals for the entities that are actually regulated.

Anna McCollister
Right. That was not a criticism.

Beth Myers
No, I am agreeing with you. It is a balance. I am happy to have a side conversation, and I am also going to be paying attention to the Task Forces themselves and connecting with teams there. We have a lot of folks that are thinking about these types of things as well, so I think it makes a lot of sense for us to try and tee up a few perspectives of things to look at. I will say I cannot tell you which ones will be the most important. That is straying a little bit into opining language, and I am trying to keep my balance here, but starting from those highlight ones, I think that if patient advocacy communities are looking at them, they will see some areas where we probably already have it right. I hate to say it that way, but there are some areas where maybe they do not need to spend as much time giving us feedback because it kind of looks good.

So, the balance there on those key areas, especially the payer data, is a really big, new space. I would spend some time focusing there because it is a really big, new space and it does have some specific patient IGs that would be important for us to understand with scoping, but all of those areas are important, so I do think that having a follow-up where you get a chance to dig into where it would be helpful for the Task Forces to have a little bit more understanding of patient impact would be helpful for us in our role in providing support.

Anna McCollister
You guys do get a lot of things right, and I would like to be able to call that out publicly when possible, just to make sure that if there is any pushback on certain things, the relevance for patients is also noted and we

are supportive of the things that we do get right. Again, I do not want to dominate the whole Q&A session here, but I will email you separately, Beth, and if anybody else on here wants to join that call, that is fine, but I would love to help get a broader input from the patient community for you guys.

Beth Myers
Sounds good.

Seth Pazinski
All right, thank you, Anna. Mark?

Mark Sendak
No worries. I put my hand down, or at least I tried to.

Seth Pazinski
All right. Are there any other questions that folks have at this time? Okay, seeing none, let me check with Bryant, Mark, and Rochelle. Are you guys okay with us going to public comment at this time?

Rochelle Prosser
This is Rochelle. I do not see myself on video, so I am not sure if it transferred over. I do have a question for Anna. Anna, thank you so much for highlighting the true patient endpoint results in what all these different subcommittees will involve and how it relates to the patient. I truly agree with you that reading some of the material was a little bit dense, but, having a clinical informatics focus, I was able to discern exactly what they were trying to say. But if we truly want full disclosure and public comment on this from the general public to which they are concerned, I do concur with you and would love to talk with you after this meeting to ensure that we meet that, especially on the information-blocking and TEFCA side. I think that is very important so that we can help the patients navigate and truly ensure that they receive the information that they need and help prevent information being blocked from them.

Anna McCollister
Do you want to meet with me, Rochelle?

Rochelle Prosser
Yes.

Anna McCollister
Okay, sure. Sounds great.

Mark Sendak
I am good with moving forward.

Public Comment (00:51:48)

Seth Pazinski
All right. So, at this point, Accel, could you transition us to the public comment slide and open us up for public comments? If you are a member of the public, if you are on Zoom and would like to make a comment, please use the raise hand function, which is located on the Zoom toolbar at the bottom of your screen. If

you are participating by phone only today, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line.

As we give folks from the public a chance to queue up if they are interested in making comments, I just want to remind everyone that our subgroup meetings will kick off next week. If you are interested in a subgroup and do not see your name under that group or if we have you erroneously under a group, please feel free to follow up with us and we will get you correctly associated with the subgroups, and we will get those meeting invites out to you. We also want to remind folks that all HITAC materials are available on HealthIT.gov. Let me check for raised hands. Accel, it looks like we have no comments on the line. Let me just check our participants. I do not see any raised hands there either, so with that, I will turn it back over to Rochelle, Mark, and Bryant for any closing remarks to close us out.

Bryant Thomas Karras
Rochelle, you first.

Rochelle Prosser
No, no, go ahead.

Bryant Thomas Karras
I just want to thank and apologize to all of the Task Force members and our newly recruited members for taking on this task over the summer. It is a tremendous amount of work, but it is very rewarding to see what comes out at the end of this task. Homework assignments are not for naught. Hopefully, we get to the finish line, and the weight of both public comments coming into the notice of proposed rule and our comments from the Task Force will make this rule the best that it can be. I am looking forward to working with you all. I will say it is going to be a consensus-driven process, so people should know going into this that it may not have everything that everybody wants in it. We have constraints, and we need to do things that are at a maturity level where we think we can get them across the line. I am committed that this is not going to be the last time we talk about enhancements and improvements to standards within the public health space, especially. It is going to continue to iterate. This is one stop of many on our journey, so thanks, everyone, for coming along on the ride.

Rochelle Prosser
For the information blocking and TEFCA, I really thank those that have already volunteered, and I encourage others to join us. We will either work forward in unification to really provide meat and potatoes in ensuring enforcement, or we will meet where we can in the middle and move forward to future iterations to ensure that we provide a pathway to ensure open access. As I look at the requirements, the caliber and expectation that will go into them are not lost on me, understanding that not all providers and not all health systems are equal, so we need to find that fair balance. I thank you for your work, and I thank you for your volunteering.

Mark Sendak
I have nothing beyond just thank you, everyone, and I am looking forward to diving into our section.

Seth Pazinski
All right, thanks, everyone. With that, we will adjourn our call for today. Thank you.

Adjourn (00:56:39)

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

No comments were received during public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Steven Eichner: I am very much interested in the public health sub, but can try to also participate in the others.

Rochelle Prosser: Thank -you for volunteering and ensuring a diverse population is represented.

Maggie Zeng: HTI-2 Proposed Rule Overview Information Session https://youtu.be/iYTiP6_kQ3c?si=xz8dhQHmDtDZYIZG

Sara McGhee: HTI-2 Proposed Rule webpage: https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-patient-engagement

Mark Sendak: There's AI to help with that

Rochelle Prosser: Thank - you Seth for this wonderful overview

Seth Pazinski: Document will be displayed during Task Force meetings, but not posted on HealthIT.gov

Rochelle Prosser: Thank - you Sarah for your overview.

Jim Jirjis: +1 Anna, though it seems to me that part of our job on the task force is to determine how it impacts healthcare and the patient and thus comment through that lense

Rochelle Prosser: Understood Anna, for the Blocking Information and TEFCA section having our perspective on end point impact can be very helpful in consolidating where or should we focus blocking determinations and the ability of TEFCA involvement by the sending or receiver.

Rochelle Prosser: +1 Anna I truly agree. I look forward to a conversation after with you about your request.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

RESOURCES

HTI-2 Proposed Rule Task Force 2024
HTI-2 Proposed Rule Task Force 2024 - July 19, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO on 8/19/2024.