Health Information Technology Advisory Committee

Transcript
April 10, 2019
In Person Meeting

SPEAKERS

HITAC Members		
Name	**Organization**	**Role**
Carolyn Petersen	**Individual**	**Chair**
Robert Wah	**Individual**	**Chair**
Michael Adcock	Individual	Member
Christina Caraballo	Audacious Inquiry	Member
Tina Esposito	Advocate Aurora Health Care	Member
Cynthia Fisher	WaterRev	Member
Kate Goodrich	Centers for Medicare and Medicaid Services (CMS)	Federal Representative
Valerie Grey	New York eHealth Collaborative	Member
Anil Jain	IBM Watson Health	Member
John Kansky	Indiana Health Information Exchange	Member
Ken Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Arien Malec	Change Healthcare	Member
Denni McColm	Citizens Memorial Healthcare	Member
Clem McDonald	National Library of Medicine	Member

Aaron Miri	The University of Texas at Austin	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
Raj Ratwani	MedStar Health	Member
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member
IB TF Speakers		
Name	**Organization**	**Role**
Michael Adcock	Individual	Chair
Andrew Truscott	Accenture	Chair
CMC TF Speakers		
Name	**Organization**	**Role**
Raj Ratwani	MedStar Health	Chair
Denise Webb	Individual	Chair
USCDI TF Speakers		
Name	**Organization**	**Role**
Christina Caraballo	Audacious Inquiry	Chair
Terrence O'Malley	Massachusetts General Hospital	Chair
HITCC TF Speakers		
Name	**Organization**	**Role**
Carolyn Petersen	Individual	Chair
Christoph Lehmann	Vanderbilt University Medical Center	SME
ONC/ CMS Speakers		
Name	**Organization**	**Role**

Lauren Richie	ONC	Designated Federal Officer
Donald Rucker	ONC	National Coordinator
Elise Sweeney Anthony	ONC	Executive Director, Office of Policy
Mark Knee	ONC	IB TF Staff Lead
Michael Lipinski	ONC	Director, Regulatory Division
Thomas Mason	ONC	Chief Medical Officer
Alex Mugge	CMS	Deputy Chief Health Informatics Officer
Steve Posnack	ONC	Executive Director, Office of Technology

TRANSCRIPT

Operator
All lines are now bridged.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Good morning, everyone. Welcome back. Good to see everyone here again so quickly. We have a full agenda today, so we're gonna go ahead and get started with roll call. Carolyn Petersen?

Carolyn Petersen – Individual – Chair
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Robert Wah?

Robert Wah – Individual – Chair
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Michael Adcock?

Michael Adcock – Individual – Member

Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Christina Caraballo?

Christina Caraballo – Audacious Inquiry – Member
I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Tina Esposito? She may not be able to join us today. Cynthia Fisher?

Cynthia Fisher – WaterRev – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Valerie Grey?

Valerie Grey – New York eHealth Collaborative – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Anil Jain?

Anil Jain – IBM Watson Health – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
John Kansky?

John Kansky – Indiana Health Information Exchange – Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Ken Kawamoto?

Ken Kawamoto – University of Utah Health – Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Steven Lane?

Steven Lane – Sutter Health – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Leslie Lenert?

Leslie Lenert – Medical University of South Carolina – Member
Here

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Arien Malec?

Arien Malec – Change Healthcare – Member
I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
I believe we have Denni McColm on the phone? Is that her?

Denni McColm – Citizens Memorial Healthcare – Member
Yes, I'm present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Clem McDonald? Not yet? Aaron Miri?

Aaron Miri – The University of Texas at Austin – Member
Good morning.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Brett Oliver?

Brett Oliver – Baptist Health – Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Terry O'Malley?

Terrence O'Malley – Massachusetts General Hospital – Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Raj Ratwani?

Raj Ratwani – MedStar Health – Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Steve Ready? Not here. Patrick Soon-Shiong? Sasha TerMaat?

Sasha TerMaat – Epic – Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Andy Truscott?

Andy Truscott – Accenture – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sheryl Turney?

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denise Webb?

Denise Webb – Individual – Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Kate Goodrich? I thought I saw Kate. Mark Roche? Chesley Richards? Ram Sriram?

Ram Sriram – National Institute of Standards and Technology - Federal Representative

Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Lauren Thompson? Okay. Also with us from our leadership team, we have Elise Sweeney Anthony, Executive Director of Policy, ONC; Steve Posnack, Executive Director of Technology at ONC; International Coordinator Dr. Don Rucker; also with us, Dr. Thomas Mason, our chief medical officer.

Just one quick mention – as we discussed at our last administrative meeting, we wanted to give members an opportunity to voluntarily disclose any work being done, either through a contract or a subcontract, grant, or cooperative agreement with ONC that relates to any current or future HITAC activity. So with that, I will open it up to our members for any voluntary . . . Anyone? Okay. Oh, sorry. Raj?

Raj Ratwani – MedStar Health – Member

So MedStar Health and the National Center for Human Factors in Healthcare have a LEAP contract – I think it's a contract – with the ONC that's currently active.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Thank you, Raj. Steven?

Steven Lane – Sutter Health – Member

I have contracted with the group that's working on the EHR reporting program as a senior advisor to their work.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Thank you, Steven. Anyone else? Ken?

Ken Kawamoto – University of Utah Health – Member

Hi, Ken here. I'm currently serving a consultant on an ONC and CDC-sponsored project for developing standards-based opioid distance support artifacts, which is actually referenced in the NPRM.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Thank you. Brett?

Brett Oliver – Baptist Health – Member

Yes. I think similar to Ken, Baptist Health has an agreement with ONC and CDC on PDP integration.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Thank you. Anyone else?

Ram Sriram – National Institute of Standards and Technology - Federal Representative
I guess that's only for nongovernmental agencies? Because if a government agency worked with ONC, as Steve knows this, I'm from NIH, so.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you, Ram.

Ram Sriram – National Institute of Standards and Technology - Federal Representative
This is Ram here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Christina?

Christina Caraballo – Audacious Inquiry – Member
Yeah, I work for – A, I worked with ONC contracting with some certification programs and on a precision medicine project, and some other things.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Anyone else? I will now turn it over to our National Coordinator, Dr. Rucker.

Donald Rucker – ONC – National Coordinator
Okay, thank you. Good morning to everyone. Apologies for the immediate repeat meeting, but as you know, some of these scheduling issues are complex and not totally up to us. I think we got a lot of good stuff done at the last meeting. We're very much looking forward to the taskforces. I know there's a lot of work, and frankly, there's a lot of hard work in the taskforces, because the issues that we're dealing with in those things are very complicated. And I think it sort of goes without saying.

We are going to have – one of the sessions today, we're gonna hear from our friends at CMS, Alex Mugge, who is the Associate Chief Health Information Officer, is gonna talk about this CMS interoperability role. And Mark Roche, who is the newly hired Chief Health Information Officer at CMS, will be joining as a federal representative on HITAC as well. The only other personnel change I'd like to make is to thank Brad Gescheider for his service. Brad had to step down, but we want to thank him for his service to the HITAC. And with that, I think I'm gonna turn it over to Carolyn and Robert.

Robert Wah – Individual – Chair
Thanks. Good morning, everyone. Welcome to Washington, D.C. again. You just missed the cherry blossoms. And I guess if you're a Final Four fan, Virginia's pretty happy this week. But anyway, great to have you. Thank you all for all your work on the taskforces and workgroups. We recognize that, as everyone said, this meeting is very close to the last one we had. But we have a lot to do before our comment period ends for the two big rule-making processes.

So this morning, we laid out the schedule. You've gotten your several batches again. Hopefully, you've had time to digest some of them. And they're mainly the presentations of the work groups. We sent out the minutes as well, and Carolyn will ask you to approve those minutes in a moment. And it was a quick run to try to summarize all those days we had before fairly comprehensively. So hopefully, that was useful for you. And then with that, I'll turn it over to Carolyn, because we've got a lot to do today.

Carolyn Petersen – Individual – Chair
Yes. I want to echo Dr. Rucker's and Robert's thanks for your attendance at this meeting again so soon, and also to express my appreciation for all the hard work that's going on in the taskforces right now. I know some of those groups are having many, many meetings, and it's a real labor of love and dedication to follow through and do that work for the HITAC. So thank you.

On the front with the fiscal year 2018 annual report, I'm happy to report that HITAC has moved that on to the national coordinator, who will soon be sharing that with Congress. This morning at 8:00 a.m., the annual report group met to start working on the year 2019 report. We have gone through the feedback we received that we had withheld for the new report and are starting to look at ideas and topics. So again, we appreciate your feedback and are already putting that to good use for the next report.

With that, I will ask for approval of the March meeting minutes. Do we have a . . .

Steven Lane – Sutter Health – Member
So moved. Steven Lane.

Carolyn Petersen – Individual – Chair
And do we have a second?

Male Speaker 1
Second.

Carolyn Petersen – Individual – Chair
And would all those who stand by approving the March meeting minutes please signify by saying aye?

Group
Aye.

Carolyn Petersen – Individual – Chair
All those against approving the minutes, please say nay? And are there any abstentions? Seeing none, we will call the March meeting minutes approved and move on to the next item on the agenda, which will be a recap of the prior authorization hearing by Thomas Mason of ONC.

HITAC Prior Authorization Hearing Recap

Thomas Mason – ONC

Thank you. I'm happy to provide a recap today of our hearing last week focused on prior authorization. Just wanted to start by providing a little perspective. From our clinician burden reduction work, we heard loud and clear from our stakeholder engagement that prior authorization is one of the top burdens and concerns that need to be addressed and needs to be a focus on how to better leverage technology to enable solutions related to prior auth. So we wanted to devote the hearing really to have a better understanding of the landscape, the history, challenges, as well as potential solutions related to prior auth. And we broke that down into presenting different perspectives to help represent a more comprehensive picture of the issues surrounding prior auth.

So we started the hearing with a clinician and patient perspective, thanks to Dr. Andy Robie and the American Medical Association for providing data and insight into the challenges and the burden reduction – or burden aspects of prior authorization. From there, we moved to HIPAA and regulatory perspective, provided by Dan Kalwa from the CMS Division of National Standards. We then moved to a standards perspective on separating that perspective into the medication workflow versus the non-medication and medical services workflow to have a better understanding of the standards-related issues with prior authorization. CAQH also presented data on the adoption rate of administrative transactions, and focused on the low rate of adoption of the X12-278 standard, and described some of the issues around the adoption of that standard and transactions. And we ended the presentations and perspectives with a payer perspective, thanks to Kate Berry, representing AHIP; Melanie Combs-Dyer, representing the work that they're doing at CMS on prior authorization; as well as Sagran Moody from United discussing his – their approach from United, as well as his work with HL7 and the DaVinci team.

Both Don and Bill Stead, I want to also acknowledge NCVHS for their participation and partnership in the hearing, that both Don and Bill sort of kicked off the hearing with two key questions that helped to inform the discussion that followed, the presentations. One, how do we better tie clinical and financial data; and two, how might we align administrative and clinical standards so that clinicians' information systems may submit a request for prior authorization for service to the payer, and the payer may adjudicate the request with an electronic conversation that does not require manual intervention.

So with that frame setting and the outstanding presentations that we heard really giving a robust and comprehensive picture of the issues and potential solutions that are out there, there were several themes that emerged from the discussion, one focusing on the burden reduction aspect for both patients as well as clinicians, in ensuring that the solutions around prior authorization really take into account the impact on patients. And the second major theme focused on authorization automation – that there was a comment and suggestion made from Leslie Lenert, really focusing on having one comprehensive summary, possibly through a CCDA, or some type of mechanism where, as opposed to having all of the individual forms or automating the different requirements of the payers to have one single set of data that's transmitted to the payers – that was one. Seeing that – and discussion point that had a significant amount of interest and support.

There was also discussion around the payers and what would the payer's role be in helping to automate the process in terms of their coverage guidelines, and discussion around how do we

potentially have payers more involved in the process and working towards solutions. But we're still – we really looked at – this is more of a listening and learning, figuring out where the hurdles are, where we can provide solutions or support from an ONC or HITAC perspective. And we have followed up with NCVHS, and have a meeting set up to further discuss and think through what are the areas where we may be able to better align and tie clinical standards and data and administrative and financial data. And I'll pass it to you, Don, if there's anything you wanted to add to supplement.

Donald Rucker – ONC – National Coordinator
No, that was a good summary. I think while this combination of financial and clinical data is admittedly some of the dryer things out there, but I think it's absolutely central to figuring out how to move things forward in healthcare. And so, we look forward to working with everybody as we sort out some of the technical challenges and possibilities here. Because some of the new standards were including things like FHIR maybe grafted onto X12, and we may have some very interesting opportunities here to get to a more seamless operation, which will power pretty much everything from prior authorization itself to things like clinical decision support, to frankly, price transparency. And I think Alex, or . . .

Robert Wah – Individual – Chair
I think Alex is next. Yeah.

Donald Rucker – ONC – National Coordinator
I don't know if you want to –

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
We have time for one comment here. Well, Les has a comment.

Leslie Lenert – Medical University of South Carolina – Member
Thanks, Tom. I just wanted to emphasize that it was more than just a standard document. I think the way the prior authorization should work is that we want to simulate human judgment here, but we would like to – and it's possible now to do that. If we submit a full clinical summary, like a CCD, to a human-centric artificial intelligence that would classify that as to whether it's appropriate or not, there's a lot of benefits that we could ascertain from this. One, you would be able to take into account a much broader range of activities than just any one single rule or several rules could do. Two, that you would actually be able to include some of the human factor issues because you're training a deep learning network to simulate human judgment. Three, you could objectively certify the algorithms, which we didn't really get to discuss. But it's clear that if you had a human panel that was reviewing these decisions and that had posted their concordance on a set of juried cases for this, then you could compare what insurance companies were using to approve with an algorithm to the patient – I mean, to what would be the gold standard for this. And this could be all transparent.

And then last, and perhaps the most revolutionary idea, is if we can generate this from the 21st Century Cares Act, data that patients have the right to on their mobile phones, then patients could do prior authorization before a visit and know what things they would be approved for before they talk to the doctor. And again, what it requires is kind of a robust clinical summary

and then a willingness to use advanced AI methods to adjudicate whether a procedure is appropriate or a drug is appropriate for an individual.

Robert Wah – Individual – Chair
Arien, did you want to add to that, or?

Arien Malec – Change Healthcare – Member
A slightly different topic. So one of the things I learned – it was a fantastic briefing. I really appreciate both the presenters and ONC for setting it up. One of the things that I learned is the regulatory interpretation CMS has, that they're allowed to select one and only one standard for anything that as defined by HIPAA. And the concern that I have about 7030 hurtling along at the same time that we're exploring FHIR-based interfaces. So a request for ONC to work with their colleagues at CMS to figure out how to square the regulatory circle. Maybe some of Steve Posnack's regulatory fu could be applied to this problem. But I think we've had success in API transition stemming from the work here and stemming from very supportive policy coming out of ONC that enabled a transition to an API world while allowing for flexibility. I think we're gonna need to do the same thing with regard to EDI and EDI FHIR-based transition. Thanks.

Steven Lane – Sutter Health – Member
I just wanted to come back to Les's point, and really appreciate Les for including that greater detail in kind of the vision of this automation of the prior authorization process. I just want to acknowledge, this is, I think, a really innovative and potentially disruptive set of ideas. We've been spending a lot of time looking at the details of prior authorizations, how to get specific pieces of data, to look at specific rules for analysis. And this is kind of a whole other paradigm that could be pursued. And I hope that we can perhaps work through some of those details and bring this back here for further consideration in the future.

Thomas Mason – ONC
We really appreciate those comments, and we'll incorporate those into our follow-ups with CMS and NCVHS.

Robert Wah – Individual – Chair
Thanks. Other comments? Seeing none, well, let's turn it over to CMS, in fact.

CMS Interoperability Rule Overview

Alex Mugge – CMS – Deputy Chief Health Informatics Officer
Thank you. And thank you all for having me here today. I know that the HITAC is not specifically charged to review the CMS rule. But the CMS rule, I think, greatly builds upon some of the foundations that are laid in the ONC rule, and the two rules complement each other very well. So we thought it would be helpful to give you a brief overview of what we have in our rule to compare and contrast, I guess, with the policies that you are reviewing for ONC.

So the CMS rule is really the first phase of interoperability policy that CMS is putting out really

targeted on specifically interoperability with a variety of entities that we regulate. Historically, CMS has really focused its interoperability policy on clinicians in hospitals through the Promoting Interoperability programs. But this rule expands that reach and starts to bring in health plans who have historically not been part of that interoperability effort and have not really engaged in this health IT space.

Unlike the ONC rule, this rule is not statutorily mandated by the 21st Century Cares Act. This is actually a homegrown effort. And we initiated this rule because we kept hearing from patients that they don't have access to their health information. I find it a little ironic that I myself am having a struggle getting my health information from my payer. And throughout this process of writing the rule, that example really stuck with me, because I know it's an inconvenience for me and for other people. It's more than an inconvenience, and it's about their safety and their healthcare.

So we have heard many excuses, I'm sure you are all aware, for why patients aren't getting their data. We've heard that it's technical problems, information blocking. And even, we've heard HIPAA used as an excuse for why information is not shared with patients. So talk about a massive misunderstanding there. But we know that the patient is not getting their data, and the data is just not flowing.

So for this rule, we gathered a collection of policies for providers and payers. I'm gonna start with the proposals that we focused on, the health plans and payers. And when I refer to health plans and payers, I'm talking about Medicare Advantage Plan, Medicaid, fee for service, Medicaid managed care, CHIP fee for service, CHIP managed care, and the qualified health plans in the federally facilitated exchanges. So, a very broad reach. The policies that we proposed for the payers are really policies designed to drive information flow. So ONC's rule has very clearly set the foundation for a health information exchange and enabled data to flow. And we are building upon that with these policies by requiring that data to flow.

So the first policy that we have proposed for health plans and payers is to require them to implement a FHIR-based patient access API, through which a patient would be able to access their claims and counter-information, including some cost information, some clinical information as well. And a patient, through that API, should be able to access their health IFN through their smart phone or any third party application. And I apologize, I always forget to advance the slides. So if we could go one more slide over, this is our roadmap that includes the timelines for all these policies being implemented. And I'll get to those timelines shortly.

So additionally for health plans and payers, we have proposed to require that they make their provider directories available also through a FHIR-based API. The purpose of the provider directories being made available is not just for current enrollees of that plan to find a provider in network, but also to enable providers to find other providers in that patient's network for the purposes of referrals and care coordination. So, making that information readily available. The goal is to better enable that information to begin to flow.

We also have proposed that health plans and payers would exchange information between each other. So we know this is happening today. We are not proposing any changes to the processes to happen today. But what changes through this proposal is that at a patient's request, their health plan would go and actively gather their information for up to the last five

years. So if the patient has changed health plans every year for the last five years, their current payer would be going back to all of those plans to get their information, aggregate it in the current health plan system, and then allow that data to continue to flow with the patient as they move throughout the healthcare system. So the idea here is, if a patient changes their health plans or providers, they shouldn't lose their treatment history. They shouldn't lose their health information, their record. That should follow them wherever they go. And the goal of this proposal would be to make that happen.

We've also proposed to require health plans and payers to join a trusted network. This is more for the purposes of enabling that data to flow to ensure that folks are connected, and they have more of that ability to exchange information in a trusted and secure manner. And then finally, we have a proposal for dual eligibles. So this really impacts just the payers, so just the states and Medicare. We have proposed that states send their enrollee benefit information to CMS daily. Currently, states can send in that information as little as monthly, which really leaves a gap in coverage for dual eligible beneficiaries. Those benefits are not coordinated, and they go for a period of time in which it looks like they may not be enrolled in Medicaid. So the purpose of this, the information exchange, is really to engage the states more in interoperable practices with CMS, and also to better the care coordination for those dual eligible beneficiaries.

Then we have a set of proposals for providers. The first of which I'll bring up is possibly our largest hammer, using the hospital conditions of participation to drive the information flow, and by requiring those hospitals to send admission, discharge, and transfer notification when a patient enters their hospital. So these notifications would go to any provider who has an established care relationship with that patient, and would establish with that provider that we have your patient. They've had a change in their health status. Or when they're being discharged, this patient is being discharged. Here's their diagnosis. If they need follow-up care, they should follow up with you, or you should reach out to them to do that care coordination piece. So this is another method of engaging hospitals in the interoperability space. And this is something that we really feel – currently we know that this is going on. But this will expand that to ensure that it's happening and that patients aren't falling through the cracks.

We have a proposal for other provider directories. Let me give a little background on this one. So last summer, CMS updated its NPES provider director to collect digital contact information. This is a new addition in the last update of NPES. And that information, digital contact information, allows providers to find each other in the digital space. So by making that information available through a CMS central directory, we are hoping that that will allow providers to find one another and exchange information electronically, thereby hopefully moving away from the use of a fax machine. So for this proposal, and to encourage providers to enter their information in the NPES directory and make it as useful as it possibly can be, we are proposing to probably report the names of the providers who do not enter that information by a certain date.

Then we have an additional proposal that's really doubling down on information blocking. So between the CMS and ONC rules, I think it's clear that HHS is taking a stand against the practice of information blocking. We are proposing to publicly report clinicians and hospitals who may be participating in information blocking. And we are doing that through some of the measures in our Promoting Interoperability programs. If the provider indicates that they may not be sharing information, we would probably report their names on a CMS website.

Then finally, in terms of proposals, we do have a proposal that is sort of – it's a combination statement/proposal/RFI out of our Center for Medicare and Medicaid Innovation. This proposal/RFI is really stating that all future models coming out of CMMI will contain some sort of interoperability requirements. So CMMI has a unique authority in that they can build those models and include those requirements. The question that is asked in that RFI is really what should those requirements look like? And what else can CMMI do to promote interoperability among their models and their participants? And because those models vary in terms of the providers that participate and what the requirements are, the interoperability requirements may also look very different among the different models.

The next RFI we have, I think, is my favorite. So I think we can probably all agree that none of this interoperability effort is possible without accurate patient identification – sending data throughout the healthcare ecosystem. If it's not for the right patient, not only does it do no good, but it can also endanger patients and detract from their care. So we have an RFI included on patient matching asking how CMS and ONC together can use their various levers to promote better practices of patient matching and more consistent uses of patient matching software. So, looking forward to reading some of the comments there.

And finally we have an RFI on the post-acute care community, and seeking comment on how CMS can further support post-acute care providers in adopting **[inaudible] [00:30:14]** IT and in engaging in the interoperability space. So, also looking forward very much to reading some of the suggestions on that one.

I did say that I would speak about timing quickly. You can see on this roadmap that our timelines for implementation run across several years. We have a policy starting as soon as January 1, 2020, and stretching as far as April 2022. So each of these does have a different implementation timeline based on what the proposal is. I encourage you to look at all those, or you can ask me or check this slide. I know that a lot of folks have comments on those just in terms of the alignment with technology, and we're very interested to read those in the comment process.

And if we go to the next slide, I want to briefly just go over some of the benefits that we are envisioning for these policies. For patients, we see the potential for really increased access to their health information, more comprehensive access to their health information, better engagement with their healthcare, and really allowing them to be better consumers of healthcare overall. Lots of benefits for patients. Also should help them understand that health information that they are receiving, so that this is not a one-sided engagement, with the provider having all the information, but all parties in their care have the same information to work from.

The next slide – this slide highlights the benefits for providers. I again want to mention that we believe this rule to be the first phase of policies that CMS will look at in the interoperability space. We are working with providers to determine how else we might support them in interoperable practices and health IT adoption. I think the policies – that this rule itself should allow providers to gather more comprehensive data on their patients and really see more of that patient's treatment history. It also has – with the provider directory proposal, it has opportunities for providers to find one another more easily to engage in care coordination and referrals, and other patient treatment.

Finally, the next slide has some impacts on payers. Again, this is really – this rule is really the first attempt at engaging payers in the health IT and interoperability space. I think this is a space that they've been interested in getting involved in, and we're really promoting that engagement, starting with the policies in this rule. This also allows for better care coordination in and amongst the plans, allowing the data to flow between them so that they can take better care of their patients. And ultimately, with all these benefits, will improve the relationship that health plans have with their enrollees. By giving them the information, a full picture of their care, they're better able to support those patients, those patients can take better care of themselves, and all around, it just is a better experience.

So those are the policies that are covered. I would like to open it up for questions if anybody has some, and just thank you again for allowing us to do this overview. We always like to talk about our rule, so it's great to do it in this context with such informed people, who already know all about the ONC rule. So I'm not sure who was first, but should we just go this way around the table?

Robert Wah – Individual – Chair

Sure. Let's start down at that end and come this way, because we always start up here and go that way, so.

Valerie Grey – New York eHealth Collaborative – Member

Good morning. Thank you. Compliments. Very good proposal, very exciting. A couple of things. On the provision that would require hospitals to share ADTs, I think that the way I read the proposed rule, it's for inpatient settings. And I'd just sort of share with you that some HIEs share that information today, and a lot of providers find the same sort of ADTs for ED, for emergency stuff, extremely valuable for care management as well.

And then a quick question on the proposed requirement for health plans to join trusted exchanges. Could you talk a little bit about how you see the proposed requirement sort of intersecting with the work ONC is doing on TEFCA?

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

So I know that we're anxiously awaiting the next draft of TEFCA, so I'm not sure that I can – that I have much information to relate there. But in terms of that proposal, the idea was really to engage them in a trusted network – not necessarily the TEFCA requirement, but a trusted network, and again, just to start that – facilitate that flow of information, and just better enable them to connect with others.

Valerie Grey – New York eHealth Collaborative – Member

Perfect. Yeah. I mean, I think that's exactly the clarification I was looking for. I totally understand that sort of as we move toward sort of our future ideal, there are short, medium, and long-term steps. And so, I think it's a good thing to try to encourage more health plans to join networks that exist today. Thank you.

Robert Wah – Individual – Chair

Andrew? Whose card is that? Sorry.

Leslie Lenert – Medical University of South Carolina – Member

Me. Yeah, hi. I just wanted to second the idea of the notification thing being the most original and potentially the most valuable piece of this proposal. It's very exciting. It is a thing that – as Valerie pointed out, it is a thing that HIEs have done and are doing well, if we can direct the data to HIEs. What I think is missing and may need to be added to the proposal is the idea of a registry for who is the primary care provider of the patient, or who are part of the patient's care team. Without that in some accessible location, we'll never really know who to send all the summaries to, or these notifications to, and that it probably should be patient controlled. That is to say that patients should be able to edit who they believe are on the team at any one particular moment. It shouldn't be providers deciding they're on the team. It should really be patients. So I think that creating the infrastructure for that is an important task, and it won't happen automatically, but it would make your policy much more effective.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Thank you for that feedback. And I did want to touch on that because we were rather intentionally vague about how the patients and their care team would be established. That is a space that we would very much appreciate specific comments on. So if you're gonna submit a comment on that, just make sure that you give us all the specifics so that we can really consider that. But that's very good feedback. Thank you.

Robert Wah – Individual – Chair

Steve?

Steven Lane – Sutter Health – Member

Just continuing on the theme of the ADT notifications via a regional HIE, I don't think it was clear in the proposed rule whether you think that methodology would satisfy the requirement on the hospital. And at your suggestion, I submitted a public comment asking that question. But I think it's an important question, because as you've heard, a lot of HIEs are doing that successfully today. And I think from the hospital perspective, it might be more cost-effective for them to simply route that data to an HIE and let them do the distribution.

Another question that I had was today, hospitals have the MU2 requirement to at least be able to send electronic transitions of care. And one question that I've had is whether those messages that already can be sent electronically would satisfy. I know that in the proposed rule, there was a statement that the system delivering the message had to at least be able to support a certain HL7V2 standard. But the question of whether – if the system does support that standard but they end up sending it via direct using the transition of care, whether that would satisfy the requirement.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Okay. Yeah. Thank you. And of course, as you said, submit a comment. That's great feedback. Thank you.

Robert Wah – Individual – Chair

Okay. Arien?

Arien Malec – Change Healthcare – Member

Thanks, Alex. Great presentation, and again, applaud the rule. Just maybe two questions. One comment or one request for clarification. When you say the word "payer," I don't think that most people use the word "payer" the way that you use the word "payer." And my understanding is the way that you're using the word "payer," you're referring to Medicare MA, Medicaid, and qualified health plans through exchanges, and that you are not including payers under ARISA, under state regulation, or other – sorry, under other regulatory frameworks, which I think would be the ordinary meaning of the word "payer." So can you clarify which payers these requirements do and don't apply to – these proposed requirements do and don't apply to? And maybe can you also comment on any work that you're doing to encourage commercial payers who aren't covered by these regulations to additionally participate?

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Sure. That's a big question. So just starting with the definition of health plans and payers, at least the way that we've just talked about it internally, a health plan would be a private payer or like a Medicare Advantage plan, or a Medicaid managed care organization. So, something outside of government. And when we talk about payers, we are more referring to the states and Medicare fee for service. So whether that's the right way to use it, that's how we've been using it in these discussions around these proposals. Specifically, these proposals do apply to Medicare – anybody that does business with CMS, so Medicare Advantage, Medicaid managed care, Medicaid fee for service, CHIP managed care, CHIP fee for service, and the qualified health plans in the federally facilitated exchanges. So it does not extend to folks outside of CMS's network of health plans and payers, of course. But we have publicly encouraged, and our administrator has given speeches and spoken on health plans to follow this lead. So even if they're not required to do so, that this is a great benefit to patients, and they should consider extending it to their enrolees.

Additionally, through some of our cost analysis and other support we've done around this rule, we believe that for health plans that have CMS regulated and non-CMS regulated plans, the parent organization, if they're going to make this available to some of their plans, we would imagine and hope that they would make it available to the rest of their plans instead of withholding that information from some patients. So certainly, that's yet to be seen. But ideally, in an ideal state, payers would see this is a real benefit to their enrollees.

Arien Malec – Change Healthcare – Member

Thank you. And then one more question. My understanding, based on your presentation and based on the rule, is that you have not yet required a station for information blocking as a condition of payment, or not yet proposed to do so?

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

That's correct. So the only information blocking at the stations that we currently have are through our Promoting Interoperability programs. When providers submit their data to those programs once a year, they say whether or not they have been knowingly withholding information. And that's what we've based some of the proposals on information blocking for this rule.

Arien Malec – Change Healthcare – Member

Okay. And in that case, the maximum penalty would be the amount withheld relative to that portion of promoting interoperability and not potentially the additional revenue that the hospital or provider may get through CMS.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Correct.

Arien Malec – Change Healthcare – Member

Thank you.

Robert Wah – Individual – Chair

Great. Well, just keep going. Aaron?

Aaron Miri – The University of Texas at Austin – Member

Good morning. Thank you. Great comments. Great presentation. One comment and one question, so I'll start with a comment first. And the presentation, it's excellent. One of the things that we are looking at particularly in Texas, at the University of Texas, Health Austin, and others, is around consent, particularly around substance and mental health and others. And I'm curious, maybe there's some way you could kind of dovetail a little bit more into our next presentation or other presentations, how CMS is offering to propose to the provider organization such as myself to deal with consent, and gathering consent to be able to share and exchange information amongst multiple entities what that would look like, what those kind of requirements would be, and how that varies obviously state to state, depending on nuances there. So that's my comment.

My question is, as it relates to other value-based items such as patient-reported outcomes and other components of care that are critically important – again, we're all in on value-based care at UT – how is that information shared? We're experimenting with using it as a discrete lab value. But are there other type of dynamics and other elements that PGHD needs to be shared as so it's understood and accepted by all the different parties? That would be a question I have for you.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

That's a good question. Thank you. We didn't touch on that in this rule, so I think – but we'd love an opportunity to address that if you wanted to submit a comment. So actually, apologies, I'm not trying to blow off your question, but I don't think that there's anything I can do around interpretation there. But we do understand some of the challenges that you're facing in that space, and we are sensitive to that. So any suggestions you have are appreciated.

Aaron Miri – The University of Texas at Austin – Member

Thank you.

Robert Wah – Individual – Chair

Clem? Is that yours?

Clem McDonald – National Library of Medicine – Member

Okay. I couldn't figure out the button. This high-tech stuff. So I had two questions. One of them is, you mentioned that both claims data and some clinical data would be available. I'd like to hear what that clinical data would be. And secondly, everything is intended to get the data to the patient, but I haven't heard of anything where the patients register and they say, send it to this URL, or this address, or this personal health record. Is anything cooking along those lines?

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Okay. So for the first piece, the clinical data, so we understand from health plans and others that some health plans collect clinical information from their providers. So in order to pay on the diagnosis, they're collecting that information directly from the provider and then storing it in their system. If they have that information available, we would be requiring them to make available – so specifically what we've mentioned in the rule is that lab test results. And then others based on the rule, payer-to-payer exchange, we mentioned the USCDI. So the idea there is if you are collecting information, you need to share it. But if you are not collecting the information, we did not propose to require you to go out and get it. Is that – okay.

And then in terms of the patient getting their information – so this is going to require some patient engagement and education on how to do this. And so, I guess the best example to you is the Medicare fee for service blue button 2.0 application, which a lot of these proposals, as well as the patient access proposal, was modeled after. So what we have done there is we have spent quite a bit of time this year working with developers to ensure they're creating applications that will be useful to patients. Now that we have those available, we have posted them on the CMS website for patients to view and to follow up. I think there will need to be a promotion of those apps in a variety of different ways for patients to understand what's available to them. And then once they choose one, they would agree to its terms and conditions, so it's critical that we all understand what those terms and conditions are. And then with the patient requesting their data to be sent there under the HIPAA Right of Access, the health plan would be required to send the data.

Clem McDonald – National Library of Medicine – Member

I still wondered why – and that's a pull, and it requires initiative by the patient in remembering passwords and all the other complexity. And it seems like at the time of registry, there could be a field where the registry clerk says, where do you want your data from this visit sent? That doesn't seem to be cooking anywhere. That would make it easy, and they would get it.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Right. So sort of taking the onus off the patient to track down all of their information, and just have that.

Clem McDonald – National Library of Medicine – Member

Yeah. Through their personal health record, or whatever tools that kind of emerge.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Yeah. I think there's definitely some work to be done in that space, and I hate to be a broken record, but if you could submit a comment on that, we would love to look into it further. Yeah.

Robert Wah – Individual – Chair

Thanks. Terry?

Terrence O'Malley – Massachusetts General Hospital – Member

Hi. And so, Alex, thank you. That was a great, great presentation. A couple of comments. Going back to the ADT piece, I recognize it's a start with the conditions of participation because I have hospitals require. Are there any plans to sort of push that out across the continuum, particularly to post-acute care, which has had also benefits in the same way the other providers do?

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Yeah. So I will make some initial comments and pass it to Kate, if that's all right, because this all falls in Kate's shop. So I think this, as they start, we are continuing to work with all of the providers in all the different settings on different ways that we can promote interoperability in the use of health IT and electronic exchange. So I think for the post-acute care providers specifically, we do have the RFI in the rule to collect information on what's most useful, and we're looking at additional things. But Kate?

Kate Goodrich – CMS – Federal Representative

Yes. So as we've done in other realms, hospitals from a technology standpoint are farther out ahead than most post-acute care providers. But there are some post-acute care providers that actually have invested in health technology as well. And we actually hear from that industry all the time that they would like to be further included. So through the RFI, but I think also just from a lot of engagement that we're doing in CMS with the post-acute care world, we are thinking about how we can in the future be able to push this out into the post-acute care space very thoughtfully, because obviously, with the conditions of participation or requirements for participation, which is what we call the ones for the skilled nursing facilities or nursing homes, we have to be able to ensure that we have policies in place that realistically, virtually every provider would be able to meet in some reasonable timeframe. Obviously, we proposed having potentially hardship exceptions for rural providers, those who are unable for resource reasons to enable this kind of technology. So that' s certainly something that we could extend into the post-acute care space as well. But I think at this point, we're a little unsure, and this is why we're seeking comment, as to whether or not what we might do in the future for post-acute care would look exactly the same, or if there would need to be other considerations that we perhaps haven't thought of yet.

Terrence O'Malley – Massachusetts General Hospital – Member

Yeah, interesting. Thank you very much, both of you. The next comment is about patient matching. So USCDI is working on the demographic section of now the USCDI-V1 dataset. And so, the question is, does CMS have in mind some patient matching algorithms? And if they do, do they match up with what's going to be in the USCDI proposal? Because it seems to me there would be a synergy there, and that the two ought to be very closely aligned.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Yes. So I think for that one, just submitting any ideas or comments would be very helpful. We don't have any proposed policies around how that would work, or what we would do to promote that, or any algorithms that we would be requiring. But we would like to gather as much information as possible before we go down the path of creating that policy, so.

Terrence O'Malley – Massachusetts General Hospital – Member

And the final comment is really a question back to ONC as much as it is to you. But it has to do with the issue of consent. And so, is there somewhere in one of our taskforces or groups that are working on sort of what are the components of consent, sort of what's the model behind it? Where are we trying to drive it? So you're off the hook on that one, if it helps.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Thanks.

Elise Sweeney Anthony – ONC – Executive Director, Office of Policy

Hi, this is Elise Anthony. So I don't – the taskforces that are currently in swing are based on the proposals in ONC's rule. But I think as we go forward, it's something that we can think about, whether that's a particular area of potential engagement, particularly with the annual report just being completed, as well as us thinking through the rest of the timeline for the year in terms of potential charges. That's something that we could put on our list to think through.

Andy Truscott – Accenture – Member

Elise? Elise? Andy. May I ask you something? Terry, sitting on either side of you are two gentlemen who can inform you of the conversations we're having. And please submit your input to it as well.

Elise Sweeney Anthony – ONC – Executive Director, Office of Policy

And of course, there are pieces of that puzzle that I would say are not just with ONC. A lot of that could be Office of Civil Rights, etc. But with any rule that either we are working on or CMS as well, we always engage across the HHS spectrum, which of course includes the Office of Civil Rights on issues related to that.

Robert Wah – Individual – Chair

Steven?

Steven Lane – Sutter Health – Member

Alex, in the proposed rule, you specify USCDI version one. And we anticipate that USCDI is gonna be an expanding tool that we'll all have available to us. And I think that there is some risk in specifying a particular version. So just a thought, that in the final rule, you might specify USCDI in its current version, so that as that continues to advance, the CMS specification would advance with it.

Another point I wanted to bring up, and I know you've got some experience doing this with the blue button already, is a lot of concern has been expressed in this body and in other settings

about the importance of fully informing patients of the potential privacy risks when they download their data and take it outside of the protection of HIPAA. And I think as we expand this from blue button to other payers, etc., I appreciated your comment about the fact that the patient would need to sign the terms and conditions. But I think it would be really helpful if, at some point in this process, we specified really what constitutes meaningful informing of the patient. What are the dimensions of that, how deep it needs to go? Because I think that there's a lot of concern, certainly amongst healthcare providers, about not only watching out for the best interests of their patients but also their own liability that may persist when information is taken outside. So I think perhaps the rule is an opportunity to be a little bit more comprehensive about that.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Yeah. So I would like to just address that quickly. And thank you for that. How many of you have not clicked through terms and conditions at some point without reading it? I don't know, is anybody gonna raise their hand there? Okay. So I know that the terms – we all know that the terms and conditions can get out of hand for some of these things, and we don't have the time to always read through them or understand them. So our blue button team has been working on a sort of a set of best practices for establishing terms and conditions, and how to really ensure that a patient understands how their data is going to be used. So I think that that is a space where there is more work to be done. And certainly, we will do our part. But I think that we appreciate just any feedback that we can get from folks on how best to engage patients and ensure that they really understand what they're signing on for. So thank you for mentioning it.

Steven Lane – Sutter Health – Member

And the last question, about this idea that you'd be publishing a list of providers that declare that they are information blocking, is that a thing? Do you have any providers that tell you, yes indeed, I'm information blocking?

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

So we did look at the historical data that we've been receiving on the programs from past years, and certainly, it's not something a provider would want to do, of course, and we understand that. But I think that this is an important signal to all those providers that we are doubling down on information blocking and that that's not a practice that will be tolerated through any of our programs or really any of our practices going forward, so yeah. I understand that that's an interesting concept, that somebody's basically turning themselves into CMS, but it could happen.

Robert Wah – Individual – Chair

Thanks.

Elise Sweeney Anthony – ONC – Executive Director, Office of Policy

And just a follow-up briefly, Robert. And on that point, I just wanted to remind folks that in the ONC rule, there is a request for comment on appropriate disincentives that would attach to information blockers as it relates to healthcare providers. So just to remind folks who are not on the Information Blocking Taskforce, health information networks, health information exchanges, and developers of certified health IT are held to million-dollar fines, to be

determined by OIG for healthcare providers, the language. And Cures statute says appropriate disincentives. So we've requested comment from the public on what those appropriate disincentives may be across HHS.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Yes. And to clarify, we don't look at this as one of those disincentives. This is independently something that we're doing because of our commitment to stopping the practice of information blocking.

Robert Wah – Individual – Chair

Any more teasers for future workgroup conversations? Anyway, Cynthia.

Cynthia Fisher – WaterRev – Member

Alex, I want to thank you for an excellent presentation. Very clearly done and well thought through. Thank you very much. Very clear. I'd like to weigh in supporting both Leslie and Clem on their comments about as we approach both ONC and CMS about really empowering the patient with this data and their information. So, too often, HIPAA's been used, Steven, in many ways to prevent the patients from getting access. And I've even been told by a flight attendant it was a HIPAA violation to try to find someone on a plane. So it's actually – they don't know that P is for portability in HIPAA. That being said, to Clem's point about allowing the patient electronic health information to be automatic, to be real-time, to be provided through the application of choice, to be free, we really forget about the unproductive work time and overwhelmingness of patients having to try to get access to their actual MRIs or their actual lab results, and the anxiety of waiting days and trying to get results from your surgeon or hematologist, with great worry and fret, whether it's a cancer diagnosis.

So having that real-time, automatic, and free, I think is really important for us not to forget, and create extra hurdles and steps in not getting this information to patients. And when we look at the empowerment, as Leslie put out about patients coming in with what they're able to have from the payers, and that payer information to provide information, both on pricing and payment. Another big factor here, which I love in your presentation, Alex, is also the goal of getting the electronic payment information to the patient. Because too often, they're overwhelmed with a drip, drip, drip approach over months of not really understanding what they're being charged for, and where or why, or having a voice at addressing that. So when we can see the comprehensive view clinically of the patient, and we can see comprehensively a price, and then have that claim match the price, we will be in an incredible place, much like we manage the rest of our lives.

And I'm encouraged by what you have here, but I also beg us not to, even on consent, Aaron, I think literally, having signed into a hospital-based urgent care for my daughter, the consent form was simply a signature line from the electronic record with no text to read, in a major hospital system. And we've compared that in the Boston area, this is state of the art. Just the signature line. You don't even know what you're signing. So that being said, I do think it's important for clarity, but I also don't think we want to use consent or HIPAA to block patients getting automatic access to their health information. They are the most important ones to have – even now that we have the cloud, they should have the MRIs and the films.

And in fact, in the ER, we're seeing patients wanting to take a picture of their X-ray because they have to go two days later to an outside system orthopedic. And they're told it's a HIPAA violation to use their iPhone to take a picture of that film on the screen. So they can't even make it that easy for themselves to carry. So we have a long way to go, but this is so doable. And I thank you for your excellence here. Thank you, for you and your team and all the hard work.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Thank you. Thanks very much.

Robert Wah – Individual – Chair

Clem, did you have another comment?

Clem McDonald – National Library of Medicine – Member

Yeah, a little follow-up. So I just want to clarify what I was saying. When you register, you put your name, your address, blabla. And you could say, my personal health record address or some equivalent. But it would be even better if a patient could say, send it to my email address, and I absolve you of any risk. Because everybody's got one. And 90% of what I've ever gotten, I'd just as soon get it as an email. In fact, I sent it to my wife as – well, I shouldn't tell you what I've done. It's a step around by email. So I don't know if that's even feasible. That's such a block. Everybody's got one. Everybody uses it. It works. But we're not allowed to use it. And maybe it's fair because there's stuff no one – you wouldn't want to risk. But if they could say, "I don't care. Please send this one to me by email," we'd be there tomorrow.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Have you ever asked a provider to email you your health information?

Clem McDonald – National Library of Medicine – Member

Yes.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

I did recently, and I was told, "We don't do that around here. But we can fax it to somebody if you want us to."

Clem McDonald – National Library of Medicine – Member

Well, it's because of all this fear about privacy. But if we had a rule that said there's a button on your registry, you can override that rule, they could send it easily.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Right.

Robert Wah – Individual – Chair

I sense some interest in this area. Let's see.

Male Speaker 1

I was just gonna note that the HHS Office for Civil Rights has a published FAQ on the covered entity's ability to send an unsecured email at a patient's request, and it addresses the liability associated with that, which doesn't exist for covered entities if they follow the patient's request. I'm happy to send that FAQ around if folks would like.

Clem McDonald – National Library of Medicine – Member

Yeah. That means it's gonna be possible or it's impossible?

Male Speaker 1

It's possible today. Doable. It is required today. Required today. Not possible. It is required today at the patient's request.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Well, that doesn't mean it happens yet in all cases, and that's what we're trying to ensure people really understand, how to get that information.

Clem McDonald – National Library of Medicine – Member

Yeah, my hematologist actually dialogues with me on email all the time. And I don't think I even told she's got permission, but I love it. So anyway.

Robert Wah – Individual – Chair

Carolyn?

Carolyn Petersen – Individual – Chair

Thanks. This is Carolyn. Speaking for myself as an individual, as a frequent and regular lifelong user of email, I can tell you that at the personal level, I absolutely appreciate that idea. And in fact, if you talk to the people who try to engage me in conversation by text, they would tell you I am a fervent supporter. That said, in this country, we still have a number of unresolved issues relating to the actual functionality of that approach. We have still some unfinished business over net neutrality. We have differing availability of bandwidth, depending on where you live and what your socioeconomic status is. Different costs for different users in places where the hardwiring is just not that good. We have a population in which we understand that there will be a growing prevalence of mild cognitive impairment and dementia that will be individuals who may be unable to access and use their information meaningfully when it's emailed; be unable to maintain their system to do so securely. And although I'm certainly in favor of finding multiple solutions to meet the needs of multiple different types of users, I caution us to look at email as a one-shot solution for everyone, because in fact, it's not exactly usable for everyone at all times in all ways. And it may be physically not possible to deliver the kinds and quantities of data we're looking at delivering to some individuals in some locales. Thanks.

Robert Wah – Individual – Chair

Andy?

Andy Truscott – Accenture – Member

Thanks, Rob. Interesting point, that, Carolyn. And without diving off down a rabbit hole too much on the net neutrality thing, etc., inequitable access to health information, I think, was kind of the core of your opening statements there, not because the information isn't being shared – because the information's not accessible. And I think that's a slight delta from what we're talking about here when we talk information blocking. Sure, we fix information blocking, everything's gonna get better. No. Information just will be shared, not necessarily accessible. Okay. And it was interesting how that ties in with Dr. Rucker's opening comments – he's now looking at me, well, what did I do? – around X12. Because something like X12 as a standard versus FHIR, where we're talking about FHIR and the HL7 standards – there's a delta in some of these modern standards to some of the older, more established solid standards in the sheer dimension, in bits and bites, that it takes to move and carry the same type of information around.

And as we deliberate and discuss here on HITAC with a focus upon health IT policy, looking at promoting new standards because they're new and shiny versus what Carolyn was talking about, that we have a hinterland that's outside of the main kind of places of this country, where information sharing is hampered by the dimensions of that information you're trying to share, not from the fact that it needs to be shared. I think that's where you're going from. And what we're recommending and suggesting newer standards, which don't necessarily have the same dimension to express the same information, we could inadvertently actually cause ourselves a walk back by saying, you're gonna share this way. The information gets shared, but it's not accessible. So it's a convoluted way of saying we just need to be cautious in advocating strongly for the bright and shiny and new when there are established ways and means which may be more appropriate to get that information out to where it's required. Is that helpful? Thanks.

Robert Wah – Individual – Chair

I also want to make sure we get an opportunity for our folks on the phone to have comments. Please feel free to interrupt us or make it known that you want to have a comment. And I'll give you this chance right now by calling you out to see if you have a comment. You don't have to, but I just want to make sure we're not missing the folks on the phone. Hearing none, we'll go back to the room, I guess.

Ram Sriram – National Institute of Standards and Technology - Federal Representative

I have a question. What do you do with inner city? Is there – the patients don't have access to anything, the computers? A lot of doctors have these people who are homeless and things like that. So how do you deal with them? I mean, they don't read their email. No access. There are homeless people.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

So that is a challenge. We do find that many folks nowadays, there is increased access to smartphones, and so they are using this technology for many things. And so, that's why having the convenience of your healthcare in your smartphone is beneficial. And there are populations where that won't be as helpful. But any access to other technology they have to access their health information – I think that overall, we just feel extremely strongly – I'll go ahead and speak for ONC here too – is to say that this data belongs to the patient. So we're trying to find the most convenient way for a patient to access it. Email is convenient, but it sort of limits the ability to aggregate data together in one usable format for a patient. So I think that both of

these rules are really focused on aligning everyone on a common standard and a common direction so that that data can be accessed, aggregated, and used meaningfully by patients and providers. I know that doesn't particularly address the challenge that you raised, but I think that that's a space that will continue to be a challenge, and we'll have to continue to work on it.

Robert Wah – Individual – Chair
Cynthia?

Cynthia Fisher – WaterRev – Member
Thank you, Alex. I'm gonna counter you, Andrew, on your comment, because to your point, Alex, we live in this mobile world where the smartphone is readily available across socioeconomic, and it's probably our best tool to push the patient data and information to the patients. And I think it would be really best if we look at 10, 20, 30 years down the road, how do we open those pipes? How do we make it free? How do we make it tomorrow? And I appreciate the timeline that we're going on, but I think we can do better. We can do better than 2022. And that's the ability to open those pipes for the innovators, and most of the Internet, open up the pipes and change the world. This is a moment in time where empowering cross-socioeconomic, pushing for the innovation of the future, and how people choose to get data – Clem made one – email, it's fine. But we need to empower the patient to choose how they want to receive it, and if that's an app, or mobile app, or a text that links to an app, or the comprehensive aggregate of that data to a link in that email, it's there. I think the most important thing is we get it in the hands of the patient for their use. And we have that ability to keep that innovation going for the next 20 years as we open this up. Thank you.

Robert Wah – Individual – Chair
Clem, do you have another comment?

Clem McDonald – National Library of Medicine – Member
Yes. Just to remind that it already is there. For example, health – there are 100 hospital systems, or maybe more, maybe 1,000 hospital systems now offer – and my employees open it up and say, hey, look, here's LOINC, and here's the FHIR – oh, you can open and see this stuff. So that's there. You've just got to get the hospitals to join it, or somebody else.

Robert Wah – Individual – Chair
Other comments. One more time with the phone. Anybody on the phone that has a comment or question? All right.

Denni McColm – Citizens Memorial Healthcare – Member
Yeah, this is Denni McColm, and I'm echoing, so I apologize. Obviously, your comment on Apple Health is a good example. I know that we've looked at participating, and it's similar to Google Health and Microsoft Health also just closed down. It's just such a limited set of data. It's hard to find it useful if it doesn't include the radiology report or the progress notes. So just a comment to make sure that if we force the exchange of information, that it has to be the information that's valuable, has its effect.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer

Absolutely. And I think that's why this is really a starting point and a first effort to get that information flowing. And then ideally, we'd like to see all of your help in expanding what information is available so that we can ensure that that's also flowing to patients.

Robert Wah – Individual – Chair
Elise?

Elise Sweeney Anthony – ONC – Executive Director, Office of Policy
I was just gonna say, unrelated to that, before we close, I see a couple more kind of cards up. But I did want to just take a second and thank CMS for all of their work on interoperability with ONC. We've always had an amazing relationship. And I think as we venture into these two rules related to interoperability and access exchange and use, it's just been a pleasure to work with you guys behind the scenes. And now, as the rules are released, which I'm sure we're all happy to have them out here. So many thanks to Kate, to Mark, to Alex, and all the teams behind it as well.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer
It's been wonderful to work with you guys too, so thank you. And thanks to all of you for your recommendations and input. We're very much looking forward to seeing what ONC has to finalize and see for ourselves, I guess. Was there another question over there?

Aaron Miri – The University of Texas at Austin – Member
I'm just gonna make one quick comment, just as an observation for you, and a real-world story. As this is rolled out, I would highly encourage CMS as well as ONC to please encourage the provider organizations and other patient-facing organizations to share as much patient data as possible, and not just data on indigent care, and say I'm meeting the rule checkmark. Even in Austin, Texas, at UT, we're trying to help other organizations see the value of sharing all their data. We're sharing all of our data. They don't necessarily want to across Austin. Just indigent care, for other reasons, not technology related. So as it is rolled out, I would just say as a real-world comment, please help coax the community to say, share all your data, otherwise, it'll just be limited to a subset of people.

Alex Mugge – CMS – Deputy Chief Health Informatics Officer
Will do.

Robert Wah – Individual – Chair
Thanks. Other comments or questions? Seeing none. So it's always a challenge up here at the front to try to juggle the schedule. You guys are all following the schedule. Our next set of presentations requires somebody on the phone. And that schedule is at the top of the hour. In the past, I've taken away breaks. So this time, we get a little break back. One word is, it's a long way to the restroom, so we thought it'd be appropriate to give you a little bit of a chance after the morning coffee to take a break. So we're gonna break until the top of the hour, but please be back at the top of the hour so we can get back on our agenda. But thank you again, Alex, for the great presentation, and thank all of you for a robust conversation. We'll see you at the top of the hour. Thanks.

All right. We're approaching the top of the hour. If we could have everybody take their seats, please.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Just a quick audio check. Do we have Chris on the line?

Christoph Lehmann – Vanderbilt University Medical Center – SME
Yeah, I'm here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. We'll get started shortly.

Male Speaker 1
Which one?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Chris Lehmann. Sorry about that.

Christoph Lehmann – Vanderbilt University Medical Center – SME
Yes. Yes, I'm on.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you, Chris.

Robert Wah – Individual – Chair
All right. Let's go ahead and try to get started here. All right. Thank you all for coming back. Next, we have our discussion of the Taskforce on the Care Continuum. And that's chaired by Carolyn and Chris, who's on the phone, I believe. We just heard his voice, yeah. So I'm gonna turn it over to Carolyn, and she and Chris can lead us through this conversation. Thanks.

Health IT for the Care Continuum Task Force

Carolyn Petersen – Individual – Chair
Great. Thanks for coming back, everyone, from that impromptu break. And welcome, Chris, on the line. We're very excited to be able to do a presentation today about the current progress of work on the Health IT Care Continuum Taskforce presentation. So basically, we're going to go through our membership, our charge, where we're at with the pediatric recommendations, review some remaining topics for our discussions, and then get some questions and your feedback. So may I have the next slide, please?

Here's our membership. Aaron is here in the room with us. Chris is on the line. And we are blessed to have several public members who have expertise in pediatric EHRs. Next slide, please? So the overarching charge was to provide recommendations on ONC's approach, recommendations and identified 2015 edition certification criteria to support pediatric care in practice settings, some related criteria to support multiple care in practice settings, and a request for information on how health IT can support treatment and prevention of opioid use disorder. More specifically, we were looking at 10 ONC recommendations to support the voluntary certification of health IT for pediatric care, including whether we should get rid of some of those recommendations. We've identified the 2015 edition certification criteria for supporting the certification of health IT for pediatric care and practice. We're reviewing some pediatric technical worksheets. We're looking at the data segmentation and consent management for API certification criteria. And we're finally looking at how health IT can support treatment and prevention of opioid use disorder, in alignment with HHS's strategy around the opioid crisis.

Next slide, please. So this is the infographic that helps us organize and keep all of these charges in place for us at one time. We have our 10 recommendations to reconsider the 2015 criteria, and some proposed new edition criteria. Next slide, please. This is an example of the technical worksheets that we have been working through. As you can see, we can have four questions there in the middle. If we go to the next slide, although we have these four questions, we're focusing primarily on numbers three and four. That would be, should any of these recommendations not be included? And should any of the functional criteria listed under the alignment with the 2015 certification criteria and the alignment with proposed new or updated certification criteria be removed as a correlated item to support any of the recommendations?

Next slide, please. So in our previous meeting in March, we discussed the recommendations one through six, which we had discussed quite thoroughly in the taskforce meetings. And we will today be looking at the recommendations seven to 10 and talking a bit about supplemental children's EHR format requirements. Next slide, please. And at this point, I will hand the presentation to Chris to go through in more detail some of these items.

Christoph Lehmann – Vanderbilt University Medical Center – SME
Thank you, Carolyn. Good morning, everybody. So the remaining four recommendations, seven through 10 – let's start with seven, transfer of access authority. And I have a little bit of a problem because I hear myself with a delayed echo, so is – yeah, that's much better. Thank you. The system shall provide a mechanism to enable access control that allows a transferrable access authority – so a change guardian, a child reaching age of maturity, emancipated minor, etc. The ONC identified that this was aligned with the 2015 certification criteria. You see there, view, download, and transmit APIs, in alignment with newly updated certification criteria for privacy and APIs again.

Next slide. The committee taskforce – sorry, the taskforce – discussed this. There were a number of barriers and problems identified. There is great complexity with the existing state and local laws that might vary. And one thing that was identified, that there's a need for a nomenclature that needs to be developed, and it needs to reflect not just federal or overall area requirements, but also state and local requirements. There is an issue with contradictory

access permission. So there's a lot of vagueness in this. For example, pediatricians are routinely put in the middle between divorcing parents.

And what the committee ultimately suggested was in the absence of existing standards for that, there should be at least, at minimum, a way of documenting this within the free text. The functionality, however, is already implemented in most of EHRs. But again, until we have a standard nomenclature, this cannot be well used for decision support or higher functions. And it's important to distinguish access versus legal decision authority, was another consideration. And the committee recommended that a best practice paper or an ad hoc limited standard should be developed, and encourages ONC and the federal government to initiate that. Next slide.

Recommendation eight included the association of maternal health information and demographics for the newborn. That has multiple levels. You think about the inpatient record, where the maternal delivery history could be linked to the child's information, as well as to outpatient settings. So the system shall provide the ability to associate the identifying parent or guardian demographic information with the child so that they can be linked that way. The alignments for 2015 care plan transitions, demographic, family health history; social, psychological, and behavioral data, in alignment with new and updated to include the USCID and the APIs. Next slide.

The discussion in the committee around this one – and I'll make a spoiler alert. The committee agreed to keep all the existing recommendations. The information should be available in a format that can be exported and easily digested by a pediatric EHR. So there is a need to be able not just to send the information, but also to integrate it into the child's record. And further integration of records between mom and child, the capabilities exist, but currently, it's mainly as text. So again, the committee realized that there was no good standard to point to for the implementation of this and that there is a need for research on the existing transmission of this type of data – how this could be leveraged to link better maternal health information to the child.

Next slide. Recommendation nine. This is about tracking incomplete preventive care opportunities. The description, that the system shall be able to generate a list on demand for any children who have missed recommended health supervision visits, preventive opportunities. In the context of the current measles outbreak, for example, immunizations. But there are a lot of other preventive opportunities that flow in that and that are outlined in the Bright Future for the American Academy of Pediatrics. The alignment with 2015 includes, yes, quality measures, APIs. And again, it flows into the new and updated.

Next slide. So when discussing this, the taskforce realized that there is a need for generation of lists for recall purposes. So a way of identifying a group of patients with specific health opportunities that have not been addressed. But there's also the need to flag individual patients, and the ability to create alerts if the patient's preventive opportunities haven't been realized. So the taskforce sort of again realized that this is challenging to implement in the EHR. But there was an urgency for this identified because a lot of children fall short within the first three years of life on their preventive opportunities. And that is something that the taskforce

really wanted to address. So they're very much in favor of this, but they also acknowledge that this is a challenging thing to do.

We had some discussion subsequently – when I say we, it's some folks that I collaborate within the context of the AEP. And I think part of the challenge that we're seeing here is the need to have that content of preventive care in a format that is digestible to EHRs. So it needs to be disambiguated, actionable, and implementable. And I think there is going to be some work that needs to be done, and hopefully, we'll have something ready before these recommendations actually get implemented.

Next slide. And the last recommendation, flag specific healthcare needs. Systems should have the ability for providers to flag or unflag individuals with special healthcare needs and complex conditions who may benefit from care management, decision support, care planning, etc. And this aligns with the problem with CDS quality measures, as well as with USCID and the APIs.

Next slide. And there was a lot of discussion about this. This essentially translated to the taskforce as an ability to determine and create generic flags. Pediatricians or childcare providers should be able to adjust the flags to their needs and be able to build decision support that feeds off those flags. The ability to transmit that information in a coded way from system to system would be highly desirable, but there was the recognition in the gaps in various sections that there's no specific standard for healthcare needs, generic flags. This is something that the taskforce would love to see incorporated in existing work, like SNOMED ICD. And there is also the need to track mental health for children. That falls into this category, and it is a critical component of this flag recommendation.

Next slide, please. Then the committee talked about the specific recommendations that were the supplemental childs format requirements that were added by ONC to the different recommendations. And we went through them and kept most of them, but got rid of some of them.

Next slide, please. For recommendation one, if you remember from the first time we presented to you, this is the growth chart one. The additional recommendation supplemental requirements included allow the unknown patient, record age and assessment and persist in the EHR, and support growth check for children. And the taskforce recommended to retain all of these supplemental requirements.

Next slide. For recommendation two, the supplemental childrens format requirements included that computing weight-based dosing – supplements included rounding for administrable doses, and the alert based on age-specific norms. After a lot of discussion, the taskforce recommends that the first one be retained, whereas there was consensus on removing alert-based age-specific norms, as that information is just not available in the public domain as of this point.

Next slide. For recommendation three, which was the ability to document guardians and caregivers, the supplemental requirements included the ability to document parental notification and permission, record parental notification on newborn screening diagnosis, authorize non-clinician viewer of EHR, and document decision-making authority of patient

representative. And where was I?

And next slide, please. And the recommendation of the taskforce was to retain all these requirements for recommendation three. And there was discussion about there might be a need for additional consideration for authorized non-clinician viewers of EHR data. And there was discussion that this should not be provided as free text, but as predefined data elements.

Next slide. I think I should be coming close. For recommendation four, there was only one supplemental requirement, and that was problem-specific age of consent. This is the segment of the age access to information. And the taskforce was pretty much unanimous that this should be removed. Without a proved centralized way to implement this – and this is again the curse of pediatrics, the different local requirements – the vendors are not able to do this. There was general support for the idea, but because pediatricians and those who take care of children are exposed to 56 different state and local requirements, this is, at this point, not implementable, based on the taskforce opinion.

Next slide. Recommendation five, which was the synchronize immunization histories with registry, if you remember that. The taskforce recommendation was that there is currently a significant problem, as there's no defined – oh, I'm sorry. The supplemental requirement was to produce complete forms from the EHR. And currently, there is no commonly determined defined childcare form. It varies from state and local governments. Each school district might have different requirements on how to report out immunizations, for example. There's also no computable language version of a school form that's currently acceptable. Although again, I'm encouraged to let you know, after working on this issue for 25 years, the AEP might be getting close to coming out with a recommendation for a school form that is based on a survey of more than 200 different school districts and communities. So hopefully there will be something that could be pointed to as a standard in the future. But currently, there isn't. But despite these obstacles, the taskforce had consensus that they wanted to retain the supplemental requirement to have a basic starting point where a basic standard form that the HR vendor creates is available.

So, next slide. Recommendation seven had only one supplemental requirement. This is a recommendation for transferrable access authority you heard me talk about earlier. And the additional requirements was that the system shall provide the ability to record the patient as an emancipated minor. And the taskforce recommendation is to leave it.

Next slide. And I'll turn this back over the Carolyn.

Carolyn Petersen – Individual – Chair

Thanks for taking us through those guidelines and all of the additional work we've done since the March 2019 meeting. So in terms of our remaining topics for some discussion and charge, we need to get to the request for information related to the opioid use disorder. This includes a number of different things looking at health IT and neonatal abstinence syndrome. To some of us, that might be known more familiarly as infants who go through withdrawal because the mother was taking medications during pregnancy. And then the 2015 edition, the DV4P, that's data segmentation and consent management for API certification criteria, we have meetings

scheduled for the next three Fridays. That would be the 12th, 19th, and 26th. We will be bringing more information to you about our work at the April 25th HITAC meeting. And I think at this point, we're ready to go to discussion.

Can we have the next, please? Well, first let's start with any questions and feedback from the HITAC members, and then we can talk about voting and the transmittal letter mechanics. So I'll start at the end of the table. Clem?

Clem McDonald – National Library of Medicine – Member

Well, there was a recommendation that there's no way to store, the way I read it, pediatric data, and it needed a new standard. And I don't think that's true, number one. And number two, I think it would be bad, because we're not different species. And that same record will end up being the adult record as we carry it further into the future. So I think that should be reconsidered. There are ways in FHIR for sure to store many kinds of data. There may be a few specialized pediatric things, but there isn't a named way to do it. But I bet within all the resources, there is a way.

Christoph Lehmann – Vanderbilt University Medical Center – SME

If I may respond to that, I think clearly, we're talking about different developmental stages of the same species. And I appreciate the point. The issue is that there is no standard nomenclature that is identified. And the same problem that you just pointed out, that you referred to, is also a problem that occurs at the end of life care. So the taskforce felt pretty strongly about the fact that there's a need to create a standard nomenclature for this. And I think it could be used downstream again in adult settings as well.

Clem McDonald – National Library of Medicine – Member

To follow up, I mean, all the laboratories are the same. The physical measures are the same. The blood pressure – the ICU variables are the same. There's an awful lot that's the same. Now if you're talking about descriptors for diagnoses, they may not be complete. I'm not sure that's true, but I think we ought to narrow the scope. What was stated was that there's no way to store any of the data, and I don't think that's true.

Christoph Lehmann – Vanderbilt University Medical Center – SME

I don't think I tried or did say that, so if I did, I apologize for that misunderstanding.

Clem McDonald – National Library of Medicine – Member

The slide said something like that. It went by fast, but.

Christoph Lehmann – Vanderbilt University Medical Center – SME

I think what you're referring to was the item eight, the associated maternal health information and demographics. And there was information that should be able to be exported. And that included the maternal and child family history. And for history, especially for history, as well as for the linking of which part of the maternal record should be linked to the childcare. Because if you think about it, we had a long discussion about what of the mother's privacy when the child turns 18 and the record is theirs, and they are aware that their mother was treated, say, for

HSV during the pregnancy? So currently, there are no standards or rules around the transmission of this data as it comes to what should be included and should be excluded from integrating into the child's record.

Clem McDonald – National Library of Medicine – Member

Well, I won't persist, but I . . . And linking two individuals is hard. And there's a lot of uses for that, but that's hard.

Carolyn Petersen – Individual – Chair

Thanks for the comment. That's feedback that the taskforce will take into account as we continue our work. Let's go to Sasha.

Sasha TerMaat – Epic – Member

Thanks. So just from a logistical perspective, I'm trying to make sure I understand, if we voted on these recommendations, what we are proposing. I think as a request, it would be helpful if we had a written copy of everything that was being sort of proposed for our feedback to Dr. Rucker prior to doing a vote. If I understand correctly, if we took one of the categories, like recommendation seven, which is about transferrable access authority, you're proposing a separate vote around whether we agree with the criteria ONC identified as being aligned with that criterion which is on the slide, and then a secondary vote on the supplemental criteria that were discussed on a separate slide, which would be additional to the aligned criteria. Would that involve the creation of new criteria? And then I guess I'm not clear where the sort of feedback that is identified on the slide around implementation considerations or relevant gaps feeds in. Is that just sort of information that we would convey to ONC, or are we recommending action changes based on that material that's identified in the slides?

Carolyn Petersen – Individual – Chair

So this gets at some of the discussion about the mechanics for today that I was gonna discuss after the other questions about the content, but I think it's fine to assess it now. We were not able to get a transmittal letter together for this meeting, so we've determined that we won't take an actual vote today. That said, I'm hoping that we can do a sort of tentative consensus or a substantial room-read, so the taskforce has that perspective in terms of what there is a desire to be reconsidered or addressed before we bring that transmittal letter forward. But we're not gonna ask for a vote today for anything because we don't have that letter and that language, so. If that's helpful. Is there any part of your comment that I didn't address?

Sasha TerMaat – Epic – Member

I would be curious, I think, what the relationship between the implementation considerations, relevant gaps material on the slide and the supplemental criteria are. What is the expectation of how ONC would be acting on the information in those areas?

Carolyn Petersen – Individual – Chair

For that, I would direct the question to Steve, or Thomas, or Elise. I mean, the taskforce can't speak for what ONC will do with our guidance, so.

Christoph Lehmann – Vanderbilt University Medical Center – SME
Yeah. And if I may add, I think what the taskforce did was provide a summary of their thoughts on the potential barriers in it. And again, when we were discussing it, my impression was always, without putting any words into ONC's mouth, that this will be considered one day or ultimately design the pediatric certification rules or requirements. So that said, that was an assumption without this ever being specifically clarified in the taskforce.

Elise Sweeney Anthony – ONC – Executive Director, Office of Policy
Yes. Sasha, does that answer your question? I think just like all of the work that comes forward from the taskforces, or, I should say, from the HITAC once the recommendations get finalized, we would consider those in terms of developing and putting together the final rule. Was that the nature of your question? Sorry if I missed that.

Sasha TerMaat – Epic – Member
I think what might be helpful is to clarify, if we are proposing a certification, are we proposing specific certification criteria, and what are they? Or if we are proposing changes to existing certification criteria, what those changes are. I read some of the recommendations, and it says things like, it's important to distinguish access versus legal decision authority. And I'm not sure, thinking from a perspective of someone achieving a certification, what would that mean? Is that something that has to be translated as just, this is a current barrier in this space? I agree. I think it's an important note. But I don't know how to translate it into sort of the next level. And if the intent of this work is not that, maybe that would be helpful for me to understand. But that's what I'm trying to parse.

Elise Sweeney Anthony – ONC – Executive Director, Office of Policy
Yeah. And I would defer to the taskforce chairs on that. I will say that recommendations come to ONC in different formats. Sometimes they are considerations, where ONC should consider the following in terms of putting together whatever our final proposals are. Sometimes the HITAC or whichever federal advisory committee will give more specifics in terms of what they think about the criteria that are proposed. Of course, we're open to whatever format they come in as.

Christoph Lehmann – Vanderbilt University Medical Center – SME
If I may, as an informatician, I appreciate your comments, Sasha. You want to understand what is actionable and how can you make a decision on things. It's all about the implementation at the end. But that said, the way I perceived, and I'm told now – I never had a doubt in my mind – our work was that we were a group of experts that the ONC asked to look for those recommendations, identify things that might cause heartburn, try to make it a little easier for them to decide how this then ultimately will translate into the voluntary pediatric certification. And I want to point out to you that on the taskforce, there is not one but two vendor representatives. So there is a strong voice for the vendor community. And I think that should provide some better sleep for you and your brethren.

Carolyn Petersen – Individual – Chair
And just to follow on that, I certainly had not been made aware by anyone within ONC that the work of this taskforce would be used any differently than the work of any other taskforce

related NPRM. As Chris noted, it is a voluntary certification. It's not like this is something that would create some absolute mandate for anyone, being that it's voluntary. And I think that even when there is difficulty in envisioning using today's technology and today's knowledge, exactly how something could be done, that shouldn't stop us from defining what would be the ideal in terms of meeting all of the known needs and challenges experienced by all the users – providers, developers, as well as patients and parents and others. And I think that is pretty much in line with what all the other taskforces as part of the NPRM are doing.

Steve Posnack – ONC – Executive Director, Office of Technology
Yeah, this is Steve Posnack. So just to piggyback maybe on Sasha's point a little bit to add some more color. We had not proposed a specific distinct pediatric certification as part of the rule-making. There are certain criteria that we identified that we believe were supportive of the pediatric setting, as well as many other settings that some of the criteria to which they applied. Perhaps to play out, as you were describing, there are some certification criteria for which these recommendations would be in scope, to Carolyn's point, that would have an impact broadly on certification criteria structure, clarifications, framing, etc., that would be applicable to all developers that come into the program, some of which may be pediatric-focused or what have you. And it would be helpful toward that implementation perspective for health IT developers that support other settings besides pediatrics, in this case, have an understanding of what those clarifications may be – if they were to have some corresponding effect that maybe – I don't want to say too pediatric-focused or centered, if we were to retain the, let's say, more generally applicable certification criteria on that point. And so, for the criteria that are part of the 2015 edition as it stands today, having clarity about what those deltas or tweaks would be from the taskforce would be really helpful.

And then similarly, as Elise was noting, in other cases, it may be that in response to comments we can include in the preamble of the final rule – not any regulatory requirements, but, per se, a guidance aspect, of here's a best practice that we heard, or some other things that need to be taken into account should be some of those may be more qualitative points that Sasha raised.

Sasha TerMaat – Epic – Member
So, Steve, if this taskforce recommended a change to an existing criteria, like view, download, transmit, you're saying effectively, that's not optional, because it would be applied universally to any product certifying, so if you download, transmit criteria, not simply to ones looking for a pediatric designation.

Steve Posnack – ONC – Executive Director, Office of Technology
So, it depends. As you all well know, we do designate certain functionality and some criteria as optional, so that would be one approach. If there was something specific to a particular setting, we'd have to consider that in the comments, as to whether or not it was, A, important enough to add into a certification criterion. B, on the basis of that, is it applicable to everybody? If it is, then it would just be specified that way. If it wasn't, then do we want to provide certification in a way for health IT developers that may serve a particularly setting to identify that they've met the additive requirements? And if that would be the case, in some cases, we do designate those as optional, so that certification is there for health IT developers to point to as a conformance requirement. The last kind of way it plays out would be we don't include it in the certification criterion at all, and we include some kind of reference in the preamble that we'd address it.

Does that help answer your question?

Sasha TerMaat – Epic – Member

It does. And I think what I would encourage the taskforce to do is to identify which of those options that Steve outlined as being proposed for some of the comments that are there, so that if we vote on it, we understand, are we proposing an optional addition to our criteria for products in a certain setting? Are we proposing what would effectively be a universal change to products accommodating in all settings, regardless of their service to the pediatric market; or if we're proposing something outside the scope of certification, but just encouraging it as a use case relevant to pediatrics, so that when we look at those, we're clear on which of those proposals the different pieces fall into.

Christoph Lehmann – Vanderbilt University Medical Center – SME

Yeah, thank you. And I think, just going back here to the origin of this, and I'm quoting from the 21st Century Cures Act, is that the secretary shall make recommendations for voluntary certification of health information technology for the use by pediatric healthcare providers. And then the secretary shall adopt certification criteria to support the voluntary certification of health information technology. So how ONC will do that, whether it's gonna be part of the general certification, or whether this is a separate process, is not anything that the taskforce really discussed or was asked to consider.

Carolyn Petersen – Individual – Chair

Okay. Let's go on to Cynthia.

Cynthia Fisher – WaterRev – Member

Thank you, Carolyn. This question's for you, Carolyn, and Steve. What process has been used to actually look at the certification criteria on a pediatric setting with input from mothers regarding some of the criteria on the linkage with the mother's record, as well as – has there been a process to focus group or gather input from the patient and family caregiver/guardianship users in getting access to the pediatric data, and what has been done or what is the plan on this issue? As well as the caregiver criteria that are added in here as well?

Carolyn Petersen – Individual – Chair

I'm not aware of any myself. I will ask Steve if he's aware of any.

Steve Posnack – ONC – Executive Director, Office of Technology

I may defer as well a little bit. But this may be something that Chris can opine on too on the phone. We've had engagements with the American Academy of Pediatrics, AFE family physicians as well, related to the earliest work on the children's model format, and then subsequently, the refinement of the wide set of functional requirements that were identified for that. And so, this is really a winnowing down or a distillation of the most important things that were identified by those two clinical associations and other stakeholders. But I mean, your points are well valid, and I think getting broader caregiver and parental input into these is important, especially as we look to other criteria that may be interesting to include in the future.

Cynthia Fisher – WaterRev – Member

Yes, thank you. And I think we need to think from a practical standpoint, this perspective is really from the developer and the provider and the physician standpoint, as we look at pushing this patient information to usability, and the practicality of better managing the healthcare of our children, it would be very helpful to have that input. And also, just on the criteria, I guess I would also beg us the question, when we make things rules-based, lives are pretty fluid and transient on who your caregiver at the time is who needs that information and where they are in your life system, so to speak, and can be timed in and timed out. But perhaps we should also look at where can we push it out and let the parent, or the consumer, or the caregiver be able to transfer and control and determine the privacy and the timing of getting that pediatric information or that physician and caregiver relationship? So, thank you.

Christoph Lehmann – Vanderbilt University Medical Center – SME

If I may briefly respond, first of all, I wanted to – I don't know who is making such a comment, but I wanted to thank you, because I think this is a really important and critical piece. And I wanted to reassure you that in the original pediatric EHR format, we sought input from patients, from caregivers, from consumer representations. So this kind of considerations absolutely were consolidated in the model EHR format. But of those 540 requirements, even with the supplemental requirements that I discussed today, it's only a fraction of the overall things that parents and physicians, other clinicians have identified as critical to actually take good care of children. So the way the taskforce was looking at this issue, that this is just a start. The way we understand it is that pediatrics is the first specialty that is working on a specific certification that targets children; that there is a possibility that similar considerations will be done in the future for other specialties. So for us, it was important to get something off the ground and start it that is better than the status quo. It might not be perfect, and we as pediatricians are only too aware of how fluid lives are, how quickly you can change foster homes, and how quickly guardianship changes, and access control needs to be modified. And that's why it made it in these recommendations in the first place.

So, but my point was, this is just the start. And the way I look at this is we just tighten that screw just a tiny bit in this first round. And as time goes by, as we identify more needs, as we identify better tools during it, I think there's an opportunity to improve on this. So my assumption is this is not the last time we will be talking about this.

Carolyn Petersen – Individual – Chair

Thanks, Chris. Our agenda calls for a public comment period at 11:45. So what I'm going to do is suspend this discussion right now. Please leave your cards up, and we will go to public comment and come back and continue this discussion.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Okay, great. So we'll start with any public comment in the room. If anyone in the public seating would like to provide a comment, please come to the presenter table and state your name. Seeing none, Operator, can we please open the public line on the phone?

Operator

Certainly. If you'd like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue, and you may press *2 if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before using the * key.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you, Operator. Do we have any comments on the phone at this time?

Operator
We have none at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay.

Carolyn Petersen – Individual – Chair
Okay. We will continue with our discussion. Let's go to Arien.

Arien Malec – Change Healthcare – Member
Thank you. I'm gonna follow maybe a little bit on Sasha's comments, and also with respect to the notion that certification criteria are optional. I think the history of certification is that what's optional becomes required practically, that certification requirements are referred to in other regulation. So, for example, one could imagine a future tie-in of certification requirements in pediatrics to Medicaid or to other programmatics. So, that's just comment number one, is let's not assume that certification requirements are optional, so we can put anything into them, and it's not gonna create hardship or burden. The second – this is more of a theoretical conversation, because I'm neither a pediatrician nor an EHR vendor. But I think we've had enough history with certification in this country, both through CCHIT and through ONC certification, to know what certification's good for and not good for. And I think anybody who believes that certification will lead to EHRs that are easier to use, more functional, more pleasant, is probably somewhat mistaken. Certification is helpful for establishing a minimum threshold or floor, particularly with respect to safety-critical features, or in particular, to interoperability.

So I think I made this comment last time, but I would encourage the taskforce and I would encourage the committee not to believe that by mandating certification requirements, we're gonna make pediatric EHRs better, more usable, and more functional. In many cases, what we do is we add regulatory in burden in areas that it doesn't actually help those attributes. I would encourage the committee to address some of these critical areas of floor capabilities relative to safety, and floor capabilities relative to interoperability, because I think the history has shown that those are very useful certification criteria for expanding access. And in particular, to Cynthia's comments, I think areas of expanding access to the children and caregivers is a desirable attribute, notwithstanding the pediatrics, which are ridiculously complicated in terms of regulatory landscape. So, that's my comment. Thank you.

Carolyn Petersen – Individual – Chair
And thanks, Arien. Christina?

Christina Caraballo – Audacious Inquiry – Member
Thank you. Thank you for this presentation. I do fully support the access for caregivers and parents and guardians, and also for pediatrics, but also for minors. I do want to highlight the recommendation four, where we're talking about removing the requirements because of segmented data. I think that this is actually a red flag to me. I understand the problems with different state laws. And when I was at Get Real Health, and we were looking at consumer access and patient access, and talking about how to do our plans about just turning off anybody under 18, because it was really hard, we started thinking, well, how do we solve this problem? And I actually started looking at all the different state laws and realized, as a vendor, I wasn't gonna figure them all out. But what I could do was enable my clients to use the technology in a way that fit their needs. So I would recommend that we look at how we can create technology that is certified to support minor access.

So, being able to – in my experience, what we did was we had proxy access for providers or patients. So they would come in and say, I delegate A, B, and C to be able to access my data, and I'm going to segment certain data that I don't want to be seen. As a default, we had an option, where any sensitive data was flagged and not shared automatically. So I think that that is another way to address this problem. And I think that's been discussed a lot within this conversation and within ONC. But I really, really want to go back to it's not our job to know all the state laws. It's our job to have the technology available to providers to implement certified EHR technology that fits into their practice. And if they want to be able to give minors and pediatrics access to the patient engagement solution portal APIs, then I think they should be able to do that.

Christoph Lehmann – Vanderbilt University Medical Center – SME
If I may, quickly. So I couldn't agree with you more. And it wasn't our intent to take away access for minors. The recommendation was to take the requirement away from the vendors to have to figure it out. As you pointed it out, you're not gonna figure it out for every place. But providing technology that allows people to implement locally acceptable ways of doing this is not off the table. We just didn't want the vendor stuck with a requirement to figure it out for everybody. So I think the taskforce agreed with you.

Carolyn Petersen – Individual – Chair
Okay. Okay, thanks, Christina. Let's go to Steven.

Steven Lane – Sutter Health – Member
Thank you. Christoph, hi, this is Steven Lane. I hope that you're gonna be able to hang around and rejoin us later at 3:30 when we have our presentation from the USCDI Taskforce, because, in that group, we have been discussing some of the pediatric vital sign issues. And there is a substantial overlap, I think, between the work of the two taskforces. Just to steal a little bit of Christina and Terry's thunder, we specifically talked about some of the suggested inclusions in USCDI around growth chart, BMI percentiles, weight for length, etc. And the challenge of whether the systems should themselves calculate and maintain as persistent data the

percentiles, and then be able to exchange that data amongst them, or whether it makes more sense to simply capture and maintain the raw data from the biometric measurements, and then to require the receiving system to do those calculations. So I think it's gonna be important that our taskforce recommendations stay in sync with one another. So I hope you can join that.

I also wanted to comment on the suggestion to remove alerts based on age-specific norms. You probably mentioned that in your comments, sort of what the reasoning was behind that, but could you reprieve that for us? Because I have some concerns. It seems like that's a pretty powerful functionality that certainly I would like to have in my EHR, for it to tell me when a pediatric patient's blood pressure is outside the norms, etc. So why were we thinking of striking that?

Christoph Lehmann – Vanderbilt University Medical Center – SME
Let me apologize, because I should have made clear when we were discussing this, this was pertaining to medication dosing and not to blood pressure or growth or BMI. This was pertaining to the fact that the dose, the age-specific dose ranges for pediatric medication dosing are not available in the public domain. So in order for – if there was such a tool that allowed this, we would love to see it. But this is only for medication dosing, not for the issues that you pointed out.

Steven Lane – Sutter Health – Member
Excellent. Thank you.

Carolyn Petersen – Individual – Chair
And thank you. Denise?

Denise Webb – Individual – Member
Yes. Denise Webb. I have a comment and a question related to recommendation eight about associating maternal health information and demographics with the newborn. My question is, was there any discussion amongst the taskforce about newborns who are privately adopted? And this sort of builds on Cynthia's comments about getting input from mothers, but also getting input from adult children who were adopted. Two in my family were adopted at the time, 40 or 50 years ago, when we didn't have electronic health records. But interestingly, when they were united with us, one of the first things they wanted to know was information about their medical family history. And so, I think it is a balancing act that's really important, to link the maternal health information to the child's record, as well as their family history, and to have that carry forward with them. Yet also, in the case of an adoption, if the mother wishes to protect her privacy, to be able to do that, but not jeopardize the child in terms of having all the information the child needs or their adopted parent to care for that child from a health perspective.

Carolyn Petersen – Individual – Chair
It is not something that we discussed specifically in the taskforce meetings. Chris, are you aware of any prior discussion about that, perhaps in the initial development of these recommendations, or Steve as well, chime in, please?

Christoph Lehmann – Vanderbilt University Medical Center – SME
Yeah. We are aware of the challenge of this issue, the need for privacy versus the desire for medical information that might be pertinent to the care of the child. At this point, that particular scenario of the biological mother of an adopted child was not included in our discussions. So it's a really challenging transposed issue.

Carolyn Petersen – Individual – Chair
Let's go to Andy.

Andy Truscott – Accenture – Member
Thank you, Madame Chair. It's great to see this kind of work going on, led by people who fundamentally understand the nuances of pediatric care. And it's wonderful to see and hear. I have a concern over a perception of over-regulation, potentially. As Arien was saying, what we state as voluntary tends to become a mandatory requirement downstream out there when people are procuring systems. So we just need to be conscious of that. I would be slightly riffing on what Sasha was saying, maybe inappropriately, but you can keep me honest here. Building on top of existing criteria seems to be an appropriate way forward, rather than accidentally recreating the criteria that exist right now. So, saying, okay, these are the criteria and this is how you should interpret them for pediatric EMR seems to be a good approach. And I'm not sure that's where you're gonna end up. I recognize that this is fluid and work in motion, so that might be where you end up, and I could only applaud that.

One other point and this is around scope, and it's kind of reflecting on what Denise just said as well. Where we have a court-appointed special appointee, etc., that seems to be an appropriate use case to include for when the court's actually said, right, these individuals are responsible for the welfare of the minor. And reflecting on that, I think you're kind of capturing that. Obviously, you sort of see that called out as well. Thank you.

Carolyn Petersen – Individual – Chair
Okay, thank you.

Christoph Lehmann – Vanderbilt University Medical Center – SME
May I quickly respond to that?

Carolyn Petersen – Individual – Chair
Yes, go.

Christoph Lehmann – Vanderbilt University Medical Center – SME
Okay, thank you. Real quick, I'm quoting earlier – I think it was Arien who said requirements create hardship and burden. I would like to remind you of the reason why the pediatric certification made it into the 21st Century Cures Act. Looking at the EHRs as of 2016, 94% of office-based pediatricians had electronic health records. If you look at those, those that are actually fully functional and have pediatric-specific requirements are about 17% of those EHRs. So a fraction of the EHRs that have been used. And what that means is that work that needs to be done, that is important for the safety and wellbeing of children, is done outside the EHRs in rigged up, workaround processes that are not beneficial to children, their parents, or their

caregivers, and certainly not beneficial to pediatricians. So when you are concerned about requirements creating hardship and burden, to quote you again, I want you to also remember the hardship and burden the currently exists.

Andy Truscott – Accenture – Member

I don't think we're disagreeing in any way, shape, or form that this is absolutely necessary, and it is important to put this through. We want to do this in a way that actually can be taken on board by the vendors and adopted rapidly to directly benefit those individuals that you're most concerned about, because we all share that concern.

Christoph Lehmann – Vanderbilt University Medical Center – SME

Yeah. You and I see eye to eye on that. Thank you.

Carolyn Petersen – Individual – Chair

Thank you. Can we go to Ken?

Ken Kawamoto – University of Utah Health – Member

Okay, real quick. I think lunch is coming up. So one of the issues that kind of came in my mind as these pediatric growth chart things kind of things came in was there are already things like free Smart on FHIR apps that are available. And I don't think there's anything in the regulations as I was reading them that say you can't use, say, something like a smart app or a FHIR-based CDS Hooks service to meet these requirements if you incorporated them. And you're told I think it might be implied by things like, a lot of existing requirements are being met by using third-party drug interaction databases, etc. But I just wanted to make sure as we move towards this kind of an app economy where you can add on features that there's nothing in the regulations that specifically prohibits using those kinds of capabilities to meet this kind of requirements.

Carolyn Petersen – Individual – Chair

Thanks, Ken. I don't recall seeing anything that states that specifically, and nothing's coming to mind that would be implied in that direction. We will take that under advisement as a committee. Terry?

Terrence O'Malley – Massachusetts General Hospital – Member

Thank you very much. Terry O'Malley. Great taskforce work on a very complicated issue. I really applaud the work that's done. Just a comment on, in my mind, what might help me understand it better. I don't know if it will help anyone else. But it seems like you've got issues of data. So, some data are available; some aren't. Guardianship, identification of who's got consent-required capability. That sort of, to me, is a piece of information that's missing. And then there's functionality. You listed up a whole bunch of different functionalities that should be in the EHR. And then finally, referencing standards to support either the functionality or the movement of the resulting information. So I'm wondering if it would be helpful to think on each of these recommendations to sort of break out data functionality and standards, and the gaps that exist in each of those. Thanks.

Christoph Lehmann – Vanderbilt University Medical Center – SME

Great recommendation. Considering the short time that the taskforce has, we haven't

addressed this. But if ONC gives us more time, we'd be delighted to address this.

Carolyn Petersen – Individual – Chair

Thanks, Chris. You must have been reading my mind. I was just thinking I should start a list of items for which we should ask ONC for additional time to work on. Hint, hint. Let's go to Aaron Miri.

Aaron Miri – The University of Texas at Austin – Member

Yeah, real quick. So a couple of things. Number one, related to what Denise said, great points, on that we did briefly touch upon the issue which I've run into in our pediatric practices with a baby boy or baby girl they're in the NICU and whatnot, and how do we really work to make sure there's continuity of care and identification and whatnot, which touches upon larger issues about identification of the patient and strategy, those sorts of things. So there was some talk – I think there's a lot more to be done there, some great points on that. Ken, your name did come up multiple times as it applies for FHIR apps and other things. I think some of the feedback that we heard was trying to leverage some of those techniques in more generalized ways. So just know that there's a lot of respect and appreciation for some of those FHIR apps.

Related to something that I think is important for this whole committee to know that I wasn't even aware of, that EMR vendors were quick to point out, which is that their school forms for immunization and others, like in New York state, that are mandated by law, that those forms apparently cannot be digitized for whatever format they're in. And I don't know how that's possible, the technologies, but so be it, that we can't automate that. So apparently, there are some barriers there that maybe a conversation that would be worth having to understand more about. And then that goes to my question here, which is – and this is a question also, Carolyn, and I'm not certain of this – is it possible for us to take these recommendations and then recommend to say – I'm gonna make this up – USCDI or another taskforce looking at standards and say, these are the items identified as related to pediatric barriers or things that we may want to consider for future standards-making, and that could be a consideration or output from this taskforce? I'm just not certain.

Carolyn Petersen – Individual – Chair

I believe – well, within the charge, ONC has asked us for what it wants definitely in terms of feedback, and we need to work to that. But of course, there's no barrier to providing additional feedback that either we as the taskforce or the HITAC as a whole feels would be valuable. And I think Chris and I would certainly be open to managing and organizing that to the degree that we can in the timeframe we're given. Of course, with the hope that we'd receive additional time to do a more thorough and comprehensive job for ONC.

Christoph Lehmann – Vanderbilt University Medical Center – SME

Yeah. And just to follow up on the comment for me, we talked about the non-digitizability of New York State's school forms. And the way we are looking at this is we need to have ONC encourage leaders, like professional societies like the American Academy of Pediatrics, to make recommendations or something that states that local government can accept something that would be congruent with their needs as well. So a recommendation that a school form is unified that has the basic elements that everybody needs, if that were to come out from ONC or from a

professional organization, that has a lot of way with the state local governments. So, in other words, for us, it is, yeah, we're working with ONC on their recommendation. At the same time, we are continuing to make whitepapers to make recommendations for the adoption of new standards in the pediatric space. So it's a continually ongoing process, and this is just one aspect of it.

Carolyn Petersen – Individual – Chair
Okay, thank you. And then Sheryl?

Sheryl Turney – Anthem Blue Cross Blue Shield – Member
Thank you. Thanks for the presentation. Sheryl Turney from Anthem. I thought it was very good. I do have a question or comment on the recommendation for the regarding consent. From a reasonable person perspective, I think this description of this particular requirement would be difficult to implement. But let's suppose you could click on a link and say, all right, here's your legal guidelines for your state. I would imagine, being a reasonable person, that that would then provide some comfort to the provider. But at the end of the day, the provider is a person that needs to be responsible for the laws of the state that they live in and that they're providing services around. I don't know if we really want it to be the system responsible for that, as we would the provider. But I do believe we need to do more in all of the work groups regarding consent, because it touches on a very important issue here.

And speaking from experience that's happened in my own family, I do believe consent needs to be encompassing, so that if you have an infant and the parent has allowed their consent for data, either on genetics, or DNA, or whatever the situation is, to go forward with that child, it should be recorded, and it should be available to the child to then make a decision how they use that data. And I don't know where in this – we keep discussing consent, but it's not clear to me exactly what the requirements around consent are and what group is really talking about that. So of course, we will be commenting on it. That's an aside.

But I do think that that merits further conversation, because for all the purposes we're talking about with AI being applied, and machine learning, and other things, the more information you have about the genetics and the DNA that come with the child or even with the adult who, for a variety of reasons, consents to have that information present, is going to help that person deal with their own health. And so, how do you make that data available, and who does that data need to be made available to, and where does that live in the age of interoperability? Because if it's an older person, or an infant, or a young person, up to whatever the legal age is, it's not going to be the person giving the permission. It's going to be someone else. And how are we gonna deal with that? That's my comment.

Carolyn Petersen – Individual – Chair
Great. Thanks, Sheryl. So we've gone around the table fully once. I see Arien has his table tent up. I'm asking if you could keep it brief, since we're 20 minutes into the –

Arien Malec – Change Healthcare – Member
Yeah, I'm in agreement. I think just because I was, I think, personally called out and misunderstood, I want to clarify my comments, that just as a matter of record, if making Sasha

unhappy led to more usable and more productive EHRs, as much as I like Sasha, I think that would be a reasonable tradeoff. I'm more making an empirical statement that certification criteria are best when they address safety critical floor standards, as well as interoperability standards, and that we haven't seen the ability of certification to magically create usable EHRs into existence. And I think the last more than a decade of experience, decade-and-a-half of experience, adequately plays that out. So I just want to make sure my comments weren't misunderstood as any hardship or burden is inappropriate, and more about saying there are areas for certification criteria that are absolutely appropriate and areas for certification criteria where you just might not get what you hope to get. Thanks.

Carolyn Petersen – Individual – Chair

Thank you. That concludes the comments as I see, based on our table tents. As I mentioned previously, we will not ask for a vote today because we don't have a transmittal letter. And additionally, it sounds like there are still some things people are thinking through. I think at this time, we will take that feedback back to the taskforce and revisit anything that seems particularly concerning, and look to bring forward our recommendations and thoughts on the 25th. With that, I will hand the mic back to Lauren to tell us how we will deal with running into the lunch break. Sorry!

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

We'll go to lunch. No, I know we kind of cut into the lunch hour, but if you could return promptly, because we have information blocking right after lunch, I'd so appreciate it. Thank you all.

Carolyn Petersen – Individual – Chair

Thank you so much, and thanks, Chris, for your input and presentation.

Christoph Lehmann – Vanderbilt University Medical Center – SME

Bye, Carolyn. Bye.

Carolyn Petersen – Individual – Chair

Can we sit down and go to our afternoon agenda? Thank you.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Operator, can we please open the public line?

Robert Wah – Individual – Chair

Have we got everybody online? Okay. Good afternoon, everyone, welcome back. I hope we all had a good lunch and a good little break. As you know, we have a very packed schedule this afternoon that we're gonna try to stay onto. And with that being said, my flight at the end of the day has been canceled, and I need to move it up, so I may actually be handing the reins over to Carolyn at some point during our discussion. But great to see everybody. Look forward to our next meeting, which will be virtual, as we try to wrap up all this great work we're doing in preparation for the rule-making that's been put before us. With that, we'll go to our post-

prandial team to discuss a topic of some interest on information blocking.

Information Blocking Task Force Update

Andy Truscott – Accenture – Chair

Thank you, Mr. Chair. Good afternoon, everybody. It's always a pleasure to have the first slot after lunch. Settling down nicely, and everyone can kick back and listen as our words wash over you. Okay. It gives me great pleasure to present the interim reflections of the taskforce around information blocking, a subject which some of you may be interested in. We're going to touch upon the outputs around relevant statutory terms and provisions, and services, communications, conditions, and maintenance of certification enforcement. We're not going to touch upon the exceptions work today. That's very definitely in flight still. And we will be reporting out on that at the next HITAC committee meeting. There is also a taskforce meeting for all taskforce members tomorrow morning. Those of us who are here overnight, we will be here in the building. Other taskforce members, please dial in. I encourage any member of HITAC who is interested in the exceptions to please dial in and connect and join us. You'll be gratefully received and appreciate your input as we go through the drawing together of our recommendations around exceptions.

It gives me great pleasure to hand it over to my co-chair, Mike Adcock, who's going to take us through the first series of recommendations as they stand in place.

Michael Adcock – Individual – Chair

Thank you very much, Andy. Next slide, please. So we'll talk a little bit about – we won't go through the overarching charge in this, but you see what we're trying to go through. We talked about that last time. So I won't talk through specific charges. But I am gonna go over the statutory terms and definitions. I will start this off by saying there has been a tremendous amount of work done in this area. And I don't know about Andy – I won't speak for him – but I honestly thought it would not be all that challenging. I honestly thought two and three would be much more challenging, and it turned out that one was a very laborious task. But it's been a great taskforce. Andy and I actually talked about this late last night and then again this morning, about the fact that it's been a labor of love, but it's certainly been a lot of work that's been done all three work groups. And it certainly brought me more engaged in the process, and I've enjoyed it.

So, next slide, please. Next slide. Okay. So here are some of our proposals. And this is meant to be – this is still a liquid state. This is still something that we're talking through. There's still lots of discussion going on around this. But the way that we framed this was around – so you can see the original text – as we talked through this in the work group, being able to see how the text is in its original state, what we're marking up, and then the discussion points, helped us walk through some of this. So the first one is electronic health information, which seems very straightforward. The only thing that we added under point one was as defined in HIPAA. If you look at the second part, we did not change anything within that except to add "and" and then a "three". On the one-year anniversary of the effective date of the final rule, an individual's consent directives, including privacy, medical treatment, research, and advanced care. So we wanted to make sure that we got the consent directives in there under EHI.

So some of the discussion points that we've had around this – this is not all of them. These are just some of the larger points that we discussed, is the belief that Congress intended 21st Century Cures to be wide in remit and to promote information sharing to further patient care as much as reasonable. We also saw the originally proposed definition of EHI as strong. We felt that it was already a strong definition. We just wanted to make some minor amendments to make it stronger. And the desire was around – we had lots of conversation around this – was for EHI to be HIPAA-plus. One of the points that came up, and a lot of discussion was had around this, was information should be machine-readable, e.g., coded. Coded information, not just written information, and also human-readable. We didn't want to leave a gap in there for anything that could be considered just data when it's truly information. We're gonna update the preamble to make that clear.

And consent is considered by the taskforce as an important class of data that should not be blocked, despite concerns over how this would be implemented. And we did have discussion in the group – I know there were lots of questions across the HITAC committee around consent. And we had those questions as well in this workgroup.

So next slide, please. Now we're gonna talk about price information. So this is one that we continue to talk about, and again, it is still very fluid. But just some of our discussion points around the requests for information about price information. The taskforce does believe that price transparency is a desirable goal that is achievable. It's something that I think you've heard across the room today and in all of our previous meetings, something that we all desire to achieve. We further believe that policy levers are required to move the healthcare ecosystem in that direction. Given the nature of reimbursement, it is a huge change. Tying together the information blocking regulations, one of the things that we watched out for was tying that too closely to price transparency with the regulation may have – not necessarily, but could have the unintended consequences of slowing down information blocking regulations about the finalization of those. So it's one of those things we'd want to move in parallel. We want to make sure that one doesn't bog down the other, because they're both things that we need to achieve.

Price transparency regulation drafting and considerations underway. We recognize that fact. We recognize that it is a big process. It's not just part of HITAC. It's something that's being discussed at the highest level of government in all organizations. Prices included in EHI should reflect all services and payments by all parties, including contract terms, rebates, other forms of incentive payments. Again, these are our discussion points. Recognize that there are many different players – for example, healthcare providers, health plans, contractors, administrators, PBMs, pharmacies, group purchasing organizations, technology companies, health IT developers, laboratories, medical devices, brokers – I could go on and on. There are lots of different players that have a part in this pricing transparency discussion.

The definition of EHI encapsulated within the TRAF regulation includes a clear reference to the past, present, and future payments for the provision of healthcare to the individual. We want to make sure that the right information is being exchanged for price transparency regulations, and we want to make sure that the regulations could be built upon a solid, interactive basis. We looked at and have had lots of discussion around this, for ONC to initiate through HITAC a

taskforce specifically charged with producing recommendations around this. We are going to produce some recommendations around price transparency as it relates to an RFI. But we're gonna focus that on health IT policy. That is the charge of this taskforce, so.

Next slide, please. Ooh, this is getting much smaller. I'm gonna have to move closer to the screen. So again, we've got the same format here, original text. This is around the health information exchange and network. We had a lot of discussion around grammar, around nouns and verbs, around capitalization or the lack of capitalization. But these are discussions around HIE and HIN. So you can see the original definition. I won't read through that.

Andy Truscott – Accenture – Chair

The next one's got the markup.

Michael Adcock – Individual – Chair

Oh yeah. I want to definitely look through this first, because when you start looking at the markup, it gets quite intense. But we'll move over to the proposed text. Our proposed text at this point has health information exchange, or HIE, means the act of accessing, transmitting, processing, handling, or other such electronic health information, or the organization or entity conducting the act. So remember that as you look at the original text. And they're both there for your comparison. We'll switch over in just a second to the markup so that you can see all that we changed.

Health information network, or HIN, means an individual or entity that satisfies one or several of the following. So you can read that, but I'll read it. Determines, oversees, administers controls, or defines policies or agreements that define business, operational, technical, or other conditions or requirements for health information exchange between or among two or more individuals or entities. Also, it provides, manages, controls any technologies or service that enables or facilitates health information exchange between or among two or more individuals.

And if you'll switch to the next slide, the discussion points are on there as well. So you can see, there has been quite a bit of markup to these two definitions. Again, we've had lots of discussion around capitalization, nouns, and verbs, lots of different pieces. But to the point where we go to this. We wanted to make sure that we added the fact that health information was an act, and we also added transmitting, processing, and handling, or other such. We wanted to make sure that the definitions – it's a tight rope that we have to walk – that the definitions are broad enough to include groups or individuals or people that are performing these tasks, so they're a part of these groups, but also not so broad that it swallows all the other definitions. So we want to make sure that we are sensitive to the actors that are described in 21st Century Cures and that are described in the preamble. There are lots of discussions, lots of definition. The problem is, HIEs and HINs are – the definition, we felt, was a little ambiguous, and it was defined different ways, we thought, in the preamble and different ways in 21st Century Cures.

So this is what we came up with. We also want to – some of the terms that you see that we've marked out here: substantially influences primarily between a particular class, a limited set of purposes. Those terms that we could not define, or that seemed broad or a little too vague, we

took out. We tried to make these definitions as clear as possible. And some of the discussion points – and these are just some, because there were a lot of discussion points around HIE and HIN. As you see, there was considerable discussion. Multiple uses of HIE within 21st Century Cures. Again, we talked a lot about capitalization, lots about nouns and verbs. We recognize that exchange and network have multiple common uses in the industry right now. We will be sensitive to that. We also believe that promoting consistency of usage is advantageous. It is used in lots of different ways.

We also want to make sure that we look into the future in how those terms might be used. Focus upon exchange as an act and network as an organizational construct. We also wanted to make sure that it fits within the bounds of the 21st Century Cures usage, especially as enforcement is built around that. We are sensitive to the fact that the enforcement has to be built around what we're defining here, so we want to make sure that we're having those lengthy discussions. We also had additional preamble to provide usage examples. We want to put some usage examples into the preamble.

Next slide, please. Practices that may implicate the information blocking provision. Yeah. You do it.

Andy Truscott – Accenture – Chair

My co-chair is suffering from a sore throat, so you're stuck with me for a bit longer. Okay. So we've had a fair degree of discussion around practices which might implicate the information blocking provision. These generally fell into three core areas around patient access, pricing information, and where there's an actor versus the information type that's being exchanged. I'm not gonna drain these out. But these are the points you can look at in your leisure. We also encourage and welcome any additional inputs which any members of HITAC might have around other practices which we should document in here that we believe would be implicative of information blocking.

Next slide, please. Okay. Looking at the parties which are also affected by the information blocking provision, we have four parties which are defined inside 21st Century Cures – providers, health information exchanges, health information networks, and health IT providers of certified health IT. We just talked about health information exchanges and health information networks. We're looking potentially for a recommendation that the definition of actors as defined in the regulation maybe includees some types of actors which will fall into each of those four buckets. Obviously, the nature of what a provider is is something which is changing constantly over time and has changed, frankly, since this committee was first instantiated. And we want to be able to recognize that that change is underway, and so organizations have clarity on whether we believe they are provider parties or otherwise. And we've included some examples in here. But again, this is for discussion, and these are recommendations for consideration to ONC.

Next slide, please. Okay. The exceptions area is this area that's being deferred. The work will be still underway. We have considerable activity. Something which I think Mike alluded to, looking at workgroup one, was if I was to equate the number of words of change to the number of hours discussed, I think it would be heavily in the side of the number of hours discussed versus

the number of words changed. And what that says to me is that actually, these are immensely well thought out and well-considered regulations as they're currently drafted. I've sat here and said this two weeks or three weeks ago when we were last here. But it becomes ever clearer with every single meeting. And the ONC team who has worked on these has done a very awesome job. Two of them are sitting to my left here. I see you, Mark and Mike. Thank you. And you've done an awesome job of actually reflecting the nature of the conversations which have gone into these regulations as they stand. And that's why we have discussed them at length, and in many cases, come back to exactly the same conclusion you have. So thank you very much, and thank you to the board or ONC team. We'll be circulating the exception recommendations drafts over the next few days to the board or committee so that we can consider them at our next meeting. Can we move on, please?

Okay. Into what we've been working on through workgroup three of the taskforce. Assurances, information blocking, etc. So we're recommending no changes to the actual definition of information blocking as a condition of certification. We're happy and content. Move on. Okay, assurances. There's a couple of different areas where we've made a suggestion here. First is in the mentions of certification. And we just wanted to make sure that if a product was withdrawn from certification, that the records would be retained appropriately. So we've included here an addition that if for a shorter period of time and not due to decertification – so if there's a voluntary withdrawal, the records are retained over a period of three years from the date of withdrawal from the health IT developer of a certified health IT product from certification. So we just thought that made it clear. We believed in the discussion it was probably the intent, it just hadn't quite made it through in clarity in the regulation.

Next slide, please. Okay. In maintenance of certification, we discussed the existing practice which is undertaken around the CHPL, the CHPL, the ONC undertakes, and that they already publish certification dates for products historically. We wish to make that a regulated practice, so it has to happen. We think that it's a good practice, and it should be persisted, and recognize that the CHPL might not be in existence in its current form over time, and the regulations will preserve until they are redacted. And therefore, staying in a publicly accessible form would be appropriate.

Next slide, please. We reserve comment on the request for information on participation in the TEF and the common agreement. We don't believe it would be responsible to make comments, notes on this at this moment in time.

Next, please. Okay. Communications, part one of seven. We wish to put in place a whistleblower protection, so that in the event there's an employee of a health IT developer makes a communication that is covered within this condition of certification to an appropriate entity, that that must not be subject to any retaliatory action which could be reasonably considered due to their whistleblowing activity.

Next slide, please. Okay. So the discussion points around this, we just felt it was reasonable to assure there was a degree of protection, and in order to promote information sharing and prevent information blocking, that this would be appropriate protection to put in place. And it should be subject to consideration by ONC for taking forward. We further felt that the

appropriate authority should be put in place. It's not a clear case where you can talk to anybody. But you actually have to communicate to an appropriate authority your concerns.

Next slide, please. Okay. There was a considerable conversation around the concept of unprotected communications. And we suggested this as an additional line item in the condition of certification. And we're suggesting that there's a class of communications that are not protected, either because they receive protection elsewhere, or they shouldn't be protected. So here is – the unprotected communications are specific communications are not extended protections or restrictions in a section where those communications are considered unprotected, and that they are either protected by other legislation regulation, or they are folks who are unlawful. So two very distinct differences of communication that we felt should be afforded unprotected status. We will include inside the preamble some examples of that. We've had some excellent examples provided from the taskforce, and those will be included inside the preamble.

Next slide, please. Okay. Four of seven. As you may imagine, there was some interest in intellectual property protections, as stated inside the information blocking provisions. "Some" would be an understatement. There was considerable consideration of these. The main discussion points were principally around fair use and the need to ensure that actually, the fair use of materials was not an infringement of intellectual property. And there obviously is a tie-in with the latter, the next slide that we'll see in a moment, of screenshots, etc. But the fact that screenshots which are utilized for fair use, downstream, that also needs to be fair use, that you can't just release into the wild and inadvertently impinge upon the intellectual property and fair use of a vendor.

Next slide, please. And then, given the volume of discussion we had, it actually came down to a very minor amendment in this regulation, that we're suggesting striking of every aspect of screen display that needs to be notified specifically to that screen display, because we felt that that would be unfeasible to implement, and we should just be looking at a list of the third party content that's included in the health IT. And that should be notified in one place at one moment in time, as opposed to an ongoing need. And frankly, that that could well impinge upon the utility of the health IT being utilized, and that would be an unintended consequence of this.

Next slide, please. Timelines. So where the regulations are suggesting – or stating, sorry – that contractual updates are required, we felt that this actually should be put on a work plan and something that should be worked through within five years, as opposed to the suggested two, purely because of the scope and scale of the opportunity. This is still definitely something which is in flight. There are other statements elsewhere in the regulations around compliance, and that the contracts updates might need to follow, but you would actually not be able to implicate upon the information blocking provision in advance. Mark, do you want to comment upon that? Because I know there's concern over the – sorry, guys. There's concern over the way that this is stated when you look at it in the abstract of other regulations. So other regulations mandate you will comply. This is purely around the contractual updates getting made. Those two things need to operate in concurrence with each other. Do you want to comment?

Mark Knee – ONC – IB TF Staff Lead

Yeah.

Andy Truscott – Accenture – Chair
Do you want a microphone?

Mark Knee – ONC – IB TF Staff Lead
Yeah. All of these things, I think we talked about, that during that five-year period, you couldn't be doing the bad acts.

Andy Truscott – Accenture – Chair
Yeah. You need a microphone. Hit the button.

Mark Knee – ONC – IB TF Staff Lead
Okay, there we go. I think all I was gonna say is that during our conversations, we talked about, in this context and in other contexts, that five-year period to update the contract, but during that time, you couldn't be doing the bad acts that we're trying to limit.

Andy Truscott – Accenture – Chair
Thank you, Mark.

Mark Knee – ONC – IB TF Staff Lead
Yup.

Andy Truscott – Accenture – Chair
Next slide, please. Okay. Oh, yeah. Sorry. Okay. We had a list of proposed recommendations. I was looking for the text. Just as a suggestion, that ONC looks at how administrative IT functions could be considered to be non-user-facing aspects, and therefore, shouldn't necessarily fall under these communication regulations. And that's for consideration. We had no suggestion over proposed regulation changes for consideration for how that could be incorporated. And we recognized that might be a copout. Sorry, gentlemen.

Next slide, please. Are you ready?

Michael Adcock – Individual – Chair
I guess my co-chair was tired of talking. Okay. So the review of certified health IT or IT developer's actions. We had lots of discussion around this, just like we did everything else. The taskforce was concerned with the idea that direct review communications could be serious in consequence, and email alone would not be a sufficient communication medium. So we added a change so – you can see we added a section, see under the proposed regulation text, notices initiating a direct review, potential nonconformity of suspension, proposed termination, termination or ban concerning the appeals process will be issued simultaneously via certified mail and email. So the practice now is in some cases to just do email. We added certified mail to that.

Next slide, please. The public listing of certification bans and determinations. We had a good bit of discussion around this, but it was all moving in the same direction. Indefinite communication of past records. Ban with start and end date if lifted seems appropriate. We want to make sure that people, whether they are people who are out looking for – organizations who are out looking for a certain type of IT system, they need to know whether or not the system has been banned. So we want to make sure that it has a start and end date. The sense of the taskforce was that knowledge of past bans was important for stakeholders. Again, as people are looking, they will know that things have been banned in the past, even though they have been corrected. We do not recommend establishing a minimum time period over which a ban must last, even if the health IT developer was a repeat offender. And the point around this was if somebody has something that's banned, and they correct it very quickly, we didn't feel – the taskforce didn't feel that they should have to wait a certain amount of time that the ban must last if they corrected the items that were deficient. The sense of the taskforce was that a minimum ban time could have unintended consequences, could limit innovation.

Next slide, please. Applicability of conditions of maintenance of certification for self-developers. So our discussion points around this, the provisions of information blocking and assurances would apply to self-developers as well. Most of the provisions of communications would also apply. We did identify one area that would require modification for self-developers, which was where the taskforce noticed that employees of a developer can have their communications restricted, but this could have the consequences of limiting communication of users of the self-developed health IT for the reasons identified under Cures. We want to make sure that we're protecting the employees. If a health system self-develops an IT platform that the employees, especially the healthcare providers, aren't limited in their communication. As you can see here, here's our proposed text. We added healthcare organizations self-developing certified systems are not permitted to restrict communication of their user employees with respect to these provisions. So again, we wanted to protect those employees who were actually users in the health IT system that developed their own certified system.

Next slide, please. That was a tremendous amount of discussion and work. Look, you said we had to rush. 30 minutes, buddy. So we knew there'd be lots of questions. And I see that Sheryl has one. We'll go through them as we go. But one thing I did want to say before we get started is, again, I wanted to mirror what Andy said around the help that Mark and Mike and the other ONC staff has provided, and also thank all the workgroup members, all the taskforce members. It has been a tremendous labor of love. There have been – we've spent a lot of time on the phone with you. There's been lots of discussion. There have been opposing points, and still lots of very professional discussion. So I'd just like to say thank you for that. We'll go to Sheryl for a question.

Sheryl Turney – Anthem Blue Cross Blue Shield – Member

Thank you, Andy and Michael. This has been a fun workgroup to be part of, taskforce, and it has, I think, gotten everybody's best efforts to come to a good conclusion. The comment I wanted to make, and also – it wasn't really a question – was regarding price transparency back over there on slide six. But essentially, the one point I wanted to make on this, and I know I probably made it in the taskforce meeting, is that there're differences and variations in terms of talking about price and cost for past, present, and future. So the capabilities that a payer would have to make price available for past is going to be much easier than present and future. So all I

think I would ask is that our recommendations recognize the technical aspects of that and perhaps have a timeline that allows for implementation over a time period. Because it's not the same thing, to be able to say what something cost and what was paid previously to what we are paying today versus what they're paying in the future. Especially as we talk about value-based contractions and how that data is all going to be processed.

Today, everything we develop has been a fee for service, and now we're all moving to value-based contracts. And even when I bring this up in the taskforce meetings, it leads to a very healthy debate, because the AVCs don't have to deal with it, and they've been dealing with it now for two or three years. So we need to have a plan on how those costs, especially for the future, are gonna be represented in meaningful ways.

And the other thing is, I do think we need to say a little bit more about the different stakeholder groups when it comes to pricing. As a result of all the discussions we've had, I went back and looked at probably 50 papers that have been produced in the last few years – Robert J. Woods Foundation and others – and they've all discussed the fact that there's no one solution for this problem, because we have people that are insured, both individual or through a group, or you have people that are uninsured. And then you have other individuals who are in products like Medicaid and Medicare. So what the needs are of the different groups are not all gonna be the same. And I do think we need to look at that and perhaps propose recommendations based on solving problems by a stakeholder group that would be more beneficial for each one. And it's not gonna be one solution for all of them.

And then the intent in terms of making it understandable, maybe having all the pricing data for future isn't gonna be as helpful when you know that – I know for some of the things we do inside of Anthem, we have 1,662 services that we make available today for pricing. But that might not be palatable for someone that's not a sophisticated user. So starting with the hundred most common and then working your way up, or something of that nature might actually make it more digestible for a patient or a member, especially one that's not very sophisticated, who's needing to look at the services and really want to understand what are they gonna pay. And most people want to look at it from, in the group that I'm in, what's my cost? I would love to say they care about the cost the insurance company is gonna pay, but our evidence shows that that's not so much the case when they have insurance coverage. And we hope – we're trying to encourage them to look at the total cost, because the total cost is really borne by everyone, not just by their plan or their employer, or whatever. But the history is what it is, and people really are looking at what's in it for me, what do I have to pay? So making that data available is very important as well.

Andy Truscott – Accenture – Chair

Thanks, Sheryl. I think the sentiment that came out from the taskforce during the price transparency discussions was that while the definition of EHI would support the understanding of transactional price, etc., for a particular episode of care, the broader potential for price transparency wasn't necessarily something that we could comment on at this point. We're focused upon the health IT policy and needs. And so, that's our focus. We want to make sure that the commentary has been made around how we can shape the regulations to support wherever we go to with regard to price transparency as a general policy. And we're here to deliver upon that as appropriate. I hope that makes sense. Clem, you – next.

Clem McDonald – National Library of Medicine – Member

There were two things. One of them, it looks like this option to show displays from a health information system has been taken away. Maybe I misread that. But it's a real problem if you're trying to describe a problem or an error or a display that's causing problems if you have to try to do it in English rather than doing a screen capture. Largely, it's forbidden, or there's a guy at a big university who has something he wants to show off at a session, and it's been three months. He still hasn't gotten permission to get a slideshow of that particular image. So, I mean, if you really – I mean, originally it was in there, and you're taking it away, I just would hesitate to take it away completely. That's number one.

And then I may be mixing up the letters, but is health information exchange and health information exchanges, they've been blended now, right? I mean, we're using the same acronym for the action of moving data around and for these things that existed as organizations – and John Kansky knows one – that kind of manages that. And I worry that if it gets blurred like that, that one of them will go away.

Andy Truscott – Accenture – Chair

Thanks, Clem. So I'll try and answer the first question. Before we ask the committee to vote on anything, we'll be providing you with a transcript, a written document, rather than asking you to comment on the slides. So I agree with you on that one. It's much easier for me to sit down and actually look at this and think about it, okay, than look at a screen. So yes.

Clem McDonald – National Library of Medicine – Member

No, I wasn't talking about your screens. I was talking about computer screens in medical record systems. And it looked like the display screen in the first version, you could do something with them, and now it looks like it's now considered the intellectual property of the vendor, and you can't do anything with it. Am I retaining that right?

Andy Truscott – Accenture – Chair

Okay. Yeah, I think so.

Clem McDonald – National Library of Medicine – Member

I wasn't complaining about your slides, but the display screen that you talked about.

Andy Truscott – Accenture – Chair

I apologize if I misunderstood you. And so, Clem, why don't we have a chat after in the break, which we might get to at some point, and we'll open it there. Okay. The second point around health information exchange/exchanges, capitalized, lowercase, yeah. We went through the 21st Century Cures statement and actually the different uses of it in there. We also recognized that there is a certain level of vernacular usage of HIE, health information exchange, both as a noun, a verb, an adverb, and several other different grammatical connotations. We have looked to attempt, rather than changing any of the scope of the actor's inclusion, is to just provide some degree of clarity over that usage. Please have a look, and we appreciate your feedback as well and have another look. We're just trying to tie it down a little bit in the freewheeling usage

and to make the enforcement easier.

Clem McDonald – National Library of Medicine – Member
No, I think that's a good idea. I just am afraid that both instances won't exist anymore. You're saying they do. You have a way to…

Andy Truscott – Accenture – Chair
Yeah, we do.

Clem McDonald – National Library of Medicine – Member
Okay.

Andy Truscott – Accenture – Chair
For right or for wrong, they do, and yeah. So we've sort of tried to provide some clarity over their usage more than anything else. Raj was next.

Raj Ratwani – MedStar Health – Member
Great, thank you. Great work on this. There's a lot to go through here, so I appreciate all the effort. I have some similar concerns, I think, as Clem was sort of expressing. And specifically on slide 21, hoping to get a little bit of clarification on the proposed modification that you have there. So on slide 21, this has to do with point number four of seven on communications. On the right-hand side, the markup from the original. Point number two, you're adding this piece that says, and with the understanding that any actor disclosing the screenshots are responsible for ensuring that each use is being put to fair use. So I want to clarify to understand, does that mean if I was to post a screenshot on a website to demonstrate a particular usability safety issue, it's my obligation to ensure that that's being used under the fair use? But is it also my obligation to ensure that anybody that accesses that website is also putting it to fair use?

Andy Truscott – Accenture – Chair
Yeah, good point. The intent was that if I am going to distribute those further, that the receiving party understands that they are to only be put to fair use, as opposed to what I think you're reacting to, which is, do I have to monitor every use of that now?

Raj Ratwani – MedStar Health – Member
Right.

Andy Truscott – Accenture – Chair
Good point. We'll take that back.

Raj Ratwani – MedStar Health – Member
Okay, perfect.

Andy Truscott – Accenture – Chair
Thanks.

Raj Ratwani – MedStar Health – Member

And then the second question I have in this space, which I'm still trying to work through my head. So this is more of, hopefully, a discussion here, is in the original text, it doesn't mention fair use, right? As much as you're kind of emphasizing here. So if you go to the left-hand side of the slide, point two does not say fair use. But it does say limited to the restrictions described in the following paragraphs, which I believe contextualizes this enough and offers what I would assess as fair protections for both vendors and those that want to share the screenshots. By adding the term fair use in there, it seems that you're putting the burden on the potential researcher or person sharing the screenshot to demonstrate fair use. And by doing that, you're potentially opening the door for intimidation and other things by certain vendors. And in many instances, those vendors have more resources to legally pursue, navigate, then does the researcher. So I want to try and better understand that potential threat here and understand potentially what some of the conversation was that drove the infusion of the term fair use there.

Andy Truscott – Accenture – Chair

Yeah, I think that's a very good point. And as you might imagine, we've had a voluptuous conversation about it. Frankly, we would welcome input on how to – language to use. We thought fair use was a good set of terms there to use because it's widely understood to have a distinct meaning, and the intimidation around trying to say something's not fair to use is kind of widely held and widely understood and widely not practiced in terms of that. But if you think there's a genuine concern, then we can definitely look at how we might incorporate that.

Raj Ratwani – MedStar Health – Member

Sorry.

Andy Truscott – Accenture – Chair

If you have a comment, you can make it. You're looking at me as if you wanted to contribute.

Raj Ratwani – MedStar Health – Member

No, I mean, I think it's a good point, and I think it's probably good to discuss. I mean, I would just add from my perspective, I think putting that term in warrants farther discussion, and it's of serious concern to me because of the asymmetric relationships that often exist between a vendor and a provider organization. And I know there's language in the NPRM that discusses intimidation. But intimidation is incredibly difficult to actually demonstrate. And so, that raises lots of red flags for me.

Andy Truscott – Accenture – Chair

Okay. Can you join the taskforce call tomorrow morning, Raj? Because I would like to get these bottomed out as a taskforce, and we can discuss this one, this particular issue.

Raj Ratwani – MedStar Health – Member

Perfect. I'm happy to try and join you. If not, I'm happy to send out the comments and then try and schedule a call to make that happen.

Andy Truscott – Accenture – Chair

True. But I think this warrants a discussion, because I think you raised some very valid comments which need to be taken on board. Thanks. John Kansky.

John Kansky – Indiana Health Information Exchange – Member

Sure. Largely reacting to a point that Clem raises. And I'm on this workgroup. And so, I want to talk about the industry use of the term health information exchange, health information network, and then trying to write a regulation that's clear and implementable, right? So, number one, Kansas Health Information Network, Michiana Health Information Network, are HIEs, John Kansky's definition. Indiana Health Information Exchange and Kentucky Health Information Exchange are also HIEs, so it's messy in that way. The federal government several years ago tried to clean this up by defining as HIOs, health information organizations, and HIE as a verb. That didn't quite stick. But it was clear, and it was helpful. So it's kind of a mess in terms of the industrial use of the terms. I don't think anything's gonna go away. They're just gonna use whatever they want.

In terms of trying to have a clean definition in the context of this regulation, my opinion as a member of the group is that the definitions are written so broadly as there's even gonna be health information – I'm sorry. There's going to be provider networks that are gonna meet the definition of health information network. And the circles are just so overlapping. But the definition that we started with for health information exchange and health information network was so overlapping, and the requirements are the same, it just seems it would be clearer and easier to interpret for those trying to comply with the regulation if we said, if you meet this, you're one of those.

Andy Truscott – Accenture – Chair

Thanks, John. Good feedback from the group. Arien.

Arien Malec – Change Healthcare – Member

Thank you. So yeah, this is a very tricky item. And trying to define these things in ways that actually have regulatory teeth and muscle but don't exclude activities that are intended to be included, and don't include activities that are intended to be excluded is very difficult. I've raised in the past concern that the way that – and I apologize for having a concern without corresponding language. And that to me just indicates how hard this is. But a concern that the way that language is drawn includes organizations that I don't believe were ever intended in the definition of HIN or HIE. And this is the confluence of definitions for EHI, electronic health information, and HIN that would include, for example, banking services that reference claims and that may or may not be intended; billing services; likewise, clearinghouse services, of which we own and operate some. And I think just being clear about where the intended boundaries are and aren't, and where there are any exclusions, I think would be useful. This is an area where I don't think we want to pull in a whole bunch of the U.S. healthcare sector by accident because the definition was broad or broad in practice.

Andy Truscott – Accenture – Chair

Thanks, Arien. As we were considering some of these definitions, on the workgroup, we were

looking at how we could use the function to help describe the actor, as opposed to the actor definition as a constituent. So we were looking at well, okay, if there is an exchange of EHI going on, then you're implicated. So then what type of organization would be doing that? And that's kind of the sentiment we tried to utilize. If we're hitting that, great. If we're not, and it sounds like we may inadvertently be not, can you give us some direct feedback through the taskforce, and especially in the preamble?

John Kansky – Indiana Health Information Exchange – Member

Yeah, absolutely. And I also think it might be worth, just to have – I'm sort of thinking of this like Battleship – drop some depth charges around the area. And if we intended to hit, we intended to hit. If we intended to miss and we actually hit, then that might be an indication that the wording may need to be reconsidered.

Andy Truscott – Accenture – Chair

Cool, thanks. And yeah, we were very focused on unintended consequences of inadvertently broadening the definition egregiously. Also, we didn't want to tighten the definition and exclude actors that we legitimately felt would and should be implicated. So, thanks, Arien. Cynthia?

Cynthia Fisher – WaterRev – Member

Yes, thank you. I appreciate all the hard work and heavy lifting we did collectively together on the taskforce, and with the outcomes, where we ended up. I would like to suggest a separate recommendation than the taskforce with respect to enabling patients and employees/employers, the American public, to get access to pricing information. And as we look at the definition of the electronic health information, the recommendation that we would have would be that the ONC should consider adopting a revised definition to EHI, by deleting in point two of the EHI definition as it stands, the requirement for the information to be identifiable. And what we would want to do is to allow that it is consistent instead with health information as it's defined in a broader term by HIPAA, and as it's referred to in the Cures Act under Section 1171 of HIPAA.

And if you look at Section 1171 of HIPAA, it is the broader definition, which includes the point and relates to the past, present, or future mental health or condition of an individual; the provision of healthcare to an individual; or past, present, or future payment for the provision of healthcare for the individual. The elimination of and deleting the requirement for it to be identifiable, it will then allow the patient to be able to see, outside of their individually identifiable information, pricing information that's provided by the institution or the payer, and to be able to shop and see comparative prices in the marketplace, and allow for, instead, a free and competitive marketplace.

Now, I know there were some objections, and I'd just like to be clear that the revision would not bring in information that is unrelated to the care or payment for the individual. And while the definition doesn't require for it to be identifiable, it must be in the preamble, it states, to be related to the health, healthcare, or payment for the provision of care. So I think we addressed the concerns, and by allowing it to allow patients to be able to shop across systems, across prices, we will get to enable a free and truly competitive marketplace, which we do not have

today. And I would just like to add that comment to Dr. Rucker and the committee.

Andy Truscott – Accenture – Chair

Thank you, Cynthia, and very important points. We are capturing those in the letter of transmittal. All those points will be captured because it is an opinion that's coming out of the committee and the taskforce. And we also recognize what our charter is. And as policy potentially changes in this country in a broad sense, we will be ready to assist and reflect that in information technology directly. So that's kind of the mindset that we have for the taskforce. But thank you very much, and it's very heartfelt. Ken.

Ken Kawamoto – University of Utah Health – Member

I'll be brief. I just want to second Raj's comments. Rereading this, the regulations, the communications with unqualified protections seems pretty clear and narrow. When I read it, I took it as almost every time I request screenshot use, I'm still gonna go through the same mechanisms I'm going through now, which is okay. Of course, nobody likes to seek permission when they're trying to get something presented in a short timeframe, but it is what it is. So I felt like what was unqualified protections was narrow. So leaving everything else, to me, to be applicable to use current processes seemed reasonable without adding in an additional fair use. So I think it's a great point, and I think if there's concern that some of the unqualified protections are too broad, then maybe try to restrict those, rather than to say everything else is out, because I think it does only apply to things that aren't specifically called out, like legally required or related to a safety hazard, that kind of thing.

Andy Truscott – Accenture – Chair

Thanks, Ken. We'll probably have a chat about that as well. Please, if you can, make the taskforce tomorrow, that'd be useful. Sasha.

Sasha TerMaat – Epic – Member

I was just gonna give a little bit of color from the workgroup conversation about screenshots to Ken and Raj, who I know raised questions there. But I think that the workgroup discussed the screenshot provisions as having an impact outside of the unqualified protections use cases, right? So it would be broadly applicable and not just limited in those ways. And I think there was concern that while examples that members of the work group would have considered fair use seemed very appropriate and of minimal concern, research is one of them, there were other use cases that the workgroup discussed that seemed to be eliminated by the use of a fair use term, but were significantly concerning, such as the copying of large volumes of screenshots of a particular product for the purpose of creating a competitive product. And so, the workgroup tried to craft language that would address some of the concerns, like copying a product, which I think we agreed was not the intention of the provision as it had been put in, while still protecting some of the uses cases, I think, that Raj and Ken mentioned around presenting successes at a conference or doing research in that way.

It seemed to us in our conversation that the fair use concept, which has already been introduced by ONC in their delineation that using screenshots seemed to be a fair use of copyrighted material, was a reasonable way to introduce some of those sort of – it's not for the purpose of duplicating the work and commercializing it inappropriately, or for using a larger

component of the work that might be appropriate without pursuing a license. Some of those concepts that seemed important with a minimal amount of words. And going back to Andy's point about how long the conversation was and how many words we used. But I think if there are other ways to address those concerns, the sort of spectrum of use cases, maybe there's a better wording approach, and I welcome more conversation tomorrow.

Andy Truscott – Accenture – Chair

So, thanks, Sasha. That's a very helpful amplification of the discourse that's been undertaken and the thoughtfulness that's gone into it from all members of the taskforce. I'm conscious we'll be moving to public comment soon after Ken's input now.

Ken Kawamoto – University of Utah Health – Member

So I think this is maybe just understanding what's stated as these are the only things that you can do without restricted, is the way I read it. So, of course, copying a whole bunch of screenshots for building a competitive product, it's not mentioned as specifically something you can do, which means it's under the already protections if you can protect it for fair use for intellectual property, etc. So that's the way I read it. So maybe it's just understanding. The way I read the regulations was unless it's one of these specific things you can do, you can't do it, is the way I read it. If that's the case, then unless it's specifically stated, I read it as you can't do it unless your vendor agrees on kind of thing.

Sasha TerMaat – Epic – Member

Let's talk further tomorrow because I don't know that that was the sense we had when we discussed it as a small group.

Andy Truscott – Accenture – Chair

Raj.

Raj Ratwani – MedStar Health – Member

I agree we should have a further discussion tomorrow. But while we have the team of ONC folks here, particularly Steve and others everywhere, can we get clarification on that so we can make sure – I think Ken and I are interpreting it the same way. Others may be interpreting it in different ways. Can you help us?

Michael Lipinski – ONC – Director, Regulatory Division

Yeah, I'll do my best. I don't have it up right now, so it's gonna be from memory. So there's the – what are they, seven categories? Usability, security – I don't have them all in front of me, for the communications. But Congress said you cannot restrict communications or inhibit communications regarding these six categories. And then what we did is we said – we actually proposed to give developers some ability to restrict. So, Congress said no restriction. It didn't give any exceptions. It didn't say, oh, but for IP, you can restrict. What we said as we looked at it and we tried to balance developer interest with what Congress was intending to – what we believed – and they had a lot of hearings, so we can look at actually Congressional intent here, what they were trying to achieve.

So we then created these certain categories, unqualified protections, where if it was regarding safety, if it was through a government agency, there was nothing that a developer could do to restrict that communication. However, we then set out – again, I forget my number – the categories. But IP was one of them. Beta testing was one of them. Employees. So these particular categories, I mean, it was them disclosing the information or for that purpose. We said if these certain conditions are met, the developers can place restrictions. And IP, as I said, was one of those. When it came to screenshots, though, we said, as Sasha mentioned, we interpret the use in these categories as fair use of those screenshots. There were only three preclusions that we put on that, or restrictions, as somebody who's gonna communicate that, a user who's gonna communicate that information. It just couldn't communicate PHI. They couldn't communicate a third party's IP.

However, even with that one, there was a further restriction they put on the primary developer there to try to obtain the third party IP rights for disclosure. So they couldn't just say, oh, there's third-party IP in there. You can't disclose it. They actually had to take affirmative steps to try to get a grant to disclose that. And then the last one was essentially, they can't distort it in a way that doesn't give it a true representation of the screenshot. So, does that help?

Raj Ratwani – MedStar Health – Member

Yes, that helps me. Ken, I don't know if you have any other questions, or –

Ken Kawamoto – University of Utah Health – Member

Yeah. I mean, it's basically saying unless – if it's saying for a screenshot, you can share it unless it's one of these things, then totally agree with putting in something like fair use. I just was reading it differently.

Andy Truscott – Accenture – Chair

We'll help make a clarification in the preamble as well. Clem.

Clem McDonald – National Library of Medicine – Member

Yeah. So now I'm totally confused about what you can really do. So I have one specific question. Could you get a screenshot, just take it, and put it in a publication, a scientific publication, or not? Do you have to do the "mother may I," which sometimes, the mother never says you may. I mean, I kind of heard that since you're intellectual property, you're screwed.

Andy Truscott – Accenture – Chair

Thank you, Clem. I understand your point, and we'll take it into consideration about how we can appropriately include that. I think we understand there are legitimate reasons why screenshots should be used, outside of the fact that actually, screenshots are sometimes used for exchanging information independent of the actual health record. And there are legitimate uses around why a screenshot is required for other use. But that use needs to be fair and appropriate, and not impinging upon the intellectual property of the vendor. That said, it's not fair for a vendor to arbitrarily say, you may not sure images of our IP. And this is the consensus from the group on balance as we talked through all the issues. Again, if you're around tomorrow morning, it would be really good to have that directly onto the taskforce, or we'll take written comments back directly and try to incorporate them to the best of our ability.

Clem McDonald – National Library of Medicine – Member

Right. I wasn't trying to suggest a change. I just was trying to understand the reality. And I think the reality is we're sort of screwed.

Michael Adcock – Individual – Chair

Mike, you had a comment?

Michael Lipinski – ONC – Director, Regulatory Division

Yeah, I'll just try to – now that I have the regulatory text in front of me. So what Congress aid for a developer participating in a certification program, is you cannot restrict or inhibit the communications regarding certain topics. And those topics were usability, interoperability, security, relevant information regarding user's experience, the business practices of the developers related to the exchange of electronic health information, and there's one more – the manner in which a user of the health IT has used the technology, which is essentially like user experience, again. So, that's the broad, okay? And so, then we broke it down to try to balance developer interest, right? Because, like I was saying before, if you just took that statement in the statute, that would mean anybody could say whatever they want or use their – about the health IT if it fell under those categories, okay? And so, we defined what those categories mean to us, or at least for the rule-making, we'll say what falls into security, what falls into usability.

Okay. But then we gave what is called unqualified and qualified protection. So it didn't matter who was saying it. So even if it was an employee, if it was regarding certain topics, there could still be no restrictions by a developer on it. So those topics could be required by law, cyber security threats – I think it was stuff about the certification program, information blocking. So we have a whole list of those. And so, that means anything. If you shared a screenshot for that, there's nothing – you're not saying they can preclude that in any way, if for any of those reasons, you were gonna be sharing with a government agency or so forth, that we lay out there. However, we said there were certain circumstances where we thought it was appropriate to give the developers some ability to restrict the sharing of the information, even in those six categories. So remember, you're still within those categories – seven. And if it's outside of that, then it's not in scope for this rule-making.

So, IP was one of them. So, screenshots, some folks will argue, developers, that it is a form of IP copyright, for example. We carved that one out particularly, screenshots, and say sharing it for these reasons is fair use, as long as you meet those three conditions I mentioned before. You're not sharing third-party IP – although, again, the developer has a responsibility to try to obtain those IP rights to be shared. Can't distort it, and it can't have PHI. So that's our proposal related to screenshots. But as I said, there are other reasons why they wouldn't – something about non-user-facing aspects, so there's a good one right there, where Congress focuses on user aspects. If they try to disclose non-user aspects, then we think the developer can restrict that. And we talked about IP. So other IP not focusing on screenshots, they could probably put some preclusions on it, and same for beta testing. The employees and contractors of them, we said they could put some restrictions on it. So I hope that is helpful.

Andy Truscott – Accenture – Chair

Thanks, Mike. Clem? No worries. Okay. With the absence of any further comments from the committee, I've been advised that public comment will be at the end of session. So we're not gonna open it up at this juncture. Thank you ever so much for your time. Thank you, members, of the taskforce. Your input is greatly appreciated and received. Thank you, Co-Chair.

Michael Adcock – Individual – Chair

Thank you, Co-Chair.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

So I know we are a little bit ahead of schedule, so I think at this point, if it's okay with the co-chairs, if we go ahead and break now, and then we can come back at . . . how about 2:30? Does that work? 2:35? Okay, thank you. We're gonna get started in about two minutes.

Operator, can we please open the public line again?

Carolyn Petersen – Individual – Chair

Can we sit down, friends, and reconvene? Thank you. I think we will continue our agenda with a presentation from Denise Webb and Raj Ratwani of the Conditions and Maintenance of Certification Requirements Taskforce. Go ahead.

Conditions and Maintenance of Certification Requirements Task Force

Denise Webb – Individual – Chair

All right. Good afternoon. So for our presentation, we'll do a quick review of our taskforce members and our charge. And then we are going to go into our recommendations. We are on taskforce today, but we'll be asking for votes from our fellow committee members. And our recommendations cover three of the four areas of our charge. One area, we had no recommendations. And we will proceed through this in an area by area fashion, as well as vote on each area individually.

Next slide. This is our illustrious taskforce. We've been meeting frequently and have had quite a bit of deliberation since the March 19th meeting. All right, next slide. And thank you to my fellow taskforce members. So the Conditions of Certification and Maintenance Taskforce was charged with providing recommendations on application programming interfaces, real-world testing, and attestations, conditions, and maintenance of certification requirements. We were also asked to look at updates to most of the 2015 edition health IT certification criteria, changes to the certification program, and the deregulatory actions for the program.

So before I launch into this first overarching recommendation, I just want to give you some highlights before we get started on how we're going to proceed through these recommendations. So at the March 19th meeting, we presented 33 recommendations. And we then received some feedback from several of the committee members. And we took that feedback and reviewed it, and we further deliberated on our recommendations. And we came to consensus as a taskforce on all of our recommendations except one that you'll see today, which is a new recommendation. And we have submitted our transmittal letter through our HITAC co-chairs, Robert and Carolyn. And like I had said, we will be asking for a vote, so hopefully, you all did your homework and read through our transmittal letter, because we don't intend to go over the recommendations that have not changed since our last meeting. We'll briefly put those up.

So today, we're presenting 36 recommendations. So that means that we have three new ones. And as I mentioned, one of these new recommendations is a draft we will not be voting on. And because we added three recommendations, and we didn't add them to the end, I just want to warn you that the numbering is not the same as when we presented these on March 19th. We have nine recommendations of the 36 that are revised. And that leaves 24 recommendations that we presented earlier as unchanged. So Raj and I will cover the recommendations for each area of our charge. And we'll quickly show the unchanged recommendations. And then we'll follow that with the new or revised recommendations for each area. And then we'll open it up for discussion, feedback, and then a vote. And we'll do that by area.

I will say that when we get to some of the 2015 certification criteria, we did not get the order flipped. We were trying to cover unchanged and then go into revised, but those are very short the last few areas. So we'll start with the first area. This is an overarching recommendation that you have already seen. And we want to stick with this recommendation, and asking the ONC to introduce a new certification, addition of certification, rather than proposed changes to the 2015 edition. I can say that we heard feedback from a number of CIOs, both from large and small healthcare delivery organizations, who endorse and agree with this recommendation. But they think – while I think we heard in the last meeting, there was a comment that the changes to the 2015 edition were considered minimal and didn't warrant a new edition, and we think the changes are significant enough to warrant a new edition. And we'll provide a clear demarcation between what exists in 2015 today that's effective in 2019, and what's gonna be required probably around the end of 2021, beginning of 2022, depending on when the final rule comes out.

So I will open this recommendation up for any questions and feedback and then would like to call for a vote. Steven.

Steven Lane – Sutter Health – Member

I guess I would just be interested in feedback from the ONC. I mean, when I read this recommendation, not having served on this taskforce, it made intuitive sense to me. I think your reasons for it are sound. I'm just curious what the ONC thinks.

Steve Posnack – ONC – Executive Director, Office of Technology

I was gonna see if I could get in on down to Mike Lipinski down there since he is here in person. That's okay. This is certainly feedback that we've received outside of HITAC as well, and it's certainly something that anybody else listening can provide feedback on pursuant to the public comment process. I'll probably restate some of the commentaries that I provided at some point at a prior HITAC meeting. Given the updates to some of the criteria vis-a-vis just the standards-related items, but not necessarily the functionality, from a full revision of the certification criterion, as well as the maintenance certification requirements that are now proposed to be part of the program as a condition of certification . . . at the same time, contextually for the industry as a whole, that the 2015 edition is first required for compliance by CMS this year, there is a kind of corresponding calculation that introducing a new edition could also be confusing, depending on how you want a look at things, about when that edition would be required, which would require CMS action, in comparison to the edition that providers are just being told – and we know that education rollout related to regulations is often difficult and takes a while. And so, CMS is making sure that providers understand that they have to implement 2015 edition in 2019, then subsequently, then having a similar edition of the year that they're currently working in could result in confusion about what the compliance requirements are.

So we are certainly open to everyone's feedback about how to best address making sure that the compliance requirements for our rules and the other rules in which they're referenced are as clear as possible to the industry. And that's a little bit of some of the context behind why we decided, at least going out, to effectively propose to keep the edition the same.

Steven Lane – Sutter Health – Member

Well, I would just say we have a nice opportunity in that ONC and CMS are doing such a great job coordinating their rules, so that if you ended up changing the name, you could do it together. And also, there's just something about looking back to a prior decade when we're talking about this is gonna be implemented in 2020, 2021, and you're looking back to an edition that has a digit off in that second spot, it just seems sort of odd. So, thank you.

Denise Webb – Individual – Chair

And I would just add that a number of CIOs that I spoke with, they said it creates great confusion, particularly in working with their vendors and scheduling releases. And 2015 dot what, what, what, versus 20-something else. That's what I was intending by the clear demarcation, and . . .

Steve Posnack – ONC – Executive Director, Office of Technology

Yeah. I mean, the only other thing I would add is largely – sorry, this is Steve again, for the transcript. Largely, this is a compliance obligation that the developers have to meet. And they will be capable and able to explain to their customers as well that they meet the current regulatory requirements that are necessary for them to continue to maintain their certificates. And we have ways to represent these new requirements that we've proposed on the certified health IT products list as well. We have tried in the past to propose having a version two of an edition, which, need I remind everyone that has been a party to that, was shot down. So, these are the different valences. We've tried different approaches in the past. And again, at this stage, in terms of the certification criteria that would have an impact on CMS's programs, were relatively modest in terms of the changes that we had proposed, was why, again, that we felt

that keeping the edition the same would cause the least amount of confusion. But again, that's the type of feedback that you're providing now and what others may provide as well.

Denise Webb – Individual – Chair
Okay, thank you. Andy.

Andy Truscott – Accenture – Member
Thanks, Denise. I think – well, I don't want to pile on too much, but it kind of – I'm gonna pile on a bit. Given the importance of these regulations, and given the fact that we are not just underlining it once, but two or three times, probably gonna stick it in red italics as well, maybe a bit of bold, and say, look, you've got to do this. This is really important. It's important for the country. It's important for where we want to go. And in terms of health IT policy, it just makes sense. Why would we not want to do a new edition of certification? I can ask Mike, if you want.

Steve Posnack – ONC – Executive Director, Office of Technology
So, perhaps just to help with any other questions that people may have – I know this kind of both a rhetorical question and a statement. We're not here to litigate the particular proposal. We're here to help you understand that context in which the proposal was made, and then you can provide us with the best recommendations for how you think the industry can subsequently respond to final rule-making. So if feedback from the majority of the industry is that a name change to the edition is welcome, we'd have to consider that and talk with our legal counsel and others about how to best address those clarifications, as well as make sure that that alignment, to Steven Lane's comment earlier, can be addressed at CMS. CMS has an explicit reference right now to the 2015 edition only. So there would be a regulatory change that would be necessary on the CMS side to update their rules as well to a new edition of certification criteria. And all this is doable with regulatory cycles and the like. But if you were to play out that change, there would be some need for realignment in the regulatory cycles. And that's just how things would get implemented.

Andy Truscott – Accenture – Member
Okay. That's helpful.

Michael Lipinski – ONC – Director, Regulatory Division
This is Michael Lipinski. I'd just add just a little more context. Not that it was determinative. But it would require recertification of all the criteria, even the ones that we're not changing. So anybody who's using public health functionality who's already been certified would have to come back in and get certified again. So it adds a lot of process, too, if you change the edition.

Steve Posnack – ONC – Executive Director, Office of Technology
Yeah. I mean, and just to piggyback on Mike's point, and that was one thing – thank you, Mike – that I neglected to mention, every time we've released a new edition of certification criteria, it creates, as Mike pointed out, a new certificate that developer's products need to be attributed to their systems. And in that case, again, given the kind of delta between the proposals that we have that we're changing certain criteria and some of the updates within criteria standards, we looked across all the criteria as part of the 2015 edition and tried to balance the burden on the health IT developer industry that has to go through the entire certification process again, in

comparison to just making updates to the certificates that their products were already issued. And so, there are lots of tradeoffs, right? There are communication tradeoffs. There's clarity related to what they're certified. There are the optics and decade number that's in the early 21st century-related references. So all those things are welcome opportunities and aspects for which we'd appreciate your comments, and I think is embodied in this recommendation, per se.

Denise Webb – Individual – Chair
Thank you. Clem?

Clem McDonald – National Library of Medicine – Member
Well, it seems like this really should be up to you guys. I mean, I didn't understand any of that with the first pass. It makes sense, package it once. But I don't think we're smart – we know enough to be fine-tuning. I think if it's the easiest for industry and all to get it done one way, same effect, the same changes, I don't know why we care.

Denise Webb – Individual – Chair
I guess my comment on that would be, I'm trying to understand how CMS's timelines for their program are going to align with when they say the provider organization has to have the version of the 2015 edition that enables all of the changes that are in the ONC rule. ePrescribing, for example, is a change that has to occur, which has a different date than the date prescribed for developers to have that in their product, so.

Steve Posnack – ONC – Executive Director, Office of Technology
Yes. I didn't know we were gonna get into this level of detail. No, I'm just kidding. There are a lot of dynamics, just to provide this context for everyone. As Denise mentioned, the current compliance state for the ePrescribing transition is January 2020, fast approaching. And that is kind of irrespective of the programs that reference certified EHR technology. That's a Medicare Part D ePrescribing requirement. The industry needs to comply with the requirement regardless of certification. And CMS has clarifications that they can provide in that regard.

With respect to the other certification criteria that would be implicated in terms of the changes to our program, and Mike can keep me honest, we, ONC, regulate those. And so, for the API certification criterion, the change from the current, let's call it non-standards-based API certification criterion to the secure standards-based API that we've proposed, that certification criterion is referenced in what we call our base EHR definition. We've set the two-year proposal for compliance requirements for health IT developers to roll those out to healthcare providers. So regardless of – without any CMS action, those compliance requirements should kick in because of ONC's regulatory authority. And so, we controlled for everything that we needed to do via regulation without needing CMS to take any additional regulatory action in order to align these two proposed – these changes.

And so, the same would be true for the EHI export certification criterion, which is also part of the base EHR definition. That change, again, would be a developer rolling out those upgrades to the healthcare providers to meet the updated certified EHR technology definition. Regardless of the edition of certification criteria that are referenced, those updates would need to occur. And if you play out 2019 being the first year that the 2015 edition is required, and past precedent

being that an edition for healthcare providers is usually in place for three or four years, we had to calculate – we had to forecast out if 2021 or 2022 is the year in which we expect these capabilities to be deployed, based on our rule-making. That would still be the edition of the product that all healthcare organizations would likely still have on the basis of the timing that those systems with the CMS regulatory cycle.

So I know that goes really deep into the weeds of the different turns of the regulatory cycles. But this is the ebb and flow of, if we release rules and then the industry takes three to five years to implement them, roll them out, use them, and then when subsequent editions and other cycles of CMS Promoting Interoperability programs go to change from a compliance perspective, that's usually another two to three-plus years afterward.

Denise Webb – Individual – Chair
Clem, did you have something else?

Steve Posnack – ONC – Executive Director, Office of Technology
I'm not sure I helped Clem, I can tell you that much.

Denise Webb – Individual – Chair
All right. Are there any other comments before we conclude on this recommendation and take a vote? All right. So for the committee and also committee members that are on the phone, all of those who are in favor of this recommendation advancing in the transmittal to ONC – and I should say that, as we vote on these, Carolyn and Robert will take all of these and compile them in their memo, their transmittal. So all of these in favor of this overarching recommendation, signify by saying aye.

Group
Aye.

Denise Webb – Individual – Chair
Any of those opposed, signify by saying nay.

Clem McDonald – National Library of Medicine – Member
Nay.

Denise Webb – Individual – Chair
We have one nay. And those who wish to abstain? All right. One abstains and one nay. All right. I am now gonna pass the presentation to Raj to go through the real-world testing.

Raj Ratwani – MedStar Health – Chair
Great. Thank you, Denise. We're on pace to be done by 9:00 p.m. tonight, so I'm gonna try to pick it up a little bit. So if we can get the next slide, please. So the majority of these are no changes. Next slide, please. We're going into real-world testing. So I'm not gonna read each one of these in detail. But please, as we're going slide by slide, if you want to talk about one in a little bit more detail or have a question, please ask about it. Recommendation two is pretty

straightforward. It has to do with the due date for real-world testing plans. Recommendation three has to do with clarity around care settings and the venue for which real-world testing should take place. Recommendation four is suggesting a template be created for vendors to use. Next slide.

Arien Malec – Change Healthcare – Member
Sorry. Before you go there, just an editorial comment. Everywhere we say CMCTF, we really should replace that with the HIT Advisory Committee, because the recommendations are being made not on behalf of the taskforce, but on behalf of the committees when they're approved.

Denise Webb – Individual – Chair
Right. So once it hits the other transmittal letter, those will all have to be updated.

Raj Ratwani – MedStar Health – Chair
Thank you. Do you mind going back a slide? Are there any other clarifications, questions on recommendations two through four, which have no changes? Okay. So, recommendation five is clarity around how successful real-world testing is met. Recommendation six is a clarification of terms, in particular, the terms "scenario," "use case," and "workflow." Recommendation seven has to do with permissible testing approaches. Those are all no changes from the previous week that we discussed these.

Michael Lipinski – ONC – Director, Regulatory Division
Can I ask a quick question, Raj? When you make these recommendations, are you making a recommendation that we clarify in the preamble, or that this should be in regulatory text?

Raj Ratwani – MedStar Health – Chair
Yeah, good question. I don't know that we thought about it at that level. I think it could potentially go in either –

Denise Webb – Individual – Chair
Actually, we did talk about that. And I believe this was in the preamble. But we could add that information and go through this to make sure that when Carolyn and Robert draft their memo, it does say this is a preamble versus regulatory. Because I think we have some places where we actually show regulatory text change.

Michael Lipinski – ONC – Director, Regulatory Division
Okay. Yeah, just because I think you guys understand that different contexts, that it's harder to change it in the regulatory text, and it has to be followed exactly as written then.

Denise Webb – Individual – Chair
Yeah, because these terms were actually used, and I'm trying to remember if they were used – and maybe one of the other taskforce members remembers whether "scenario" and "use case" was used interchangeably in the actual regulatory text. I think they were. But we can go back and look.

Raj Ratwani – MedStar Health – Chair
Mike, can you expand on the difference between modifications to preamble versus the regulatory text? Because we may not all be familiar with that.

Michael Lipinski – ONC – Director, Regulatory Division
Well, I mean, we can issue interpretive guidance. I mean, here, you're asking for it in a final rule, so it'll be how we expect it to be implemented. But if it's in the regulatory text, you could have to issue a new regulation to change it if it wasn't quite exactly either the way you anticipated it, or there was ambiguity to the term. So it's just really an issue of what type of flexibility is permitted in interpreting the regulation.

Raj Ratwani – MedStar Health – Chair
Okay. Sasha, did you have a comment?

Sasha TerMaat – Epic – Member
I was just gonna answer Denise's question. Scenario and use case focus testing are in the regulations. Workflow is used somewhat synonymously, but not in the regulation. That was just in the preamble. And I agree with Denise's conception that I think our intention was the preamble guidance to the final rule clarify if all those terms mean the same thing, or if they have different meanings, what the meaning of each of the terms was.

Michael Lipinski – ONC – Director, Regulatory Division
Okay. And I was really asking about all of your reason – I hadn't looked at them all. You're going over them now. But if there was any – I guess you'll specify where you do want it, probably.

Denise Webb – Individual – Chair
Yeah. I think you'll see in some of our recommendations, we actually show changes to the regulatory text, like around ePrescribing. And I would have to say, on this particular recommendation, if you all look at this and then you look at the definitions, and you determine the definitions of the two are different, then we definitely need the clarification. If you discern that the definitions are the same, then you might want to consider changing the regulatory text to take that ambiguity out of the regulation.

Raj Ratwani – MedStar Health – Chair
Okay. Any other questions or comments on these three recommendations? Okay, so moving to the next slide. I'm noticing that we skipped a recommendation number, so it went from seven to nine. Sorry, what?

Denise Webb – Individual – Chair
It's revised.

Raj Ratwani – MedStar Health – Chair
Got it. Thank you. Okay. So, recommendation nine has to do with clarification of the expected involvement of providers and third-party support for real-world testing, so there's no change to this one.

Next slide. Recommendation 10 has to do with flexibility around real-world testing where there's no difference in the testing approach for the capability. And we have the suggestions listed there. Next slide. Recommendation 11 has to do with a description of measurement when it comes to real-world testing. Sorry, Andrew. Stand up and wave.

Andy Truscott – Accenture – Member
Yeah, no, I'd be willing to **[inaudible] [05:42:50]**. Just a quick question. When you say no change, do you mean no change?

Raj Ratwani – MedStar Health – Chair
No, sorry. What we mean is there's no change in this recommendation from the previous presentation of the –

Andy Truscott – Accenture – Member
Okay. So I was listening to something – you probably said that, and I was just completely missing the point.

Raj Ratwani – MedStar Health – Chair
No, you're right. That's ridiculous.

Denise Webb – Individual – Chair
No, I did.

Andy Truscott – Accenture – Member
Or you did. Sorry. I didn't mean to –

Denise Webb – Individual – Chair
You must have been asleep.

Andy Truscott – Accenture – Member
Same recommendation.

Raj Ratwani – MedStar Health – Chair
Exactly. So these are all recommended changes. And where we say no change, we have not changed the recommendation since the last time we presented these to this committee.

Andy Truscott – Accenture – Member
Thank you for correcting my ignorance.

Raj Ratwani – MedStar Health – Chair
Okay. So recommendation 11, again, was clarification on the description of what would constitute measurement. Recommendation 12 has to do with standards version advancement. No change to either of those from the previous presentation. Next slide. Recommendation 13.

The ONC should clarify the role and expectations of third parties when it comes to real-world testing. Recommendation 14. ONC should review and revise the regulatory impact time estimates.

Next slide. This is why we went out of order. Recommendation eight was the key one where we have a revision, and there are two components – I think actually a few components to this. The first is that we sort of rephrased the language here to strengthen the role of usability and human factors when it comes to the use of exchange data. So where there is an examination of use, there should be more human factors in usability testing. And the second modification is when we're talking about foreign data and native data, and the representations of those data, not being overly prescriptive, and instead, emphasizing the need for a user-centered design approach when it comes to the representation and testing of those elements.

And then the final is to recognize that as we construe the use of data as requiring or should involve usability testing, realizing that there is a significant expense to doing that. And so, it's mostly to call out that we understand that there's a significant expense there, and that should be built into the estimates, which is one the previous recommendations, or additional recommendations.

Denise Webb – Individual – Chair
Right. And I'll just add that you'll note there that there was no cost considered for users or providers being involved in this real-world testing, and that probably needs to be revisited.

Raj Ratwani – MedStar Health – Chair
Arien, question?

Arien Malec – Change Healthcare – Member
I'm maybe confused about what we're actually proposing and recommending. Is all of the subordinate bullet text part of the recommendation, or is it additional considerations for ONC relative to the recommendation?

Denise Webb – Individual – Chair
All of the above.

Arien Malec – Change Healthcare – Member
So, I'm sorry. I understand that if this is adopted as is, we're recommending that ONC should provide clarification around testing, both relative to exchange and use, and noting that exchange and use have different considerations with respect to human factors design. And then with respect to the broad recommendation, I'm having a hard time –

Denise Webb – Individual – Chair
The second part, the first bullet is around specifically used of data. Testing use of data.

Arien Malec – Change Healthcare – Member

What's the recommendation?

Raj Ratwani – MedStar Health – Chair
Yeah, I think it's a good point. And the recommendation, I think, is that first paragraph and the two bullet points are more of context around the recommendation. So in this case, that's a little bit more of trying to represent the dialogue and conversation that we had, and why that recommendation is being made. Others, please chime in, because I don't know that we actually talked about it in that way, but in my quick scan of it now, that's the way that it seems.

Denise Webb – Individual – Chair
The last sentence in the first bullet does specify a recommendation around the use of data testing, that that use validates the data user receives in the certified health IT is viewable, actionable, and reportable, alongside the user's native data. And we're not suggesting that we prescribe how that's architected or how the health IT developer decides to do that. But there's been a lot of feedback about – and again, this came from a number of CIOs – how data comes in from outside, and it's put someplace else. It's not easily accessible alongside their native data. It's not really user-centered design.

Arien Malec – Change Healthcare – Member
Yeah. So my meta-recommendation here is – and work that I've done in the past when I've formatted recommendations letters is to separate findings or discussion from the formal recommendation itself so that you can tease out what you're actually agreeing to relative to the recommendation, and that ONC understands the context and then the actual recommendation.

Raj Ratwani – MedStar Health – Chair
Yeah, good point.

Denise Webb – Individual – Chair
Do we want to hold on voting on this and have it reworked?

Elise Sweeney Anthony – ONC – Executive Director, Office of Policy
So I leave that to the committee. And Arien, please correct me if I'm wrong – it doesn't sound like Arien's saying that there is a substantive issue. It's more in terms of how it's organized. So if that is the understanding of the taskforces, you can probably vote on it and change the format. And I'll turn to Lauren to make sure I'm correct on that. Okay, yeah. So the substance is there. I think it's just – and you can even say, a friendly amendment to note the sub-bullets as findings, and vote with that friendly amendment standing.

Arien Malec – Change Healthcare – Member
Yeah. That amendment is so offered.

Denise Webb – Individual – Chair
Okay, that'd be great. And then we can reword it for Robert and Carolyn as they put it in the larger memo that's going to encompass all the taskforce's recommendations.

Raj Ratwani – MedStar Health – Chair
So I'm gonna go in the order that I saw them. So, Clem first.

Clem McDonald – National Library of Medicine – Member
So I think that the red stuff is spectacular. And I don't know what's the finding and what's the other one. But that will force the generation of messages that work, because that means you gotta have a code for potassium that will line up with the code for potassium in your own system, more or less. And if they can find another way to do it, that's fine. But I mean, that's what's essential. And it's like you said, it's horrible. It just goes into a dump bucket somewhere with all the other stuff. So I think it's a great recommendation.

Raj Ratwani – MedStar Health – Chair
Thank you, Clem. Don.

Donald Rucker – ONC – National Coordinator
Yeah. I would just say, as processing with the language of these things, we have to be careful in how much language we put in, because there's an arbitrary complexity to the real world, right? The real world is complex. So if you say we're gonna represent the entire real world, I think you want to sort of what I think in computer science is a cut set. So you want to think about, there has to be some boundary. And I think frankly, some of this will evolve over time. So some of these things are setting a direction of where we want to go. And that may be, to Clem's point, using standard vocabularies. But some of the recommendations here, I think there's not a definable boundary. And I think we just want to be real careful as to what that is, so we can have something that's actionable. So I would throw that definable boundary as a subtext on some of these language things because otherwise, you're never going to have anything that people can act on. And obviously, Congress left it pretty ambiguous. And so, it is for us collectively to sort out over time how these things are implemented.

Raj Ratwani – MedStar Health – Chair
Thank you. Andrew.

Andy Truscott – Accenture – Member
Thanks. I think this might have a bit of an unintended consequence the way it's currently drafted. It does feel like a bit of an overreach in trying to mandate how solutions are constructed and built. I agree with Clem's point that actually, this is great. But that should be up to the market to decide, not for us to mandate.

Raj Ratwani – MedStar Health – Chair
So can you elaborate a little bit more in specifically –

Denise Webb – Individual – Chair
Which part?

Raj Ratwani – MedStar Health – Chair
Yeah. Which component here?

Andy Truscott – Accenture – Member
Oh, the first section of red text up there. Yeah, user-centered design. It's all good stuff, okay? But we shouldn't be mandating. We should let market dynamics within the boundaries of regulation, as opposed to saying – being really tight and rigorous.

Raj Ratwani – MedStar Health – Chair
Yeah, I think that's a really good point. I am a strong proponent of market forces. When it comes to usability and safety, which I think this touches heavily upon, we tried to mimic what was in safety-enhanced design, which is in the existing regulations around usability testing of the base product. So that's why we stayed at the level of saying – encouraging a user-centered design approach. That mimics and mirrors what's in the current regulations under safety-enhanced design. And I think that's where the taskforce felt comfortable in terms of how prescriptive we would get.

Andy Truscott – Accenture – Member
I understand how you got here. I'm just responding to what this means in the real world. And also, user-centered design means different things to different constituents. Whether you're a developer, or whether you're a consumer, or whether you're someone who's gonna be purchasing health IT, this means different things. And we don't really want to use regulatory text to dive into that definitional work, I don't believe.

Raj Ratwani – MedStar Health – Chair
Okay. Any other questions or comments on this slide? Okay. Next slide. And I believe that is the end for real-world testing.

Denise Webb – Individual – Chair
Question. How do we want to proceed? Do we want to vote on each recommendation individually? Or do we want to pull some of these out and then vote on the rest of the group?

Raj Ratwani – MedStar Health – Chair
Well, let's maybe take a couple of questions first, because I saw two more pop up. Sasha?

Sasha TerMaat – Epic – Member
I'd like to suggest that we incorporate some of the suggestions from Dr. Rucker and Andy, and even Arien, to the wording and the formatting, and perhaps provide less ambiguity for when we do move it forward for a vote.

Andy Truscott – Accenture – Member
I agree. I think we all agree this is good stuff. We just want to maybe massage it a little bit more. And if we've got one way to do so, then that would be good too. I'm looking at Elise as yours.

Elise Sweeney Anthony – ONC – Executive Director, Office of Policy
You're looking at me, and I was looking at Carolyn. It's up to the committee. It sounds like

what's on the table is either whether you vote on it or now, or whether a couple of tweaks are made and it comes back. And that's up to the committee, how they want to proceed.

Arien Malec – Change Healthcare – Member
Just as a point of procedure, can we vote via email rather than in-person meetings? Because we don't have time to do an in-person vote relative – before the comment period time, right?

Elise Sweeney Anthony – ONC – Executive Director, Office of Policy
There is the 4/25 meeting. Or do it beforehand? So there is – I know the Information Blocking Taskforce will be coming back via the virtual call on 4/25, and that might be a means for us to tackle the voting for this there as well. **[Inaudible background voice] [05:55:30]** Yeah. Okay. Carolyn, does that sounds okay to you?

Carolyn Petersen – Individual – Chair
Yes.

Donald Rucker – ONC – National Coordinator
I mean, we should be able to – is there any regulatory reason under FACA why we can't do this by email?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
No. We would just need to have every member copied on that email.

Donald Rucker – ONC – National Coordinator
Okay. So I think people are accountable for their vote, as they are in person. Obviously, email is a better record of that than the voice vote. And I think we can readily do it that way for people's time efficiency, and yeah.

Raj Ratwani – MedStar Health – Chair
So I think it would be helpful for us to maybe get a little bit more feedback from the committee on which of the specific recommendations we should focus on as we go through our refinement phase, just in the interest of time. So, totally understandable that we're not going to want to vote on all of these now or any of those particular ones. But if we can get a little bit more direction. Noted on recommendation eight, I think there was certainly some work that needs to be done. Are there others?

Denise Webb – Individual – Chair
I also heard, based on Mike's comment, that it would be helpful to ONC if we looked at each of our recommendations and specified whether we're suggesting further explanation in the preamble or actual regulatory text changes, which we can do.

Raj Ratwani – MedStar Health – Chair
Aaron, did you have a question?

Aaron Miri – The University of Texas at Austin – Member

Yeah, I had a question real quick. Well, I didn't see it in your recommendations, but maybe I just missed it, or maybe it's an appendix part that I'm just not seeing here. Do you have any linkages and other items in here regarding synthetic data and what that actually looks like? I know you talked about data looking like it looks in the real world for testing and whatnot. But there are certain standards out there from just government bodies and others saying what synthetic data could look like in standards and such, and referencing, and that kind of thing. That may help in terms of clarification in addition to formatting. It's pointing at relevant data sources out there to say, and we mean this, right? And that will help alleviate and answer some of the questions, because those are standard formats out there if such a thing exists.

Raj Ratwani – MedStar Health – Chair

Yeah, that's a good point. I don't think we've articulated that anywhere. If you have specific pointers, that would be greatly appreciated.

Aaron Miri – The University of Texas at Austin – Member

Yeah, MITRE and a bunch of others have some great, great stuff out there. So I'll point it to you.

Raj Ratwani – MedStar Health – Chair

Great. Thank you. Okay. Before we move on, other recommendations from this particular set around real-world testing that you'd like the taskforce to focus on during our next refinement phase?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

So, Denise and Raj, just as a heads-up, I see we have just one slide regarding attestations. If you have time, we can address that before we need to move on to the next taskforce presentation. Otherwise, we could wrap up now and then move on.

Raj Ratwani – MedStar Health – Chair

Yeah, I think we should do attestations if we can. And this is a pretty straightforward one, is that ONC should include a specific deadline at the middle of the year/end of year, and end of year/beginning of year. So it's just a clarification on the timeline.

Denise Webb – Individual – Chair

Lauren, would it be possible – and I know we're tight on time – but to point out the other three new recommendations?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Sure. I think we want to give folks time to consider that. Is that the idea, Denise?

Denise Webb – Individual – Chair

So, if you could advance the slides to the first new recommendation, number 19. So I think that's three slides. This is a new recommendation that we added, and also one of our revised

recommendations. And recommendation 19 has to do with, instead of referencing the Argonaut implementation guides, to require compliance with the HL7 U.S. Core FHIR implementation guides that are derived from the Argonaut implementation guides. So this is a new recommendation. We'd ask the committee to carefully review this.

And then the next one is on the next slide, recommendation 21. This concerns providing formal guidance on compliance with relevant privacy and security regulations such as HIPAA, current uses of FHIR APIs, such as Smart on FHIR applications or CDS Hook services.

And then the last, if you'll scroll forward to self-developers, we were not going to ask for a vote on this today. But if you all could take a look at this and provide input, if you have any, we would like to do a little more deliberation on this as a taskforce, because our entire group had not reached consensus prior to the meeting today. And the proposed rule requested comment on whether the conditions and maintenance of certification requirements should be applied to self-developers. And obviously, this taskforce only looked at real-world testing APIs and attestations. And the information blocking taskforce looked at information blocking assurances and communications. So this is the third new recommendation.

And then you'll see in these slides the other remaining revised recommendations. There are three under API, two under EHI Export, and then a revision under the ERX, one under CQM, and one under Privacy and Security, 2015 edition. Aaron, did you have something?

Aaron Miri – The University of Texas at Austin – Member

Yes, I did. So again, I think I'll get more reference component of it when you're referencing the privacy and security component and clarification around, especially API. There was a lot of work done on the API FACA and others in prior groups. Maybe referencing those and saying build upon this. Particularly with API FACA, OCR did a great job of trying to clarify and help give some guidance, and they give good rubrics in that. We also referenced that in the annual report workgroup. So maybe reference that and say build upon this. Start here, so we're not starting from zero, and then go forward, right? Anything else that's come up in the past, I don't know, year, year-and-a-half, two years since then.

Raj Ratwani – MedStar Health – Chair

Thank you. Arien.

Arien Malec – Change Healthcare – Member

Yeah. A couple of pieces. So one with regard to recommendation number 19. I would advise us to reword the recommendation. It contains some text that I think is maybe not intended as inflammatory but could be taken as inflammatory, with regard to the relationship between HL7 and Argonaut. Generally, the way that Argonaut works is that there's a formal relationship between Argonaut and HL7. We take the membership fees that we have, and we actually support and sponsor HL7 activities. And I think there's no issue with the notion that implementation guides should go through the process through HL7, and that that's the appropriate place for that to happen. But the remainder of the text, I think, makes some statements that I don't think are advisable in recommendation text.

And then I'd also note that ONC generally needs to follow, under executive order – help me out here, Steve – the one that references voluntary consent standards. Okay, great. Thank you. Well, there's the Acton and there's the EO that enables the Acton, etc. So I think there's already generally guidance that ONC should be adopting voluntary consensus standards. Again, I have no issue with the notion that we should be asking for use of HL7 or other voluntary consensus body implementation guides, just would request we take out some of the additional sentences.

Denise Webb – Individual – Chair

So are you specifically – I mean, to help us out, do you either want to send us an email or are you speaking where it starts? And I don't know if we can put 19 up on the screen here – where it starts with "This is because Argonaut is closed"?

Arien Malec – Change Healthcare – Member

Yeah, I would just strike –

Denise Webb – Individual – Chair

Strike that?

Arien Malec – Change Healthcare – Member

I would just strike everything other than the – I mean, I think the first two sentences are fine. And again, that's generally the way that we work anyway. With regard to the notion of ONC providing guidance for HIPAA compliance, it's, first of all, gonna be hard for me to figure out how ONC's gonna provide general guidance. Secondly, I think OCR would be the agency, to the extent that there's any guidance relative to interpretation of HIPAA. So you might want to rephrase that to ONC should work with OCR with regard to – and I believe the particular issue is scoping of data requests relative to CDS Hooks and apps. And so, maybe I'd request a modification for ONC should work with OCR and other agencies regarding the appropriate scope of data requests to CDS Hooks, apps, and other activities in order to address use minimization or something of that nature. Because I think that's actually the specific concern.

Ken Kawamoto – University of Utah Health – Member

Minimum necessary.

Donald Rucker – ONC – National Coordinator

Yeah, minimum necessary. That was Ken. It's the discussion about the minimum necessary and how to define that. Maybe whether that is better defined as the purpose of use to actually get something done, rather than as some de minimus.

Arien Malec – Change Healthcare – Member

Yup, exactly. Thank you.

Carolyn Petersen – Individual – Chair

And with that, I will thank the CMC taskforce chairs for their presentation and the excellent discussion we've had this afternoon, and we will move on to the USCDI presentation.

Arien Malec – Change Healthcare – Member
Sorry. Again, just a point of procedure. We voted on a set of these recommendations. We did not vote on the subsequent set. Okay.

Carolyn Petersen – Individual – Chair
Yup.

U.S. Core Data for Interoperability Task Force

Christina Caraballo – Audacious Inquiry – Chair
Okay, let's get started. So, say we are going to go over our updated recommendations. We can go ahead and move to the next slide, next slide. On the agenda, it does say that we're going to vote. We don't have our transmittal letter done today, so we're going to refrain from voting today, but hope to tighten up all the recommendations, so that's just a quick vote in our next meeting on the 25th. So, review of our charge. We are looking at the proposed data elements in the USCDI and making recommendations on them. This includes new data elements in patient demographics, provenance, clinical data notes, pediatric vital signs, as well as any other missing data elements that the taskforce identified.

So, go on to the next slide. We've all seen this. This is just a snapshot. In purple, you'll see where we're focusing our comments today. Just a reminder as we go through this that the USCDI is the base requirements of standards for interoperability. So, next slide. A few things as we went through our recommendations that we wanted to point out to the group because they're kind of our guiding principles. First, we wanted to be very parsimonious with our recommendations as we thought about new data elements. And we looked at dividing those recommendations into two groups of buckets. First, those that can be implemented now. So every time we considered a data element, we said to ourselves, is this something that is available and can be done, and it makes sense to recommend to ONC to turn it on right now in USCDI, or is it something that's not quite ready for prime time and needs to go into our next process that we'll save for when we go over our expansion process, throwing it into bucket two.

So with that said, each of the sections of the data classes that we will be reviewing today starts off with the ONC recommendations for data elements to include within the data classes and the taskforce's responses to those. And then we move into additional recommendations from the taskforce, as well as we provide some information on the justification of how we came to our recommendations.

So moving on to the next slide, we're going to start with the patient demographics. One thing I'll note is that in the slides, anything new is in red. So if you remember during our earlier committee meeting this month, we went over patient demographics, which were well received, and then started with provenance. And then today, we're going to introduce the clinical notes and pediatric vital signs. So we really didn't see many changes or updates to patient demographics. For address, we've recommended the use of standardized format for address. Actually, one thing that we did put in that didn't make it into the red was considering an international standard. So, we had referenced a hema report and the use of the United States Postal Service. When we get to our discussion, one thing we want to discuss is the reference to

an international standard for address.

Our second recommendation under demographics was the phone number. We've highlighted the cell phone as primary and landline as secondary. So, move on to the next slide. For address, whether it's under address or another data element, we've also included under demographics to add the email address. And then other things that we've identified – so I guess we did make a couple changes here in red – were to add a section specifically denoted to the pediatric demographics, including contact information for individuals or individuals with consent authority. This really addresses multiple parents, guardians, custodians. And then we also want to include multiple addresses for schools and these additional guardians and parents.

In addition, this is not new to our discussion the last time, but we have added language to consider adding the last four digit of the Social Security number, as well as vetted IDs when available, but not as a requirement, and to continue to consider thinking about those that are experiencing homelessness or displaced and refugees. We also added self-reported gender identity through our discussions.

Next slide. Oh. These are general discussion. Sorry, moving on to provenance. So this is kind of a snapshot of things that came to light as we were going through the patient demographics discussion. We identified three use cases that we think are really important, and patient demographics can help with, including patient matching clinical care and identity verification. We highlighted that the standard address should include a past address as well. The mobile phone number really came across as the most stable patient identifier, so we wanted to highlight that. While we talked about biometric data, we do not think it can be supported by the USCDI at the time. But that was discussed in our conversations. We also added that the pediatric demographics that recognizes an immediate need of service providers provide clinical care. Secondary attributes as components to matching logic in USCDI are valuable and can really help facilitate downstream magic and linking.

And then finally, as we went through our recommendations and discussed each of the different data elements, we constantly thought about the benefits versus the burdens.

Terrence O'Malley – Massachusetts General Hospital – Chair

Okay. So the way we're gonna do this is we're gonna go through each section. And then at the very end, we have a series of questions we want to ask you as the HITAC, and perhaps save your questions for that same section at that time, so we can get through and get everyone back on their planes in time. So for provenance, we took the ONC proposed data elements on the left – author, time stamp, author's organization – and we essentially did two things. We changed the term "author" to "agent entity," which is more consistent with some of the standards that are out there, and we essentially collapsed "author" and "author's organization" into "agent entity" as being similar and a little more parsimonious, and agreed that the time stamp was also a critical piece.

The next slide, please. So, lots of red on this. And we recognized that "author" and "author organization" are the first step. It's by no means how granular we could get or we're probably going to need to get to identify these folks. But for example, the FHIR descriptors include 17

attributes for an author or for the agent entity. We'll start with two, which is really kind of a reasonable spot to start. And then what we really wanted, and what came out of our discussions, was the realization that what provenance can probably give us, besides some reassurance about the trustworthiness of the data, is it really can give us a unique identifier for a particular data element, and one that could really persist for that data element across multiple transitions. And with that sort of unique persistent data identifier, we can do a lot more with the data. It's gonna be easier to parse and certainly will help us with provenance. And we recognize that no such data field exists right now in metadata, that there's no persistent identifier. So we're gonna have to create a new metadata field.

Next slide, please. So some of our discussions were that it's really sort of the who, what, and when. And so, the first who and when, so the author, author organization, is really agent entity. That's the who. The time stamp is the when. And then the third component is really the what. And then what is what kind of data is this anyway? Is this a note? Is it a lab piece? Is it a prescription? What is it? So there are taxonomies of data types that are out there which we can point to and which we will point to. So the three things, the who, what, and when, we think is the basis for the unique identifier. And obviously, starting with these three, it can just be the beginning. If it looks like we need more, then we can go to more. So again, the unique persistent identifier. And our rationale for choosing agent entity versus author was basically a bit more general term. So, not all authors are agents and entities. And not all agents and entities are authors. So we wanted to make sure that we included under "agent and entity" machine-generated data, data aggregators, other data manipulations.

So, next slide, please. Okay. So that's provenance. And the next piece was clinical notes. And there were – along the left-hand side, the ONC proposed data elements or note types. And our conclusion was, these are all great, and they're extraordinarily valuable, and everyone should have them. No real comments, other than Clem raised the issue of making sure on the laboratory report narrative that people can't use that to just dump lab results in. It ought to be restricted to actually specific special reports and narrative about a particular lab, rather than the lab itself. And then their procedure note, our only question was, does this include an operative note? Operations are procedures sometimes, but do we need a separate and distinct note?

Next slide. So this is the others. So these are more recommendations that we made in addition to what ONC proposed. And really, one is just confusion about data element versus note. We wanted to change that to note or document. And then add the following clinical note types. And these are really based on CCDA document types. But it included continuity of care, operative note, referral note, transfer summary, and care plan note. And our question was, why not include them all? They're already there. They're standards-based note types.

And then there were three more notes that are not in the HL7 group but are of extraordinary value, particularly to providers of service who are not sort of the eligible providers, beyond the hospitals and the ambulatory care. And it's really groups of information that are valuable across the whole care spectrum, including home and community-based services. And actually, long-term post-acute care in between. So, one was the reconciled medication list, and the realization that A, reconciled, so who did it and when did they do it, is an extraordinarily valuable set of information. Advanced care planning is another, again, a very discrete dataset that we thought

was important. And then finally, long-term services and supports. This is really the bridge between clinical care and supportive services. And I think we're gonna find that that bridge is gonna be traversed more often as we get to value-based payment.

Next slide, please. So some of our discussion was that we just added everything else, the document types that are already out there. And particular comment about the transfer summary note, which we took to mean information that's specifically required for the ongoing care of an individual, and contrast that with the discharge summary, which currently plays that role, but is actually a poor substitute, because it includes a lot of extraneous information that's of absolutely no value to the downstream clinician and omits a lot of information that is of particular value to the downstream clinician. So we wanted to make sure the transfer summary got included. And the new note types – advanced care planning and long-term services and supports, again, have value across the care continuum, and I think are important to add. And of note, the long-term services and supports care plan is currently in the ballot at HL7. And there'll be an IG coming up.

Next slide, please. And pediatric vital signs. So we finally did something unique in the history of our taskforce. We actually reduced the number of proposed data elements from what ONC provided. Instead of adding another 10, we actually two away. And the basic point was, focus on the core data, the raw, core, basic data, the weight, the age, the height, the length, and not take that and generate secondary data elements that require a calculation, a nomagram, another data set. So, BMI is a calculated value, right? It's based on age, weight, and sex. And it's a nomagram. There are several nomagrams for BMI. There are many nomagrams. So, instead of sending you a different nomagram with a different BMI, we said, just send the core data. The only item that's a new pediatric vital sign, we thought, was vixabal frontal circumference. So basically, head circumference. And we clearly think that's of huge value.

Next, please. And we just wanted to make sure, unless you're standing up, in which case you have height, you otherwise have a length. So just add length as another core measure. And then, just again to be clear, and we just couldn't find the clarity, is that the current USCDI vital signs apply to all age groups and not just the adults. And then finally, when and if we require calculated values, that they apply to all age groups. Because there are a lot of calculated values that are pertinent to adults as well.

Next slide, please. So, our discussion. This is when we actually had a difference of opinion, which we tried to solve. But one group said that just send the raw data, and let the receiving system calculate it in the way that they feel is most appropriate for them. And we learned from Ken, who hopefully is on the phone, that there are smart apps out there that they can actually do that calculation now. And the other group felt that there are groups of users, stakeholders, particularly patients and parents, who may not have this capability readily available for them, in which case these values would have some pertinent value. So we decided our compromise was if your system already calculates these values and stores them, then send them. But if you don't already do that – say you're just calculating the value on the screen, but it doesn't persist as a data element, then that won't be a requirement.

Next slide, please. And then we've got to – this is our gratuitous set of recommendations. These

are extra at no additional cost, was under provider demographics. So, the care team. We thought we probably needed a provider demographic, and this was our first stab at it. And there are probably better ones. But if you think about building a provider registry, what do you need to know that it's a unique provider? And so, that's sort of the thought behind provider. And then we also thought about, do we need a consistent quality template that allows an entity to, A, know what their quality metrics are and respond to them in a sort of standardized way, given the recognition that the quality metrics are gonna drive a lot of how healthcare is provided? And the question is, do we need something like that that just makes it easier to participate? And then finally, there are some Medicaid-mandated pediatric measurements – hearing screening, development, vision – that are useful identifiers, and again, sort of promote good patient care.

So, next slide, please. So for the additional recommendations, again, for provider demographics, in addition to the provider registry, it really gives us the opportunity to ultimately pin the specific clinical responsibility to a particular provider. This provides really critical for care plans. And again, we're gonna be building care plans, and they're very complex documents. But this is a fundamental piece of them. Including the Medicaid required reporting elements, the vision and hearing screening, is just, again, a way of introducing quality measures into the dataset that we're proposing for certification. And it recognizes, again, the tight link between quality metrics and where we're hoping to go. So that's the last bullet, is again, thinking about quality measurement as its own category.

So now we're gonna go to questions. So we have questions for the HITAC. Here are our questions for you guys. And we will also entertain questions for you. And let's keep it to patient demographics. And we're gonna go through all four of them, so. We'll start – should we recognize – I don't know who got up there first, but we'll go – why don't we arbitrarily go down the right side? Dr. McDonald.

Clem McDonald – National Library of Medicine – Member
I don't know – you said Clem, right?

Terrence O'Malley – Massachusetts General Hospital – Chair
I said Clem.

Clem McDonald – National Library of Medicine – Member
Okay. So this isn't only demographics. Except for the provider, the NPI has all that stuff you want, except the specific connection to the patient, which would not be part of a provider demographic, because that's a patient crossed with the provider attribute. So I think you're pretty much there already if you've checked the fields in the NPI. Do you want to just limit the questions to demographics?

Christina Caraballo – Audacious Inquiry – Chair
So on that one, Clem, we recommended that it go under the care team.

Clem McDonald – National Library of Medicine – Member

Well, I thought the heading was provider demographics.

Terrence O'Malley – Massachusetts General Hospital – Chair

Well, this one's patient demographics. We had provider demographics under Other. So we'll get to Other. Want to come back to that?

Clem McDonald – National Library of Medicine – Member

Okay. Then I'll wait for that.

Terrence O'Malley – Massachusetts General Hospital – Chair

All right. We'll come back to you, Clem.

Clem McDonald – National Library of Medicine – Member

I'll say the same thing then.

Terrence O'Malley – Massachusetts General Hospital – Chair

You will. Okay, Arien, off in the corner?

Arien Malec – Change Healthcare – Member

Yes. So I have a few important comments and one nitpicky comment. So with respect to length and height, these are two names for the same underlying attribute and requiring a separate field for each of those just complexifies [sic] the situation. So I'm thinking about my mind as an interoperability developer, where I've got to look for both, and then if both are present, then I've got to figure out which one I use or not. And then maybe I implement logic. If under three, then I look here. Better just to have one attribute and say it's height, and it is interpreted as length for people who can't stand and need to be measured foot to tail, or foot to head, or otherwise. Yeah.

Terrence O'Malley – Massachusetts General Hospital – Chair

Yeah. Agreed.

Arien Malec – Change Healthcare – Member

Yeah. Foot to tail would be a different measurement. Okay. So with respect to identifiers, there's a very important contract. So first of all, I applaud the taskforce for including persistent stable identifiers. I agree with the taskforce that it's gonna be probably one of the biggest bangs for the provenance buck. There's an important contract that goes along with identifiers, which is that if you send me the same identifier – so first of all, we need to make sure that they're appropriately scoped or are globally unique. And then there's an important contract, which is that if you send me the same identifier, then you're asserting that the underlying data hasn't changed. And if you don't do that, then you're back to scraping all the data and trying to figure out whether it changed. So we just need to make sure that that contract is enabled such that users of UCSDI can rely on the stable identifier.

And then the third is with respect to notes. I believe there is –

Terrence O'Malley – Massachusetts General Hospital – Chair
Arien, let's come back to notes once we're done.

Arien Malec – Change Healthcare – Member
Okay.

Terrence O'Malley – Massachusetts General Hospital – Chair
We're gonna do one section at a time.

Arien Malec – Change Healthcare – Member
Perfect. Okay. Thank you.

Terrence O'Malley – Massachusetts General Hospital – Chair
My mind can't think of three sections at once. Okay. And who've we got? Andrew.

Andy Truscott – Accenture – Member
Thanks. Arien took most of my points. I was ticking them off. The other ones were, you mentioned vetted IDs. So a bit more specificity on what you mean by vetted. You sort of listed out state driving licenses. Well, obviously, we have secure – well, Clem's sign went up immediately when I said that. So what is vetted? What is in state driving licenses? What do we mean, secure ones, or what? Because there are actually two classes now besides –

Terrence O'Malley – Massachusetts General Hospital – Chair
Yeah. Secured ones. Yeah.

Andy Truscott – Accenture – Member
There are many different uses of the word vetted. It would be nice to have some clarity around that. Actually, no. We need some clarity around that.

Terrence O'Malley – Massachusetts General Hospital – Chair
Well taken. Okay. And Clem, are you back up?

Clem McDonald – National Library of Medicine – Member
It's not repeating. So, the idea of using a cell phone, I think is a very good one. But do realize that it doesn't always identify an individual. I know many families where the husband and wife have the same number, so. Some families have, I think.

Terrence O'Malley – Massachusetts General Hospital – Chair
Yeah. A unique identifier for the user. Okay, yeah. I hear you. All right. And Carolyn.

Carolyn Petersen – Individual – Chair
Just a gentle housekeeping note. We're at 4:03, and we do need to break at 4:15 for public

comment. We can keep our closing remarks fast and short, but time is not on our side.

Terrence O'Malley – Massachusetts General Hospital – Chair
Thank you.

Andy Truscott – Accenture – Member
Yeah. Just to respond to Clem's comment there, yeah, cell phone numbers, telephone numbers, in general, are not necessarily globally unique. However, their use in a particular time slot in a period of time is, and there are actually companies out there right now that do track precisely that kind of information. And they also can correlate geospatial patterns around that same cell number and detect changes, etc. But the cell number's actually, I think, quite a valid one because it doesn't manifest – it's not imbued with the same manifest privacy concerns as other identifiers are, because hey, I can just change my cell phone. Give it to Clem.

Terrence O'Malley – Massachusetts General Hospital – Chair
All right. Can we go to the next group, please? Next slide. Thank you. All right. Provenance. Here's what we want to ask of you guys. So we already heard that unique identifier makes sense. But let's just have some comments on provenance. This time, Clem, we're gonna go around the other way. So we'll go to Steven.

Steven Lane – Sutter Health – Member
Thanks. And a word on saying both of you for just a great job you're doing with this taskforce and the presentation today. It's been really excellent. You talked about the author versus the source organization. And I think it's worth just taking a moment to clarify that really, I think what the taskforce is suggesting is that we really just start with the organization; that the challenge with the author is that it really varies by data type. The author of a vital sign, the author of a test result, the author of note, the author of an RX. And either it gets way more complex, or it gets simpler until we have the time to go back and deal with that level of complexity. When I speak to people who are interested in provenance data, there's the original author and there's the last touch. That's the thing that people seem to be most interested in. Where did I get it from, and where did it come from originally? And I think starting with that at the level of the organization is certainly reasonable. Certainly, if you're talking about a clinical note, hopefully, the name, the provider or clinician, is gonna be in that note somewhere. But it's very difficult to define the author of a blood pressure in a way that's gonna be consistent across all systems within a couple of years.

Just a brief comment on the unique persistent stable ID. Arien, you made a comment that if the data changes, you want a new ID. This idea came up in our ISPTF taskforce. And the whole idea of the persistent ID is if the data changes, you've got the same ID. That if you're versioning the data, if there's an updated – somebody modifies the node, or if there's a final on a radiology result, that it goes back to the same ID, not that they give you a fresh ID, so that you can connect that first version with the latest version.

Arien Malec – Change Healthcare – Member
Maybe you then want a stable ID and a version identifier. The practice that I was describing is areas where we're trying to do reconciliation of information. And we would get the same

information multiple – I mean, multiple, multiple, multiple times. And it would be highly useful to have a stable identifier such that we could just go skip, skip, skip, skip, skip. I think your point is right on. When there's a change to the data, it's useful to know that as well. And so, the notion of a stable identifier with a change flag or a change identifier would also be really useful. That's a great point.

Steven Lane – Sutter Health – Member
Agree.

Terrence O'Malley – Massachusetts General Hospital – Chair
I think Sasha.

Sasha TerMaat – Epic – Member
I agree that a stable ID with a version identifier would be very helpful. I think that would be a useful addition to provenance. I am still, I think, left, based on Steven's comments and what's on the slide, a little puzzled as to exactly what is expected for the agent entity for a particular item in the USCDI and for the agent entity organization, both of which I think are, in our analysis of how we would implement them in our software, surprisingly complex to determine. And I'm worried that if they aren't done consistently across the industry, they will turn out to be quite low value. There's some conversation within HL7, I understand, that emphasizes the role of the entering user in the system, whether that's a device or a person. And I'm not clear if that's what's intended by the words "agent" and "author," or if the agent and author have more of a responsibility and role that supersedes exactly who entered something into the system. But I really think that for this to be implemented in a way that is useful, we will need really clear guidance on what that means for each of the different data classes so that it can be done meaningfully.

My suggestion would be to focus on medications and notes as use cases where I would see the sort of value as being very high. Focus on those first, and leave items like blood pressure – Steven used it as an example – to a future round of clarification so that we can avoid having to redo the implementation of this information if it's done inconsistently in the first round.

Terrence O'Malley – Massachusetts General Hospital – Chair
Thank you. Yeah, Clem.

Clem McDonald – National Library of Medicine – Member
So, I don't agree with that. I mean, what I've seen the horrible clutter is in drugs and in tests, where you can't see the forest for the trees. And you get them from many places through a secondary or third party. I don't know if that's as true for notes. So I wouldn't be distinct. The idea of needing to know the what, I think, is – we talked about it. That's in the record that you're putting a provenance on. If it's a test, it's gonna be saying what the test was and a lot of other things. If it's a drug, it's gonna be saying what the drug was and a lot of other things. So I don't think there's a need for what, because provenance doesn't stand alone. It's kind of a piggyback on some other resource in the FHIR vocabulary.

And then back to the unique identifier, I think its major value is to get rid of clutter. And you may be right. I mean, right now, it's just you kind of match. You've got a date and time, and you've got some other things. And I think if we could nail the organization, I think that would be the best one. And maybe even say it's got to be an NPI – it doesn't work for everything, but it works for a lot of things. Hospitals have NPIs as well, of course. But I mean, I don't know the answer. This needs an HL7 discussion, I think, to sort it all out. And I guess that's really all. Oh. There's a possibility we could use the ID, what's called the observation ID, or there's an equivalent one for every record in the resource, each resource. You name the resource, name the ID, and then it may need to have something else on it, an OID. And that would work if you carried it as a separate field forward. Anyway, just some thoughts.

Terrence O'Malley – Massachusetts General Hospital – Chair
Okay. So, time check. We've got three-and-a-half minutes. Andy?

Andy Truscott – Accenture – Member
Well, I really want to have a OID conversation now, but we'll pile that one for later in the bar. I think we need to draw a distinction between having a stable identifier and stable identity. Identifiers are gonna change over time, and they will change over time, but we need to have them referring back to a constant identity. So I'm just picking up on Arien's comment there. And also, when it comes to nomenclature, if we are leveraging standards, development organization things like HL7, **[inaudible] [06:41:53]**, you name it, we should utilize their nomenclature and not seek to redefine terms, otherwise, we're gonna end up with unending ambiguity.

Terrence O'Malley – Massachusetts General Hospital – Chair
And Sasha.

Sasha TerMaat – Epic – Member
Just on the point about organization, I think we all agree that it would be undesirable from a workflow and usability perspective to be consistently popping up questions about what is the agent entity organization for this blood pressure or this data entry into the system. And the assumption I would put forward is that the organization should be contextually based in the health IT product based on other things, like the department, or the role of the user, and so forth. But we know from other types of health IT work that making those assumptions about what organization a particular user is representing at a particular time is actually quite complex. Many users use the same health IT with different organizational relationships and different business entities that they might represent. And there will certainly be cases where the organizational affiliation has to be guessed at or isn't accurate in the system. And so, I think that sort of that consideration, I agree with. Clem, we're not gonna figure them out today, but they're gonna be really critical to implementing the provenance concept in a meaningful way.

Terrence O'Malley – Massachusetts General Hospital – Chair
All right. We still have two minutes. Okay. Next slide, or back a slide.

Christina Caraballo – Audacious Inquiry – Chair
I think they're wanting us to break for public comment.

Terrence O'Malley – Massachusetts General Hospital – Chair
Oh, you want to open the lines now, and then we'll come back.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sure. Why don't we go ahead and do that now, and then we can keep that time.

Terrence O'Malley – Massachusetts General Hospital – Chair
Okay. Yup.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Do we have any public comment in the room, to start with? If anyone has a public comment, please come to the presenter table and state your name. Seeing none, Operator, can you please open the public line?

Operator
If you'd like to make a public comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press *2 if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the * key.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
And do we have any comments in the queue?

Operator
Not at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. I'll hand it back to you, Terry.

Terrence O'Malley – Massachusetts General Hospital – Chair
Thank you. If we can go back a slide. Yup. No, I think you can come forward, forward, forward, forward. Keep coming.

Christina Caraballo – Audacious Inquiry – Chair
One more.

Terrence O'Malley – Massachusetts General Hospital – Chair
One more. There we go. Clinical notes. So, questions for you guys. Does it make sense to add the clinical notes we did, or is it too much? And then you can have any other questions. Steven.

Steven Lane – Sutter Health – Member

I think that adding the full range of notes and document types that are represented in the CCDA make sense. I think having different standards or portions of standards included in regulation is just gonna be confusing to the industry. CCDA does a good job of adding things as needed. They recently added a few more notes. I think it does make sense to point to that standard as opposed to having a separate one in this rule.

Terrence O'Malley – Massachusetts General Hospital – Chair

Andy?

Andy Truscott – Accenture – Member

I'm musing on whether – I think adding the CCDA's makes sense, but I'm musing on whether we don't want to appear to be recommending a limitation because these things are gonna change, right? In 10 years' time, FHIR will be old hat. I would kind of like these regulations to persist. So maybe working out some language so that we're not finding ourselves putting something in place which, in the not too distant future, has moved on, would be . . . I was gonna say X12. X12 has a place in the world. And quite frankly, I think some of the things we're gonna be doing around the payment information – we're gonna depend upon X12. Probably, it would be some kind of mapping into FHIR resources all together. So, yeah, that would be my kind of suggestion as you consider this one out.

Terrence O'Malley – Massachusetts General Hospital – Chair

So taken. And Steve? Arien's first. All right.

Arien Malec – Change Healthcare – Member

Steve knows what I'm gonna say, so he's got the luxury of knowing that he can build on top of my comments. So one question occasioned by maybe the question of all the different report types, the note types, is when there are semantic considerations for each of those types that are highly specific, we need to be thoughtful about whether we want all of the note type to be included, and then make sure that we build all the bidirectional capabilities, as opposed to having – I don't know if the intent is to do that or if the intent is to make sure that there's a LOINC code that says this thing is a block, because there are very different requirements for adhering to all the standards in all cases. And then this has been a previous comment, but there may be – for previous rounds of certification, there may be some report types that just aren't applicable for all EHR types. So we need to be careful about what we're asking and how we're asking it.

And then I think there's a role for the unstructured note type, in particular, with regard to the Cures requirement that all data be available. We are not gonna structure all data. And so, we need a mechanism, both in terms of EHR export, as well as in other cases, to be able to offer unstructured information. And when unstructured information's available, it should be provided as is, and when applicable, should have the applicable text associated with that note. That text is useful for machine learning and other kinds of purposes. But just a plea for the use of an unstructured note as one of the permitted note types in USCDI to allow for all the data to be exchanged. Thanks.

Terrence O'Malley – Massachusetts General Hospital – Chair

No, you identified one of our omissions. So ONC omitted some notes. We omitted that one. Steve.

Steve Posnack – ONC – Executive Director, Office of Technology

Speaking of omitted notes, part of this is, as you all have probably read at least once, the context that we included in the proposed rule in the preamble about the choices that we thought through relative to the amount and quantity and types of clinical notes to include. The sensitivity that I would say over the past decade that we have acquired through our regulatory efforts is there isa wide catalog of specifications that different standards development organizations produce, and the implementation guides associated with them, that frame in technical ways how to do things that are not ever or always implemented by the implementing community. And the kind of juxtaposition that we're in is trying to gain as much insight from industry stakeholders before we issue rules. The interoperability standards advisory is one of those places, and then other advisory committee meetings and other events that we get to attend, where we are able to assess where people are actually implementing things.

So one of the historical aspects of the CCDA is prior to the consolidation of all the CDA documents, they were all their own separate implementation guides, and it was hard for people to implement. So they all got consolidated into the consolidated CDA. And then what we saw from a certification and kind of revealed preference, as you might say, from an implementation perspective, was how the IT developers were just using the CCD to get the job done. And the other document templates that were included in the CCDA were not being implemented or deployed in production in a wide support type of approach. So that gets back to my earlier statement of just because they're in specifications and perhaps available technologically does not always mean that the implementer community has found them easy to implement and/or useful in a real-world way. And so, we just have to be careful about looking to what's in the standards development catalog to say, these are things that should be in when we don't have a lot of implementation experience to back up that they'll be well implemented when we regulate them. A forewarning of experience that we have from the past few years.

Terrence O'Malley – Massachusetts General Hospital – Chair

Yeah. Thank you. And Andrew? Still up? Nope, still down. And is that Arien? Are you . . . Dr. McDonald.

Clem McDonald – National Library of Medicine – Member

So this is actually a response to Steve. So everything you guys just said is true, and I believe it. But Medicare has a claims form. Man, it's – bam, they just do it. And there's the other challenge – these are network phenomenon. And if I'm the first guy with a telephone, it's kind of hard to sell telephones, so you gotta get a critical mass of users. And then it could be self-fulfilling. So, yes, you're right. But we got to push them a little bit to see if we can get over that hump where we get kind of continuous burn.

Terrence O'Malley – Massachusetts General Hospital – Chair

Right. Thanks. Thanks, Clem. Pediatric vital signs. So, our big burning question. Send the raw

data or send the calculations? And any other pediatric vital signs comments you would like to make. So, Anil Jain, we'll put you up.

Anil Jain – IBM Watson Health – Member

Yeah, sure. So one of the things that we have to recognize is that when the systems are collecting the BMI, or measuring the BMI, or even the percentiles, they're doing so based on the model at that time. So if a clinical decision is made with that number, and then we're expecting some downstream system to recalculate that, I think that's a mistake. I think we should be sending whatever information is available for that clinical decision support at that time, which would include the raw data plus any calculated value that might be relevant. Especially if you have a vulnerable population like Down syndrome, you can be looking at a different growth chart. So my recommendation would be to include all that information, especially if it's being used to make the decision. Whether it's stored or calculated, if it's being presented to the clinician, it should be sent along.

Terrence O'Malley – Massachusetts General Hospital – Chair

Yeah. And we actually had that specific discussion about recognizing that there are different nomagrams based on conditions, as well as which certifying body nomagram you want to use, CDC or someone else. But point well taken. Thank you. Steven?

Steven Lane – Sutter Health – Member

Yeah, I think, Anil, to that point, that one of the challenges is that when I look at a pediatric growth chart, there're all these points. And each one of them, whether I'm looking at the height, the weight, the BMI, the head circumference, they've each got a percentile. And I can click a button, and I can change which nomagram I'm using. And then they each have a percentile. And so, we're talking about orders of magnitude more data that needs to be stored, and then needs to be transmitted, and then needs to be received and stored again. So I think we were really looking at what is the cost benefit here? That when you think about it, the computer programming that's required to do a quotient to give you a BMI or a weight for length is pretty low-level computer programming, right? I mean, even a PHR or any old system out there, they could hire a teenager, and they could have that programmed for them. And so, it's not difficult programming.

I think your point is well taken. If a decision is made based on a calculated value. But I think the challenge from a computer science perspective is how do you know which one of those potentially tens of thousands of calculated percentiles were used to make a decision? So I think that's where we thought, let's keep it simple at the start. Let's add that head circumference for sure. If a system calculates and stores a value, then they should go ahead and send that. And there's value to that. But if they don't, why ask the systems to suddenly have to calculate and store all these values that are probably of very, very low value?

Terrence O'Malley – Massachusetts General Hospital – Chair

Thank you. So, three minutes, all right? The three-minute shot clock is up.

Clem McDonald – National Library of Medicine – Member

It's fair to send it if you have it. And I don't think it's fair to compute it if you don't have it. And

probably, they didn't seem to make a decision if you didn't. So, I mean, I think you came up with a good compromise with that last proposal, and I just would stay . . .

Terrence O'Malley – Massachusetts General Hospital – Chair
Thank you. Andy?

Andy Truscott – Accenture – Member
Yeah, hi. I think it's fair to send what you've got. And if you've got a calculation too, send that. But just say what you're sending. Frankly, many lab tests, the calculation you have to do, because you can't just send the raw data, because that's gonna be fairly meaningless if you don't understand the entire context of the result that's being generated. And otherwise, there were certain things that actually, you might want to recalculate because you have a different protocol, and that would be fine. So I think send both, and just say what you're sending.

Terrence O'Malley – Massachusetts General Hospital – Chair
Ken? And Steven, you're back up.

Steven Lane – Sutter Health – Member
Yeah, not looking for the last word here, but I think we breezed over the point, which is that if your system – if we do have a requirement to send percentiles, don't just send it for the BMI. I mean, blood pressure percentiles are every bit as important. Length percentiles. If we're gonna go down the path of percentiles, it should apply to all vital signs. And you included that. But I just wanted to highlight that point.

Terrence O'Malley – Massachusetts General Hospital – Chair
All right. No more flags. We're on time. I pass it back to Madame Chairman.

Carolyn Petersen – Individual – Chair
Awesome. You gave me a minute back. This is groovy. So we are at 4:27 on a meeting that's scheduled to end at 4:30, and we want to be respectful of you. So I will do the bullet point closing comments. Our next meeting is April 25th, and then there will be another virtual meeting in May on the 13th. At this time, that April 25th meeting is our final shot to vote on everything that we've discussed today and some other things that haven't come up yet. It may be wise to block some additional time on your calendar, because it seems we are very likely to need it, given where we are today. You can find all the materials for this meeting, previous meetings, transcripts, audio and verbal information about all of the taskforce meetings, on the calendar on the ONC website. So if you heard about something today that you'd like to know more about or get more context for, you can click on all of those things off the taskforce calendar on healthit.gov. And there is also a schedule of upcoming meetings. So if you have more input, please, please do call into these taskforce meetings. We're always happy to hear more from our colleagues on the HITAC.

With that, I will just conclude by asking our ONC colleagues to please make a decision about extending the timeline of the 4/25 meeting as soon as possible so we can do what we need to do to clear our schedules. And at this point, I will thank you all for your honest attention, the

great respectful conversation today, and pass it to Lauren.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

We are adjourned. That's it. Thanks, Carolyn.

Carolyn Petersen – Individual – Chair

Thank you.

Duration: 419 minutes