Information Blocking (IB) Task Force

Transcript
March 15, 2019
Virtual Meeting

SPEAKERS

Name	Organization	Title
Michael Adcock	Individual	Co-Chair
Andrew Truscott	Accenture	Co-Chair
Cynthia A. Fisher	WaterRev LLC	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil K. Jain	IBM Watson Health	Member
John Kansky	Indiana Health Information Exchange	Member
Steven Lane	Sutter Health	Member
Arien Malec	Change Healthcare	Member
Denni McColm	Citizens Memorial Healthcare	Member
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin	Member
Sasha TerMaat	Epic	Member
Lauren Thompson	DoD/VA Interagency Program Office	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member
Lauren Richie	Office of the National Coordinator	Designated Federal Officer
Cassandra Hadley	Office of the National Coordinator	HITAC Back-up/Support
Mike Lipinski	Office of the National Coordinator	Staff Lead
Mark Knee	Office of the National Coordinator	Staff Lead
Penelope Hughes	Office of the National Coordinator	Back-up/Support
Morris Landau	Office of the National Coordinator	Back-up/Support
Lauren Wu	Office of the National Coordinator	SME

Transcript

Operator

All lines are now bridged.

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

Okay, thanks. Good morning, everyone, welcome to the full task force meeting of the information blocking group. We are excited to hear progress from each of the three sub workgroups today, so with that we'll get started, starting with roll call. Andy Truscott?

Andrew Truscott – Accenture – Co-Chair

Present.

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

Michael Adcock?

Michael Adcock – Individual – Co-Chair

Here.

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

Steven Lane?

Steven Lane – Sutter Health – IACC Workgroup Member

Here.

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

Sheryl Turney? Denise Webb?

Denise Webb – Individual – IACC Workgroup Member

Present.

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

Sasha TerMaat?

Sasha TerMaat – Epic – Task Force Member

Here.

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

Aaron Miri?

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Task Force Member

Good morning.

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

Arien Malec? Arien?

Arien Malec – Change Healthcare – Task Force Member

Good morning.

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

Great. Valerie Gray?

Valerie Grey – New York eHealth Collaborative – Task Force Member

I'm here, good morning.

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

Good morning. Anil Jain?

Anil K. Jain – IBM Watson Health – Task Force Member

Good morning.

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

Cynthia Fisher? I don't see her on Adobe, we'll maybe get her on the phone later. Lauren Thompson? John Kansky? and Denni McColm.

Denni McColm – Citizens Memorial Healthcare – Task Force Member

Yes, I'm here.

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

Great. Okay, I am going to turn it over to Michael to get us started with an overview of the workgroups' progress to date.

Michael Adcock – Individual – Co-Chair

Well, good morning. Thank you very much. Good morning, everyone, welcome to our task force meeting. I guess this would be our second major task force meeting. I wanted to say good morning and happy Friday to everyone. I hope that the weather is improving wherever you are. I want to start out by saying thank you. Thank you to all the members of the task force, and all the individual workgroups that are out working. There has been a lot of great discussion, there's been a lot of progress that has been made. I'm very impressed with the progress that has been made up to this point. I wanted to thank the staff from ONC for keeping us on task, and for making sure that we have done what we need to have done up to this point. We'll thank the folks from Excel, as well, for making sure that these calls all go well. There's a lot going on, I think this would be our seventh call this week, just out of the task force. A lot of work going on, but I won't belabor that point. I'm going to guide us through the overview of the workgroups, just like we did last week.

We're going to talk through workgroup one, two, and three, call for any proposed recommendations that we have out of those workgroups, but again, that's just going to be informational for everybody, we won't do a whole lot of discussion or any discussion during that point, it's just bringing everybody up to speed on what the workgroups have going on. Then, Andy and I will open it up and talk about some of the big picture and overarching issues that we've come up with this week from the individual workgroups, and just try to remind us of what we are trying to get done, importantly, but also any of those big topics that we need to discuss we'll discuss there, and also anything that you hear during the updates that you want to discuss, we can certainly discuss those as well. If we can move to the next slide, please.

Steven Lane – Sutter Health – Task Force Member

Michael? Comment? I'm assuming that in this process we will also be identifying key items that we'll want you to include in the update to the HITAC next week? Yes?

Michael Adcock – Individual – Co-Chair

Certainly. We will discuss that at the end, so if you will note those while we're going through it. The most time that we have is in that last little bullet item, overarching issue. So yes, we will discuss that during that time.

Steven Lane – Sutter Health – Task Force Member

Perfect.

Michael Adcock – Individual – Co-Chair

Thanks for that question. That's a great question. So, here's the overarching charge for the task force. I don't know that we need to remind you of this, but you know what we're trying to get done and what we're doing, so we'll move to the next slide. So again, the draft timeline. One thing that I want to point out here, and we'll kind of skate through this on the rest of them, but I know that we've been pushing really hard to try to get to the point of where we are now, which is draft recommendations for HITAC for next week. I just want to remind everybody – and Lauren mentioned this yesterday on the call, and Mark may want to speak up to this point, but this is basically a progress check for us. So, we're going to present any draft recommendations that we have during the HITAC meeting next week – but that doesn't stop things. It's not like we have to be complete.

We have one more group that is very close to being complete, as far as what the workgroup progress needs to be, but we have two others that have a lot of content and still have some outstanding issues, and we'll talk about those today, that we need to work through. We're going to continue to work through this, even after the HITAC meeting. You can see on here that there's more than one presentation of the recommendations to HITAC. So, we've got a couple meetings pretty close together, so we will be able to discuss those. We've got some time left on this, I know we've been pushing really, really hard to try to be as close to complete as possible by this week, but I just wanted to remind everyone that we do have time left, there are some issues left that we have to work through that are complex. If they weren't complex, we wouldn't be tasked with trying to look at them, so we still have time left on that.

This is just the group one meeting schedule. We've had multiple meetings, we had two meetings each week. Next slide, please. So, the topics discussed, we spent a lot of time talking about health information networks and exchanges. The one proposal that we had is when you look at those definitions, we think that the distinction between an HIE and HIN should be clearer. One of the discussion points that we had is whether the definition would cover the broad scope of entities, but such terms should cover based on the intent of Cures. We want those definition of HIE and HIN to be broad enough to capture the intent of Cures, but not so broad that it removes any other category from being necessary. Everybody should not fit into one category, they should fit into the category that they are acting on at the time. So, we have to make sure that we're working through the definition, and we are.

We revised the definition of HIE to mean an individual or entity that enables, facilitates, or performs the access, exchange, processing, handling, or other use of electronic health information. If you look at the way that proposal is, compared to what is in the rule already, we added those few pieces as far as facilitating, and looking at processing and handling instead of just access and exchange. We also removed some language at the end that was, to the workgroup, very vague. It had possibly, in some other pieces in there, limited scope and limited group. It wasn't very clear, so we removed some of that. We will revisit that definition at the end in the workgroup, next time we talk. But that's what we are looking at right now. We're still working through the HIN definition. We've all been tasked with some homework to look through that on our own to try to come up with some possibilities and some proposals.

The electronic health information definition proposal: add text to the preamble that clarifies information that is inclusive or human or machine-readable form. This is something that Andy discussed and others agreed with, brought up some actual real-world examples – so that we make sure that information is clear, that we're not just talking about something that can be read by a human. We are talking about stuff that could be considered data in previous forms. We don't want there to be any loopholes for things being left out of information blocking. So, that will go in the preamble instead of the definition, just so that we make sure we are clear. We had a lot of discussion around pricing information, on the consensus that proposed the definition of EHI should be read to include pricing information. We're going to review ONC's RFI regarding price information to provide more detail about the scope and parameters of price information, that will be included in the implications of including such information in the definition.

Another piece of the discussion that we had – it could be on the next slide, I'm not sure. But a big part of that discussion was around unintended and intended consequences, and the overall cost of including pricing information in this rule. So, we are looking at that, we are having discussions further around that. This will be one of the issues that we discuss in our overarching issues. Next slide, please. So, that's the end of group one. A lot of great conversation, I think a lot of people thought that the definitions might be a little bit easier than potentially the exceptions. But I'll tell you, after sitting in that group for four phone calls now, there are a lot of things that we have to be very careful of, and part of that is because we know providers can act as health information exchanges or can be part of that, and we know that HIEs and HINs sometimes are confused, so there is a lot discussion around definitions.

Group two is the exception group. Again, lots of great work going on. We've had multiple calls on that one as well. Lots to discuss, again, making good progress. We've had lots of great discussion. Next slide, please. We talked a lot about promoting the security of EHI. We proposed that they clarify documentation requirements for when a practice does not implement an organizational policy. We had consensus around that when the requester is the data subject, or patient, then security is no reason to prevent sharing. Unless there is a legitimate doubt of the identity of the patient, determining whether the current drafting requires a proposed recommendation. So, as long as we know it's the patient, there's no reason that we should not share that information based on security. Again, only if there is a concern about who the patient is, and we can't confirm the identity of the requester is actually the patient.

Responding to requests that are infeasible, we had a lot of discussion around the meaning of "providing a reasonable alternative." So, one of the pieces in there is that there must be a reasonable alternative, if it's deemed infeasible. It can't just be that you just don't want to do it or that you want someone else to do it, it has to meet multiple criteria. The group thinks that the requirement that "the actor timely respond" is unclear. Anytime you see just "timely respond," that is left up to interpretation, so we're trying to look into determining whether or not we need to propose a revision for clarification to that particular point. Next slide, please.

The licensing of interoperability elements on RAND terms. So, again, we had a great deal of discussion around this. A lot of this was around time frames, but we did have a lot of discussion. We proposed that we add the requirement that licensors must publicly post contact info for requestors

to contact them, and requirement that requestors must use that publicly posted list to contact licensors. The confusion around that is if you have only a certain amount of time from the time you're contacted, there's one thing to contact a public number, or your media contact, or public affairs office. It's another to contact the person that can actually do something about that concern. There is a responsibility that falls on both parties there. One, that whoever is receiving that request has to post who should receiving it, and then again, whoever's contacting them must use that publicly posted list to contact the licensors or it does not kickoff that timeframe.

We determined that the 10-day response period in (a) is unreasonable for offering license – to try to get from request to license in 10 days, I don't know what organizations everyone works in, but I can tell you in every one I've ever worked in, 10 days is nearly impossible. So, we're looking at proposing an alternate timeframe. The other proposal is to build in timeframe for licensor to acknowledge receipt of request in the overall response timeline. So, instead of just ignoring it or waiting until the actual license estimate or quote is put out, we want to suggest potentially 72 hours to acknowledge that receipt, so that you know whoever's requesting those, that the request has been received by the correct person, and that the process has started. We are considering a proposal to clarify the scope of rights. We did not get through this entire exception, it was a very large exception, and we will continue to work through that. Next slide, please. That's the end of workgroup two.

Workgroup three: conditions and maintenance of certification. Again, lots and lots of conversation around this. I will say, this workgroup is probably the closest to having draft recommendations, and if I'm not mistaken, this is one that we don't have – we had a meeting late yesterday afternoon, I don't think we have all the updates on the next slide, but I'll walk through them as much as I can. Next slide, please.

So, the topics that we discussed: under assurances, we proposed that the three-year retention period for products that are withdrawn. Also, the ONC should retain records on the CHPL indefinitely for ongoing references – which products were certified over which time period. The discussion around that, and Andy can certainly chip in if he wants to, was around if a provider happens to be part of a lawsuit, or something like that happens, but he says he was part of a certified EHR at that time, but there are no records to show that it was certified at that time – that could cause issues, and turning things off after three years could be an issue. We want to revisit TEFCA RFI to make recommendations when the revised draft of TEFCA is published, or have the other task force address it, either one. There was a TEFCA task force. Once the proposal comes out – or the draft comes out – we need to revisit that, because we can't really revisit it at this point.

Under communications, we had a lot of discussion. This is the proposal. We want to clarify that administrative functions could be "non-user facing aspects." We want to determine how to address the issue, possibly through a functional definition or the examples in the preamble. We want to make sure that those administrative functions that really don't have anything to do with the user-facing aspects, that we have some way of making sure that those don't necessarily fit under information blocking.

The second proposal under there is: unintended consequences of "fair use" and other usages should be further explored by ONC. There are concerns about risks to vendor intellectual property that the task force wishes to be sensitive to. We do not want to impinge upon innovation. That's one point that came up over and over again and is a great point. We don't want to slow down innovation, and if "fair use" isn't clearly defined as it pertains to this, there could be unintended consequences. One of the examples was about someone writing a scholarly article that included screenshots and other pieces of multiple EHR vendors' products, and then once somebody else got that using it under something, it would not be "fair use." So, we just need to explore that further, or ONC needs to explore that further.

We also want to draw a distinction around the purpose of use regarding screenshots. We want to make sure that the purpose is clear. We're still determining the details of proposal, we don't have the proposal finalized on that one yet. Next slide, please. Again, we're continuing communications. We had lots of proposals under this one, lots of discussion again. We want to clarify via a list which third-party content might appear in a screenshot. Enumerating elements per screen is not feasible, there's just too much going on there.

The next proposal there is to eliminate the two-year timeframe for contract amendment and propose update at next renewal. So, that's something that we saw trying to – and Andy brought an example up of this one, if his company went through and had to meet a two-year timeline to amend every contract they had going on, it would have required four additional attorney FTEs, so it just wasn't feasible. We want to look at that around contract amendment time, but also make sure people have a plan, that there is a plan developed on how they're going to do that within a certain time period, and then that it gets done within another time period. So, we're still working through that. That's some of the stuff that didn't make it that we discussed yesterday.

Next proposal: unintended consequences of "fair use," and other usages… okay, we discussed that already. Create a third communication bucket for "unprotected" communications; examples there are false communications, attorney-client privileges, etc., we feel that's important. Enforcement, the proposal is to make sure we use both email and certified mail for notices initiating direct review, potential non-conformity, non-conformity, suspension, proposed termination, and termination. So, there's a very defined process for where the developer is in that, but we need to make sure that instead of just emailing, that if we feel this is important enough, especially if it leads to a ban, that we use not just email but also certified mail.

As far as the ban, we had a good bit of discussion around that. We talked about whether appropriate to list the ban that is lifted. One of the proposals that we came up with there – and it's not on here – that companies that have a ban impose on them, even once they clear it up – they can clear it up as quickly as possible, but even once they clear it up, it is listed on the CHPL indefinitely. The purpose of that is to make sure – it would be listed not as active, but actually the dates of the ban – that it would be listed so that – and this is a recommendation. It would be listed so that anyone that's looking for that would be able to find, okay, well this developer was banned during this time period. It's over now, it's an information point so that we have, as consumers and as people potentially looking for some of those developers' products, that we have a place to go look and see if something's been banned, and if it was banned, that it was cleared up.

We talked a bit about self-developers, called out an exception to proposed communications for self-development systems, so that communications by health IT users aren't restricted by virtue of being an employee of the same company doing the development. So, what we're asking for here is that if a hospital or a health system develops its own software, that the users of that software aren't restricted just because the hospital developed, or the company they work with developed that software. Users shouldn't be held under that. Next slide?

Okay, so that was the end of that. And again, there were some things that we talked about yesterday under task force three that may not have made it, just because it was so late and we had the slides out in plenty of time for the public meeting today. But again, I want to thank the workgroups for all the hard work. I'm not saying that's the end of the hard work – there's still lots of work left to do, but certainly there has been an amazing amount of discussion, and points, and the one thing that I do appreciate is that even though we've had differing opinions, people have shown nothing but the utmost respect and professionalism as we've discussed those. I think that there are lots of groups that could learn from that, being able to have differing opinions and still discuss them in a manner that is respectful. It's been great, it's been an honor talking about those, and open it up to Andy to talk about anything I've missed, and then potentially move on to the next point, which are the overarching things.

Andrew Truscott – Accenture – Co-Chair

I don't think you missed a thing, thank you so much for that. I'm hoping that members that are on the call, you can see how the deliberations that you've been involved in are manifesting themselves now, in the broader implications of the group, or where we're at, too. Now, as everyone's aware, we're moving into the phase now of actually putting together our deliberations and our thinking into consolidated proposed recommendations for the task force to make to HITAC. I really want to encourage you and urge you all to log on to the Google Docs, to get down and describe what you think the recommendations should be, look at what other people are doing, and update so we have a single view across your workgroup, which we'll then be discussing in the workgroup calls as we go forward in the next few days. That is the process that Mike and I put in place, and that's the one that we want to stick to. It's proving pretty dynamic and pretty good, and resilient right now. I think we're putting together some really good recommendations which are well thought out.

Enough of my loquaciousness on that. There are two key thoughts that I just want us to discuss as a team. One is around the concept of simplification. It's kind of an ongoing and emergent scene that's coming out of all the workgroups right now. The rules are complex. They are complex in their instantiation and in manifesting 21st Century Cures, they – I'm going to try and channel Dr. Lane, when Steve goes, "It's all about the ands and the ors," and we sit there, in Steve's words, and we highlight all the ands and the ors in these misty paragraphs just to work out exactly what this really means. Where we can simplify, I'd like us to encourage that. I think these regulations will get read, reread and interpreted, and removing as much ambiguity caused by verbose craftsmanship as possible, I think that will be a good thing for us to do.

We all recognize, given our positions in the market and the broader health ecosystem, that making things simple and easy to digest, and easy to implement, is very, very important. It's going make

some of the difference between confusion and ignoring of information blocking obligations, versus adherence and actually demonstrably improving the benefits we deliver to our patients and their healthcare because of it. Team, what do you think around the simplification premise? I'm opening this up to the floor. I'm astonished if no one has anything to say. Don't make me pick on somebody.

John Kansky – Indiana Health Information Exchange – Task Force Member

Andy, it is John Kansky, if I could chime in. I absolutely agree; we had a robust discussion in our workgroup where on the one hand, absolutely correct, is that we want this regulation to achieve the desired end of more fluid information across healthcare systems on behalf of patients as well, but on the other hand, any vagueness, or fuzziness, or lack of clarity, only makes it harder for those that are going to seek to understand how to comply with regulation, whether they are subject to the regulation. And then, fuzziness and confusion have the potential to lead to a lot of necessary claims of information blocking that are going to need to be adjudicated. It's not the goal of the regulation to create the need to adjudicate a bunch of information blocking claims. The goal of the regulation is to make sure that no one is information blocking. So, the degree to which we can simplify and achieve clarity, whether it be in the definitions or in the requirements of the regulation itself, that will serve to have a more effective, precise regulation in the end. Thank you.

Andrew Truscott – Accenture – Co-Chair

Thanks, John.

Arien Malec – Change Healthcare – Task Force Member

Hey, this is Arien. So, one thing that I was expecting to see in the NPRM and didn't is either a formal safe harbor, or practices that would be considered reasonable under information blocking provisions, and at least would create a presumption of non-information blocking. In particular, I was expecting to see some tie in the NPRM to the TEFCA, and practices that would constitute information sharing that could be potentially simpler to comply with. So, I share the premise that the current exception-based approach to information blocking regulation just creates a significant amount of complexity, so absolutely endorse approaches to simplify it. One way to simplify it is to outline or enumerate a set of practices – is to enumerate the opposite. So, anywhere you've got exceptions that if you don't meet the exception, you are an information blocker, I think it would be useful to outline a set of actions that, if you comply with them, you at least have a – and I hate to use the word "safe harbor" because I know it's a legal term, and I know it's a regulatory term – but you would at least, if you comply with those actions, be presumed to not be information blocking.

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Task Force Member

I was just going to note that… Bury the request for information about the common agreement in the rules, that's all I want to note.

Andrew Truscott – Accenture – Co-Chair

Yeah, rule 170.402.

Cynthia A. Fisher – WaterRev LLC – Task Force Member

Yeah, this is Cynthia, I think John said it very well, and I applaud John for his articulate way of conveying the need for clarity. I would say to drill down exceptions, keep it to a narrowness, but I do think the intention of 21st Century Cures and the information blocking rules was to cast the net wide and keep it broad so that there is accountability. So, I get concerned when a request for safe harbor comes up, because the whole issue here is compliance of pushing the information to the patients that can be shared across systems, with their providers, and caregivers. So, I think John said it well, of looking at just being as clear as we can on the terms and definitions we provide as we move forward.

Andrew Truscott – Accenture – Co-Chair

Thanks Cynthia. So, John has his hand raised – John, did you want to say something more?

John Kansky – Indiana Health Information Exchange – Task Force Member

Yes, please. So, this is a bit of an Arien-inspired comment. What I said earlier was little bit vague, and I'm trying to offer more concrete suggestions about how to simplify – Arien's talking about safe harbor to the extent that we can describe those things that will simplify the regulation. I think it would simplify compliance with the regulation, in some cases, where we can offer additional examples. For example, in the preamble, there's some examples of things that might implicate information blocking. That was super helpful. One of the suggestions that came up in our workgroup was is it possible to suggest organizations that meet the definition of the four different actors, and some examples of organizations that don't meet any of the definitions of an actor, just to help organizations trying to figure out how to comply with the regulation. Thank you.

Andrew Truscott – Accenture – Co-Chair

Actually, that brings me neatly onto one of the points I wanted to discuss further, and that is around the scope of this. There is a continued focus across the workgroups ensuring that the spirit of the 21st Century Cures is carried onto the recommendations that we are making into the regulations. One topic which has come up in every workgroup in some way, shape or form, is who do these regulations apply to? Now, opening definitions, we talk about what is an HIE, what is an HIN, what is a provider, what's a health I.T. developer, where do they overlap, all of that kind of stuff, and that's the intricacy. But in general, the basic premise – and some of the workgroup members have raised this a few times – do we really mean that these regulations should apply to any organization – and I'm paraphrasing slightly here from the regulations – that is handling, processing, using, exchanging patient-identifiable information?

The general sentiment I'm hearing, and I want to make sure that myself and Mike are able to reflect the sentiment across the task force back to the board at HITAC, which is where we're going to need to present these recommendations to, is that actually, yes, we as a group so believe that the manifestation of 21st Century Cures in these regulations is meant to touch an impact upon any individual, or organization, or other entity who is in some way processing electronic patient information, electronic health information as we defined. I just wanted to get that out there for the group to discuss as a whole about whether we as a group do believe that or not?

Arien Malec – Change Healthcare – Task Force Member

First of all, on the notion of a safe harbor, what I have in mind would be, for example, with respect to patient access, if I host an API that allows the totality of information to be accessed by any patient, any time with reasonable identity assurance, that would be one of those activities that would qualify or be presumed compliant. With respect to the question you just raised, I think one way of getting at that, that I tried to do in the sub task force, is to paint some extremes around the edges and ask ourselves the question of, "Do we think that is a health information network under Cures that is subject to the seven exceptions, or subject to information blocking, and must comply with the seven exceptions? I've poked around the edges at… A bank. Is a bank an organization that, because it sends and remits electronically with a identifier number that ties back to a claim, that ties back to PII – are all banking transactions in healthcare associated with payment for procedures rendered and for claims, health information networks subject to information blocking provisions?

And I'm doing this as a way just to poke around the edges and create some of these cases. Is a clearinghouse a health information network? Is a billing service a health information network? Is a records-retention organization that digitizes records a health information network? And the answer could be yes or no, but I think it's useful to create some of the boundary cases and adjudicate this on the notion of boundary cases. Because it is easy to say that the definition should be broad; we may have a different conclusion if we actually poke at some of those exceptions, or some of those edge cases.

Andrew Truscott – Accenture – Co-Chair

Thanks, Arien. That's why I'm trying to stimulate this conversation across the group, by talking about the function. So, do we believe as a group that these regulations should be applying to any individual, entity, organization who is processing, exchanging, handling, whatever verb you want to use, electronic health information?

Arien Malec – Change Healthcare – Task Force Member

And again, to my point, do we think of any health information network that should be subject to this regulatory framework?

Andrew Truscott – Accenture – Co-Chair

Yeah, I don't want to get into the health information network or health information exchange, any of those definitions of sub-types and actors. I just want to say, in terms of the function, is that what we believe as a group? And John Kansky's got his hand raised. John.

John Kansky – Indiana Health Information Exchange – Task Force Member

Thanks, Andy. So, like Arien, I've been trying to think about the boundary cases to make sure this holds water. On the surface, philosophically, it's very easy – and I think you're suggesting this, Andy – to say, "Well yes, of course, why would we want anybody to be carved out of this?" But I think there's clearly, the way that the definitions of the actors are written, there's going to be lots and lots of types of organizations pulled into this that go beyond the intent of Congress. Now, I'm not Congress, but I'm trying to extrapolate. When you write a definition that's called health information network, and then you realize that a physician practice can be a HIE, or a bank can be a HIN, or Lyft or Uber, a taxi cab company, can be a healthcare provider, is that really what you're expecting in terms of a regulatory burden to place on the system? I don't have an answer for you, except to say,

Andy, that I'm very nervous about the broadness of the definitions, and the burden of the regulation that is going to be created.

Andrew Truscott – Accenture – Co-Chair

I am, too. And the burdensome nature will mean inevitably that non-compliance happens, and it just becomes a nightmare to police because there's so much non-compliance – it's just a domino effect. Which is why I want to have this conversation, because the regulations, yes, we have some boundaries around some of the actors right now. But they are pretty broad, and… Thanks for the sentiment from yourself. Sasha, have you got your hand raised?

Sasha TerMaat – Epic – Task Force Member

Yes, so I wanted to continue Arien and John's suggestion of bringing up some of the scenarios that came up in task group three that also made us question if the definitions were working as intended. One of our task group members – Les, to give fair credit – pointed out that some of these provisions, including about electronic health information and sharing it with the patient themselves, could have presumably unintended consequences on clinical research. Les brought up a scenario that if a patient is participating in a clinical trial, information about the patient's participation in the clinical trial would presumably be electronic healthcare information, that would seem to meet the definition. But the inclusion of that information to a patient would potentially invalidate the ongoing results and data being gathered as part of that clinical trial.

That's what the patient signed up for when they decided to participate. That was one example that came up in our task force, we were thinking about the electronic health information export provision when that example came up. But I think thinking about some of those cases helps us decide as we're thinking through where do these definitions fall, and if they are incorporating the right things, and too much one way or another.

Andrew Truscott – Accenture – Co-Chair

Thank you, Sasha, I agree. That's good input. Anybody else?

Denni McColm – Citizens Memorial Healthcare – Task Force Member

So, this is Denni. I'm sorry I didn't raise my hand, but I'm thinking even of companies even closer to healthcare that it doesn't seem like would be subject to these rules as they're written. Like companies that are contracted to abstract charge, or reporting to the state cancer registry, they certainly would have electronic health information to do their job, but it doesn't even seem like they have authority to be releasing or sharing that information. Do you see what I mean?

Andrew Truscott – Accenture – Co-Chair

Absolutely. I think that's why we need to make sure that the exceptions are well constructed. That it wouldn't be reasonable for them to be where you go to accuse them for information blocking, because of the purpose of what they do. I agree with you. We need to make sure the regulations suitably allow for that. Aaron Miri?

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Task Force Member

Thank you. So, I also want to voice some concern about the way the rule is written, to the degree that it relates to substance abuse, and mental health information, and sharing of that data. As you know, there is a litany of additional state privacy rules that are in effect, especially where I am in Texas, that explicitly forbid transmitting that information against a patient's wishes. It has to be at the direction of the patient. So, to the degree that this rule can flex a little bit to understand and deal with, and/or remediate and standardize those processes, I would be in favor for it.

Andrew Truscott – Accenture – Co-Chair

Thanks, Aaron. What I'll do is I'm going to ask Mark Knee, who's supporting us from ONC off-line, if you can get some thoughts together about the precedents, just so we can give a single back to the board or task force around where that would sit with precedents set to a state registration. Cynthia, you had your hand up first?

Cynthia A. Fisher – WaterRev LLC – Task Force Member

Yes, thank you, Andy. I just think as we look through the suggestions that have just come up on comment, whether it be research or other patient information, I do think the intention is to provide relevant medical, clinical, and price information to the patient that it is relevant to them receiving the best quality of care, and share that it would impact improved health, and improved diagnoses decisions, in combination with their provider. I think that it should be very well considered, because we know there's a lot of big data aggregated in many different ways behind the scenes on patients, and yet, the patients don't have access to relevantly manage their life, or their care, or the decision. So, I just think as we look at this, we really need to be well thought through and considered about the deployment to the patient.

Andrew Truscott – Accenture – Co-Chair

Thanks, Cynthia. Arien?

Arien Malec – Change Healthcare – Task Force Member

First of all, just to summarize, maybe some of the themes or consensus, No. 1 is – just to double down on Cynthia's comment – that the goal here is to provide greater access to patients, and also greater access to information to improve care, improve payment administrative operations, and other activities that are associated with healthcare transformation. We should really start with the high-level principles and then ask the question about whether the proposed regulatory framework A) serves that need, and B) significantly increases burden in ways that would either undermine the need or, overall, burden the U.S. healthcare system. If I read the text of 21st Century Cures, the Congressional text of 21st Century Cures, the discussion of the health information exchange or health information network is always in conjunction with provider or health information technology, and I believe that the intent of Congress was to facilitate information exchange, particularly clinical information, relevant for treatment, care, operations, and payment.

But I do not believe it was the intent of Congress to regulate banks, or even to regulate some of the other ancillary services around healthcare. I think if it had been the the intent of Congress, then Congress would have written the definition in ways that enumerated potential classes of organizations, to clarify the intent. I think one of the clear consensus items coming out of this conversation, maybe with a little bit of dissent, is the notion that we have an obligation to simplify what it means to be compliant with information blocking in ways that facilitate information flow and

reduce the burden of compliance. So as an example, if, as a provider organization, I offer an API that allows access to the totality of health information contained about the patient, I make that API available to patients with reasonable identity assurance, and I make that API available to providers and payors, in order to facilitate many of the actions that are associated – or what we're trying to drive in Cures – that I should be presumed to be not an information blocker. Things that we can do there do a double duty of actually encouraging the kind of exchange that we want to see and reducing the overall compliance burden.

Andrew Truscott – Accenture – Co-Chair

Okay, Arien. Thank you ever so much, that's helpful in there, too. Thank you everyone who has commented so far. I think just one aside, when we're talking about simplification, there are a couple of different sides to this. One is where we want to simplify so that the – as you just outlined, Arien – compliance is straightforward as possible. Right now, for that drafting that we're doing, the recommendations that we are making to go HITAC and to go back to ONC, I am pretty focused on simplification of the language that we are using so that it's understandable what that compliance would be, ahead of actually performing the compliance itself. Without further ado, we've gotten down to 20 past the hour. I would like to take the opportunity to open it up to public comment, please.

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

All right. Thanks, Andy. Operator, can we open up the public line?

Operator

Certainly. If you would like to make a public comment, please press star one on your telephone keypad. A confirmation tone will indicate your line is in the queue, and you may press star 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 star keys.

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

Thank you. And I just want to confirm, did we have Sheryl Turney join us? I don't think so, but just want to be sure. Okay. Or Lauren Thompson? Okay. Operator, do we have anyone in the queue at this time?

Operator

We have no one in queue at this time.

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

Okay. I will give you guys 10 minutes back, if there is anything you would like to wrap up on before next week?

Andrew Truscott – Accenture – Co-Chair

Task force, are there any issues emerging that you would like to cover?

Steven Lane – Sutter Health – IACC Workgroup Member

Do you, Andy, and Michael have a clear sense of what, of all this, is going to be presented at HITAC next week?

Andrew Truscott – Accenture – Co-Chair

A clear sense? It's becoming clearer. My proposal right now is – I'm not sure exactly how long we get, but I will do not too verbose a description of the process we've undergone and where we're at in it. And then, it is our intention to present, certainly, the key emerging themes from each workgroup, whether we want to present the absolute recommendations as we have them drafted, that might well be premature, but I think – that's just where my head is. Mike and I haven't really discussed anything at this point. What do you think?

Michael Adcock – Individual – Co-Chair

No, I agree with that. I think that we – I don't know how much time we get, maybe ONC can speak to that. But I agree with what you're saying. We need to walk through how we've broken this work up, and the process we have gone through, and emerging themes. We have multiple other opportunities to make sure that the recommendations are presented to HITAC and presented to ONC, so I think that we should do exactly what Andy has said right now. We have not discussed what the cadence of that is going to look like, or how the flow goes. We will be ready by our time to present for sure.

Andrew Truscott – Accenture – Co-Chair

Is there anything in particular that the task force would like to raise before HITAC at this point?

Aaron Miri – The University of Texas at Austin, Dell Medical School and UT Health Austin – Task Force Member

It will be a fun debate.

Andrew Truscott – Accenture – Co-Chair

Yes, and frankly, it will be good to get the input from the rest of HITAC anyway, and it will also be good to see what the other task forces have got to as well. We hear rattles from the ONC staff, but it will be good to see where they're at. I also intend at some point, probably, that we should have a bit of a sidebar, at least as workgroups, if not as the task force, just to touch base with each other outside the main meeting while we're in DC as well because we are all physically together. If that's okay with people?

John Kansky – Indiana Health Information Exchange – Task Force Member

Yes.

Andrew Truscott – Accenture – Co-Chair

Okay, great. We'll look forward to seeing you in Washington, DC next week. If there's nothing else, we'll give you five minutes back.

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

Thanks, everyone. We will adjourn, thank you.

[End of Audio]

Duration: 50 minutes