HTI-1 PROPOSED RULE TASK FORCE 2023 MEETING

GROUP 1: INFORMATION BLOCKING

May 30, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Steven Lane	**Health Gorilla**	**Co-Chair**
Steven Eichner	**Texas Department of State Health Services**	**Co-Chair**
Hans Buitendijk	Oracle Health	Member
Hannah Galvin	Cambridge Health Alliance	Member
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Member
Deven McGraw	Invitae Corporation	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Daniel Healy	Office of the National Coordinator for Health Information Technology	ONC Program Lead
Mohammad Jafari	Individual	Discussant
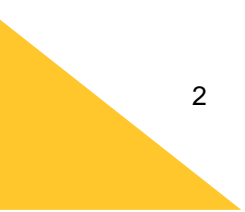
Call to Order/Roll Call (00:00:00)

Michael Berry
Good morning, everyone, and welcome to the HTI-1 Proposed Rule Task Force. I am Mike Berry with ONC, and I would like to thank you for joining us. All of our Task Force meetings are open to the public, and your feedback is welcomed, which can be typed in the Zoom chat feature throughout the meeting, or can be made verbally during the public comment period that is scheduled toward the end of our meeting today. I would like to begin rollcall of our Task Force members, so when I call your name, please indicate if you are here, and I will start with our cochairs. Steven Lane?

Steven Lane
Good morning, and welcome, everyone.

Michael Berry
Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Hannah Galvin?

Hannah Galvin
Good morning.

Michael Berry
Adi Gundlapalli? Deven McGraw?

Deven McGraw
Good morning.

Michael Berry
Eliel Oliveira?

Eliel Oliveira
Good morning.

Michael Berry

Fil Southerland? I know Sheryl Turney is out the next couple weeks, so she will not be able to join us, but thank you, everyone, and now, please join me in welcoming Steven Lane and Steve Eichner for their opening remarks.

HTI-1 Proposed Rule Task Force Charge (00:01:09)

Steven Lane
Thank you so much, Mike, and welcome, everyone, especially those members of the public who are joining us today. I see a number of friendly names on the attendee list, so, thanks for coming, and we really want to remind members of the public to feel free to participate in the chat and to share any thoughts that you have verbally when we go to verbal public comment 10 minutes before the noon hour on the East Coast. So, this is our agenda for today. We are going to jump through our charges quickly, and then jump into the draft recommendations. I have spent some time trying to pull forward the member recommendations into drafts that I would like to review today. We need some input from Deven, Ike, and Hans in particular to try to clarify some of these. I think we are also being joined by Mohammad. Are you here? Not yet. Mohammad Jafari was going to join us as a discussant today as well. We will see if he has a chance to join us to discuss some of the things that he weighed in on before, and then, as I said, we will cut to public comment 10 minutes before the noon hour on the East Coast. Ike, do you want to add anything?

Steven Eichner
There is not much to add. That is a wonderful introduction. I will just reemphasize my welcome to all, and I look forward to a good day.

Update and Revise Draft Recommendations (00:02:48)

Steven Lane
Great. Let's quickly review our charge. I think this is familiar to pretty much everyone who is here today, the charge to review and make recommendations regarding the recent ONC NPRM. To save time for our discussion, we are not going to go through the individual bullets. The next slide continues the listing of the charges, and then, the slide after this focuses on the piece that our group has been responsible for. These are all the items that we have worked our way through, and we will be preparing recommendations for most of them. We did not have much to say about some of them, and there is nothing wrong with that. I think the next slide takes us to the spreadsheet, so let's cut over to the spreadsheet. We are going to be on Tab 1, Group 1 Recommendations.

Column J is where I have brought forward the recommendations from the member recommendations and endeavored to clarify and tighten those up as much as I could. Can we increase the view? Really, all we need to see is Column J. Actually, I guess seeing G and J at the same time is not a bad idea, so slide a little. There we go. That is just perfect. If I just bring this in ever so slightly, it will all fit. Okay, good. So, we had a number of member recommendations that were submitted early on in terms of this particular item. Just a reminder here that we are looking at the item information blocking defined terms and proposals related to this that we reviewed some time back. It looks like somebody has hidden…oh, no, there they are. I was not seeing them. So, this is an item that we reviewed on May 2nd at the beginning of the month, and Hannah, you originally submitted a suggestion that I think you decided we did not need to specifically include.

Hannah Galvin
Yes.

Steven Lane
Ike, you submitted a couple of suggestions. So, for one of those, this very first one, recommending whether nonprofit and other private organizations that operate disease or other patient registries are considered actors, I think we had a discussion with Deven about that, and there was a sense that that was not really necessary, that that was pretty clear in the rule as it exists, that the actors are well defined as providers/HIEs/HINs and developers of certified health IT, so that would tend to exclude these other nonprofits and private organizations. So, Ike, if you are comfortable, I was just going to leave this one off.

Steven Eichner
I think that is okay. Again, nonprofits in that space are kind of in a weird environment. They are not necessarily healthcare providers per se. They perform services that may be similar to public health or hospitals, but whether the scope of providing that kind of access is or is not information blocking is still kind of out there.

Steven Lane
Yes, but because they are not actors under the rule, I do not think it pays for us to spend time on it.

Steven Eichner
Okay.

Steven Lane
Good, all right. That brings us to the next one.

Steven Eichner
Which I added this morning looking at clarification in the same kind of vein. We had some discussion with some other folks. There was a question that came up about whether camps or other entities that are not focused on healthcare delivery but may offer ancillary healthcare services, whether it be wellness checks at nonprofit conferences or a summer camp. Are they considered healthcare providers for the purposes of information blocking?

Steven Lane
Again, Deven or others can certainly weigh in. My sense is if they are providers and they are providing healthcare services, then they are certainly going to be covered under the rule as providers, and if they are not, then they will not. I do not think it really has anything to do with the NPRM itself, so it would seem a little bit out of scope for this, but Deven, what do you think?

Deven McGraw
Yes, if they meet the definition of a provider under the Medicare regulations, it is not like the HIPAA definition, where you are billing insurance. If you are a provider under Medicare's rules, then you are an actor/provider under the information-blocking rules, and then, whether you are offering health IT or not would be subject to all of the different regulations and explanations. I think it would be highly unlikely that a

camp would provide health IT, and I also am not sure whether they meet the definition of a provider under Medicare.

Steven Eichner
Okay. Let's pull it, but let's consider as a general recommendation or advice for ONC to provide better information for the community about what is or is not a covered entity.

Steven Lane
How about we consider referring this to the Annual Report Workgroup?

Steven Eichner
Sounds good.

Deven McGraw
Yes, I agree. I think it is helpful for ONC to provide clarification from time to time about who is in, who is out, and what types of activities trigger information blocking, so that is never a bad thing.

Steven Eichner
Yes, because there are people that live within these rules and know them really well, and there are lots of people that do not. I just deleted it.

Steven Lane
Well, I just highlighted it for referral. Sorry, we were both in there at the same time. The next one was recommending that ONC clarify that meeting one or more exclusions in one rule or offering does not mean an entity is not covered by the rules with respect to other products or services that do meet the definition of offering certified health IT. Again, it seems a little redundant to me, and kind of self-evident, but I do not think there is any harm in leaving that in if people feel strongly that it belongs. Does anybody want to weigh in for or against that one?

Hans Buitendijk
A little bit. This is Hans. The next one in Row 3 might be combined. This could cover it. So, maybe once we get to that, we may come back, or do you want me to clarify the one on Row 3? I think they relate.

Steven Lane
That is fine, yes. Why don't we slide down to Row 3? Let me see if I can facilitate those showing in the same screen. Look at that! What did I tell you? You have to know your way around Excel. Go ahead, Hans.

Hans Buitendijk
The challenge there is that it is one of these multiple-rule scenarios. We will start with a provider. If you have a provider that self-develops and that uses consulting, outsourcing, or whatever staff, not their own employed staff, to do that work, that can come from generally one of two areas. It can come from a consulting/outsourced firm that just does that, or it can come from a firm that not only does that consulting and outsourcing, but also develops their own HIT that may be subject to this.

It seems that the staff that is involved, and therefore how that relates to both the provider and to whomever provides the resources to do that work, that things change a little bit on how they are being perceived, and that consulting/outsourcing staff is not considered the same depending on whether they come from a pure consulting firm, which is the term I will use for a moment, or from one that also creates and offers software. It is not clear on how that actually is done, so it is that dual role that comes out. So, it may be an example to be used for that. Would they fall under offering certified health IT or would they not? In that role of consulting, what exactly is happening? That is not clear.

Steven Lane
So, are you referring to the provider who hired the consultant or the consultant themselves?

Hans Buitendijk
The consultants themselves primarily, and if that means there is any difference also on the provider themselves. I think the latter is clearer, but the first is not.

Deven McGraw
But would we want to exempt somebody who consults with a self-developing provider and then turns around, develops their own products, and offers them? It seems to me like they should be picked up by the rule.

Hans Buitendijk
I am not saying they should not be picked somewhere else, but it seems like the implications for a pure consulting firm or consultants that work for offerors otherwise is different.

Steven Eichner
This is Ike. To support Hans's position, for a state health department, if we hire an individual for staff augmentation to work on a project or Epic hires someone to work staff augmentation to finish off a product, that individual or that company that has hired that individual is providing programming services. They are not really offering health IT.

Hans Buitendijk
The thing is that in that scenario, the consulting staff works under the direction of the provider, of what they want to happen, on things that they control, and that is where it comes in. Are they being considered working under the provider's direction, and therefore that is how they are being counted, or are they deemed to work under the company they come from? At that point in time, it would be odd if they do what that company…

Steven Eichner
What Hans and I are speaking to is the concept where there is technology that is developed but is not really under the control of a particular programmer or entity that was contracted to develop it and then turn it over. It is no longer theirs. Maybe the language that we need to insert is "work for hire."

Deven McGraw
Right.

Hans Buitendijk

So, that is the clarification to have better understanding on what is meant there because it seems that would create undue differences in essentially the same staffing arrangement.

Steven Lane

So, what is our actual recommendation? What do we think it should be? How do we think it should work?

Hans Buitendijk

From our perspective, they are treated the same, so whatever consequences there are to the organization that is involved in it or not, there is consistent treatment of that scenario.

Steven Lane

Which "they" are we treating the same? Go one at a time.

Hans Buitendijk

The organizations that are sourcing the staff for, let's say, the provider. So, it would be either the pure consulting firm or the mixed developer/consulting. For that staff, that team that is there, they are being considered the same.

Deven McGraw

I think I get what you are saying, Hans. Do you mind if I give it a shot and you can tell me if I am wrong? So, if you are a contractor and you are developing a product for a provider as a work-for-hire, you should be treated like that provider. You are not offering health IT to the provider because they asked you to create a solution for them, and it would be the same as if they developed it themselves. However, if that same consulting firm is developing products that it is selling out into the marketplace, not providing work for hire for a provider to use in its own environment, if they otherwise meet the developer definition, then they should be covered. In other words, Hans, I think the way you are articulating it is "Who hired you and for what purpose?" If you are hired by a provider to create a homegrown solution, you should fit under the exemption. If you are not under that exemption and you are offering health IT, you are offering health IT and you are covered by the rule.

Steven Lane

Deven, I am still not clear, though, and I am really trying to get this phrased so we can do it. So, you are saying for the purposes of the work that they did for the provider, the should be exempt, but for the purposes of the work that they do in their own right, offering health IT, they should not be exempt. Is that it?

Hans Buitendijk

Correct.

Deven McGraw

That is my understanding from Hans as well.

Steven Eichner

I think the key language we need to insert is "work for hire."

Hans Buitendijk

Yes, that is the key, because they are doing it under the auspices of the provider, and they are not doing it differently than anybody else, so in that context, that is how they should be treated. If not, because they are doing other work, then they should be treated as an offeror or developer.

Steven Eichner

Right, and I guess the same would even hold true, not just for… It gets a little bit sticky looking at "developer" or "operator." In the example where I, the state, hire someone to provide a contracted, one-off service, such as running my EHR, they are not providing it to anybody else.

Hans Buitendijk

That happens also. There are organizations that do develop and also outsource and support, and as part of the support, they do not only work with their own software, they support it for their entire IT, whatever that might be.

Steven Eichner

Right, but where I was differentiating is if it is a one-off, then that is still work for hire, and I will not say "exempt," but the entity should not be included as an actor in this space. If it is a development company that is offering product to multiple entities and it has control over the software, that is a different animal.

Steven Lane

Okay, I am really trying to get this, so let's see what you guys think of this. It feels a little wordy, but can you read that?

Hans Buitendijk

Yes.

Steven Lane

In Column I.

Hans Buitendijk

I am okay with that.

Deven McGraw

Yes.

Steven Lane

All right, let me take that, stick it over in J, and then, your thought, Hans, was that this obviated the need for one of the earlier recommendations.

Hans Buitendijk

I think it is the second bullet, where this is a particular scenario of that.

Steven Lane

Okay. So, here, we have "clarify that meeting one or more exclusions in one rule does not mean an entity is not covered by the rules…" Okay. This is a much more specific instance, right? Because we were general.

Hans Buitendijk
Right, they should be together because they are about the same type of thing.

Steven Lane
Sure, let's put them together.

Steven Eichner
They are similar in nature. They are not quite the same.

Steven Lane
Not identical, right.

Steven Eichner
The first one is not necessarily so much recommending a change in the rule, it is amending, for lack of a better word, the interpretive language or the presentation language.

Steven Lane
All right, I think I got then. To back up to Row 2, then, what did we do with 2J1? I think I lost my edit. Ike, why don't you just let me edit?

Steven Eichner
I have not touched it in some time.

Steven Lane
Okay, so we do not step on each other.

Steven Eichner
I am not in, have not been…

Steven Lane
I think we did it once. Okay, the first one is going to be referred to Annual Report Workgroup.

Eliel Oliveira
Steve, this is Eliel. Can you hear me?

Steven Lane
Yes. Hi, Eliel.

Eliel Oliveira
I was thinking about this and was going to suggest that maybe one recommendation here for ONC on this topic is to consider the owner of the intellectual property because that may influence who has been required to comply with any regulations. It might be that in a contract for hire, you say, "I am going to pay you to

build something, but it is yours, and then it is going to benefit me." I know that is not a common setup, but it can happen. So, again, I do not want to deep dive too much. I know we talked a lot about this, and I like the language, but I just thought that maybe adding the consideration for ownership of the product may have something to do with who needs to be complying.

Steven Lane
Okay, do you want me to add that?

Steven Eichner
This is Ike. I think we have it addressed if we use the language "work for hire" rather than "intellectual property ownership." From a technical standpoint, that can get really complex.

Hans Buitendijk
Yes, and that gets it much more quickly. If I did the work for the provider and then I have the rights to sell it, and maybe there is whatever arrangement with the provider based on that shared IP or whatever, in that context, I am starting to become an offeror again because I am going to be able to take that product and do something with it, as opposed to strictly for hire, which is just for that provider, not for anybody else.

Steven Eichner
Right. I think the key is the term "for hire." Again, using the language of ownership of intellectual property creates a bunch of upstream issues because the developer is using software that is owned by somebody else that they are operating under a license.

Steven Lane
Well, let's leave it as it is for now. Eliel, if you want to recommend some specific alternative language, maybe pop that in the spreadsheet and we can come back to it later, okay?

Eliel Oliveira
Sounds good.

Steven Lane
Okay, on to Row 5. Are we up to Row 5 already?

Steven Eichner
Do we need to go back and finish 1 or 2? We jumped to 3.

Steven Lane
So, we have done Rows 2 and 3. Oh, no, we did not do the second one on Row 2. You are right. So, real quickly, the way I have that drafted is "recommend that ONC clarify that the provision of access to registries and similar data services provided by public health authorities and the issuance/utilization of related credentials are not considered providing health IT, regardless of the route used to request, access, or receive data." And then there is "e.g., through direct logon to public health information system by an app or third-party tool or by HIN/IKE. This change is necessary to provide users the flexibility to connect to the data resource in the manner of the user's choosing." Any thoughts on that, positive or negative?

Deven McGraw

So, this is another one where a public health authority would not meet the definition of an actor, typically, because even in the HIN functional definition, you have to be exchanging data between two disparate entities for treatment, payment, or operations, which a public health authority would not do.

Steven Eichner

Well, actually, look at things like organization registries, which could potentially count as…

Steven Lane

HIE/HINs.

Steven Eichner

Right.

Deven McGraw

All right, let's leave it then. If there is sufficient ambiguity where, in some circumstances, a public health authority might get looped in…

Steven Eichner

Quite frankly, any time we are sharing information back out of a registry, unless at the individual level, unless we are pushing it back to the original requester, that is sharing data back to somebody else, and that is an exchange function.

Deven McGraw

Right, but for the HIE definition, to get looped in, you have to be exchanging for treatment, payment, or operations. Then, once you are in the definition, the purpose of the **[inaudible – crosstalk] [00:26:28]** does not matter.

Steven Eichner

Right, and again, looking at that exchange out of registry, as an example, many times, providers will request data from our cancer registry for coordinating care for their individuals, even though the primary purpose of that registry is not for coordinating care.

Steven Lane

And certainly, when one requests data from immunization registries, it is part of the care process.

Deven McGraw

Fair enough.

Steven Lane

Okay. I guess the only question, Ike, is is all of the language in that first sentence necessary, for example, "and the issuance/utilization of related credentials"? Is that really necessary for this recommendation?

Steven Eichner

I think we can get rid of that clause.

Steven Lane

Okay, good. The rest of it is good. All right, we just want to keep it tight. So, that was Row 2. I think we have been through Row 3. Row 5 is blank. Row 4 is the TEFCA manner proposal. There were extensive recommendations here from a number of us, and this is how I boiled them down. So, take a look at these. The first one is "recommend that ONC limit the requirement to utilize TEFCA exchange when offered to apply only to those use cases for which a TEFCA standard operating procedure has been finalized and published by the RCE, and for which responses are required under TEFCA."

So, that is a pretty substantial limitation from what they had said. I do not think most of you have seen this because this was my recommendation, and a number of us weighed in. As opposed to saying "any TEFCA exchange," exchange for any of the purposes which we feared could disincentivize TEFCA participation, by limiting this to only those TEFCA exchanges that have been fully defined and are required, which are two different things that we should talk about separately, and again, the rationale here is to require the use of TEFCA exchange before the relevant use cases and technical requirements have been finalized may inadvertently disincentivize TEFCA participation. So, Deven, I am particularly interested in your thoughts on this.

Deven McGraw

Thank you, Steven. I think two recommendations that are on there are not compatible with each other. That does not mean you cannot argue in the alternative. I understand why ONC went in the direction they went in. Creating incentives to use a voluntary network is a good thing, but I think that where they went is going to have a lot of unintended consequences, particularly with respect to fees, because it basically forces an acceptance of fees because you do not get to go to the manner exception alternatives because if you are participating in TEFCA, you are in, and you can be required to exchange under TEFCA-permitted rules without the information-blocking exceptions coming into play, if that makes any sense. So, I think there could be some unintended consequences, even in a circumstance where there are agreed-upon SOPs, because the SOPs to date are not touching the fee issue. They are allowing the QHINs to set their own fees with respect to participants and sub-participants; they just cannot charge each other in the QHIN environment.

And so, in general, I understand why this proposal was put forth, but I think it has some unintended consequences. Particularly, I think about the individual access use case when I think about the ways that individual access… There will be a great desire to be in TEFCA, but it could be financially prohibitive because the requirements of the fee exception are not going to apply. So then, that is when I came up with another alternative, which is rather than required exchange under TEFCA, you create what is called in legal terms a rebuttable presumption, that if you are participating in TEFCA and are compliant with the rules, at least with respect to those types of exchanges that are approved TEFCA use cases, you are considered to not be information blocking, unless, of course, it turns out that you are… That presumption can be rebutted by bad behavior.

Steven Lane

Right, right. Hans, your hand is up.

Hans Buitendijk

Yes. Generally, on the first one, I like the direction where that is trying to get more specific because if it is only out there still in work, maybe published, but not yet required in TEFCA, the progression that I think you put in there is very helpful, and from that perspective, the question that you raised, we may need to define what is considered defined, required, and agreed because the puzzle that I have is should it include that it has already been deployed and is considered to be operational. Where is the cutoff point? If it is still defined, but it has 12 months to go before everybody has to adopt it, is that sufficient, or do we need to wait for that date by which it should have been adopted and production QHINs can support it so now, we know that you can connect to that. Whether the support on the QHIN is brokered, facilitated, or whatever it is, the QHIN is ready to now run it, and I think that is the part of the defined/available required, that that seems to be the element. Once that is available, you can start to have a reasonable expectation that somebody now can truly use it. I think that would be the part of refinement where the line is to be drawn.

Steven Lane
Wait, are you recommending a change in the recommendation? I think there are key questions as to what we recommend. The SOP has been finalized and published. Do we recommend that the responses are required? And then, I think you are suggesting recommending even that you wait until actual exchange occurs. It seems to me that once responses are required, exchange will occur pretty quickly. So, are you supporting the recommendation as written, or are you suggesting a change?

Hans Buitendijk
I would change it to be more specific that the QHIN is available for running it, not just that they are required to do it in a couple of months' time, but they are up and running. They are ready.

Steven Lane
Hmm. So, once the SOPs are approved, everyone will be on notice as to when exchange will be required.

Hans Buitendijk
Yes and no. Practically, it would be great if that stood, but I am not convinced that is happening, and it is not until the SOP has been opened up. So, a couple of SOPs and QDS are currently ready. The QHINs are not yet, for all kinds of good reasons, do not get me wrong, but that still takes time. We are not sure when that happens. There is a timeline, so I do not think you can expect everybody else to then work with that until the QHIN is ready.

Steven Eichner
And availability of exchange between QHINs does not necessarily mean that providers or participants at either end can actually ingest or generate a message either.

Hans Buitendijk
I agree with Ike. There is a ripple effect there. I am concerned that if we say strictly on SOP available in itself, and required, that that is not necessarily a point in time that people can practically do it up and down the stack. So, I agree with the intent that is being put out here, but I caution that until the pipelines are open, it is hard to expect that it is done.

Steven Eichner

I think another issue is that it is requiring the use of TEFCA. I could make it available via TEFCA. That also should not necessarily be sufficient as a real issue for public health, where there may be statutory prohibitions about public health potentially participating in TEFCA or issues about looking at sovereign rights. There may be some components written in the TEFCA language that makes it difficult for governmental entities to participate.

Steven Lane
Yes, but that is all going to be covered under applicable law. We do not have to consider every hypothetical as we write our recommendation.

Steven Eichner
I guess there is still a question out there, Steven, about applicable law. To whom, and in what circumstance?

Steven Lane
Right, of course.

Hans Buitendijk
Could we state that when it is operational in TEFCA and leave that gray zone about where exactly that sits, that we leave it a little bit open and flexible? There is time between an SOP-defined QTF that needs to be in place as well, etc. When it is operational, then you can say now it is reasonable to expect, and we can argue where exactly that line is.

Steven Lane
Okay, I added it. Hannah, your hand has been up.

Hannah Galvin
Yes, I agree with Hans on this. Thinking about the information-blocking rules from an endpoint perspective, is that data available to the patient? Is the data available to the provider? I like adding "Is it operational?", and to some extent, I want to see if it is successful. I think we are still in this very theoretical building-block stage with TEFCA. We have not yet seen it operationalized, we have not seen the barriers in building this in an exchange from QHIN to QHIN yet, and I have seen some of the boots-on-the-ground challenges already with HIE data exchange with some of the interoperability frameworks and the actual data quality that is being shared, and I understand the desire to have this safe harbor for anybody who is a participant in any way within TEFCA, but in reality, I expect that there are still going to be a lot of bumps in the road, and at the endpoint of "Hey, I am not getting my information here" because we are still working out a lot of these bumps, and then to not be able to hold participants accountable because they are participants feels like we are maybe going in the wrong direction there, so I would like to say that it needs to be operational and we need to have some way to hold participants accountable, to actually be successful in the data exchange. So, that is my recommendation on this, that we add something around "operational" and "measures of success" for that data exchange within TEFCA.

Steven Lane
I guess I just worry that we are putting so much "and this, and this, and this" that it ends up disappearing in terms of the value as an incentive, and I think the point here is that ONC is really attempting to incentivize

TEFCA. My personal opinion is I want us to do what we can to incentivize the use of TEFCA, and if we water it down too far, then it loses all meaning. Ike, I think your hand is back up.

Steven Eichner
No, that is over.

Steven Lane
Okay. Deven?

Deven McGraw
Well, I think it should be totally watered down. With all due respect, and Steven, I thank you for reminding us that you work for a QHIN because, obviously, for a voluntary network to work, it is helpful to have incentives for people to participate, but I really do feel like this could actually have the opposite effect. In other words, this is one more thing that people will take into consideration, that they lose some of the flexibility in the information-blocking rules in terms of being able to get data in a way that meets the fee exception in a manner that works for them because if they participate in TEFCA, they are potentially roped in for every single use case for which there is an SOP that has been operational, and even with all of the language that has been suggested by Hans and generally seems to be agreed upon by the group, I still think it is premature to create such a strong incentive or something that looks like a strong incentive, but, in fact, could be a big disincentive because once you are in, you actually do not have a choice anymore to participate.

What I had suggested was something quite a bit softer in terms of a rebuttable presumption that gets rid of what ONC has proposed altogether, not a modification where, if you are in TEFCA, you can be pulled in for any use case that has been adopted and is functional and working. It is more that we are going to presume that you are not information blocking in any sort of context unless we get contrary evidence that you are being a bad actor in some way, shape, or form. I know we do not have to be unanimous on these things, and I seem to be the only one who is out on this limb, but I want my dissent noted.

Steven Lane
Well, you are dissenting from the first recommendation here.

Deven McGraw
Yes.

Steven Lane
You are just saying that this idea of utilizing TEFCA as an exception is just not a good idea at all.

Deven McGraw
That is my view, yes.

Steven Lane
Okay. With the second one here, which really was drafted out of your language, I do not think that anyone has raised any objections to the second recommendation. Deven, were you comfortable with the language that I pulled forward here?

Deven McGraw

Yes.

Steven Eichner

This is Ike. I am a little uncomfortable with the second component looking at potentially the exception rules and pushing people to TEFCA. I think it works a lot better, and Deven, I want to figure out a good way where everybody wins. What happens if it is shifted to if both the requesting and receiving entities are participating in TEFCA?

Deven McGraw

That is already what has been proposed.

Steven Lane

Yes, that is what we are commenting on, is that recommendation.

Deven McGraw

Let me see if I can come up with an example so you can understand where I am coming from. I think about it more in the context of individual access. So, today, for individual access to occur, if you are using certified FHIR APIs, for example, you do not get charged as a patient for being able to access your record. If you are a participant in TEFCA, which I do not see individuals doing on their own, although I guess in some model, they could, but let's say they use an app.

Steven Eichner

Right. I could be a sub-participant, and up the chain, the participant is being suddenly charged for connectivity. I very much appreciate the issue. I work for public health. Public health does not have a history of paying for data. We do not have the flexibility as a public health entity to suddenly raise revenue or charge a rate that we charge somebody else, so I very much appreciate the concern.

Deven McGraw

Right, so there are constraints around fees for every use case in the fee exception in information blocking, but you are not going to get the advantage of any of those. The fee exception in information blocking has constraints around fees. You do not get to take advantage of any of those because when you are a TEFCA participant and you are exchanging with another TEFCA participant, you are lifted up into that category. You are exchanging in the agreed-upon manner. None of the fee constraints apply in information blocking, and you cannot get out of it under this proposal because you have agreed to participate in TEFCA, and your data holder that you are seeking data from is also a participant in TEFCA, and that ropes you into whatever is the fee infrastructure for the QHIN participant or sub-participant that you are connected with.

Steven Eichner

Yes, because the other thing that I was concerned about is looking at a push to use from one participant who was participating in TEFCA to say, "Hey, I am making this data available in TEFCA. You, the requester, need to participate in TEFCA to get the information."

Steven Lane

That is not being contemplated.

Deven McGraw
Yes, that is not what is proposed. So, that is my major problem with this, that because that kind of exchange is not subject to the fee exception, it puts the potential for high fees back on the table, so therefore, if you decide to participate in TEFCA, you have to know up front that you could get roped into paying whatever is the going-rate fee because you do not have the protections of the fee exception, and therefore, it might actually be a disincentive for participating in TEFCA because I can get a better deal financially by exchanging through these other manners, and I am entitled to ask for them if I am not participating.

Steven Eichner
Right.

Steven Lane
So, Deven, so we do not lose this one altogether, how about we do it this way, and have the first recommendation be the one you proposed, the safe harbor with rebuttable presumption, and then, second, if, however, this proposal for the TEFCA exception goes forward, then they limit it only to the approved SOPs?

Deven McGraw
Yes, I would be okay with that.

Steven Lane
All right. Hans?

Hans Buitendijk
On part, though, and again, only for the situation where both parties are part of TEFCA…

Steven Lane
Oh yes, that is what we are commenting on. That is the baseline here.

Hans Buitendijk
In that context. I thought there was something that, from an HIN perspective, is subject to information blocking. Where do we feel that fees need to be reasonable? The comment that you are making, Deven, that I am curious about from your perspective is where can the fees that RCE, TEFCA, etc. are raising would go beyond a level that would be considered unreasonable, and therefore become subject to the information-blocking considerations around not being able to charge unreasonable fees for interoperability? Where do you see that threshold kicking in? I understand your concern, that if you are locked into a regimen that has no limitations on the fees themselves either, and therefore you are locked in and you have to go along with that, that could become problematic. I understand that. I am trying to figure out if there is a ceiling effectively there as well, because as an HIN, they are still in that same boat.

Deven McGraw
Sorry, Hans, I do not understand your question.

Hans Buitendijk

A party can be considered an information blocker if you are charging unreasonable fees for information sharing.

Deven McGraw

Well, only if the person who is requesting data from you does not agree to pay your fee. So, if somebody grants you access in exactly the way you have asked, you can charge them a fee that is not subject to the fee exception. That is already in the rule. That is already part of information blocking. So, you only get kicked to the negotiation and the fee safe harbor, or the fee exception, I should say, if that agreed-upon way of exchange is not agreed upon by both parties. Then, you get kicked down into what manner you are going to exchange, and if you have certified health IT, that is one option, or the machine-readable, agreed-upon mechanism of exchange is the third one, and both of those options are subject to the fee exception. So, you do not get kicked into fee-exception land until you reach the point where what you are offering me as a mechanism for exchange does not work for me.

Hans Buitendijk

I do not want to do this right now because it would take too long, but I want to check with some folks because I thought that basically, if you are charging too much relative to alternative ways, means, or otherwise, that that in itself is sufficient to raise the claim of information blocking.

Deven McGraw

Well, keep in mind that when you are using certified health IT as the mechanism for exchange, you are already in the alternative manners part, so that is probably going to be the use case that certified vendors see most often as people wanting to connect up, but currently, if you are a requester and you say, "Here is how I want the data, in exactly this way," and the actor on the other end with the data says, "All right, I am granting it," that is already under the information-blocking rules. You are not kicked into the fee exception.

Hans Buitendijk

I want to check with some folks. I understand your concern, so do not get me wrong there, but I thought there was still another safety valve, if you will, when you were part of TEFCA because it in itself is effectively an HIN, and therefore they need to charge reasonable fees.

Steven Lane

So, Hans, you go ahead and look into that. We can come back to that next week. So, I want to point out to folks that if you just scroll up a little bit, I have highlighted the rows above this in green because we are done with them, and I have highlighted this one in yellow because we have work yet to do to revisit that, and now I would like to move down to Row 6, where we are talking about uncontrollable events and third parties seeking modification use, so let's go on with those. Under the uncontrollable events, "recommend that ONC expand the definitions within uncontrollable events condition to include impediments of data access, exchange, or use 'because of' any disaster or emergency declared by an authorized governmental agency. In addition to declared emergencies, this would include response recovery periods associated with natural disasters that impact the availability of providers' information systems or data." This was yours, Ike. Are you comfortable with the wording?

Steven Eichner

Yes.

Steven Lane
Does anybody have any concerns about this? I love it.

Deven McGraw
This is essentially what they proposed, right?

Steven Lane
Yes, but Ike just wants to be sure.

Deven McGraw
I agree, and plus, it is always worth endorsing, in addition to giving them… "You got it right."

Steven Eichner
The modification here, Deven, is that the original language reflected a public health emergency. We are looking at expanding or changing the underlying condition because something could be an emergency that impacts lots of people, healthcare providers and the like, but is it a public health emergency?

Deven McGraw
That makes sense. Thank you.

Steven Lane
All right. No hands up? Thank you. The next one is the one that came out of a long discussion we had about my enthusiasm for supporting providers being able to write access to their EHR databases. It became clear that I was not going to win that one this time around, and Ike suggested instead "recommending that ONC update certification requirements so as to support providers' ability to utilize third-party applications other than the primary EHR with write access to USCDI data elements maintained in certified health IT while minimizing risk to data security and EHR performance, e.g., write access to existing APIs and support for user-created fields." So, this was my best attempt to reword this one. How do you guys feel about that?

Steven Eichner
I have a minor edit. Should it be "write access utilizing APIs"?

Steven Lane
Which part?

Steven Eichner
The very last line, clarifying, basically, what "existing" is, so that it is not existing today, it is at any point you are actually using it.

Steven Lane
So, just that word change there.

Steven Eichner

Right, and again, because you are utilizing the API with your third-party app. Basically, the app is using the API. It is not separate access.

Steven Lane
Okay. Anybody have any concerns about this? Again, it is recommending that they work towards it.

Hans Buitendijk
I think that last part, "working towards that," could be made more clear. So, "update" sounds like "do that now," and I think "working towards" means to really identify if there are actually subsets of USCDI to focus on in particular and other ones that are not quite ready, because even with third-party apps within the provider space that serve the provider, there are still some variations in what data is actually needed when you write to make that underlying system work correctly, and that is not necessarily where we are all on the same page yet that there is one consistent definition on how you can write to each given USCDI element. There are minimum requirements that each and every system will have that will vary somewhat.

Steven Lane
So, how do you feel about that rewording there, Hans?

Hans Buitendijk
I am okay with that because I think it is a fair direction to be heading, but there is a bit of water to flow under that bridge before we get there.

Steven Lane
Right. Okay, can I turn this cell green?

Hans Buitendijk
I am good with that.

Steven Lane
No hands? Eliel, you are good? Hannah? It is green.

Eliel Oliveira
It is good.

Steven Lane
Okay, we have 20 more minutes, and we only have a couple more rows. We are killing it, guys! Row 7 is manner exception exhausted. Deven provided a thoughtful recommendation that I boil down to "recommend that ONC further clarify what is meant by 'entities similarly situated to the requester' to clarify that responding actors are responsible to exchange data for the purpose and the manner requested if they are able to do so, even if they are not accustomed to utilizing the requested transaction pattern." Deven, you will recognize I stole that "transaction pattern" terminology from the work we are doing in California. It is a useful term, right?

Deven McGraw

I think so. The point here was I did not think that ONC had said enough about what was intended by is an actor exchanging similarly situated actors, and I thought that it could have the perverse effect of hardwiring in existing exchange partners and patterns.

Steven Lane
I like it.

Deven McGraw
The point of the information-blocking rules was to open up some avenues and to say to entities that you cannot just choose your swim lane and never get out of it.

Steven Lane
So, does anyone have any concerns about this as drafted? Hannah, Eliel, Ike, Hans? All right, I am loving this. Okay, now I want to again thank Dr. Jafari for joining us today because we are now going to jump into a longer batch of these recommendations and, in so doing, probably run out of time, but we have time to come back to this next week. So, let me try to rearrange columns in such a way that we can actually see this in one screen. Hah! I did it! How about that? Okay, good.

So, let's just take it from the top. Deven, I think this first one was yours. "Recommend that ONC focus its efforts on supporting individual requests for restrictions and the ability of recipients of data for which a restriction was requested to honor patient requests as much as possible." That sentence kind of goes without saying because that is what they are proposing anyway, but that is all right. "Since a requested restriction does not have to be granted, either by the direct recipient of the request or subsequent recipients of the relevant health information, this gives entities receiving data for which a restriction was requested an opportunity to discuss requested restrictions with the patient representative and to grant or partially grant such restrictions." So, what do you think of that?

Deven McGraw
Hannah has her hand up. I am very eager to see what she has to say.

Hannah Galvin
Some of the comments that **[audio cuts out] [00:59:59]** together around this. I think it is interesting to think about the HIPAA request restrictions around this. The previous work that has been done around granular segmentation has been done according to 42 CFR Part 2 that has not been a use case where the restrictions have to be requested and granted, so, previous use cases have not required a third party in the flow of data, where I, as the patient, say I want to redact my data, and now it has to go to a third party to say yes, you can or no, you cannot, and I think we need to really understand a couple of things. One is what does that look like from an operationalization and an administrative burden perspective if that makes sense as a use case?

I think one of the things that I will be saying in my personal comments or in chef's comments around this is asking for some clarification around the interpretation of HIPAA patient-requested restrictions in light of both 21st Century CURES and the interpretation now where patients are supposed to own their data, and so, does that change in any way what happens if I want to request restrictions and the organization says, "No, you cannot have restrictions on this data under HIPAA," and how do we interpret that in light of 21st

Century CURES? And also, the fact that the HIPAA privacy rule was written in 2001 or so, and it was an entirely retrospective workflow at that time. "I have data in my chart, and now I want to restrict where that data goes."

But now, with standards and new technology, we can do this prospectively. I can say, "I do not want any of my data pertaining to reproductive health to be shared," and we can put that rule on my data prospectively, and I think that was not necessarily anticipated under the HIPAA privacy rule, and understanding how that should be interpreted or that type of workflow should be interpreted, so I think those are open questions that I have in terms of thinking about how patient-restricted workflow would actually be built out using standards and operationalized. Deven, I wonder if you have some thoughts on that. If Mohammad is on, he and I have discussed that at some length as well.

Deven McGraw

I can appreciate that we do not have a lot of experience with the implementation of the HIPAA right to request restrictions, in part because it has always been completely optional, with the exception in the post-HITECH era a requirement to restrict exchange with a payer at the patient's request if they pay in full out of pocket, and in the preamble to that rule, there are some caveats around how you operationalize that because obviously, it has its challenges, but historically, it has just been a right because it was completely voluntary on the part of the entity to grant. It has not really gotten much traction or experience. I can tell you that the 21st Century CURES Act does not change that HIPAA right to request restrictions into a required restriction in any way, shape, or form, and the privacy exception under 21st Century CURES Act would allow an entity to block an exchange of data based on a restriction that they had honored for that particular patient. It is already covered in the privacy exception.

In my view, the 21st Century CURES Act does not really alter this scenario at all, and part of the reason why it feels like a very appealing use case is because in the past, every time in a non-standards, strictly policy context, when this discussion of allowing patients to granularly consent, pull back certain data, allow data to be **[inaudible] [01:04:46]**, the very same arguments get launched, and we get stymied into this box, which is that we cannot cover all the data because of the way that either do document exchange or we do not exchange granularly, and even if we did, we might miss inferential data that is not directly related to that condition, but infers that condition. Does the patient really understand that if we leave their meds out, it could kill them? There could be really serious consequences to not exchanging all the data. In my experience, that is something that, as providers, you know even better than I do that is super strong.

So, to me, the right to ask can be honored in a much more nuanced way if we have tech that can help and we are able to have a moment with the patient, because it has to be on patient request, to say, "Hey, is this something you really want to do? Are you sure? It could have consequences. We may not actually be able to get all the data because there is inferential data, and by the way, it is not downstream. This is just our restriction. Once you agree and we share it, then you are kind of responsible for going forward with it, but it takes off the table all of that angst around some of this stuff because it still provides that discretion, but by facilitating the creation of some technical abilities to honor, we create room for there to be more agreement to grant some of these things as opposed to, as you know very well, in a Part 2 context, in a state law context, there are the rules, and they are nonnegotiable.

Hannah Galvin

And you can build out algorithms just based on those rules.

Deven McGraw
Right.

Hannah Galvin
I just want to point out and call out to this group and ONC that in this context, you are putting… There are good things and bad things about putting a human in the middle. The good things, as you have called out, is you are putting a human in the middle, and there is some discussion that would need to happen. The bad things about putting a human in the middle are administrative burden. That is the other side of the coin, that others have called out how much cost, burden, and time this might be putting on the health system. It does not mean it is not the right thing to do, and my personal view is it is very much the right thing to do and the right direction, but I think there is that piece.

Steven Lane
Can I bring us back to the recommendations? We have only so much time available to us. I also want to point out that we are going to have some of this discussion again tomorrow in Group 2. Remember, in Group 2, we are dealing with the question of the very specific proposal to support patient requests for restriction. In Group 1, we are dealing with additional potential capabilities. This is a request for information. The other one is feedback on a proposal. The one thing I would ask is since this first recommendation in this cell has to do with the proposal regarding respecting patients' HIPAA requests for restriction, should this go over into tomorrow's segment?

Hans Buitendijk
I have a general question in that regard. I just put a thought in K around some email exchange this morning, but this set seems to be the overall picture. A subset of this for tomorrow is to determine which ones of these, one or more, are candidates to already consider or not, as part of certification criteria. So, I think we can keep it separate to what are all the things that we need to consider here, and the subset is tomorrow as to which ones that we pick out, and maybe something else as well, but that we particularly pick out that are ready for certification. Would that help?

Steven Lane
Yes, I think that is a good way to think about it, Hans. Again, back to this first one, recommending that the fact that a restriction was requested, whether or not it was respected or accepted, having that fact travel to subsequent recipients of the data so that they are aware that that restriction was requested and/or accepted. Is this something that we want to recommend?

Hans Buitendijk
As an overall response to information, I agree. As a specific certification criterion, there are a couple prerequisites that I think we need to talk about first to see whether this is viable to not send everybody in different directions.

Hannah Galvin

I agree. I think that we are not quite ready with the standards yet, and I do not know if Mohammad can speak yet, but we have a maturity model that we are laying out, and I think within three to five years, we could be ready for a certification standard around certain use cases for this, but not quite yet.

Steven Lane
So, that would suggest leaving it here in the Group 1 recommendations as opposed to moving it into the Group 2 recommendations because this is where we say, "These are the things you should be looking at in the future."

Hans Buitendijk
Agreed at this point in time, since I think we have to go through the full list, and Steven, if I may ask whoever controls it, could you move one column over? That allows us to see J and K at the same time. To what I think Hannah is talking about, that first dash created clearly the fine set of sensitivity and confidentiality flags, at least those. If you have that, you can start to truly segment flag data and begin to do that consistently. You can start to share it. Now, setting up rules that can work against that is the next step that I can define as a patient, etc., but that seems to be one of the critical first steps that need to be done. Are we all in agreement? The lists that are currently in the standards suggested seem to be a lot bigger and leave a lot more space for interpretation than if we can hone in on what is that set that we truly agree needs to be collected and shared.

Steven Lane
So, Hans, when we get to this tomorrow, those details have been specified.

Hans Buitendijk
Good point. We will get into that further. Here, today, was why I was asking whether that is meant to be the overall set. That notion of these, whether it is certified or not, needs to have it, and in this list, it seems to have a reasonable place in context of the last two bullets, and the first one is going to be heavily dependent on it, which we just said, but this is the list of the things that we need to do for certification. This may very well be one of the first ones that we could do if we are comfortable that the current set of standards would support that, and I think there will be different opinions on that.

Steven Lane
Okay. Seeing no hands, what I would like to do is see if we can get through one or two more of these before we cut to public comments. The second one here, in Row 8J, "recommend that ONC work with OCR, AHIMA, other relevant industry partners and patient representatives to develop standardized patient education materials regarding the consequences and limitations of requested restrictions, and that ONC encourage and/or require actors who receive and manage individual requests for restriction to provide such education." So, this really came out of Sheryl's recommendation, and a number of touched on the value of this patient education. How do you feel about the way I have worded that?

Deven McGraw
I agree with it.

Steven Eichner

One quick modification: "Patient organizations," perhaps, so it is not just looking at individual patients, but looking at patient organizations as well as patient reps because organizations like AARP, American Diabetes Association, and Rare Disease Association might be really, really helpful, as well as getting some individuals as well.

Steven Lane
Sure, okay. I will add that to the next one, too, where I used the same language. Okay, so, we are liking that one. That is good. All right, we will be coming back to the one above. I see no hands, and we have four more minutes. For the third one, "recommend that ONC work with OCR, AHIMA, and other relevant industry partners, patient representatives, and organizations to develop recommendations and standards regarding the need to periodically review and validate applied restrictions with the individual representative so as to prevent unintended restrictions of data access."

Steven Eichner
The only thing that I would clarify a little bit is that these are restrictions that have been deployed or set, not looking at discussion on the concepts.

Hannah Galvin
So, instead of applied restrictions, you mean deployed?

Steven Lane
Yes, this was by applied restrictions.

Hannah Galvin
So, by "applied," we mean "deployed."

Steven Eichner
Yes.

Mohammad Jafari
This is Mohammad. I think "deployed" is a more accurate or less ambiguous term, if we could use that term.

Steven Eichner
Yes, that was where I was aiming. It is really looking at technology support for changing or facilitating change, of things that have actually been said.

Steven Lane
This is very strange. For some reason, it is not…there we go. Are you seeing the change? Maybe refresh the display document, just because I have changed it and I am seeing the change to "deployed." Anyway, I added "deployed." Trust me, it is there. All right, two minutes. Let's see if we can do one more, which is to say, with the same beginning, "patient representatives and organizations."

Steven Eichner
The third bullet does not make sense at the moment.

Steven Lane

No?

Steven Eichner

I think it would be "unintended rerelease of data."

Steven Lane

"Unintended restrictions of data access."

Steven Eichner

I am looking at the third item.

Steven Lane

I am in Column J, third recommendation.

Hannah Galvin

That is what we just discussed, was the third.

Steven Eichner

Yes, but the edit may not have gone through. "To recipients of restricted data so as to prevent unintended restrictions…" Yes, it just still reads a little peculiarly. I think the concept is there, we just need to refine.

Steven Lane

Okay, if you can think of clearer wording…

Hans Buitendijk

I have one other comment there about "should be communicated to recipients." Depending on how we end up with an infrastructure, it is actually not communicated to other recipients. They have another way to figure out what they can and cannot do. So, I am not sure what the better word is, but this assumes a chaste data approach as opposed to a knowledge sharing approach.

Steven Eichner

Hans, I appreciate where you are going with that. We will label the hub/spoke just for the moment. In my mind, that is still a communication.

Steven Lane

Okay, let's cut to public comment and come back here.

Public Comment (01:18:18)

Michael Berry

All right, sounds good. Could we put up the public comment slide? We are going to open up our meeting for verbal public comment. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. So, let's

pause for a moment to see if any members of the public raise their hand. I am not seeing any hands raised, so I will turn it back to our cochairs. Thank you.

Steven Lane
Thank you. We will keep an eye out for raised hands. So, again, I am sorry, we sort of slid into the third recommendation here because I moved what had been 1 down to the bottom so we could come back to it, so I am just trying to move through some of these. We were on the third one, which I never had the chance to fully read, so let me just read it real quick. It was "To recommend that ONC work with industry partners to explore how revocations of previously applied/deployed restrictions can and should be communicated to recipients of restricted data so as to prevent unintended restrictions of data access." Again, this is like "Let's look into this." Hans, your hand is up.

Hans Buitendijk
I was going to go back in part to my last comment, a small change of "communicated" to "shared with." I am completely in sync with Ike. It is not the intent, but the word "to" is giving a little bit more of the push model than "sharing with."

Steven Lane
Got it, okay. I hear you. Since we are just exploring, that is totally fine with me.

Hans Buitendijk
Ike, are you comfortable? I think we are in sync.

Steven Eichner
Yes, I wholeheartedly agree with your point. If it works better, fantastic.

Steven Lane
Hans, your hand is still up.

Hans Buitendijk
I need to withdraw that, sorry.

Steven Lane
Okay, no problem. So, we made it through that third one. The fourth one, which I will now separate out with some space around it, is "recommend that ONC work again with OCR, etc. to establish standards for providing…" Oh, "providing patients and representatives with a more comprehensive accounting of disclosures of their health information, including what data was shared, when, with whom, and for what purpose, "again, this should probably be an "e.g.," "beyond the limited accounting currently required by HIPAA." So, we have had a number of points in our discussion where people have talked about the importance of an accounting of disclosures, and especially in the TEFCA era, but we all know that HIPAA's requirement for accounting of disclosure is pretty slim, so the idea here is shall we ask ONC to look into something more comprehensive? Deven?

Deven McGraw

HIPAA is actually very comprehensive on this point because it was amended by HITECH in 2013 to require an accounting of disclosures for treatment, payment, and operations. When OCR did their proposed rule to implement it, it was vehemently opposed by industry stakeholders. Subsequently, the Health IT Policy Committee did an extensive amount of work, including a hearing, on this issue and came up with some recommendations. There was also a voluntary certification criterion for certified health IT that never really got implemented. This is an incredibly complicated issue. Having said that, it is already law, it just has not been implemented. It is supposed to be on the HITAC roadmap, it just has not been scheduled. So, to me, this feels like one where it does need further exploration. I am not sure it lands as just a comment in an RFI slot around this particular issue, but whether that is through an annual report recommendation or something along those lines, it is just…

My biggest beef with the way this is framed is it does not recognize that, in fact, HIPAA as amended by HITECH does require more, it is just that the regulations have never been amended to make it happen, and that it is identified as a priority issue for the HITAC under the 21st Century CURES Act, we just have not gotten to it. It is complicated, but I do not know if it lands here. As a side comment, go work with industry.

Steven Eichner
Can I ask a favor? Below the recommendation, can you include a rationale just summarizing what you just put out? I agree with you. I would not want to constrain, based on what you just said, the comment solely to this recommendation. On the other hand, I do not want to push it off solely to Annual Report where there is an opportunity to make a relevant comment in this space. I think we can probably do both. The other modification I would put within this comment is that really, leveraging technology and standards that have already been adopted is a critical thing to include here because you are right, in 2013, we were in a completely different technological environment than we are today, and actually accomplishing it would have been very difficult, given the technology of the moment.

Given the technology we are at today, I would envision at least some things would be an awful lot easier, that if a provider or an EHR is tracking data that it has pushed out for an internal audit purpose, for example, all the patient information is already in there. It might not be terribly difficult to write a query that that data is available to the patient on an automated request. I may be oversimplifying it, but I might not be. Again, I think the point here is we are not asking or suggesting that it be a new invention from absolute scratch. It is building on the policy and legal foundation that exists, but also leveraging our new technology environment as well.

Steven Lane
I have been winnowing this down to make it even tighter.

Deven McGraw
I am happy to work with it. It is actually established HITECH standards that have not yet been fully incorporated into HIPAA, but as a statute, what HITECH did was amend the HIPAA rules. Eliel asked a good question about enforcement. OCR will not enforce anything that they have not done implementing rules on, and they gave it a try, and the industry said, "What you have suggested is not tenable." At any rate, I am going to try to dig up some of the background on this from archives, but in the meantime, I am happy to put some sub-bullets in there per your request, Steve, to try to provide a little bit of history.

Steven Lane

Right. So, I think this probably could be in our Task Force recommendations as well as being referred to the Annual Report Workgroup. Is that fair?

Steven Eichner

Yes, and from my perspective, it is not just under TEFCA. TEFCA is another element that makes it relevant, but whether I am using TEFCA or not, it is still a relevant issue.

Steven Lane

Right, okay. Hannah?

Hannah Galvin

I liked what you had in there, Steven, around purpose of use and where it was going, etc. I do think that it is important, and I fully support the accounting of disclosures, to give patients context around the accounting of disclosures. Technically, that is very difficult to do. There is an HL7 purpose of use that you can try to require from a standards perspective, but that is going to be hard to translate into patient-facing language. So, wherever we put this, whether it is in the Annual Reports Workgroup, I think some of those pieces need to be sorted out. How do you do this? Deven, I can imagine where some of this has died in committee a little bit. How do we actually do this in an operational way, leveraging standards, because we are going to need that in order to scale this, but then translate it into patient-facing language that will not then result in 10,000 calls to the help system saying, "Why didn't you send my data here?" So, I think it is a challenge, but it deserves some dedicated work.

Steven Eichner

Hannah…

Steven Lane

Actually, Steve, I am going to cut you off because we are at time and I do not want to go over. We will come back to all of this next week. There are a number of additional recommendations here. I invite all of you to continue to look and add suggestions. As members of the Task Force, do not monkey with Column J. I like what you did, Hans, adding Column K, and we will try to get through the rest of these. I am looking forward to tomorrow, Ike, when you are going to take us through draft recommendations for Group 2. So, as you can see, these are upcoming meetings. We will be developing our final recommendations, report, and slides over the coming weeks in anticipation of getting this to HITAC on the 15th. So, thank you, everyone, for your time and participation.

Hans Buitendijk

Thank you.

Deven McGraw

Great job. Thank you.

Adjourn (01:29:05)