Information Blocking (IB) Workgroup 2

Transcript
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Virtual Meeting

SPEAKERS

Name	Organization	Title
Michael Adcock	Individual	Co-Chair
Andrew Truscott	Accenture	Co-Chair
Valerie Grey	New York eHealth Collaborative	Member
Anil K. Jain	IBM Watson Health	Member
Steven Lane	Sutter Health	Member
Arien Malec	Change Healthcare	Member
Mark Knee	Office of the National Coordinator	Staff Lead
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Operator
Thank you. All lines are now bridged.

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

Hi, everyone. Welcome to the HITAC information blocking task force. This is workgroup number two. We are going to dive right in today. I know we have a full agenda and a lot to cover. Just a quick roll call. Andy Truscott?

Andrew Truscott - Accenture - Co-Chair

Here.

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

Michael Adcock? Valerie Grey? Anil Jain?

Anil Jain - IBM Watson Health - Member

I'm here.

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

Arien Malec?

Arien Malec – Change Healthcare – Member

Hello.

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

And Steven Lane?

Steven Lane - Sutter Health - Member

I'm here.

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

Thank you. I will turn it over to our chairs, or at least to Andy.

Andrew Truscott - Accenture - Co-Chair

Thank you so much. Hello guys. It's Andy Truscott here. Mike was intending to be on, but something unavoidable popped up. So, I'm afraid you're stuck with me with the next two hours of your life. If you notice me speaking slower and attempting to annunciate clearer than usual, it's for the benefit of whoever's doing the closed captioning. We have discerned that my voice becomes the [indiscernible] frequently. So, I'm going as slowly as possible. Okay, I'm going to hand over initially to Mark Knee who is supporting out taskforce just to give an overview of what we're going to work through today. And then it will come back to me and I will talk through how we're going to go about recording this.

Mark Knee - Office of the National Coordinator - Staff Lead

Thanks, Andy. Thanks very much. Welcome, everyone, to workgroup two, exceptions. I think this should be a really interesting conversation. I just want to go over quickly the structure of the workgroup and what we're going to discuss today. I think you should be able to see on your screen, I'm sharing my screen right now. We are working off the document that was circulated that provides the regulatory text for the various exceptions that we are going to be talking about, as well as, preamble language, further request for comment, which we will talk about as well. I want to emphasize, I know this came up in the full task force call but I'll say it again, that while I put the regulatory text in this document because that's the language that we use. It's the clearest way to talk about it. The preamble is very important because it provides examples, and color, and an explanation

as to why ONC made certain proposals and how we got where we are. I just want to emphasize as we go through even though I have reg language up there we will site back to the preamble, which is very important as well.

In the document it's pretty straightforward. We just go through the seven exceptions. You have an opportunity with the Google Doc, which if anyone needs the link and doesn't have it we can send it back out or I think they can post it. You can open it up on your screen and in real time you can make edits, and it will show on my screen, which I am sharing as Andy is doing right now. Today we are going to try to get through the first three exceptions. Exception for preventing harm, exception for promoting the privacy of EHI, and the exception for promoting the security of EHI. It's a lot to cover. As Andy and I have been doing with the other workgroups we are going to try to get through all this, but of course we are going to circle back and talk about the issues that are still outstanding. We are definitely not going to get everything solved today. We are also going to bring the highest level issues to the full task force meeting this Friday for the full discussion.

That's the general structure. Let me just scroll down. Once we get through the exceptions this work group is pretty long, but this work group also has some requests for information about additional exceptions and the complaint process, as well as, disincentives for healthcare providers. Because as you probably know, in Cures**,** there's penalties laid out for health IT developers, exchanges, and networks, but disincentives for healthcare providers is still an open question. We have a request for information out for that. That's a high-level overview. I'm here to try to help out as much as possible to help you understand what ONC put into the information blocking section of the rule, why we did it. I'm limited to what we put in the preamble and reg texts, but I'll try to help as much as possible in citing to the language in the rule that will help us move the conversation along. With that I'll turn it back over to Andy, and I look forward to the conversation.

Andrew Truscott - Accenture - Co-Chair

Thanks Mark. So, hi everybody. I'm going to assume you all have access to do to the Google Doc. Is that correct? Anyone saying no? Great okay. In the way we work this with other work groups we've been working through the Google doc together in order and actually jointly collaborating and annotating in the comments and recommendations as we go. But we do that as a team. So, anybody and everybody should be contributing into that. And as we discuss and dismiss or discuss and agree that's where we are going to capture those dismissals or agreements. Does that make sense?

Anil Jain - IBM Watson Health - Member

When you say we do that as a team, are you suggesting you would rather that we not work on this independently between are workgroup meetings?

Andrew Truscott - Accenture - Co-Chair

I would rather that you worked on – If you work independently between work groups meetings, you do so on the Google docs version.

Anil Jain - IBM Watson Health - Member

Right, no. That's what I mean. But that's acceptable?

Andrew Truscott - Accenture - Co-Chair

Absolutely. I think it is going to be required for us to get through this, as well.

Anil Jain - IBM Watson Health - Member

Okay. I just wanted to be clear.

Andrew Truscott - Accenture - Co-Chair

Absolutely. Thanks for seeking the clarity. What I don't want is everyone to work on their own versions, on their own hard drives, which takes a bunch of sifting through. And we end up having to discuss all the discrepancies between them. Do it in one place. Make sense?

Anil Jain - IBM Watson Health - Member

Yes.

Andrew Truscott - Accenture - Co-Chair

Awesome. Without further ado we have three rules that we are supposed to be looking through today. I've anticipated this will be the most discussed group out of the three. And given that the other two have been more discussed than I anticipated, I'm eagerly anticipating lots of discussion here. So, without further ado, let's jump into the exception on preventing harm. There are copious amounts of preamble, which I am sure we have all read. I am going to hand over who wants to speak first, basically, around this. I think, Anil, you've made a comment. I've made a comment. But –

Arien Malec – Change Healthcare – Member

I'm trying to make comments and maybe I cannot make comments. So, I may have to validate that from how I'm working from a hotel. This is Arien.

Andrew Truscott - Accenture - Co-Chair

Oh hello, Arien. We can't cope without you making comments in line.

Arien Malec – Change Healthcare – Member

No, and I have, as everyone knows, I have a ridiculously long Twitter thread that covers information blocking and the exceptions. One subpart of that thread covers the two exceptions associated with corrupt or inaccurate data and misidentification of patients. The concern that I have is that those

could be rather large holes that you could drive a dump truck through unless we define criteria for what is meant by a corrupter inaccurate.

Among the examples that I have used is that almost everybody's record has some level of inaccuracy in it, because diagnoses were entered wrong or provisional diagnoses are still in the record, or someone mistyped something. And if the standard for inaccurate does not incorporate the right of a patient to view the same record that the provider is seeing and correct that record or the ability for another provider who has a permissible use to be able to see the same information that provider A has, then I think we are misapplying the corrupt or inaccurate standard. We need a standard that is rare in practice and is confined to cases where the data are known to be garbage due to a bug or other kind of true data level corruption not mere inaccuracy.

The second comment is related to the misidentification standard where if there is no obligation on the data holder – in particular the provider organizations – to take reasonable steps to identify and match patients then that misidentified patient standard could be, again, an easy exception to apply in practice in ways that will limit information flow. So, I think, for those two main exceptions there need to be clear standards and clear obligations for counterparties to meet such that those exceptions should be fairly rare in practice.

Steven Lane - Sutter Health - Member

And I think that that's a really good point to be made generally about all the exceptions. We need to make sure that they are as clearly specified as possible so we don't have people employing them and getting away with it where we, in our hearts, know that they shouldn't.

Andrew Truscott - Accenture - Co-Chair

By definition, they are exceptional. How do you propose doing that, Arien?

Arien Malec – Change Healthcare – Member

So, again, I think there's a good standard on the corrupt or inaccurate where I think inaccurate may be a misleading word. We should limit this exception to true data corruption. That is cases where the data holder knows that the data are not reflective of what parties normally would access due to some hard level data corruption. The standard is not applicable to cases where the record is the record. It's the record that people use or actively manage but may or may not have some inaccuracies associated with it.

With respect to the misidentification of patients, I think, we, again, should limit the exception to cases where we know we are given the wrong patient's data in response to a request. There needs to be a standard for business reasonable or appropriate maintenance of patient matching standards and patient matching technology that is efficient in order to meet the test of patient identification.

Anil Jain - IBM Watson Health - Member

This is Anil. I think, one way we could think about this is if the clinician was to use that record to make clinical decisions, no matter how incomplete it is, or how inaccurate is, because it is being used for

clinical purposes or clinical decision making then that record should be shared. I don't think that we are going to be able to expect that the record is going to be fully complete or that it is going to be fully accurate for all the reasons.

And I agree. You don't want people to say I'm not going to share it because it's inaccurate when they are already making clinical decisions and then reading past the inaccuracies, for example, to do that. We do have to come up with some examples of where it is a technical corruption. It is a technical issue that would prevent someone from using that record that should also then prevent them from sharing that record.

Steven Lane - Sutter Health - Member

I will validate that from clinician's perspective. We have recently been entertaining requests and having a discussion in my organization about the desirability of, for example being able to see notes that are still in progress or encounters that remain active and open. For example, if a patient is in the hospital in one institution and their primary care provider or consulting specialist is in another institution and they want to be able to interact with information.

Or if you make a referral, if I as a PCP make a referral to a specialist, and I haven't gotten around to closing my note, and I've gone on vacation, it's still valuable for that specialist to be able to look at my note in progress even if it's not finalized to be able to glean whatever information. We allow folks within our own institutions to do that, to see documentation in progress. We shouldn't limit that to individuals that might be accessing the data remotely.

Anil Jain - IBM Watson Health - Member

Clinically when we practice, when I was practicing, there would be occasions where two patients were erroneously merged. You can call that an identification issue or you can call it a corrupt record, whatever you want to call it. As a clinician we were immediately aware that there's a problem here. If a patient was to request that chart I think that would be a very good reason not to. And then to remediate that by contacting health information management and having those records separated. Until it was mitigated you would not want to share it.

I think, having examples – And that's what I was trying to get to in my comments on the spreadsheet – where there are some very tangible examples of where it is appropriate and where it is not appropriate, I think, would help. We are dealing with an imperfect record, and now we are trying to put some boundaries on it – too many reasons why people might hide behind that.

Andrew Truscott - Accenture - Co-Chair

A couple of comments. I was picking up on Anil's viewpoint just there. If a patient requests a record and we know there is an entanglement, there is in an inadvertent merge taken place, we are still going to give them a record **[inaudible] [00:15:30]** first. And the message to patient is yes, we are going to give you a record once it's been untangled. That's not blocking.

Anil Jain - IBM Watson Health - Member

It is blocking.

Andrew Truscott - Accenture - Co-Chair

There's no timing on this exception. And in the actual rules is there a time on the blocking?

Steven Lane - Sutter Health - Member

I am going to seek a correction from the ONC colleagues. The way information is defined in the role is the right to access exchange and use clinical data for permissible purposes or permissible uses is unlimited unless it's covered by one of the exceptions.

Mark Knee - Office of the National Coordinator - Staff Lead

That's right.

Andrew Truscott - Accenture - Co-Chair

I cannot believe that the access was –

[Crosstalk]

Mark Knee - Office of the National Coordinator - Staff Lead

There's an unreasonable standard which could be used in some cases for I want it. I want it right now. If you don't give it to me then you are an information blocker that could fall into the unreasonable standard. But generally the right is non-constrained unless covered by an exception.

Andrew Truscott - Accenture - Co-Chair

There some boundaries around time. It's short. It's one business day. They actually do have some boundaries.

Mark Knee - Office of the National Coordinator - Staff Lead

This is one of those it depends. If the data is electronic availability and you implement the electronic standards for access then that's not a reasonable standard. If it's a record that needs to be copied to PDF then there may be another reasonable standard. But again, I think that all should be discussed under the unreasonable exception as opposed to this exception.

Andrew Truscott - Accenture - Co-Chair

The first point I was going to make was that the definition of inaccurate there. If every record is inaccurate – This is not referring to a record. This is referring just to data. So, any data being inaccurate would have rendered the entire record block **[inaudible] [00:18:03].**

Steven Lane - Sutter Health - Member

That's a good point. Should we be looking at this at the full record level or at a lower level? It could be an individual piece of data. It could be an individual encounter. It could be some subset of data or encounters.

Arien Malec – Change Healthcare – Member

I might be misreading the text. In many of the reg texts, there are caveats that the permitted blocking must be minimal. And I think in this case, if there were subparts of the records that were known to be corrupt then the minimization of that blocking would argue for just blocking the small subpart that is going to be incorrect until it is remediated.

Anil Jain - IBM Watson Health - Member

I think that could be problematic clinically. We have to trust the judgment of those actors who are making that decision. Let me give you an example. If we were to give a patient their medical record but we decided that were some inaccuracies in their allergies and we therefore we withheld the allergy data but gave everything else that could cause problems down the stream.

Andrew Truscott - Accenture - Co-Chair

The important **[inaudible] [00:19:29]** page 387 is the preamble. We know, however, that known inaccuracies of some data within a record may not be sufficient justification to withhold the entire record, if the remainder of the patient's EHI could be effectively shared without also representing the known incorrect or corrupt information as if it were trustworthy. What validity does the preamble have versus the actual reg?

Mark Knee - Office of the National Coordinator - Staff Lead

It's a good question that can be somewhat contentious at times. The regulatory text is what people look to first. But preamble expands on what is in the reg text. They are supposed to be looked at hand-in-hand even though the reg text is really the law in essence, but the preamble is part of it and should be enforced as well.

Steven Lane - Sutter Health - Member

The way I think about it – and correct if I'm thinking about this the wrong way. The way I think about this is the reg text is the reg text and in a legalist view, which these issues are inevitably going to come to some level of legal dispute, it's the reg text that's dispositive. But in cases of ambiguity about what

the reg text – reasonable ambiguity about what the reg text actually means, the preamble or commentary provides guidance for interpretation.

Mark Knee - Office of the National Coordinator - Staff Lead

I'm not going to say I have the answer. That's generally right, but it is open to interpretation. I will say that throughout when we're writing regulations you never want there to be conflicting information in reg text and preamble. There should never be a requirement in preamble that is not in reg text. Really the requirements should all be included in reg text, and then the preamble acts to explain and provide examples and highlights our thinking behind the reg texts. I think courts might disagree on how it is enforced perhaps, but that's generally what we do.

Andrew Truscott - Accenture - Co-Chair

We need to make the reg text then as accurate as possible without causing bloat.

Arien Malec – Change Healthcare – Member

By the way the clause that I'm thinking of is B4, which is no broader than – the policy must be no broader than necessary to mitigate the risk of harm. The same thing first C, which is practice necessary – no broader than necessary to mitigate the risk of harm. I think, that covers the case where portions of the record are corrupt, and it is reasonable to provide the rest of the record without that portion of the record.

Andrew Truscott - Accenture - Co-Chair

Shouldn't that be in A as well then?

Steven Lane - Sutter Health - Member

That same statement?

Andrew Truscott - Accenture - Co-Chair

No broader than necessary to mitigate the risk of harm.

Arien Malec – Change Healthcare – Member

This is the standard of the practice. The way the exception works is that it defines the practice. The practice must meet the terms under A, which are corrupt, misidentified, or actual harm. There are two tests of the practice. One is whether it is based on an organizational policy, and that organization policy must be minimal. Or if it's ad hoc then it must be documented in writing and also minimal.

Andrew Truscott - Accenture - Co-Chair

It must meet the following conditions, apart from two of them being ifs.

Steven Lane - Sutter Health - Member

Right. Must meet all of the following conditions and that wasn't clear to me the first time I read this.

Andrew Truscott - Accenture - Co-Chair

Actually, it doesn't say all the following. It says the following conditions of –

Steven Lane - Sutter Health - Member

That seems ambiguous.

Mark Knee - Office of the National Coordinator - Staff Lead

The way I think about this, and I'd love for correction, is that part A is the major portion and parts B and C are qualifications on the policies that are used for enforcing part A. If it is an organizational policy it must meet all the tests under part B, and if it's an ad hoc policy it must meet all the text under part C.

Arien Malec – Change Healthcare – Member

When I first read this I was worried that B was the big door they would drive the truck through, because all they needed was to have a policy. You just clarified this for me. It has to be A first, and then they need to have a policy.

Mark Knee - Office of the National Coordinator - Staff Lead

Yup. Or ad hoc –

[Crosstalk]

Arien Malec – Change Healthcare – Member

Or make a finding, as they say.

Andrew Truscott - Accenture - Co-Chair

If they do have a policy it has come to those four things, but you have to make a discrete finding.

Steven Lane - Sutter Health - Member

Can we dive into A3 a little bit as we're starting in on this? I just want to set the table. Is that timely? I've done a lot of work in the area of adolescent confidentiality, and it's a very thorny area. We have challenges in endangering the safety of patients when we think about adolescent data. Where you might have an adolescent who has the right to access their own health information, but they've also got a parent or guardian who has potentially the right access to that information. Then the parent or guardian accessing that information could potentially put the patient in danger. In our organizational policies, as well as, many such policies around the country we basically prohibit access for parents and guardians for kids between the ages of 12 and 17 inclusive, even to the point of not allowing the adolescent to give consent to release the data because that could be done under duress. To me that's a big area that we need to think about in terms of this particular piece of the exception. It certainly was the first one that came to my mind when I read preventing harm.

Anil Jain - IBM Watson Health - Member

That's a really complicated area, because as you know there are state laws in California that line up against that organizational policy. There are states that have the entirely opposite law that force disclosure to parents. Some of that would belong in the privacy in subpart three. Is that right? Two. In your case, Steven, the issue that you're raising is where disclosure of this information could cause direct harm based on suspected or clinical judgment of parental actions.

Steven Lane - Sutter Health - Member

Right. And it is tricky, too, because there are two levels of disclosure. One is disclosure to the parent guardian, who may otherwise have a right to access a patient's record. The other is disclosure to another organization where you can't necessarily rely on them having the policies and procedures to protect that information from that disclosure. When we got to that second piece we shrugged our shoulders and said we can't not release it if the patient moves or is getting care at an outside organization; we have to do that. We have tried to figure out is there some way to flag this data as adolescent confidential with the hope that the receiving organization has a way to deal with that. But in my soul I never feel like I've done justice to the privacy needs of the adolescent when that data is released.

Arien Malec – Change Healthcare – Member

It occurs to me though; this exception is one of the ones where the reg really pushes this to licensed healthcare professional exercising professional judgment, reasonably likely to endanger. It seems like there's broad enough language here that relies ultimately on clinical judgment or interpretation.

Steven Lane - Sutter Health - Member

And again, this is all about the exceptions. This is somebody saying this is the reason I didn't release the data. In some sense my concern is on the flipside of this. I want to make sure we give organizations the opportunity to protect the privacy and safety of adolescents where they feel it's appropriate. The way this is set up where this is the reason; this is the policy; or this was the specific finding in this case. It feels like this does cover my use case.

Andrew Truscott - Accenture - Co-Chair

The use case that always comes to mind when I see these kinds of statements is around some of the specific mental health conditions. So, Munchausen by proxy those kinds of things, where actually for the patient to be informed could actually be detrimental to their well-being. Does that make sense?

Arien Malec – Change Healthcare – Member

[Inaudible], propensity for self-harm. There's a whole bunch of them.

Andrew Truscott - Accenture - Co-Chair

The example that's given in the preamble is around domestic abuse and the pregnancy results of a partner, where the partner has access to the records, and there is suspected abuse. I must confess I find the illustration in the preamble a bit problematic, because that seems to be overstepping – Steve or Anil jump in on me here. But it seems to be potentially overstepping the clinical boundaries. I suspect domestic abuse; that's a bit of a stretch. I think **[inaudible] [00:30:26]**. I think, Anil, you just listed a bunch of much more relevant ones. Where we talk about a licensed healthcare professional, that's a broad church. Everything from nurse practitioner through to clinical social workers and physical therapists. So, would it be worth –

Steven Lane - Sutter Health - Member

I think that's appropriate though. I don't want to be too physician-centric here.

Andrew Truscott - Accenture - Co-Chair

I have no problems with the statement. Just to qualify that the professional judgment needs to be person to the data.

Anil Jain - IBM Watson Health - Member

I think the key here, guys, is that if there's an organizational policy, and it is compliant with local and state rules, and it is applied uniformly without discrimination then the electronic disclosure should follow that. And we should refer to the licensed professionals and give them an ability to document why the exception was being made. My concern would be this idea that is in number three that says the patient has been afforded any right of review of that determination. I don't quite understand it. I'm not a lawyer. I don't quite understand that one. If we're saying as clinicians or their stakeholders have the right to say why they didn't want to release it, but that information then needs to be made available as to why to the patient that in itself could be problematic. I don't want to over complicate things. I think the way it's written, for the most part, is pretty good. I'm concerned about how does the health IT vendor and how does the health system deal with this ability to then have a patient review why something was not done. Maybe I'm over complicating.

Steven Lane - Sutter Health - Member

I believe this is under HIPAA, and I'm looking at information excluded from right of access, which includes... I'm just looking there. Keep going.

Anil Jain - IBM Watson Health - Member

No, that's not what I'm getting at.

Steven Lane - Sutter Health - Member

This is more from ONC. That's primarily where the right of review came from was under 524, 164.534. And so, provided that if required by applicable law or state law, we were very sensitive to the fact that in some states and under federal law there is a right to review. And so, that is where that came from.

Anil Jain - IBM Watson Health - Member

This is not a special requirement for documenting the exception itself. Whatever mechanism people do today around HIPAA, we could use that same mechanism so there's no undo additional burden on the healthcare system or the vendor of the IT system. They are leveraging the system that exists today.

[Crosstalk]

Mark Knee - Office of the National Coordinator - Staff Lead

That's what we are trying to do with this exception.

Andrew Truscott - Accenture - Co-Chair

Just so I can – I've got my grammar hat on for a moment. At the end of A1 it's an or really isn't there. It's A1, A2, or A3.

Mark Knee - Office of the National Coordinator - Staff Lead

It could be multiple, but it has to be at least one of them.

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

Hey, Mark. This is Lauren. If you're still screen sharing, is it possible to zoom in a little bit?

Mark Knee - Office of the National Coordinator - Staff Lead

Sorry about that. Let me try to do that.

Mark Knee - Office of the National Coordinator - Staff Lead

That should be, in each of these areas where there are sub clauses, at least one of. It must meet the following conditions and then it says A, B – Sorry. That is actually fine. So, under A it probably should say arising from at least one of...

Andrew Truscott - Accenture - Co-Chair

It's interesting. A is an or list; B is an and list.

Steven Lane - Sutter Health - Member

That is a really good point. It makes sense.

Andrew Truscott - Accenture - Co-Chair

It makes sense. You just have to read it and reread it. I am trying to hope we make these things as understandable as possible when someone reads them the first time. Wishful thinking because it has taken us 27 readings to get this far.

Anil Jain - IBM Watson Health - Member

By the way, I find it helpful to read these as reasons that are permissible. Although it is permissible to withhold so you end up with all these double negatives. You think about the exceptions, what is positive for the exception, and it does end up being confusing.

Andrew Truscott - Accenture - Co-Chair

This is the allowance to stop me doing something – to allow me to do something, stop it**.** In A1, I've highlighted there just for discussion. The term recorded that seems to apply very much to an activity inside of the EMR within an organization. Should we consider changing the word recorded for exchanged?

Anil Jain - IBM Watson Health - Member

It probably should be accessed.

Steven Lane - Sutter Health - Member

Or just documented.

Anil Jain - IBM Watson Health - Member

Maybe we should use the language that is in the rest of the information blocking provision that should be accessed, exchanged, or used.

Steven Lane - Sutter Health - Member

And I agree with you that patient's electronic health record is narrower than the intended application of information blocking provisions, which cover electronic health information that is exchanged or used.

Andrew Truscott - Accenture - Co-Chair

I think the point here is the data is part of the electronic health record already, whether or not it is corrupt or inaccurate. The data is there. Should it be accessed, exchanged, or used? Oh no, I don't think it should. I'm going to block it.

Anil Jain - IBM Watson Health - Member

The electronic health record, there are activities that fall under the information blocking provisions that are part of the electronic health information as defined by the definition terms. It may not be part of any EMR, or EHR or any coordinated record.

Steven Lane - Sutter Health - Member

I'm going to play devil's advocate for just a moment. I'm reading this a little bit differently, and I'll defer to you experts. It sounds like they might be trying to carve out, or we may be trying to carve out, where you may have interfaced let's say with – and this happens all the time clinical medicine – you have interfaced with the lab. The lab has sent incorrect data and being recorded in the chart. It's not made its way into HER, because it was stopped. If someone does request all their EHI, electronic health information, we should not have to give that inaccurate data to them. It was never used. It was never accessible. It was never exchanged. It was simply interfaced from a system poorly, and therefore was inaccurate and corrupt. And I think, maybe the word recorded is referring to that act activity that never made its way in to the EHR.

Arien Malec – Change Healthcare – Member

I can think of a number of examples in the world I lived in where we are – So, I'll give you an example of a claim status inquiry on an administrative network where depending on how the patient identification is configured you could respond with the wrong claim status or the status for the wrong claim. I can give an example. I think the lab one is a good one, but it's not just that the lab was incorrect. It also might be that patient matching logic was misconfigured, and lab records are showing up in the wrong portion of the record or against the wrong patient. Or it could be that there is data corruption and data that is exchanged is corrupt in practice or that data – this happens all the time. You have a HL7 lab feed that is misconfigured and the HL7 data is non-interpretable. You want to make sure all of those would be covered by the provision. And I think the way the provision is written it's very narrow to the electronic health record and recorded or incorporated. I think if we broaden it

and refer back to accessed, exchanged, used for electronic health information I think we get back to the intended ways that cover all those use cases.

Andrew Truscott - Accenture - Co-Chair

I like the term accessed, exchanged, or used, because used covers both recorded and incorporated.

Arien Malec – Change Healthcare – Member

Yup. That same thing would apply for two as well. That says electronic health information so that's okay.

Andrew Truscott - Accenture - Co-Chair

That's okay, I think.

Valerie Grey - New York eHealth Collaborative - Member

Hey, everyone. This is Valerie. I'm sorry I joined late. I was just listening to this conversation and of course I come at this, at least in my current life from a health information exchange point of view. When I look at this I certainly understand the misidentification of a patient or there are often times when we are not confident that we've got an accurate match and it goes in a bucket. And there's a whole manual process to reconcile. Certainly we wouldn't want health information exchanges to send that along. The corrupter inaccurate data being recorded or incorporated in the EHR, I'm struggling to step back and say how would that work from my current vantage point.

What goes in to the HIE is what's sent by the participants, typically providers, coming straight from their EHR, common clinical data set, or U.S. BDI eventually. The HIE wouldn't really be in a position to know there's inaccurate data being transmitted. Clearly we try to do data quality checks to the extent we can; but we're not in the same position as a provider recording stuff in an EHR. How do you think that would work from the perspective I just described? I'm sorry if I'm missing something. And I am relatively new to this. I'm totally new.

Anil Jain - IBM Watson Health - Member

I think we already provided comment that addresses that. We believe there should be standards for this area. And the standard should be confined to cases where there is a reasonable belief, or knows, or likely, or whatever the right language there – that there's actual corruption as opposed to a vague standard of any possible inaccuracy, which my comment is that every record is inaccurate in some way. We want to confine it to known data corruption in areas that are much more stringent.

Valerie Grey - New York eHealth Collaborative - Member

That makes sense. Thank you.

Arien Malec – Change Healthcare – Member

This raises the issue of if the message does not conform to standards and is not reasonably interpretable does that follow under an inaccurate or corrupt standard? Do we need a standard for non-interpretable data?

Andrew Truscott - Accenture - Co-Chair

That's a good point, actually. I'm just making some notes here. So technical corruption, inaccuracy is kind of, excuse the term, clinical corruption. You can have something which has been appropriately coded but not understandable. Maybe somebody doesn't understand SNOMED. What do you do?

Anil Jain - IBM Watson Health - Member

This is Anil. I thought in the preamble they do comment that it could be based on technical issues. I don't think the lack of interpretability of the standard would not be counting. There are also other exceptions that might fit into.

Andrew Truscott - Accenture - Co-Chair

Here's an interesting point. This recognized risk is limited to corruption and inaccuracies caused by performance and technical issues.

Anil Jain - IBM Watson Health - Member

Exactly. So, would not being able to interpret the message be a technical issue?

Mark Knee - Office of the National Coordinator - Staff Lead

This is an area where I think we are interpreting the commentary text, but then when you look at the reg text, it is not what the reg text says. I think the commentary text is right on, and maybe the commentary text should be better reflected in the reg text.

Andrew Truscott - Accenture - Co-Chair

Does that mean then, let's say we've got an observation for left kidney failure. It says right kidney, or left kidney removed, or something like that. The actual receiving physician knows that is not the case. It's an obvious, inaccurate observation. That isn't covered by this.

Steven Lane - Sutter Health - Member

It should be a right of correction, but that could also fall under the patient harm exemption. If you're sending left kidney removal and it's right kidney removal. It creates a risk of a wrong-side surgery.

Arien Malec – Change Healthcare – Member

The way that's clinically handled would be that, just as Stevens said, you fix the error. You make the change, and then you would exchange the record or provide the record. I think those are probably easier to deal with because there's clinical context. I think the hard ones are where there's corruption or there has been mixing of records and inappropriate merging. That's probably the one we want to make sure to address for sure.

Andrew Truscott - Accenture - Co-Chair

If this reg is purely about technical corruptions. How as a clinician going to make an informed decision that there is an error of a technical nature?

Arien Malec – Change Healthcare – Member

I can give you examples. We typically will review the chart when we're seeing a patient. Let's assume for a moment that there has been – and this happens in every EMR world that someone has used that record to do some testing, or to try something out, like a new widget or whatever. And you start to see 100 different comorbidities in the problem list that are clearly, by human eyes, a problem. What we typically do is make a referral to health information management and say, hey go figure out why this record is messed up.

I would not give a copy of that record to a patient. It would be wrong to do that. That's an example of where it's obvious that there's corruption there. Where it's not obvious that there's corruption I think, all bets are off. That's what happens today. We see that all the time in exchange. I think, when a doc or another clinician, a licensed practitioner, knows there's corruption involved because they can see it; it's obvious then I think, they have an obligation to do something about it and prevent that record from being shared if they think it is going to cause harm.

Steven Lane - Sutter Health - Member

One is the obligation to do something about it. The other is the obligation to prevent sharing. I think we want, I want to optimize sharing and encourage sharing. How do we encourage corrections to be made in such a way that corrected data can be shared appropriately? As opposed to giving people an exception where they say well we just don't have a process to correct our data, and therefore we're just not going to share it.

Arien Malec – Change Healthcare – Member

I think that's policy. Organizational policy would be required there.

Anil Jain - IBM Watson Health - Member

Well it says no policy necessary to mitigate the risk of harm, but it doesn't prevent an obligation in the case of corruption or misidentification to correct the corruption or misidentification.

Steven Lane - Sutter Health - Member

In the preamble, I thought, there was language around that. I could be wrong.

Arien Malec – Change Healthcare – Member

But the preamble isn't the reg text.

Steven Lane - Sutter Health - Member

I get it. Maybe something needs to be brought forward into the reg text. They do talk about mitigating the error or mitigating the problem.

Arien Malec – Change Healthcare – Member

That could be interpreted under no broader than necessary to reduce harm. Hey, I do think we need to add to the standard of corrupt also uninterpretable, which is slightly different from corrupt.

Steven Lane - Sutter Health - Member

So, uninterpretable by what standard and according to whom?

Arien Malec – Change Healthcare – Member

So, what happens all the time in information exchange or for networks is that you get a HL7 feed or an ANT X12 feed, and you parse the record. Sometimes that record fails to parse, because it doesn't meet the standards applicable for that record, and you kick it out. You return it back to sender, or you put it through your exception process for communication back to the originating point.

Andrew Truscott - Accenture - Co-Chair

Actually the case of an HIE, the ones which are agnostic to the actual carriage of semantics of the data, they would actually persist and exchange it or whatever without actually parsing it.

Arien Malec – Change Healthcare – Member

I'm thinking more cases for orders and results, interchange, cases for EDI interchange, and the like. The definitions here are HIE but also health information network that is transmission of electronic health information between two dissimilar entities.

Andrew Truscott - Accenture - Co-Chair

We spent two hours on that definition this morning.

Arien Malec – Change Healthcare – Member

Absolutely and it's really confusing as to what's included or not included. But at least according to that standard there's a whole bunch of things where you get an HL7 feed in. You kick out some of them, because they don't make any sense. And that's the way the world works.

Andrew Truscott - Accenture - Co-Chair

I was **[inaudible] [00:50:49]** here between syntax of HL7 and semantic of the vocabulary or terminologies that we use within it. We're on the same page. We're saying the same thing.

Arien Malec – Change Healthcare – Member

In some cases we incorporated information into a record, but there is some information that's uninterpretable. You incorporate part the record but not the whole thing, because there's a portion that is uninterpretable. That's the garbage you got. I think that should be the standard.

Andrew Truscott - Accenture - Co-Chair

I agree, but the point is this exception is clearly where there has been a technical glitch. It's not where Dr. Lane has recorded something completely egregious, and I just don't agree with him, and I don't think it is right.

Arien Malec – Change Healthcare – Member

That's right. Technical corruption needs to include cases where there are standards failures or other failures where the data are uninterpretable.

Andrew Truscott - Accenture - Co-Chair

And is the clinician who is making this judgment call, **[inaudible],** obligated to record why. I can't find anything regs. Can someone point it to me if it is there?

Mark Knee - Office of the National Coordinator - Staff Lead

It's either there is well-documented organizational policies, or it is ad hoc and there's an obligation to record why.

Andrew Truscott - Accenture - Co-Chair

But where do they record it?

Mark Knee - Office of the National Coordinator - Staff Lead

It's either in the organization policy or it is in the specific findings.

Steven Lane - Sutter Health - Member

The making of the finding. Presumably that needs to be recorded somewhere.

Andrew Truscott - Accenture - Co-Chair

Does make and record a finding?

Mark Knee - Office of the National Coordinator - Staff Lead

Good point.

Andrew Truscott - Accenture - Co-Chair

You know what these doctors are like. For the purpose of the record that was a joke. Make and record a finding. I think, if the practice implements an organizational policy the policy must be all these things and include a recording of the finding.

Mark Knee - Office of the National Coordinator - Staff Lead

You should capture that in your comments.

Anil Jain - IBM Watson Health - Member

I think, we need to be careful though not to have – So, in the case of clinical determination I agree. In the case of corrupt or misidentified if you have a burden to record the reason for all these things then you put a bunch of operating process in what's often an emergent situation.

Andrew Truscott - Accenture - Co-Chair

I thought with the standards it should be the only way this exception would play is if it was a technical corruption. It's only ever going to be a clinical observation of either a technical corruption or a misidentification.

Arien Malec – Change Healthcare – Member

It could be a technical identification of a technical corruption. Or there could be an automated process. Again, in the examples that I have been using of an HL7 message that fails to hit its standards I hit it with an error response or a 987 response and an 837 **[inaudible] [00:54:09]**. That's my determination is this thing fails.

Andrew Truscott - Accenture - Co-Chair

Well, an 837 is going to be return to sender saying this is a malformed claim. HL7 is probably going to be entered into a queue and somebody's going to eyeball it.

Arien Malec – Change Healthcare – Member

It's not a written determination that for each one those rejections I have to go back and note in an audit log that is inspectable by a...

Andrew Truscott - Accenture - Co-Chair

But it knows – In your 837 example that would be written to an audit note to say that this particular message, this ID, was rejected and sent up **[inaudible 00:54:42]** the record. Where you've got someone eyeballing an HL7 that says this is now malformed, return to sender.

Anil Jain - IBM Watson Health - Member

So, a lot of these things when you do these determinations – If you want to keep the logs around forever logs can be incredibly voluminous and you've increased the cost of exchange pretty significantly for the off chance that somebody's going to go audit you for information blocking provisions. As opposed to something where I say I am following standards and here is how I follow the written standard in the case of audit. I'm just trying to make sure we don't put in –

Andrew Truscott - Accenture - Co-Chair

If a clinician makes a finding, it should be recorded.

Anil Jain - IBM Watson Health - Member

That's right. I think that's appropriate. Let's put the burden on the clinicians.

Andrew Truscott - Accenture - Co-Chair

Should this be articulating what they decided?

Steven Lane - Sutter Health - Member

We chuckle but it's important. The habit and even the willingness of physicians to document that sort of thing is quite variable. So, if we're going to – And of course, there is such a sensitivity these days about clinician burden and the challenge of regulations increasing that burden et cetera, et cetera . We have to think through and ensure that that really is the right place. I mean, it sounds like it is. We should not make that judgment lightly. I think we have two clinicians on this very small work group.

Andrew Truscott - Accenture - Co-Chair

[inaudible] [00:56:25] is a competency test that you'll be going to determine how competent the patient would be to receive that information is part of that judgment call.

Steven Lane - Sutter Health - Member

Say that again?

Andrew Truscott - Accenture - Co-Chair

I would imagine that as part of A3, when you enter – when you withhold information from a patient there is a competency decision in the middle of all that as well about how competent they are to receive that data.

Steven Lane - Sutter Health - Member

I don't know about that. I'm not sure you want to include medical literacy or...

Andrew Truscott - Accenture - Co-Chair

I'm not. I'm not. It was a discussion point more than anything else. There's a whole bunch of decisions you're making at the moment in time.

Anil Jain - IBM Watson Health - Member

Isn't that covered under permissible use? So, the blanket provision here is it has to be access exchange or use for a permissible use.

Andrew Truscott - Accenture - Co-Chair

My only point with raising that is saying there is a large number of decisions a clinical is making at that point of time; and it's not only making this disclosure decision. That's all I was saying. Okay. How comfortable are we with B as it stands? I noticed Steven, you've highlighted the word and.

Steven Lane - Sutter Health - Member

I read better when I can see the high point. I'm being selfish. You pointed out one was an or and one was an and list, and I'm just helping us without monkeying with the text too much.

Andrew Truscott - Accenture - Co-Chair

I did the indents just to help.

Steven Lane - Sutter Health - Member

I appreciate it.

Mark Knee - Office of the National Coordinator - Staff Lead

I need to drop at this point. I apologize. We got through the exception that I had the most commentary on that was on our remit today. So...

Andrew Truscott - Accenture - Co-Chair

Are you comfortable with where we are?

Mark Knee - Office of the National Coordinator - Staff Lead

I'm very comfortable with where we are.

Andrew Truscott - Accenture - Co-Chair

Okay because I am recognizing the pattern that you have been thinking about this for probably longer than most of us have been thinking about health IT. And you are comfortable. Okay. That's good.

Anil Jain - IBM Watson Health - Member

So, Andrew, to your question – This is Anil. To your question, yes I'm comfortable with how B looks. I think it cover what we discussed.

Steven Lane - Sutter Health - Member

I'm in agreement.

Andrew Truscott - Accenture - Co-Chair

That's good. Actually it's gone smoother than the other groups. I'll tell you that. Okay. I struggled a bit with B2. In that A1 is clearly about technology. A2 – oh, I see A2 is a clinical determination. And in A3 is clinical... Okay fine. When you use language like and other appropriate, I'm like, mmm, okay. It just seems a bit –

Steven Lane - Sutter Health - Member

You said you were struggling with B2.

Andrew Truscott - Accenture - Co-Chair

B2, other appropriate.

Steven Lane - Sutter Health - Member

And the whole issue of expertise. How deep does that go? In whose eyes? By whose judgment? There's organization A's expertise that they bring to bear as comprehensive as organization B's. The point of all these is that these will be trotted out when there is an accusation of information blocking. The OIG or whoever is investigating this would look to these rules to evaluate the charge. Right?

Arien Malec – Change Healthcare – Member

They would determine whether the expertise was appropriate.

Anil Jain - IBM Watson Health - Member

I like the idea that it's a little bit vague in terms of other appropriate expertise because some of this – as Steven said – will happen over time. We don't want to have a very specific type of skill be represented and then keep adding to it. If you put other appropriate expertise that gives some wiggle room for an organizational policy that matches their institution.

Arien Malec – Change Healthcare – Member

The other type of expertise that comes to mind is operational. So many of these issues related to interoperability and why it does or doesn't happen have to do with having workflows and operational processes in place. Often at least as much as the clinical and technical processes. If one were going to supplement B2, I would at least consider adding operational to that short list.

Anil Jain - IBM Watson Health - Member

I think it will be institution dependent. Some healthcare systems that we do business with, for example, those people that Steven is talking about would either be in clinical support organization or the technical IT office. So, if adding the word operational is more inclusive that's great. But I think, it all depends on the institution what those folks are considered.

Steven Lane - Sutter Health - Member

Certainly at in our institution, which is a very large one, it is very clear. There are clinical leaders. There are operational leaders. There are technical leaders. They are totally different groups. The clinical folks while we contribute to discussions about how operations do things, we don't control it. We have a COO; we have a CIO; we have clinical leads. You are right. Certainly in a small office practice there's a lot of overlap.

Andrew Truscott - Accenture - Co-Chair

I think – put my grammar hat on again. The use of the term relevant and the use of the term appropriate in this exception, I think, are back to front. So, I think in B2 we should say relevant expertise. And I think, in the opening **[inaudible] [01:03:18]** we should say at all appropriate times. I think appropriate certainly in B2 should be relevant. That's grammar police.

Steven Lane - Sutter Health - Member

That's not grammar. That's diction and it's important.

Andrew Truscott - Accenture - Co-Chair

I think, it's relevant expertise. I'll make a note. Mark's sitting there going...

Mark Knee - Office of the National Coordinator - Staff Lead

I think you're right. I think that's fair.

Anil Jain - IBM Watson Health - Member

So, you're talking about basically just flipping those words appropriate and relevant.

Andrew Truscott - Accenture - Co-Chair

The point would be that something is relevant if it's appropriate or connected to the matter. Relevant things are helpful. Relevant things are appropriate. It makes sense at that particular time. **[Inaudible] [01:04:12].** I wax lyrical about the advantages of a British education at this point. Okay. C. Hang on, we use the term practice. In B and C we use practice both times.

Anil Jain - IBM Watson Health - Member

Right, because this is directed at the healthcare entities.

Andrew Truscott - Accenture - Co-Chair

Should we say entity?

Steven Lane - Sutter Health - Member

No, no, no. This is the verb practice. It's not the noun.

Anil Jain - IBM Watson Health – Member

Oh, I got you. I got you.

Mark Knee - Office of the National Coordinator - Staff Lead

This is Mark, from ONC. It's the practice. It's a verb.

Anil Jain - IBM Watson Health - Member

I got you. Then that's fine.

Andrew Truscott - Accenture - Co-Chair

What is the practice in this context?

Mark Knee - Office of the National Coordinator - Staff Lead

The action. The action that was accused of being information blocking.

Andrew Truscott - Accenture - Co-Chair

So, if they are preventing harm. If the exception **[inaudible] [01:05:22]** the policy. That doesn't make sense.

Steven Lane - Sutter Health - Member

It's in the top line there. I just turned it red. Practices that are reasonable and unnecessary.

Andrew Truscott - Accenture - Co-Chair

Got it, but if I look at B2, sorry B. If the practice implements –

Steven Lane - Sutter Health - Member

Ah, good point.

Andrew Truscott - Accenture - Co-Chair

Or if the practice does not implement.

Steven Lane - Sutter Health - Member

But the practice itself is done to implement the policy.

Mark Knee - Office of the National Coordinator - Staff Lead

So, in that case that's still the verb practice.

Andrew Truscott - Accenture - Co-Chair

It's still wrong.

Mark Knee - Office of the National Coordinator - Staff Lead

Why is it wrong?

Andrew Truscott - Accenture - Co-Chair

If the practice – if the – If the action of doing this is implements an organizational policy what –

[Crosstalk]

Steven Lane - Sutter Health - Member

Instantiates. It instantiates a policy or is consistent with the policy.

Andrew Truscott - Accenture - Co-Chair

If the practice is instantiated in policy and if the practice – and then C this is cumbersome now. But B, if the practice is instantiated in an organizational policy the policy must be. So, if the policy is defined in this practice – Got it. If this practice has not been implemented in organizational policy then you have to make a finding in each case.

Mark Knee - Office of the National Coordinator - Staff Lead

Can I make a recommendation? If the practice invokes an organizational policy then the policy must be. Because the practice is that it has to invoke a reason why it's resulting in a block. So, it has to be invoking a policy. You are not going to be implementing a policy at the time of the practice. It has to be done in advance.

Andrew Truscott - Accenture - Co-Chair

If an organization implements an organizational policy of this practice. Who's going to take that one on, Steven?

Steven Lane - Sutter Health - Member

I think you took more grammar than I did. I think, it could be clearer. I think, it's also acceptable as is.

Mark Knee - Office of the National Coordinator - Staff Lead

Appreciate that.

Steven Lane - Sutter Health - Member

Since we have the author on the phone.

Andrew Truscott - Accenture - Co-Chair

[Inaudible] [01:08:09].

Mark Knee - Office of the National Coordinator - Staff Lead

A number of people at ONC over time.

Andrew Truscott - Accenture - Co-Chair

Okay. So, you've got plausible deniability. **[Inaudible 01:08:24]** with the policy. C has a few issues in it if you say if the practice does not implement an organizational policy. The activity wouldn't implement anything.

Anil Jain - IBM Watson Health - Member

I definitely see what you're saying. But I guess if there was an interference based on harm that was listed in the policy. That's what we are getting at. The practice.

[Crosstalk]

Andrew Truscott - Accenture - Co-Chair

I am happy with C that notwithstanding.

Steven Lane - Sutter Health - Member

Do we want to go back and say the actor must make and record a finding? Did we discuss how that finding that they've made would have to be somewhat available later on?

Andrew Truscott - Accenture - Co-Chair

I put that up in the notes. Please include that when a clinician makes a finding, it should be recorded somewhere accessible. Not on the Post-it note on the monitor. Okay. We're only 72 minutes into the call. Should we move on to promotion of privacy of electronic health information?

Mark Knee - Office of the National Coordinator - Staff Lead

Sure. We can always go back.

Andrew Truscott - Accenture - Co-Chair

Oh, we will be.

Mark Knee - Office of the National Coordinator - Staff Lead

I think, taking a first pass at each of these is a good thing.

Andrew Truscott - Accenture - Co-Chair

That's been the approach on the other workgroups as well. Okay. Who is going to open this? This exception is you need to do one of the lettered things.

Steven Lane - Sutter Health - Member

A, B...

Andrew Truscott - Accenture - Co-Chair

Trust me, it's really confusing numbering.

Anil Jain - IBM Watson Health - Member

I think my broader point on this one – and it may not make sense. Maybe the preamble covers it in more detail than I had time to skim. This seems like a lot of onus on the organization. Somehow, it needs to be tied in with other institutional mandates that should be leveraged. It just seems like a lot of onus. So, I put a comment in here that you guys can see. It is not clear to me what the overhead requirements for organizations to address all the policies would be for this one. Because back to Steven's point that he made earlier about the adolescent who you may want to limit information sharing, for example. How does that get instrumented in the context of this particular rule above and beyond what might already exist in HIPAA? I don't know if that makes sense.

Andrew Truscott - Accenture - Co-Chair

I'm just parsing everything you said, because A1 definition is basically the –A1's definition is **[inaudible] [01:12:20]**. I agree with you. So, A gives us this whole definition of individuals. Out of interest, does anyone have any insight as to what any other natural person means?

Steven Lane - Sutter Health - Member

Sounds very legal.

Andrew Truscott - Accenture - Co-Chair

It begs the position of what an unnatural person is.

Mark Knee - Office of the National Coordinator - Staff Lead

Oh, a natural person. This is more from ONC. So, as opposed to a corporation or a limited liability company. That's what we mean by natural person. That's what we mean by that. An actual human being. How about that?

Steven Lane - Sutter Health - Member

What was the point of making that distinction?

Mark Knee - Office of the National Coordinator - Staff Lead

The purpose is that given that the HIPAA privacy rule and state law – We wanted to make it consistent with those laws. And so, there were several buckets of what we were trying to capture, because electronic health information is broader than just HIPAA, covered entities and business associates. And so, an individual under A1 is the HIPAA definition. And so, what we were trying to capture are other human beings' information that was outside the definition of HIPAA. For example, –

Anil Jain - IBM Watson Health - Member

Does this mean other people? This is like the note about the husband that references the wife because that's another person who is the subject of the information?

Mark Knee - Office of the National Coordinator - Staff Lead

I will give you an easy example. In certain situations, let's say, a health IT developer is not subject to HIPAA, but they have access to individually identifiable health information. In that case they would be another person who would be the subject of EHI. That would be an example. Another example would be a concierge medicine physician who doesn't electronically bill, but has patients. That would be another example of who would be subject to EHI.

Andrew Truscott - Accenture - Co-Chair

That's helpful. Okay. I find the preamble clearer than the reg on this one. Because the reg actually says an individual defined by 161.03. Two, a person who is the subject of EHI that is being accessed, exchanged, or used. Three, a person in that **[inaudible] [01:15:39]** I find the preamble easier. Maybe it's just the use of the word person, natural person. I am happy with A, apart from that. Anil, Steven?

Anil Jain - IBM Watson Health - Member

I am good with A.

Andrew Truscott - Accenture - Co-Chair

B. If the access by states or federal privacy law to satisfy conditions prior to providing access, exchange, or use. See, the term accessed, exchanged, or used. That's just the right way of referring to it. I think, going back to that previous rule when we talked about was it recorded or something like that or incorporated. Accessed, exchanged, or used. **[Inaudible] [01:16:55]** access, exchange, or use of such **[inaudible]** if the precondition has not been satisfied. Well, I get that. Okay, the numbers – So, one the access practice, two, if the precondition, and three the access practice. Okay, I think those are ands; however, the Is and IIs, I don't know if they're – They are ands. But the capsule A, B, C are ors. No, they're ands. Oh it's... ONC guys, can you help us here? In condition one the I and II, they look like they might be ors between each other; however, the other Is are ands. Is that right?

Mark Knee - Office of the National Coordinator - Staff Lead

So, the practice either must be implemented and conform to the written organizational policy or the practice is documented by the actor. So, that's an or right there. So, that's the same kind of situation that we had in harm. Organizational policy or individual practice documented. And then you go down to two here. And then it says it's an and. Right there you can see.

Anil Jain - IBM Watson Health - Member

You are not adding those, Andy. You are just highlighting them, right? You aren't messing with the text itself?

Andrew Truscott - Accenture - Co-Chair

No, I'm just highlighting it. I'm not actually changing it.

Anil Jain - IBM Watson Health - Member

Okay, good. Sorry.

Andrew Truscott - Accenture - Co-Chair

But that one – This is a bit clunky. Is there an and that is supposed to go in? Just type in **[inaudible].** Is that supposed to be an and or not?

Mark Knee - Office of the National Coordinator - Staff Lead

Well, it's up for comment. You guys can weigh in on that.

Andrew Truscott - Accenture - Co-Chair

What's the intent of what's drafted right now?

Mark Knee - Office of the National Coordinator - Staff Lead

I think, you might be right that an and might be appropriate. I need to think about it more. We are saying that it is one or the other. The organizational policy, the practices document, and then the practice must be tailored. The practice must be implemented and consistent, in a non-discriminatory manner. If the pre-condition relies on permission of consent or authorization, blah, blah, blah. It does all the things. I believe that's right.

Andrew Truscott - Accenture - Co-Chair

Okay. So, you think, at the end of two it should say instead of 2.II, it should say and the access practice is tailored to **[inaudible] [01:20:04].** So, basically it's just one long sentence with the only optionality being between 1. I and 1.II.

Steven Lane - Sutter Health - Member

Everything else is an and.

Andrew Truscott - Accenture - Co-Chair

I think so.

Mark Knee - Office of the National Coordinator - Staff Lead

I believe that's right but I'll look at it some more.

Andrew Truscott - Accenture - Co-Chair

I guess, I should read the actual subset, the actual content now. The practice conforms to organizational policies, procedures in writing specify the criteria, and have been implemented. **[Mumbling]** Do we actually say somewhere that policies and procedures are lawful?

Anil Jain - IBM Watson Health - Member

You're asking if we say that or should we say that?

Andrew Truscott - Accenture - Co-Chair

Well, do we say that?

Steven Lane - Sutter Health - Member

You're saying in 1.I. conforms to the actors organizational policies and procedures. You're saying do we have to state that those are lawful policies and procedures?

Andrew Truscott - Accenture - Co-Chair

Yeah. Otherwise I'll just write an organizational policy and procedure that says it's all right to keep it secret. Any suggestions from anyone?

Anil Jain - IBM Watson Health - Member

Repeat why we should put down that they are lawful.

Andrew Truscott - Accenture - Co-Chair

I'm asking whether we say anywhere in the exceptions – And I'm thinking back to what we were discussing preventing harm with – It could be in there.

Anil Jain - IBM Watson Health - Member

Right. Right. They have procedures that are in writing. But what if their procedures are flawed?

[Crosstalk]

Andrew Truscott - Accenture - Co-Chair

We do say if you are required under state or federal policy law; we've got that. But my policies therefore, should also be lawful.

Steven Lane - Sutter Health - Member

I would assume that since – Maybe we don't make assumptions. In my head it's a little redundant that the policies would be more than what's legally required. But it's also giving the institution the ability to go above and beyond. But if you think we need to write that the policies and procedures must be lawful I think that is probably overkill. But that's just my perspective.

Andrew Truscott - Accenture - Co-Chair

Oh, actually you say that. I've actually had clients who have bought an entity, moved across the state boundary as they bought that entity, and have implemented the acquiring organizational policies and procedures. And one of them, they bought a physician's group in Pennsylvania and found themselves completely off kilter with state policy legislation.

Steven Lane - Sutter Health - Member

I will defer to the team. If that's the case will put that in here, we will need to put that in every single place where we allow an actor to have an organizational policy.

Andrew Truscott - Accenture - Co-Chair

Isn't there a catchall place that we could put that? Where we could put it in one place and it covers the entire rule?

Steven Lane - Sutter Health - Member

What if we put it in the material prior to the exceptions? And say that organizational policies and procedures must comply with local, state, and federal laws.

Andrew Truscott - Accenture - Co-Chair

That will do it for me. Mark, can you make that note?

Mark Knee - Office of the National Coordinator - Staff Lead

On the actual document you're talking about?

Andrew Truscott - Accenture - Co-Chair

Yeah. Well, it's not inside any of the **[inaudible] [01:24:07]** exceptions here. I think the logical place to put it would be – Let's look for the term lawful.

Mark Knee - Office of the National Coordinator - Staff Lead

If we're going to be –

Andrew Truscott - Accenture - Co-Chair

The term doesn't appear. It's not said anywhere in the rule as it stands.

Mark Knee - Office of the National Coordinator - Staff Lead

I will say that – Andrew, I'm sure you've had the same experience – but I think if we're going to make comment about how institutions must organize and have their policies. You might need to go further and say that they need to be reviewed every year or that they need to be reviewed every other year. Something like that. I think we'll get into –

Andrew Truscott - Accenture - Co-Chair

I wouldn't go as far as that. That's operational. An organization determines how they reasonably should act. But I do think it's **[inaudible]** to say that a policy should be lawful.

Mark Knee - Office of the National Coordinator - Staff Lead

Sure, yup.

Andrew Truscott - Accenture - Co-Chair

There isn't any – I'm looking at the actual draft of the rule. There's nothing ahead of a practice shall not be treated as information blocking if the actor satisfies an exception to the information blocking provision. Blah, blah, blah. There's nothing ahead of that. So, it might actually be, we put it in – If we agree, and I'm looking for consensus across the group, not just me forcing this one. If we agree, we probably insert it every time we have a reference to an organizational policy.

Steven Lane - Sutter Health - Member

Or couldn't it just be inserted up front, as you suggested earlier?

Andrew Truscott - Accenture - Co-Chair

There isn't anywhere up front without adding a line. We're adding a line at the beginning of our blue box for preventing harm. Actually, those first two lines is the general statement across this entire section, subpart B. I will make a note, and we can come back to it. Oh, someone's made a note.

Steven Lane - Sutter Health - Member

That was me, Andy. Just a suggestion if you are thinking of adding it as an overarching principle – I am not weighing in on if that's good or bad – there is a discussion about the exceptions overall before we get into the meat of the each exception, prior to the harm discussion.

Andrew Truscott - Accenture - Co-Chair

It's two lines long though isn't it?

Steven Lane - Sutter Health - Member

What's two lines long?

Andrew Truscott - Accenture - Co-Chair

It's pretty short. The discussion about the exceptions, the beginning of subpart B, is very short. It's 171/200, which is like 2 1/2 lines.

Steven Lane - Sutter Health - Member

I was talking about in preamble, I guess.

Andrew Truscott - Accenture - Co-Chair

I'd like it in the reg, if possible.

Steven Lane - Sutter Health - Member

Okay.

Andrew Truscott - Accenture - Co-Chair

Just because I noticed it as we went back to it. In 201B, we talk about an organizational policy. In 202B we talk about organizational policies and procedures. Is that meant to be a difference there?

Steven Lane - Sutter Health - Member

I was just making a note. Say that one more time where you are.

Andrew Truscott - Accenture - Co-Chair

In the do no harm one, we talked about organizational policy – singular. In the privacy exception we talk about organizational policies and procedures. Is there a reason for that difference?

Mark Knee - Office of the National Coordinator - Staff Lead

This is Mark again. The term policies and procedures came from state privacy laws, as well as, from HIPAA. That's where that language comes from.

Andrew Truscott - Accenture - Co-Chair

I like it. I find it more conducive. Maybe we can let that filter into the previous one as well. It is good language.

Anil Jain - IBM Watson Health - Member

In the preamble – I know we're not talking about the preamble right now – but there is a comment about a qualifying organizational policy. I'm assuming in the regs there's something about a qualifying organizational policy. Is that fair?

Andrew Truscott - Accenture - Co-Chair

Is that qualifying policy or qualifying organization?

Anil Jain - IBM Watson Health - Member

No. qualifying organizational policy, page 391.

Andrew Truscott - Accenture - Co-Chair

My question is are we serving to an organization that's qualifying or to a policy that’s qualifying.

Anil Jain - IBM Watson Health - Member

No, it's saying that we anticipate that an actor would demonstrate that the practices it engaged in were consistent with an organizational policy that were objectively reasonable and no broader than necessary. I think, it does fit what we are trying to discuss here. Even though it might not be in the exceptions area there may be definitions – and I'm really asking the ONC team. There may be a definitely of what a qualifying organizational policy, what is an acceptable one where we can throw all this language into if it doesn’t already exist. As opposed to dealing with it in the exceptions. Organizational policy does have a role in other parts of the rule.

Mark Knee - Office of the National Coordinator - Staff Lead

I don't believe there's a definition of organizational policy, but we do discuss it in the preamble.

Andrew Truscott - Accenture - Co-Chair

Qualifying organizational policy.

Anil Jain - IBM Watson Health - Member

What I'm suggesting is it may be in the definitional area as opposed to try to do it in the exception so that it is consistent with the rest of the regs.

Andrew Truscott - Accenture - Co-Chair

You heard Arien's views of the reg versus the preamble. It's going in the regs. Let's go back to 202. **[Inaudible] [01:31:18].** In 1.I., B.1.I, my only concern is that the policy is awful. All that could be true, but it might actually be something that isn't lawful.

Anil Jain - IBM Watson Health - Member

You made a good point earlier. It was consistent with both state and general laws.

Andrew Truscott - Accenture - Co-Chair

[Inaudible]. Within B2, if the precondition relies on the provision of consent or authorization from the individual, would that consent be recorded?

[Crosstalk]

Steven Lane - Sutter Health - Member

Should it be the documented provision of consent or authorization? Here they are the referring to the precondition. This is the requirement of the state and federal privacy law. So, we can't determine whether the state or federal privacy law requires the consent be documented.

Andrew Truscott - Accenture - Co-Chair

Oh, absolutely no we can't. But can't we say that if you're depending upon a dissent expressed under state privacy law, you could be called out for that, right?

Steven Lane - Sutter Health - Member

Say that again.

Andrew Truscott - Accenture - Co-Chair

It says if the precondition relies on the provision of consent or authorization for individual. The fact that the actor did all things reasonably and necessary within its control to provide the individual meaningful opportunities to provide the consent or authorization, and did not encourage. Should it not be recorded that I did not encourage this, I provided them with meaningful opportunity, and the patient expressed dissent?

Steven Lane - Sutter Health - Member

And specifically that 2.II. Did not improperly induce them to not comply.

[Crosstalk]

Steven Lane - Sutter Health - Member

Did not discourage consent.

Andrew Truscott - Accenture - Co-Chair

Isn't consent a fairly binary thing? You give it or you don't.

Steven Lane - Sutter Health - Member

Generally, yes. I mean, you consent to specific practices or actions.

Andrew Truscott - Accenture - Co-Chair

We can imply consent, or we can get express consent.

Steven Lane - Sutter Health - Member

On here they are referring to a precondition.

Anil Jain - IBM Watson Health - Member

I think, what they are saying guys... If I were a provider and I'm required to have consent before I can share but I don't make a reasonable attempt to get that consent from patient then I can't use this reason to do it. Because I didn't do everything I need to do. So, I can't use that precondition. You know what I'm saying? I'm the actor, and I can't hide behind something that I should have done that I didn't do. And then –

Steven Lane - Sutter Health - Member

Right, because you didn't put the workflow in place.

Anil Jain - IBM Watson Health - Member

Exactly.

Steven Lane - Sutter Health - Member

You don't either properly encourage or induce them to not. It seems pretty clear as written.

Anil Jain - IBM Watson Health - Member

I agree.

Steven Lane - Sutter Health - Member

Andrew, it seemed like you had an issue. Maybe I misunderstood.

Andrew Truscott - Accenture - Co-Chair

No, my quietness is my rereading again and again and again from the top of B downwards. I just want to know what it is that we are looking to achieve with the statement, and I think I'm okay with it.

Anil Jain - IBM Watson Health - Member

If I were to boil this down to English I think what they are saying is if all the requirements were not satisfied you had better not be the reason they weren't satisfied before you can claim that you were okay not sharing the information. It has to be something beyond your control.

Andrew Truscott - Accenture - Co-Chair

Yes, I agree with that.

Steven Lane - Sutter Health - Member

Or capacity.

Andrew Truscott - Accenture - Co-Chair

How many lawyers wrote this?

Mark Knee - Office of the National Coordinator - Staff Lead

I can't confirm that.

Steven Lane - Sutter Health - Member

I can neither confirm nor deny.

Anil Jain - IBM Watson Health - Member

My sister's a lawyer, and you should see the emails she writes to me.

Andrew Truscott - Accenture - Co-Chair

I imagine just general conversation going on between all the ONC guys right now saying oh these idiots from HITAC. Don't they understand what we want?

Mark Knee - Office of the National Coordinator - Staff Lead

I think, the summary you gave for what we're trying to get is accurate.

Steven Lane - Sutter Health - Member

I agree, Mark. That's what we're trying to get at. Should we go on to C?

Andrew Truscott - Accenture - Co-Chair

Let's go to C. **[Inaudible] [01:38:40]** not covered by HIPAA. IT developer. Dumb question. Anil, **[inaudible]** there are an awful lot of health IT developers, right?

Anil Jain - IBM Watson Health - Member

Yeah, I mean there's a whole bunch of that would not be covered entities for example, right? There's a huge bunch.

Steven Lane - Sutter Health - Member

IBM, for example.

Anil Jain - IBM Watson Health - Member

Well, no not necessarily because we have BAAs with our health system clients. But we're not going to talk about that right now.

Steven Lane - Sutter Health - Member

You could be covered by virtue of that BAA. This is a non-covered entity not yoked by a BAA to HIPAA.

Andrew Truscott - Accenture - Co-Chair

I imagine this is people like apps developers and that kind of stuff.

[Crosstalk]

Mark Knee - Office of the National Coordinator - Staff Lead

There's a discussion in the preamble where we get into. I can pull it up if you'd like but we go into the types of actors that we're talking about. I think we do note that we expect this to be a small number. So, Anil, if you think that it's a bigger number that might be something to clarify. If you think there lots of these types of folks out there.

Anil Jain - IBM Watson Health - Member

I was going to say that you're saying certified health IT. That could be a module, the HR 2015 rules. So, if that is a module, and it's an app that could be sitting in EHR, you can certainly have a lot of these folks out there – in my opinion based on what I understand.

Morris Landau - Office of the National Coordinator - Back Up/ Support

Just to clarify – this is Morris again with ONC –

Anil Jain - IBM Watson Health - Member

Potential folks.

Morris Landau - Office of the National Coordinator - Back Up/ Support

We were thinking of not covered by HIPAA meaning covered entities, and business associates, and sub-contractors who are have business associates. So, these are non-conferred entities and non-business associates. Because we assume all business associates are going to have a BAA – a business associate agreement. So, that was the thinking behind it. That's what we meant.

Andrew Truscott - Accenture - Co-Chair

The inclusion criteria of this is you're not covered by HIPAA – got that – but your IT is certified health IT. Why is it **[inaudible] [01:41:20]** not capitalized because isn't that a defined term.

Morris Landau - Office of the National Coordinator - Back Up/ Support

No, health IT is not. And so, health IT developer certified and health IT is, if you look in the definitions, we define health IT developer or certified health IT as a developer at the time of the conduct that's in question that is believed to be an interference with access, exchange, or use had at least one product certified under the program. But the conduct doesn't have to be related to that product. So, it's broader. There's a tie in to having at least one product certified in the program. And we do request –I mean, it's outside the scope of this group – but we request comments on that definition, I believe.

Anil Jain - IBM Watson Health - Member

And this particular point refers to everyone that doesn't fit that. It's the folks who are not covered by HIPAA. So, I've to read this one more carefully. I agree based on what you said. It sounds like it is going to be a smaller number than I was thinking.

Andrew Truscott - Accenture - Co-Chair

Again, grammar police. You see health IT developer that's not required to comply with HIPAA. Not the certified health IT is not required to comply with HIPAA.

Mark Knee - Office of the National Coordinator - Staff Lead

Where do you see that? It says if the actor is a health IT developer of certified health IT, then it's not required.

Andrew Truscott - Accenture - Co-Chair

No. There's no grammar in that sentence. If the actor is a health IT developer of certified health IT, then it's not required to comply with the HIPAA privacy **[inaudible].** The compliance with the HIPAA privacy law is dependent on the health IT developer, not of the certified health IT.

Mark Knee - Office of the National Coordinator - Staff Lead

So, it does go to the actor, but we say electronic health information provided so that the actors practice. So, we are talking about the conduct by the actor.

Andrew Truscott - Accenture - Co-Chair

I know.

Mark Knee - Office of the National Coordinator - Staff Lead

I think Lauren is saying something to me, but I can't see the screen.

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

That's okay. We're past the time check.

Andrew Truscott - Accenture - Co-Chair

Oh wow, Mark. You've done something very peculiar with your screen.

Mark Knee - Office of the National Coordinator - Staff Lead

This is a matrix right here, or something.

Andrew Truscott - Accenture - Co-Chair

Yes, in three minutes we will go to public comment. I understand what this entity is trying to say. It's just very long and non-grammatically helpful.

Mark Knee - Office of the National Coordinator - Staff Lead

I think that's only if you have extra suggestions for improving. I think that's fine. I was trying to clarify.

Andrew Truscott - Accenture - Co-Chair

If it were to say who is not required to comply with the HIPAA... But the rest of it, I'm fine with it. That makes sense. Although meaningfully is quite a subjective term. Steve, Anil, what do you think?

Steven Lane - Sutter Health - Member

Meaningful according to whom?

Anil Jain - IBM Watson Health - Member

I'm not sure what meaningfully means, but I'm not sure that's our biggest issue with this one yet.

Morris Landau - Office of the National Coordinator - Back Up/ Support

So, I can give you what we were trying to get at or the purpose behind that. The word meaningfully was a notice, some type of notice needs to be disclosed to the person's product or service, similar to a notice that you would see. A notice of privacy practices. So, it can't just be a flyby. What we meant by its plain language, something that is meaningful to a person as opposed to just clicking on something and saying okay. That was the concept we were trying to get at.

Mark Knee - Office of the National Coordinator - Staff Lead

We were trying to get at not just checking a box. Actually providing a real opportunity, which is hard, to describe.

Anil Jain - IBM Watson Health - Member

Is there a process that is written in another rule like HIPAA that you can refer back to so that the word meaningful is not vague?

Morris Landau - Office of the National Coordinator - Back Up/ Support

That word meaningful disclosed does come from the privacy rule when they talk about the notice of privacy practices.

Anil Jain - IBM Watson Health - Member

There could be a reference there. Maybe putting a reference there would help. Just as a shortcut to try to get folks to understand what meaningfully disclosed means in the context of this language.

Morris Landau - Office of the National Coordinator - Back Up/ Support

ONC had a model notice that talked about meaningful disclosed.

Mark Knee - Office of the National Coordinator - Staff Lead

Did someone document? Andy, did you get that down in the Google Doc, because I don't have I because anymore.

Andrew Truscott - Accenture - Co-Chair

It's ten to the hour. I'd like to – Lauren, if we can open the lines for public comment?

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

Absolutely. Operator, can you open up comment to the public line?

Operator

If you like to make a public comment please press star one on your telephone key pad. A confirmation tone will indicate your line is in the queue. You may press star two if you would like to remove your comment from the queue. For participants using speaker equipment it may be necessary to pick up your hand set before pressing the star keys.

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

We have another small group today. We will see if we have any public comments. Any comments in the queue at this time?

Operator

No comments at this time.

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

Okay guys. You just won back 10 minutes, if you want to wrap up the last bit here. Otherwise, we can break or plan for our next meeting.

Andrew Truscott - Accenture - Co-Chair

I'm okay to **[inaudible] [01:48:10]**. Guys, what do you want?

Steven Lane - Sutter Health - Member

I wouldn't mind getting nine minutes back. But if we need to go until six I'm happy to do that.

Andrew Truscott - Accenture - Co-Chair

Let's try to get through this exception.

Anil Jain - IBM Watson Health - Member

Let's try to get through it.

Andrew Truscott - Accenture - Co-Chair

Does anyone else have any other concerns with C?

Steven Lane - Sutter Health - Member

Similar to what we've been through already.

Andrew Truscott - Accenture - Co-Chair

I won't raise policy.

Steven Lane - Sutter Health - Member

Can someone remind us what's in this part of CFR?

[Crosstalk]

Morris Landau - Office of the National Coordinator - Back Up/ Support

Mark, do you want to take it?

Mark Knee - Office of the National Coordinator - Staff Lead

I am happy to take it. So, we refer to the privacy rule here, the specific provision to the HIPAA privacy rule. A1 is a right of access with some limited exceptions. You have a right to get a copy of your protected health information and designated record set. Certain exceptions don't apply such as psychotherapy notes, information compiled in a reasonable anticipation of a civil or criminal action.

That's the basics of A1. A2 talks about what we call unreviewable grounds for denial. So, if you go to your medical records department let's say in a hospital they can deny access without review in certain situations. For example, in a correctional institution, in a research protocol, or if it's subject to the privacy act, or there is a promise, a contract of confidentiality. That would be A2.

A3 are what were called the reviewable grounds of denial. So, if a patient goes to a hospital, and they deny your medical records, then you can have that request reviewed for an appeal. Usually it requires a physician but a licensed healthcare professional who believes that the person is likely to be in danger – sounds familiar – likely to be in danger of the life or physical safety of the individual or another person. Or they believe it is going to cause substantial harm. Let's say a parent who believes there is some type of child abuse. The patient can review that decision for denial based upon some due process rights. Hopefully that's covered.

Steven Lane - Sutter Health - Member

That's very helpful. It sounds like so much of this is already covered in HIPAA.

Mark Knee - Office of the National Coordinator - Staff Lead

Right.

Steven Lane - Sutter Health - Member

Did we need to do as much as we did up above?

Andrew Truscott - Accenture - Co-Chair

Good point.

Morris Landau - Office of the National Coordinator - Back Up/ Support

I can tell you what our intent was. The first one – Let me give you an example. The precondition question is one in which for example under the privacy rule you can only send a minimum necessary amount of information. There's that standard for non-treatment purposes such as operations and that type of thing. And so, that would apply in those situations where, for example, a recipient would want more information than the minimum necessary. And the covered entity would say no we can't do that, because it hasn't met our precondition of minimum necessary. In this example we're talking about specific requests by an individual, which has been denied by a covered entity for access to their protected health information, generally their medical record. So, they are two different concepts we are trying to get at. Does that make sense?

Mark Knee - Office of the National Coordinator - Staff Lead

Just a note overall. We worked very closely with the Office of Civil Rights, whose expertise is HIPAA. We tried to – like Morris said, there are differences and we are kind of flipping the script a little bit, because as far as information blocking goes, we are working off of everything should be shared unless

there is a good reason not to or it is required be law. Whereas HIPAA works the other way. It limits the amount that can be released. So, we want to work within HIPAA and in a way that's complementary to HIPAA, but it was kind of necessary – at least in our opinion – to layout these exceptions the way we did.

Anil Jain - IBM Watson Health - Member

Did you get a sense from the OCR folks what kind of burden this additional set of tasks might impose on the overall support for HIPAA that most organizations would have to deal with?

Mark Knee - Office of the National Coordinator - Staff Lead

If you're going to give – Sorry, go ahead.

Morris Landau - Office of the National Coordinator - Back Up/ Support

No, we worked quite a bit with the Office of Civil Rights on this one. One of the key concepts we want to make sure we got correct was it had to be consistent with the privacy rule. In other words, we did not want a heavy lift for covered entities and business associates who already comply with the privacy rule to do any extra work for not disclosing.

Mark Knee - Office of the National Coordinator - Staff Lead

The tricky thing was that in **[inaudible] [01:54:30]** it talks about required by law but with HIPAA – like Morris explains before – there's a lot of times when it's not necessarily required but a condition needs to be met. So it was kind of a tricky, it could be or it couldn't be. So, we had to work that out.

Andrew Truscott - Accenture - Co-Chair

Great. I think D – Morris as you explained it –makes actually pretty good sense to me.

Steven Lane - Sutter Health - Member

We don't have a lot of time for E. Having given it some thought, it certainly seems reasonable. It's very patient centric.

Andrew Truscott - Accenture - Co-Chair

I was going to say I quite like it. I understand it.

Steven Lane - Sutter Health - Member

I do too.

Andrew Truscott - Accenture - Co-Chair

I'm sure Arien's **[inaudible]** wrong when he comes back on the next call. Anil, were you comfortable with this one?

Anil Jain - IBM Watson Health - Member

I am except number two. It says, such request was initiated by the individual. I think in other places I see individual or a legal designate or something of that sort. Like a guardian or someone else who –

Andrew Truscott - Accenture - Co-Chair

I think individual has a definition.

[Crosstalk]

Anil Jain - IBM Watson Health - Member

Okay. Well then I'm good with this.

Andrew Truscott - Accenture - Co-Chair

It's the natural person one.

Morris Landau - Office of the National Coordinator - Back Up/ Support

Sorry about that.

Andrew Truscott - Accenture - Co-Chair

Well, that means I'm not going to forget that one. We are doing something similar back in the UK and we used the term denizen instead or citizen and it caused the same level of discussion.

Steven Lane - Sutter Health - Member

What's missing from this one is any reference to the organization having a policy to support this.

Andrew Truscott - Accenture - Co-Chair

I think, this goes over and above. I don't think it needs to be bound any way does it. **[Inaudible] [01:56:34].**

Steven Lane - Sutter Health - Member

That's fair. Again, this is being used essentially as a defense for not releasing. So, we did not release the information because they asked us, and we satisfied all these conditions. We do have a policy for this. I helped to write it, which is why I'm thinking about it.

Andrew Truscott - Accenture - Co-Chair

[Inaudible] it should have a policy so that they have a defensible position **[inaudible].** This does not need to require it, because it's kind of an absolute. Irrelevant to whether you have a policy or not, you can be asked.

Morris Landau - Office of the National Coordinator - Back Up/ Support

Guys, I'm sorry but I have a call.

Andrew Truscott - Accenture - Co-Chair

Thank you so much for doing this. I appreciate the amount of time it's taken out of your day. Please continue to comment on the document before the next meeting. Anil went through this one already. I think all of us should. And we're going to come back and actually start suggesting some modifications on the next call as well. We're working pretty quickly through this, actually.

Anil Jain - IBM Watson Health - Member

For those still on our next call is on Friday at 2:30 Eastern.

Steven Lane - Sutter Health - Member

I have to drop a little early on Friday. I see that that is acceptable. We have a state-wide work group that starts at 4:00 Eastern.

Andrew Truscott - Accenture - Co-Chair

I never said it was acceptable. I just didn't complain when **[inaudible] [01:58:30]** did it. Of course. No problem at all. I appreciate it.

Mark Knee - Office of the National Coordinator - Staff Lead

Hey, Andy and Michael, do you have a minute to talk? Thanks, Steven.

Michael Adcock - Individual - Co-Chair

Sure.

Andrew Truscott - Accenture - Co-Chair

Sure

Mark Knee - Office of the National Coordinator - Staff Lead

Great. While I have you, I just wanted to – I was telling Andy earlier, I have to get some slides together for the full task force presentation on Friday at 11:00, and I have to get them to **Assel** by 24 hours before, by 11:00 am tomorrow. I was just wondering, what you're thinking about putting in there. I guess, Andy you had mentioned putting in a slide that says topics we discussed for each work group and some of the issues. I think it might be tough at this point – I'm not sure how exactly the best way to flush out some of the issues. Any thoughts would be helpful.

Andrew Truscott - Accenture - Co-Chair

Let's just be absolutely factual and say we got through X rules out of Y, and we're progressing as planned.

Mark Knee - Office of the National Coordinator - Staff Lead

That works for me. What do you want to cover in the discussion? Do you want to get into substantive topics for each workgroup or...?

Andrew Truscott - Accenture - Co-Chair

Who is the audience?

Mark Knee - Office of the National Coordinator - Staff Lead

It's the full task force, so all three workgroups.

Andrew Truscott - Accenture - Co-Chair

I think maybe we should get out on the table the key issues that are arising.

Michael Adcock - Individual - Co-Chair

In perspective, do you want to maybe – Would it be possible just to put a few bullets down, and I can do the same thing tonight based on the calls? What you think would be good ones. I won't put much detail on the slides, but –

Andrew Truscott - Accenture - Co-Chair

[Inaudible] [02:02:19] We should probably put down whistleblower. We should probably get down the intellectual property concerns. We should probably get down alignment of all the answers so there's common approach across all answers even though the penalties are different. I got that from workgroup three, as well as, workgroup one this morning. Those are probably my big ones so far.

Mark Knee - Office of the National Coordinator - Staff Lead

Okay. If you think about it more sometime tonight or in the morning just send me bullets. I will look through the Google Doc and should be able to pull out the issues as well.

Andrew Truscott - Accenture - Co-Chair

We might **[inaudible]** a comment.

Mark Knee - Office of the National Coordinator - Staff Lead

Do you guys want to – I think I'm supposed to have you review the slides before I send them. If I send them to you in the morning would you be able to give them a quick look?

Andrew Truscott - Accenture - Co-Chair

Sure. All my days are spent doing this for you now, Mark.

Mark Knee - Office of the National Coordinator - Staff Lead

We're gonna become best buds. Invite me over to the pond for a little trip.

Andrew Truscott - Accenture - Co-Chair

Mike, are you being able to **[inaudible].** I'm exhausted from today. That's four hours of this.

Michael Adcock - Individual - Co-Chair

I am worn out.

Mark Knee - Office of the National Coordinator - Staff Lead

You will be okay, toughen up. I will let you guys go. I do appreciate it. It was good conversation. We will talk tomorrow a lot I'm sure.

Andrew Truscott - Accenture - Co-Chair

How are the other task forces going? Are you involved in any of the others? Lauren's still on. Lauren, how are the other task forces going?

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

I think, you guys are probably making the best progress so far. I think probably because we have the most work to do.

Michael Adcock - Individual - Co-Chair

It's not a competition, right?

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

Not at all.

Andrew Truscott - Accenture - Co-Chair

It's totally a competition.

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

No pressure.

Andrew Truscott - Accenture - Co-Chair

I'm glad we're not behind the others put it that way. I know we are slightly behind where we wanted to be. We are still – We are getting a lot of conversation, which I'm pleased about.

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

For sure.

Andrew Truscott - Accenture - Co-Chair

I'm surprised there's no more public interest.

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

Well, I think because we just flipped these over to be public meetings yesterday, this morning. They haven't been public notice for that long, but next week it will probably be a different story.

Andrew Truscott - Accenture - Co-Chair

Oh boy.

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

So, get ready.

Michael Adcock - Individual - Co-Chair

Great job Andy and Mark.

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

Thanks again.

Mark Knee - Office of the National Coordinator - Staff Lead

Talk to you tomorrow.

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

Bye-bye. [Event concluded]

[End of Audio]

Duration: 124 minutes