



Collaboration of the Health IT Policy and Standards Committees

Consumer Task Force
Final Transcript
September 27, 2016

Presentation

Operator

All lines are now bridged.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a joint meeting between the Health IT Policy and Health IT Standards Committee's Consumer Task Force. This is a public call and there will be time for public comment at the end of today's call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll; Donna Cryer?

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Donna. Angela Kennedy said that she was sick?

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Hi.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Oh Angela, are you there? Brian Ahier are you here?

Brian Ahier – Director of Standards and Government Affairs – Medicity

Yes, that is I.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Brian. Carolyn Kerrigan? George Mathew? John Derr? Kevin Fowler? Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hey, Leslie. Mark Savage?

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

Here, thanks.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Mark. Patty Sengstack isn't able to join us. Susan Brown?

Susan Brown – Health IT Director – Telligen

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Susan. And Susie Hull?

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children's Hospital Medical Center

I'm here, thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Susie. And from ONC do we have Margeaux?

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Yes, this is Margeaux.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hey, Margeaux. Okay, with that, I'll turn it over to Donna.

Mike L. Lipinski, Esq. – Director, Division of Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Michelle, just to let you know, Mike Lipinski's on, too.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Mike, thanks for joining.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Okay, is this a better sound quality>

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

A little bit, thanks, Donna.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

How about this?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

I don't hear a difference, but it is better, it was...thank you.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

All right, all right, we'll limit...we'll do with what we can. So, it seems given the robust set of comments, and thank you again to the ONC staff officially, now that we're on the record, for a great job. It had to be an arduous job summarizing the robust and very detailed, nuanced, very thoughtful comments that came through from the task force, so thank you everybody for doing your homework as well as the public comment.

I just thought...it seemed to make most sense just to sort of go through the questions and so people can verbalize and maybe clarify any of the comments that were put into the template or things that they saw in other comments that they thought should be carried through, or not, so that we end up with a Model Privacy Notice document that is helpful to both developers and to users.

So...one thing I wanted to just ask the staff before we started was just a little context about clearly we know this is a review of our update of policies that were put out for personal health records in 2011 and so we're looking for a new version; is there anything that you wanted to say about the timing of the new version, as well as you know where it's going to be housed and how people will find it as well, before we start delving into the four questions.

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Sure, this is Margeaux from ONC and Mike, I would love for your...please jump in as well. And just firstly just to echo Donna, I would...I just want to say thank you to everyone for all of your really thoughtful feedback and comments on the Model Privacy Notice. You know I know we had a quick turn around and we really, really appreciate your really thoughtful feedback on the content and really making sure that it was consumer friendly.

So we're still going to be focused on the content; we're hoping to turn it around and have something by the end of the year that will then be in a, you know in a good spot based on your comments and feedback to then have the public... As we did, you know I believe this will be available as we had some of the PHR, our previous notice, a lot of the background materials and links will probably be housed on our website, healthit.gov; but Mike, please jump in if you have any other additional information or things you would like to add.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Okay, hearing no jumping in or adding, we'll go with that which is...

Mike L. Lipinski, Esq. – Director, Division of Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Yeah, nothing more, nothing more from my end.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Okay, great. So the first question was, is the language clear and terms understandable to consumers...apologize, I cannot control the airlines, airplanes...outside, is the language clear and are

terms understandable to consumers? If not, suggestions you have to make the content more consumer-friendly and easier to understand. So, that's where we started and I think, looking through the comments, several people made...refer to the fact that there were some terms that are jargony and may need to be changed, just a few. And there also were just some terms that we all recognize need to be used, but may benefit from definitions in place.

So, do people want to comment about you know, their favorite pet term or, you know the words that they thought were particularly you know, in need of work in the document, which is...which was generally overall seen as positive and clear, particularly when compared with a lot of other...government things that we have seen in the course of our lifetimes, this is in fact a model. So kudos to the staff, but there were a few words that were drawn out, would anyone on the committee like to talk about things that needed to be better defined or...

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

This is Mark, I'll throw out, it's not quite responsive to your question Donna...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Okay, go ahead.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

...but it was another solution to the same issue, which is in that balancing point to, you know for the electronic version to perhaps use hyperlinks or info buttons so that got the best word, yes you do need more, is that a way to keep a word so it stays streamlined and yet get more information for those who need it, as long as those underlying explanations are plain language. So that was a solution that...where we kept the word or changed the word, but it was a way to get some additional helpful context in if needed.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Great, great. And so you know one of the things that myself and that category is the difference between security and privacy...or as people understand them, that your data may be completely secure but not private. Do people have thoughts on that or are they happy with the version that are present...?

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

This is Mark; I think in the...when you look at the range of consumers, there will be...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Mm-hmm.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

...there will be some who may not understand the distinction and wonder why a distinction is being made. They may think mostly in terms of security, excuse me, in terms of privacy and not think in terms of security. So, from a...that might be an area where an info button or hyperlink might be helpful for those...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Mm-hmm.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

...who want to delve in; but if you start capturing all those differences within the text of the notice itself, people may get bogged down.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, it's Leslie; I think there has to be an explanation because you can securely exchange information on a very public website...I've exchanged the information in a secure way to make it as un-private as I choose to be or public as I choose it to be. So I think it's worth describing, but perhaps at the front.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Mm-hmm.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And I sent some comments late, so I'm sorry they're not included in the presentation, but I...so I won't mention all the detailed comments I provided, I'll just leave that just to process if that's okay.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Okay. Well, I look forward to seeing that and so between just doing this as a here in this location. So, umm, the other terms that sort of came out were about de-identification and explaining that to people. I think there is...there have been two lines of thought in the world today, and I may be oversimplifying, but one is that the...understanding of you know stripping out your you know name, address and other sort of common things as have been explained results in de-identification and letting the general public sort of know that. And then there are the folks that sort of understand that no matter how much information you pull away, someone, somewhere is probably going to be able to put the pieces together and identify you.

But just even a simple basic accepted sense...de-identification I think was one of the things that was drawn out as an area to make sure. I think...I feel hyperlink is fine, but to make sure for people who want to, you know so that people would surely come away understanding this, you know what their actions entail or the consequences as they're making choices, making sure people have and, you know an understanding of de-identification I think is, you know one of the most important things to have gotten across. Other thoughts on that?

Susan Brown – Health IT Director – Telligen

Yeah, this is Susan; along those same lines, I had highlighted the word aggregate because I think those of us in healthcare can automatically sort of picture in our...or visualize in our brains, oh, the data's all combined together so an individual person can't be, you know their data's not shown. And that's how we visualize it working in healthcare, but I don't think most of...most people use that word aggregate. You know I think people probably know what it means for the most part, but it was just along the same lines of, the point is that you can't be personally identified in the data set.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Mm-hmm.

Susan Brown – Health IT Director – Telligen

So there might be a simpler way to convey that versus aggregate and de-identified.

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children’s Hospital Medical Center

Yeah, this is Susie Hull; I apologize I did not send any written comments, but I did make some notes here. I think that the first section around identifiable personal information and then the second one is de-identified information or data. And then I think either of those could be aggregated or statistical, so I actually felt that we almost needed three boxes in this order because the way that we’ve grouped aggregates statistical or de-identified may not be as relative, because it’s either identifiable or de-identifiable. And then I was thinking either of those categories could be aggregate or statistical; but maybe I’m misunderstanding the way the privacy notice is organized.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

ONC folks, would you like to make a comment on your thought process as you were putting this together relevant to that comment?

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Sure, this is Margeaux again from ONC. We really appreciate your thoughts on sort of that data piece and how to term it in a way that actually makes sense to consumers. We have the two separated categories of de-ident...of identifiable information and de-identified statistical and aggregate information, in part informed both from the public comment period that we had mentioned in the last task force meeting where we put this out to ask for, you know and receive public submissions on sort of what the data category should be. And also based on sort of some of the HIPAA definitions of how they classify data under HIPAA as well.

So that’s I think how we came up with those two kind of broad categories, but you know this is why we came to you guys, is because we really want to hear you know does this actually make sense? Would consumers and your everyday person who is already privacy and security is already such a complex issue, would they understand exactly what data is actually being referred to here? And I know that you guys provided a number of suggestions on how to change that wording.

For example for aggregated or de-identified things like, added up or grouped or making it more clear; I think Mark you mentioned having maybe some sort of pop-up box or little in text icon that you could click that would allow people to see more of the clear definition of what those mean. But yeah, I hope that provides a little bit more background on sort of where we got there, but we’re also, again, this is really a time for us to turn to you guys and hear sort of what makes sense. So all of this feedback is really helpful and we’re going to take it back and make this into something that hopefully makes sense and will be useful.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Leslie. Some suggestions we had for that was that, I’ll just, this information can include all of what is listed under identifiable information, but this information is modified or reduced so that all ways to identify you are removed. And we suggested an example, and an example might be a letter or note would not show the name of the sender or receiver, it would only show the content of the message, and as long as the content of the message contained nothing to identify you and that’s de-identified data.

So just getting to very plain language, conversational tone at the top layer and then get into the detail I think at the hyperlink layer, which is very important.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

I really like that, that...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We're saying in the identified or the aggregate statistical, we're going to use it...we could use that data in the same way, so you can simplify the forms...we collect any kind of data to improve our product services or software applications, to market our products...to conduct research or to report about our company's operations. So those would be checked or gathered, identified across either one of those. So, just some thoughts.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

I think the...I totally loved that, I also think I took away from that as well a very important point on tone and trying to make this more conversational as it goes through to make it approachable for people as well as, you know the content but just telling the format for that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So to give you an example, if you use the word acetaminophen, that takes it up to like an 11th grade level and so grade level isn't enough, you have to get the tone, because you're not going to want to not use acetaminophen when you're describing treatment for fever. But you can say something in plain language that says when you have a fever, you might take something you can buy at a drug store like Tylenol; this is an acetaminophen and be found in other name and brands and generic brands. Even though I've used the word acetaminophen, I'm now speaking in a tone and in plain language that can serve all types of grade levels.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Fabulous, fabulous. Okay, I'm switching over to the next question or, forgive me if I'm going out of order as I'm going between different points. There were several...get back to the document where the next question was, I believe, what are consumers' primary concerns with privacy and security of their data when using health Apps or devices and are there concerns that are missing from this draft notice template?

So first I think just the general conversation amongst ourselves about how we think consumers actually think about privacy and security. And as I pointed out...started out at the beginning, I don't know that they necessarily understand the difference between the two, so we could certainly deal with that. So just as you're thinking about what are common assumptions that we think the average person has about their privacy and security when they're putting information into an App or this into...or some other type of electronic format.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think in general...this is Leslie; it's obfuscated as much as possible, nobody wants to say something directly like, look when you...we're going to use it for marketing and advertising, so the more that we can do very direct language, the better people will understand it rather than get to the gobbledygook for the check box at the bottom.

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children's Hospital Medical Center

So this is Susie Hull again; just to sort of build on Leslie's comments. I think one of the things that's missing in here, and I don't know how you dealt with this in the previous comments you received, but we're sort of implying that this health information or health data is sort of coming one way and actually it could be person-generated, it could be device-generated, it could be sensor-generated, it could be healthcare provider-generated all about me as a consumer.

And so...and then these things are going to start to get blurred up when people start using health Apps and they're adding their own data say into something even as simple as MyChart and the health system that they're a part of is sending data. And then we're getting data from other care settings; so I think this idea of who's actually generating the data and the types of health data that might be used is important to consider.

And the other thing I noticed, I do agree with the comments about those drop-downs on the right-hand side, but we've actually missed the data for just actual healthcare services. It seems like that the data actually could be used for just healthcare services in addition to the other purposes listed.

Mike L. Lipinski, Esq. – Director, Division of Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

This is Mike with ONC, I just want to make one comment on that because that's a comment we've heard from various stakeholders and what we struggled with there is, you now the App is going to have a purpose and it should explain what that purpose is, right? Like some Apps are going to intentionally do a lot of the things you just said which is pull data from...your health data from a, you know that you generated, and use it and pass it on or so forth.

And I guess, what we were trying to achieve here and maybe that isn't the complete focus, or shouldn't be the complete focus of what we have is to make consumers aware of what they wouldn't anticipate or expect would be happening with their data, based on the fact that they've chosen to download the App in the first place. Does that make sense?

W

Yeah so we're...

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children's Hospital Medical Center

It absolutely makes sense; I still find my cam...find myself in the camp that because we are advising developers on their best practices as well as the consumers, I think making sure that the functionality of that particular App is one of the things that is explained ideally. I'm in the camp that believes that that should be part...should be included.

Mike L. Lipinski, Esq. – Director, Division of Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Okay. Thank you.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

And I do want to say that as part of the larger project and the context, there was a question you know asked about you know, who should this model apply to and there were you know a variety of opinions, as I'm sure you talked...you mentioned in the last call, but it seems that to me a propensity came down on the side of the scope of people who could voluntarily you know use and would benefit from this model would be broad, would be sort of everyone broadly defined you know healthcare Apps, HIPAA, non-HIPAA compliant, you know etcetera, etcetera, that the more people, more developers for whatever they develop using this model for the greater consistency across the marketplace and the greater, I think general understanding of the public of these concepts would be. So I think that's the context that is surrounding this as well, and always correct me if I'm wrong or have misspoken in any way about something like that.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

This is Mark; I wanted to add one thing...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Mm-hmm.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

...to Leslie's original comment, just to reinforce it from another perspective as well; consumers don't want to be surprised and if you want to preserve trust, you really don't want them surprised.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Right.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

So it's another re...another really good reason to lay out the categories of uses and to be clear instead of hiding what they're...what's going to be happening, because it helps on all sides of that equation to preserve the trust.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Thank you, absolutely. Okay, several suggestions came in for additional categories. Again trying to keep this as simple as possible and I know that's the next question, how we can simplify; before we get to simplify, just want to make sure that we have everything that does need to be included in here in here, and I know that there were several suggestions that were, you know incorporated for different types of data that would be collected or shared, sales, operations, etcetera, those you know those were captured...have been captured by staff, so thanks for putting on your imagination hats and walking through all the potential categories.

This is one of the reasons why I, you know sort of go back again and trying to visualize you know where this privacy notice, if it is adopted by a developer you know would be and how it would be rolled out to the user sort of all at once in that you know terms of agreement that we never read or on a more granular or modular basis when you're actually making a decision about whether or not to share data. So, and I think that would probably depend on the App or platform that is using this, but I think that becomes an important part of how people digest this information and how truly...how they understand it and are able to act upon it. So, just as part of the larger context in which I know some are thinking about the use of this rule.

So the next question was really just how to simplify it, thoughts on that? You had check down lists and I think the general structure and brevity of the rule...of the notice rather, is you know was given high marks. Are there...hyperlinks we've talked about to make sure that it's you know we keep it decluttered while giving additional information. Other comments on simplification? Maybe it's...that simple, you know I'm happy to if...I will warn you if I don't...

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children's Hospital Medical Center

This is Susie Hull again...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

...if I don't...response...go ahead.

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children's Hospital Medical Center

I'm sorry, I didn't mean to interrupt. I think you may have...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

No, no, no, no...

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children's Hospital Medical Center

...already done this but for simplicity sake, just consistency of terms like data and information and deciding sort of one way, are you going to go with data or information or are you going to use both terms? It's still confusing and doesn't necessarily make it...doesn't make it simple.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Leslie; also I think there needs to be, who do I call when I have problems, how do I get in touch with you when I have questions about how my data is being used?

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Right. So, you know towards the bottom it's, you know how will we notify you if our privacy policy changes or notification, but...and sort of a contact us with questions part. Is that section sufficient, those sort of bottom three parts or can that be simplified? Does that need to be a single, you know button, I have a...information use question? Is that the area that needs to be simplified? Should they be compacted together? I...suggestions on to follow up on that point about okay, what happens if you know...one of the questions I know I asked was, what happens if the App or the company goes out of business, what happens to my data then? Are there other scenarios or things that people would need to reach out about that aren't captured here?

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children's Hospital Medical Center

Yeah, this is Susie...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I think those are great and I also think people can also put on their provider hat, what do you want to know when the patient signs up for the API and attaches a portal because the providers are going to be concerned about well, they'll call me and what did they actually sign? And part of the recommendations came through in the API Task Force is that that data would be collected from the actual privacy notice back into a provider's system so they would know, here's the provider developer need, here's where the data is stored that the patient's afraid to use.

So look at it from both those points of view, where would the patient be protected the most and I think as well as the provider knowing these things as well as patients being informed what their rights are, who they contact if they have a problem? Where does the FCC come in play and all of that?

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children's Hospital Medical Center

Yeah, this is Susie...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

How...yeah, I can do that.

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children’s Hospital Medical Center

...kind of a related comment was, I don’t know how relative, if this is too much detail or not, but let me just put it on the table. I think that consumers are not aware of what happens to the immediacy of their data and the long term of their data. So say I participate in a mobile health for three months in an App and I’m exchanging data and I know where it’s going; I stop using it, but then I get back on and at some interim there’s been a change and now my data’s integrated into some large electronic health record system like Epic, I thought it was just going to be on the mobile App, I didn’t really understand where it was going or who it’s been either resold to or this sort of ecosystem of data and data provenance.

I...there...so there’s a level of that that’s too complex for the consumer, but it’s also important to know. And then many of these health Apps or these kind of technologies are not giving anything back to the person, they’re just sending it to some, you know some other place, some other cloud or for the benefit of others rather than what is the data that’s actually returned to me.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Mm-hmm.

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children’s Hospital Medical Center

And it’s not certain that we have a thing about how do I actually get my data back from this or do I get any data in particular back to me or how would I get my own heal...my own data? I guess I put two or three points in that comment, but...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

No, I understand that, I’m just looking to find them. I think some of them are covered in earlier sections about access, storage, access and sharing. I think the part that perhaps is not covered is that change of control, that you know what happens if the company’s acquired or the hospital or you know it’s subsumed in some other entity, and maybe that’s the addition that this privacy notice, does it apply? You know does the same understandings that I had when I put it into an App, do they apply or do they not or do I need to sign another...will I get notified that maybe it’s under you know how will we notify you if your policy privacy changes?

Maybe something under there is one of...an example could be, you know people would ask well why would it change? These are some circumstances of why it might change, you know updates, added functionality, company bought, just helping people think about the things that we already sort of know and assume happen. I think it’s this line between we want to...you don’t want to scare people, but we do want to, I think better inform people about the realities of the ecosystem. Are there thoughts on that or, I don’t want to take us off...

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

So this is Mark. I...we had raised a related question and so maybe it’s a place to incorporate a change in control as well and that’s what happens when the individual terminates the account? Do they get...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Yes.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

...do they get all of their data back? And I'm realizing as I'm staring at the now that it's probably useful to add something about getting it both on the download and in getting it back that you get it back in a usable or useful format since that can be an issue that you get something back that's not in a useful format. But, the termination of the account from the use...from the consumer side is, maybe there...that's either it's another question or it's the same place for saying it, or the if there's a change in control at the company level, what happens to my...does my data get erased or do I get to continue my account; that kind of thing.

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children's Hospital Medical Center

This is Susie Hull again; we have a situation where we've had a couple of projects that are in a research mode and they've had a major investment, they've had patients on it for two or three years and then our health system has decided no longer to invest, so we sort of cut the whole thing off. And patients, some of them that have used the product and the tools for you know sharing and collaborating with their providers are completely lost because they didn't get really...they got notified of the termination, but they didn't terminate the agreement, they still wanted to keep using it and then at the end of the road, there's sort of nothing for them. So I think it's...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Right.

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children's Hospital Medical Center

...what happens when I terminate, but what happens when the company terminates this product to me?

Brian Ahier – Director of Standards and Government Affairs – Medicity

This is Brian. One thing I think that is important to note for us, but also in this plain language explanations that are going to be provided to patients, is that the data doesn't get deleted. You know if you think about the notion of a shared care plan and sharing data among clinicians and including patients in the sort of the circle of trust there, this is also a shared record.

So these are business records of the healthcare provider; they can't just delete them because you leave and go to another practice or move away. You know they could potentially be subpoenaed for court or there could be a fraud investigation from CMS; all kinds of reasons why they have to keep the business records and so electronic health information is very important for clinical care and very important for you know the patient to have...certainly to have unfettered access to.

But it's a shared record and so you know this question of ownership I think is tricky and you know perhaps we could get our friends over at OCR to even further clarify that, because I'm seeing things out in the...you know articles that are written by really smart people that are passionate about the issue, you know and that are great clinicians and brilliant technicians, but maybe not lawyers. I know that you know the advice that was given to me was that ownership is a bad word in this case because it's shared ownership actually.

So I just want to point that out, you know if you have health information stored somewhere and it's a covered entity, and the relationship ends for whatever reason, then...or a business associate of a covered entity and the relationship ends, you certainly have...still have a right to access, to have a copy

of that information, but they're not allowed to delete it because it's...they're also responsible for the stewardship of it.

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children's Hospital Medical Center

Thank you, that was great.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Very helpful. So I think that the charge is to raise the additional issue and to find a simple, you know non-legalistic jargon way of explaining to patients that a service may terminate or there may be a change in control in some fashion where the data would pass to another entity, but it's still going to exist in some form. And then the second part of what I heard from the group was that will people still have access to their data in a usable form. So even if it still exists in perpetuity, will they be able to get that data so that they can continue to use it in some fashion that they choose. Did I capture the thoughts correctly, the two thoughts, the two basic premises correctly?

And I think that brought us also into very...some very helpful discussion of the last question, which is about detail on privacy and security terms for consumers to understand. Besides defining them up at the beginning, hyperlinks and talks in defining certain terms, changing others, I think that this concept of depending on the App or the electronic platform that it's in, the concept that this is a...that this is shared, this will continue on in perpetuity and may go into another entity that may cause people to choose not to participate in a particular App, and I think that's okay. But it seems like that's something that needs to be made explicit. Is that correct?

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

Donna, this is Mark; can you repeat that again please? I'm not sure I understood it.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Sure, I just said that the last question was about additional details on privacy and security, I think we've captured that up in earlier parts of the conversation.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

Right.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

One was defining the difference between those two terms, but also the last part of the conversation on shared use, change in control, your data continuing on and I guess the fourth point that was raised about you getting your...

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

Okay.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

...information back in a usable format. I wasn't sure what else besides what we have discussed, was left untouched in terms of data and security...

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

Got it; thank you.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

...as we try keeping as simple as possible.

Mike L. Lipinski, Esq. – Director, Division of Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

This is Mike Lipinski with ONC, can I ask a question for clarity, because that's what we always have to do with the rule when people ask questions, what do you mean? When you say usable format, I think that was you Mark...

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

Yes.

Mike L. Lipinski, Esq. – Director, Division of Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

...what did you anticipate because people, everybody may have a different understanding what usable format means, like the way that they provided it or the way that they view it? Like how would we try to address that in as simple, plain language way.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

Well I know that in the switching over to the Meaningful Use Program, when you download you're supposed to be able to get it in a usable format and the notion is, it doesn't work if you just provide it you know in some sort of encoded way that you've got within your EHR, but it's not one of the common ways that most of the real world uses it. So I used the phrase, usable format, useful format as just a summary word to try to capture that notion. It's a privacy notice so going into a whole lot of detail about that isn't going to help...

Mike L. Lipinski, Esq. – Director, Division of Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Mm-hmm.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

...it's going to confuse. So I was thinking that just those two words might be sufficient, but maybe not.

Mike L. Lipinski, Esq. – Director, Division of Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Okay, no I just wanted to, in case you had an expectation of you know what that meant to you and if, you know from a consumer who reads that, trying to figure out if we can say it in a way that they'll know what that means, too; whether maybe again it's a hyperlink or something like that as to how they provide it back or so forth.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

But to give you some real world examples, sometimes what you, you know you're doing all this stuff electronically, what if they're only giving you a PDF back and wanted structured data.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Right. So you know for example, I think that's an excellent point Mark and you know I think about if you're...if the App decides to...go out of business or the portal you know terminates or whatever, is all of your data going to be, you know automatically sent to a new App or portal that you'll be able to use. Just like if you close down a non-profit organization but all of the assets are then transferred over to another organization and then, you know you can still continue on without disruption.

So, some type of what happens next? Do you...are you going to get that PDF or are you going to...is it did they take the time or opportunity to transfer it into another App that you can use pretty much you know seamlessly if you changed over from a Jawbone to a Fitbit or something. Or is it just that you're now going to have to do a lot of work to put in everything that you may have put in for the past three years? So, for the purposes of the notice, it's simply perhaps a guidance to developer to let the user know in what format their data will be available moving forward, based on whatever type of change happens. Is something like that what you contemplated or helpful or sound right to people?

It's a quiet group this morning, but you were thoughtful in your comments, so I know we gave ONC a lot to work with and wrestle with and that might be it, that this is still quite an iterative process and thanking everybody here and the ONC staff for being so thoughtful in teasing through not only the content but the implications of the content.

So if I were to summarize briefly, not in...form, it seems that overall we think that the model notice is well done, that there are some certain terms that would benefit from either would benefit from hyperlink or just...hyperlink definition for some, change in other terms like aggregation, that the tone could perhaps be given...the tone could be, of this whole notice could be sort of given a review for tone being more conversational. There are certain additions that were made to the type of use or sharing that will be added to the various drop downs, but that that format of drop downs was helpful.

We talked about the relative usefulness of the two different categorizations of data and then in terms of privacy and security, being a little more clear with patients, consumers...users, not only the difference between those two terms, but what happens in certain scenarios and how they can...what the consequences of those would be and how they can get more information either from the App developer or the provider or someone to get more information. How was that?

Susan Brown – Health IT Director – Telligen

That's a good summary, thank you.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

This is Mark, sounds good.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

All right. Anything else that people would like to add?

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children’s Hospital Medical Center

This is Susie Hull, one other comment. I think really finding the essence and the simplicity of this Model Privacy Notice is really the task that we’re up to and you are really leading the way on. I also think that there’s also guidance for developers or guidance for health systems; so it may be that the notice and the guidance we think about being related, but not necessarily all the guidance needs to be in the notice.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Mm-hmm.

Susan Hull, MSN, RN – Chief Nursing Informatics Officer – Cincinnati Children’s Hospital Medical Center

Because the growing body of work and we’re really all learning what it’s going to take to make this work at both the essence level and the additional guidance.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Agreed. So what I heard was to keep the notice as simple as possible, but there is additional information for developers that could be housed on the ONC site to help them operationalize this. I think that that’s a really true...very valid point.

I would still repeat my request at some fut...sort of for a future call, and maybe the sort of final call on this, but just thinking about how this is delivered to developers as well as to the user is sort of all at once, is it up front, is it at a modular basis; I think that it does make a difference in terms of people being able to digest the information and to make thoughtful decisions about how they’re going...how or if they do want to share or give consent or add more information or send it to particular parties. So, that’s the question; I have no expectation that it’s going to be answered on this call, but I would just ask that the ONC staff note that and we perhaps might come back around at the end of this process and address it again.

Hearing that, would ONC staff, would you like to task the committee with any other questions or clarifications or open it up for any public comment that we have for folks who might be listening and either could participate from a public point of view? And thank you for sending those great comments around; they’re brilliant and full...

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Margaieux or Mike, do you have anything further you want to ask?

Mike L. Lipinski, Esq. – Director, Division of Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

This is Mike, I would just say thank you, I think you’ve given us a lot more to think about, which is good. And so again, we appreciate you, under you know tight timeframe and little notice, jumping right in on this and giving us great feedback.

Margaieux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

I...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Well we thank you for the opportunity to have this very diverse group comment on this, so, you know I consider it a privilege certainly, as a consumer to be able to weigh in at this stage so, thank you for putting this on our...on the task force agenda. So, but I think we can open up the lines if people would like.

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

There's just one final comment that I have, this is Margeaux.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Mm-hmm.

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

And just to echo Mike again, just thank you, thank you, thank you, thank you everyone on this call, the task force members for all your thoughtful comments and feedback on the NPN. One additional plug I just want to make is that we will be having a...as part of National Health IT Week this week, we will be having a Twitter chat on the NPN; that's going to be Thursday, this Thursday September 29 I believe at 2 p.m. Eastern time.

So, that one is really just you know more around just kind of raising awareness of the NPN and just kind of a listening discussion around it. So it was great feedback to hear that many of you received a lot of feedback and interest from your own outreach in your groups when you brought the NPN to them. So we really, if they're very...if they're interested in chatting more, we welcome people to join us on this week for Health IT Week to discuss the NPN chat.

Brian Ahier – Director of Standards and Government Affairs – Medicity

Yeah, that's going to be awesome and I'm encouraging all the wild-eyed visionary e-Patient types and patient advocates of all stripes and...to attend that so we can make sure that we capture a wide variety of viewpoints, a kaleidoscopic view of the issue.

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

...thank you.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Thank you so much for setting that up for having that; I think that is just a great example of the spirit of your group, encouraging inclusion and conversation throughout this process. Kudos once again.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay, well it sounds like we're ready to open up for public comment.

Public Comment:

Lonnie Moore – Virtual Meetings Specialist – Altarum Institute

Okay. If you're listening via your computer speakers, you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the phone and would like to make a public comment, please press *1 at this time. Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

So while we wait for public...I just want to reiterate everyone's thanks for all the contributions that we received. We do have our next meeting scheduled for October 11th. We originally were planning to discuss patient-generated data, but we may make an adjustment and talk about the Playbook. We'll give you some advance notice and let you know, but one of those two items will be the topic of discussion. And with that we have no further public comment. So thank you everyone and we'll talk to you in a couple of weeks.

W

Okay, thank you.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

Thank you very much.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Thank you, everyone.