

**HIT Policy Committee  
Certification/Adoption Workgroup  
Transcript  
April 28, 2014**

**Presentation**

**Operator**

All lines are bridged with the public.

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

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Certification and Adoption Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Larry Wolf?

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Here.

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

Hi, Larry. Marc Probst? Carl Dvorak?

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

Here.

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

Hi, Carl. Diane Bedecarre? Donald Rucker?

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

Here.

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

Hi, Donald. Elizabeth Chapman? Liz Johnson? George Hripcsak? Jennie Harvell?

**Jennie Harvell, PhD – Senior Policy Analyst – Office of Disability Aging & Long-Term Care Policy**

Here.

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

Hi, Jennie. Joan Ash? John Derr?

**John F. Derr, RPH – Health Information Technology Strategy Consultant – Golden Living, LLC**

Here.

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

Hi, John. Joe Heyman?

**Joseph M. Heyman, MD – Whittier IPA**

Here.

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

Hi, Joe.

**Joe Heyman, MD – Whittier IPA**

Hi.

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

Marty Rice?

**Martin Rice, MS, BSN – Deputy Director, Office of Health IT & Quality – Health Resources and Services Administration**

Here.

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

Hi, Marty. Maureen Boyle? Micky Tripathi? Mike Lardieri?

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

Here.

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

Hi, Mike.

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

Hi.

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

Paul Egerman?

**Paul Egerman – Businessman/Software Entrepreneur**

Here.

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

Hi, Paul. Paul Tang? Stan Huff? And is Kate Black on from ONC?

**Kate Black, JD – Health Privacy Attorney – Office of the National Coordinator for Health Information Technology**

Good morning, Michelle.

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

Hi, Kate. Is anyone else on from ONC?

**Lee Stevens – Policy Director, State Health Information Exchange Program – Office of the National Coordinator for Health Information Technology**

Hi, Lee Stevens.

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

Hi, Lee.

**Lee Stevens – Policy Director, State Health Information Exchange Program – Office of the National Coordinator for Health Information Technology**

Hi.

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

And with that we'll turn it back to you Larry.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

Hey, Michelle, this is Liz, I just wanted to let you know I was on.

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

Thanks, Liz.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

You bet.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So, I'd like to welcome everybody back, we had a short pause in our deliberations on the NPRM and the 2015 edition. And I think it looks like a great set of slides for discussion this morning. I want to encourage everybody to get multiple points of view out there and see if we can get to some kind of consensus. This is our one topic for today, it is incremental rulemakings and we have plenty of time, maybe we can even set a record and be done early. So, with that –

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

You just jinxed us Larry.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

I'll pass it over to Paul Egerman.

**Paul Egerman – Businessman/Software Entrepreneur**

Great. Thank you very much, Larry. And basically there's a short slide presentation that I am going to take you through that I put together working with Carl Dvorak. And what we are talking about is exactly what Larry said, we're talking about this concept of incremental rulemaking or incremental certification and we are going to talk about it like – almost like in two flavors. So first we're going to talk about it as it relates to Stage 3 of Meaningful Use and then we're going to talk a little bit about it just in general, as it relates to what's called leveraging the certification process for HIT.

And you see on your slide, and I tried to send these slides around early so that people could have a chance to comment on them. You see on the slide the comment about incremental certification, and this is a phrase that is taken from the Executive Summary in the NPRM. It says, ONC intends to update certification editions every 12 to 18 months in order to provide smaller, more incremental regulatory changes and policy proposals. Now what I did here was I sort of emphasized smaller – the word smaller and incremental, that's not – that's like my emphasis added, it doesn't look this way in the NPRM, so I put in bold and did this little technique, I made the font a little bit bigger so it looks like that that's really the emphasis. But the reason I did that is because the comments that I'm going to be making going forward, and again, this has been done with Carl Dvorak, we are going to be making comments that this is really not small or incremental and we're going to be expressing some concerns about it as relates to the 2017 edition and some concerns in general.

So first, as it relates to the 2017 edition, which is also called Stage 3. I mean the basic concept of this special edition is to sort of give vendors a running chance to get done everything they need to do for Stage 3, and that is certainly appreciated to get as much notice as possible. But there is also a concept here that vendors will be, as soon as this is all done, what's called the 2015 edition, the vendors will be able to like start their engines and get going. And what we wanted to do is put forward the idea that there are two different challenges or obstacles with that concept, the 2015 edition will cause vendors to immediately start coding and certifying.

The first one is there's really no guarantee that what's in the 2015 edition will be included in Stage 3. And so, you have to kind of wait and see what happens in Stage 3, in fact, you can make comments on things in the 2015 edition, if they're going to be included in Stage 3, I assume that they will be included in the Stage 3 NPRM. And so there's a good chance to make another comment again. So, there's no guarantee, there's clearly some sense of direction that's helpful, but you don't know for sure.

There's a second issue that's interesting to know also, which is from the vendors standpoint, even if you understand that the measure is included in Stage 3, even if it does make it through that process, there's no guarantee that if you did the 2015 certification, that that would – that you would not need to repeat it again for Stage 3, which is 2017. And so those two things together are obstacles. I didn't want to describe it like that they're like deadly or anything, they're not necessarily issues that prevent anybody from doing anything, but they are simply obstacles and it would probably be okay if what was being asked as actually something that was small to get done. So I think people would live with this if they were being asked to do a couple of very small things and that they really were incremental. But unfortunately, that's not the impression at least that I had in reading the NPRM.

Basically the NPRM does include not only incremental things, but includes things that have never been done before in EHR systems or have never been done before in that way. So there are some things like ordering laboratory results that have been done, but they just haven't been done with that order process that is brand new. And so we have these different observations that we wanted to make on this issue of the things that are like brand new. One is that the regulatory process itself for certification simply involves long time periods and significant testing costs. And that first bullet I'm trying to say that as an observation, that's not in any way a criticism of the ONC certification approach, it's simply, that's the way it is. So if you're going to do certification as part of rulemaking, you're going to have long time periods for these regulatory processes.

The second comment is related, is certification should not be used for Version 1 of standards or for new functionality. So, that's sort of like a statement of a proposed recommendation, but the reason why I'm saying that is, and I think Carl agrees, is that when you're doing something brand new, when you're doing Version 1 of anything – I've done a lot of these systems for many years and it never works the way you think it's going to work. What's written on paper never works in reality the way you think it's going to work, there's always something that needs to be changed and there's frequently, when you do Version 1, there's a lot of need for changing things. So you need to have some amount of flexibility if you're going to do something that's brand new, to make changes and that's sort of like inconsistent with this inflexible 12-18 month regulatory process. That sort of slows down the entire process.

So the next bullet that we have here, which is again also in the form of sort of like a recommended – proposed recommendation is that before certification is proposed, there really needs to be significant operational usage, which should be required. And operational usage goes beyond just piloting or balloting. So, we have some things in the 2015 edition that had simply been balloted, that means a good group of people worked very hard and they voted and that's terrific, so that they did that. And so you have concepts about how we're going to code pedigrees for family history, and you have concepts about the new approach for providing educational material. You have concepts about a new approach for ordering laboratory orders. That's all wonderful work, and has a lot of potential, but we don't know yet how effective those are.

So you look at like the new approach for ordering laboratory – placing laboratory orders, really an important thing. But how well will that necessarily meet the needs of physicians, is an unknown until its put into operation. And when you think about that, we also have to think about what will it mean to put the governments, ONCs like logo on something and say it's been certified, what is the expectation that creates on the part of the physician or on the part of the user? And somehow to me that creates some expectation that gee, there's some value in what you're purchasing, and I think people will get very frustrated when they buy things and they just simply do not work well or do not work well at all in their environments.

So, those are some comments. And there is a fourth comment here, which is that once you sort of like mandate a standard, in other words, once you sort of like certify it and sort of complete the process, you've sort of like – it's almost like carving it in granite in some sense. Because we still have these consensus driven teams working on things, but they might consider that well, there's less careful consideration given to those issues that have already been certified, because there's certainly a long list of other things that could be done. And so if you don't do it right the first time, which is always very hard to do, there is a huge risk that people won't look at it again. So I'm going to make a few more comments, but let me pause a minute Carl, am I saying things that you –

#### **Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

Absolutely agree and I thought I'd maybe toss in an example of the, I don't know if we call it policy being made through certification, but the data segmentation work I think fits into this category. I think data segmentation will likely evolve over time, but it's an extraordinarily complicated field and it's just ripe with patient safety concerns. And I think the notion that we can mandate that sort of thing through certification, when in fact it needs careful policy consideration, and it probably needs to grow through time in some sort of learning environment rather than a presumption that an ONC mandated approach would actually work in practice. So for me, that data segmentation one is a great example of things to avoid through certification.

#### **Paul Egerman – Businessman/Software Entrepreneur**

Okay. So, and I'm going – we're going to take some questions in a minute, but the main concept that we're trying to – that I'm trying to put forward here is, what we see in the 2015 edition isn't just incremental changes. It is an effort to somehow advance the EHR development through certifying new measures, new concepts. And we're saying, that's both a dangerous and expensive way to do things. There's a comment I also want to make about whether or not this is a small increment, which is, it is extremely difficult to even make comments about what is included in the 2015 edition. And I keep calling it the 2015 edition, I think people should know that the EHR Association has published its comments about this edition and among their comments, I mean, they were, I don't want to generally characterize them, but they had a number of criticisms, but among their comments is, they asked that it be renamed the 2015 edition because there's too much stuff here and it's too complicated for it to get done in 2015.

So this is like – they asked that it be called the 2016 edition. But consistent with that, it's very difficult to really digest what's going on here and to comment on it. I mean first there's – well, you've got the NPRM that's like maybe 60 pages long, but then you have over 200 pages, I think it was 240 pages of text for the actual regulation. But when you go through the text, it refers to like other standards and other things in particular, so there are a lot of other regulatory references, and in particular, it refers to several

implementation guides. So you have to like read the 200 pages, you have to read the implementation guide and, on top of that, you need to know what has been balloted, because there's at least one situation where something has been balloted, there is no implementation guide. And the regulations actually refer to an implementation guide that will be published in the future, but hasn't been published yet, which makes it particularly difficult to comment.

And if you look at this total picture of having to know what's going on in the balloting, having to read through all the 200 pages of regulations and having to have all the references to other things – to other regulations, very hard to digest for anybody, but particularly hard for a small physician or a single physician to understand it, for a small vendor to understand it. There's this concept that we have that gee, we're going to somehow have vendors that are able to produce individual measures, and you don't have complete EHRs anymore, you can choose different things to produce. Well, very hard to find like that needle in the haystack here when you're trying to understand how to do things, especially since it's also important to understand that these things all interrelate with each other, which is why there are all the different references that occur.

So if you look at something like the transitions of care document that is – first, that's an extremely important document that's – it's one of the priorities for ONC, as well it should be. But that is influenced by what happens with the unique device identifier, which is a separate certification measure. And it is influenced by what happens with the demographic data, where you have things like military and industry and a whole series of other things that are being coded, which is one of the places where there's been balloting, but no implementation guide. And so my point is, if what you wanted to do was work on transitions of care, you would have to be reading through and understanding all those other things that might have an impact on that process.

And again, this is important to understand, we're going to talk a little bit more outside of Stage 3 in the minute, but you think about the LTPAC vendors, we talked about them being a number of very small vendors in a somewhat fragile vendor community, who's not yet been exposed, I think, to this entire process. And I don't see how they have a really good chance to influence it, is what I would tell you. I would tell you that this is a process that really works well if you're a large corporation, if you have like an army of attorneys among the very first people who commented on the entire process, like Shawn Nolan from Microsoft. And I'm not trying to make that like any criticism at all of Microsoft, of course they're fully – have every right to comment, in fact, I really appreciated Shawn Nolan's comments, because when I read his comments, I had a better understanding of what was going on with the Direct protocol than I did actually from the reading the NPRM.

But not every organization, not small organizations can do that, can participate in the balloting, have enough people to read through this complexity and comment on it. And it's really unfortunate also that this is the situation, because to its credit, ONC does a wonderful job of listening to the comments. I mean, ONC really does pay attention and so the point we're trying to make is if you had something that was smaller, that was really incremental, then you probably would have a chance to get better comments. If you had – if it focused only, for example, on the transitions of care document, you could probably get a really good discussion and get some valuable information, but in this environment, very difficult.

So based on that, we have a few recommendations – additional recommendations, again, these first relate to Stage 3. And basically what Carl and I are suggesting is a much narrower and focused approach that incremental certification, first bullet, should focus on increments, that's – should focus on increments to previous interoperability standards. So if we do an incremental certification and you have something with interoperability and there's some reason why it's important to make a change to go from Version 2.1 to 2.2, that would be a good thing to do with incremental certification.

We secondly said it is a good idea to update vocabularies and data definitions in incremental certification, we think that one is a great thing that ONC does is tell the industry, now use SNOMED, use these definitions of these fields. That is very, very useful and helps with interoperability. It also helps physicians and staff who have to move from one organization to another or who have to practice in more than one – or work in more than one organization.

And the third thing is we say that incremental certification should be used for corrections of technical errors to previously announced standards. And that does exist in the 2015 edition and that is very – that's useful, that's very helpful and I think everybody appreciates that. But this is a narrower approach. I would say with this narrower approach, that would reduce the size of the 2015 edition by maybe 80-90%, it's just a much narrower approach, but we think would give you also a better public discussion.

There are other areas where we think that it would be very useful to get public discussion, so on some of these things that might be included in Stage 3 or might be areas of future development that people are interested in. Instead of doing the formal certification program, we suggested something like an advanced NPRM to just simply try to get people's comments. Again, the comments are useful and we think an advanced – something like an advanced NPRM might be particularly useful if it were structured in a way that you could first ask for a lot of information at a very high level, without having to go through all of the details. So, let me pause again, Carl, do you have any comments or anything you would like to add?

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

I think just a couple of things to reinforce. One thing by way of background, and Paul, you mentioned the EHRAs submitted commentary, one of the things that we've become aware of through the early stages of Meaningful Use that persist today is that the development estimates that are put forward by ONC are generally only about 10% of what it actually takes to get the features done. And that's across a broad-base of large and small, cloud-based and traditional packaged software-based kind of organizations. So I think one thing that we really need to understand as we look at this foundationally is that ONC today does not have a good handle on what real implementation costs are. And so, that's a piece of background.

With regard to incrementalism, I think we should also think about incrementalism in the testing. Right now, if you make an incremental change to a vocabulary item or update a definition in a process, you'd have to retest the whole process. It would be nice also if as we think about incremental changes, we could put a tighter band around what would actually require retesting, or maybe even declare it unlikely to need retesting. And to make the testing voluntary if the change is sufficiently straightforward enough, because that also is a bit of an expensive burden as time as well as money.

**Paul Egerman – Businessman/Software Entrepreneur**

So those are good comments, Carl. And on the issue of ONC and development costs, I mean, I have a few additional comments. I mean one is, in general it's very hard to project development costs unless you have detailed information. And even with this NPRM, we don't have all the detailed information because some of the implementation guides haven't been published, so that's one comment. But I agree with your comment, Carl, also about ONC and projecting the development costs. One of my concerns is, as I look at the entire cost sections, it talks about the cost to development, but doesn't talk about the cost to actually deploy the systems, which are costs on the part of the vendor. And there are huge costs on the part of the provider, on the physician and the hospital, to deploy these systems, to train people, to test them, because they have to test them also before they deploy anything. That was a conscious decision on the part of ONC, so somewhere in the cross-section they say, we're only talking about the development costs, but the development costs are actually smaller than the deployment costs.

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

Yeah.

**Paul Egerman – Businessman/Software Entrepreneur**

Much smaller than the deployment costs –

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

I think it's –

**Paul Egerman – Businessman/Software Entrepreneur**

– and usually the deployment costs on the user side, on the physician and the hospital side, are frequently and usually higher than the vendor cost to deploy the system, because there are huge – the basic problem of deploying any computerized EHR system is really a people challenge. It's like, how do you deal with the workflow and get everybody trained and get everyone to understand what's going on. And you want to do something like provide ordering for laboratory results for a physician's office, well somebody's – there's some work there involved in making sure every physician knows what they're supposed to do and how they do it. And I would just say that the costs – the extent I disagree with Carl, Carl says the costs are off by an order of magnitude.

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

Yeah.

**Paul Egerman – Businessman/Software Entrepreneur**

I think it's an order of magnitude plus a factor of about three.

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

I wouldn't disagree. Just for reference, I'm not sure people are familiar with it, but the ONC cost estimate to implement 2015 certification edition was 3,280 hours, and that's about 1.6 FTEs, that's for everything in 2015 certification edition from a developer's – a vendor's implementation requirement to actually build up the features and execute on the requirements. So that doesn't include the customer side of it or release side or change of management or awareness building, things like that. And what the developers have been tracking now, and have been consistently tracking this, they would project the 2015 edition would require about 25 FTEs in total, that's for a year.

So I do think we've got – we will need to tackle that because if I'm in ONCs role, if I think my requirements cost one FTEs worth of work or two FTEs worth of work, I'm much more aggressive and liberal in putting stuff out there. If we truly understand what the real cost to implement this is, even as a developer, I think you might find people being a little bit more thoughtful about what's going in these.

**Paul Egerman – Businessman/Software Entrepreneur**

I mean, that's correct. And it is somewhat odd – the way the system works is, in the entire commenting process, the comments are like disassociated from the costs. So you will see people say, now we think this is a great idea, we want to do more patient education. But they say that in the absence of the actual cost data, which is sort of lumped together totally at the end.

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

Um hmm.

**Paul Egerman – Businessman/Software Entrepreneur**

So it's hard – it's unusual when you talk about the benefits about the cost, and it's also unusual where nobody looks at what the total picture is, what the total costs are, because sometimes things are – each individual idea makes sense, but the piling on too many of them is problematic, which is one of the factors here. But anyway, these are our comments as it relates to Stage 3. What I'd like to do now, before we talk about the HIT in general that's still limited to Stage 3 is pause, and see what reactions we have. We want to be clear in making these comments, we're actually making some specific recommendations that are quite a bit different than the direction ONC appears to be heading, where we are saying, do operational testing before you propose certification. And we also are saying, limit the incremental certification between Stage 2 and Stage 3 to these interoperability increments. So what comments do people have?

**Jennie Harvell, PhD – Senior Policy Analyst – Department of Health & Human Services/Office of Disability Aging & Long-Term Care Policy**

So this is Jennie and I just have a general question. Part of what was in the 2015 NPRM included this new structure of moving from I think comprehensive to this more modular kind of strategy. And so one of my two questions is, what about a notion like that when ONC is thinking of a new regulatory scheme,

should they include that as a proposal in this kind of interim or off-cycle rulemaking? Or what are you thinking – what is your thinking about that? And then the second related question is, in this NPRM they also talked about extending their Certification Program to certify other types of provider – technologies used by other types of providers not eligible for the Meaningful Use Program. And what is your thinking about where that should appear in the ONC rulemaking cycle?

**Paul Egerman – Businessman/Software Entrepreneur**

So, two great questions Jennie. I mean the first one is the modular certification is, by itself, not new, that was part of what we originally – actually this workgroup originally proposed when the process was getting started. The only piece that's new as it relates to modules – two pieces, one is the definition of package and also the definition of complete EHR, and I think we've already discussed those issues, I don't think there's val – that we should rediscuss it. It's certainly appropriate in an interim – it's certainly appropriate at any time for ONC to put forward different ideas about changing certification. So that's at least my view on issue number one. Issue number two, which is you talked about the other providers – trying to say is I wanted to divide this discussion into two parts and – my ideas, so let's talk about the first part first, which is the whole thing as it relates to Stage 3. And then let's have that exact discussion that you're asking about, Jennie. I don't know if Carl, if you wanted to comment on that.

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

I agree with your comments on the modularity, it doesn't change this a bit. And then we can tackle the other provider types. And Jennie, I do think this issue of certification for others; again, I do think we want to carefully bring the others into that discussion because what we're really talking about are unfunded mandates for the most part. And that'll trickle down to the users also to the vendors that provide them systems. And then you're going to have vendors that do systems for multiple venues, so home health, long-term PAC, skilled nursing facilities, rehab hospitals, assisted living, as well as primary care, patient-centered medical homes, critical access hospitals and regular hospitals. People do software for a variety of them, so I want to come back to this notion of the use of an Advanced NPRM for comment gathering instead of trying to put a certification out there. Because I know, ONC has technically called it optional for the Meaningful Use Program, while it seems to be encouraging other parts of government to make it mandatory for different programs.

And I do think we should wrestle that issue to the ground because we could really get people tangled up in a regulatory cycle that smothers customer and vendor initiated innovation. In my perfect world, I'd make ONCs role to develop regulatory requirements for a 3-year cycle and let customers and vendors do a round of their own innovation, and then ONC could learn from what customers and vendors are doing. I think in part what made Stage 1 reasonably successful was ONC didn't actually invent the features and functions, ONC looked out at the world and saw what seemed to be working and seemed to be beneficial to patients and harnessed it and maybe guided and directed and decided on some standards issues. But I worry that we're entering a new phase where ONC feels like its inventing, and I wonder if that's better left to the customers and the vendor communities that live in those worlds every day.

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

This is Mike Lardieri; I have a couple of things. I agree with the point that the NPRM shouldn't include things, at least I don't think, it shouldn't – should not include items that are not going to move forward into the next stage. I mean, to use the NPRM or interim process as a testing ground, I don't think that works because then if it's not going to carry through to the next stage, then everybody's wasting their time testing it out. And I don't think that's the right place to do it, under certification.

And then I have a couple of questions. So, with the addition of code sets and those types of things, so for behavioral health, we don't pass enough information in what's required for the transitions of care document to actually be that meaningful to behavioral health. So we want additional code sets added. So would the – in your way of thinking, would ONC identifying that, hey, there are additional code sets, we want code sets for housing, we want code sets for suicidal risk, homicidal risk, a couple of other things. And if they were to identify, all right, going forward, use these code sets and then they'd carry over going

forward into the next edition and then if there are changes to the code sets, well everybody changes because those code sets get updated and everybody knows where to point to them. Does that work in what you're looking at?

And then the other piece to that is making sure that vendors can pass the data and receive the data, maybe it's not a requirement for certification, and maybe I don't even know if that works, but they have to be able to send it and receive it. And maybe they can still – to the smaller set to get certified. But somehow, that has to happen, otherwise the whole care coordination process between behavioral health and physical health will never happen.

**Paul Egerman – Businessman/Software Entrepreneur**

And – this is Paul. My response to what you're saying Mike is, first of all, I'm glad that you're asking about coordination of care and transitions of care. Because I personally think that that's like the core of the process, and that's where certification can really be most useful is in that entire area, especially the entire area of making sure people can send and receive this stuff. That's where I think certification can really shine.

On the issue of what are the needs for behavioral health within the transition of care document, I would view that question as sort of like as an example of why you need to do a lot of operational usage and testing before you certify. That these systems need people to use them in multiple environments to make sure that they are useful in those environments and – because otherwise what we are going to do is we're going to certify something for transitions of care and it just may not work at all for behavioral health. Because it doesn't have the things that are most useful and one needs to find out what those are, and it's not always the best way to do it is by having a nice group of committed people, who may be experts, put their feet up and say, well here are the requirements. As good as they are I just don't think that they can really like nail it.

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

Well, the only thing I disagree there, we've done a lot of work – okay, so I'm part of that group, experts, working with SAMHSA, experts there. We've brought in vendors, we've brought in providers, we've brought in the APA, psychologists, social workers as well and others, to comment on those. They all say, yeah, these are the standards that we want to carry forward, I mean, how much more do you need to do before you say, okay, yeah, these are the code sets, these are the data elements – how much more do we need to –

**Paul Egerman – Businessman/Software Entrepreneur**

The points where I would be encouraging testing as you put that forward is, I would first say, there ought to be some vendors and some behavioral health organizations and other organizations who use it, to make sure it does work, so you have some validation of it. And I think – I'm not sure I'm interpreting what you say about code sets but if what you're saying is, this is how you want the data coded, or what I sometimes call vocabularies, I don't think you necessarily have to test that in advance, if you're using code sets that already exist. If you say, this is –

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

Right.

**Paul Egerman – Businessman/Software Entrepreneur**

– a lot of what happens is, there are like three or four or five different ways that people code things, and if ONC chooses one of those five and says, this is the direction we're all heading, that's very useful.

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

Yeah, that's where I'm getting at. But on the other side, though, in terms of usage, you'll find that in behavioral health and the behavioral health vendors, they're all doing this for people in behavioral health and coding to certain ways, because across the board we all need to use that information. The problem is, when we get to those transitions, well nobody's ready to receive it because they haven't gotten the message yet, hey, you need to – you have to be able to receive this if you're going to do coordination of care. So it's good one-sided from behavioral health and it's usage on that side, but on the medical side it's not, so how do we cross that bridge?

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

Well, Don Rucker. I think that – I think part of the challenge with code sets that we're sort of seeing on things like, for example, the AMDIS Listserv in the sort of user community is, I think people often – there's a tension between the amount of structured data you'd like to have and paying for it, right? So if somebody who sends a psychiatry patient to an ER doc, to psychiatric facilities it's – there's literally no time to sort out the details of these coding in sort of busy clinical environments like emergency departments. So even if you had a code set, I think, there are huge challenges.

I think the other challenge that I think colors sort of maybe the entirety of some of the coding issues in Meaningful Use is there's an implicit assumption in all of these transmissions that we can identify things with a high degree of accuracy. But for example, the things you mentioned like suicidal ideation or homicidal ideation, most of the time that is a very, very hard thing to sort out from a patient. With HIPAA we mostly actually have to sort it out often from family members or other people that we can't really mention, or that we can't talk to or that we can't really communicate with fully.

So I think as we look at code sets and as we look at the regs, I think we've got to – we have to understand that a lot of this rulemaking is far to crystalized and concrete to actually be used in the real world in any way. And that we don't want to sink Meaningful Use and IT in general because of insisting on these things and I mean, I think people saw that with the IDC-10. It doesn't sort of play in Peoria. And anybody who has been on the user side, I mean physicians on the user side almost uniformly, not the IT physicians, but just practicing folks, have very negative impressions of the institutional ICD-10 efforts that we're required to be part of. I just want to throw out that real world data that I think we want to acknowledge as we try to figure out the core of what we should regulate.

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

Yeah, I understand –

**Paul Egerman – Businessman/Software Entrepreneur**

Yes, and this is Paul again. I'm sorry, go ahead Mike.

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

Yeah, I say, I understand that and that whole issue, that I think which was a good one, about being in the ER and trying to figure out if somebody's suicidal or not and you may not be able to do it. But I guess what I'm advocating is some sort of middle ground that if the data is there, send it and be able to receive it. I don't think we can wait until 2017 before we say, okay, now we can send it and receive it. I think we have to have some middle ground that maybe it's not required to send it, but if it's there, be able to send it and if it's there, be able to receive it, I think that'll help us move forward, if we're able to do that.

**Joe Heyman, MD – Whittier IPA**

This is Joe –

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

I mean I think the challenge would be in all of these things, right, because clinicians hate to send stuff that's not accurate, right? I mean, there's all kinds of risks, as you could imagine, of sending things that are maybe 50% or 52% accurate, if that and I'm not sure as a program we've really thought about the fact that much of what we're facilitating here is extraordinarily low quality data. I'm just throwing that out, that's the real world of this stuff.

**Joe Heyman, MD – Whittier IPA**

This is Joe.

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

It depends on where you come from, I mean, from our –

**Joe Heyman, MD – Whittier IPA**

Could I just say one thing?

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

Okay, go ahead.

**Joe Heyman, MD – Whittier IPA**

I think this is a really interesting thing that you're discussing and I also think that you're right that the core of this is we ought to be able to send and receive the data. I think the problem – one of the problems, anyway, that comes up all the time about this, and I realize it isn't necessarily certification, although I think you have to certify that you can measure it. And the problem is the measuring, the problem is that it isn't just that we want to be able to send and receive; we want to be able to say that we can measure something to prove that we can send and receive it. And that measuring always seems to end up adding things to the process that would drive the person in the emergency room nuts.

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

Yeah, okay, I certainly agree with that, and I don't want to get to that, but I do want to get to the sending and receiving. But I understand your point.

**Joe Heyman, MD – Whittier IPA**

Right, no, I understand and I agree with you that it's important to be able to send and receive it, but I constantly try to keep reminding people that it isn't the pro – it isn't the ability of this stuff to be able to do something that's driving everybody crazy. What's driving people crazy are the extra steps that are necessary to measure to prove that you can do the things that you can do.

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

I would also point out –

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

I think with the diagnosis list we actually already have regulations on that, right. I mean we already have problem lists and things like that, so these things should, right – I mean, these are sort of add on things to things that, I think the challenge would be maybe to say, why didn't it work with problem lists, right, because that is sort of sending a problem list.

**Paul Egerman – Businessman/Software Entrepreneur**

And this is – this is Paul. It's an interesting discussion and Joe's comment is particular interesting because in the one sense to bring in the Meaningful Use requirements seems like not related to the certification issue, but it actually is. Because if you think about like the transitions of care document, and I may be stating this wrong, but I think physicians have to something like 10% of something with the new transitions of care document and to send to some other vendor. But if the document, if the capability was really useful, 10% would not be a problem, right, I mean 10% should be like an easy thing to do. I think if somebody starts using it and it's useful to use, they're going to use it everywhere.

And the fact that some of these things are such a struggle sort of indicates that something is wrong that either they haven't been designed correctly, so they don't have adequate information to do transitions of care. It could also be that we – that ONC has been overly prescriptive in describing it. Maybe the transitions of care document would have been far more e – far better if there was – it was a little less coded and there was a little bit more free text that could write something about the patient that is useful when you do the transitions of care. And I don't know what that solution is, I – perhaps I'm looking at it through my lens. I'm saying it's still an example of how you need operational testing before you do certification because we're just driving people nuts, or going to be driving people nuts trying to get them to do things where the intention was good. But it's like a round peg in a square hole; it just doesn't quite fit the physician's environment in which they have to operate.

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

This is Mike again.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

This is Larry, I want –

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

The only thing I can say to that is that that's from one side I would agree with you, from the medical side, yeah, they've never tested it, they've never used it, they never thought about it. And I don't mean to be pejorative about that, they probably thought about it, but, too hard. On the behavioral health side, think about it all the time, have to do it, we're gathering all this data, so it's been tested on one side, it hasn't been tested on the other side. Certainly useful for behavioral health, probably would be useful on the medical side, but they won't find out until they start seeing it and that's, I guess –

**Paul Egerman – Businessman/Software Entrepreneur**

And so Mike maybe what you're doing is –

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

– successful.

**Paul Egerman – Businessman/Software Entrepreneur**

– let me put it a different way, if what you're doing is you're saying we're just codifying stuff that already exists, people are already doing, and that's to me also a reasonable argument.

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

Yeah, yeah, because they're already doing it, it's not just within the context of the providers who are most generally Meaningful Use providers; it's in the other set. But, they're doing it on a regular basis.

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah, so if your argument is it already exists and the only issue is transmitting it electronically and receiving it electronically, that I think is – that makes sense to me if that is –

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

Yeah, that's really what I'm getting to. Yeah, thanks.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So, this is Larry, I want to jump in with either a naïve comment or maybe a helpful one. My understanding is, one of the arguments for CDA from the beginning is that it allows both coded and uncoded information in some sense – so you could have a problem list that had some problems that were fully coded and other problems that had either very general codes or no codes on them. And so you could communicate to the humans, but the computer might have problems operating, if you will interoperating, on the data. And that that was always seen as a good way to create transitions so systems could be at various levels of sophistication. And it seems like that's part of what could be going on across the different care settings.

We have specialists of many kinds, not just behavioral health, who have detailed descriptive languages that may be very heavily coded as well, or not, it might just be very detail descriptive of their specialty. And those are sent to other providers who may be able to make sense of them as a clinician reading it, but whose system might not be tuned to do anything with it or who might recognize the terms. But they're not terms it would generally use and has to sort of think a little bit about what they're actually trying to tell them. And so, am I right to say we shouldn't focus on – we should acknowledge the flexibility in the document structure and that, in fact, might open gateways for some of the kinds of testing that's being advocated today so that people could –

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah, and Larry, this is Paul.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

– be experimenting.

**Paul Egerman – Businessman/Software Entrepreneur**

This is Paul. I'm not sure that's right as related to the transitions of care document. I mean I participated in an Information Exchange hearing where people at University of Missouri complained about this very issue, because they had an EHR system that preceded the whole Meaningful Use Program and they had coded – they were not coding the patient's problems and diagnosis, they had them in free text. And they ran into a problem with the transition of care document because they had so many problems in diagnosis that were still free text oriented, and at the time, Dr. Tang says, well, SNOMED's been out for a while, it's time that they coded up all of their problem list. But I got the sense there was not as much flexibility as what you just said, although maybe somebody can correct me if I'm wrong, because I –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

So this is Liz and you can send across uncoded, it's just a matter of how you built the system. For example, in our systems, we don't allow non-coded and we do it on purpose; now hearing this conversation I need to go back and revisit that. But we're trying to make the data usable for data purposes, not just for the CDA.

I was also going to just while I'm here, I was just going to add the comment that some of the difficulty around ToC is finding the ability to do it because external partners frequently don't belong to an HIE, don't have a HISP and don't have a Direct mailbox. So although there are certainly issues around the content, there are also issues around the ability to transport. If you have the right connection and receiver, there's no problem whatsoever, but if you don't, like many, many nursing home, rehab, assisted living, so on, they don't have it. So, that needs to be sort of taken into consideration as well.

**Paul Egerman – Businessman/Software Entrepreneur**

Those are helpful comments. What we want to do is, let me try to see if I can raise the discussion up a level, so we're starting to talk about some of the details and challenges of transition of care and code sets in behavioral health. I want to look at the concept of what we tried to propose, which is to say you need operational testing. I get the sense that there's agreement we need operational testing, there's sort of a little bit of a middle ground, based on what Mike seemed to be suggesting. If something already exists in operation that then you have it, right, it's sort of the concept and if people are already transmitting and coding documents in a certain way on paper, that that could be considered validation of the usefulness of it. So, I'm wondering if we can think about what we were trying to say that you need to have operational usage and sort of modify it with those comments. Is that something that there's a consensus about?

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

I think the operational – Don Rucker; the operational usage is I think a great thing. And maybe what needs to be part of our comments to this is to try to put a little bit of a definition on operational usage, right? Because I think that's one of those things that where a definition might be very helpful so it might be something, let's say, even as simple as three pairs of unrelated parties exchanging information using a certain protocol or a certain standard. That shouldn't be a very high barrier, where you have three for 80 or 90% of their potential transmissions with some "n" of let's say 100 or 1000 or 1000 is probably too high for something let's say like a lot of these things. But let's say an "n" of 100 for three pairs of unrelated, so true interoperability as opposed to people at a site or people who are economically related. I think having that kind of a standard on these protocols might be an interesting way of not just sort of tightening up the usability of the regs, but also even facilitating some of the learning about them, right, because looking for sites will probably be quite informative as a sort of a process.

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

And I'd just like –

**Paul Egerman – Businessman/Software Entrepreneur**

And so – I'm sorry, who was trying to speak?

**Michael Lardieri, LCSW, MSW – Vice President, Health Information Technology & Strategic Development – National Council for Behavioral Health**

That was Mike. I was just going to say, I would like to add, when we look at operational usage, that we need to look at it across not just the usual Meaningful Use, but also those ineligible Meaningful Use providers.

**Paul Egerman – Businessman/Software Entrepreneur**

So, my suggestion is, I'm listening and these are good comments, is sort of like defining what constitutes adequate operational usage. That could be like a separate whole discussion that's very interesting, because again as you just said Mike, you might want to talk about outside the EHR system to providers that are considered ineligible, ineligible as it relates to the Meaningful Use Program. But also the – how you go about it might also be determined by what the actual measure does, in other words if – I mean so far we're talking entirely about interoperability, but there are a lot of things here like search capability on text within the record, that doesn't involve interoperability. There are a lot of things here that you might say we want to have a different criteria.

So I'd like to – what I'm hoping for is as I'm listening to the discussion, I'm not hearing anybody say, no, we don't need operational usage, there's more of a discussion about well how much do we need and are there some circumstances where some different things qualify as operational usage. I just want to find out if I'm hearing this right, there is a consensus that there needs to be operational usage before something is proposed for certification. So that's what I'm trying to ask, is –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

So Paul, I think you are hearing – this is Liz. Let me just ask a question, and maybe this is not the meeting for that. I'm trying to figure out how you do that, because it wouldn't be part of the certification it would be something they present to the certifiers.

**Paul Egerman – Businessman/Software Entrepreneur**

No, no, no. This is before ONC proposes it.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

Oh, got it. Okay.

**Paul Egerman – Businessman/Software Entrepreneur**

So ONC is part of this process, where they bring people together, ONC does terrific work, they bring together Workgroups and Task Forces, they work on things, they ballot things. They come up with ideas and then ONC would need to create some additional process in the vendor world we call it like "beta testing." Where you get some people who are some healthcare organizations or physicians and some vendors who will go ahead and implements the idea and try it for like a month or two or three and possibly keep their workforce or Task Force together, talk about the results, seeing – making sure that people think it's useful. And do that as an additional step before you hit certification proposal, before you issue the NPRM. And then maybe in the NPRM, describe what that testing process was, the entire – one of the things that's in the NPRM is a thing called the unique device identifier.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

Right.

**Paul Egerman – Businessman/Software Entrepreneur**

So I read about that over on the FDA side of the world, and the way the FDA approached that though was, they did these advanced NPRMs and got comments, but they had a number of sites who actually implemented it as some sort of a test project. And when they issue their NPRM or whatever they issued, they were able to cite, here are the institutions where this has already been used and tested. And so that's sort of like the missing piece.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

I see.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So Paul, what I'm hearing from you, and I think it's been a great exposition of all of this today, is that there's, if you will, a macro-process around things coming to certification. There are things that happen before hand, and some of its work that ONC has a track record of doing, a lot of the efforts of S&I Framework are doing exactly that, trying to get things tested. And that there's also industry experience that vendors and providers have been doing things.

And one of the reasons there were so many folks who could get through, well, you didn't say this but I'm going to say it, get through Stage 1 certification is the criteria were not a big leap or a leap at all from things people had been doing for a while. They were functions that existed in many systems and they were things that providers were already using. Whereas the shift to Stage 2, in – I don't know – I'm trying to choose the right words here, but the shift to Stage 2 created a variety of barriers that we're continuing to hear about, even though we're pretty late into the Stage 2 process. And they're demonstrating some of the issues around certification where things haven't been as fully tested or where there might be multiple versions out there in the world and transitioning from one to another, from the one that didn't win the

sweepstakes to get chosen for certification to the one that did, takes time and effort. Time both for vendors and providers to make that transition.

So it seems like we've got a whole long timeline here, if you will, that looks to validate things in the world and where things aren't distinct, to create a development process that allows them to get tested. And I like the operational part of that, I think that's really important, and that that's done in advance of any rulemaking, because once things do get in cer – regulation, it then locks them down for a long period of time. And that the intention that we're hearing from ONC with the interim piece is they want to find a way to shorten the development cycle. So I'd like to come back to that notion, but I want to stay with the primary thing that we've been talking about.

#### **Paul Egerman – Businessman/Software Entrepreneur**

Yeah, and so you did a good summary Larry, and so to sort of like build on his summary, it's to sort of say, this sort of thoughtful process. And to do this testing process, that should be where you do these kinds of functionalities that appear in the – in certifications that might occur every three years, as Carl talked about. So this 2015 edition has a lot of totally new concepts as it relates to clinical decision support, as it relates to coding, pedigrees for family history, the unique device identifier, a whole series of things that have really never been done before. Even producing educational material from the EHR, education material specific to the patient from the EHR system, possibly in multiple languages, these are totally new things, they're exciting, but you can't be doing that every year. The government – that's not the governments – the government's not going to be able to get that right with this process, if we don't do any operational testing. That should occur every three years, but you could do incremental testing for incremental certifications for small things that relate to interoperability. That's what we're trying to say.

#### **Larry Wolf – Health IT Strategist – Kindred Healthcare**

So I guess I'm hearing is you're looking to make some pretty focused recommendations with regard to this NPRM and the process specifically as it relates to some of the technical things where small updates really would be incremental, whether they're accommodating changes in new versions of code sets or correcting technical issues with an earlier rule.

#### **Paul Egerman – Businessman/Software Entrepreneur**

Yeah.

#### **Larry Wolf – Health IT Strategist – Kindred Healthcare**

And that the bigger framework, which I would like us to spend time on if we can wrap up the court here, is to kind of go back to ONC's original intention, which was they said, we heard that there is a lot of effort to get through certification. Would an incremental process make it better? And maybe we should listen to their question more than their solution and be asking ourselves, what process or processes would make this an easier thing? And we've outlined one kind of roadmap, if you will, it's a long timeframe roadmap, but we outlined one. And maybe we could talk about others.

#### **Paul Egerman – Businessman/Software Entrepreneur**

And the other is what you see on the screen or what I'm saying is, what would make this work would be if you'd simply focused on the interoperability issues alone on an incremental basis. And you did what the words were that I emphasized, you made it small and incremental, then you would have – so instead of having, I don't know like 25 or 30 measures, you had 2 or 3 things you were trying to accomplish, then you have a much better chance of getting it done. And so I'm saying the incremental approach as it relates to Stage 3, as it relates to a rulemaking every 12 to 18 months, this is what it should focus on, and this is where you could get a lot of good things done, I think, in terms of really being able to help people. I mean, one example would be, I mean if instead of focusing on everything that's in the 2015 edition, if you had a 2015 edition that was solely related to the transition of care document. Did not include any of these other things, unique device identifier, just like incremental changes to the transition of care document, some incremental changes to the transport process, if ONC worked with vendors and said what can you do and how much can we get done so we can get something done in 2015. I bet you could have gotten some incremental progress on that one thing, which would have been very helpful to a lot of patients and

I think vendors and a lot of people would have been excited to try to just do – get one or two things done and make progress.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So I'm hearing a voice of small is beautiful.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

Hey, Larry and Paul, this is Liz again. Can I make just one friendly, potentially friendly amendment and that would be, I think Paul is right on, the whole group is right on. The one other thing I would like to see included, there were some technical fixes in the 2015 edition, which were discovered after the rule came out. It wouldn't – it just makes what we're already doing, some fixes on implementation guide, I'd be glad to provide them to you by email, that wouldn't – I'm not even saying – I don't know whether you have to certify them or not, I'm not trying to make this more complicated. I like Paul's focus, so that you get real benefit. But we also need – there are just some small things that were broken.

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah, and isn't that what I have on third bullet there? There are corrections of technical errors –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

Right, and your good with that, still.

**Paul Egerman – Businessman/Software Entrepreneur**

Pardon me. Yes, absolutely. I'm saying all three of these, I mean the third thing is sort of a different category, but it's sort of like –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

Yup, that's fine with me.

**Paul Egerman – Businessman/Software Entrepreneur**

– it's like the old days before we had word processors, you get to the end of a document and it would have like three pages of errata or something, would say on page 5, when I said this I meant that.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

Okay.

**Paul Egerman – Businessman/Software Entrepreneur**

And replace this word with that word –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

Yeah.

**Paul Egerman – Businessman/Software Entrepreneur**

– and it actually didn't really fundamentally change what was said, but it made what was said reasonable.

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

And Paul, this is Carl. I'll throw one concern in this that we noticed and that is that because there was going to be this incremental 2015, people held back on publishing the corrections and basically we didn't get the corrections that came in 2015 until you pretty much had to have all your 2014 stuff certified and

ready to go for Stage 2. So I would argue also, it's a good place to put corrections as they become known, but to have a fast track so that you can correct things as soon as you know they're broken –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

Boy would that –

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

– and I think the notion that you'd hold back on corrections to make an official, midstream document isn't as helpful as correcting individual things as they happen so that we can fix them before we go into testing and production and move things out to customers.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

Yeah.

**Paul Egerman – Businessman/Software Entrepreneur**

So maybe a better solution for the point three would be to create a process for ONC to issue corrections to technical errors that doesn't require going through the cert – the reg – the entire certification regulatory process.

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

And in some cases they may need to for commentary reasons, but most of them, I don't think so, I think –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

Yeah.

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

– they could do it faster.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

I agree that's an excellent suggestion.

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah, that would be great, so we could –

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So, I guess I'm hearing, to continue your example of the errata from pre-word processor documents, that there could be a lot of small updates that maybe get refreshed into integrated documents, but that that integration process shouldn't hold up updates.

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah, there ought to be some things that they can do without certification and there ought to be – if there are some things that are bigger than the, it's like adding an "s" to the end of the word or something like that, then incremental certification would work for it. But it's still; to get back to that higher level, this is a proposal as it relates to Stage 3, that somebody said small is beautiful. I probably wouldn't have use those words, but ONC used the word small and so, I'm saying yes small, focused approach, much narrower than what is proposed.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

I'm also hearing your suggestion that there are a lot of multipliers in here, so many small changes become large. And so your emphasis on focus here is also that there really should be strategic focus on,

these are the few areas that we particularly want to advance on an interim basis, where there's a reason to move things more quickly than what happens through the regular 3-year cycle.

**Paul Egerman – Businessman/Software Entrepreneur**

Exactly right. So the sense I'm hearing, I don't want to put words in anybody's mouth, I'm hearing there's agreement on these – this recommendation or these concepts. I mean, obviously we've got to write it down and sometimes when you write it down, the agreement starts to disappear. But, that's the sense I have. Operational testing, a much smaller and narrower focus for incremental certification as it relates to Stage 3.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Yup. There's something we mentioned in passing, Paul that we should test with the group whether we can include it here or not. And that's sort of the chicken – maybe chicken and egg's not right, maybe it's more horse and cart issues of, in some ways the value to the government of a certification program is it gets referenced by other programs that say, we're going to fund something or we're going to regulate something and we're going to point to this technical certification as a piece of what we're doing. And we had some earlier discussions about children's format, that turned out actually had had some development work that we didn't know about and that an agency was looking to bring that forward in a more formal way.

And so that's sort of one of the issues, below the cover issues if you will here, of we're not seeing clear requests from other agencies asking for particular certification criteria. But we're concerned that as soon as the criteria become published and there is testing of the modules, that they could become referenced and then any sense of voluntary really goes away for anyone who's going into that space, because now they've been referenced. So as part of the bigger framework of how all of this stuff unfolds, would it be useful to highlight that requests from other agencies to the extent that they can be made public before rulemaking, are made public. So that people understand the general direction HHS is heading in and we don't have ONC going in a direction where we're scratching our heads and going, well this looks like an unfunded mandate when, in fact, someone is planning to issue grants in an area.

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah, certainly that makes sense. I mean, the whole concept – it's like my comment about the balloting and the unpublished implementation guide. The whole concept of the NPRM, this is a good concept, is you're trying to solicit comments from the public about what the regulations are going to be. And when you solicit those comments, the people need to know as much information as they can possibly know, because that way you'll get better comments. And so if there is some intention say from SAMSHA to use certification in a certain way that should be part of the NPRM. And by making it part of the NPRM, it could cause people to look at it in a different light, possibly more favorably, possibly less favorably, I don't know, but it's more information that's valuable.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Good. So I don't want to mess up the consensus and the fact that we're way ahead of schedule here –

**Paul Egerman – Businessman/Software Entrepreneur**

Well, we have one other thing I want to talk about still, which I have on the screen.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Okay. Okay.

**Paul Egerman – Businessman/Software Entrepreneur**

But, I didn't want to interrupt you if you were going to come up with some really great, motivating summary everyone's going to get all excited.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Well I wasn't – I was going to offer, as part of our general wrap-up, when we get closer to bringing things back to the Policy Committee, that this whole broader notion of the intention of building what's already out there, the desire to achieve some of the things that ONC set out to achieve with this NPRM. But our concerns that they may be way underestimating both development costs and provider implementation efforts. We didn't talk a lot about that, Liz just briefly and Mike did a little bit and Don did a little bit I guess as well.

**Paul Egerman – Businessman/Software Entrepreneur**

Well those –

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

– your context is the right context.

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah. That's correct and those are helpful comments. I just want to make sure that I do what others – the assignment was which was, we not only wanted to talk about this as a way to Stage 3. We also wanted to talk about sort of like the voluntary process and what you see on the screen says concept of leveraging the ONC certification program to the ineligible providers, like LTPAC and a whole series of other things. Are we ready to transition to that discussion, Larry?

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

I wanted to make –

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

I think we are.

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

It's Don Rucker, wanted to make one additional comment on the cost thing, which is, it's not just the cost of the developers and the cost of the users to install it. But some of these things have huge cost embedded in their ongoing use, which might be again, another order of magnitude bigger than the cost of a site to actually just get the software up and running. And I think we need to at least understand some of the costs of using these things in any kind of way, in our discussions. So there are three classes of cost that are embedded here, not two.

**Paul Egerman – Businessman/Software Entrepreneur**

I agree 100%. There are probably even more than those three, because there's operational costs, there may also be equipment costs, which may seem small, but if you want to produce educational material in multiple languages, you might need a printer that has – is able to print certain like fonts to print language symbols. And you may need to buy a new printer because not necessarily all printers are able to do that. UDI, unique device identifier, I believe requires people to get scanning devices. And again, none of these are necessarily overwhelming, but people need to see the total. But the ongoing operational cost that you mentioned is certainly the case if you're going to code patient's occupation, for example. Somebody's got to code it, it may not be the physician, but somebody's got to code it and so there's an administrative cost there.

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

Well, for example, trying to find pedigree –

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

I'm hearing nothing about subscription fees.

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

– yeah.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

There could be subscription fees for updates to knowledge data sets. There could be transaction fees, there could be a lot of fees that become – are small in a pilot and irrelevant in a pilot in many ways, but become large over a full organization's rollout, and may not actually be part of the initial implementation approach.

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

Especially as these regs sort of have the effect of narrowing the pool of vendors who succeeded in meeting them, the ones who remain can then raise their prices when this happens.

**Paul Egerman – Businessman/Software Entrepreneur**

Yup. So this is, are we ready – great discussion and great comments about the cost. Are we ready to move on to this last slide, Larry?

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Yes.

**Paul Egerman – Businessman/Software Entrepreneur**

So, in addition to talking about the incremental certification as it related to Stage 3, there was a request, and I think Jennie also asked this question during the discussion, about how – do our comments – what do we think about this whole process as it relates to the ineligible providers and voluntary certification going forward. And indeed, sort of like the assignment that we got was to talk a little bit about the policy program alignment and leveraging the ONC HIT Certification Program.

And my comment about that is that it's an interesting expression when ONC says they want to leverage the ONC HIT Certification Program, because you might think to yourself, why are they trying to leverage their certification program? And my suspicion is, it's like this old saying, if your only tool is a hammer, the whole world looks like nails. And the issue that ONC has is after the Meaningful Use incentives expire, which I think occurs in 2016, but I'm not sure if I've got that right, I think 2016 for hospitals. But after the incentives expire, sort of like certification is its primary public policy tool and so the certification tool is starting to be used as a vehicle to somehow like regulate or have an impact on the entire health HIT industry. And my comments about that are just the same as the comments I made about Stage 3, I mean I think that certification can play a huge role as it relates to interoperability, and that that's a good place for it to work. And that to the extent however certification is somehow used to create new capabilities and advance the state of the technology, I think that is less than optimal.

I also think that a comment somebody made about the transition of care document that fits also in this whole discussion is it's hard to know how you can get all the partners or the trading partners to participate. So you look, one of the things that's very important in the 2015 edition is the whole discussion about laboratory orders and laboratory orders as it relates to CLIA. So the idea that physicians can order tests and they can be sent to a commercial lab and the commercial lab can receive it, process it, and then send back a result, I mean that's like a really extraordinarily important thing to be done and it's terrific that ONC is doing it. But the unknown piece, and it's just an unknown piece is, well maybe you create the certification criteria and the EHR vendors create it, but there are very few commercial laboratories who actually will receive that order electronically. And there's no – ONC doesn't have any reach onto the other side. So even on the interoperability side, I'm saying there may be some limits as to what ONC is able to accomplish.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So I'll jump in, Paul, this is Larry, with your CLIA reference. So, in my line, that would be an example where the folks who regulate the labs through CLIA could go to ONC and say, we're responsible for the labs and many of our labs use existing standards and many of the labs don't use standards for their vocabularies, for example. But we were thinking it would be good, in support of broader interoperability, if we set up a roadmap through our regs, to transition to LOINC for lab tests and maybe SNOMED for some of the path findings. And to put all that in place and to leverage your certification program on the – your existing program for EPs and EHs, but also to extend it and set up a lab program that would narrowly focus on the ability of labs to send – commercial labs, to send stuff using the standards that are already in place for the providers.

**Paul Egerman – Businessman/Software Entrepreneur**

And so what you just described, if I heard it right, Larry, that sounds like excellent stuff, if you can coordinate that with the other agencies or with CMS and we can make improvements on interoperability, that is exactly the right sort of thing that certification should be doing.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Right and your concern is when it's the flip side, when certification is –

**Paul Egerman – Businessman/Software Entrepreneur**

My concern is you can't just put out certification criteria and assume that accomplishes anything. It's sort of like if you're going to place the order, somebody's got to receive the order.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Right.

**Paul Egerman – Businessman/Software Entrepreneur**

And that's my comment there, but – and the CLIA thing was particularly complicated if you read through the NPRM because CLIA has these rules that were really created before computer systems that were created before current technology. But the basic concepts that every single interface has to go through a specific testing cycle, which makes it very hard to set up these interfaces with laboratories. And so it's an area where significant improvement could be made, as long as it's coordinated with other agencies and specifically, I think in the situation of CLIA, with CMS.

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

It's worth understanding also that sometimes these things could be – by radically different approaches. I mean, I once heard Clem McDonald comment, Clem McDonald the inventor and developer of the whole LOINC standard, which we're talking about here in part. That he thought rather than mandating these things, if Medicare just paid one dollar more for each lab panel submitted electronically, that that would be the most elegant solution to it and to let people sort out the details of it. So, we've – with sort of the ONC body of work, we're increasingly getting into a very, very prescriptive, very detailed set of things. And maybe sort of the middle ground would be to more explicitly focus on transmission standards as transmission standards, without putting a lot of the other sort of wrapper around it; just throwing that out as another option here.

**Paul Egerman – Businessman/Software Entrepreneur**

I personally think that makes sense, what other comments do people have.

**Carl Dvorak – Chief Operating Officer – EPIC Systems Corporation**

I agree with it as well. It's a simple way to change the world.

**Jennie Harvell, PhD – Senior Policy Analyst – Department of Health & Human Services/Office of Disability Aging & Long-Term Care Policy**

So this is Jennie

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

It must have been Don who made the original comment about transmission standards.

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

Yeah, Don Rucker.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Okay, thanks Don.

**Jennie Harvell, PhD – Senior Policy Analyst – Department of Health & Human Services/Office of Disability Aging & Long-Term Care Policy**

I was just going to say that I'd have to go back and read the 2015 full again proposal to see if they referenced the Health Information Exchange Strategies and Principles document that the Department published last summer, which was developed in collaboration with CMS and ONC. And it described the Department's strategy for accelerating health – electronic health information exchange including across the long-term post-acute care and behavioral health and other sectors as well. So the comment about needing to work with the sponsoring agency, for example, CMS, about its desires and that agency working with the Office of the National Coordinator about leveraging the tools that potentially could support the program's interests. I think in fact happened in the case of the Strategies and Principles document for accelerating interoperable health information exchange in long-term post-acute care, behavioral health and other areas.

**Paul Egerman – Businessman/Software Entrepreneur**

Okay, well that's a very useful comment. So I'm trying to think where we are in the discussion. I think there is some agreement that as we go beyond Stage 3, focus on interoperability and a greater focus on the technical aspects, the transportation aspects of interoperability and perhaps less on the content could be extremely useful. That coordination with other agencies is an important part of the process. There's I guess a statement that maybe we're like reinventing the wheel, that perhaps this is something that ONC is already doing, although I didn't get that sense at all from reading this NPRM. And there was that interesting comment about Clem McDonald – that Clem McDonald made about CMS providing an incentive. That's another way to think about what Clem McDonald's comment, apparently made about LOINC is that the Meaningful Use Program itself was an incentive program and in the absence of incentive programs, it's very difficult to get all the different players to move on these things. Although it perhaps reiterates the idea that interoperability might be the one place where you can get people to really voluntarily make changes because they can see the value.

**Jennie Harvell, PhD – Senior Policy Analyst – Office of Disability Aging & Long-Term Care Policy**

Yeah, and also just to follow up, because maybe folks didn't have a chance to read it or just don't recall what the Strategy and Principles document laid out, but it described a path forward starting with incentives and moving into program requirements as a way to accelerate interoperable health information exchange across these different sectors.

**Paul Egerman – Businessman/Software Entrepreneur**

Okay. Very helpful. So do we have any other comments on this topic, did we discuss this adequately? So Larry, I think we've had an important discussion. I don't know – it's a little bit of work to summarize all of this, but hopefully we get it all summarized for I guess it's next week, is it next week or the week after? I guess that's next week, the Policy Committee meeting.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

The next week. Yeah. Yeah, so I don't yet have a clear statement from my ONC buddies on exactly what they're expecting us to present.

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah, this is very different than what they want us to do, but at least very different than what the NPRM –

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

In terms of what's on the agenda –

**Paul Egerman – Businessman/Software Entrepreneur**

That's not a fair statement, I mean ONC –

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

– not the conclusion, not the conclusion, but what are the topics that we need to be presenting back to the Policy Committee.

**Paul Egerman – Businessman/Software Entrepreneur**

I see.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So, I know we have another call later in the week and hopefully between now and then we can get clear what needs to be on our agenda for next Tuesday.

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

Hi Larry, this is Michelle. I just want to clarify, so I think what ONC will do is we will go back and try to summarize all the comments we've received thus far, and hopefully have an almost final document to share during the call later this week.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Okay.

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

We'll hopefully share that with enough time so that we're really just sharing the final document and not making a lot of final edits during that time. And then there are other agenda item to pivot us back to the LTPAC and behavioral health conversation later this week. But we will follow up with more detail.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Okay and we're correct in thinking that we should be providing our comments and recommendations to the Policy Committee Tuesday.

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

Yes.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

On the 2015 –

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah, that was the schedule because actually the – if I remember the schedule right, the comments on the NPRM really end today.

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

Correct.

**Paul Eggerman – Businessman/Software Entrepreneur**

That because we're a part of the Policy Committee, in effect we got a few extra days to present.

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

Exactly.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Very good. I know they were doing the same thing with input to the 2017, so that's good. So, should we go to public comment at this time? Anything else the workgroup needs to say before we do that.

## **Public Comment**

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

Okay, sounds like we're ready for public comment. Operator, can you please open the lines?

**Rebecca Armendariz – Altarum Institute**

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press \*1. Or if you are listening via your telephone, you may press \*1 at this time to be entered into the queue. We have no comment at this time.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Well, thanks everybody for the discussion today. It looks like we've got another call at noon Eastern on Thursday. So we should be looking to wrap this up and be getting ready for some additional topics as well. So, thanks again and have a great week.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation**

Bye now.

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation – Ohio State University College of Medicine**

Bye.

## **Public Comment Received**

1. There will be many more FTEs required than 25 as just reported. It will be closer to 45-50 FTEs by our review of the NRPM.
2. Slide #6: Agree having a regular technical update with corrections. This is like the release of a Supp, on year after a new operating system. The Supp will have minor updates and corrections. In this context, the regulatory burden should be minimized.
3. Could someone reassure me that the process will not increase the cost? Do I have to keep asking?