

**HIT Policy Committee
Certification and Adoption Workgroup
Draft Transcript
April 30, 2010**

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning, everybody, and welcome to the certification adoption workgroup. This is the federal advisory committee, so there will be opportunity at the end of the call for the public to make comment. Let me do a quick roll call. Paul Egerman?

Paul Egerman – eScription - CEO

Yes, good morning.

Judy Sparrow – Office of the National Coordinator – Executive Director

Marc Probst? Rick Chapman or Larry Wolf? Adam Clark? Charles Kennedy? Scott White? Latanya Sweeney? Steve Downs?

Steve Downs – Robert Wood Johnson Foundation – Assistant VP

Yes.

Judy Sparrow – Office of the National Coordinator – Executive Director

Micky Tripathi? Joe Heyman? Terry Tuki? Carl Dvorak? George Hripcsak?

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Joan Ash?

Joan Ash – Oregon Health & Science University – Associate Professor

Here.

Judy Sparrow – Office of the National Coordinator – Executive Director

Bill Munier? Chris Brancato? Paul Tang? Anybody else on the line? Kathy Kenyon and I are on the line, anybody else?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Hello, it's Larry Wolf, I'm calling in for Rick.

Judy Sparrow – Office of the National Coordinator – Executive Director

Good, great, thank you, Larry. Alright, with that, I'll turn it over to Paul Egerman.

Paul Egerman – eScription - CEO

Thank you, Judy. Good morning to everybody. I appreciate your dedication having a meeting early on Friday morning. I was talking before we started briefly to Joan Ash because I'm actually on the west

coast for one of these calls for the first time and actually looking out my window at the Pacific Ocean. The people who are on the west coast and have to do these calls at 7:00 a.m., I have a new sense of admiration for you. So I just wanted to say thank you for doing that.

What we're going to be trying to do today is to discuss our comments on the permanent certification program that is described in the NPRM. And comments are due May 10th, if I've got that right, which means we're on a very tight timeframe unfortunately. Whatever comments we want to make, I'm going to probably do my best to write them up over the weekend and then get them to you hopefully over the weekend, and then probably give people no more than a day to make sure that it's accurate. And then we'll have to put it through the rest of the policy committee for approval and try to get it done by Thursday or Friday of next week.

And as long as it's okay with everybody, the way I thought we would do this is I'd walk through this working document that I put together. The way I put together this working document was I read through the NPRM and I tried my best to pull out the areas where the NPRM asked for public comment. I figured if they're asking for comment, then we should be responsible and give them comments, so that's a place where they're asking for suggestions. We don't have to comment on all of these issues, and furthermore, we can comment on anything that we want. Including, if you want to, we can make no comments, but I think there's a responsibility to make a comment. We also already made a comment on the temporary program, I'm sure everybody knows that.

On the permanent program, unless people object, one of the things I did do on the temporary program is, I think it might be good on the permanent program, to write a little paragraph that says something like, we're happy that the ONC listened to our recommendations and separated out the testing and certification process. And so that we say something positive, because otherwise it seems like all we're doing is criticizing. Does anybody have any objection to that?

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

No.

Paul Egerman – eScription - CEO

Great.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

I think it's probably a good idea to acknowledge the basic structure they're creating.

Paul Egerman – eScription - CEO

Yes, because that's the headline of this whole thing. What we're going to be doing here in our comments is we're sort of getting down into the details and into the weeds, which are really important, because the devil's in the details. The basic structure is important.

I just got an e-mail that Carl Dvorak has joined. Are you on the call, Carl?

Carl Dvorak – Epic Systems – EVP

Yes I am, Paul, thanks.

Paul Egerman – eScription - CEO

I'm pleased to have you Carl, thank you. First, walk through the elements that I wrote. And when I wrote it up, it's not quite the same order as the NPRM. I tried to put the most interesting ones first. The first issue is the elements of surveillance. Surveillance is something very new, basically the certification

bodies are supposed to submit an annual surveillance plan, and it just says that there will be surveillance. And so the question is, do we want to make any comments or recommendations as to what some of the basic elements of surveillance should be? What should they be looking at? Do we have any suggestions?

Joan Ash – Oregon Health & Science University – Associate Professor

I was wondering if to be consistent with what we've done with the safety issue, we shouldn't have some sort of safety reporting recommendation for egregious problems or something like that.

Paul Egerman – eScription - CEO

Okay. And that's a good comment; that was Joan Ash. Joan, you need to say your name before you start talking, I need to ask everyone to do that. It's a good suggestion, however, it's sort of like this NPRM is ahead of our safety recommendations. So we can't really in our comments refer to our safety recommendations, because we don't really know what is going to be approved.

But what we could do is say that one of the elements should be labeling and any other certification requirements that don't involve software testing. So that's sort of like a broad category, but that would include if assuming the patient safety stuff gets approved, that would put that in that category. It's sort of like labeling, and how best to articulate it, but it's labeling and non-testing. It's almost like behavioral activities that we're expecting from the vendors.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Right. Paul, it's Larry. My understanding is the intent of surveillance is to verify that products that were tested in a controlled environment are performing as expected in the real world.

Paul Egerman – eScription - CEO

That's correct. That would be one expectation, that's an excellent expectation for surveillance. The other thing would be not only that they're performing, but I don't know how best to describe, but it's something like you want to make sure something very simple, let's say for example, somebody passed a test on the interface specification and they sell their software as certified, that it actually contains that interface.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Right.

Paul Egerman – eScription - CEO

I don't know if that's, it may seem like very basic stuff, but it's like a variation. It's like you buy a car and it gets 20 miles per gallon, at least that's what it says on the sticker when you buy it, but you drive it and you don't get 20, you only get 10. That would be a surveillance issue. So it falls short of whatever the expectation is.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Right.

Steve Downs – Robert Wood Johnson Foundation – Assistant VP

This is Steve Downs. I guess what I was thinking is how can we make this as simple as possible? And I like sort of the notion of is there an ability for a customer to report something that is certified is not performing a function that it has been certified on? And that may be a very simple way to do it. Again, it's a little bit like the EPA stickers, it said 20 and it's 10, the EPA should know about that kind of thing.

And then the other notion would be I think around safety. Without getting ahead of the recommendations, if we could simply say if there are safety issues, those should be reported. And I think the only question or the question is sort of to whom, but perhaps we could leave that open and let that come through the safety recommendations.

Paul Egerman – eScription - CEO

Okay. One of the suggestions you have is that basically consumers if that's the right word should be able to report nonperformance of particular functions and that should be the basis of surveillance.

Steve Downs – Robert Wood Johnson Foundation – Assistant VP

Yes, I'm just trying to give, is there any reason that under what circumstances should something be either not certified or would be one reason. It's been certified, but that needs to be pulled back for some reason, and safety is probably to me would be the biggest driver of that. But it may also be useful to know that if the certification process is certifying systems and there's a pattern of systems that don't actually perform up to certification, it may speak to the quality of the certification process, so that that would be kind of a useful surveillance element. Again, keeping it as simple as possible.

Paul Egerman – eScription - CEO

Okay. I like the concept of keeping it simple. What I've got here is like two concepts. To do the second one, the most recent one first, is I got, that you want to have an ability for users to report any nonperformance, so surveillance should really be investigating reports or especially if there is accumulative number of reports.

And the first issue I labeled was this category called labeling and non-testing only, which is where people want to put in the patient safety issues. On labeling, the reason that I want to suggest that that's important to do, is I'm really worried that we're going to have situations where somebody gets certified for a module, and they claim that their whole EHR is certified or they use the word certification very loosely. So that's an area that I'm concerned about. I don't think that's an appropriate area for surveillance. What do people think about that?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Paul, this is Larry. You're raising a question about vendor behavior, essentially separate from the product itself.

Paul Egerman – eScription - CEO

That's exactly right. The first category I have is like vendor behavior. The second category is like software performance. So vendor behavior is a labeling thing. And to me on the labeling things there could be two or three parts, that one is the labels are incorrect in the sense that somebody says they're certified for stage two and they're only certified for stage one. The label could be incorrect in the sense that they say they're certified for more things than they're really certified for. And then there's another possibility that they say they're certified and they're not certified at all, right?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Right. There's a fourth one, the label is accurate, but the rest of the material is way beyond the scope of the label.

Paul Egerman – eScription - CEO

I don't understand that, can you explain that one?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Yes. It says, this vehicle is only safe for off-road use, but the dealer says that you can use it to get to work, and sells it to you so that you can use it to get to work. This module is only certified for CPOE and doesn't do any of the charting site stuff, but the vendor tells you go ahead and use for the charting site stuff.

Paul Egerman – eScription - CEO

Well that's interesting. That's actually what I have with medications where a drug is approved for a certain purpose and then the physicians prescribe it for other purposes.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Yes. And so the physician might use it that way, but the drug company can't sell it to them that way.

Paul Egerman – eScription - CEO

Right. My question is, that's an interesting comment, when we make our comments, how should we do this? Should I just do this as Steven suggested, do this like in two simple broad categories, vendor behavior and software performance or should I go through any of this detail about the different types of mislabeling that might occur?

Carl Dvorak – Epic Systems – EVP

Paul, this is Carl. Is the question about setting up a process for the certifying entities to monitor? What I could picture is that if on the label you had to tell a customer if they feel that certification was not represented accurately, they should lodge a complaint with the following e-mail address or agency or something. And then the next time that vendor goes to get certified, part of the process at the certifying agency is to look up the complaints on whether they accurately represented their certifications. And you have to either clear them or defend them at that point.

Are we talking about the process for how to handle it or talking about the need to create a process to handle it or just commenting that it would be good if somebody thought through what to do in the event of either a vendor misrepresenting certification? I think a more complicated one is, the vendor pass certification, labeled it appropriately, but darn it's hard to use that application for that purpose. And the customer really feels like, maybe the certifying agency didn't do a thorough job and they're stuck with the lemon; although it passed the certification, it sure is near impossible to use it for that purpose.

Paul Egerman – eScription - CEO

Yes, and actually that's the third category. But just to answer your question, what we're trying to do is simply respond to a question that was in the NPRM. In other words, the NPRM says that the certification bodies have to have an annual surveillance plan, but that's all it says. And it doesn't say what are any specific elements of that plan. And it asks the public what should be the elements of the plan? So we're simply answering the question.

Although, Carl, I love your comment about that the label should have directions on how to report any issues, because there are issues. As you said, there's this third category of issues. There are issues that need the certification. The process itself is defective, so things pass certification. They're labeled correctly, but the software still doesn't work right. It's a valuable complaint, it's not a surveillance problem, but it's a valuable issue to get.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Actually, Paul, this is George Hripcsak. In reading the thing, they talk publicly about we're going to create publicly available information related to the implementation and the performance of complete EHR in the

EHR module. So this is not just about necessarily that you met the letter of the law on certification that this surveillance includes things beyond that.

Paul Egerman – eScription - CEO

So you do want to have then, basically what you're saying, is there really should be a third category. I don't know what the right words, but how defective is the system?

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Yes. That's what the NPRM implies. Now whether that's feasible and we need to scale back because it's too complicated to do that is our decision, that's what our discussion is now.

Paul Egerman – eScription - CEO

Yes.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

But the NPRM is implying that it's fairly broad charge.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Well I think that's actually a really useful thing to add, this notion of, we haven't asked, we're encouraging diversity of how people implement things. So there likely will be lots of variations on how specific things are done. The testing's intended to support that variation. So to get feedback from use on, we have all these functions we've asked you to test against, how well are they working? So more on some kind of effectiveness assessment rather than just absolute I can't use it or it's a lie or something like that.

Paul Egerman – eScription - CEO

Okay, so the basic concepts I've got here, this is very useful, first, the label should include a direction on how to report issues. And then the three elements of surveillance I have is the first category called vendor behavior, so that includes labeling and other interesting issues related to vendor behavior. The second one would be, I wrote software conformity to the specifications or to the test results. And the third category is sort of like effectiveness of the system. I don't know if I'm articulating it right, but is that a correct summary of what we're saying?

Suniti Ponshe – IBM Global Services – Associate Partner

Paul, this is Suniti. A question would be, the last category you talked about is how do you differentiate the variations in implementation? Because some of it is not, the system does what it's supposed to do, but how it got implemented varies from one place to another. And that sometimes the onus is on the people who are implementing it, not the product or the vendor, right?

Paul Egerman – eScription - CEO

That's right.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

This is Larry. My sense is in fact that is a very useful thing for us to be learning.

Paul Egerman – eScription - CEO

That's right. Because we're the adoption workgroup also.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

If the certification surveillance process, it's almost like saying, this product is certified that it can meet meaningful use, that's sort of the unstated statement. And the people are going, yes, I bought it to do

CPOE. It technically does CPOE, but I can't get more than 5% of docs to use it to do CPOE. It could be me or it could be the design or some combination of it only works in certain kinds of organizations.

I don't think we want it to have like an absolute thing in here. But I think we want to get the feedback of this vendor has had great success implementing these functions, but in certain markets they don't work well.

Carl Dvorak – Epic Systems – EVP

Yes, you're starting to cross over, this is Carl, into almost the consumer reports class kind of world. I wonder maybe that's where you kind of draw the line and say that's free market and let that be. And what you could do if there are complaints, take them into consideration as you define how you certified. But that feedback would be strictly for modifying your approach to certifications that you can more accurately catch those kinds of issues and maybe have a more rigorous certification so that next time it comes through certification as a better product somehow, someway. But I do worry, you quickly cross into that consumer reports territory, and I wonder if that really is the right thing to do or not.

Suniti Ponshe – IBM Global Services – Associate Partner

Yes.

Paul Egerman – eScription - CEO

Picking up on your comment, Carl, and it sounds like something I think I heard Larry say earlier, maybe the way to do this is to take the word effectiveness, and to qualify its effectiveness in meeting the meaningful use requirements. Because that's what certification is supposed to be limited to anyway.

Suniti Ponshe – IBM Global Services – Associate Partner

Right.

Paul Egerman – eScription - CEO

So it's sort of like, in some sense it's broader than just software conformity, because it sort of says can I do what I'm supposed to be able to do with the software? Which is really meet the meaningful use, I say obligations, requirements in order to get the ARRA incentives. Is that responsive to your comment, Carl, if we limit it that way?

Carl Dvorak – Epic Systems – EVP

Yes, I think that will be good. The only thing is if ARRA is denied that would create a situation where you'd want to know about it. And then just try to deal with that level of problem, is that what you're suggesting?

Paul Egerman – eScription - CEO

Yes, or part of the surveillance is, somebody could say, I bought the system and it's like it's just really hard to do. It doesn't quite work right or something, I don't know.

Carl Dvorak – Epic Systems – EVP

The governments going to need a big help desk.

Paul Egerman – eScription - CEO

I know.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Paul, this is George. So there's two possible outcomes of doing surveillance, and the appearance seems to point to the second of these two. The first one is you get a report and you go and act on it. The vendors packaging is wrong and then is it up to the certifying body to go or someone to go fix that one problem?

The second is that you're gathering data, then you present that in a public database, so that people see kind of an aggregate of what happens. The value of that one is if someone is saying, it says order entry work, but I can't get it working, that maybe an anomaly and that may be that groups fault, and that will come out in the statistics. So is this a surveillance where there's actually going to be then an action triggered by individual reports or is it just a general thing?

Paul Egerman – eScription - CEO

The only actions that we could possibly trigger that I perceive from this, unless all people like a better suggestion, one would be a public database of what the reports are. And the other relates to the next topic, what are the circumstances under which there would be decertification? In other words, the certification bodies don't really have an ability to say to the software vendor that I want you to fix this problem. It leads into the next topic of decertification.

We could create a situation. It's really whether the national coordinator could step in and say to this vendor, you're misrepresenting your product. You're labeling something that's not correct and I've got 10,000 complaints and I'm removing your certification status, which should be a very powerful club to threaten people with. And so that's a topic we should discuss. But before we move onto that remedy, if remedy is the right word.

What I'd like to make sure I understand have we discussed the elements correctly here? Are we comfortable with this concept of the label has the directions on how to report? The reporting is vendor behavior, three categories, vendor behavior, second is software conformity, and the third category is effectiveness in achieving the meaningful use requirements.

Joan Ash – Oregon Health & Science University – Associate Professor

This is Joan. So where would the safety reports come in?

Paul Egerman – eScription - CEO

I probably would put that in that the effectiveness of achieving meaningful use. Because I would say that if there's a safety problem, it ought to be, you're saying that it's not an effective way, that's probably a good place to put it. It's like it passed the test, but the screens are too complicated to use and we're getting lots and lots of problems as a result. And so that's where I would put that.

Joan Ash – Oregon Health & Science University – Associate Professor

Okay.

Paul Egerman – eScription - CEO

If we have the three categories, what I want to try to do is I'm going to try to write like three or four sentences on each of the categories to describe them, but to keep the description pretty broad.

My first question is before we move on to, I think it was George who raised the question, the remedy in decertification, are we comfortable with these as the basic elements of surveillance?

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Should we use the words implementation and performance since that's what was used for category three.

Paul Egerman – eScription - CEO

I'm sorry, say again please?

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

This is George. Should we use the words I think implementation and performance is what's in the NPRM I think? If I remember correctly. In that category three like what are we talking about and that's how they characterized what we're gathering data on.

Paul Egerman – eScription - CEO

Okay.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

If I'm not mistaken. It's an option to use those words if we want to.

Paul Egerman – eScription - CEO

Okay. I think that that's fine. And again, as I said before, I'm going to do my best to write this up over the weekend and when I do, I know I've got everyone on a short timeframe, but if I leave something out that you think is important, please be sure to help me fix it.

I'm assuming that we're okay then with this first issue in terms of the elements of the surveillance. So the next issue then is what do we do with it? Clearly, we want to have some public database of the results, that part is easy. But the issue that's raised in the NPRM is decertification which is, what it says, should the national coordinator proactively step in to protect the purchasers by taking such actions as decertifying complete EHRs and EHR modules, if a pattern of unsatisfactory surveillance results. So what do we think about that?

Carl Dvorak – Epic Systems – EVP

Paul, let me ask you a question, this is Carl again. Let's say there is a problem and 20% of a vendor's customers raise a serious concern and it's accurate, and yet 80% of those customers use the same product and are getting ARRA stimulus. If they redraw the vendor certification status, it would make sense if none of the customers of that vendor were able to meet ARRA, but if some were and some were not. And you would attribute it to the vendor being sloppy in some way. We'd have to make sure and grandfather the ones that were able to achieve meaningful use, so that didn't accidentally get pulled out from underneath them.

Paul Egerman – eScription - CEO

Yes, I think that makes sense. The picture I had there was also a reason that somebody might be decertified, a major reason might be decertified, one would be is I keep calling it labeling violations. What I'm very worried about is basically marketing excesses where people are making unreasonable claims. So you have a labeling excess flow and the software still conforms, there's no reason to redraw the certification for the existing customers.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Yes, I sort of see where this is leading into the kind of consumer reports or class reporting.

Paul Egerman – eScription - CEO

Pardon me?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

This is Larry. I sort of see where this is leading into those concerns about are we doing more like a consumer reports assessment of a vendor. I'm thinking about that 80% do it fine, 20% don't do it. You don't want to say the product is therefore defective, it can't be, it's sort of—

Paul Egerman – eScription - CEO

Sure.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

If it were a safety issue, you might say, well 20% are experiencing a safety problem, it is an issue. But if it's not a safety issue, but it's an implement ability issue, the fact that you're getting 80% of your customers to successfully implement might be great. A lot of software projects if they make it to 50% are doing well.

Paul Egerman – eScription - CEO

So maybe one way to approach this would be to turn to the three elements that we had and discuss on those three elements, what would it take to decertify? It seems to me on the first one, vendor behavior, perhaps one element could be if a vendor continues to misrepresent their product after being warned, that would be a way of doing it.

Then on software conformance, it could be basically, same thing, if there is a significant non-conformance and the vendor doesn't correct it after being notified of it. And then the third one, effective use, could be if there's patient safety concerns that are serious about the product that a pattern of patient safety concerns. So we provide some criteria to establish it. Does that make sense as a way to approach it? Silence means it does?

Carl Dvorak – Epic Systems – EVP

Yes, I think silence always means, yes, I guess.

Paul Egerman – eScription - CEO

Okay. Unless people disagree, I think it's really important that there be decertification power. My guess it would be rarely or maybe never used, but otherwise, this thing doesn't have any teeth to it and people can sort of say and do whatever they want.

Joan Ash – Oregon Health & Science University – Associate Professor

This is Joan. I was puzzled by the actual language, the question in the NPRM, because it specifically says if the ACB has not taken any measures to evaluate the poor performance, then the national coordinator can step in.

Paul Egerman – eScription - CEO

I didn't understand that either actually.

Joan Ash – Oregon Health & Science University – Associate Professor

That's what they were asking us to comment on.

Paul Egerman – eScription - CEO

Because I didn't think the ACB could decertify, can they? Well, maybe they can.

Joan Ash – Oregon Health & Science University – Associate Professor

So I was wondering if one of the options we would have would be to suggest some sort of process for investigation.

Paul Egerman – eScription - CEO

Okay, so do you want to do that? In other words, do you want to suggest an actual process or just say there should be an investigation process?

Joan Ash – Oregon Health & Science University – Associate Professor

There should be an investigation process. To me it looks like they want us to comment on what if something were really egregious what's happening and the certification body wasn't doing anything about it.

Paul Egerman – eScription - CEO

Yes.

Joan Ash – Oregon Health & Science University – Associate Professor

And so the process should probably include some sort of investigation of the ACB as well.

Paul Egerman – eScription - CEO

That's a good comment. It sounds to me like our comment should include the word egregious. In other words, decertification, for a vendor, that's a significant clause. You do all this work to get certified and the idea that somebody could pull that out from underneath you is significant. It should be the concept there's an egregious violation and there should be an investigation process that says that function should definitely exist. Okay, so I'm assuming silence means people agree with that.

We're making great progress, we have the elements of surveillance done. We have a concept on decertification. The next interesting issue is differential certification, which at first I thought was easy, but then when I read through this one, it gets a little harder. What this is you've got stage one and then you come out with stage two a year or two later, and stage two has a lot of overlap with stage one. And do vendors have to get re-tested if nothing's really changed between stage one and stage two for some things? So maybe CPOE, nothing's changed about CPOE, do you need to get that thing re-tested?

Although, when you read through the detail, one of the tricks in this in stage one some people may have been certified under the temporary program and some people may have been certified under the permanent program, and so they may have had more rigorous testing. And so maybe you want to do something different for the ones that had the more rigorous testing than the ones that did less rigorous testing. What do we think about this concept of differential certification between the stages?

Carl Dvorak – Epic Systems – EVP

This is Carl. I like the idea of differential certification just to keep it as simple as possible. It's pretty onerous today with the current CCHIT. I like the concept a lot.

Paul Egerman – eScription - CEO

How can you keep it simple? What do you recommend?

Carl Dvorak – Epic Systems – EVP

I'm working on that.

Paul Egerman – eScription - CEO

Pardon me?

Carl Dvorak – Epic Systems – EVP

I'm working on that. No, I don't know if there's a great way to keep it simple. I guess it's going to depend on the temporary versus the permanent. I'm not as well versed on how that's actually evolving at the moment, but it seems to be pretty vague still.

Paul Egerman – eScription - CEO

I have one idea, Carl, I don't know if you're going to like it, to sort of say, first of all, we want to say that the label should say what stage it was certified against. So it should say it's certified against stage one or certified against stage two. And that if a vendor has some software that passed the certification say for stage one and then nothing about the testing process changes for stage one or stage two, then they can ask or apply to the certification body that their labels be simply upgraded and not have to test that component again. As long as the vendor also says that they're not changing the version number. In other words, if the software doesn't change and the test process doesn't change, there's no reason to repeat it. But if either one of them changes, then it ought to be repeated.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

You're arguing for regression testing is what I'm hearing. If the version number changes, we want to re-test, because we don't know what else might have changed.

Paul Egerman – eScription - CEO

Right.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

And if the criteria changes, we need to test, because it's a new criteria.

Paul Egerman – eScription - CEO

Right. And that's—

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

But if the new stage doesn't require either of those, then we should say if the old version worked and the old testing worked, we don't need to re-test that piece. So that's what I'm hearing?

Paul Egerman – eScription - CEO

That's my suggestion.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Yes. I like that. Because my initial take was that the suggestion was that we shouldn't be doing regression testing when the version changes, but you said if the version stays the same. I'm good with that.

Carl Dvorak – Epic Systems – EVP

This is Carl. You'd have to define some, the use of versions change almost continuously with little patches or minor modification up through major like in the Windows world, that have service pack 1, service pack 2, up to a Windows, Vista versus a Windows 7. You have to define what you mean by the version doesn't change. I assume you mean the major version?

Paul Egerman – eScription - CEO

Yes, that's correct. I have a way of defining it. I've defined what I would call a minor version change, minor changes would not count. A minor change would be changes that are either correct errors or correct operating characteristics without changing basic functionality.

Carl Dvorak – Epic Systems – EVP

I don't know if you want to go there, because again you can sometimes change the basic functionality but in a minor way. You probably want to leave that door open at least a little bit, otherwise you might get too religious in the interpretation of it.

Paul Egerman – eScription - CEO

That's true. Although, another way to think about it is if the labels have the version number on it, it's also in some sense up to the vendors. I would think a vendor if they really had a major version change would want the new version to be tested. The customers know it's a new version.

Carl Dvorak – Epic Systems – EVP

Right. I agree with that. I think the thing I was commenting on is that sometimes in service pack 1 or service pack 2 it really does change the functionality a little bit, but not in a significant way. You just want to write that so that any functional change didn't disqualify the annotation process.

Paul Egerman – eScription - CEO

So it's not like we got add, there's no significant functionality—

Carl Dvorak – Epic Systems – EVP

Right.

Paul Egerman – eScription - CEO

—and changes or no significant usability changes.

Carl Dvorak – Epic Systems – EVP

Yes.

Paul Egerman – eScription - CEO

Yes.

Carl Dvorak – Epic Systems – EVP

And I think of some of these things though as fodder for, there always seems to be a variety of customer/vendor lawsuits over things like this. Thank God I've never had one, but you hear about them out there. I think some of this language will probably be called up somewhere in court down the road where somebody's mad that it didn't work out well for them and they're trying to differentiate implementation problems versus software problems versus certification problems. So I think we'd want to be at least thoughtful about how this stuff could be used in those things down the road.

Paul Egerman – eScription - CEO

The other way we could approach this though then, having heard that, Carl, would be to sort of punt on the issue. And say, you can go to stage two, you've got to test everything over again, that's life, and give us your latest and greatest version and we're going to make you test it all over again.

Carl Dvorak – Epic Systems – EVP

Yes, I like the idea if your testing the same version for stage two and you've already passed for stage one, then just do the differential of the stage two requirements versus stage one. If you're testing a new version, you should be required, maybe it's the new major version and you have to recertify the whole thing. Because it might be too hard to differentiate or be nitpicky about did you change enough of it to warrant a full recertification? Maybe on a new version you certify it against the then current stage. You definitely don't want to certify against stage one or anything like that, right?

Paul Egerman – eScription - CEO

Right.

Carl Dvorak – Epic Systems – EVP

Because if you certified stage two, it's presumed stage one done. I think maybe on a major version, you recertify. And maybe on trying to upgrade your certification from stage one to stage two to stage three, which you made the actual what we think will have three versions that might qualify for stage one, so we've got to go certify three versions, that's kind of the oddity of it all. Because the customers don't necessarily want to upgrade at an inopportune moment if they don't have to. The notion that a version may be upgrading its certification, that's where differential might be very, very helpful. The notion where I've got a new version, then I probably just need to bite the bullet and certify it at the then current certification stage.

Paul Egerman – eScription - CEO

And that's a good comment, Carl. I think about vendors like eClinicalWorks or Vetatech that has like a thousand customers or more, and they may have three or four or five different versions in the field.

Carl Dvorak – Epic Systems – EVP

Right.

Paul Egerman – eScription - CEO

When they look at all this stuff, to recertify all those different versions each time would drive them nuts and the certification bodies nuts too. They'll have situations where they're clearly, it's the same version over and over again. And they just need to certify against interoperability changes, that could work out very well.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Some of this is feasibility as you just said. Are we trying to weed out the ridiculous systems, because we know we would like to, but we can't achieve saying this product will work in your practice. I know the lawmakers want that, but why don't we just go to doctors and say, we're certified that you can cure cancer, and then we're done ...

Paul Egerman – eScription - CEO

Yes.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

We don't need to do all this stuff. We have to think about what actually is possible. So I am leaning towards weeding out the ridiculous ones, but I see all the problems of liability once we call something, something. Once we call a system certified, how would that be used against the vendor, against the government, against whoever in court?

It would be nice if the words certification, well certification, what does that mean? Do we need a definition of what certification actually implies?

Paul Egerman – eScription - CEO

That's a great question. Presumably the answer is yes. You could add that to a label for the EHR. Anybody selling a complete EHR would be, it's sort of like caution. This does not mean that you're going to be happy with this product.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Right.

Paul Egerman – eScription - CEO

Yes. That might be an important labeling issue.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Legally it means that if you use this system you're allowed to collect your incentive. It doesn't say it'll work, but you're allowed to collect that incentive. So that's really what we're doing. But the goal was of course to use certification to make sure that the systems are good enough. But we can't, what are we really guaranteeing or not, and then that kind of, it's that answer that drives how crazy you go about recertifying versions.

Paul Egerman – eScription - CEO

Yes, certification is supposed to be a minimal, at the government level it's supposed to be minimal. It's supposed to be, the way we've defined it, that this has the minimum technical requirements to meet meaningful use, to meet privacy, and interoperability requirements. It doesn't mean that you're going to be happy with the system. It doesn't mean the system is going to necessarily work well. It's like an emission control on your car, it means it meets the regulation, it doesn't mean that you're going to like the car.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Yes.

Paul Egerman – eScription - CEO

Okay. So getting back to the comment about differential. I get the sense that we're in agreement that we're going to offer this. We're going to suggest differential should be offered as long as there's been no change in the criteria and no change in the version number. And that we're going to write, I'll write a sentence or two about giving some flexibility that no change in the version number except for minor operational changes, and I'll write that up. Are we in agreement on that?

Joan Ash – Oregon Health & Science University – Associate Professor

That sounds good.

Paul Egerman – eScription - CEO

Okay. So then moving onto the next one. The accrediting agencies, this is an interesting thing. The main thing that the permanent program has compared to the temporary program is now you have this accrediting organization that accredits the certification bodies. There's really two groups, there's NIST, the effective accredits of the testing labs, and there's the accrediting organization that accredits the certification bodies.

And so the first thing it asked was the ongoing requirements that has to maintain conformance with ISO-17011. I have no idea what that is. And accrediting certification bodies verify conformance at a minimum to guide 65. Actually guide 65 I've learned is very important apparently, that's where the issue of conflict of interest involved, so that make sure that the certification bodies for example don't have any vendors on the board of directors or involved as judges. So that's actually a very important issue.

Carl Dvorak – Epic Systems – EVP

Paul, does it address the issue of consultants and customers of vendors on some of those boards as well?

Paul Egerman – eScription - CEO

Yes, my understanding it does.

Carl Dvorak – Epic Systems – EVP

Okay.

Paul Egerman – eScription - CEO

There's not supposed to be any, I think it's called third parties. And these customers, I don't know about consultants, I imagine it means consultants, but it means customers or customer parties or vendors. They're not supposed to be involved in the certification process. It's going to have a big impact on CCHIT I suspect.

Suniti Ponshe – IBM Global Services – Associate Partner

Paul, this is Suniti. The ISO standards, these are the international standards for accreditation bodies that I think NIST was involved with ONC on identifying the standards that would apply.

Paul Egerman – eScription - CEO

Yes. We're sort of skipping over what's the detail of that stuff, because it's so, it seems ... but it's good stuff. Anyway, the issue that we've got on the table are we going to ask the accreditation organization to do anything more than this? So the third thing is to make sure their performance are great, but make sure that the certification bodies are performing surveillances.

This is like a surveillance of the certification body. They review the certification results, and they're asking for public comment on these responsibilities. And if there are any other ones to make sure to ask the ONC AA to fulfill. Although, I'd have to say when we make a general comment about what a good job ONC did, one of the things I'm tempted to say is they've done a superlative job of inventing acronyms.

The question is for the ONC AA, the accreditation organization, is there anything else we're supposed to be asking them to do? I personally couldn't think of anything more, but maybe there is something that I'm not thinking of here.

Joan Ash – Oregon Health & Science University – Associate Professor

This is Joan. And to me, it seems like the bottom line is they need to make sure that these ACBs are doing a good job. And one of the important factors would be whether their process is timely enough so that there isn't a backlog.

Paul Egerman – eScription - CEO

That's an excellent comment.

Carl Dvorak – Epic Systems – EVP

Has anyone delved into that? As I was crunching numbers it really becomes frightening to think about how many certifications they'll have to push through in such a short period of time. We had submitted commentary on that too. They had asked about the pricing and it felt like that they kind of underestimated what it would cost to actually certify. But we just recommended they hold that price then and simplify the process until they can do it for that price.

But secondly, we were very concerned about the huge backlog. Because when you look at the timeline, it feels like with the release of the rules, the development of the stuff, the certification of the stuff has to

happen probably within like a 30 to a 90 day window for most vendors in order to get that stuff to customers for the earliest possible stimulus periods.

Paul Egerman – eScription - CEO

In the short term, there's definitely a train wreck coming in terms of the time period of how we're going to possibly get this stuff certified, make sure it's installed. And customers know what, providers know what they're supposed to do all before October 1, 2010. It's all of that, the good news is that's on the temporary program, and this is a sketch of the permanent program. So we could sort of neatly sidestep that very serious challenge that we have looming ahead of us for the next few months.

And on that basis, I think the comment that Joan just made is really a good one in terms of the ongoing responsibility is to review the timeliness of the ONC ACBs; to make sure that vendors don't have an unreasonable time period to wait and are able to get their certifications done in a prompt manner. I suspect the vendors would love a comment like that, that's one of the—

Carl Dvorak – Epic Systems – EVP

Yes.

Paul Egerman – eScription - CEO

I don't want to put words in your mouth, Carl, that's one of the things vendors are very afraid of is basically waiting in line.

Carl Dvorak – Epic Systems – EVP

We did comment on that. And I think probably we should recommend that if the line becomes a problem then customers would be eligible for retroactive coverage once the vendor did get certified. So for example, if the customer was doing their stimulus as early as possible and you had to wait six months to get certified, that even though you got certified six months after that customer had been using that version, that that customer could claim stimulus credit for that time they were using that version that eventually did get certified.

Paul Egerman – eScription - CEO

That's a great comment, Carl. Unfortunately that's not a comment for this NPRM though.

Carl Dvorak – Epic Systems – EVP

Okay.

Paul Egerman – eScription - CEO

This is just the certification process. That's more a comment of how CMS does its payment of incentives. I don't know how they're going to handle that issue. But getting back to Joan's suggestion, I think it's a terrific suggestion that on the ongoing responsibilities, we add evaluating performance timeliness and the existence of any backlogs that the ONC ACB should have. Is there anything else you want to add for the ongoing responsibilities?

Okay, not hearing anything more, I will go onto the next issue, which is the number of ONC AAs and the length of their approval period. The current proposal is that the status would expire after three years and if ONC would accept basically applications for a new ONC AA after 120 days, but there would only be one of these ONC AAs. The question here is like all those metrics, should there be more than one? Should it be instead of three years, should it be five years? And it didn't ask this question, but five years or two years? It didn't ask this question, but also 120 days in terms of applications? What comments do we have about this?

Joan Ash – Oregon Health & Science University – Associate Professor

This is Joan. Why would more than one be any kind of advantage?

Paul Egerman – eScription - CEO

I agree. I think more than one would be a disadvantage. I think that you need to only have one.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Yes, I agree, George.

Paul Egerman – eScription - CEO

Okay. I think we all agree that it's important to have only one. Then the next thing is these various metrics, whether it should be two years, three years, five years. Anybody have an opinion on that?

Joan Ash – Oregon Health & Science University – Associate Professor

This is Joan again. I really feel strongly that two years is ridiculous, and three years probably doesn't seem long enough. We're ramping up an organization here and it takes time to get organized and it seems like five years is more reasonable than three.

Paul Egerman – eScription - CEO

Okay. Other comments?

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Joan, this is George.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Is it one thing out to say four.

Paul Egerman – eScription - CEO

We can say whatever we want.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

I agree three feels short, but five feels long if in fact there's a problem with the accreditation process.

Paul Egerman – eScription - CEO

Okay, the only issue I have with four, if I'm thinking about this right, let's say we say four years, is four going to get put ineffective, end of 2010, beginning of 2011, four years takes us out to 2015, isn't the whole program done by then? Do we still need a certification program after that?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

No.

Paul Egerman – eScription - CEO

Maybe not, maybe we do.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

You will, because of the penalties and stuff, but I kind of agree with that. I think two is too short, but I was thinking that three is short enough. We don't want to change them. We're just going to revoke it because we think that this didn't work out so well. Otherwise, presumably the person who does it the first three years will do it the second three years and they got six years.

So given that we're making all these doctors do meaningful use in 18 months to get the full incentive, the idea that we need five years to get the certifier of the certifier running. So they should be able to move swiftly, at least as swiftly as we're expecting of our doctors. I think two years is way too short, but I was thinking that three, was the compromise between the program kind of being in its penalty phase versus going too fast. My mode, like I'm pretty flexible on this point, but my mode right now is at three years.

Paul Egerman – eScription - CEO

Okay. So three years, does that change your view, Joan, on five years?

Joan Ash – Oregon Health & Science University – Associate Professor

I trust George.

Paul Egerman – eScription - CEO

Okay. Do we have a consensus on three years, anybody—

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Yes.

Paul Egerman – eScription - CEO

Okay. The only other issue I had, and maybe this is really too technical, but 120 days, four months, to get a replacement seems awfully short to me. I get the sense the government doesn't really move very fast. I wonder if we should make the recommendation to increase that to 180 days. It's an important issue and I would think that opening applications and giving the chance for people for the government to make a decision, they might need a little bit more time or do we think we should just leave that alone? If they could do it at 120, we should just let them do it.

Carl Dvorak – Epic Systems – EVP

I agree with you, it seems impossible to accomplish anything in that timeframe, given what we've seen so far.

Paul Egerman – eScription - CEO

Okay. We're going to suggest then that we go to 180 days. We're saying we like the way it is, there should be only one, it should be three years. We just think that they need a little bit more time to consider applications for replacement and we recommend that be 180 days.

The next issue was promoting participation in the certification program. And they asked the question basically, they want to make sure that there's a lot of, in some sense it addresses the issue that Joan just raised about the backlog. They want to make sure that there's enough certification bodies there and they're asking is there anymore that they should be doing to promote participation and make it easier for people to enter?

And I actually had one suggestion on this, which is as reflected in the comment we made on the temporary program, which is to allow people to be certifying bodies that certify only ambulatory or physician EHRs. So that that is a stepping stone and that that would be helpful. Instead of the way it currently is, you have to complete EHR which is both inpatient and what they call ambulatory or you could do modules, but there's nothing in the middle. And so having that middle piece to be able to do the ambulatory or the physician EHR I think it would make it easier for some people to get involved. What do people think about that?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

I agree. You're going to get people who want to specialize and there's no reason that they shouldn't.

Paul Egerman – eScription - CEO

Okay.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Okay.

Paul Egerman – eScription - CEO

Anything else that we can suggest to the government on this issue? Great.

Then the next stuff starts to get very technical. And again, this is a little out of order from the NPRM. The next issue is the Stark Exceptions. And the concept there is, I assume everybody knows what the Stark Exceptions is, but the current certification process that CCHIT does basically qualifies that EHR for the Stark Exceptions. What ONC did was try to create in which probably took a fair amount of legal work to create the situation where if you're certified for the ARRA, you're also certified for the Stark Exceptions. So you don't have to get certified twice. And they ask for a comment on that. And I think my comment would be good idea. I don't know if anybody wants to disagree with that, but I think we've got a confusing enough situation if we ask people to get certified twice and we're just going to go nuts.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Good.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Yes, I agree.

Paul Egerman – eScription - CEO

And then the next one again is also somewhat technical. It has to do with dual accreditation. Again, go back to basics here, there's certification and there's testing. Those two concepts have been separated. And testing process or testing labs are basically accredited by NIST. It's actually accredited by a laboratory and VLAP, which I guess is part of NIST. Certification is going to be accredited by the ONC AA, the accreditation agency.

And so what is going to happen, I think generally is going to happen, is people are going to get dual accredited. What I hope is I picture CCHIT being dual accredited both for testing and for certification. And so the question is should there be some other destination for the ones that are dual accredited and give them some special designation so that we have yet a new acronym or something for them? Do we have any comments on this?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

I personally like less is more and have the two certifications.

Paul Egerman – eScription - CEO

Okay. No more acronyms is what you're saying.

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

Good.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Unless someone's going to argue for the benefit of having a third one that's like the umbrella term. I assume that this notion of dual accreditation will get used as just a descriptive phrase and I think it communicates just fine. I guess the counter argument would be is there any reason that separation would be a good thing and we don't want dual. And if you're going to be dual, you got to do something further to make sure that there's no cross pollution, so like the consultants and the accountants were split up.

Paul Egerman – eScription - CEO

The issue that also is this designation really is important primarily either to vendors or I guess to people who are self-developers. This sort of alphabet soup of acronyms really doesn't get exposed to consumers, hospitals, and eligible providers don't have to necessarily worry about this. They only worry about whether or not they've got a certified product. It's just an observation.

But what I'm hearing on this call is nobody particularly has any interest in dual designation. There's nobody saying that there's a benefit to that. It seems like this—

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

This is George. Yes, I don't think I have a great feel for the concept of splitting it like what are risks. So it's hard to say whether it's too risky to have someone do both or not.

Carl Dvorak – Epic Systems – EVP

I almost like the idea of someone doing both, because what I've always experienced in life in many walks is that if you don't actually have to practice the art, you can sort of become ivory towered insensitive to the needs of what happens on the ground. So it wouldn't bother me a bit if they were responsible for both as long as that didn't lead to any special conflict of interest.

Paul Egerman – eScription - CEO

Yes, I agree with Carl. The question is so in one sense you're saying we should encourage both. The question that was asked is a very narrow question is if you do both do you get a special designation? Do you get like a blue star, do you get some special designation?

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

I think it would be confusing to have a new designation. And we're not from a competition point of view allowed to favor one that happens to have dual, because there's probably law against that. So I think you just get your two, we're going to have enough trouble explaining that there's testing and certification. And if we add a third thing, which is both, that'll be like an extra paragraph in every news item about this.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Yes.

Paul Egerman – eScription - CEO

Okay. Great, okay. So I understand the view there. And then the last issue, no, I actually have one other issue I wanted to make sure I raised. The last issue on the list is authorization to certify, I wrote it down badly, other HIT systems. The comment I give you is, the Markle Foundation invited me to participate in a discussion about what the Markle Foundation's comments are about the certification process.

And they actually spent a lot of time commenting on this part of the NPRM. Because the NPRM basically provides a capability eventually for the certification bodies to certify other HIT systems beyond EHR systems, so that could involve PHRs for example. The question is do we want to comment on that at all?

I personally felt if you're going to create this process, if you create it, it probably makes good sense to create it broadly enough to give you the flexibility to do interesting things in the future if you want to, but maybe other people disagree.

Joan Ash – Oregon Health & Science University – Associate Professor

This is Joan. And I really agree, because we know PHRs at some point will be needing certification. People are already thinking about that, and so why not build the capability in.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

We thought that other things where there isn't certification today, but we're concerned like retail pharmacies or commercial labs.

Carl Dvorak – Epic Systems – EVP

Paul, my comment will be a little bit different. I watched CCHIT evolve a bit, and once an organism exists it seeks to survive and thrive. And we went from certifications for a handful of reasonable things to a proliferation of certifications that each came with a very expensive price tag.

It makes me nervous that if we do this because we have a few really important things we want to accomplish as a nation, okay, that's just fine. If the organism seeks to do this, even though people are nonprofit, they often become profitable nonprofits. If this becomes sort of a business and the certifications proliferate, I see that as a problem. I don't know if it's a benefit to the industry really.

Paul Egerman – eScription - CEO

Okay. So that's a different view, any reactions?

George Hripcsak – Dept of Biomedical Informatics Columbia University – Chair

I guess the question would be, certification would be in support of something. Right now there is no legislation or authorization for ONC to have any enforcement around any other certification. They could create certification, but it's not tied to any good things or bad things.

Paul Egerman – eScription - CEO

Right. So maybe one way you could sort of unite these comments would be to say certification still needs to be limited to where the legislative authority is, which is for the ARRA incentives. And to the extent that it extends to other HIT systems that should be to the extent its needed to achieve meaningful use. So that basically what you would do there is you would say if we're going to talk about retail pharmacies or we're going to talk about PHR systems is that the extent that the certification bodies, the certification process would get involved would be to the extent that it's required for either the meaningful use or the interoperability needs of the EHR systems.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Or maybe it should be, we think this is a good process that's being described, and if future systems need certification it seems reasonable that we would want to reuse this process. And to the extent that it's feasible and helpful, reuse the organizations themselves, so that we don't create lots of different overlapping processes and criteria and certifications that are going to be cluttering up the label on the software if you will, but that we want to go for parsimony. We don't want to just create certifications for the sake of certification and they should be in support of activities that ONC's authorized to undertake.

Paul Egerman – eScription - CEO

I'm trying to figure out how to weave this together. I'm hearing two or three different things. If I heard right, Joan say, yes, we should provide the flexibility to do other things. I heard Carl say, watch out for mission creep. I don't think those were exact words, but that's at least what I heard.

Carl Dvorak – Epic Systems – EVP

Yes.

Paul Egerman – eScription - CEO

I hear Larry say, let's make sure it's within ONC's authority.

Carl Dvorak – Epic Systems – EVP

Or how about if it's directly tied to a future CMS stimulus program or penalty program with software as a prerequisite for that program.

Paul Egerman – eScription - CEO

Great. In some sense it has to be. In other words, I think about the concern you're expressing, Carl. A certification body can't say I'm going to do HHS certification of PHRs or retail pharmacies in the same way that CCHIT could. Because there has to be this other thing that exists, there has to be this IFR. There has to be certification criteria that the government approves. And we can't write the regulations for that unless there's some legislative authority. In other words, the only way you can do an IFR and an NPRM is if there's some legislative authority for doing that. So I'm wondering if the very nature of what we're doing mitigates some of your concerns, Carl.

Carl Dvorak – Epic Systems – EVP

Likely it does.

Paul Egerman – eScription - CEO

Pardon me?

Carl Dvorak – Epic Systems – EVP

Likely it does.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Paul, sorry, one of the things I was trying to say in that little ramble was that this looks like a good process, so if there is a need to certify other things, we would encourage reusing this process.

Paul Egerman – eScription - CEO

So maybe a way to do this is to weave this all together could be to have sort of a sentence or a few sentences. So that we think it's a good idea to provide this flexibility as long as we keep in mind the fundamental goals of the certification process under ARRA; which are meaningful use assuring that you have the capabilities for privacy and security and interoperability that those remain the focus of the process. All we do is repeat the focus and then say it's fine. Does that seem like a way to comment on this issue? Does that address your concerns, Carl?

Carl Dvorak – Epic Systems – EVP

I think so, yes.

Paul Egerman – eScription - CEO

And Joan, does that seem reasonable to you?

Joan Ash – Oregon Health & Science University – Associate Professor

Yes. And I like Larry's idea about reusing the process.

Paul Egerman – eScription - CEO

I do too. Okay, I will do that when I write this up. Then what we've done is we've gone through my word processing document. The other issue I have to raise is we made a number of comments on the temporary certification program. And I first have a question for the ONC folks, which is, are we supposed to repeat all of those recommendations on the permanent program? Because all these things exist in the temporary and in the permanent.

The thing we said before, for example, about how we want certification of modules to work in the temporary program. I'm unclear, but I think we have to just repeat all those things again. I don't know if anybody on the call from ONC could tell me what I'm supposed to do. Unless somebody tells me anything different, I'm just going to repeat them all.

Judy Sparrow – Office of the National Coordinator – Executive Director

I don't know the answer to that, this is Judy, but if Kathy is still on, she might.

Paul Egerman – eScription - CEO

Are you there, Kathy?

Suniti Ponshe – IBM Global Services – Associate Partner

Because Judy this—Pardon?

Paul Egerman – eScription - CEO

Is that Suniti talking?

Suniti Ponshe – IBM Global Services – Associate Partner

Yes. I think you do need to repeat that.

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes, I think it's better to be overkill than ...

Suniti Ponshe – IBM Global Services – Associate Partner

Yes. Because the common processing process would be different for temporary and permanent, so I would repeat that.

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes, I agree.

Paul Egerman – eScription - CEO

I just want to make sure you said we should repeat it?

Suniti Ponshe – IBM Global Services – Associate Partner

Yes.

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes.

Paul Egerman – eScription - CEO

Okay.

Kathy Kenyon – ONC – Policy Analyst

And Paul, this is Kathy, it took me awhile to hit the mute button, but I agree with them.

Paul Egerman – eScription - CEO

Okay.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you.

Paul Egerman – eScription - CEO

So for the workgroup, how do you want to handle this, do you want me like read through these one by one to make sure we still have consensus on this? It's just that I'm going to repeat everything we did on temporary, but I wanted to make sure—

Judy Sparrow – Office of the National Coordinator – Executive Director

Okay.

Paul Egerman – eScription - CEO

There's Joan and George and Steve and Carl, do you want me to reference through this really fast?

Carl Dvorak – Epic Systems – EVP

Sure.

Paul Egerman – eScription - CEO

Okay. So the first one was certification of EHR modules with other modules. And basically what we said on that was whether or not you should test for interoperability, and we said, no, just handle that with a labeling requirement. Then you should say what things were labeled for. The second one was authority to certify for ambulatory settings, which is actually what we commented again on the marketing one.

The third one is an issue about testing location. I made a comment on this in one of my e-mails. It turns out the recommendation that we made on location was based on information that I had that was wrong, because the NPRM says the primary test location should be the test facility. Secondary test location should be remote or at the user site I guess for a self-developed system. And the feedback that came back from CCHIT was the CCHIT doesn't have a test facility. They say they do all of their testing remotely. They said that the remote should be listed as primary.

Carl Dvorak – Epic Systems – EVP

I agree a hundred percent with that. We go through this all the time and it's very, very effective and a great way to reduce cost.

Paul Egerman – eScription - CEO

Is this Carl speaking?

Carl Dvorak – Epic Systems – EVP

Yes, Carl, sorry.

Paul Egerman – eScription - CEO

Yes. What I was going to suggest on recommendation three was that we fix this and that we simply say that testing can occur at any of these locations, but that nothing be identified as primary. It's really up to the ONC ACB or ATCB in the circumstances as decided.

Carl Dvorak – Epic Systems – EVP

I would even offer, maybe a stronger suggestion. I would suggest that remote testing should be primary, and only the rare exceptions that one would need to come onsite for it because it's simply much, much, much more effective. It would certainly be depressing if the certifiers chose to simply for their convenience have everybody come onsite. What a sad waste of resources that would be, because it wouldn't add any value. So I'd almost more strongly recommend that given the technology era that we live in fortunately that we employ remote testing as the primary method.

Paul Egerman – eScription - CEO

Okay. That's fine. And also clarify, Carl, the places where you would go onsite, what we envisioned when we did our original certification recommendations would be for people like say Intermountain Healthcare that have self-developed systems where they may not just be set up well to do remote testing. If the systems operational in particular then an onsite visit might be a reasonable alternative.

Carl Dvorak – Epic Systems – EVP

I don't think they'd even need to do that, Paul, because I've actually been on webcast with people from Intermountain where they showed me stuff. It's actually very, it makes no difference for Intermountain people to do the same sort of presentation through a webcast is the same as we do. And I think they would think we'd all benefit by not incurring travel and lodging and expenses for something where you're both just going to stare at a computer screen and walk through a check list.

Paul Egerman – eScription - CEO

Okay.

Joan Ash – Oregon Health & Science University – Associate Professor

You're also saying, Carl, this is Joan, that the homegrown systems that have been certified up to this point, they were tested remotely, like partner systems.

Paul Egerman – eScription - CEO

They haven't been certified.

Carl Dvorak – Epic Systems – EVP

I don't know about partners, but I believe Cat Hill's was tested remotely just—

Joan Ash – Oregon Health & Science University – Associate Professor

Okay.

Carl Dvorak – Epic Systems – EVP

—the CCHIT method that we used.

Paul Egerman – eScription - CEO

The other issue though that we put into this was we said if something is tested onsite, so maybe I got this wrong, for self-developed systems, the certification should only exist for that site. This was actually an issue that your organization, Carl, Epic raised.

Carl Dvorak – Epic Systems – EVP

Yes. I think that's true.

Paul Egerman – eScription - CEO

We wanted to make sure that self-developed systems weren't certified for resale, because they felt vendors have gone through more work. If we're saying everything's done remotely, I don't know how we can justify that recommendation anymore.

Carl Dvorak – Epic Systems – EVP

No, I think it still doesn't matter, because the system that is, so if Marceo Cat Hills gets certified and chooses to become a vendor, I don't have any problem with that. It's to me not a function of who does more work. I think that if Cat Hill chooses to sell a system to another, then it should go through the same certification process I go through. It shouldn't be allowed to avoid that process or you will create an accidental disparity. With regard to certifying remotely, I think sure it saves them time and effort as well. So they should be able to, anyone should be able to certify remotely even independent site certifications for home built.

Paul Egerman – eScription - CEO

So testing remotely actually.

Carl Dvorak – Epic Systems – EVP

Testing remotely, yes.

Paul Egerman – eScription - CEO

Okay.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So guys, I guess I have a question. If I put a paranoid hat, I would go is the odds of fraud better if it's remote versus if they have to come to the testing site?

Carl Dvorak – Epic Systems – EVP

I don't think it makes a bit of difference.

Paul Egerman – eScription - CEO

Okay. So what we're going to on this is that we were in error and that the primary location should be remote testing; that testing facility at the certification body or at the healthcare organization sites are acceptable secondary locations. But that the location, this is just a comment about testing, it has nothing to do with certification of vendors versus onsite organizations. So that's what we're going to say about testing locations.

Carl Dvorak – Epic Systems – EVP

I agree.

Paul Egerman – eScription - CEO

Okay. So the next one was this business about minimum standards and floors for testing on version numbers and I think we state the same on that. The fifth recommendation was we recommend the national coordinator have the recommendation to revoke an ONC ATCBs status. So that recommendation doesn't carry over to the permanent program, because that's only a recommendation on the temporary program, that becomes a responsibility of the accreditation agency.

And then the last one was comments about clarification, certification clarity for stages of meaningful use where we made a number of comments about labels to make sure it's clear, that you get certified. Our recommendation is that the label say that you're certified for stage one or stage two or stage three. We were concerned it'd be very confusing otherwise. Particularly in an overlap period where some people are still trying to get stage one certified and enter the process; and some people have gotten stage two; other people haven't gotten stage two certifications. So we wanted clarity there. So that goes through all of the letter.

Now the one thing that we didn't comment on last time in the letter and in this discussion was the privacy and security issues. The privacy and security issues were the same in the permanent program as they were in the temporary program in terms of these things that are called like carve outs. And what I did with that this last time is I sort of handed that issue to the privacy and security workgroup and they're going to make the same recommendation that they made last time about that. We're free to make our own recommendation on that also, but I didn't think it was helpful or important to be redundant. And I figured since really all the recommendations eventually come from the policy committee, we would let them handle that issue.

So I've gone through all of the issues, is everybody comfortable with everything? Does anybody have any other issues they want to raise?

Carl Dvorak – Epic Systems – EVP

Can I ask a question, Paul, it's Carl again?

Paul Egerman – eScription - CEO

Yes.

Carl Dvorak – Epic Systems – EVP

With CCHIT, they basically charge you, the rule got written from the Stark Exceptions Safe Harbor requiring an annual certification. So right now we have to send a check in, I think it's like \$5,000. I don't know if that's supposed to be confidential or not, but we have to send a check in to get a version that's not changed re-stamped, to be recertified again simply because that rule is written to require renewals of them.

I didn't read all the regulatory language, so part of the proposals. Is that something we need to write? It would certainly be nice not to have to every year send in a check for every version that a customer still operates simply to say it's still certified and have it relisted on the Web site as certified.

Paul Egerman – eScription - CEO

Yes. My guess is I don't know where that's coming from, but that probably is somewhere in the Stark regulations that you have to be recertified once a year.

Carl Dvorak – Epic Systems – EVP

Right.

Paul Egerman – eScription - CEO

And the issue is this doesn't change that Stark regulation. All this does is says the certification bodies that are set up under this rule can also give a Stark Certification at the same time. If the Stark stuff says you have to renew each year, I think you're still stuck with that. I don't know if Kathy Kenyon's on the call or somebody else can tell me if I've got that right.

Kathy Kenyon – ONC – Policy Analyst

I think you do.

Paul Egerman – eScription - CEO

Yes.

Carl Dvorak – Epic Systems – EVP

And when you try to wire into this little correction that said if the version hasn't changed and the regulation hasn't changed that an attestation letter would be sufficient without additional fee.

Kathy Kenyon – ONC – Policy Analyst

This is probably an issue that needs to be dealt with in some form other this.

Paul Egerman – eScription - CEO

Yes, I have a feeling, it's a good comment, Carl, but—

Carl Dvorak – Epic Systems – EVP

Alright.

Paul Egerman – eScription - CEO

And I understand it's annoying. But the regulatory process, it's like an interesting process, and it's actually a very good process. The intention is very good. It's trying to get public involvement and to make sure things are done correctly. So the intentions are very good, but we have a very rigid structure and we have to comment simply on the stuff that's in the NPRM. And I think you're raising an issue that's really outside of what this NPRM is.

Carl Dvorak – Epic Systems – EVP

Okay.

Paul Egerman – eScription - CEO

That's my sense. A good comment and I'm sorry it's annoying and I'm sorry I can't help you.

Carl Dvorak – Epic Systems – EVP

No, that's alright. Thank you, Paul.

Paul Egerman – eScription - CEO

Any other comments? Anybody have anything that they're uncomfortable with? Okay, at Starks, anybody have something they were about to say? Okay, that's excellent.

Again, to repeat what's going to happen next. First, we're going to listen to the public comments, then after that I'm going to write this up over the weekend. I'll try to get it to you sometime on Sunday. And then I'm going to ask you to comment on it, if you don't mind, and probably by the end of the day, Monday, so that I can get a letter together for Judy and get a policy committee meeting probably Thursday or Friday. I don't know if that's possible, Judy.

Judy Sparrow – Office of the National Coordinator – Executive Director

We'll hear back from you.

Paul Egerman – eScription - CEO

To get this done by May 10th. May 10th is a week from Monday.

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes.

Paul Egerman – eScription - CEO

I think that's what I've got to do, right, don't we have to get it done by Thursday or Friday?

Judy Sparrow – Office of the National Coordinator – Executive Director

I think you're absolutely right.

Paul Egerman – eScription - CEO

Okay.

Judy Sparrow – Office of the National Coordinator – Executive Director

Are you ready for public comment?

Paul Egerman – eScription - CEO

I certainly am.

Judy Sparrow – Office of the National Coordinator – Executive Director

Alright, good call. Operator, could you see if there are any comments from the public please?

Operator

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

We do have public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director

Great. If that person, please identify your name, organization, and it's a three-minute time limit, please.

Michael DeCarlo – Blue Cross Blue Shields Association

Thanks. It's Michael DeCarlo with the Blue Cross Blue Shields Association. Paul, I've been listening to your call and you got to the one issue about whether there should be a separate certification bodies just for inpatient or just for ambulatory EHRs. And I think I heard that you were going to recommend that that would be permissible.

I just think you should consider that in the NPRM, ONC estimated there would be 167 EHR products for stage two, and 170 EHR products for stage three. If you multiply that by the expected cost of certification, you get a market that's got a potential revenue in stage two of about \$8.4 million and in stage three about \$8.5 million, which is not a very big market. And the more you shave that by dividing it up at the less viable, those independent certification bodies would specialized in either inpatient or ambulatory might be. So I would just suggest that you give that some consideration.

Paul Egerman – eScription - CEO

That's a good comment, although, I'm assuming that these certification bodies do other things besides certification of the EHRs. CCHIT for example, assuming that they become one of them most likely will also continue to offer their own certification. And I know I talked to people at the Drummond Group who I understand are intending to apply, but they also do other testing and certification in addition. But it's a very good comment, Mike, and I appreciate you making it.

Michael DeCarlo – Blue Cross Blue Shields Association

Thanks, that's all.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. Anybody else from the public? Okay, Paul, back to you.

Paul Egerman – eScription - CEO

I just want to say thank you. I want to thank you, Mike DeCarlo from the Blue Cross Blue Shields for making your comment. I want to thank, I don't know if Jim Miller is still on the call, another member of the public, who told us that he was on the call. And I certainly want to thank all the workgroup members who participated in this process. And of course our very dedicated staff at ONC, Judy Sparrow, Kathy Kenyon, Suniti, and I'm sure I'm leaving somebody else out, but I want to thank everybody who helped us with a lot of detail, and simply say thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Paul.

Paul Egerman – eScription - CEO

Great.

Judy Sparrow – Office of the National Coordinator – Executive Director

Alright. Goodbye.

Paul Egerman – eScription - CEO

Goodbye.

Public Comment Received During the Meeting

1. I may have missed this discussion, but did you consider having credit given to meaningful use criteria passed under Stage 1 under the temporary program so that a vendor would not have to retest Stage 1 criteria under Stage 2 certification?
2. Did you cover any recommendation to allow a certification status attained on one version to be inherited by future versions of the same software against the same basis of criteria?