FTS-HHS-OS

Moderator: Jodi Daniel
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Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode until the question-and-answer portion of today's call. I would like to inform all parties that today's call is being recorded and if you do have any objections, you may disconnect at this time. I would now like to turn today's call over to Jodi Daniel. You may begin.

Jodi Daniel: Thank you very much. It's a pleasure and to have the opportunity to talk to folks a little bit more about our proposed rule for the establishment of certification programs for Health IT.

I am the Director of Policy and Planning at ONC and I have with me Steve Posnack who is in charge of our regulatory efforts and Carol Bean who's in charge of our certification program efforts who will be talking in detail about the proposals that we have put forward in the Federal Register.

We published our proposed rule on March 10 so just a few weeks back and we have a comment period of 30 days for our temporary program and for 60 days for our permanent program so that would be 4-9 for the temporary program and the close of the commentary for the permanent program will be 5-10.

What we're hoping to do is really just give folks a more in-depth understanding of the proposals that we put forward. We are going to stick to what is in the regulations itself.

At this point because we're in an open comment period, we're happy to take questions at the end where people have factual questions about what we've said or what is in the rule but we will not be able to talk our deliberations or our thinking that goes beyond what's already in the regulations.

So there's some limitation to what we will be able to answer or not based on the fact that we're in an open comment period so please understand that if we don't response to your question directly.

We also really want to encourage people to provide comments to us formally through the formal comment process so that we can consider all of your input and we can make sure that we incorporate the thinking of a variety of different stakeholders before we finalize these proposals.

I want to thank you all for participating and with that, I'm going to turn it over to Steve Posnack to talk through the proposed regulations.

Steve Posnack: Thanks, Jodi. I think we are trying to make sure that folks have good audio and there is additionally a phone line that you can dial-in to in addition to listening-in to the Web and as soon as I get that number, I will provide it to you.

I do talk very loud anyway in general, so I will try and pronounce everything and articulate everything as clear as possible, so today as Jodi mentioned is

about making your more familiar with the proposals in the Notice of Proposed Rule Making for the certification programs that we recently published.

And I guess I'd like to call it navigating the NPRM so to speak. Both of my parents are teachers so I decided to start my first slide with some learning objectives and what I hope will be my measure of success in terms of at the end of today - at the end of this Web session - what you will be better equipped in terms of understanding.

So I want to make sure that you know how all the high-tech regulations relate to meaningful use fit together. That's going to be some of my initial slides then diving into the proposals for the temporary certification program, the proposals for the permanent certification programs, and then areas where your input is specifically requested and I'll call out some of those areas and give a little bit more context for the types of public comments that we're looking for.

Okay. So as many of you who have tuned in to the two presentations that Carol have given at the HIT policy committee or the HIT standards committee, you will have seen this slide before - and it hopefully will work in its animated fashion or else I'll have to give my best radio voice. But the question is how does all this work and this slide just seems to - sure.

Jodi Daniel: We need to interrupt to ask people to be sure to mute their phones and if you are listening in on your computer, to mute your computer. And we do regret that the phone lines are full, so if you are only on the computer and were trying to dial in, we have apparently reached our capacity, but we are getting feedback from people who are listening in out there and so please mute.

Steve Posnack: Okay. Public service announcement number 1, so if you could please mute your phone or your computer if you have that capability and I guess all the phone lines are tied up.

Back to our animated slide. All right, so how does someone become a meaningful user of certified EHR technology? The policy architecture required to implement this and to implement meaning for use is comprised of three interdependent rule makings.

All three have now been published. You got an opportunity to comment on the first two which would be the meaningful use NPRM and the interim final rule on standards implementation specifications and certification criteria.

The third, which is our topic for today and currently out for public comment, has to do with the HIT certification programs rule so in order for someone to become a meaningful user of certified EHR technology, it's important to understand what it means to become a meaningful user and that is - I think the animation is a little fast - all right, and that is as CMS has articulated in their proposed rule, a number of objectives and measures.

And those really describe what someone needs to do, what an eligible professional or what an eligible hospital would need to do in order to qualify for the incentive payments and how they would need to use certified EHR technology.

The rule making that we published at the same time as CMS's proposed rule on meaningful users was the interim final rule on standards and certification criteria where we specified certification criteria that were correlated to the meaningful use objectives so we wanted to make sure that the technology

could provided the capabilities that a healthcare provider would need to achieve meaningful use.

Those certification criteria in a number of places also reference standards to make sure that either data is exchanged appropriately according to a specific standard or a specific code set is used.

And the other two concepts that we identified in the interim final rule were two definitions, one being a complete EHR and another being the EHR modules.

So a complete EHR is an EHR - a health information technology - that's designed for either an ambulatory or an inpatient setting that's certified to all of the applicable certification criteria adopted by the Secretary.

So electronic prescribing is a specific certification criteria that's only applicable in the ambulatory setting so an ambulatory complete EHR would include electronic prescribing.

We've also included the concept of EHR modules and this a concept that we think is going to prove to be more valuable going forward and into the future as hopefully the industry can find new ways to innovate and it will also allow folks to customize their health IP solutions.

So we wanted to make it an option early on and set the foundation for eligible professionals and eligible hospitals to adopt modular technologies that they could use to customize and piece together something that would meet the definition of certified EHR technology.

So the question then becomes how does something become certified, and that's where this regulation that we're talking about today fits in. So we've got two acronyms down there that I will go into more detail about and the easy way that I've found to describe how to remember them is that an ONC-authorized testing and certification and ONC ATCB belongs to the temporary certification program.

So the Ts are your clue there, and an ONC-authorized certification body belongs to the permanent certification program. So either of these two bodies under their respective programs will be responsible and authorized by the national coordinator to conduct either testing and certification of complete EHRs in the EHR modules or to conduct the certification of complete EHRs in the EHR modules.

Now in the definition of certified EHR technology which also lives in the interim final rule, we explain that it could be - you could meet the definition in one of two ways.

You could meet it either by being a certified complete EHR and that would meet the definition of certified EHR technology, or for the applicable certification criteria for the setting that the eligible professional or eligible hospital is in, one could assemble a proper combination of certified EHR modules.

So one could meet the definition of certified EHR technology through either of these two ways and we wanted to make sure that folks were clear that - okay. I'm getting more feedback, so this is Public Service Announcement number 2 that we're still having a little bit of feedback issues with folks being on mute.

I apologize for the inconvenience and if you have any ability to mute your computer audio or your mikes that may be connected or your phones, please try and do so.

Soldiering on and I believe it is our intent to have these slides available on the Web so if - not that it would be anything less than the stellar presentation that you're going to get from Carol and I with our voices - but at least the slides will hopefully be useful to you.

Moving on to the basics here, this is our authority for issuing the Notice of Proposed Rule Making on certification programs. As you can see, it requires the national coordinator to consult with NIST to keep a recognized certification program or programs but a voluntary certification of health IT.

I would stress here as Congress intended that this is a voluntary certification program. No one is mandated to get certified. Of course, if you want to be able to sell your products to potential eligible professionals or eligible hospitals that will need to use certified EHR technology, it's a pretty good idea.

There is also additional authority that is in a subsequent section of the High Tech Act where the director of NIST is required to support the establishment of a conformance testing infrastructure that may include a program to accredit independent non-federal laboratories to perform testing.

And we've been in consultations with NIST since the High Tech Act was signed into law and we have been working with them on our proposals ever since so a number of questions have come up over the course of time as to why we have to go through rule making to do this.

There are numerous interpretations of the statutory language but I felt that it would be helpful to give people a little bit more context in terms of the legal principles behind why we felt we had to go through rule making.

And that would be - and this is not an inclusive list - these are the two that are kind of easy to get across points that I understand that I think everyone will - it will make it easy to grasp the concept of why we had to go through rule making, the first being when we impose obligations on the private sector. That's an instance where rule making is generally an approach taken.

The second being where we provide legal benefits or grant legal rights to certain entities, and those are two kind of legal principles that when we consult with our office general counsel and when we look at the approaches that we can take to implement statutory language, we have to weight as to whether or not we go through rule making.

All right, next slide, so this is just a summary of the HIT policy committee recommendations. I suspect that if you're dialing-in to our call today, you have been at least following one of those two committees so we appreciate your attendance again.

The HIT policy committee recommended these five core recommendations: one, that we focus certification on meaningful use, that we leverage the certification process to improve progress on privacy, security and inoperability, that we improve the objectivity and transparency of the certification process, that we expand certification to include a range of software sources, and that we develop a short-term certification transition plan.

And we believe that we've embodied many of these recommendations in our proposals, both within the interim final rule and the proposed rule on certification programs so I will move on. Right. Mastering the Webcast moving forward here.

Put simply, the programmatic purpose is two-fold: to establish the process for the national coordinator-authorized organizations to perform the testing and certification of health IT, specifically in this case complete EHRs and the EHR modules. And we also specify how complete EHRs and EHR modules would be tested and certified and this really picks up on some of the certification issues that we've seen in some of the comments that we've gotten through already on our interim final rule on standards and certification criteria.

So hopefully reading through the preamble, some of your question will be answered. It may raise more questions but we hope that given the two scopes of the two rules that we had to put out, we had to choose the best communication vehicle and the best rule making really to include our proposals so I will keep trudging through.

Here's our rule making approach. It's a little bit different and as Jodi alluded to, we do have two separate comment periods so I wanted to make sure our folks were clear on what we plan on doing and that you can keep abreast of where we are in our process.

We're proposing - we've included - our proposals in a single Notice of Proposed Rule Making; however, we anticipate finalizing our proposals in two separate final rules.

We will issue a final rule for the temporary certification program sometime synchronously with the final rules for meaningful use, Stage 1. And for the - as I like to colloquially say - the double final rule on standards and certification criteria so all those three rules will come out as close in time as possible as we can, understanding all of the time constraints that we're under.

The permanent certification program we anticipate finalizing sometime later this fall. We will - as you can see here in the table - we expect the temporary certification program to be operational and certify complete EHRs and EHR modules for meaningful use Stage 1.

We anticipate that the permanent certification program will pick up the reins sometime before meaningful use Stage 2 starts in order to make sure that products are certified through meaningful use Stage 2 in some advance time period.

Again, there are two comment periods. We want to expedite under the time constraints that we're under the temporary certification program final rule and we have provided for a 30-day public comment period.

At the end of those 30 days, we're going to take what we've got and we're going to march forward as fast as we can to get out this final rule on the temporary certification program.

That being said, you will have an opportunity if you choose not to comment on both proposals at the same time to continue to submit public comments on the permanent certification program up until May 10, which is Day 60 if I'm not mistaken.

When we go to finalize the final rule for the permanent certification program, we will take into account all comments received from Day 1 to Day 60. So depending on the approach that we need to take in our temporary certification program, we may defer certain programmatic aspects to the permanent certification program, but those will be policy decisions that we'll need to take heed of consider based on the public comments that we receive from you all.

I'm going to move on. All right, so I have a number of slides. The heading is labeled based on the certification program that I'm discussing. I'm going to start walking through the temporary certification program and next to the title, there are numbers to indicate that I'm still in the temporary certification program.

A lot - I'll preface this up front - a lot of the proposals in the permanent certification program and I'll highlight these later are very similar in nature to the temporary certification program which is why we put them together in the same rule making.

Not that I can't imagine why you wouldn't love to review a second regulation on certification programs but for us - from a programmatic perspective and for making sure that the public at large had sufficient context to comment on both of these - we thought it would be beneficial to include them both in the same rule making.

So there are a few key definitions in the temporary certification program that we highlight, the first being an applicant. As I'm sure you can imagine, that's someone that's applying for ONC ATCB status and the one thing that I guess I would call out is that we see an applicant being either a single organization or a consortium of organizations that seeks to become and ONC ATCB.

So in the temporary certification program and I'll get into this in a little bit more detail, we expect ONC ATCBs to do what their name indicates, that they both test and certify all in one shot.

And if there are particular organizations out there that only do certification or only do testing, we didn't want to preclude them from linking up and submitting and application as a consortium to become an ONC ATCB.

So an ONC ATCB is defined as an organization or a consortium of organizations that has applied to and been authorized by the national coordinator and it says pursuant to the sections below to perform the testing and certification of complete EHRs and/or EHR modules under the temporary certification program and I'll get into a little bit more detail about how the authorization applies.

Finally, you wouldn't that it is important to define the word "day" or "days." But when it comes down to it, it's a question that we knew we would get; what do we mean by a day? And it could either be calendar days or business days and what we establish is that they would be calendar days so any of the days that we reference in the preamble and in the regulation text has to do with calendar days.

And the day is important as I move on to my next point which has to do with correspondence. We want to default to e-mail as much as possible. I'm sure you can understand that's an efficient way to communicate. A lot of business are on the e-mail nowadays.

Man: Your audio; you've lost your audio.

Jodi Daniel: Okay, you can't hear on the phone?

((Crosstalk))

Coordinator: Your line is back in conference.

Steve Posnack: Thank you. Sorry, everyone. I guess we're having technical difficulty still. Everyone on the phone line can hear me but apparently the Webcast is experiencing some technical difficulties so I think we'll take a quick pause to see what's going on.

All right, we're going to continue on. We know that everyone's time is valuable. Can I get to my next slide, please, so just quickly on correspondence.

We are going to correspond via e-mail as much as possible, but in either case if we do receive information either via fax or through the mail, we wanted to make sure that the data receipt is established because there are time periods that we've proposed for communications between the national coordinator and applicants and the national coordinator and ONC ATCBs.

So in order for us to have finite time periods, we need to be sure the days are counted. All right. So there needs to be an application process. Applications for the temporary certification program are welcome at any time.

Clearly we would appreciate it if folks apply early and often as possible. Step 1 would be the request to the national coordinator and - not yet, sorry - don't submit your applications yet until the temporary certification program's final rule has been finalized.

The e-mail address in there that we know it hasn't been officially activated yet and we won't be able to respond to you with an application until we finalize our policies so we did receive a couple of questions about that as well. Thanks for Carol for reminding me.

So Step 1 would be to submit a request to the national coordinator and indicate the type of authorization sought and that will be for complete EHRs and EHR modules and we also require that the applicant specify the type of EHR module authorization that they'd like to do.

So if they'd like to be authorized to certify e-prescribing modules or clinical decision support modules, we want them to specify the type of authorization that they'd like to receive and what they'd like to specialize in because that's what the scope of their authorization will comprise of.

Step 2 will be to complete an application. Part 1 of the application comprises of general information, a point of contact, etc., some general information about the applicant, requires the applicant to submit documentation related to ISO IEC Guide 65 which has to do with the - it's an international standard on the general requirements for bodies operating product certification systems.

And there is also documentation required related to ISO IEC 17025 which is the international standard that specifies the general requirements for competence of testing and calibration laboratories and I know that there was a point of clarification that I feel I need to make sometimes too.

When we talk about testing laboratories, it's an overloaded term in the healthcare setting. What we mean are laboratories that would test complete EHRs and EHR modules.

And I think the computer is back, so welcome back everyone on the Web. Sorry if you missed some of this conversation but you didn't miss too much and I need to speed up my walk-through anyway so we will continue to march on.

The second part of the application would be a proficiency exam and there are going to be three sections and we've discussed these sections at length in the preamble.

One would be a knowledge quiz and that's to make sure that the applicant understands the certification criteria and standards that are currently in the interim final rule that will be in the final rule on standards and certification criteria.

The second being that they can properly identify the test tools and methods that are applicable to the certification criteria and then third be that they can properly use test tools.

And we expect to give sample datasets and indicate - and require them to indicate - whether or not a test indicates a pass or a fail and if failures occur, why those occur because we want to make sure that the applicant understands and can demonstrate to us that they can tell the difference.

Moving on. The one other element and part of the application that applicants will need to sign-on to are the principles of proper conduct so these are essentially the programmatic requirements that we expect ONC ATCBs to follow, essentially the rules of behavior, the rules of engagement and how we expect them to be upstanding organizations.

They include certain things like attending trainings, notifying ONC in the event of key personnel changes, and then another key element would be reporting to ONC information on certified complete EHRs and EHR modules.

So for this one, if you've caught either of the presentations Carol and I made to the HIT policy committee or HIT standards committee, we expect to make publicly available a public service that will aggregate what we hope is data from multiple ONC ATCBs in a single location, that potential purchasers - eligible professionals and eligible hospitals in this case - will be able to go to to refer and identify whether if they're going to make a purchasing decision, if the products on the list are certified, and that they meet certified EHR technology.

If they've already purchased something and they just want to make sure that it's on that certified list, or if you want to assemble a customized collection of EHR modules and you want to validate that all of them have been certified and that we also require that the - we propose - that the ONC ATCB would have to provide us with the certification criterion or criteria that EHR modules have been certified to, so that potential purchasers can be sure that they cover all the applicable certification criteria they need to meet the definition of certified EHR technology.

And then we're also going to be referring to the principles of proper conduct to determine whether an ONC ATCB is in good standing and I'll discuss that in a little bit more detail.

So the application review process, fairly straightforward. They're going to be reviewed in the order in which they are received by ONC. That's what we proposed. We proposed that we would permitted up to 30 days to review an application.

I've underlined "up to." We hope that it doesn't take 30 days to review an application but we couldn't make it an infinite amount of time so we chose that and we believe that that's a sufficient and acceptable amount of time.

We will review the applications thoroughly according to the parts so we'll review application Part 1 and then we will review application Part 2. An applicant with a completely satisfactory application would then be granted ONC ATCB status.

Moving forward. So what happens if the application includes deficiencies? As I mentioned, we'll review them in the parts, Part 1 and then Part 2. We've built-in some flexibility for minor corrections or omissions that we identify that don't really rise to the occasion of a formal deficiency notice.

If we don't receive the information related to these requests for a minor correction or omission, you know, this could be an accidental forgetting to attach something or leaving a section not as well-described that requires us to ask additional questions that may require a very simple answer in response.

If Part 1 or Part 2 of an application is deficient and we feel it necessary to issue a deficiency notice, an applicant will have 15 days to respond. If the applicant does not respond or if upon review of the revised application the application still contains deficiencies in either part, we will provide them with a denial notice.

And at that point, the applicant will have a final opportunity essentially permanent part so there are really two final opportunities to submit a reconsideration request and we've limited the reconsideration request to only

situations where the applicant can demonstrate that clear factual errors have occurred in the review of their applications.

And due to the amount of time that we are permitting applicants to engage and revise their applications, we think if we get to this point which we hope we don't have to, but I hope you can understand that we had to build all these kind of due process steps into our proposal. Because if we didn't, then if this type of situation were to arise, we wouldn't have a framework to go by.

Moving on, so once an ONC ATCB is granted its status, we would make their names publicly available and we would also make available what the scope of their authorization - what they're authorized to test and certify - and that will either be complete EHRs or the specific types or type of EHR modules.

Here's an area where public comment is important. We'd ask for public comment on whether authorization for complete EHRs should be split to be specific to ambulatory and in-patient so that would provide the potential for an organization to simply seek the authorization to test and certify ambulatory EHRs and nothing more.

As it currently stands, someone who is authorized to test and certify complete EHRs would need to be able to test and certify ambulatory and in-patient EHRs.

Under the temporary certification program as I mentioned about our timeline earlier, there's no renewal of status requirement for ONC ATCBs so that is one thing that we just wanted to get out on the table.

Now moving on to EHR module testing and certification. EHR modules according to their definition are required to be tested and certified to at least one certification criterion. That's at a minimum.

They could be certified up to everything; N minus 1 essentially an EHR module of certification criteria. Now one of the areas where we request public comment on and we are interested in your thoughts is our approach and framework for when privacy and security requirements should apply to EHR modules.

The framework that we've proposed is that EHR modules must be tested and certified through all privacy and security certification criteria unless - and we state three exceptions - the first being if an EHR module or modules are presented as a precoordinated integrated bundle which could otherwise constitute a complete EHR.

So a priori, a group of EHR module developers would package their EHR modules together and present that as one complete bundled component to an ONC ATCB in which case it would essentially look and feel like a complete EHR but it was just made up of EHR modules.

The second exception would be that if the presenter which in this case could be a self-developer or of a complete EHR or an EHR module or a vendor of EHR modules would be able to demonstrate to an ONC ATCB that it would be technically infeasible for an EHR module to be tested and certified in accordance with some or all of the certification criteria.

But the burden to demonstrate that privacy and security don't apply fall to the presenter of the EHR modules to make the case. The third exception would be

if the presenter can demonstrate that the EHR module is designed to perform a specific privacy and security capability.

And this is one that I hope will make some sense to everyone in that if there is a particular EHR module that's designed to do encryption, it doesn't make a whole lot of sense for it to also include an automatic logoff capability.

So we encourage public comments on this framework and any alternatives that we should consider. And I will - oh, and there's one other public comment related to EHR modules which we are interested in public comments on - and that is whether ONC ATCB or ONC ATBs - this is applicable to both certification programs - whether they should certify that EHR modules can integrate with each other.

So for those of you that have an iPhone or another smart phone and you've downloaded a bunch of apps, it's not necessarily a fact that those apps can talk to each other.

This would be we recognize a complex task and there are multiple combinations out there so we wanted to get a sense from the industry and from the public whether or not this would be a worthwhile endeavor and any feedback and operational concerns that we would be aware of.

Okay. Moving on, I'm on - the title slide should say Temporary Certification Program 8 if you're following along - testing and certification in newer versions of certain standards.

In the interim final rule, you'll notice that some of the regulatory text identifies certain standards as minimums and that was done for a specific reason and we include in the preamble a larger discussion about what

minimum standards are and at the present time, they represent code sets like LOINC which is identified as a minimum standard.

And we're interested in public comment as to whether folks should submit newer versions to be approved by the Secretary under the Secretary's acceptance or ONC ATCBs to voluntary test and certify complete EHRs and whether or not the Secretary should proactively identify newer versions that could be used.

So in this case as these two sub-bullets connote - the second one which I'll also mention - we wanted to make sure that if someone were to upgrade their certified EHR technology to a newer version of a standard, that that newer version didn't invalidate the certification status.

And we have proposed that if the Secretary accepts a newer version of a minimum standard that someone would be free to adopt that on a voluntary basis without invalidating their certification.

Moving on. Authorized testing and certification methods. We have a little bit of a Column A, Column B proposal here, completely open to public comment. I could see a number of different methods that we could choose should we go to finalize these proposals which could include moving some from Column B to Column A and from Column A to Column B; some combination of the two and we're interested in everyone's comments in this regard.

At the present time, we've proposed that it's required than an ONC ATCB must have the capacity to test and certify at its facility so EHR vendors or self-developers must have an opportunity to bring their complete EHR or EHR module to the ONC ATCB.

The additional methods that we propose and one of these additional methods must be provided as a capability of an ONC ATCB would be whether they can test and certify at the site where the complete EHR or EHR module has been developed. So going on-site to a vendor would be one example at the site where a complete EHR or EHR module resides.

So this would be going out and testing and certifying a complete EHR - a combination of EHR modules - in vivo at a hospital or remotely which we think has a lot of promise too whereby various Web technologies or other types of automated tools could be established to test and certify through electronic transmissions.

Moving on. Maintaining good standing. As I noted earlier, we expect ONC ATCBs to adhere to the principles of proper conduct, that they refrain from other types of inappropriate behavior and that they follow applicable federal and state laws.

We also had to put in revocation procedures because the question would arise, what do we do if someone's not behaving appropriately and can we do something to either warn them or to revoke their status if we don't believe that they're an appropriate ONC ATCB and that they're not maintaining good standing and following the principles of proper conduct.

So we've established two types of violations. Type 1 violations would include violations of the law or temporary certification program's policies that threaten or significantly undermine the integrity of the temporary certification program.

These would include fraudulently certifying health IT products - incomplete EHRs and EHR modules - and then Type 2 violations would include

inappropriate conduct by an ONC ATCB and violations of the principles of proper conduct.

This would include as I mentioned failing to adhere to the principles of proper conduct or engaging in other types of inappropriate behavior and inappropriate behavior that we put forth as an example would be misrepresenting the scope of their authorization.

So if someone is authorized to test and certify electronic prescribing modules and then they go about testing and certifying clinical decision support modules or some other type of module, that wouldn't be within the scope of their authorization and that would be an inappropriate behavior that we would find to be a violation - a Type 2 violation.

Moving on. So if we revoke an ONC ATCB status or an ONC ATCB status foreshadowing, we knew a priori that a question would be asked well what happens to the certified products of those now former ONC ATCBs or ONC ATBs and we've proposed that the national coordinator would review their facts around why the revocation occurred.

I'm personally hoping that we never have to pursue this, but it's one of those things that you have to build-in because you want to be prepared and you want to have a plan. And if the national coordinator determines that fraudulent certifications were issued, improperly certified complete EHRs or EHR modules would need to be recertified by an ONC ATCB in good standing within 120 days.

And we are interested in our comments with respect to this but we had to - we felt that it was necessary - to propose this contingency to make sure that

people had an opportunity to comment on this; in the very unlikely event that it would occur, we wanted to make sure that we had an approach.

So with the temporary certification program, we would have a permanent certification program and we include a sunset section where right now we really have what is a contextual trigger whereby on the date when the national coordinator has authorized at least one ONC ACB - Authorized Certification Body - to pick-up the reins, that's when the temporary program would sunset.

At that point, ONC ATCBs would be prohibited from accepting new requests to certify complete EHRs or EHR modules and that we've also proposed though that they may complete what is in their queue already so folks that are in process would still be able to get tested and certified.

Everyone else that would want to get certified going forward would need to go to the ONC ACB or hopefully ONC ACBs after the temporary program sunsets.

I'm now moving on to the permanent certification program and I'm going to pick-up a little bit of pace but I only have a couple of more slides left. Definitions, again the same. The only one that I would call out here is the ONC-approved accreditor.

We've identified in our consultations with NIST and in order to build a more rigorous and a more objective and transparent certification program harkening back to the HIT policy committee recommendations that the competencies for testing and the competencies for certifying complete EHRs and EHR modules are different, and there are qualified personnel that are necessary to perform each of those tasks.

So we've proposed and I won't go into too much detail here that in this permanent certification program that NIST through the national voluntary laboratory accreditation program would be responsible for accrediting complete EHR and EHR module testing laboratories and the national coordinator would be responsible for approving an accreditor for certification bodies.

So we have a very brief specific application process for any organization that would like to become an ONC-approved accreditor and we specify the requirements for them to become one. We would only approve one accreditor.

We believe that this consistency is needed and that the applicants for ONC ATCB status would - that that consistency is necessary for them - and that the status for an ONC-approved accreditor as we've proposed would be three years, at which point we would open it up again for any other organization that would want to at least submit an application for ONC-approved accreditor status would be able to compete with the incumbents.

Moving on. Now I'm going to get into saying a lot of this is the same, a lot of this is the same. Correspondence pretty much the same as the temporary certification program; no surprises there.

Types of certification. In the permanent certification program, we expect - and back to the authorization slide that I referenced a lot earlier - the authorization that we were given by Congress and what we interpreted isn't limited to just compete EHRs and EHR modules and we've tried to build in the flexibility for us to certify other types of health ITs.

This could include personal health records, network exchange type of activities and we wanted to make sure that this authorization framework was available to ONC ACBs and that we had the flexibility to do this.

The application would be more streamlined on the ONC side and accreditation as I alluded to earlier would be a major prerequisite and then the principles of proper conduct for ONC ACBs are very similar to the temporary certification program.

The one thing that I would call out to your attention is that surveillance is going to be a more explicit requirement and ONC ACBs would be required to submit an annual surveillance plan on the products that they've certified to annually report their results to the national coordinator. And we would make those surveillance results available to the public once we received them from the ONC ACBs.

And we've requested public comments on the type of priorities that ONC ACBs should look into when they do their surveillance and we would issue guidance including certain priorities for the upcoming year related to surveillance.

So my third slide here on the permanent certification program is all the bullets listed here are all very, very similar and almost the same to the temporary certification program proposals. We're going to skip right through.

Additional specific here. If any of you are familiar with the physician self-referral prohibition and anti-kickback EHR exception and Safe Harbor final rules, we note early on in the preamble that there was a prior process for "recognizing" certification bodies.

We discussed that it's our intention, and as we mentioned in the interim guidance document that we published that we would need to go through notice and comment rule making to do the formal recognition of certification bodies, and that this rule making and these health IT programs would supersede that guidance, and that bodies authorized by the national coordinator in accordance with this rule making would also be included as the "recognized" certification bodies.

The one thing that I did want to call out to folks' attention is the length and validity of certification so the question would be how long does my certification last, and it's really a question of how long is it valid for, how long are the capabilities that the product has been certified to applicable to meaningful use?

So for Stage 1 and what we've - there's a lengthy discussion in this; I hope people find it to be as clear as possible - that as meaningful use changes, and there's been lengthy discussion about getting on an escalator and ratcheting-up meaningful use over time, the capabilities that certified EHR technology will need to provide will also ratchet-up, and the standards would change and increment and there will be additional specificity there.

So to the degree that the certified EHR technology can no longer provide the capabilities that an eligible professional or eligible hospital will need to meet meaningful use - a next stage of meaningful use - that would require them to go back and get recertified to the next stage.

The third thing that I wanted to call out to people would be differential certification. And that's a terminology that we've come up with in terms of I know that it means, that ONC ACBs would be able to test - would be able to certify - complete EHRs or EHR modules to the differences between

certification criteria in a previous year and certification criteria in the present year.

So if only five certification criteria change and all - let's say the other 20 - previous certification criteria are exactly the same, would it be appropriate to just do a differential and certify those other five certification criteria?

It could expedite certification and reduce costs and we are interested in A, when that differential certification could take place, recognizing that there's a difference in rigor between the temporary certification program and permanent certification program and B, other considerations that we should be aware of with respect to maybe why or when differential certification wouldn't work.

So I'm going to turn it over to Carol real quickly to walk through these remaining graphics that if you tuned into our prior presentations you've seen a lot of.

Carol Bean: And I am in the interest of allowing just a couple of minutes at least for some questions just going to tell you in an indicative fashion what these last four slide do.

We're aren't going to go through them but I note that they will be posted and just for your reference, the first two of the last four show the temporary and permanent certification programs in a graphic fashion, primarily focusing on the organizations and stakeholders that are involved in it.

The last two slides show how products and technologies would be certified under the two programs overlaid on the general process that is depicted in the

previous slides and there you will see some numbers that'll say one, two, three, four, five.

Those are identical in both the temporary and the permanent certification programs, so what this facing out to the public an eligible provider who's interested - or household - who's interested in purchasing something or somebody who's interested as Steve talked in the very beginning about checking what certification criteria are available would be the same for them. But it shows how those things interface with the programs themselves, and that's all I'm going to say about these at this point. Thank you.

Jodi Daniel: So this is Jodi Daniel. This is a very quick overview of the details in our proposed rule for the certification program. As I said, we wanted to give at least a couple of minutes for some questions.

I ask that you ask factual questions about anything that we covered today or anything that is specifically in the regulations that we've proposed and again with the caveat that we are in an active comment period so there'll be some limited to what we can answer.

Also again, just want to make the public service announcement that we'd like to encourage folks to comment on our regulations so that we can have the benefit of your wisdom in thinking through our policies for the final rule, as well as if you clarify anything that is not clear in our proposed rule when we finalize it.

So with that, if we can open up the lines for questions?

Coordinator: Absolutely. If you would like to ask a question on the audio, please press star 1. Unmute your phone and record your name. Again, star 1 and record your

name to ask a question. One moment while we wait for any questions to queue. Our first question comes from (Susan Hinton). Your line is open.

(Susan Hinton): Yes, thank you for the presentation. I had a question on Slide 19 if you could return to that slide, please. On this slide, you talked about the date when the national coordinator was going to authorize at least one of the ACBs and then you went on to talk about the ATCBs would no longer be accepted once you have authorized at least one ACB.

So my question is, if we have vendors who are very, very well-prepared and immediately put in their applications for ACB once you start accepting applications and your turnaround - I don't remember what you said your turnaround time was. But let's pretend they get certified in a three-month period, that means that it could be possibly be that very early on in the certification timeframe you could stop accepting ATCBs; is that correct?

Steve Posnack: We don't - with the accreditation process that we've proposed - we believe that it will take some time to both stand-up the accreditation program through NIST and the accreditation program through ONC. So the timeframe that we - in the table that we have in our earlier slide - is what we think the longevity of the temporary certification program will be relative to the permanent certification program so we would expect ONC ACBs to be operational sometime in the beginning of 2012.

(Susan Hinton): Oh, it's their operational as opposed to the application?

Steve Posnack: Correct.

(Susan Hinton): Okay, okay, that's better, I was going to say because vendors would have to start making a decision which way they want to go very early on in the game

and in lieu of that, is it possible for a vendor to put in an application for an ACB as well as an ATCB?

Steve Posnack: I don't necessarily know that they would do both because the ACBs will exist kind of after the ATCB.

(Susan Hinton): Okay. All right, thank you.

Steve Posnack: Yeah. I mean, it will be dependent on the program that is up and running at the time.

Carol Bean: An entity that qualified in our proposal - an entity that qualified under the temporary - could then once we stand-up the permanent apply and qualify under the permanent program. So it could in fact be the same entity that qualifies as a certification body under both the temporary and the permanent but we would only have either the temporary or the permanent occurring at a particular point in time.

(Susan Hinton): Okay, all right. Thank you very much.

Steve Posnack: We did I guess one quick public service announcement that we (unintelligible). We will be posting these slides on our Website. They we hope should be available at the short URL that we have.

I know that we have a portal-oriented Website so the URLs get fairly long. It's healthit.hhs.gov/certificationnprm and we will put up the slides from today's Webinar up on that Webpage and I think if you go to the spotlight corner on the right, there's a certification NPRM link as well that you can click on.

So there's a quick question from the Web. I will try to address a couple of quick questions. One would be when the certification body - the ONC ATCBs - would be announced.

First we have to finalize the temporary certification program's final rule, then they need to apply and then we would need to review their applications which we will do as fast as we can and then at the point where we've deemed them acceptable and qualified, we would announce that they've been granted ONC ATCB status. We would expect that that would occur early summer; late spring or early summer.

Coordinator: We have a few more questions on the audio. Our next question comes from (Brian Ahare). Your line is open.

(Brian Ahare): Hi, thank you for the Webinar today. In reading the NPRM, I noticed there was quite a bit of talk about both open source and full and modular EHRs and just my understanding and my sense is that the certification process is going to be the same for open source as well but could you touch on that?

Steve Posnack: I don't know how specifically to respond to your question. If a product is presented for testing and certification, it would need to meet one of the certification, you know, at least one of the certification criteria if it's an EHR module regardless of it's open source or closed source or proprietary, etc.

(Brian Ahare): Okay, thank you.

Steve Posnack: I know we're running out of time. We'll try to squeeze in a couple of questions.

Coordinator: Our next...

Steve Posnack: How many ONC ATCBs do I expect? Sorry, I'm just pulling it off the list. We mentioned in the preamble that we hoped that there would be up to three. We're received early indications that there are at least three entities interested and there could be more.

That's not to say that all of them will actually be qualified at the end of the day but I think we're seeing a good strong showing of interest that there'll be multiple ONC ATCBs.

Can I repeat the URL? That one's an easy one. It's no www dot. It's just hgtpd://healthit.hhs.gov/certificationnprm. If you go to - it's essentially ONC's main Website. You hopefully should be able to navigate your way.

Jodi Daniel: Operator, are there any other folks on the phone or in the queue to make a comment?

Coordinator: I sure do. I have (Michael Hall). Your line is open.

(Michael Hall): Yes, thank you for a great presentation. My question is is that I've not seen anywhere including in today's presentation what the fees might be that would be charged by the ATCB or the ACB to the vendors for going through a certification. Have you guys come across that topic or breached that subject yet?

Steve Posnack: Sure, so in the impact analysis section of the rule, we tried to rely on the best data that was publicly available which came from CCHIT's presentation I think late this summer - this past summer - which we have associated I think with complete EHRs to be in the several tens of thousands of dollars range

and EHR modules to be in the low thousands of dollars to a couple of tens of thousands of dollars.

That being said, if there are multiple ONC ATCBs, I could not foresee a situation where there wouldn't be price competition and that there could be lower costs, especially if ONC ATCBs specialize in a particular module, their operations and costs may be proportional to the work that they're doing.

(Michael Hall): So you're not going to regulate the rates that can be charged?

Carol Bean: We have not proposed to regulate the rates that would be charged; that's correct.

(Michael Hall): Okay.

Jodi Daniel: Is there another - any other folks on the phone? Well, we'd like to thank everyone for their participation on this call. We hope that that helps you clarify some of the specific issues that are addressed in our Notice of Proposed Rule Making and we look forward to reading your comments and developing a final rule base on some of that feedback that we get. Thank you very much.

Coordinator: That does conclude today's conference call. We thank you for your participation and you may disconnect at this time.

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