

Temporary Certification Program Informational Calls

**Moderator: Janet Marchibroda
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4-5 p.m. EDT**

Coordinator: ...and thank you all for holding. Your lines have been placed on a listen-only mode until the question and answer portion of today's conference. And I would like to remind all parties the call is now being recorded. If you have any objections, to please disconnect at this time. And I would now like to turn the call over to Carol Bean. Thank you. You may begin.

Carol Bean: Okay. Thank you very much. My name is Carol Bean as she said. I'm the Director of Division of Certification and Testing here at the Office of National Coordinator for Health IT. I am joined today by Steven Posnack who is Director of the Federal Policy Division.

This call is an informational call about the ONC Temporary Certification Program. Today's call is targeted at vendors and developers of EHR technology. As you know, ONC posted the final rule on this program on 6/18 and it went final on 6/24.

During today's call Steve will provide an overview of the rule including the differences between the proposed and final version. We are trying to target are

comments to the audience that we have here but also to provide general context.

After Steve, I will provide an overview of the application process for the testing and certification bodies which is a little bit different from the group that's here but I think it's helpful for this group to know what those entities will be doing and then how that impacts you.

In addition, we'll discuss or provide some information around the timing of milestones that are going to be occurring over the next few months and then we will open for Q&A. So I will now ask Steve to (kickoff).

Steve Posnack: All right. Thanks a lot Carol. Thanks everybody for joining us today. Again, another 4 o'clock call but we really appreciate your time. And as Carol mentioned I'll go a little bit into the history of the regulatory process and how we got to where we are today. I know that there are a lot of folks on the line and we thank you for your patience for starting a little bit late. We wanted to ensure that everyone that probably got that hold music the minute before you dialed in at 4 o'clock got a chance to get on, so I will get rocking and rolling here.

So in March - the middle of March we published a proposed rule that outlined both proposals for the Temporary Certification Program and the Permanent Certification Program. So we acknowledged in the proposed rule that we would be separately finalizing these two programs into two separate final rules.

The first rule that recently came out being related to the Temporary Certification Program policies and, you know, this is the first big step that will really set into motion one of the processes that need to be in place, the

certification processes for EHR technology. It will also help certain other ONC programs ready part of their operation.

The Regional Extension Centers for example who will be providing support and resources to healthcare providers in their area seeking to achieve meaningful use, this rule helps kind of set the groundwork for them to communicate what we expect to be coming out in the relatively near future, certified EHR technology.

So generally speaking the rule serves two purposes and as many of you know if you've, you know, received the information for this call, we've tried to target our conversations in the information session to specific target audiences. Today as Carol mentioned is really geared towards the EHR technology developers. So my comments and some of the highlights that I'll give on the Temporary Certification Program final rule will comprise of those facets that are probably of most interest to this target population.

So general speaking the rule serves two purposes. It establishes the process for the national coordinator to authorize organizations to test and certify EHR technology and a lot of the rule focuses on this aspect, the applicants' requirements, what they need to do to successfully achieve what we call ONC Authorized Testing and Certification Body Status. The acronym is ATCB. So you'll hear me say ATCB a lot.

And the application process is an open application process. We encourage any organization that believes they're qualified to review - obviously review the regulatory provisions first before, you know, submitting a request and the requisite information that they'll need to demonstrate their qualifications and competencies. But it's an open application process that anyone can submit an application for.

The other purpose of the rule is to set some of the parameters around the testing and certification of EHR technology. And I'll get into a little bit more detail with respect to my prepared remarks for the highlights of the Temporary Certification Program final rules.

So (taking) together this rule paves the way for developers of EHR technology to get their products tested and certified in a timely manner. This also gets to us to 1/2 of the equation of the phrase "meaningful use of certified EHR technology."

Once this process is stood up and this pipeline is open for products to get in and get tested and certified, you know, will get us to that next point in time where there's EHR technology available that's been certified that can be used to help eligible professionals, eligible hospitals, (unintelligible) hospitals, they're eligible for the incentive payments to attempt to achieve meaningful use or under the Medicaid programs to adopt, implement or upgrade to certified EHR technology.

So I thought as I mentioned that I would gear my remarks to the audience that we requested dial in today. So as I alluded to, there is an application process and a lot of the regulatory provisions are related to that application process. We specify the types of, you know, the definition of an applicant, what an applicant needs to do to correspond with a national coordinator, the prerequisites, the types of qualifications and competencies that they're expected to demonstrate.

We also include a number of kind of - I'll qualify them as due process provisions where deficiencies are identified, in an application, the processes

that an applicant for ONC-ATCB status can expect to go through in order to try and correct their application and so on and so forth.

So a lot of the regulatory provisions really focus on the applicants with the exception of some that are more specific to what an ONC-ATCB needs to do with respect to the testing certification parameters.

So out of the application process will come ONC-ATCBs and we hope that there will be a good handful of qualified applicants and that we will also authorize a good handful of qualified ONC-ATCBs. And out of that application process and the authorization process, there will really be two types of ATCBs generally speaking.

There will be ONC-ATCBs that are authorized to do complete EHR certification. And complete EHR is the term of (ours) that's defined in the interim final rule on standards, implementation, specification and certification criteria. The - an ONC-ATCB that is authorized to test and certify complete EHRs, they're author - the scope of their authorization encompasses both ambu - complete EHRs that are designed for ambulatory and inpatient settings and the scope of their authorization also includes any type of EHR module. So they're really the all-in-on, one-stop shop if you want to get tested and certified.

They're - we hope and we think that this could be a potential avenue for certain organizations that may specialize in certain types of testing and certification and they would focus on the EHR modules which is also another term of (ours) that's defined in the interim final rule.

So ATCBs that are authorized to test and certify EHR modules, what their authorization and the scope of their authorization is going to be limited to the

types of EHR modules that they seek to be authorized to test and certify. So an easy example of that I always like to use is electronic prescribing.

So if there was an organization that wanted to focus specifically on testing and certifying EHR modules, they - and they requested authorization for such, they would be authorized solely to test and certify EHR modules that relate to electronic prescribing and their authorization wouldn't apply to something else. So they wouldn't be able to go out there and convey to the developer community that they also had authorization to test and certify something else like a problem with module.

So the next thing that I wanted to highlight for folks would be the parameters - some of the parameters around getting tested and certified. And these are some of the requirements that we imposed on the ONC-ATCBs that they will in turn expect to either receive or condition on the certifications that they issue to EHR technology developers.

So we have a section which is 170-423 which we call the Principles of Proper Conduct for ONC-ATCBs. Now the Principles of Proper Conduct are really the rules of the road for ONC-ATCBs but it also includes certain specific requirements that they are required to follow in terms of how they operate their testing and certification program.

One being - which is a transparency-oriented requirement in that the Principles of Proper Conduct require that they adhere to certain provisions and that when an ONC-ATCB issues a certification that it hold a complete EHR or EHR module developer through certain transparency requirements as I said which include identifying certain information associated with the product.

And I'm not going to read the rule verbatim for you but there are certain things that when a certification is issued that need to be communicated to perspective purchasers and that's specified in the Principles of Proper Conduct. We also identified situations where refunds are justifiable and there are a couple situations identified in the Principles of Proper Conduct as well.

Another issue that is a difference between what we propose in the Notice of Proposed Rulemaking and where we wound up based on public comments and I'm sure many of the comments that some of you out there have submitted had to do with the authorized testing and certification methods. So in the proposed rule we had laid out a bit of Column A/Column B situation where in Column A we propose that an ONC-ATCB would be required to offer testing and certification services at their facility and then they could choose a number of other methods, one of which they needed to select that I, you know, that I put in the Column B testing and certification method.

Where we wound up in the final rule essentially based on a lot of the public comment and our own assessment of what would be most effective and efficient for the industry was to require that ONC-ATCBs provide for remote testing and certification both for where the EHR technology is developed and where the EHR technology may be deployed.

So in that situation an EHR technology developer may solicit the - an ONC-ATCB's availability to test and certify their product and they would be able to request that the product be tested and certified at their headquarters, at their software development lab, et cetera. And that would be at the development site.

There are the other situations where someone may have an EHR technology that is ready deployed, it's in operation and it's not so easy to test separately

outside of its operational environment, that would be at a deployed site. And we require that in ONC-ATCB offer the ability to provide testing and certification to either of those sites.

Now that's what we require. We don't preclude ONC-ATCBs however they want to structure other business models, et cetera, to offer other types of services. So if they want to fly out a team and they want to offer an in-person review team to come onsite to review the EHR technology, that's well within the realm of, you know, their own discretion. We don't require them to do that. All we require is that they do remote testing and certification for developed or deployed EHR technology.

I'll - got one other section that I wanted to run through quickly and that has to do with both 170-445 and 170-450. And I'm sorry to go into the reg speak but just to identify those sections for you. They have to do - they specify the parameters around complete EHR and EHR module testing and certification respectively.

So the first thing that we wanted to clarify for folks and commenters that wrote in was that we specify that an ONC-ATCB must provide the option for a complete EHR to be tested and certified solely to the applicable certification criteria adopted by the secretary which is at Sub-Part C at of Part 170. And the same is true for EHR modules.

And we provided this clarification in response to comments trying to understand if we envision ONC-ATCBs being able to condition potentially other certifications on the certifications that we were concerned about which would be to the criteria adopted by the secretary. So we made clear that at a minimum and solely EHR developers - EHR technology developers could

expect an ATC - an ONC-ATCB to offer just testing and certification to the certification criteria adopted by the secretary and nothing more.

That doesn't preclude an ONC-ATCB from offering other types of services related to testing and certification. It doesn't preclude them from testing and certifying other types of capabilities that aren't related to the certification criteria adopted by the secretary. All those who are within the realm of possibility and again in this situation we felt that it was helpful to clarify that at a minimum they needed to offer this service so that folks could request to be tested and certified to the criteria that we expect them to be able to demonstrate compliance with.

The other one thing that we tried to do to build in some flexibility, understanding the EHR technology development environment and ecosystem is ever-evolving. And any of us that have been involved in software development or have received upgrades related to software development understand that there are numerous versions out there, numerous development cycles and what we tried to do - and what I hope, you know, folks will agree with that we built in another provision in response to comment which we call inherited certified status.

And to walk through an example of that real quickly is that if a complete EHR for example that is Version 1.0 is tested and certified and it achieves certified status and then somewhere down the line, six months or so, bugs are identified, other functionality that may not be related to anything that got certified or optimized or made more efficient or upgraded, we wanted there to be a more streamlined process for vendors to get those products acknowledged as certified. So what - and this is another expectation that you all out there in the EHR technology developer community can expect an ONC-ATCB to request from you and that you should be prepared to provide.

So in order to get inherited certified status, we take the complete EHR Version 1.0, if there is a Version 1.1, in order for that to receive inherited certified status, you would need to submit an attestation to the ONC-ATCB to enable them to determine whether the newer version has adversely affected any previously certified capabilities.

If it's not - if the upgrade or the bug fixes, et cetera, don't adversely affect any of the previously certified capabilities, the ONC-ATCB has the ability to grant you the inherited certified status and that product would also be considered certified. So we hope that that is a - helps add some streamline and effectiveness to what would otherwise probably be an onerous process of having to get everything re-certified.

So there is a couple other things that I'll probably leave to Carol but just in terms of mentioning in terms of how it fits into the rule, another requirement as part of the Principles of Proper Conduct are that ONC-ATCBs report to ONC. The information on their completed and positively issued certifications on complete EHRs and EHR modules and specific information about them and that's also certain information if you read into the Principles of Proper Conduct, certain information that they're going to require from a transparency perspective of you all to also communicate the perspective purchases.

So that will be the certified HIT product list which the ONC-ATCBs will report to us. I don't want to steal Carol's thunder in terms of all the specifics around that, so I will conclude my prepared remarks here and turn it over to her.

Carol Bean: Thank you Steve. I don't know what to say. You covered - no, thanks. Actually what I'm going to talk about is primarily within the context of the

ATCBs and some of that focusing on what they're required to do and what they're going through in terms of the application process and some of the whys of this.

And one important reason that we believe that the Temporary Certification Program can provide the sort of assurance that we need to have in the industry and for the incentives program is because it's based on state-of-the-art methodologies, best practices and international standards that determine the competency of entities that perform the testing and certification.

We have the application is ready for distribution. We have just sent out this afternoon the first (bowl) list of those applications for authorized testing and certification body status. The ATCB applicants have had to request in writing with organizational information and will be required to do this.

Let me just sort of interrupt myself and say the application period will be open - for ATCBs will be open throughout the entire Temporary Certification Program. And so we - once an organization or an entity submits a properly formed request, they get an application and the application will be reviewed. There are no limits likewise on the number of ATCBs that we are willing to authorize under this program as Steve suggested in the beginning. We welcome and expect to have multiple entities participating as testing and certification bodies authorized by the Office of the National Coordinator for this program.

So once an organization requests in writing an application with their organizational contact information, they must also specify the scope of authorization and that is whether they are going for complete or modular and if modular, which module they are seeking authorization to test and certify.

We have already received quite a few inquiries and a handful of actual what we call properly formed requests and so we are confident that this aspect of the program will go forward with multiple ATCBs.

The application itself for these bodies consists of three components. Instruction which is - an instruction set which is really rather important because the test itself is for people who - for organizations that have not been in this business before, maybe a little less than (unintelligible) think your tax returns and the instructions that come along with that. These aren't quite so detailed or long but they are very important to understand the application itself anyway.

Part 1 was provided in the rule, the content that is Part 1 which essentially is evidence of conformance to the International Standards for Testing and Certification Bodies and the Principles of Proper Conduct.

Part 2 tests - of the application tests the knowledge and competency with health IT with the standards and certification criteria and with testing and the testing tools themselves.

Part 1 is the same for all applicants because applicants can come in for various kinds of things, specifically complete or modular and in order to be sure that we reduce the chance of sharing of tests having a negative impact on the rigor of this, we are individualizing each application Part 2 so the applicants will be required to submit both Parts 1 and 2 in order to have a complete application.

We began accepting applications today but owing to a little bit of technological and bureaucratic snafu we didn't get those applications out until today. So as soon as people or organizations are ready, they can submit them for authorization to test and certify under this program.

Once we receive a complete application we will render a decision within 30 days on the authorization itself. During that period the applications will be reviewed by an internal review board for conformance to the standards and for competency to test and certify.

Once successful in the application process, once the review is complete and a decision is made to authorize, we will post on our Web site the name and contact information of those authorized testing and certified - testing and certification bodies that are available to you as vendors and developers, available to anyone who wants to it. It's a public Web site.

And then what we expect though is that this list will begin to be available that we will have completed review, that we will have authorized testing and certification bodies. They will be operational by late summer. Vendors, developers, et cetera, should work - will work directly with the ATCBs and that's a lot of what Steve went through in the - in his presentation, what some of the aspects of those interactions, relationships, what you can expect working with them, et cetera.

By fall we expect that based on our best estimates that the certified products will - that products will be certified. And here's the thunder that Steve was talking about, a second thing that we are going to have as a public Web site is something that we're calling the CHPL which is the source of truth. That's my little joke.

But truly the CHPL, the Certified Health IT Product List, is discussed and described in the rules. This is a public service Web site that aggregates the lists of all products that are certified by the individual ATCBs. They will post as they deem necessary or according to their own business practices, you

know, on their own Web sites or whatever - however they want to issue that information.

But they are required to report this to ONC and we will post a combined source of all of the products that have been certified under this program in addition so that people can come and sort of do one-stop shopping literally and figuratively and be able to identify all the complete EHR technologies and the modules and what certification criteria these things have been certified to and how to - and information about the vendors.

In addition, another service that we will provide is the capacity for a user to render combinations of products particularly where these are modules and to determine whether in the aggregate the combination that they select on the Web site will satisfy all of the required certification criteria that are associated with completely certified EHR relative to the meaningful use incentive payments.

So that's essentially what the ATCBs sort of this - from the ATCB perspective and we are well aware of the timeframes. We have been working like mad to get this program stood up and I think we have achieved the near impossible with this in getting the rule published and this program is now operational in terms of the ATCB starting down that particular road. A lot of people have worked very hard on this and we are pleased to welcome everybody to this process. We are looking forward to it. And at this point we will now cease our blather and open it for questions.

Coordinator: Thank you. And at this time if you would like to ask a question, please press star 1 on your Touch-Tone phone and you will be prompted to record your name. To withdraw your request, star 2. And once again to ask a question, please press star 1. And one moment please for the first question.

Our first question today is from Larry McKnight.

Larry McKnight: Hi. This is Larry McKnight from Siemens. I actually had two questions. The first would be on the area around a testing of the vendor to new versions. What constitutes a new version? And then the second - for example does a service pack qualify as a new version or are there some rules around that?

And the second question is, for a customer, how do they actually claim the certification that we undergo? For example, do they have to provide some kind of proof of sale or licensure or something and does the customer - or does the vendor have any responsibility in policing that the customers are using that certification seal of our software correctly?

Steven Posnack: So I - this is Steve. I am going to take number one and I'm desperately trying to flip through my copy of the rule here so I can point you to the right footnote which I believe I - we added in. But it's escaping me. Oh, here it is. All right. So we didn't propose to or presume that we would be able to specify what a new version would be. It's kind of really in the eye of the (ACT) developers.

So in certain cases as I understand as a general concept, you know, there is a dot (skimmer) that's used most of the time where minor versions are typically denoted by changing the number on the right side of the dot and the major version is noted by changing the number on the left side of the dot.

So, you know, minor version would be the difference between 3.0 and 3.1 and a major version may be the difference between 3.0 and 4.0. But those too are in the eye of the beholder and however many dots you may have to the right of the first number.

So we didn't specify any types of requirements around what may be a new version. If an EHR developer determines that it is a new version compared to what was certified and they would also like to make that available with this certified status of the prior version, that's where the attestation and the inherited status fits in. And I think Carol can best address the second point.

Carol Bean: Well part of it Steve. I think you - essentially you were asking what cons - you know, what constitutes - what somebody needs to do to make a claim for the incentive payments and that is with respect to the CHPL, the Certified Health IT Product List.

So they said a user, and in this case we would be talking about a purchaser, would put in or select depending, we're still actually developing the - all of the features of this particular technology system, but what they will do it put in the products that they have or select the products that they have and it may be a single product or it may be a combination of products in the case of modules and they'll be able to determine how close they are to satisfying all of those criteria for - that would be necessary for certify - for the complete set of certified EHR technology for meaningful use reporting.

Once they have satisfied all the criteria with the combination of products or the single product, they will be able to retrieve - they will be assigned - that combination will be assigned a single number that will be used for meaningful use reporting and any combination, anybody else that comes through with this particular combination will get that same number.

And so it is sort of - if you think of it as a bundle composite, bundle of products that in the aggregate constitutes certified EHR for purposes of meaningful use reporting and that is the number that they provide to CMS with the rest of the information that is established by that particular system.

Did you have anything you wanted to add?

Steven Posnack: No.

Larry McKnight: Can I follow up with that then I guess? Because the question that - supposing for example that we have a separate financials product and a separate clinicals product and the financials product has eligibility and claims checking and the customer - so that gets a bundled certification from us and we certify everything in one big complete EHR now. Now the customer would - maybe only has the clinicals portion of that.

Does that imply that the customer is attesting to something that they have some piece part of the solution set or do we have to bring multiple certification seals for them to attest to? And then would there be any kind of check other than a self-attestation that they're - they actually have license to use the product and that they are, you know, have it actually installed or are using the components, you know, as (known) interpretation or anything?

Carol Bean: Okay. I think that we'll try to answer this pretty quickly because I suspect that others would be interested in this too but then I think we probably have lots of people queued up for asking questions and we'll be happy to discuss with you directly offline any further (unintelligible)...

Steven Posnack: Details.

Carol Bean: ... that we don't answer here.

However, if you are selling products, if you are distributing products in pieces, you know, as opposed to a complete set, you know, first time if you

have something that's everything, then that gets its own number but if you're selling those pieces and distributing those pieces then those would have those individual certification numbers, those would be tested and certified separately.

So somebody who is just using the one would just have a number that is associated with that one component or in that case that would be a module or a bundle of modules, you know, and we're trying to be completely flexible about we don't want to pin vendors down and we don't want to pin purchasers down in terms of what they can do.

Now we are not, you know, certainly ONC is not, testing whether somebody is actually using, you know, any of this stuff. There are audits that - but as far as the incentive payments and the reporting stuff that's going through, and Steve's getting kind of wiggly here so I think he wants to say something, but that's CMS, not ONC. So I will let Steve rescue me from (unintelligible).

Steven Posnack: No, that's fine. I think - no. It's a great image for everybody on the phone for those of you that may know me. So I think your question really bridges across, you know, both this program and the meaningful use final rule and the final rule for standards and certification criteria that will come out. And it's an issue that I think, you know, will probably (pete) itself out, you know, over time.

The other thing that I did want to mention that Carol also mentioned as well which came up yesterday and made a thought occur to me. For those of you that have intimately experienced the HIPAA privacy and security rules, you will be familiar that over the course of the past six or seven years, the Office for Civil Rights has developed quite a large FAQ database to interpret situations relative to both those rules.

So, you know, there may be questions that haven't presented themselves to us today or before when we were drafting the rules and we may not have a specific answer for you right off the cuff. Clearly if there's a clarification (we) can make in the rule, I can attempt to do so. Some of them we may just have to ask for your patience and to take them back and to see if we can address them through the FAQ process.

Moving on please.

Coordinator: Thank you. And our next question is (Mark Segal).

(Mark Segal): Yes. Thank you. And thanks again for having this call. So I've got a question that relates to the attestation regarding upgrades. If a vendor has two current products available now both of which would be, you know, potentially able to be certified, you know, they share a common code or what have you but one is in effect an upgrade of another, would it be possible to in effect submit the earlier version for certification and then simultaneously submit an attestation regarding the later product? So in effect you're doing this sort of in parallel rather than, you know, sequentially several months later.

Steven Posnack: You make me smile because this is a good question. And it's probably a real world question that obviously you've thought about. So I think that that factual scenario is probably true provided that it meets, you know, the criteria, the framework specified in the rule.

So if there's a product that has the base code and that is for lack of a better phrase, the parent version, and there is an upgrade that I would call the child of that parent version it - I think it would be potential for them to be submitted either jointly or shortly thereafter and that would probably be something that

you'd want to just make sure you communicate to the ONC-ATCB that the one that's getting the primary certification and then the second one would be inheriting that primary version certification.

(Mark Segal): Thanks very much.

Coordinator: Thank you. Our next question is from Jim Tate.

Jim Tate: Yeah, it's Jim Tate from EMR Advocate. Just a process question please. For the potential applicants for the ATCB program, if you - do you intend if you approve those to announce them publicly or are you going to hold it and announce a batch at a time? And kind of a corollary to that, if you get a well-prepared application next week, do you think you'll be announcing ATCBs by August 1?

Carol Bean: Thank you...

Jim Tate: Thank you.

Carol Bean: ... for the question. We - the rule requires that we review them in order in which we receive them. We will - we - once we - the government ONC receives a complete application which is a fully fleshed out Part 1 and Part 2 plus all of the supporting documentation that is required, we have 30 days to render a decision on that.

Understand that the part - that the burden for the ATCBs is actually - for the applicants is actually fairly rigorous to fill out one of these applications and to provide all of the supporting documentation. Essentially they're having to satisfy two complete sets of international standards plus some additional technical requirements that we've added to that.

The Part 1 of the application is the same for everybody and that was published so they theoretically could have been prepared to - already prepared Part 1 for us but nobody will have had Part 2 until they receive the application from us.

Part 2 is the proficiency test, the knowledge exam, the - it tests capability in addition to general knowledge of the program and the standards and certification criteria, tests their competency to use the test tools to test data, the actually perform the testing and certification itself. And this is something that I doubt somebody could do overnight or even in a couple of days.

And so I think that the applicants for this authorization have a fair amount of work to do to be ready and then for us to review that will take some - as much time as well to come up with these decisions, you know, assuming that everything's good. And the expectation is that we will have multiple bodies that will be authorized to do this.

But we are confident that by late summer based on what we have seen, the research that we've done, the public comment, the analyses that we've prepared that we will have these bodies in operation before the end of summer. But, you know, we are - I must confess since we haven't done this before, starting a whole new program like this from scratch we've got to keep our fingers crossed and...

Steven Posnack: I mean there's - just a follow up on Carol, I mean there are also some practical realities about an application process where I think, you know, we're encouraged by the amount of interest that's occurred thus far. We think that there are a few people that, you know, have gotten a good (jump) that have been following, you know, the regulatory process so they at least know what's gone on with Part 1.

And, you know, it's quite possible that we could get a couple applications within a few days of each other and, you know, they'll be processed in the order in which they're received. And it's going to depend on if, you know, we get three applications right away and one of them has a deficiency, you know, that deficiency will need to be addressed and work through the process and the other two may sail through.

So I - with respect to announcing them, we do specify in the rule that we will make the names of the organizations that are granted ONC-ATCB status. We'll make that publicly available. We'll put them on our Web site so that everyone will know who those organizations are.

I don't want to commit to anything in terms of timing with respect to, you know, lumping them in a batch or anything but I think if we have them ready at the same time, we'll make that information available. If it doesn't look like they're going to be ready at the same time, then we'll have to cross that bridge when we come to it.

Carol Bean: But specifically speaking, we're not going to hold anything back. We need to be efficient with our processes but we're not going to hold anything just for the purposes of batching it.

Steven Posnack: Next question please.

Coordinator: Our next question is from (Joe Wolf).

(Joe Wolf): Hi. I have a two-part question. One, is there - are there going to be any pricing guideline for the ATCBs in pricing the certification for modules, et cetera?

And secondly, as time goes on, what body or bodies will provide oversight of the ATCBs and of the developers?

Steven Posnack: So I'll take number one and then I guess maybe partially number two. So pricing was an issue that came up. We did not believe that it was something that should be addressed by our rulemaking. Our rulemaking was to establish the process for authorizing the certification bodies and some of the parameters around testing and certification. And we tried to address potential pricing concerns by creating a competitive marketplace which we think we've succeeded in doing based on the number of applicants out there.

So it's going to be a supply and demand, you know, market-based environment out there where if, and we hope that there will be, multiple ATCBs, there will be some pricing pressure for folks that are interested in getting tested and certified.

And then the second one was...

Carol Bean: About monitoring.

Steven Posnack: ...monitoring.

(Joe Wolf): Oversight monitoring.

Steven Posnack: Yeah. So in the Temporary Certification Program, and I'll do a little bit of a compare and contrast between the Permanent Certification Program, in the Temporary Certification Program, we, ONC, will be the kind of oversight mechanism with respect to the ATCBs.

We require that they adhere to the Principles of Proper Conduct which I mentioned earlier that they have to - there are a number of requirements that they need to follow in terms of making sure that they continue to be compliant with and conformant with the international standards that Carol mentioned, that they attend training programs, that they communicate with us on a regular basis if they change key personnel, et cetera. But they're otherwise following all of the rules that we specified in the Temporary Certification Program.

So if we find that they aren't doing any of those things, we also specify certain types of violations which you can find in Section 170-465. There are two types of violations and for some of those we provide the opportunity for them to correct and identify violations.

So if they skip out on a mandatory training session, there's the potential that they could be cited for what's called a Type 2 Violation and they'd be give an opportunity to become compliant. So, you know, could potentially require them to attend another training class. And, you know, that will be a little bit different in terms of what we proposed and this is strictly proposals because we haven't finalized the Permanent Certification Program rules. Let me make sure I squeeze that caveat in.

You know, in the Permanent Certification Program we laid out a little bit of a different approach where there would be an accreditation layer so what we call an ONC Authorized Certification Body in the permanent program would need to be accredited by and accreditation organization. And in that environment if those proposals get finalized as they were, hypothetically speaking, you know, there would be some additional oversight which would probably more be directly be in line with the accrediting organization and the ATCB in that case.

But for the sake of being specific and answering your question in a nutshell, ONC has a lot more of that responsibility in the Temporary Certification Program. Carol's going to comment on that.

Carol Bean: And I would like to add, you talked about oversight and monitoring of both the ATCBs and the vendors. And in the permanent program we have proposed a full-blown - the permanent program is much more full-blown third party conformance assessment. And part of the certification there is surveillance and it would essentially amount to a post-market surveillance program. And if that component is part of the final permanent program, that will be one way in which the vendor side will be monitored in addition to the other things that Steve talked about.

One final thing we are investigating, again based on comments and questions that we have received, investigating mechanisms for complaint. And this is both complaints about the - any of the entities that are participating and this is about any of the entities that are participating in the program. That would be whether they are testing bodies, certification bodies, testing and certification bodies or vendors relative to product.

The consumers are very concerned about having a way to - having a voice in this as well and so we have not established anything yet but are investigating appropriate mechanisms for that.

(Joe Wolf): Maybe Steve's home phone number.

Carol Bean: There you go.

(Joe Wolf): Thank you very much for your answer. I appreciate it.

Steven Posnack: So I think we've got time for a couple more questions. We obviously want to be cognizant of folks that have other things to get going to I'm sure. I'm sure you would love to stay on the phone and I know we would too to keep discussing things. But like I said earlier in my comments, you know, we envision that we'll have to come up with a more comprehensive FAQ system that will evolve and mature over time. So we'll take a couple more. For those of you on the West Coast so you can get to you 2 o'clock and operator let's like someone else up.

Coordinator: Our next question is from Zachary Morgan.

Zachary Morgan: Yes, I'm Zachary Morgan with the MEPS Corporation. I'm sure you have some idea in terms of what to expect related to the range of fees, if you can perhaps share that with the group. And second of all - secondly, would there be opportunity once we are certified whether it's complete or on a modular basis, will we be able to put some type of seal on our technology?

Steven Posnack: Sure. So, you know, the - when we approach a - and I have to do this from a regulatory perspective. You know, when we approach the writing the rules, there are requirements that we have to go through a regulatory impact analysis. And in the back of the rule, you know, we kind of go through some of those numbers. And what we try to do is come up with reasonable estimates that can be based on assumption.

And in certain situations if there is data available to inform those assumptions and estimates, we try to use that data. So what we did was DCHIT had Certification Commission for Health Information Technology had presented I think at some point last summer at this point potential pricing ranges for certification and we generally use those as the range for our estimates.

That being said, as I mentioned, you know, we're hoping that the competitive environment that we have tried to create with an open application process and the interest that we've tried to generate with the certification program that, you know, that there will be a different cost structure and potentially one that may be more advantageous for vendors to get their products certified.

I couldn't say what I would expect their potential range to be. I mean I think we'll see how competitive some of the authorized testing and certification bodies want to be.

And then with respect to the seal, we do require, and this is in the Principles of Proper Conduct, that the ONC-ATCBs when issuing a certification to a complete EHR or EHR module developer that that complete EHR or EHR module developer communicate in any of it's - on its Web site or marketing materials or other communication statements, certain information to perspective purchasers.

There's a few lines of information that we expect to be communicated in addition to some of the other specific information that they also need to report, so the vendor's name, the date certified, the product version, any specific unique certification number that the ATCB may assign it.

I'm assuming, and this is going to be up to the ATCBs, we don't specify specific seal or label other type of image but as long as it's within the parameters of what we expect to be communicated to potential purchasers, that's something that could be determined by the ONC-ATCBs.

Zachary Morgan: Thank you.

Steven Posnack: One more question.

Coordinator: All right. We have one more question from (Maneer Ahmed). Your line is open. (Maneer), your line is open. Please check your mute button or pick up your handset.

Steven Posnack: You're caller Number 7.

Coordinator: Okay. We'll go to the next question. That will be from (Rodney Mariwalla). Your line is open.

(Rodney Mariwalla): Yeah. Hi. Thanks. This was a very nice session. I wanted to direct a question at you with regard to the two additional elements that have been mentioned that need to be listed on the Web site of the ATCB and those are with regard to the clinical quality measures and about any applicable additional software that a complete EHR module is relying upon.

So my question is, in the factors that be measures, the quality measures have not yet been released, so how does a vendor who's applying for an ATCB (rule) communicate to the ONC that he has the capability to test the clinical quality measures because they have not yet been released?

Steven Posnack: Right. Some of this is a timing question but some of this is also what needs to be communicated once the product is certified and that's really where these requirements come in. You know, there are - as they're framed in the interim final rule, there are complete EHR and EHR modules designed for an ambulatory setting and there are complete EHRs and EHR modules designed for inpatient settings. And each of those settings have different types of quality measures that apply to them. So we wanted to make sure that there wasn't any confusion related to those quality measures.

And that being said as I mentioned on one of the prior commenters there is a - this kind of bridges over to the fourth coming final rule at which point more specificity will be available. But regardless at a point in time when a product is ready to be certified, that's the type of information that would be communicated.

And to answer your second point, the relied upon software, we do provide an example in the rule and I'm going to try to remember it verbatim but forgive me if I don't, you know, there are situations we recognize where a complete EHR or EHR module may rely on other software to satisfy a certification criteria and to demonstrate to an ONC-ATCB that it was compliant, fully compliant with that certification criterion.

So the one that we use that I'll use again had to do with the automatic logoff. You could design EHR software that includes natively the capability to automatically log a user off after a predetermined amount of time. You could potentially also rely on the operating system to time someone out. And if that type of capability is relied upon when demonstrating to an ONC-ATCB, it would need to be cited as software that was relied upon rather than something that's natively capable that the EHR technology is natively capable of.

(Rodney Mariwalla): Right, right. Thank you.

Steven Posnack: All right. Well I don't want to do it on behalf of Carol and I but I'll start and then she has one public service announcement. We are very thankful for your time. We expect to engage with you on future endeavors and, you know, as I mentioned we'll probably be putting together more comprehensive FAQs as things mature and as questions come up and as they become more frequent. And I will turn it over to Carol.

Carol Bean: Yes, Steve is absolutely correct. We are developing and continuing to compile and develop FAQs, information, that kind of stuff. And to help us do that if you have further questions or comments, we set up an email box and it's onc.certification@hhs.gov. And that email box I monitored and we will - we're setting up the parameters for response times. But as you can imagine we're getting a lot of questions right now and please continue to be patient but we will respond as soon as we can and your questions are very, very helpful to us. And we thank you and look forward to continuing to work together.

Steven Posnack: It's all yours operator.

Coordinator: Thank you. That concludes today's conference. We appreciate all your participation and you may now disconnect.

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