

Temporary Certification Program Informational Calls

Moderator: Janet Marchibroda

June 30, 2010

4 – 5 pm EDT

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen only mode.

At the end of the presentation we will conduct a question and answer session. To ask a question please press star 1. Today's conference is being recorded, if you have any objections you may disconnect at this time.

Now I will turn the meeting over to Miss Janet Marchibroda, ma'am you may begin.

Janet Marchibroda: Hello and welcome. This call I'm actually turning it over to Carol Bean who directs the certification program here at the Office of the National Coordinator.

Carol Bean: Okay thank you Janet was instrumental in getting these calls set up so we very much appreciate this. Welcome to everyone as Janet said my name is Carol Bean, I am the Director of Certification and Testing here at the Office of the National Coordinator.

This call is the first of four informational calls that are targeted to specific stakeholder groups who are interested in the Office of National Coordinator's temporary certification program. This particular call is directed at potential applicants to achieve status and authorization as an authorized testing and certification body.

And during today's call we have Steve Posnack who is the Director of Federal Policy Division. Steve will give - provide us with a brief overview of the rule including some of the history and timelines there as well as some of the difference between the proposed rule and the final version.

Then I will provide an overview of the application process and some of the timing of some of the important milestones over the next few months and where we're going from here.

Then we will have a Q&A session. Our conference moderator will assist us in unmuting people when they want to talk and it should be noted as well that again that this conference is - this call is being recorded and transcripts will be available on line on the ONC Web site at some point in the near future.

So I would now like to turn it over to Steve Posnack.

Steve Posnack: All right thanks Carol, thanks everyone for dialing in between the 4 and 5 o'clock time at least on the east coast. So I'm going to give a little bit about the history and catch us up to where we are today.

And then shoot it back over to Carol to get into more of the details of the temporary certification program itself. So just to catch you up in case you haven't been keeping track as much as you would have liked, in early March

we published a notice of proposed rule making that included proposal for both a temporary certification program and a permanent certification program.

We noted in that proposal that we would finalize each of those programs separately. The rule that we're here to talk to you about today is the rule related - the final rule related to the temporary certification program.

So this rule is really the first big step that will set into motion one of the processes that needs to be in place, the certification processes for EHR technology.

It will also help certain other ONC programs already part of their operations, their regional extension centers for example who will be providing support and resources, the other health care providers in their areas seeking to achieve meaningful use.

Generally speaking the rule serves two purposes. It establishes the processes the National Coordinator will use to authorize organizations to test and certify EHR technology.

It's an open application process, completely open so as Carol mentioned the target audience for today's call are potential applicants so I'll kind of focus my bit of summary of the rule around the areas that potential applicants should keep in mind.

And the second general purpose of the rule is to set some parameters around testing and certification of EHR technology.

So taken together the rule paves the way for EHR developers to get their technology certified, tested and certified in a timely manner.

And it gets us one half of the equation once something comes out of the testing and certification process to that one half of the equation of the phrase meaningful use of certified EHR technology.

So I'm just going to step through very quickly for potential applicants and highlight of the temporary certification program final rule.

I'm kind of grouping it into three general buckets, three or four general buckets and I will go forward. So there's an application process and the application process Carol will get into a lot more detail about.

But generally speaking it specifies the submission parameters and the timelines associated with submitting an application and the review process.

But generally speaking the application process is to assess an applicant's qualifications and competencies and in order for them to demonstrate to the National Coordinator that they are fit to test and certify EHR technology.

There are also a number of sections in the regulation that I won't get into in any detail on this call but let's specify some due process.

In the event that deficiencies are identified with the application, it lays out a process that applicants can expect both to be engaged in and for us to follow with respect to reviewing the application.

So the second kind of general bucket that I'd like to convey is that there are rules that need to be followed and in many of the sections that once authorized by the National Coordinator ONC authorized testing and certification bodies or ONC ATCBs.

So you'll hear me say ATCB a lot, I'll use that acronym from now on that these ATCBs need to follow so I'll - one is how you will represent yourself once authorized.

So in communicating your authorized status, making sure that you're making the scope of your authorization properly known to the potential people that seek, gather products tested and certified by you.

If you're authorized to test and certify complete EHRs which include both EHRs designed for ambulatory and (ambient) patient settings, you're also authorized to test and certify EHR modules.

So that's one of the things that we discussed at length of the preamble of the final rule. If you're authorized to test and certify solely EHR modules, one of the application requirements that you'll note is a prerequisite noted in the rule that you need to specify what types of EHR modules you'd like to be authorized to test and certify.

And that will encompass the scope of your authorization if you test and certify EHR modules. So for example if you seek to test and certify electronic prescribing modules and that's all that you request authorization for, that's all the authorization that you're going to get.

That doesn't mean that you can't seek authorization down the line to do other EHR modules, it's just means that at the present time your request for authorization for that scope is what it's going to be.

So there are also some - with respect to the testing and certification of both EHR modules and complete EHRs, there are some implied steps that you

should be aware of as potential applicants that the folks that interact with you via EHR developers will need to provide you.

So one example would be in the final rule we provide some flexibility for complete EHR developers or EHR module developers to upgrade their products to different version numbers provided that they haven't adversely affected any of the certification - the capabilities associated with the certification criteria adopted by the secretary.

So if bugs are identified, if additional functionality not related to something that needs to be certified is improved or made more efficient or optimized and it calls for a version number change, we've provided for some flexibility which we call inherited certified status.

And as part of that process you get inherited certified status complete EHR developer for example will have to submit an asset statement to an ATCB to explain what the changes were and to attest that they haven't made any changes that would adversely affect the certified capabilities.

So that's one of the things as a potential applicant and maybe as a future ATCB you need to be aware of in terms of information that needs to be submitted to you. So carrying on, there are also what we call the principles of proper conduct.

And this is section 174.23 which specify really the rules of the road for ATCBs. It includes a number of different requirements that we expect ATCBs to adhere to.

Some related to transparency, some related to training and general interactions with ONC to keep us up to date on what's going on. So the last thing that I'll

note is that kind of walking you through from the birth of an ATCB to the - to any requirements that you need to follow is that we've also built in some processes that if you're not adhering to the principles of proper conduct or if you know for whatever reason there's some other type of legal issue that the ATCB is involved in.

We do have a requirement that the ATCB maintain good standing and if they cannot maintain good standing we have kind of two processes well built into the rule that there's opportunities to correct any of the issues that we may identify or that may come up that could affect an ATCB status.

Or there are also processes to in the very unlikely event that we need to pursue revoking someone's status we have those processes laid out as well so that you know what to expect.

With that being said I will turn it over to Carol to walk you through the application process and other facets.

Carol Bean: Okay, thank you Steve. That was a really high level and fast trip through documents and ended up being about 250 pages long. And some of the important policy implications of the decisions that were made underlying the regulatory decisions themselves.

I'm going to actually believe it or not be a little squishier in the things that I talk about. I would like to hit the highlights of the operational side of things here which is the things that we're shifting into at this point.

Having had the rule finalized we are now ready to implement and would just like to say at the outset that one important reason that the temporary certification program can provide this sort of assurance that we need to have

in program of this magnitude importance and scope is because it is based on state of the art methodologies, best practices and international standards for determining the competence of entities to perform testing and certification.

Now I will provide in my own small set of highlights about what's coming next and the timing of some important milestones. We are right now in the final stages of preparation of applications for distribution.

We expect if all goes well and the internet stays up and the river don't rise we will send out applications tonight to those who have requested, who have issued proper requests and requests have to be - and this was stated in the rules - need to be by somebody who expressed what their organization was and specifically the scope of authorization that they were seeking.

Or the scope for which they were seeking authorization contact information and things like that. Just FYI we have received approximately 40 inquiries and approximately 15 formal requests thus far and so we will be responding to those as soon as we can.

We will begin accepting applications tomorrow so if you're fast and can get it done and back to us overnight I'm kidding, this is a little bit small - certain sense of humor here.

But truly given that the Part 1 of the application was published in the rules there's no reason to expect that people who are interested in achieving status as ATCBs have been preparing.

And I think we've gotten a lot of evidence indicating that that actually is the case. So we are ready - stand ready as soon as we send these things out and ready to accept the applications and to process them.

The application itself consists of three components. Part 1 which was in the rules provides evidence of conformance to the standards for testing and certification bodies and the principles of proper conduct that Steve mentioned.

And one of the key things I would like to say right there is there is a stipulation to attend mandatory training sessions when those are deemed necessary. And I believe we probably will have several of those starting very quickly, as soon as we have authorized testing and certification bodies in place.

So the Part 1 of the application as you have seen if you've familiarized yourself with the rules, it captures general identifying information, self audits to ISO IEC Guide 65 and ISO IEC 17025, 65 deals with the requirements for certifying bodies and 17025 for testing and calibration labs.

Also requires - Part 1 requires the submission of additional documentation that is related to the self audit such as a quality manual, a couple other things.

And then the principles of proper conduct. Part 2 - Part 1 is the same for all applicants, that's one reason why we were able to print it in the federal register and part of the rules.

Part 2 will be individualized. As we noted people have - entities have the option of requesting authorization to do complete EHR technologies or also to do modules.

And once an entity expresses the scope of authorization through then we are able to produce tailored Part 2 is the proficiency test which tests general knowledge about the program, about the test methods, about the data.

About the test procedures, about the test tools, etcetera and so those can be - those aspects can be customized to the scope's authorization thought. And as well we are no - just FYI Part 2 will be individualized also with respect to the specific questions that each individual applicant will receive.

No two Part 2s will be the same and so you will be tested against some of the certification criteria, these are fairly rigorous tests we believe.

But to ensure that each test is unique we will be testing each applicant on a subset. So it's a very large subset but on a subset of the criteria.

Just also application parts one and Part 2 may be submitted separately again because with the realization that people may already have prepared or have gone a long way down the road for preparing Part 1 while they have not seen Part 2.

And they won't see it until we send it to them, we will accept Part 1 prior to Part 2. So we will accept the two parts separately. However an application is not complete until both parts - until all components of both parts are in our hot little hands.

And we'll form a completeness review of those to ensure that all aspects of the application are there. At that point once an application is complete our time clock starts. And we must provide a decision within 30 days of the receipt of the full and complete application.

So we will begin accepting applications tomorrow. Once we have an application the application will be reviewed. For every app they will be

reviewed in order and for every applicant Part 1 will be reviewed before we review Part 2.

You must be successful - have a successful application of Part 1 and Part 1 as you may recall tests the conformance to the standards for testing and certification body.

Part 2 again is the competency test and knowledge test so we will not review Part 2 until there is successful review of Part 1.

So that's one key factor. As soon as the full review has been completed on the part of ONC's internal review board, the National Coordinator, a recommendation will be made to the National Coordinator.

And the National Coordinator will make - or his delegate will make a final decision on authorization. And we will notify the applicant of that decision.

And provide the necessary paperwork, etcetera, an actual shiny certificate, something nifty you can hang on your wall. But the papers that - and the number that gives you the authority, not gives you but the letter gives you the authority, the certificate will demonstrate that.

We will also provide a list of all ONC authorized testing and certification bodies, the ATCBs on the ONC Web site so that anyone who is speaking to identify who are the bodies who are authorized to test in this program, test and certify in this program can find them very easily.

We expect this is our expectation programmatically that ATCBs then will be operational. Now we understand that once you were authorized there is still

some work to do on the part of a successful applicant who is authorized to certify under this program.

But we are anticipating that ATCBs will be operational in late summer. And as Steve discussed, vendors, developers, etcetera will work directly with the ATCBs.

One of the things that we are requiring is that ATCBs provide us on a regular basis as indicated in the rules, lists of the certified products with specified information about the version number, the product, the vendor, things like that.

As well as the certification criteria to which these products are certified. We will post those, we will have what we are calling a CHPL, the C-H-P-L, certified health IT products list available from our Web site as a public service that will aggregate the list of certified products and certification criteria to which they are certified in one location.

Of course an ATCB can post their - the products on their own Web site but we are compiling an aggregate list as a service to the public with respect to that.

Another - and that we expect as soon as there are - to have available as soon as they are you know completed by the ATCBs and the market.

The final thing I would say is the CHPL will also later in the year, this will not be immediately but later in time, the anticipation that's in time for when the actual reporting goes on for meaningful use will provide the capacity for someone to come in and particularly if they choose the modular route to say I have these modules.

If I put them all together do I have complete certified EHR and this will provide them the capacity to sort of build composite pictures of the aggregate that they themselves have or are considering.

And to determine whether those products in the composite do satisfy all of the criteria. So that is pretty much I think what I wanted to say at a very high level and so I think at this point we will open for questions.

Coordinator: Thank you. We will now begin the question and answer session. If you would like to ask a question please press star 1. You'll be prompted to record your name.

To withdraw your question you may press star 2. Once again if you would like to ask a question please press star 1. One moment please for our first question.

Our first question is from (Sanjay Matal), your line is now open.

(Sanjay Matal): The question I have is for in order to apply for this certification, to be able to test the EHR, the organizations which would be given priority would be non-profits or for profits then we can also apply for it?

Steve Posnack: We don't specify the type of organization.

Carol Bean: And it's first come first served.

(Sanjay Matal): Okay. Can I ask another question?

Steve Posnack: Quickly.

(Sanjay Matal): Sorry about that. Do you need to have a certain number of these testing already done in order to apply or you know any new company can start applying for it as long as they meet the criteria?

Carol Bean: As long as you satisfy the requirements and the application we will consider any entity for authorization to do the testing and certification.

I would assume that it will - as I said early on these are fairly rigorous requirements to - and you know for the international standards to meet these international standards even though the application may look rather short.

It's a self adaptation that one is - that one's organization is in conformance with all of the requirements of the two guides, 65 and 17025 that I mentioned.

And some documentation that demonstrates the conformance to that, however it is the sort of - how to put this, I don't think it's something that someone could do overnight.

I think if you're not familiar with the guide, familiar with the requirements, familiar with the processes it may be more difficult to do this from scratch.

However I would say we certainly are willing to entertain applications from anybody, whether you've ever done this before or not. If you can meet the requirements for authorization, you're there.

The other thing that I would encourage is this is Part 1 of our entire program. We have this temporary phase that is intended to get things up and running very quickly in order to meet the statutory requirements.

But as Steve noted there will be another program that will follow behind this that will start you know in the future sometime after we are able to develop it.

It will be even more rigorous but that will also provide newcomers to this industry a little more time to be able to prepare themselves for this.

(Sanjay Matal): Okay, thank you so much.

Coordinator: Our next question is from (Ann Matthews), your line is now open.

(Ann Matthews): Thank you. Is there a limit on the number of ATCBs that will be approved?

Carol Bean: No.

(Ann Matthews): Quick one other, what kind of organizations are you expecting to apply?

Steve Posnack: Can you clarify the kinds?

(Ann Matthews): Right, what types of organizations are you expecting, are you expecting other vendors to apply or are you expecting consulting companies or what type of entities are you expecting or are you hearing from?

Steve Posnack: I think our general expectation is the organizations that are in the conformance testing and certification realm that have expressed the most interest. Like Carol said though if someone can demonstrate to us their competency in meeting the international standards, ICO Guide 65 and 17025 you know we would review their application just like anyone else.

I think it's also important to mention that there are specific conflict of interest requirements in those guides so you know there's no kind of fox guarding the

hen house issue if there's a concern in terms of you know untoward relationships, so a body that could be authorized and also be certifying products that it may have a competitive interest with so to speak.

Carol Bean: I would like to if I may for both the previous question and this one I think both Steve and I have focused on the international standards. But there is Part 2 which is the competency exam as well.

The proficiency test to determine competency in using the tools in testing and certification. But we would still expect entities who have had or who must be - and who must be able to demonstrate their competency in using these tools.

So let's all don't forget Part 2.

(Ann Matthews): Thank you.

Coordinator: Our next question is from (Marvin), your line is now open.

(Marvin): Yes hi, this is (Marvin). I wanted to ask let's say we become one of the ATCB but we also have developed an EHR program in house.

Is it possible to self certify that the technology or not?

Carol Bean: No. That would be against the conflict of interest aspects of the program.

(Marvin): Okay, thank you.

Coordinator: Our next question is from (Kelly Broder) your line is now open.

(Kelly Broder): Hi, my question is with respect to the mandatory training sessions for ATCB and it's whether - are applicants - would they be required or permitted to attend those sessions before they're approved as an ATCB?

Steve Posnack: You have to be an ATCB before you're required to attend the mandatory session. I think is your question more along the lines of if someone that's not an ATCB could also attend those?

(Kelly Broder): Correct.

Steve Posnack: We haven't made a policy determination on that but I would expect that we would most likely for the first round work with just the people that we've authorized.

(Kelly Broder): Great, thanks.

Coordinator: Our next question is from (Elliot Sloan), your line is now open.

(Elliot Sloan): Yes hello. I have a question about the testing methods. The final rule explains that the open endedness of a substantial equivalent testing has been eliminated and that any proposed alternatives to the NIST tools would have to be submitted for consideration.

First is that a correct interpretation?

Steve Posnack: So what we did in response to public comment in terms of trying to restructure that requirement was to provide a single point of submission for test methods, regardless of who the kind of author of the test method was.

And the National Coordinator would review those to determine their you know certain factors when we specified this in the preamble with respect to how they associate with the certification criteria to make sure that they're comprehensive enough to be able to use, to test and certify.

So anyone can submit testing methods.

(Elliot Sloan): Okay. Then is it - would it be acceptable to submit a - what I might describe as a super set of testing methods that would perhaps be more like the NHIN exchange that also explicitly exposed and covered each of the mandatory NIST tests.

So could an organization that has a much more complete EHR solution possibly tested in a more extensive way with a test set being acceptable test set to submit?

Steve Posnack: So the - one of the clarifications that we made in the final rule was that the ATCBs were required to offer the option to test and certify complete EHRs or - well in most cases complete EHRs so that only the certification criteria adopted by the secretary - the test methods that we would adopt - that we would approve through the National Coordinator would be associated with the certification criteria.

So if there are others that went above and beyond or were you know related to other certain types of functionality that were required for certification, I don't necessarily think that they would be part of what we would approve.

Carol Bean: The things that we would approve would be directly related to the certification criteria adopted by the secretary and I'm going to sort of restate what he said but in a different way just to make sure.

Any ATCB and as a matter of fact we expect that many would be testing and certifying in other areas and for other things. But they also must in order to be authorized to test under our program have a testing certification program that is limited exclusively to the standards and certifications to our program itself.

And so they would be welcome say to have some other kind of certification but they can't call it that and we have labeling requirements that protect you know the folks that are having the certification.

Essentially so anything that we would approve would be similarly limited to the criteria that are specified in the rules for our program.

(Elliot Sloan): Okay, thank you.

Coordinator: Our next question is from (Sanjay Matal), your line is now open.

(Sanjay Matal): Thank you. This is in relation to extension of the question that was asked before if for a company who gets this ONC ATCB status they cannot - if they have a product they cannot you know certify that product, that would be conflict of interest.

But they can take their product to other ONC ATCB and that should be okay, right, that's not a conflict of interest in that case, right?

Carol Bean: I don't think so.

(Sanjay Matal): Okay, so what's the answer? Answer is a company cannot be a certifying body but they can have their own products?

Carol Bean: There must be - okay there are a couple things, there must be - they can have their own products if - but they cannot self certify, they cannot certify their own products.

Those must go through a completely 100% totally separate third party specification process as well we would expect that certification body to look very closely at something like - I mean they're going to look very closely at everything but at anything that comes through that's what they're supposed to do.

But there I think would need to be a fairly I would imagine a fairly strong firewall between those two components of your business if you want to be an ATCB plus a vendor developer type kind of entity.

Because those aspects are addressed within the guidelines, the international standards 65 and 17025 about how you must separate out your different aspects of your business and what can touch what and who can see what and things like that.

So presumably it's possible to do that if one satisfies all of those criteria.

(Sanjay Matal): Okay. Thank you.

Coordinator: We have no further questions at this time.

Carol Bean: All right, well thank you very much. We appreciate your attention. We will post - we are going to have the transcript of this presentation and the question and answers as well.

We'll post those as soon as we get them prepared and would like to encourage you to if you have further questions contact us.

And that is at the mailbox directly for the certification program is onc.certifications@hhs.gov and if you would like to request an application for authorization to be an ATCB that would be atcbapplication@hhs.gov.

And you would need to provide organizational name, contact information and the scope of authorization sought. And that ends our public service announcements. Thank you very much for your patience and your interest and we look forward to hearing from you.

Coordinator: This now concludes today's conference, you may disconnect at this time.

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