

Temporary Certification Program Informational Calls

Moderator: Janet Marchibroda
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10 – 11 am EDT
[Health IT Developers]

Coordinator: Thank you for standing by.

At this time, all participants are in a listen-only mode. We will conduct a question and answer session during the conference. To request 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.

I will now turn today's meeting over to your host, Carol Bean. You may begin.

Carol Bean: Thank you. This is Carol Bean at the Office of the National Coordinator. I am Director of the Certification Division.

This call is an informational call about the ONC Temporary Certification Program. It's the third of a series of four kick-off calls and we are targeting them to specific segments of interested parties, stakeholders, if you will. This call is targeted towards developers, particularly those, what we call self-

developers, those who have developed systems or expanded them sufficiently and how to warrant that designation.

And, what we have today is pretty much a discussion of the rule that was recently published for the Temporary Certification Program and that presentation will be given by Steven Posnack, who is the Director of Federal Policy Division here at ONC.

And then I will follow with a few brief items about the application process for authorized testing and certification bodies, since that's who you will be going to for your certification and highlight some of the important milestones and events that will be occurring over the next couple months.

I would note that the question and answer session will be at the end after both Steve and I speak and I will let you know when that is.

So, without further ado, we will hand it over to Steve.

Steven Posnack: All right, thanks a lot, Carol.

So for those of you who aren't in the Washington, D.C. area, I feel obliged to let you know that it is a perfect day today, zero humidity, nice and sunny, blue skies. So, I think it's putting us all in a good mood before the holiday weekend.

So, thank you for joining us on a Friday before a holiday weekend. We recognize that you've taken time out of your busy schedules to be a part of ours and I will go through a little bit of the history of the rulemaking thus far to catch you up on where we are today, how we got started, what's included and what we'll be discussing.

As Carol had mentioned, we have been trying to target different stakeholder bases. This one is targeted particularly at those of you that may be what we coin “self-developers” and that are, you know, healthcare providers that may have developed their own systems in-house that we’ll seek to get tested and certified rather than purchasing or adopting a vendor product off the market.

So, I will proceed on with a little bit of history first. In the middle of March, the Office of the National Coordinator for Health IT published a Notice of Proposed Rulemaking that laid out proposals for both a Temporary Certification Program and a Permanent Certification Program.

In this rule, we acknowledge that we would be finalizing these two programs separately and issuing two separate final rules. So, what recently got published, a couple of weeks ago now, included the final policies and requirements related to the Temporary Certification Program. We will be finalizing the Permanent Certification Program rules and policies sometime later this fall and that is not the subject of our call today.

So, the publication of this final rule was an important first step. It was a big first step that sets into motion one of the processes that needs to be in place to support the whole meaningful use in the EHR Incentives Program, the certification of EHR technology.

It will also help certain other ONC programs, already part of their operations, the Regional Incentives Center, for example, who will be providing support and resources to healthcare providers, like yourselves, in their areas where you all are seeking to achieve meaningful use.

So, generally speaking, the rule serves two purposes. The first being it establishes the process the National Board leader will use to authorize organizations to test and certify electronic health records technology. This is

an open application process and we've already started that whole process, but we encourage any qualified organizations to submit their applications and to request them first and Carol will get into far more detail about the application process than I will. And, the second general purpose is that it sets some of the parameters around the testing and certification of EHR technology.

Taken together, this rule paves the way for developers of EHR technology to get their products tested and certified in a timely manner. Once EHR technology has been certified, it gets us to one-half of the phrase equation that I like to say of meaningful use of certified EHR technology. So, we are marching forward as fast as we can to get these programmatic aspects up and running.

And I thought it would be helpful, given our target audience, to talk a little bit about some of the provisions of the rule that you all may be most interested in. As I said, a majority of the rule itself and the regulatory sections revolve around the application process and the first purpose that I specified of all of the steps that are involved in the National Coordinator authorizing an authorized testing and certification body.

So, I'll do my first acronym check. We have these organizations that we call ONC-ATCBs which stands for the Office of the National Coordinator for Health IT – Authorized Testing and Certification Bodies. So, you will hear me say ATCB very often and those are organizations that have achieved authorized status.

So, there will be an application process and we specify a number of sections in the rule that layout the application process and the specificity around that and the competencies and qualifications that an applicant for ONC-ATCB status must provide in order for us to review their application and to determine

whether they are competent and qualified. And Carol's remarks will cover a lot of that information.

So, skipping forward, out of the application process will come ONC-ATCBs. And those organizations, once they're identified and have been authorized by the National Coordinator, will be made known, publicly available on our Website. And I'm sure if you – one public service announcement real quick – if you haven't already signed up for our LISTSERV, please go to our Website and do that. It's healthit.hhs.gov in the bottom right corner there's a – you can type in your email address.

You know, we'll make, as soon as we have programmatic announcements like – of the magnitude of, you know, identifying ONC-ATCBs, we'll be sure to make those – to make that information publicly available so that you can find out who those organizations are and queue up to get tested and certified if that's what your plan is.

So, once there are ONC-ATCBs, there will be potentially two types of ONC-ATCBs. And that further breakdowns with the second type that I'll get into really quickly.

So, the first type of ONC-ATCB will be one that seeks to be authorized and seeks to have the scope of their authorization to comprise of Complete EHRs and those are EHRs as we define in the interim final rule for (unintelligible) and certification criteria. EHRs that are designed to meet all of the certification – applicable certification criteria adopted by the Secretary to the setting in which they are designed.

So, an ONC-ATCB that is authorized for Complete EHR testing certification, the scope of their authorization encompasses both Complete EHR designs for an ambulatory setting and a Complete EHR designed for an inpatient setting.

That also includes the scope of their authorization also includes that they are able to test and certify any type of EHR Module as well.

These organizations will really be the ones that are the one-stop shopping regardless if whether you've got a Complete EHR or the EHR Module that you want to get tested and certified. Any organization that's authorized to test and certify Complete EHRs will pretty much have the whole kit and caboodle of authorization.

With respect to ONC-ATCBs that are authorized for EHR Modules, they're required to specify in their application the scope of the authorization for which they seek. So, the example that I always use is electronic prescribing because that's an easy one for me to explain. There's an ONC-ATCB that seeks or an applicant that seeks to be authorized for a specific authorization to test and certify just EHR Modules related to electronic prescribing, they're permitted to do that.

The one thing to note if you're interested in getting your health IT certified, is that those organizations that become ONC-ATCBs and have – are specific to certain modules, the scope of their authorization is solely to those EHR Modules for which they've been given authorization.

So, someone that was given authorization to test and certify EHR Modules wouldn't also have authorization to test and certify a problem with modules, for example, you know, their authorization is limited to what they're granted.

So, those are the two types of ONC-ATCBs, generally speaking.

The next thing that I thought would be helpful to get into in terms of a little bit of detail for you all, would be the parameters around getting tested and certified. And, as I mentioned, the majority of the regulatory provisions are

really geared toward, in effect, the applicants and then, once authorized, the ONC-ATCBs and how they need to behave, the rules they need to follow, what they need to maintain good standing and keep their authorization. But there are a few that set implicit requirements that developers of the EHR technology should be aware of.

The first being – some related to transparency and we include these in the Principles of Proper Conduct for ONC-ATCBs and there are a number that are specific to ONC-ATCBs, but there are some others that they are required to adhere to that also influence what they'll be looking for in terms of information from EHR developers.

So, the first being, like I mentioned, one related to transparency when an ONC-ATCB is going to issue a certification, we require specific information that they require as part of the certification to be communicated. For those of you that may be self-developing, this may not be something that is a direct influence, you'll still be required to have this information and make it available.

But, comparatively to any EHR developer that is out there in the marketplace, actively marketing their and communicating their EHR product to numerous stake healthcare providers, they'll have to make this information transparent and openly available to them. In situations where you are going to be the sole user of the EHR technology, they can certify that there won't be instances where you would have to actively communicate this information because you yourself are the person or organization that is responsible for the EHR technology.

There are also other certain situations that are identified in the Principles of Proper Conduct where we discuss refunds and when refunds would be appropriate.

And when EHR technology has been certified by an ONC-ATCB and we hope and expect that there will be multiple owned ATCBs and Carol will get into more details on the application process again, that there will – they are required in the Principles of Proper Conduct to report certain information about the products that they certify and we will make that information, again, publicly available on our Website, another thing that Carol will give you more detail on.

So, if you are out there and you're not potentially a "self-developer" you will be able to go to our Website and identify potential EHR technology that has been certified that you may be interested in or you may have already adopted a prior version of and you can check out and see what version has been certified and determine whether or not you want to adopt it.

The next thing that I wanted to mention about a specific regulatory provision that will be potentially most helpful to this target population that we held this call for today has to do with the authorized testing and certification method that ONC-ATCBs must offer.

In the proposed rule, we had proposed, what I lay out for simplicity, was more of a Column A, Column B type of requirement whereby we proposed to require in Column A, as a sole requirement that ONC-ATCBs offer testing and certification at their facility. And then, in Column B, we have them – we had proposed that they needed to offer one of three other ancillary-types of testing and certification, one of them being remote testing and certification.

A number of the public comments that we got back relayed that we should focus on what would be most effective and useful for the industry and we agreed with those commenters and, as a result, at a minimum, we require that ONC-ATCBs provide remote testing and certification options both for

development sites and for deployment sites. And I'm going to elaborate that in a little bit more detail.

We determined, you know, based on, obviously, the folks that we have on this call, there are some EHR technologies that already, you know, built in operational and that bringing them anywhere or disconnecting them in order to test them somewhere else, would pretty much be a non-starter. So, we wanted to make sure there was some flexibility built in and availability in the marketplace in terms of what an ONC-ATCB offered to accommodate these types of EHR technologies.

So, for the more so commercial vendors out there and EHR technology developers out there that have developed in-house, at a software development lab or at the headquarters, etcetera, they will be able to request remote testing and certification from an ONC-ATCB for their developed product. And then for those of you out there that, let's just pick any random hospital that already has an EHR technology installed and operational and would like to get that – and is assuming the responsibility for paying for the testing and certification of that EHR technology – you would also be able to request remote testing and certification at your deployed site. So we wanted to make sure those two things could be accommodated.

And I would like to clarify also that we specify that as a minimum requirement, again, that ONC-ATCBs provide for remote testing and certification at the developed and deployed sites. We don't preclude them from – as part of their business model or business practices from offering other types of services. So, an ONC-ATCB could have a team that they fly out in person to assess and test and certify your EHR technology onsite. We don't require that as part of the rule but, again, don't preclude that from happening. So, if that's a service that an ONC-ATCB decides to offer as part of their additional package, then they are free to do so.

The one last thing that I'll touch on briefly and I'll have to quote the regulatory citations for this, just to point you in the right direction, had to do with Sections 170.445 and 170.450, which discuss the Complete EHR and EHR Module of testing and certification parameters. There were a couple of clarifications that we included in there.

The first thing being that an ONC-ATCB must provide the option for a Complete EHR or EHR Module to be tested and certified solely to the applicable certification criteria adopted by the Secretary. And we did this in response to comments to clarify certain questions that we were getting in terms of – there was concern expressed that it – just meeting the criteria that the Secretary had adopted wouldn't be enough to get certified and we wanted to be clear that, at a minimum, the certification – we were concerned, first and foremost, with the certification criteria adopted by the Secretary.

Now, that being said, this doesn't preclude an ONC-ATCB as part of their other business practices, etcetera, from offering other types of certification above and beyond what are specified by the certification criteria adopted by the Secretary. Those things that we clarify in the rule need to be separate and distinct from the specific testing and certification to the certification criteria adopted by the Secretary though.

The other thing that I would point out which we clarified had to do with what happens if you need to update your product and it was already tested and certified to the – previously tested and certified version? Say it's Version 1.0, you either optimized other functionalities that weren't associated with the certification or you identify bug fixes and other types of regular maintenance that you do as part of a semiannual, quarterly, yearly cycle and you haven't adversely affected the certified capabilities, we wanted to provide some

flexibility for you to – for those products to inherit – to “inherit” – certified status.

So, if Version 1.1 includes certain bug fixes and other types of performance updates and it's still – it's basically the child or derivative of the first product that got certified, 1.0, the requirement that we specified is that an EHR developer, in this case, would need to provide an attestation to an ONC-ATCB explaining that they hadn't adversely affected any previously certified capabilities. And it would be at the ONC-ATCBs discretion to review that information and then to grant inherited certified status.

So, I think that pretty much wraps up my prepared remarks and I will turn it over to Carol.

Carol Bean: Okay, thank you, Steve.

I just have a few things to say. I would not expect most of the people who have been targeted on this particular call to be seeking authorization to test and certify EHR technology, although I believe it is useful for you to know what the ATCBs are required to do and some of the processes that they must go through in order to be authorized to test and certify electronic health record technology.

And, one important reason that the ONC Temporary Certification Program can provide this sort of assurance that it can, is because it is based on state-of-the-art methodologies, best practices and international standards to determine the competency of entities to perform testing and certification under this program.

So, the rule came out on the 18th of June, it was finalized the 24th, we are accepting at this point application requests for authorization from the Office

of the National Coordinator for entities to be able to – be authorized to test and certify under this program. Now, we've distributed the first (unintelligible) of applications that – for which we have received requests. Organizations must request in writing and specify the scope of authorization, that is, whether they want to certify – test and certify complete or modular and, if modular, which module.

This is important because when we distribute the application, the application has two parts. The first part essentially provides evidence of conformance to the international standards for testing and certification bodies, the Principles of Proper Conduct, etcetera. Those are common to all applications and all applicants must successfully complete those parts of the application.

But, Part 2 of each application is individually tailored to the applicant for the scope of authorization that they have sought. And it tests general knowledge of the program, of the certification criteria and standards as well as specifically the testing processes, the testing tools, the methodologies, as well as the procedures and the use of those things within, again, the scope of their authorization.

Once we have received a complete application, that is part (unintelligible) B and C, Parts 1 and 2 complete, we have 30 days in which, by the rule, to render a decision on that application. It is possible for an applicant to submit Part 1 separately from Part 2, because Part 1 was issued within the proposed rule and the final rule and so people were aware of what that would entail and could prepare those aspects in advance, which demonstrate their conformance to standard – to the standards and the evidence that would support that.

So, after we get – so, we would potentially be able to begin taking a look at those early, but we are not going to review the complete application until we have everything in hand.

So, what this means, essentially, is that we anticipate that we will get applications – begin getting applications very soon – and that we will be able to review them using our internal review board and expect to have authorized ATCBs before the end of summer. And, at that point, they will be in business.

The authorization comes from the National Coordinator. They are authorized to a specific scope for which they have been tested themselves and demonstrate their competency and conformance. And then, once the authorization has been issued, we will post the name of the ATCB and the scope of their authorization on our ONC Website.

At that point, vendors and developers can contact them directly. And we'll deal directly with the ATCBs for the testing and certification of their products, technology, systems, etcetera.

Once a product technology system is certified by an ATCB, the ATCB provides that information to the ONC and we have – will have on – available through our Website, something that we call the “CHPL,” certified health IT products list – C-H-P-L – which can be thought of as the source of truth for certified products. And, at that point, that is a place that's intended to be a public service Website where the list of all certified products and systems are aggregated in one central location as provided to ONC by the individual ATCBs. So, we get the information for the CHPL from the ATCBs directly.

Another feature that will be coming later, it will not be available on the CHPL at the initial rollout, the list of the products and systems and all of the criteria to which they are certified, will be available in August at the point of which we – or before the end of summer – the point at which we expect summer/fall – I misspoke there – we expect the ATCBs to be operational before the end of

the summer. We expect products to be certified and up – notification on the CHPL in the fall.

And, after this first phase, which is the list, there will be a feature that we are developing on here for folks who have chosen the modular route to purchase or install, that essentially they can test whether the combined set of products that they are technologies that they have will satisfy the criteria – all of the criteria in order for them to be certified under the meaningful use standards. And then they would – those combinations that do, in fact, satisfy all of the standards and criteria will receive a single number that could be used to report to CMS for that.

A couple of questions that we typically get, I would like to be sure and state is that there is no limit on the number of ATCBs. We have encouraged as many as can qualify and be successful in this process to apply and we have received quite a bit of interest, inquiries in this.

We have, at this point, distributed 14 applications, so we are pretty confident that we will get and have authorized, multiple ATCBs both for Complete EHR technology as well as the modular approach.

And the other thing is that this has been a question more from ATCBs, but, you know, when does the process close? And the authorization process will be effective throughout the entire Temporary Certification Program. So, we don't have a window where we're saying, time's up, you can't apply any more.

And another thing that tends to get asked is, what's it going to cost? And, essentially, other than the requirements that are in the international standards that basically prohibit gouging and things like that as well as we expect the competitive market to drive the cost and pricing structures for this. We, ONC, will not require particular ceilings and costs. There are certain aspects of the

Principles of Proper Conduct that address the pricing issue. However, we expect the market, the competitive market, to keep the pricing competitive for the ATCBs.

So, with that, I think our prepared remarks are over and we will open for questions. We will need to stop at five minutes before the hour; so, until then or until your questions are done, we are at your disposal.

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 will be prompted to record your name. Please remember to unmute your phone and record your name clearly when prompted. To withdraw your request, please press star 2.

One moment please for the first question.

Once again, if you would like to ask a question, please press star 1.

Our first question comes from (Jorge Ferreira). Your line is now open.

(Jorge Ferreira): Hi, Steve and Carol, good morning.

This is a (unintelligible). I have a question. Steve, can you define for me, when you say, EHR Module, what that means?

Steven Posnack: Sure, an EHR Module, as it's defined in the interim final rule, can be any, in a paraphrase the regulatory language, but it's anything, essentially, that meets at least one certification criteria adopted by the Secretary.

So, an EHR Module could be in the interim final rule there's a certification criteria for problem lists. And if although it may be unlikely that that would be

an EHR Module that someone could develop and market solely, you know, that's an example of an EHR Module.

I will expand on that example also to say that as the definition goes, that something that meets at least one certification criterion that doesn't mean that it only needs one certification criterion. So, the other example that I like to use, I like to use the easy examples, is that there could be a list EHR Module where we have the certification criteria for different lists, problem lists, medication list, medication allergy list, so a list module could comprise or encompass all three of those certification criteria, that would still be called an EHR Module, even though it provides numerous capabilities. There could also be an EHR Module that addresses the suite of privacy and security certification criteria as well.

And the logic that I also like to add in is that if you need all the certification criteria that are applicable to something then you're a Complete EHR. If you don't, then you're an EHR Module.

(Jorge Ferreira): Okay, very good. But based on what you just described, if you don't have clinical decision support, then you're an EHR Module – you're a fully EHR and, if you do, then you're an EHR Module. Is that correct?

Steven Posnack: Umm.

(Jorge Ferreira): Because absent of clinical decision support and physician order entry, you can actually have overlap of the two operating systems.

Steven Posnack: Well, in terms of how the regulatory definitions work, a Complete EHR is something that needs the full suite of applicable certification criteria for the setting in which the EHR technology is defined.

So, if a Complete EHR would include clinical decision support and other such capabilities, you know, specified in the certification criteria. If an EHR technology doesn't have a specific capability associated with one of the certification criteria adopted by the Secretary, then it would fall into the EHR Module definition.

(Jorge Ferreira): Okay, very good. Thank you, I appreciate that.

Coordinator: And our next question comes from (Gary Keith). Your line is now open.

(Gary Keith): Hi. Thanks a lot, Carol and Steve. We utilize software that we have been assured will be certified as a Complete EHR. However, currently, we are using, for some measures, other software to meet these things. Some of them is in-house developed, some of them are vended products and some of the measures we're meeting with a combination of both this Complete EHR package as well as self-developed software. Will we have to certify those measures separately?

Steven Posnack: That's a great question and just for a clarification, when you say measures, because that's a term that gets hooked on a bunch of things, what measures are you specifically referring to?

(Gary Keith): Well, within the scenario of like 20 some measures here to meet the meaningful use objections.

Steven Posnack: Okay, I'm just separating that from clinical quality measures that are also other types of measures that you may need to meet.

So, one thing I'll say first, just to – as a preemptive caveat/comment, is that for those of you how experience the HIPPA privacy and security rules over the past six or seven years, they have developed OCR, the Office of Civil

Rights, have developed a huge question, FAQ question, bank related to, you know, how the rule – both of those rules are interpreted in certain, you know, situations where additional clarification is needed. So, I foresee us building a more comprehensive frequently asked question database, for lack of a better phrase, over the course of time that, you know, where real world situations come up, where clarity is needed in terms of how we would interpret the rule and play that situation out.

We would be, you know, we're positioning ourselves to be able to take those questions in and figure out how to best address them. But, to get at your comment a little bit, I would first point you to the definition of certified EHR technology, which is, at the end of the day, what you'll need in order to have the assurance that you'll have all the capabilities necessary to meet the meaningful use measures that are finalized.

So, if, at the end of the day, you have what meets the definition of a Complete EHR and that has been certified by an ONC-ATCB, then presumably you should have something that constitutes certified EHR technology.

If you've got a hybrid, you know, depending on what had been certified and what hasn't been certified, you may have a gap. Again, it's tough for me to work that all the way through. If you've got a Complete EHR, I would presume that you've got every thing you need. You know that might be something we will need to consider going forward.

(Gary Keith): Yeah, I just don't want to get caught shorthanded at the end of the day, you know?

Steven Posnack: Sure.

(Gary Keith): So how would I get that answered?

Steven Posnack: I think it's – some of it's going to depend and this bridges over to the final requirements for meaningful use in the final standards and certification criteria rule.

(Gary Keith): Okay.

Steven Posnack: There, you know, based on your analysis of the interim final rules requirements and what was proposed for meaningful use, you will probably be able to do a pretty quick gap analysis of any differences that there may be and what capabilities you may have or that may need to be tweaked in terms of providing the certain functionality that you'll need to meet the meaningful use measures.

(Gary Keith): Okay, thanks.

Coordinator: And our next question comes from (Dr. K.J. Lee). Your line is now open.

(K.J. Lee): Hi, how are you? First I'd like to comment that I have listened to many conferences like this from the government and this one is particularly clear and helpful and I thank you for the preparation to present this.

I have three short questions. The first one is, if a vendor product is so-called has a stamp of CCHIP certified already in '07, '08, does it automatically – this is certified or does this product have to be recertified again?

Steven Posnack: So, the answer to – the short answer to your question is those previously certified products would not meet the definition of certified EHR technology. And there are a few kind of functional reasons from a regulatory perspective why, but there's also, since the final certification criteria and standards aren't

yet available, anything that was previously certified wouldn't necessarily have the capabilities necessary to achieve meaningful use.

(K.J. Lee): Thank you. Is CCHIP automatically becoming a certifying and testing body or they have to reapply like anybody else?

Carol Bean: They need to apply like anybody else.

(K.J. Lee): Okay, thank you. And then my next question is, could you expand on clinical decision support. What that means?

Steven Posnack: I think that's probably going to be clarified and better addressed in the forthcoming rule. So, you'll just have to – I'll have to defer to them at the point in time when they come out, it'll have additional clarification.

(K.J. Lee): Thanks. Would it be generically clinical decision support meaning, following certain practice guidelines if there's a best practices, whether the doctor is following those. Is it on that kind of line of thinking?

Steven Posnack: I can't specifically comment on that at the moment.

(K.J. Lee): Thanks. And then, would the process – my last question – is the process of a vendor provider developed type thing sort of how to apply for certification, the process will be outlined when you all know more about it – the to do list. So I can follow a to do list, they'll be coming out. Is this correct?

Carol Bean: Basically, that will depend on the individual ATCB. We are not specifying how they – most of them have procedures and processes already in place or are developing them to accommodate this particular set of requirements and we are not requiring them to do it in a particular way. So that would be dependent on how they do their business, what their business practices are.

(K.J. Lee): Thank you very much.

Steven Posnack: And thank you for your compliment earlier.

(K.J. Lee): And then, one last question, you said ATT, with my hearing aid, is it B or V, the last alphabet?

Steve Posnack: It's A as in apple, T as in testing, C as in certification and B as in boy or body.

(K.J. Lee): Ah, okay. A-T-C-B.

Steven Posnack: Correct.

(K.J. Lee): Thank you. I'll buy new hearing aid.

Coordinator: Our next question comes from (David Mendelssohn). Your line is now open.

(David Mendelssohn):Hi. Thank you very much. I agree; we're getting some clarity here that's helpful.

My question is a twist on one of the previous questions. Let's presume for a moment that an enterprise owns or has licensed three Complete EMR products, each of which has been unto itself certified, but that you selectively choose elements of each to comply with the different measures that you need to satisfy.

If you're selecting from products that have an overall certification, does that cause any difficulty if you pick an ADT module from one, a billing module from another, a decision support module from the third and the only way they were certified was as complete products?

Steven Posnack: This may be one of those questions that, you know, we'll need to think through a little bit more in terms of frequently asked questions to provide further interpretation of how the rules would work. Some of it also depends on the interim final – the final rule for standards and certification criteria.

But, to your point, at the end of the day, one needs to possess certified EHR technology, which is a definition – a regulatory definition that can be met in several different ways. And, you know, it can either be met in a Complete EHR, a single, solitary Complete EHR that has been tested and certified, all the applicable certification criteria or a combination, a proper combination of EHR Modules that would otherwise constitute a Complete EHR and meet all of the same certification criteria so the check boxes would align.

But, in terms of picking and choosing pieces out of certified EHR technology is something that – or from three separate Complete EHR would need to be something that we would need to further – consider further.

(David Mendelsohn): So, is the way that an institution going to indicate this to ONC through self-attestation initially?

Steven Posnack: That you have certified EHR technology?

(David Mendelsohn): Correct.

Steven Posnack: I believe that's specified by CMS and you'll have to look to their final rules for how they're going to require eligible hospitals or eligible professionals to submit their meaningful use attainment requests, etcetera.

(David Mendelsohn): Okay. Thank you.

Coordinator: And our next question comes from (Kent Foyer). Your line is now open.

(Kent Foyer): Okay, thank you. One of the things you didn't cover when you talked about the testing, the requirements on these organizations that will be doing the certification that is contained in the final rule is that they are supposed to use either the NIST testing methods or something alternative approved by – I believe that's my reading of the rule. Is that correct?

Steven Posnack: Well we clarified in the original provision was with something along the lines of NIST test methods or something that was functionally equivalent. We – excuse me – we changed that provision to fully reference test rules and procedures that were approved by the National Coordinator.

So, while we have been working with NIST in accordance with our statutory obligations to help develop – to have them help develop test methods associated with the test certification criteria adopted by the Secretary, it doesn't preclude any other organization, person or entity from submitting test methods that they would seek to have approved by the National Coordinator and we would consider them.

But, for the beginning – excuse me – in the beginning, we expect that our consultative relationship with NIST will result in the test methods upfront. And, you know, they will have to come into us, I mean, I'm not saying that they're by any means getting a rubber stamp, we're going to analyze them and go through the process that we laid out in the rules to ensure that they are sufficiently comprehensive for their certification criteria and that they're traceable to the requirements and the capabilities specified by the certification criteria as well, just like we would if any other organization submitted them.

(David Mendelsohn): Okay, thank you.

Coordinator: And our next question comes from (Lana Dubinsky). Your line is open.

(Lana Dubinsky): Ah, yes, hi, good morning. Just a validation on the footprint, the actual HIT footprint, within an organization, a multisystem IBM for example. If they're running off-the-shelf products or platforms that have been either customized or are adopted under older version, that the vendor will not certify but they feel they are meeting meaningful use with that footprint, can they go get that certified so it's not necessarily self-developed but it's either highly customized or the vendor is not going out to certify it, can they go out on their own and get this level of certification?

Carol Bean: This is a very good point of clarification and I think we failed to make the distinction there or to express that this would also cover legacy systems too. And systems perhaps that have been customized beyond what a vendor originally sold and installed that they may have enhanced something. Yeah, you would be able to come in and get your system certified.

Steven Posnack: So that, yeah, just to piggyback on Carol's point, you know, there are a couple of situations, one of which that you've identified, where, you know, I'll just kind of walk through them in a spectrum. So, you've got any type of company out there, let's just say, Steve's EHR or, you know, 100, 1000, 1001 product, and I'm out there and I go to an ONC-ATCB and I get my product certified and then I try to sell my product to as many eligible professionals and hospitals that I can find.

There are other situations where an eligible professional or hospital has previously purchased something that may have been certified in the past, that may not have been certified in the past, something that they've self-developed, a bunch of things that you've assembled from off the shelf that have been purchased over the years and between you and your software development team or in-house experts, you feel that you have met – that you

are able to meet the capabilities specified by the certification criteria adopted by the Secretary, you very well have the option to seek to have your system as you have it there, tested and certified by an ONC-ATCB.

The point being though in the first example, me, Steve the developer, I assume the costs for getting the EHR technology tested and certified. In the latter example, you, as the primary source of the EHR technology, would assume the cost of getting the EHR technology tested and certified.

(Lana Dubinsky): And so that's – that's great, Steve. Thank you.

And so that brings up just two more questions. One is that latter example where the hospital or the IDN goes out and assumes the cost of testing, what are we talking about here? Is it similar to the CCHIPS vendor costs? Or is it going to be free via these ATCBs? Is it just internal costs that you're referring to?

Steven Posnack: Sure. As Carol briefly mentioned and, you know, pricing is obviously a question on a lot of folks' minds. You know, as she also mentioned, which is encouraging, we sent out 14 applications, it would be great if all 14 of them were qualified. I mean that would be an outstanding result; probably, more realistically, some subset of those will be first authorized, etcetera. But what we're expecting and what we hope is that there'll be a competitive marketplace.

Some of the – I can understand, you know, your question and uncertainty, certainly, and those of others and this is the third call that we've done, so no stranger to this question now. And I think we're in a little bit of a transitional period between what the kind of prior paradigm of testing certification included and what this new paradigm will include for the purposes of – specifically for, you know, related to meaningful use and that we've identified

Complete EHR-type systems, EHR Modules which may vary greatly between – in terms of the capabilities that they may provide. And then, also trying to provide a competitive environment.

And, I'll keep piling on in terms of the differences here. You know the situation that you've identified where, previously, there really was no specific requirement except for being able to confirm that you've got a kind of modern day electronic health record system for getting certified, especially more so in a hospital setting. And now, you know, there are these requirements and prerequisites up front in order to qualify for the incentive payment, having a certified product.

So, the market, the paradigm has changed a little bit and I think all of us are kind of interested in seeing how this is going to play out. And, you know, the more ATCBs that we have, they'll probably have to look at the market and see how they want to attract potential customers and maybe there's one out there that really targets those of you that are at the IDNs or other types of large hospital systems and they make that their niche and they can offer competitive price point for you.

(Lana Dubinsky): Okay. And last question, within the context of the legacy environment and provided that I go out and get it certified under the new measures, is it going to be required if you are under this self-developed/legacy certification that you go out and get recertified annually or what do you foresee? So, in other words, how long does that certification last?

Steven Posnack: Sure. So, we talked a little bit about the validity of a certification and there's a section in the rule that we took great care to try and make it as clear as possible. From a capability perspective and some of this is driven by changes to – future changes to meaningful use and the future stages of meaningful use and how we support that through the technological capabilities that we require

in terms of adopting certification criteria. So, say for example, and this is completely hypothetical, you meaningful use Stage 1, includes 10 objectives and measures – 10 measures and, you know, as the kind of precedent that we set right now, we've adopted certification criteria to support those 10 measures.

If for Stage 2, somewhere down the line, either the standards associated with some of those measures change or there are additional measures added that it goes to 13 from 10 in meaningful use Stage 2, then the capabilities that your certified product as of today will include, will no longer get you to where you want to be for Stage 2 and, at that point, I hope you would agree, that it would need to be recertified.

(Lana Dubinsky): Okay. Thank you so much.

Steven Posnack: Yup. And I think, per Carol's warning, we have back-to-back calls here, so we're going to have to call it a day on this call. We really appreciate your time, especially dialing in right before the holiday.

Carol has a couple of public service announcements just in terms of email addresses and then we'll conclude.

Carol Bean: Yes, thank you very much. These questions are very useful and your feedback is both useful and sought on a continuous basis. We will be – we've got some materials that we are posting information materials and, as Steve noted, we will compile the FAQs and other information on materials. If you have specific questions that you didn't have a chance to ask here, you can send them to us or things you think we need to be thinking about and aware of, the email address for this would be onc.certification@hhs.gov.

And, in addition, there is an 11 o'clock call for all providers, all eligible providers and hospitals and so you're welcome to join that call to hear what we have to say. A lot of it will be repeated but there may be some additional information or questions asked there that would be of interest and use.

So, thank you very much.

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