HIT Policy Committee
FDASIA Workgroup
Regulations Subgroup
Transcript
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Presentation

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thank you. Good morning everybody, this is MacKenzie Robertson in the Office of the National Coordinator for Health IT. This is a meeting of the HIT Policy Committee's FDASIA Workgroup, the subgroup on Regulations. This is a public call and there is time for public comment on the agenda. And as a reminder, the call is also being recorded and transcribed, so please make sure you identify yourself for the transcript. I'll go through the roll call. Julian Goldman?

Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System
Hi, I'm here.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Great, thanks Julian. Brad Thompson?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Good morning.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thanks Brad. David Bates? Todd Cooper?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.
Buenos Dias.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Oh great, thanks Todd. Anura Fernando?

Anura S. Fernando. MS, MD – Principal Engineer, eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories
Here.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thanks Anura. Lauren Fifield?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Here.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thanks Lauren. Robert Jarrin?

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
Here.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thanks Robert. Mo Kaushal?

Mohit Kaushal, MD, MBA – Partner – Aberdare Ventures/National Venture Capital Association
Good morning.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thanks Mo. Joe Smith?

Joseph M. Smith, MD, PhD, FACC – Chief Medical and Science Officer – West Health
Good morning.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thanks Joe. Steve Posnack or Jodi Daniel?

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
Here.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thanks Steve. Bakul Patel? Simon Choi? Matt Quinn?

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Here.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thanks Matt. And for other FDASIA Workgroup members on the line, I have Elisabeth George?

Elisabeth M. George, MS – Vice President, Global Government Affairs, Standards & Regulations – Philips Healthcare
Here.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Are there any other workgroup members on the phone?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
This is Meg Marshall.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Ah, great, thanks Meg.

Richard M. Eaton, JD – Director, Industry Programs – Medical Imaging & Technology Alliance
Rich Eaton.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
And Rich, thank you. And for ONC staff, I see Kate Black. Kate, are you on the phone?

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology
I think she might just be listening.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Okay. With that, I will turn it over to Lauren.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Okay. Well good morning everyone. In sort of our robin round of overviews of existing regulatory regimes in the world of Health IT and medical devices and other health products, today we're going to go through an overview of ONC's regulations, that's the Office of the National Coordinator for Health IT. And some of this may be things that you already know, some of it may be news to you. I know that we have folks coming from different parts of the healthcare industry and so if there are questions that you have, stop me. If you have thoughts to add, please do so. MacKenzie, do I have control of the slides, or –

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
You don't but if you do want control, they can give you control, so it's up –

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yeah, can I please have that that would be great.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Caitlin, are you on the phone?

Caitlin Collins – Altarum Institute
Yup, you can have it now.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Okay, perfect.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Okay, great. Thank you. So what I have in line for us today, for those of you can see the slides, great and for those who cannot, just an introduction to the Office of the National Coordinator, this was developed as a new agency, I thought that that would be a good thing to do. And then also sort of couch their existence in the larger overview of the HITECH Act and then delve into the EHR certification process that currently exists. I'm not planning to go through each EHR certification element, but certainly if there's desire, we can go through those. We will go through enough for folks to get a sense of, I think what the certification program looks like, what's entailed, what's call – what the vendors are called on to do. And then finally get into the discussion topics. I took a lot from Brad's crew, but I did decide to hold kind of the question of, is this a good fit for Health IT to kind of a broader discussion at the end. Certainly I think there are areas where we can talk about that as we go, but I didn't want to get us too distracted or anything like it. So, if that sounds good, we'll get started.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Sounds great.

W
Sounds good.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Okay. So, again, some of this may be old news to you, but I just want to make sure that we have a good level setting for everyone. In 2009 the HITECH Act, which is part of the American Recovery and Reinvestment Act, gave CMS or HHS about $19 billion dollars to promote the adoption of electronic health record. Within HHS, there are two agencies working on the program and the goal for the program is really to get better technology to then lead to better data and then ultimately HHS's goal of transforming healthcare.

The EHR Incentive Program with kind of a street name of Meaningful Use was originally established with a framework of three stages. Stage 1 of Meaningful Use occurred – began in 2011 and actually moved into 2013. Vendors and the agencies and providers are currently preparing for Stage 2, which will begin in 2014 and then Stage 3 will begin at some time in the future. But the whole goal is to sort of get vendors and providers to sort of move to different uses and standards of health IT, of EHRs and the sort of these ultimate goals that are here on the screen. There are some other sort of street terms that have become acronyms that I'm familiar with, but I'll make sure everyone here knows them. So in the program Meaningful Use, which was delivered by CMS and managed by CMS, an eligible provider can participate and eligible hospitals can participate, so, you might often hear EPs and EHs. And those providers and those hospitals participate in the program to adopt certified EHRs and then hopefully, successfully achieve Meaningful Use to earn incentive payments.

As I mentioned, there are two organizations within the Department of Health and Human Services that kind of jointly oversee the program. And there are certainly other agencies and departments that are involved in some of the provisions, like privacy provisions and whatnot, but the two heavy lifters are CMS, the Centers for Medicare and Medicaid Services and that Department is responsible for the Program that the eligible providers and eligible hospitals participate in. So, and what it is those entities need to do to achieve meaningful use, so this percentage of patients need to have "X" reported or you need to support these clinical quality measures. And the Office of the National Coordinator was charged with creating the ONC HIT Certification Program, so they're on the side that's looking at vendors and with some other entities that we'll get into in just a bit, to make sure that the technology is capable. So they work together quite a bit in the drafting of the regulations and a tremendous amount of coordination there.

And then just sort of again at the high level, I think Brad has pointed this out in the past but, the HITECH Act also introduced the definition for health IT and so I'll read it just in case there are folks who are just dialing in, so health information technology per the HITECH Act is hardware, software, integrated technologies, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access or exchange of health information. So, just something to kind of think about when it comes to the role of the ONC and what they're authorized or charged with certifying.

Moving into an overview of the Office of the National Coordinator. This office was established with the HITECH Act and they actually have quite a bit on their plate, certainly certification is one of the main items or one of their main duties, as outlined in the HITECH Act, but they're also responsible for duties related to the HIT Policy Coordination. So again, there is that sort of sharing the work with CMS and other agencies I mentioned and the Federal Advisory Committees, so the HIT Policy Committee and HIT Standards Committee, also continuing the work of the HIT Strategic Plan. For those of you who haven't read that, it might be worth a read just to kind of get oriented with kind of the things that have led up to meaningful use and some other activities, kind of where their goals are long term. And then that kind of laundry list of other things including implementation of standards, governance or Nationwide Health Information Network and a number of other things.

The organization has a number of departments that are kind of the active engine, and their goal is in conjunction with HHS's overall goal to transform healthcare to pursue the modernization of American healthcare system through the implementation and meaningful use of health information technology. So, probably no surprises there. I think that there are three areas that are most relevant within the office, relevant to our kind of work, the Office of Policy and Planning. Those are the folks like Steve and Kate

that work on developing and coordinating policies, so kind of writing the regulations and surveillance plans for patient safety and really I mean as a constant guidance coming from the office.

And then there's the Office of Certification, so that's the group that's working with testing and certification bodies, answering questions from vendors, making sure that all the tools are in place for successful certification and then it's all aligned with the CMS program. We'll go through the HIT Certification Program, but just sort of that office that handles certification sort of handles a bit of a complex process to go from a developer entering the certification process to actually being certified. And they also have, apparently, a raising brick wall and we'll talk about that, too.

And then the kind of third office that I think is most relevant to our discussion is the Office of Science and Technology and that office is really working on the promotion of standards – accelerating standards, implementing standards, convening stakeholders to agree on standards. So really important work that is being done through activities like the S&I standards and interoperability framework, different pilot projects, again, a lot of convening of stakeholders, so, development, testing, acceleration of those standards.

The other sort of thing that the ONC has done quite well, and I think other agencies are starting to see this, but it's really investing in innovation. So there are different sort of government grants allowed for agencies to invest in innovation and they're program is i2 and under i2 the ONC has already held a number of challenges, including a Million Hearts Challenge that I think most of us have heard about. And it's really to get – to sort of focus on Challenge.gov criteria and provide incentives to support the goals of HITECH Act, HHS goals, the Regional Extension Centers and a learning health system. So really trying to get the market, private public and public just to sort of work together and come up with innovations and unique solutions to different issues and opportunities that we're faced with in healthcare.

So that is an overview of the ONC, I'll stop there. Hopefully that's helpful in thinking of this to kind of get everyone on the same playing field. Steve, since I'm speaking for your organization, is there anything that I've missed or misrepresented?

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
No, that's fine.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Okay. All right, I'm actually surprised. Okay, so we'll now dig into the ONC HIT Certification Program, which is the official name. And we'll touch on sort of general characteristics that that certification program, the actual requirements and then process. So in general I just want to remind everyone that as of right now, the certification program is tied to Meaningful Use. So Meaningful Use is what the providers are intended to do to either earn an incentive payment or essentially avoid a payment adjustment. And the certification is tied to the stages of meaningful use.

So as I mentioned, Stage I of Meaningful Use started in 2011 and has gone on until 2013. Stage 2 was delayed to 2014 and because of that, we have sort of this year, in 2013, where providers are allowed to use either the 2011 edition of certified technology as – or the 2014 edition. As of 2014, all providers, whether they're doing Stage 1 or Stage 2 of the program, have to use 2014 edition technology. I think it's also important to take a look at this because I think although a lot of folks don't quite get this. The meaningful use follows an arc where a provider will perform Stage 1 for 90 days in one year, the next year Stage 1 for a year and then Stage 2 for a year, Stage 2 for another year and sort of kind of this lockstep of stages; 2014 is a bit unique in that everyone will have the ability to perform the program for 90 days.

But I think when I first started thinking about Meaningful Use, I had assumed everyone would just sort of move to the next stage together. But in 2014, we'll have providers using a technology to complete both Stage 1 and Stage 2 and in the future, we could have providers foreseeably using a technology to complete Stage 1, Stage 2 and Stage 3, if a practice has different providers that have started the program at different times. I think the ONC has done a good job in that they have tried to harmonize between the

stages and have vendors certify to an addition of certification that will serve all the stages that are happening in that given year. But there is quite a bit of complexity there.

And another sort of introduction to certification for 2014, I think it was sort of there for the first round of certifications, but the ONC has really emphasized this characteristic, which is that certification, is modular. So they have defined what it is to be qualified as a base EHR and so a certified EHR module, so if you want to have that stamped for a certain width of certification requirements you have to achieve during certification. And then there are sort of these different rings, as you can see on the screen here where a technology developer can certify to those additional items. Some EHRs will become a 2014 edition complete EHR, right, so kind of one-stop shopping, but others may decide to only certify to a set of requirements, because providers may be using other certified modules to handle specific measures. So maybe a vendor has decided to partner with a variety of modules that are certified for messaging between providers and patients or sort of other features.

The goal here is really to get volume into the market, so lots of different solutions to the kind of different measures the providers are being asked to achieve in Meaningful Use, so, more flexibility. And I think the other important characteristic here is the gray area that kind of at the very outside, and that's just referencing capabilities above and beyond Meaningful Use capabilities, the vendors would develop and implement which has nothing to do with Meaningful Use. So, I'm glad that they highlighted that, later we'll talk a bit about some of the constraints, and how that might be – that gray area might be affected. But definitely, modular I think is really important to this edition. Does that make sense to everyone? I think everyone's on mute, but, if it doesn't, speak up.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
It's helpful, thank you.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Sure. Okay. So in terms of kind of scope or a broad level, the certification is currently limited to electronic health records or to module functionalities. Like I'm not – I'm a developer and I'm going to certify to some of the kind of certification criteria that align with a measure or a particular measure. The HITECH Act does grant ONC broader authority to certify health IT, as I put in it earlier, the definition of health IT in the HITECH Act is definitely broader and the certification program was established as a voluntary program. So, that is in the HITECH Act and was made very explicit and I know that the ONC folks often reference that, so, interesting point that really for all parties, Meaningful Use is voluntary. Of course for providers, there is a payment adjustment associated with Meaningful Use, but for vendors, it is voluntary.

At a very high level, the certification requirements, which I'll show in just a second kind of in more detail and kind of fall along four groupings. So again, these are all certification requirements in support of the measures that you may be more used to hearing about, the reporting smoking status and submitting quality measures and patient and health information. So underlying all of those functional behavioral things that providers and hospitals can do with technology, there's a set of capabilities that EHRs need to be able to do for those activities. So, there is vocabulary and code sets, so LOINC, RxNorm, SNOMED CT, a common MU data set, which is a data set that is kind of those data elements that are intended to be part of the different clinical care summaries and shared care documents associated with exchange. So that's kind of one bucket.

Another bucket is those certification elements associated with transport. So an example would be the applicability statement for secure health transport. There are others like Direct that are intended to facilitate the exchange of health information in a standardized fashion. A lot of those standards and vocabulary sets have come from the work of the Science and Technology Office and work through the S&I framework. There are also certification requirements related to kind of content exchange and utilization, so the HL7 Infobutton for patient education, sort of a context aware button capability. The consolidated CDA so that's kind of that document that standardized content to be sent in the case of a transition of care or exchange; QRDA categories I and III, so these are referring to physician has clinical quality measures and standards around what data is included; HL7 2.5.1, which is for submitting to an immunization registry or other surveillance. And again, for each of these requirements, quite bit of private

and public collaboration, many, many hours of phone calls determining the standards happen to ensure that again, there is adoption of specific standards for the physicians.

And then there's a final bucket called other, which is sort of elements related I think more to Meaningful Use or not directly related to specific measures, but more towards just some other factors that have kind of emerged as important. So automated numerator recording, so making sure that any module can provide the right numerator so that they can pass that on to an EHR or other technology if they're not going to be doing the calculating of measures themselves. Safety enhanced design, so each area, making – seeing if the vendor has safety enhanced design practices and what are those; medication related certification criteria, quality management systems, does the vendor have the instruments for quality management system, if so, what is there; price transparency and then test result transparency. So, I think some of these have a bit more to do with the market and interestingly I think, more to do with our work.

This bull's eye it looks slightly more legible in PowerPoint, but – probably isn't, I can send it out or you should definitely reference it in PowerPoint form. This particular bull's eye is sort of a complete set of certification criteria for a vendor wishing to support eligible hospitals, and there is a matching bull's eye for vendors wishing to support eligible providers. Sort of set of certification criteria is fairly extensive, although there's good continuity from your – from the sort of prior certification edition. And again, there are different clusters of certifications sort of about base EHR capabilities, the certification criteria related to the core measures that providers are intended to fulfill and then criteria related to menu measures that providers are intended to fulfill only a set up and is at their discretion and ability. There's also measures related to security and privacy here and then some other measures related to clinical quality measure facilitation. So I'll stop here. I'm going to go – I'm planning to go into the certification process next, but certainly if folks want to dive into individual certification elements now, we can. Or if there are questions about any of the certification standards and criteria or other thoughts. I know we have Meg on the phone and other folks who might want to articulate –

Bakul Patel, MS, MBA – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
Hi Lauren, this is Bakul sorry I joined late. This may probably be a question for you and/or Steve or Jodi, if they're on the line. Would you – I'm looking at the bull's eye chart, would you characterize that as sort of functionality level regulation?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
What would you say – can you clarify functionality level regulation?

Bakul Patel, MS, MBA – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
Just big product features is what I'm thinking.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
What is it – you're saying is features?

Bakul Patel, MS, MBA – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
Yes.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Interesting. While – so yes for some, no for others. So certifying to a particular transport standard, on the face of it isn't necessarily a feature, it's sort of a capability that the vendor is allowing. But it does fit in systems because the vendor's are presumably working closely with their providers or their hospitals to make sure that not only are they providing the certification ability, but they're also making sure that that experience of fulfilling that other measures related are usable, enjoyable, efficient ones. And so in some cases I would say that the combination of the CMS regulation and the ONC reservation sort of lead to

some regulation or sort of lead to functionalities requirements or kind of a little more narrow set of functionality options.

Bakul Patel, MS, MBA – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
Um hmm.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
But certification on its own doesn't necessarily, certainly a guide will get some of the certification does narrow the options available. So I think that's how I'd answer it, it's hard to almost separate the two programs and so sometimes that really does feel like there is functionality that – or a limited set that's being asked to implement as opposed to just standards.

Bakul Patel, MS, MBA – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
Yeah, I was just trying to sort of emphasize that and just to look at it and saying if I had the capabilities, product features or functionality that this regulation provides.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yeah, yeah. Does anyone else have thoughts on that because I know that other folks are working on this program?

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
So this is Steve from ONC. I mean, just to I guess elaborate a little bit more, right. So, I mean, I think it's helpful for folks to understand the context under which the certification criteria are adopted and included in regulation today. As Lauren's been explaining to you, is in direct support of the Medicare Medicaid EHR Incentive Program. And so largely on this list of certification criteria that are on this little chart here, those are largely adopted to support the capabilities that the eligible provider seeking incentives would need to demonstrate use of in order to get an incentive payment from CMS. And so that's really been a driver, I mean, like folks understand from the authority and scope slide earlier, I think there are roughly 50 certification criteria that we've adopted thus far in support of the various capabilities that are relative to the program.

We could adopt other certification criteria. The drivers for the Lauren's and the Meg's of the world are not necessarily the same once you get past the point of whether a provider needs to use it to demonstrate Meaningful Use to get incentive payment. And there are other situations where we could focus on a different type of technology that would be for a different purpose and context that – I think we would approach things differently, depending on what the market needs would be.

Bakul Patel, MS, MBA – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
That's helpful, thanks Steve.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Lauren, this is Brad Thompson. I want to ask a big picture question. I'm not exactly sure if this is the right time to ask it, so maybe I'll just state what my question is and then if you want to defer discussion until later in the presentation, that would be perfectly fine, but it's the question that's kind of nagging in my mind.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Sure.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
So let's say a famous doctor, let's say Julian Goldman, wants to pull up the medical record for one of his patients, a nerdy lawyer named Brad Thompson. And he tries to pull it up but instead he gets the medical record for Brad Thompson the minor league baseball player. And it isn't clear, because it's Brad

Thompson and so it causes some confusion and ultimately, much to Julian's chagrin, causes him to mistreat poor Brad Thompson. What are the consequences, in the ONC world, what are the consequences of that? Is it all certification – I mean it's a big picture question, does it somehow reflect on certification or does it reflect – or does it cause some other series of actions?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Well Brad, I think we should definitely defer it because I think that might be a scope-gap kind of topic. Yeah, why don't we revisit, but I'm going to write it down –

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Okay, that would be great.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yeah, because I – yeah.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
So Lauren hi, this is Meg Marshall and perhaps this is what Steve was getting at, and if I miss it, I certainly apologize but do you intend during the presentation to talk about the dependencies on the ONC Certification Program? And specifically I'm thinking about the EHR – the proposed EHR Donation Rules, so other requirements perhaps that point back to this program?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Umm, I wasn't intending to – I don't have slides about interdependencies, but one of the things that Jodi and I had discussed was, in the kind of discussion area was to talk a little bit about dependencies and whether that was something we wanted – something that would be helpful going forward or if it would be sort of unhelpful. So, we can talk about that now or we can talk about it kind of at the end in sort of a future thinking mode, but yeah, if we just talk now, definitely go for it.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
Well, I don't want to disrupt your presentation and we can defer. It just seems – my opinion is that it would provide some value in understanding overall context of whether –

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yeah, sure.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
Thank you.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Hey Lauren, this is Matt from FCC and maybe this is a little bit focused on what Meg is talking about. One of the questions, in my mind at least, is that the current certification processes and other programs at ONC are developed in the context of HITECH and voluntary certification program there. And one of the key questions about the feasibility of roles is ensuring that there's proper resourcing and capabilities of different agencies, and some of the funding plans moving forward around those. And so maybe that's part of the discussion, too, is FDA and ONC and FCC each have to both have the governance plan for what's in their domains, but they also have to have the plan for resources to actually do it, and that's important.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yes. So why don't we hold the – it to later, that was also sort of on my docket of sort of things to think about, but definitely a good point. What I'll do is, I'm going to hold on Brad and Matt's points, because I think they are definitely really forward-looking. But I will talk a little bit more about what Meg was saying now, because I think maybe I've gotten so used to this program and how it's become a part of everything that we as EHR vendors consider, I think it is worth highlighting before we get into sort of some of the process. So as Steve pointed out, right now, and that's not to say that this is something that they intend forever or have to take forever, but each of these certification requirements is tied to at least one or potentially more capabilities the provider has to achieve through the use of a certified system.

And as Meg is pointing out, the EHR or the EHIT – the ONC HIT Certification Program certification criteria has also started to be cross-referenced and tied to other programs including the Physician Quality Reporting System Program, there's harmonization and alignment there about reporting and submission. The accountable care organizations the final rule doesn't necessarily have specific measures that are required, but Meaningful Use is kind of one of the areas where kind of earning a – having a certain number of providers that achieve, count for one of their measures. There are other, I think, on the kind of reporting side, areas of harmonization that's kind of the standards and certification criteria are kind of feeding. And then as Meg pointed out, there is an EHR Donation Safe Harbor that is – that was introduced in 2006, so the Anti-Kickback Statute and the Physician Self-Referral Law. And in the 2013 Proposed Rule, the OIG and CMS have proposed that rather than having the Secretary sort of deem covered technology covered, instead they would like to defer to the ONC, as that deemer of covered technology and to the certification edition, as reason for a covered technology to be considered covered. So, again, I'm glad that Meg pointed out the program really has started to become tied to other areas – other government programs and the certification criteria, I think those standards are definitely sort of begin feeding into them. Meg was that a good characterization? Do you have other –

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
Yeah that was great Lauren, thank you.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Okay sure. Yeah, I do think it's a really important point and it's also not necessarily explicitly been the ONC saying this is what we want, definitely it's been a force and I think part of it is because there are standards emerging, so, as we'll be able talk about later, one of the potential benefits of having the program. But I do want to get through a little bit of the process, because I think it's a really important element to the ONC HIT Certification Program that is really important to call out because once the regs are produced Steve can finally go on vacation for a day. There is a lot more work to be done by the Office of Policy and Planning, by the Certification Office, by the vendors and other associated entities.

So this is sort of a little time line, the chevron symbol up here, but at a high level, vendors create products that meet – whether complete or module functionality, then there are these kind of testing bodies that have testing tools and procedures that are used to test the actual products, so for the different validation tools. And those testing products are used by these authorized certifying bodies and – to conduct the certification. And then finally, if successful, those products are listed publically for EPs and EHs to consume and use, kind of shopping cart style, to say that yes, I've adopted a certified technology to then perform Meaningful Use. So, as I mentioned, these accredited testing laboratories create the different tools and testing activities. They have to be accredited by the National Voluntary Laboratory Accreditation Program and once they have these approved test procedures and test tools, they are then used by an ONC authorized certification body for certification. So sort of a first step.

I believe ATLs have been deemed and so those testing tools are available. I do think an important point, and we can get back to this, is that the ONC has encouraged other stakeholders to submit testing tools and testing procedures. I think that most entities that might be interested in so doing are – then get constrained, but definitely a potential place for innovation begins – goes back to that point. So certification bodies are accredited by ONC and then seek ONC authorization to be able to certify new things that – both testing tools and procedures. An authorized certifying body can jointly be an accredited testing lab, but they have to have a strong firewall, so that was that kind of raised before, with the brick wall. So they can be both, but they just have to have a strong firewall. And the ONC ACBs have to renew their status every three years. So those are the folks that actually go through the certification of different – of the vendors.

And I don't know technologically if we can do this, but I was hoping to actually go into a test procedure and test data example. Is this possible? Can I share or do you guys have that loaded potentially?

Caitlin Collins – Project Coordinator, Altarum Institute
You want to share your screen, is that – ?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Well, or if you guys have the test procedure –

Caitlin Collins – Project Coordinator, Altarum Institute
I don't know what that is.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Okay. Yeah, can I share my screen, is that possible?

Caitlin Collins – Project Coordinator, Altarum Institute
You are able to if you go to the top right of your screen, pod options, there's a share my screen.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Okay, we're going to look guys. Hopefully nothing's popped up on my screen – okay, so, can I just do full screen?

Caitlin Collins – Project Coordinator, Altarum Institute
No, you'll need – oh, it'll show full screen for you, you won't be able to see this room anymore.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Okay, and what do I do, I go to share, I think.

Caitlin Collins – Project Coordinator, Altarum Institute
Um hmm.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Okay, here we go. Hopefully this will work.

Caitlin Collins – Project Coordinator, Altarum Institute
It may prompt you first to download the plug-in, but we'll see.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
So the goal of this is not just to demonstrate that we can be technologically savvy on these calls. But I do want to dig into one of these test procedures because I think that will also demonstrate the complexity of one, both the policy-making, two, the coordination with the actual CMS measure and then three, all of the work that's done beyond. So, can everyone see the test procedures for §170.314?

Caitlin Collins – Project Coordinator, Altarum Institute
It doesn't look like you're sharing the screen yet with us.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Hey Lauren, is this one of the handouts that was circulated, is it the referenc –

Lauren Fifield – Senior Policy Advisor – Practice Fusion
It was, yeah, it was –

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
There's already a document uploaded Caitlin, so we just need to put up, reference for FDASIA –

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yeah, okay, cool. Thank you.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
– Workgroup test procedure.

Caitlin Collins – Project Coordinator, Altarum Institute
Test procedure.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Yeah.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Okay, great. Thank you. And for those of you who become so fascinated by this, I can send out a link after to the sort of 2014 edition full set of test procedures and test data. Each of the criteria has at least a test procedure and then most have associated test data that go along with them. And so these are the test procedures that the ONC worked closely with the authorized certifying bodies and with vendors to produce. This one is for vital signs. The vital signs measure, so on the CMS side, was one that providers were intended to capture. There are some nuances there in Stage 1, and it's also a measure that has changed. So one of the things – one of the reasons I think it's important to go through this is – I'll come back to later, but that for Meaningful Use the Program, being able to determine if a provider is successful is definitely one of the bigger hurdles in the program for vendors.

So beyond just creating certified functionality, vendors also have to be able to give providers a means to knowing if they are achieving what it is they're supposed to. So whether its documenting something for a certain percentage of a given patient population or completing a test of something or submission of something, vendors are supposed to let providers have insight into that achievement. And for certain measures, particularly those that have an associated percentage, there's a numerator and denominator, sometimes there are multiple numerator and denominators for a given measure. And so this measurement and compliance function is definitely something we'll discuss later, but is one of the elements of certification being tied to another program.

And so for this test procedure, we go through the – and this is sort of a standard format. The certification criteria are listed, so sort of what it is the technology is intended to enable the user to do, to require change and access, patient's height, weight and blood pressure, calculating body mass index and then optionally plotting it as plain growth chart. And this one measure that for vendor's three associated capabilities. The test procedure fairly nicely call out language from the final rule that clarifies any comments or suggestions or feedback, just to help reduce ambiguity for questions in the industry. This definitely I think something learned from Stage 1 and this has been a huge help and good for information sharing. Each of these test procedures was curated by the vendors and other stakeholders, so they came out in waves, there was an enormous amount of work to develop them and a lot of collaboration back and forth with different questions, concerns about values that were intended to be used, concerns about the actual scenarios that had to be gone through.

Because this measure was also part of Stage 1, it's referencing language from its first iteration. It clarifies changes from the 2011 to 2014 edition, so how vendors will have to change their right to their functionality to support providers in 2014 and on and then test procedure for vital signs. So, kind of an informative test script, when you have the vendor actually on the phone remotely going through the test with the testing body. You have your supplies of test data and you've created some areas in your EHR or product, whatever kind of technology it is that you're using, and then you actually go through the designated procedures with the testing body. So this particular test is in three kind of sections, so the ability to record change and access that information. So those three capabilities demonstrating that the user can, in fact, do that. And it's going through here and there are just more details, lifting the different certification criteria that are necessary – so that's the access. And referencing the test data and then for each of these, particularly if the vendor is to supply ultimately the ability to calculate. A vendor eventually to sort of demonstrate that they can calculate each of these measures, has to go through another test that demonstrates that for X, Y and Z patient, those that should enter the denominator do and those that

should enter the numerator based on the testing do enter the numerator to get kind of a sort of result back that the testing body expects. So the individual measures are intended to capture that the technology enables the behavior and then there's sort of a test for the ability to calculate each of the measures, based on this functionality.

So, for each of the certification criteria, there is a test procedure and accompanying test data document. So I think the point here is there's an enormous amount of coordination, an enormous amount of information and then it's not just a simple, here's the certification element and implement it. So, we'll head back to the PowerPoint, unless anyone has questions about the procedure.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
It was helpful, thank you.

Bakul Patel, MS, MBA – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
Lauren and perhaps Steve, this is Bakul. Steve, can you share, I mean the context that you talked about as it relates to this particular – since we are focusing on the test procedure regulation, and how does that relate to the overall big picture?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Can you say that again, sorry?

Bakul Patel, MS, MBA – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
When Steve talked about how the certification is tied to CMS payments –

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Uh huh.

Bakul Patel, MS, MBA – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
– how – so my question is, how is this testing procedure tied to the bigger picture?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Sure, okay. Sure. For this particular test procedure, there is an associated measure for eligible providers and eligible hospitals. So, once the provider – or once the vendor has certified for this, the providers, whether they're in Stage 1 or 2, have their own sort of requirements. And so for this particular measure, for Stage 2, so in 2014 and beyond, the measure is that more than 80% of all unique patients seen by the eligible provider, have blood pressure, for patients age 3 and over only, and/or height and weight for all ages, reported as structured data. So what's sort of entailed there is that patients that are 3 and over only would be in the denominator of that patient seen population for recording blood pressure. And any patient of any age that's seen during that reporting period would be in that denominator for height and weight. And again, the certification criteria are really just designed to make sure that a user, so a provider or user in a hospital setting, can chart change, accessing change to those structured data fields of blood pressure, height and weight.

But then kind of tying it to the actual measure that providers are intended to fulfill, there are also a set of exclusions for this particular measure. So, if a provider doesn't see patients 3 or over, then they don't have to record blood pressure. If the provider believes that all 3 vital signs aren't relevant to the scope of their practice, they're excluded from recording them. If the provider believes that height, length and weight are not relevant – are relevant, but blood pressure is not, then they don't have to record blood pressure. If they believe that blood pressure is relevant to the scope of their practice, but height, length and weight are not, then they're excluded from recording height, length and weight. So sort of beyond the realm of JCAHO certification criteria, there's a whole set of considerations that the EP and EH is making and that are generally supported by a vendor, the kind of health standards things like exclusions, to make it kind of help providers understand if a patient is even entered into the denominator.

Another example would be that vendors give providers the capability to report smoking status and that particular measure is only for patients that are 13 and over, so you probably wouldn't necessarily have a prompt in the system, if that's something that's helpful from the utility perspective, for babies. Right, so there's definitely what's required for standards and certification criteria and then there's the world beyond that's tied more to the activities of the EH and EP.

M
So – thank you.

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
So is it, so go ahead.

M
I'm sorry, who is that, was that Bakul, keep going Bakul.

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
No, it was Steve from ONC.

M
Oh, okay – go ahead guys.

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
Okay. So just for the folks that aren't steeped in this area of the world, right. I think this is really a classic evolution of something that Congress includes in statute to authorize, in this case the Department et al to implement a program. Congress defined some – this general scope of what they wanted to see and make available incentive payments to doctors and hospitals and they said, doctors can get incentives if they demonstrate meaningful use of certified EHR technology. And they said CMS can set the requirements for what doctors and hospitals need to do to get the money and ONC can set up the program to establish what the technology needs to be able to do in order to support those doctors. And that's like the first level of evolution here in the broad context.

Going down a step, is where, in the executive branch, right, we have to figure this out in more detail, what are the programs and other statutes and laws that we have to coordinate with and make sure that we're having somewhat of synergy or not interfering with. And then we come at kind of the program perspective where if you're a doctor and you want to get these incentive payments, and you have to, as Lauren was describing in eloquent detail, you have to show that you've done something 80 – greater than 80% of the time, well how do you do that when you're using software? And that's where some of the I think what is unique at least at the present time in terms of the linkage between ONC certification program. And its support of and kind of in service to the EHR Incentive Program is that I think for the first time, from a kind of regulatory policy perspective, we're measuring the use of – provider's use of the software as opposed to in other cases, how well their patients have fared from a particular treatment or not. And so in some of these situations for the Incentive Program, it's 80% of their patients have data on their demographics.

And that's just a slightly different paradigm than I think folks were used to pre-2011, and something that's unique, I would say, and Lauren and Meg can chime in from their perspective, that it's probably not necessarily something that they had as a core feature prior to the certification program being stood up. But that's one thing where by virtue of how the program needed to be implemented and the data that needed to be available to providers to attest to the measurement that they were being assessed against, are things that evolved over the course of implementing the statute. And so that's really – and, at the end of the day, making sure that they're accurate, which is another responsibility that we have, just from a kind of consumer protection standpoint, that the capabilities work as the EHR technology developer stated that they do, which is one prong of ONC's Certification Program. And then the other, making sure that the numbers and the elements that need to be measured are accurate. Those are all the little droppings that I guess I would add in.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
So Steve, this is Jarrin, and that's a great segue to the question/comment I'm going to make. How those vital signs, for example from the last test procedure that we're talking about, derived from the meaningful use requirement, how those vital signs get recorded into the EHR is something, I think, that should be of interest to this group. Because I realize what the congressional intent was for the Meaningful Use Program. I realize the great definition that Lauren actually put in, which helps to give us perspective as to what exactly is Health IT. And I see a large area of gaps that are not being covered by the Meaningful Use Program and I think that that might be an area of interest for this group to ponder, and possibly put into whatever recommendation we end up putting into.

If we talk about those aspects not being covered by meaningful use, the overview talks about how it should be, health IT is much broader than some of the stuff ONC has focused on, which right now is EHRs, EHR systems, EHR modules and their certification. But how about the hardware, software and integrated technologies in the definition that Lauren provided. It should not be – it should not just be in the interest of this group to talk about the current way that its being done, but also to specifically talk about the interoperability of certain aspects of health IT. From my understanding, most of the way that vital signs are being recorded is still manually, someone's inputting them manually into the EHR. There could be some instances where it's being done through interoperability of medical devices, but my understanding, and please correct me if I'm wrong, most of that is still being just captured literally when the patient goes into the healthcare setting and it's being put into a computer.

So shouldn't we be talking about interoperability of health IT via things like remote patient monitoring technology such as sensors, medical devices, mobile medical apps, etcetera, all of which actually capture and then help derive personal health information into, hopefully, the EHR, which is the part that's not happening right now.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
So I think, Jarrin, that I have a call out and discussion kind of tie for us to talk about exactly that, and again, it's sort of that forward looking. I think you can hear in Steve this sort of we have to answer the call of the HITECH Act and in some ways I think the fact that there are these specific requirements for an EHR vendor to provide capturability, it may actually is almost limited folks, EPs and EHs horizons in terms of what solutions to implement. And that moving forward, it may be focusing more on the outcome, we want to be able to allow providers to capture vital signs with high fidelity and in structured form, and then sort of give a little bit more flexibility as to how that's done. I think that's definitely a topic for the end, we're almost there, so, if we could switch back to the slides, we can – I'll take it home on process and then we can kind of start digging into the topics. Does that make sense?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Sounds great.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
I will take silence as yes. Okay, so if we could hop back into the presentation, that would be fantastic, I'm not sure, I think I do nothing.

Caitlin Collins – Project Coordinator, Altarum Institute
We've switched back, do you not see it yet?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Umm – let's see, ah, yup, I'm back. Okay, so once a vendor has gone through the process of certifying he has a complete EHR, he's got the whole set or certifying for different modules with an authorized certified testing body, then those products are sort of given to – handed off to the ONC on the certified health IT product list, called the CHPL. And those products are listed again as either complete electronic health records or EHR modules. That website is managed by the ONC and provider – and vendors are given an identification number for their certified product and a provider or an eligible hospital, when they go to a test, and this is with CMS. They're able to enter the sort of certification ID number for one or more products, to sort of say, this is the compilation or product I'm using to say that yes, I have adopted

certified EHR technology, and then they go on to attest. So, the – you can take a look at the CHPL, there are lots and lots of certified products there. It also lists any sort of assist – tools that are used by a particular vendor to certify.

I think one thing that I'll point out, because we were thinking about this yesterday in the Innovation and Risk Assessment call, is that there's still sort of a philosophical – I think that CHPL was great place to sort of see the difficulty of regulating software almost like a product. As someone who's been part of a cloud-based vendor, there are many, many versions that are released beyond certification that don't have a material effect on the actual certified elements, but sometimes that can be challenging to reflect in a place where things are still listed as products more so than software. So, something I think to be solved for, but I think that this list provides pretty good flexibility, but even in the world of EHRs, there's still that kind of struggle to try and adapt to software and kind of rapid delivery mechanism. So, that's the CHPL.

And then I don't have control anymore, so –

Caitlin Collins – Project Coordinator, Altarum Institute
Oh, I see, it looks like the Internet kicked you out, let me give you a new one.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yup, awesome. Okay, we're back. So that's it for the overview of the Certification Program. If you all want to go through case studies of another measure we can. I do think with probably given time, it would be best to kind of move into discussion topics, also because I'm sure you're tired of hearing my voice. So, unless you want to go into any measures, we can always take another – I'm always happy to get on the phone with folks and kind of walk through some more. But, does everyone feel okay about moving into discussion?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
That would be great.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Okay, excellent. So, I'm going to kind of scroll through these. The way that I've been trying to think about our work here, it's sort of what could be the role of government, the private sector, individuals, vendors, whatever, on kind of three areas. So, reducing risk of harm and harm could be safety health, privacy, kind of market assurances so that kind of concept of the need for assurances around quality, trust, integrity and then promotion of innovation. So, it's sort of hard for us to kind of look at the goals here and I think, I just wanted to call out at least some things that I've uncovered and certainly welcome others to jump in.

But, I think the ONC, HHS's Certification Program, some of the elements that really do well to reduce risk of harm, our standardization around kind of drug-drug and drug allergy interaction warnings, tons of research out there about the efficacy of decreasing medical errors. Adoption of standards for the exchange of information and vocabulary for documenting conditions and sort of standards around reporting, certainly I think it's a floor. And I know that industry is hoping to innovate and create kind of standards that facilitate even more functionality. But I think those standards are really important. Kind of that the – of privacy and security capabilities, so having that standardized I think is really good when it comes to reducing risk of harm. And then kind of standards around clinical reconciliation, so that if I would receive a continuity of care document from another provider, there are some standards about how that data is absorbed into my system. And again, the standards around exchange, which I think are important.

So, this, I think shows – I don't know if others have any – that they want to call out for sort of how the program is kind of currently addressing this concept of risk of harm. I will say as sort of an aside, it's not – in this program, but it is through the ONC and they are soon releasing their Patient Safety Surveillance Plan. So sort of another activity by the ONC and the concept of safety or adverse event reporting was raised in the proposed rule for the 2014 edition, that sort of passed, given that the market and industries weren't there, but definitely another sort of area that they've dug into. I think when it comes to market assurances there are standards, which are – ,of having vendors listed on the CHPL. The ONC has

conducted surveillance following certification and has actually recently revoked certification from an EHR vendor.

I think the criterion around transparency in the quality management systems and safety-enhanced design processes, I think it's feasible in that the ONC is really focused on process. So they've not been overly prescriptive such as saying do you have a process and making that transparent to providers and eligible hospitals. And then kind of standard guidelines for listing of clinical decision support interventions, so the sources and what information has to be presented to providers as they're getting those interventions. Promotion of innovation, as I kind of called out before, the modular certification just sort of getting volume of products into market. The different challenges they're doing convening stakeholders – but also kind of standards development work and other activities. Acceleration of standards development and then actually shifting initiatives to private, kind of private public sector, so the National exchange – Information Exchange Network actually moved over into a non-profit. So these are just some things that I called out.

And then this is probably where there's more discussion, but I'll scroll through these just so you can kind of see how we're thinking about it. But, please now I would lover for everyone to kind of get in here. But I sort of also took a look at challenges and risks to innovation or just sort of – it's more challenges in general and from that, I think, it's that their funding source we could talk about. So, I think here is where discussion may be good. I don't know if you guys want to go through the list of items that I deferred first?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
So, I mean, this is Brad. I had mentioned – I'm trying to look at this through the lens – it's not really a use case as much as it is just trying to understand when something goes wrong, how does the system react to that? How does a government agency become aware that something has gone wrong and then, if it's ONC, what does ONC do when something goes wrong, when the Health IT hiccups in some way that produces a safety issue. So, I don't know if that's an appropriate place to start, but that's the prism through which I'm looking at this is trying to understand when something goes wrong, how does this system react to that?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yeah, sort of a backstop. And just to make sure, in case folks were on mute, getting coffee, whatever. The sort of example you gave was, what if as a provider I call up the wrong patient record, not Brad Thompson the gentleman dressed in the 3-piece suit at 9 a.m., but Brad Thompson the baseball player, and as a result the provider delivers the wrong care, potentially leading some sort of incident, or not, and kind of how that might fit into the Meaningful Use Program. I think Steve probably could best answer it, I know that they're doing work on the concept of patient matching, ensuring better fidelity there and certainly, as I mentioned, the kind of in the proposal, the discussion around reporting adverse events, might be a kind of initial answer to that. But Steve, do you want to talk a little bit about kind of the backstop?

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
Sure. This is Steve Posnack from ONC. So, when something happens that is a safety concern, do we care? Absolutely, right, because that's part of our broader mission, we want to make sure that health information technology is safe, we want to make sure that providers can use it effectively. And so, taking a step down from that and into the current kind of regulatory paradigm that we have at the present, I guess to try and answer your question a little bit more discretely Brad, is that if folks remember that kind of – the concentric squares or the nested squares slide that Lauren had, it wasn't drawn to scale. And, she's going to go back for me, so the gray box or the blue box is really probably should really be, if we drew this to scale, like the size of the black box that's down there in the corner. And then the universe of all these other capabilities for which there is no regulatory paradigm, there are no certification criteria, there is no certification body oversight because they're not within the scope of what's required for certification.

And so it becomes complicated, I would say, from an oversight perspective to say for those ONC authorized certification bodies that we have. If there's a capability that is not performing correctly for which they have issued a certification, they have the ability and authority to investigate those in response

to complaints, in response to other such feedback that we receive. They can go and figure out, is there something wrong with the product that we certified because our name – our stamp of approval is on this to say that it worked, for these capabilities. If it's something beyond that though, and especially into some of the scenarios that Robert pointed out earlier, if it's medical device to electronic health record software interoperability or mobile health apps to electronic health record or some other type of patient-generated quantified self-type of thing. Those may be already outside the scope of even what we have an oversight paradigm for already. And so that's just one thing, while I have the microphone here, and I'm not putting Bakul on the spot, but he can probably chime in with his perspective as well, I think it might be important to think about the umbrella of the agencies. And when I, as I understand FDA, when something is in essentially from the sta – from a legal perspective and meeting the medical device definition, it's in, it's underneath FDAs umbrella. For ONC, we actually have to create an umbrella first for regulation and then things can voluntarily become certified underneath them and subject to some form of oversight. So it is a different, in terms of either having abilities proactively or having abilities subsequent to action and then retrospectively to go ahead and oversee health information technology in different ways. So, I don't know if that – I wasn't trying to drone on and on about the differences here, but I think there are some nuances in terms of how each agency has oversight and what we can do in response to like a scenario that you brought up, Brad.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Can I just maybe before Bakul talks about the second scenario, the interoperability, if I can just stay with a patient mix-up scenario –

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
Yeah.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
– for a moment. So when you were describing what happened, I wasn't clear whether you were talking about in theory the way a system could work in the future or you were talking about the way the system works today. Can you comment, I mean today, if there is a patient mix-up scenario, what happens or what has happened so far? Does certification get revoked? Do – I mean, what's the real experience with that presently?

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
So –

David Bates, MD, MSc – Senior Vice President for Quality and Safety – Brigham & Women's Hospital & Partners
Could I jump in, this is Dave Bates? I mean – Steve may not want to say this, but, the reality is this is not a role that ONC has played. Certification is something that you do one time, you do it at the beginning, you're certified, you're not certified. I don't think that there's a mechanism to revoke a certification that exists today, and there's not a place for – one central place, for providers to report problems like this when they do come up, which is, I think – which is one of the things that we're being asked to think about.

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
Yeah, so that's ah – David said it more directly than I probably would have in an indirect way. But I mean to build on that, as David mentioned, right, so Lauren's company brings their product in to get certified. No one could be a customer of that product yet, and they get the certification because they've proven that the capabilities for which we have certification criteria work. There's a whole other set of capabilities that are not subject to certification and then the product goes ahead and gets implemented in a thousand practices. If one of those pulls up the wrong Brad Thompson, there's not really a system or process or mechanism in place, aside from them complaining to their Lauren's company, them complaining to the certification body, them complaining to us. And by complaining, I'm saying kind of a feedback loop that something didn't work correctly, but there's – maybe that's enough. Is that enough Brad?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yeah, you've answered my question. I appreciate it, thank you.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
And Brad, I would also suggest that when the ONC's Safety and Surveillance Plan comes out, to take a read. I think they are – one of the things that the ONC, and I think that it's in a slide, has done well is that they have left that gray space and are working with private sector to see if there are solutions that can be adopted outside of the program. But do definitely take a look at that Plan, some of the ideas are to address what you're talking about, maybe within the context of certification and Meaningful Use and in other ways outside of that context.

But I think we – there is also an RFI that the ONC put out about governance and health information exchange and the industry, and not vendors, but the entire industry says, too soon, too soon, we're not ready to handle any other specific requirements, let's work on it a bit more. And so I think it actually speaks well to the point I have on the screen here, which is the fine line between being too prescriptive versus identifying kind of outcomes and then letting technology and other stakeholders sort of do their thing to get to that outcome. But, I think that Plan will be definitely good to read for this group.

Bakul Patel, MS, MBA – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
This is Bakul and I was going to just amplify or probably jump off David's point there. There are, I mean one of the things that as a gap I see, there are places for people to report issues, like PSOs, like FDA, other places, but there's not a centralized, like a one-stop shop. So I may say that there is not a one-stop shop for people to report all health IT issues, there may be many different places and some places capture certain types of data and some places capture some different types of information or event information, but necessarily does not capture everything together. So, that may be a nuance to what David was just talking about.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
And this is Matt. I would argue that the current mechanisms aren't providing the level of transparency that most folks need to really know what's going on.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
This morning, right as Lauren's call was beginning, I sent out a proposed agenda for future discussions among the Regulation Subgroup and you all will see that I think the fourth of fifth meeting we were actually dedicating an hour to look at nothing but data collection and reporting associated with adverse events and otherwise. It's a topic that Julian very much feels passionate about and he's going to lead that discussion down the road. So, that's – I think that's a really important point and one that we're going to dive into deeper.

W
Hi –

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
I guess I want to go back to Steven's point about the umbrellas between the agencies and I appreciate that and I realize that ONC has worked hard over the last four or five years to develop the umbrella for electronic health records and systems and modules. And I also appreciate FDAs oversight and regulation of medical devices in the space of Health IT, but what I see is a huge gap where the interoperability of medical devices with EHRs and EHR systems is really lacking. And if we're talking about a learning health system, which I keep on hearing folks mention, then I think that's something that this group should actually discuss and bring forward. And I realize that ONC is considering things like patient-generated health data into the EHR with respect to Meaningful Use Stage III, but I think that's part of what really our mandate is. Our mandate is to create a report that contains a proposed strategy on an appropriate risk-based regulatory framework. And to not talk about something that in the future is obvious, and that would be the interoperability of these medical devices, which falls into even some of the topics that Julian wants to talk about I think would really be a lost opportunity.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
I think along those lines it's also, and Meg pointed this out earlier, but it's definitely interesting to consider; again, this is sort of in the ONC context as it currently stands. Given that the program is tied to Meaningful Use, if there is some sort of integration – data integration measure on the provider side, then the ONC is charged with sort of creating some sort of certification criteria. And so I think one of the things that the group should consider is, is the certification process something that should continue to be tied to sort of a program like Meaningful Use or behaviors of providers. Or is there – are there certification needs for standards that address kind of issues that aren't tied to particular measures.

And I definitely think that tying the program to measures creates an even greater level of complexity, which is sort of one of the challenges I point out here, and also some regulatory scaling concerns, given that there's a lot of coordination and lockstep activities that have to go into place, rather than just presenting standards. But it's definitely, I think, as we're – if we're looking at the ONC existing regime to kind of call out greatest hits for – and is proposing other – a framework for Health IT, it's definitely worth if everyone could think about, do we keep tying certification to programs or is this something that we kind of want to get away from? Do we want certification to go back to the private sector, before the ONC HIT Certification Program, there was private certification, so just some things to think about along that line.

Brad, should I move to the next slide? It's sort of this kind of more points around some of the potential challenges within the program.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
That would be great.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Okay, great –

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
We need to be sure to leave like ten minutes or so at the end for public comment, so you have about sixteen minutes total left.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yeah, absolutely. So just kind of on the screen, as I've touched upon most of these points, but I think one thing that I'll underscore again, is really the fine line between prescribing technology, prescribing workflows, functionality versus letting technology serve as a means to an end. So I think, personally, I'll speak for myself, I definitely think the more that we can define outcomes. So we want certain care outcomes or we want providers to be able to exchange information or be able to pull up a chart with strong – validated it's the right person and then sort of let technologists figure it out with their end-users, that's my preference. And I think in some ways the certification program does it well and in others, in part because they're having to tie criteria to specific measures, they're have been cases where things have been prescriptive.

I can send out an email to our subgroup, but Keith Larsen had highlighted a number of sort of examples kind of along those lines of – that but in some ways the program has forced vendors to create functionality or workflows that they might not otherwise have created or create functionality that their users don't necessarily want. And so he kind of calls those measurement risks, but in order to measure and ensure that a provider has complied with the program, the vendors have had to create different submissions that aren't necessarily answering use cases or problems or outcomes. And then also as you've seen, the complexity of this method certification process doesn't yield a tremendous amount of flexibility. And so I think particularly if we're going to move to a place where Jarrin is talking about it of expanding to integration in other Health IT, that flexibility constraint is definitely an issue and I think that kind of ties well with the concept of scaling. I know the ONC is working as hard as they possibly can, but I probably also sort of feel the pains of scaling, and I know they've tried to be as flexible as possible within the statutory limitations, but I think if we're to expand certification out of all that, those are two points that would need to be addressed.

So that's all I have. And then Matt Quinn, I know you had brought something up earlier, I don't know if you wanted to raise that now or if folks have other sort of stuff on different – potential challenges, things that they liked and any other questions. We have got 5-10 more minutes before we open up for the public comment.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
I'll defer to other folks, thank you though.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Okay, sure.

Elisabeth M. George, MS – Vice President, Global Government Affairs, Standards & Regulations – Philips Healthcare
Lauren, this is Elisabeth from Philips. First off I wanted to say thank you very much for that excellent overview because it actually helped answer a number of questions I had about the ONC process, to try to understand. And I think that Brad's idea of trying to discuss a little further at later meetings how we deal with post-market and things like that are going to be really valuable. So I do plan on delving into this a little bit more to see a little more of how the process works, since maybe I'm fortunate, I haven't had to deal with it, or maybe I'm unfortunate that I haven't had to deal with it.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
No comment while regulators are on the phone – no, yeah, I can, actually the ONC has done a great job, they have tons of different sort of reference materials. But I'm also always happy to kind of dig in with anyone if you want to kind of go through the program. But I can send out some links to this group for some self-education about kind of the program.

Joseph M. Smith, MD, PhD, FACC – Chief Medical and Science Officer – West Health
So Lauren, this is Joe. I wanted to thank you as well. I thought that was just a fabulous review, not what I do day to day and so I felt like it was getting a drink of water from a fire hydrant, but I think you did it really well. I heard in your voice perhaps things not completely said, this notion of extending kind of the process of certification around internal process metrics versus providing some latitude so that there can be perhaps a good deal more vendor innovation. And then echoing the comment about the gray box being enormous with respect to the rest of the small set of requirements, do you, as you look forward, do you see the kind of strategy of certifying around the very specific particulars of features? Do you see that going into some senescence and that we'll eventually have a little bit more market-based innovation without kind of central specification of functionality?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Definitely we have been – the vendor community, anyone who will listen to me, which I don't know who that crowd is, but definitely been advocating, within the context of Meaningful Use, for CMS to again set outcomes. We want providers to be able to do "X" or we want a provider to be able to say that "X" percent of their population of diabetics has controlled A1c levels, or something like that. Or just sort of set more outcomes rather than sort of we want a provider to enter this data in this way. In some ways I think Steve was sort of saying this, in some ways I think the first stage or two, was almost a necessary, I don't want to call it evil, but, necessary prescription in that there was such a scattered market and such scattered behavior pattern of use.

But hopefully we can move away from enter this here, do this here, present information like this and really move to a place where a technologist can sort of work more with their users to kind of create solutions to whatever problem or challenge CMS sets. And I think the other sort of thing that I think will be important is to simplify the program and to really narrow the scope so that the market can kind of innovate and address user needs outside of the program, continuing maybe to draw on standards work to make sure that standards that should be used – are and are well adopted. So that's kind of the hope, I think it's actually incredibly possible, but it really relies on kind of narrowing scope and simplifying quite a bit.

Joseph M. Smith, MD, PhD, FACC – Chief Medical and Science Officer – West Health
Thanks, that's terrific.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Also, since I, in – I think in couple of weeks, I'm planning to kind of do a survey of any and all either government or private methods of addressing concepts of risk – to individuals or kind of addressing the need for quality, integrity and trust assurances. So taking a broad survey of lots of different industries, not necessarily to say that any agencies or private parties that are carrying out those activities should be doing so in Health IT or that there should be any assumption of existing processes by the FDA, ONC or FCC. So just really to get a discussion going about other options to include in a risk-based framework. And so this is sort of an open call to all of you, if you have any things that you've seen in other industries, whether it's by the government or in the private sector, please let me know, would love to include it in that sort of survey. I'll just sort of – kind of a compilation of things that might not work at all for Health IT but could work, just want to kind of broaden our horizons and make sure that we're not feeling like we have to, by addressing existing regimes that we have to address Health IT within those regimes or that just sort of want us to try and think outside the box. So if you have any, please email me.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
So Lauren, this is Brad Thompson. Since we covered the FDA stuff, I wonder if you'd be willing to do a bit of comparing and contrasting when it comes to the required testing and evaluation of the performance of the software. So let's take something like functionality around vital signs in an EHR. In the FDA world, if those were made under the quality system regulations, there'd be some validation required to demonstrate that the software performed as labeled. And by perform, I mean perform reliably, that if tested through a variety of mechanisms to show that it repeatedly comes up with the right answer, so that we can be assured that the coding was done correctly and the design and so forth. When you were going through the test procedures and so forth, I wasn't reading all of it so I didn't fully absorb it. Can you compare and contrast how is the ONC system similar to the FDA required validation and how is it different from the FDA validation?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Sure. So I don't know what you saw on the phone, but I think actually Meg Marshall could probably provide the best comparison. I can certainly take a stab, I don't want to put her too much on the spot, but I don't have much experience with FDA processes as I've never really dug into the space. Meg, are you still there and willing to take a stab?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
This is Meg. And that's an excellent question and a very sweeping question as well. I wasn't able to sit in on the call last week, but I'll go through the recording where you discussed the FDA. There will be some crossover, the quality management system, for example, crossing over into the Meaningful Use Certification, so there certainly are elements that maybe are known by different names or different terms. The post-market surveillance reporting, for example, through – very similar to Patient Safety Organization, the activity, the verb itself is the same, you're recording events that occur after your product's been released, but the process itself is of course different. So, I think that it's worthy of a discussion and certainly a cross-walk matrix and I'd be more than happy to take a stab at it. I just – I don't think I'd be able to do it justice in the two minutes it seems that we have left today.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Well maybe if I can just put a little bit finer point, I'm really focused more, in my question anyway, on premarket validation rather than post-market oversight. So, before the product is ever released to the public, what does ONC certification require be done to test and evaluate the software versus what FDA does – requires to be done to test and validate the software?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
ONC, you go through various scenarios so the test data generally provides sort of different patient types that could or coul – should or should not be applied to the denominator for that patient population for which the measure is being applied. Or, so as an example test data, which has – the sort of vendor would

go through kind of almost script-like and enter data, let's say for vital signs I enter blood pressure for a patient that's – five, I capture their height and weight and I demonstrate that that was sort of successfully done. I go back and I demonstrate that I can access that information, okay great. I go back and I demonstrate that I can change that information, again, for the criteria. If I am prescribing a medication using the system, I have to demonstrate that I am in fact using the vocabulary and code sets that are required. I then have to demonstrate using particular use case scenarios, so a drug that they've asked me to prescribe, but in fact that that kind of task – that submission electronically works.

So there – for each of the measures, there is that kind of script-like process that you go through and in many cases, there are sort of multiple kind of either test patients or test scenarios that you have to go through. I think that's kind of to prove that repeated – through repeated verification that the product is working as it should. So it's kind of just like a – you go through the script with the tester, just to make sure that that – for things like submission using an HL7, you have to sort of – there is actually a system that kind of receives that submission via the standard and the HL7 2.5.1. And so each of those certification criteria is something that you go through with the testing body using their test data. And then for the purposes of calculation, there's a whole set of test procedures that you go through to enter data based on different patient types to assure that the calculations are being done accurately and as would be expected for the program.

So I think it – for the clinical quality measures, there's a whole other testing tool that also kind of allows submission of those measures and validation that the numerators and denominators and other exclusion properties are working, as they're intended to. I think it actually might be somewhat, I understand, somewhat similar.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
This is Meg. I think the important thing to note is that the EHR Certification Program is very prescriptive because it's intent is to certify EHRs, so it needs to get to that functionality level and the test scenarios have to be really prescriptive, are you completing the function? Whereas otherwise, it's more that you're testing against your own processes, you're testing that your product is doing what it says that it's doing. So I think that that's – there's inherently a major difference in the two approaches, and certainly something that I wouldn't encourage that we would recommend is trying to take a stab at defining functions that are required for different types of HIT that may – where the certification may expand is not necessary. But again, the main focus is on the process itself, are you developing – how are you developing? What are you developing? Is it doing what you think that it's doing? Are you testing against that purpose? Do you actually have this function in your code or in your software and are you able to complete it?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
That's a great point Meg.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
I guess from the FDA world, Brad and correct me if I'm wrong, regulated software usually has to go through verification and validation, verification being more the purely engineering test that compares what the product is to what the design specification says it's supposed to be. As compared to a validation test, which confirms that, the product meets its intended use. So, it's a much more user-focused type test, usually performed at the end of whatever the product cycle is for that type of software.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
I think that's well said. So maybe –

Elisabeth M. George, MS – Vice President, Global Government Affairs, Standards & Regulations – Philips Healthcare
Brad, this is Elisabeth, I'd like to add one other point is I think that it sounds like, and I'm not understanding the ONC totally, but, it sounds like it's the total software, so all aspects, even the non-medical, from our perspective, must go through verification, validation and go through our full design

controls. Versus the ONC model that sounds like it targets elements or functionality and may address the total software package, but that's not the focus of the certification, if I understood that correctly.

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator
Yeah, I mean, this is Steve from ONC. And just to pick up the vital signs example that Brad brought up earlier. I mean the vital signs certification criterion, the first requirement is that the electronic health record technology can record, change and access the patient's height, weight and blood pressure and that they are recorded in numerical values. And then it can calculate body mass index, so BMI. And so if you were to put in height and weight, and then the second element of calculating BMI, if that didn't calculate correctly, then it wouldn't pass the certification criterion. But that's kind of the – we don't tell you how you do it and there are a number of different ways to record that information, but at the end of the day, it is targeted to demonstration that the functionality that a provider will be using can perform appropriately. And then there's the kind of nuance to the programmatic requirements of Meaningful Use that, as Lauren was mentioning, there's a subsequent capability as well, which I would say is like a secondary capability to kind of measure how many patients that are in this specific time range have had that done.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
This is very helpful. I have to say though we have about five minutes left and I do want to make sure that we give members of the public an opportunity to participate. So Lauren, before we switch to the public comment, anything else you want to add?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
No, no. Thanks so much everyone for participation and feel free to ask questions and, no let's go to the public.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Great, MacKenzie or whoever controls the phone, can we –

Public Comment

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Sure, operator, can you please open the line for public comment?

Rebecca Armendariz – Project Coordinator, Altarum Institute
If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue. We have no comment at this time.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Okay, well thanks and certainly to any member of the public, if you want to send me or send Lauren, I'll even offer Lauren an email with questions or comments. I can't promise that we'll respond to everything, but we would love to hear of any concerns or issues that anyone has identified.

So I mentioned at the outset that just as this call was getting going, I sent out an email. Julian and I had met earlier this morning in order to basically try and come up with an action plan for the rest of the calls that this group would have. And I distributed that for comment and I would love to get people's comments on it. The next scheduled meeting of this group is at this exact same time tomorrow, when I believe that Jarrin and Mo and Julian will sort of walk us through the FCC world, so that we can understand what the regulatory system is there. And then start to understand how it connects up or relates to the ONC that we heard today and to the FDA that we heard last week.

Then what I've proposed is that we have another meeting as soon as we can schedule it, but ideally next week, where we would again ask Lauren and by email earlier today I also invited Meg if she wanted to participate in helping to construct this, the agenda for it and to organize it. But to have a discussion

around other regulatory and legal structures, and also private structures and international structures, sort of the regulatory and legal environment outside of the three agencies. Because one of the things that we're charged with looking at is duplication and figuring out whether there's stuff that maybe the three agencies don't need to do because someone else is already doing it. So, we wanted to schedule a call for that. And then, and I'll let you read the email, I basically lay out a plan for July to take us hopefully in a thoughtful way through the balance of the issues and come up with a work product.

So please everyone, if you would, read that email and let me know what you think. Then we want to start picking dates for subsequent calls, so everyone can get it on their calendars and we know basically what needs to be done. So with that, I just want to thank Lauren for all of her hard work and the terrific job she did in the presentation today. I found it, I'll echo the comments that I found it very, very helpful to learn about the ONC world. So with that, is there anything else we ought to talk about before we adjourn? If not, thanks everybody, I look forward to talking to you all tomorrow. Take care.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thanks everybody.