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Moderator: OS ONC
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Coordinator: Welcome, and thank you for standing by. At this time, all participants are in a

listen-only mode until the question and answer session of today's call. At that

time, if you would like to ask a question, please press Star 1. Today's

conference is being recorded. If you have any objections, please disconnect at

this time. I would now like to turn the meeting over to your host, Chartèse

Day. You may begin.

Chartèse Day: Thank you so much. Thank you all for joining us this morning. We're super

excited to talk to you about the release of our draft interoperability roadmap,

as well as our draft 2015 standards advisory. My name is Chartèse Day, I'm

the Director of the Office of Public Affairs and Communications at ONC.

This morning, our agenda will go as follows.

We will start with Dr. Karen DeSalvo, National Coordinator for Health IT and

Acting Assistant Secretary for Health to give us a very high level overview of

interoperability, how it ties into overarching programs we're working on

throughout the U.S. Department of Health and Human Services. We will then

turn it over to Erica Galvez, our interoperability and exchange portfolio

manager, who will walk us through a very high level overview of the actual

roadmap.

We will then turn it over to Steve Poznak, Director of the Office of Standards and Technology to give you an overview of the first critical action deliverable coming out of the roadmap, which is our draft 2015 standards advisory. Then we will turn it back over to our operator, who will facilitate the question and answer session and take questions from the line. So with that, I will turn things over to Dr. Karen DeSalvo.

Dr. Karen DeSalvo: Thank you, Chartèse, good morning everybody. Thank you for joining us. We wanted to have an opportunity to give you some time to hear from us about the interoperability roadmap and ask some questions. We look forward to ongoing dialogue in the coming weeks as people begin to really dig into what is a meaty document.

And I just want to begin by thanking the team at the Office of the National Coordinator, our federal partners, and the partners in the private sector. There are so many people and organizations who, over the past many months, have been contributing intellectually and otherwise to seeing that we can come up with a roadmap that will make sense for the nation, not only from the federal perspective, but in partnership with states and the private sector.

We began this journey several months ago, and some of you may be aware that we published a vision document last summer that outlined a pathway forward and a set of use cases that we thought would make sense to get our country to a place where we could unlock data in an appropriate fashion.

And be able to put it to use for consumers to be engaged and empowered for clinical care, quality improvement, payment reform, public health and to advance science efforts in areas like precision medicine. This vision of a learning health system we worked backwards from to see what would be the

critical path areas that we would need to address, particularly in the short run, to get us on the right road.

So we have been working internally and with our federal partners, but also externally with our advisory committees and experts in the field to identify what we consider four big areas that need to be addressed in order to get us moving forward as quickly as possible on behalf of the people of America. The first is to be clear about standards.

There has been great advancement in the past five years in particular in the adoption of electronic health records, and in the advancement of health IT technology. And this has also meant that there's been a flurry of opportunities to define the way data will be captured and shared. On the other hand, what we have clearly heard from partners in the public and private sector that the time has come for us to be more explicit about standards.

And so a companion document to this roadmap is an interoperability standards advisory that Steve Poznak will describe in more detail later. This would be a list of what we believe is the widely used and set of standards that allow us not only to collect data in a similar fashion, but to see that it's shared in a similar way. So it reduces the complexity for people on the front lines.

Secondly, we want to motivate people, and organizations, and developers to use those standards. And so we have worked out what we consider to be a strong set of incentives and motivators that we can bring to the table as the federal government. So in addition to programs like certification or meaningful use, also the payment programs through CMS, grant programs, and in partnership with the VA and DOD.

The last few areas involve trust in the system. So collecting data and seeing that it - people are motivated to use it is all great. We want to make sure that it's being done in a fashion that gives trust and comfort to the American people and to the providers and others who have data in that system.

This involves seeing that we're attending appropriately to privacy expectations, that we're clear about what HIPAA is and what it's not, and that we can work with our state partners in particular - a call to action with them to see that we can get clarity on ways to align state level privacy and security expectations. So that as people move across state lines, their information can go with them and reduce the burden on the individual and on providers.

The last area related to trust is about how we can create an environment where data is collected, shared, and used in such a way that there is comfort that entities, exchange entities, other actors in the health IT environment, are using the same rules of the road. That they're following some expectations of behavior about decision making for the data, and about how to handle situations where people are not following the rules of the road.

We've had great conversations with many of the existing entities that have come up in the last few years in the community about a willingness to align with a set of best practices in the space of governance. And we will look forward to working with those entities on adopting those best practices by a date certain.

So that we can understand the best way for - that we can recognize through efforts like certification, trust in entities that can give comfort to folks that the system is working well and on their behalf. And really also thinking about the broader societal opportunity for data, whether that's for public health and

preparedness or advancing in science as appropriate. So those four areas are the big critical pathways we've identified.

You know, what you all and others will see in the document, and Erica is going to walk through, is a fair amount of specificity. We have also, though, been prior talking what we believe we can get done and by when in order to execute on this such that we can meet everybody's expectations. We look forward to doing this in partnership with the private sector.

This was developed in concert with them. This is designed to be something that we do together. It's a shared opportunity to really make a difference in the country, and we believe that by going forward together and holding each other accountable that we're really going to get to a place where we have the information necessary to see that we have better care, that we can have smarter spending, and healthier people in the country.

Just a final comment about those words, which are the language that Secretary Sylvia Burwell is using to describe her work around delivery system reform, a world in which consumers have the kind of coordinated care, access to care, information about their care.

A world in which providers are able to deliver that kind of care because they're not hindered by old payment models, but in fact are moving into ones that support care coordination and population health.

That better care model and those better payment models require better data models, and that is what we are laying forward in our interoperability roadmap is a pathway to a place where we can really provide the information

that is so necessary to see that new world emerge. So with that, I will stop, and I believe turn it over to Erica to ask her to walk you all through a little bit more detail. And then we'll have Steve step in.

Erica Galvez: Thanks, Dr. DeSalvo, and thanks, everyone else, for participating in the conversation today. Also about, one thing I'd like to emphasize with folks is the concept of nationwide interoperability, which is what we have built the roadmap around.

There have been a number of successful efforts focused on exchanging health information, and in some cases, even achieving interoperability in regional settings, in integrated delivery networks, a number of subnational venues.

But the reality is, none of those efforts to date have scaled to the level we need them to scale in order for information to follow a person wherever they need it, whenever they need it, regardless of geographic boundaries, regardless of organizational boundaries, technology developer boundaries, et cetera. So the roadmap really focuses on interoperability at that nationwide scale.

It also focuses, I think as the good doctor mentioned, on the actions - the critical actions that we can take for some near term ones that put us on a path and a trajectory toward a longer term learning health system.

In the near term, the goal that we have set for the next three years is focused very specifically on making sure that the majority of care providers across the broad care continuum, and individuals - we use the term individuals in the roadmap generally to refer to consumers.

Making sure they reach a place where they can electronically send, receive, find, and use a specific set of critical health information. And we do detail in the roadmap what we believe should be in that common set of electronic health information. It's the stuff that doctors, nurses, individuals, a number of different care providers generally need to make decisions that support health.

The roadmap is organized according to five building blocks. Hopefully all five of these building blocks are familiar to you, we've been talking about them since we put out the vision paper last year. The first is core technical standards and functions. The second is certification to optimize health IT products and services. The third is privacy and security.

The fourth focuses on environmental factors - business, regulatory, clinical and cultural environments, and the fifth is focused on governance and rules of the road. If you've taken a look at the document since we released it this morning, you know that it's over 150 pages. There's no way through the course of this conversation that I can give you a preview of all of the material in there.

But what I can do is give you a little bit more detail than Dr. DeSalvo mentioned on some of these critical pathways and each of the building blocks. So starting with standards and core technical functions. This section of the roadmap does address not only standards for areas like vocabulary, format, transport, security. It also addresses critical issues like patient matching and individual identity matching across systems, as well as resource location.

Many folks think of provider directories as part of that component. Critical actions in the near term that we really call forward related to standards in addition to the call for ONC to identify the best available standards for core

interoperability functions, which as was already mentioned, our colleague Steve Poznak will talk about in some detail.

Other actions focus on reaching semantic interoperability for that core set of common clinical data that we've put forward in the roadmap, addressing data provenance for that health information so that providers and individuals know where information is coming from and can trust it, improving consistency of consolidated CDA implementation. This has been a big topic of discussion given CCDA's connection to meaningful use.

And curating RESTful APIs. This is really important for making interoperability more nimble and scalable. Really comes into play when we take the frame of reference of nationwide - seamless nationwide interoperability. Fourth, the certification building block. Certainly, an evolution for ONC's certification program to advance interoperability through not only criteria, but testing (unintelligible).

But also a real focus you will see on the roadmap on the need for testing tools beyond certification programs, this notion that the devil really is in the details when it comes to interoperability. And we need to have mechanisms well beyond the ONC certification program to provide developers and the technology community with the ability to test and correct issues that may arise in their systems.

On the privacy and security front, I'll focus for purposes of this conversation just primarily on what we put forward around privacy. There are a number of different policies and organizational policies, state level laws, and in fact federal laws that apply to the sharing of health information. There has been

clearly a number of misinterpretations or misunderstandings of our federal framework provided through HIPAA for health information sharing.

And so one of the things the roadmap calls for is some additional education to advance common understanding across the nation of that federal policy framework. The roadmap also calls for some harmonization around state level and organizational level policies that apply to information sharing.

At this point, there are so many different definitions of data categories and rules around how information can and should be shared, it makes it very difficult for individuals to understand their choices related to their information - their health information. It also makes it very difficult for technology to automate and persist their choices about how their information will be shared. So some very precise calls on the roadmap around that kind of harmonization.

On the business environment, that environmental building block, I won't rehash what HHS has put out earlier this week in terms of delivery system reform goals. I think many of you have probably seen those. But I will note that the roadmap really looks to both federal, state, and commercial policies that are going to begin rewarding providers for outcomes as key mechanisms that create an environment where interoperability makes business sense.

There are - those are also mechanisms that can be used to reinforce interoperability through links to things like the use of certified health IT and even the best available standards that ONC is putting forward.

And then last but not least on the governance front, the reality is that although a number of different networks exist today that I mentioned earlier, a number

of different data sharing arrangements, there is not a clear process or set of rules for facilitating interoperability across those existing networks and existing regions.

And so on the governance front, ONC is clearly committing to establishing a nationwide governance framework with a common set of rules of the road, as well as identifying a mechanism for recognizing the organizations that comply with those rules, and holding organizations accountable to do so.

There is a very clear call to action related to this to stakeholders across the industry to come together from an operational level and establish a single process for ironing out the more detailed pieces that would need to be ironed out to really advance interoperability across the nation.

And those things in concert, we think, will help provide that mechanism that's so desperately needed to scale trust and scale interoperability. So I think I'll stop there. That's at least a high level taste, and pass it over to Steve Poznak to talk about our standards advisor.

Steve Poznak: All right, thanks, Erica. And so as Erica just mentioned, the ONC also published its first interoperability standards advisory today. It's applicable to calendar year 2015, and we intend to publish an updated standards advisory on an annual basis, meaning every December for the upcoming calendar year. I've started to think of it as a standard stocking stuffer, so to speak.

So this advisory reflects what we consider the best available standards as of December 2014 for particular interoperability purposes. I'd also like to emphasize that the advisory is non-regulatory in nature. Throughout the

roadmap development process, we interacted with a ton of stakeholders, and one of the most frequent requests to ONC was, what standard should we be using to achieve interoperability for X or for Y?

Can ONC step up and bring stakeholders together to identify common ground and hash out differences? With those requests in mind, we saw an opportunity for ONC to lead and industry-wide collaboration to identify the best available standards and implementation specifications for different interoperability purposes. And so here's the thing about interoperability. Why and for what purpose it is needed really matters.

In other words, the intended outcome in mind. As an industry, we owe it to ourselves to get specific, because different combinations of standards are often needed to reach a desired outcome. The interoperability standards advisory reflects ONC's decision to pursue a straightforward approach to advising the industry on interoperability standards and implementation specifications.

This approach is designed to more clearly link standards and implementation specifications to a specific purpose and interoperable use. It represents the model by which ONC will coordinate the identification assessment and determination of the best available standards implementation specifications.

And it is also designed, and this is important, to begin an interactive process that will ultimately result in an annual list of standards and implementation specifications for a broad range of clinical health IT interoperability purposes. It's really intended to be an all hands on deck experience for the ONC, for our federal partners, for everyone out in the industry together.

The 2015 advisory was prepared to give stakeholders a body of work on which to react, and is meant to prompt focused industry dialogue on areas where disagreement exists regarding the best available standards, as well as create a certainty in clarity on - in the areas where widespread consensus exists.

An advisory is intended to provide clarity, consistency, and predictability for the public regarding ONC's assessment of the best available standards and implementation specifications for a given clinical health IT interoperability purpose.

So in that regard, we expect going forward, the stakeholders who administer government programs, procurements, testing, or certification programs with clinical health IT interoperability components would first look to an advisory in order to leverage the standards and implementation specifications listed in one advisory to achieve their interoperability goals.

And so we believe this look first philosophy can help build momentum toward the consistent selection, implementation, and use of particular standards. Kind of last points here. The advisory will be open for public comment for about 90 days, and the comment period will expire on May 1.

Then, we expect to follow an open and transparent and structured process that includes advice in the (HIT) Standards Committee, ONC Federal Advisory Committee, and the public at large.

Chartèse Day: Thank you so much, Steve. So just to reiterate, the draft interoperability roadmap is open for public comment, and the public comment period will

expire on April 3, 2015. The standards advisory will be open for public comment, and that will expire on May 1, 2015. At this time, please submit your questions to the operator on the line, who will field them to us, and we will open the line up for questions from the media.

Coordinator: Thank you. We will now begin the question and answer session. If you would like to ask a question, please press Star 1, and record your first and last name clearly when prompted. Your name is required to introduce your question. To withdraw your question, you may press Star two.

Once again, if you would like to ask a question, please press Star 1. One moment please for our first question. Our first question is from Alex Ruoff from Bloomberg BNA. Your line is open.

Alex Ruoff: Yes, thanks for hosting this. I just had a question, I guess for Dr. DeSalvo, but I wanted to ask more about how this ties in to the precision medicine initiative. You spoke to it a little bit, but I was kind of curious if you'd give me a more direct link to, you know, how this supports that, and very specifically, how those kind of overlap.

Dr. Karen DeSalvo: Sure, thanks for the question, Alex. In just a little bit of time, the President's going to be making an announcement how - what they would like to see the administration do going forward on precision medicine. And, you know, critical to that effort is that we must have the information about individuals with their consent about their clinical experience.

About their overall health beyond the healthcare environment. About some of the biometrics, some of the fundamental pieces of information about things

like their vital signs and their laboratory studies to take advantage of what is a really exciting emerging technology in the genomics area that can target treatments to a person in a way that we would only have imagined a few years ago but has already shown promise in many environments.

So this roadmap, the workaround standards, for example, the workaround data privacy and security are a couple of spotlights I would give you that will weave right into the President's initiative that will allow us to do this work and simultaneously support that learning health system goal.

Coordinator: Our next question is from Laura Unger from USA Today. Your line is open.

Laura Unger: Thank you very much. Actually, I have sort of a combined question, and the first part is, when do you anticipate that the various different types of systems from all over the country will actually be able to "talk to each other and share information among them" in a real way? So that's number one, like, is this a decade down the road, or when do you see that happening?

The other thing is, what are you doing in this process to ensure the safety and accuracy of medical records and ensure that medical mistakes aren't made, you know, based on incorrect information and records?

Dr. Karen DeSalvo: Thank you for the question. You know, we believe that to have a ubiquitous sharing of this data, to have this learning health system where we're swimming in the information that can be turned into this kind of knowledge is - ten years is the long view on that.

The truth is, is that today, it does happen in this country that there are communities where there is interoperability, which provides us not only hope, but also a model for what works.

So places in tech communities in Tennessee, communities in Indiana, those are - Minnesota, there's communities all across our country that have shown us the way, and this is an opportunity for us to learn from some of those best practices and apply them more ubiquitously.

Laura Unger: And on the safety issue?

Dr. Karen DeSalvo: Oh, thank you for reminding me. On the safety issue, the clarity around standards actually really does begin to provide help in a couple of ways. One is that knowing that it is a three-pronged plug, as we would say, that it's going to have certain specifications, then frees up the developers of products like electronic health records or other health IT tools to innovate in the space of their user interfaces for consumers, and for doctors, and for other clinicians.

That actually really does enhance the safety and usability of the products. As a separate conversation, would love to talk to you more about the work that the Office of the National Coordinator has in partnership with AHRQ around safety with health IT. It's an agenda item that we are - that we've been addressing for some time.

Though I would just - it was the specificity in this roadmap on a call out that clarification on standards provide more freedom for the marketplace to innovate. And that supports the advancement of safety, if it's addressing usability.

Laura Unger: Okay, thank you.

Dr. Karen DeSalvo: Mm-hmm.

Coordinator: Our next question is from (Ken Perry) from Medscape. Your line is open.

(Ken Perry):   Hi, my question is, what role does direct messaging play in your roadmap, and
                   would the widespread use of direct be an important step for interoperability?

Steve Poznak: Hi, this is Steve Poznak. So direct messaging, and if you're referring to the
                   direct protocol, is, you know, one means, and it is an important means that we
                   have invested a number of ONC resources in a collaborative way to advance.
                   But it isn't the only means, and I think that's some of the feedback that we
                   received from stakeholders in the field.

                   I think that's reflected in the interoperability roadmap, as well as the standards
                   advisory, that there are going to be a number of different ways that
                   stakeholders are going to need to exchange data. And that the purposes that
                   they have in mind, and the outcomes that they seek to achieve, are going to
                   require different standards.

                   So those standards develop to the direct oriented messaging. They will be the
                   best fit and the kind of best fit for purpose, so to speak. And then maybe other
                   standards that will be more effective and optimized for reaching different
                   kinds of outcomes.

(Ken Perry):   Thank you.

Coordinator: Our next question is from (Mary Ann McKee) from Information Security
                 Media Group. Your line is open. Your line is open. If your line is muted, you
                 can press Star six to unmute your line. Again, your line is open.

(Mary Ann McKee):   Hi, can you hear me now?

Steve Poznak: Yes.

(Mary Ann McKee):   Okay, sorry about that. When it comes to governance and the rules of the
                 road, what do you foresee will be the sort of mandatory rules of the road? You
                 know, someone had mentioned that, you know, you would hold organizations
                 accountable. So in other words, would they be, you know, would there sort of
                 be any regulatory enforcement involved, or, you know, a carrots and sticks
                 sort of thing? Or, what do you envision with that?

Jodi Daniel: Great question. This is Jodi Daniel, the Director of Office of Policy. So we are
                 - in setting forth the rules of the road, we think that this provides the principles
                 and the overarching framework of policies and practices that folks who are in
                 helping to facilitate health information exchange to follow.

                 To make sure that health information follows the patient, to make sure
                 information is protected, to make sure that it's following the standards and
                 best practices that are out there. We are expecting to also, and we've had a call
                 to action for industry to facilitate a public/private process to address
                 implementation operational level issues. And a third piece is what you're
                 asking about, which is accountability.

At this point, we are exploring all options. We are considering regulatory options, we're considering how we can leverage certification to ensure accountability with the rules of the road. We are looking at how best we can not just set for those principles, but hold people accountable for meeting the principles and for operationalizing them in a way that facilitates interoperability.

(Mary Ann McKee):   Thank you.

Coordinator: Our next question is from (Ata Allen) from Politico. Your line is open.

(Ata Allen):   Hi, I just wanted to follow up on the governance question. Does the, you know, the CMS made this announcement that talked about pushing people toward care that requires more interoperability. And so I'm wondering, do you have a timeline for getting some of this governance action going?

Some of the accountability, whether it's through configuration, certification, or whatever? Because it seems like you have these two things that depend on each other and feed off of each other, but so that the timing might be kind of important.

Dr. Karen DeSalvo: You are correct. This is Karen. In the - DeSalvo, sorry - in the press release, you'll notice the Secretary remarked air quote, which refers to her delivery system reform effort about (unintelligible) spending and healthier people. The three action streams in there around payment changes that historic announcement we made Monday about payment reform will have associated with it a learning action at work, which will be a table set by HHS.

At which payers can talk about their past forward with the public and private sector to defining alternative payment models, and included in that conversation, we have heard from private payers, and we certainly are interested in talking through how our payment models can support and advance health IT and interoperability.

So there - these are related and completely tied efforts to have that better payment model that's going to require better data. And it's going to require that data to be unlocked so it can be put to the use to assess value that at the same time, those payment models need to reinforce that there must be data standards that we all agree to. And a set of business practices and that the data will be shared.

Chartèse Day: And we have time for one more question.

Coordinator: At this time, there are no further questions.

Chartèse Day: Well thank you all so much for joining the call. We look forward to speaking with you further.

Dr. Karen DeSalvo: Thank you.

Coordinator: This now concludes today's conference. All participants may disconnect at this time.

END