Health Information Technology Advisory Committee

Transcript
February 20, 2019
Virtual Meeting

SPEAKERS

HITAC Members		
Name	**Organization**	**Role**
Carolyn Petersen	**Individual**	**Chair**
Robert Wah	**Individual**	**Chair**
Michael Adcock	Individual	Member
Christina Caraballo	Audacious Inquiry	Member
Tina Esposito	Advocate Health Care	Member
Cynthia Fisher	WaterRev	Member
Brad Gescheider	PatientsLikeMe	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil Jain	IBM Watson Health	Member
John Kansky	Indiana Health Information Exchange	Member
Ken Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Arien Malec	Change Healthcare	Member
Denni McColm	Citizens Memorial Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Aaron Miri	The University of Texas at Austin	Member

Brett Oliver	Baptist Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
Raj Ratwani	MedStar Health	Member
Steve Ready	Norton Healthcare	Member
Patrick Soon-Shiong	NantHealth	Member
Sasha Termaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member

ONC Speakers		
Name	**Organization**	**Role**
Lauren Richie	ONC	Designated Federal Officer
Donald Rucker	ONC	National Coordinator
Elise Sweeney Anthony	ONC	Executive Director, Office of Policy
Steve Posnack	ONC	Executive Director, Office of Technology
Seth Pasinski	ONC	Director of the Office of Planning, Evaluation, and Analysis
Mike Lipinski	ONC	Director, Regulatory Division
CMS Speakers		
Name	**Organization**	**Role**
Alex Mugge	CMS	Deputy Chief Health Informatics Officer

Operator
All lines are now bridged.

Lauren Richie - Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Okay. Good morning, everyone. Welcome to our first HITAC meeting of 2019. Glad you all could be with us today. I appreciate your flexibility and rearranging the schedules for the year, but we have a very full agenda, as I'm sure you've probably noticed already. With that in mind, I'm sure there's going to be

plenty of questions and discussions. So, as a reminder, if you're in the Adobe, please us the hand-raising function. If you're only on the phone, feel free to pipe in and remind us that you're on the phone and we'll put you in the queue.

At this point, I will officially call the meeting to order starting with roll call. Carolyn Petersen?

Carolyn Petersen - Individual - Co-Chair
I'm here. Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning. Robert Wah?

Robert Wah - DXC Technology - Co-Chair
Present. Good morning, everyone.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning. Michael Adcock? Not yet. Christina Caraballo?

Christina Caraballo - Audacious Inquiry - Member
Good morning. I'm here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Tina Esposito?

Tina Esposito - Advocate Healthcare - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Cynthia Fisher?

Cynthia A. Fisher - WaterRev, LLC - Member
Yes. Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Brad Gescheider?

Brad Gescheider - PaitientsLikeMe - Member
Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Valerie Grey?

Valerie Grey - New York eHealth Collaborative - Member
Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Anil Jain? I think he said he may be a little bit late. John Kansky?

John Kansky - Indiana Health Information Exchange - Member
I'm here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Ken Kawamoto?

Kensaku Kawamoto - University of Utah Health - Member
Here.

Q;
Steven Lane?

Steven Lane - Sutter Health - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Les Lenert?

Leslie Lenert - Medical University of South Carolina - Member
I'm here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Arien Malec?

Arien Malec - Change Healthcare - Member
Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denni McColm?

Denni McColm - Citizens Memorial Healthcare - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Clem McDonald? Not yet. Okay. Aaron Miri?

Aaron Miri - The University of Texas at Austin - Member

Good morning, everyone.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Brett Oliver?

Brett Oliver - Baptist Health - Member
Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Terry O'Malley?

Terrence O'Malley - Massachusetts General Health - Member
Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning. Raj Ratwani?

Raj Ratwani - MedStar Health - Member
Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Steve Ready?

Steve L. Ready - Norton Healthcare - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Patrick Soon-Shiong? Sasha TerMaat?

Sasha TerMaat - Epic - Member
Present. Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Andy Truscott?

Andrew Truscott - Accenture - Member
Present.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Sheryl Turney?

Sheryl Turney - Anthem Blue Cross Blue Shield - Member
Sheryl's here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denise Webb? I do believe Denise is on. Kate Goodrich?

Denise Webb - Individual - Member
Yes, I'm present. Sorry. I took the mute off.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
That's okay. Do we have Kate on the line? Chesley Richards? Ram Sriram? And Lauren Thompson?

Lauren Thompson - DoD/VA Interagency Program Office - Federal Representative
Good morning. I'm here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Good morning. I just want to confirm we have Alex Mugge from CMS?

Alexandra Mugge - Centers for Medicare and Medicaid Services - Deputy Chief Informatics Officer
I'm here.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Perfect. And from our ONC leadership team, we have myself, Seth Pazinski, Elise Sweeney Anthony, Steve Posnack, Mike Lipinski, and Dr. Don Rucker. With that, I will turn it over to our National Coordinator, Dr. Rucker, for a few opening remarks.

Dr. Don Rucker - Office of the National Coordinator for Health Information Technology - National Coordinator
Okay. Thanks. First of all, thanks, everyone for attending. It's our first meeting of the year. It turns out to be virtual, I think, as folks know from the government funding issues earlier in the year. Today is a big meeting because we're going to really go over and give you an in-depth on all of the work on Title IV in 21st Century Cures Act.

So, we released at HIMSS last week a proposed rule that implements the pervasions around seamless and secure access exchange and use of electronic health information as required in Cures and look forward to getting your input and feedback on that rule.

The specifics of the rule or the somewhat specifics of the rule are requiring secure APIs without special effort, which we really see as standards-based application programming interfaces. A number of reasonable, necessary activities to do that, exceptions to the prohibition on information blocking. The information blocking is banned under the law already. We're charged with the exceptions. Then some of the certification program steps that are needed.

The basic things you're going to see, then, are the secure standardized API work, information blocking, the certification program. We've also put in a request for information for what additional information would be needed for price transparency, which is a big, big national issue that comes up with patient access and control.

The Cures Act, the rule, actually, when you look at it, it pretty much maps exactly what Congress had as the three priorities for HITAC, which, as you remember, are interoperability, privacy/security, and then patient access. So, I think we're pretty much on center point with that. I know there's also work on the annual review.

To come are the Draft Trusted Exchange Framework and an area we're going to get into not today, but in a short future meeting, some of the things around prior auth. Our burden report really identified prior auth as an issue. There are some very interesting things on the interaction of standards around prior auths and related things like clinical decision support and there may be some opportunities to do some things there.

Thanks, everybody in advance. I'm going to turn it over to Alex Mugge from CMS who's a Deputy Chief Health Informatics Officer. Alex can talk about the companion CMS rule. Alex?

Alexandra Mugge - Centers for Medicare and Medicaid Services - Deputy Chief Informatics Officer
Great. Thanks, Don. Thanks, everyone for having me on the call today. I did just want to offer a few remarks on the CMS rule and its relation to the ONC rule. The two rules definitely take slightly different approaches to interoperability due to our different authorities and different target audiences, but I think we can agree that they both have the same end goal in mind.

The CMS rule, which has an extremely long title, but the shorthand is that interoperability and patient access proposed rule. This rule touches on just about every entity that CMS regulates. We have policies in this rule for health plans, clinicians, hospitals, and post-acute care providers, so really running the gamut of what CMS oversees.

We worked very closely with ONC on the development of this rule. I think that demonstrated a way that the rule complements one another. Both rules have adopted the FHIR standard for interoperability, which was a critical move to support the API technology and CMS's enhanced focus on seamless data exchange.

Our proposal for information blocking – I know this is really an area the ONC rule is focused on and this is an area where ONC has made a huge milestone by releasing their information blocking rule. We also have a small information blocking proposal in the CMS interoperability rule and this was, in part, to demonstrate our commitment as a department to stop the practice of information blocking and really double down on our efforts to prevent that going forward.

I know you all are not actually tasked with reviewing the CMS rule, but we did just want to offer this comparison of where some of the policies do overlap. I'm more than happy to address any follow-up questions that folks may have in a later meeting. I know you have a lot to cover today, so I won't take any more of your time. Please feel free to follow-up if you have questions on the CMS rule or if there's anything we can offer to help from our perspective in the work that you're doing here.

With that, I will just wrap up and hand it back to ONC.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Great. Thank you so much, Alex. Dr. Rucker, at this point, I will turn it over to our Co-Chairs, Carolyn and Robert just for their review and approval from the December meeting minutes.

Carolyn Petersen - Individual - Co-Chair
Thanks, Lauren. Good morning, everyone. It's great for us to be able to get together in the new year and to have our first meeting. We have quite an excellent agenda. Two major items – first, we'll be reviewing the 21st Century Cures proposed rule overview and establishing taskforces. Then we will have a presentation on the HITAC annual report draft review. Really great to see everyone. I will now ask that we approve the minutes of the December meeting, something we need to do before we dig into our presentations. Those minutes were sent out in your –

Robert Wah - DXC Technology - Co-Chair
Move approval.

Aaron Miri - The University of Texas at Austin - Member
Second.

Carolyn Petersen - Individual - Co-Chair
And could everyone who is in favor of approving the minutes please signify by saying aye?

Multiple Speakers
Aye.

Carolyn Petersen - Individual - Co-Chair
And could everyone who is not in favor of approving the minutes please signify by saying no? Do we have any extensions? All right. I think we have approved the minutes from the December meeting. I will now pass the mic to Robert for his remarks.

Robert Wah - DXC Technology - Co-Chair
Thank you, Carolyn. Again, thanks to everyone for your patience and understanding as we dealt with the many changes at the beginning of the year for the meeting. As Carolyn notes, we have a very full schedule. Our plan is to spend the bulk of the time on the 21st Century Cures proposed rule, but also, it's equally important for the work that Carolyn and Aaron did as Co-Chairs of the annual report draft review.

So, we have a scheduled time for public comment at 12:45 that we will try to honor, as we have in the past, to make sure that we are meeting our commitment to the public to have their period of time to comment. We'll try to make sure that stays at the 12:45 p.m. timeframe. I look forward to a good meeting and hopefully look forward to seeing you all soon after our next face-to-face meeting.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Great. Thank you so much, Robert and Carolyn. At this point, we will just dive right into it. I know we are all anxious to get started. So, I would like to turn it over to Elise Sweeney Anthony, our Executive

Director of Office of Policy within ONC. We're going to do a little bit of tag-teaming between Elise and Mike Lipinksi, who's the Director of our Regulatory Affairs Division, and then we will take a brief pause about halfway through to continue on to hear from Steve Posnack, who's our Executive Director of Office of Technology.

With that, I will turn it over to Elise.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy
Thank you, Lauren and thank you to everyone for joining us today. I know at least over here in DC, we're in the midst of snow coming down, but many thanks to teleworking for us to be able to have the call today.

So, we're excited to share with you the 21st Century Cures Act, interoperability, information blocking, and the ONC Health IT Certification Program proposed rule. The proposed rule includes many policies that ONC has been working on and thinking through to support the access exchange and use of electronic health information for the benefit of the patient and the providers who serve them. Go to the next slide.

As Lauren said, we have a lot that we are going to be presenting. This is actually the deck that we have used for the presentation at HIMSS. This disclaimer really applies to folks who might see this online because we do post the decks on line. So, we do want to note for the public or those who view it, we encourage folks to submit their comments online. So, for all those who are listening from the public, please do submit any comments you have through the process that's noted in the proposed rule.

I'd also note that the rule is currently on our website, which is healthit.gov/nprm. We expect it to be posted to the Federal Register shortly. Once the actual posting does occur, that's when the timeframe for the public to respond of 60 days will start. We'll update our website accordingly as that goes forward. Next slide.

That's our agenda for today. As you can see, it's pretty packed. We'll talk a little bit later about the taskforces that we expect to charge the HITAC to look at around the – someone's line is live if you guys want to mute off. Thank you. We talk a little bit later about the taskforces that we will charge the HITAC with to look at some of the policies that are included in the rule. For now, we wanted to walk through the specific provisions that are in there so folks have a general understanding of what we have included.

As Lauren did note, there is a lot to go through. So, we do have a little bit of time for questions, but we will also have the taskforces starting up very quickly and I think that's where you'll see a lot of the deep dive into questions that the HITAC may have. All right. So, next slide.

All right. So, just to talk a little bit about implementation of the 21st Century Cures Act and the work that we have underway – so, what we've included – these are also on our website – are some infographics or fact sheets that identify some of the things that are addressed in the rule that we've put together.

That includes everything from pediatrics and includes some provisions related to the recommendations that Congress asked us to develop around supporting the pediatric care setting as well as we also include some certification criteria updates to support the interoperable movement of information

related to pediatric care settings.

4002 focuses on the conditions of certification. Soon, I'll turn it over to Mike to talk more about what those are. But the main thing I want folks to remember here is that the conditions of certification would be part of the health IT certification program. In the past, we've focused on the technical requirements and the functional requirements that attach to health IT that is being certified by ONC. Those continue to be critical to supporting interoperability and exchange.

The part that Congress has asked us to also think about is what are the conditions that sit on top of that and developers that are being certified by our program should be held to. Those conditions are very clearly laid out by Congress and they include things like certified developers should not information block. They should not restrict communications. They should report as part of the EHR reporting program when that's ready. Those are some of the things that we are including in the conditions of certification and we'll talk way more in-depth about as part of the presentation in a second.

4003 includes a definition for interoperability which we talked about, I think, as of last year about the overall definition of interoperability that Congress has laid out. We take that as a consideration as part of our development of the rule. Next slide.

4004 is information blocking. Just as a reminder, we'll talk about this as well, but the goal that Congress has asked ONC to take part in is the identification of the exceptions to information blocking. So, where information and action may fit under the definition of information blocking that Congress has laid out, but there's an exception to that for a number of different reasons. We've developed seven that we think work, but we look forward to hearing from HITAC in that regard.

4005, we've included a request for information to help us learn more about how some of the health IT that's out there now, including things like FHIR 4, could help with registries and exchange of information from registries.

And then 4006 is patient access – that's something that is woven throughout all that we've done, not only in terms of our development of the Cures rule, but also in terms of everything we're doing at ONC, really thinking about patient access and how best to support that access through our policies. I think you'll see that articulated very much so in everything, from the conditions of certification, but also through information blocking as well.

So, next slide – we also include this slide just so you can see some of where our focus is, not only in terms of implementation of what Congress has asked us to do, but executive orders that support things like competition and innovation in the healthcare space. What we've tried to put together is a rule that supports that development.

Some of the provisions around APIs, for example, that would allow a landscape to exist where new entrants can enter into the health IT environment and support the needs of patients and providers or where existing participants, existing developers can find new and innovative ways to support the needs of patients and providers as well.

Then we also include some components in our rule around deregulation and ways that we can update the certification program by taking out some components that we think are no longer necessary. So, for example, removing the 2014 Edition, which is an old edition of certified health IT technology, with the

2015 Edition now up and running and continuing to be implemented across the board. Next slide.

So, the purpose overall – I talked a little bit about this already, but innovation and competition are critical. We should want to support an environment where competition can occur and where innovation thrives. The API provisions are just one example of that, but also supporting things like the right of access and the ability of the patient to decide where and what technology is used to hold their information, creating an environment where new apps can support the needs of patients to pull their information from multiple sources. It's just another example of how innovation and competition can come together through this rule.

We also focused on reducing burden and advancing interoperability. So, again, thinking about the API requirements, that's just one. We include things like the electronic health information export, which supports two use cases. One is the patient being able to pull all of their information out of a health IT system that's certified or for a provider to be able to switch who they're working with for their health IT systems.

Then, of course, our USCDI standards, which is the United States Core Data for Interoperability, which is a set of information we think is critical to be able to move for interoperability needs. We start with a version one here, but we plan to expand on that over time. I noted patient access, which, again, is woven throughout all of our work here. Next slide.

All right. So, I'm going to turn it over to Mike Lipinski, who is our lead reg writer. He leads our Regulatory Affairs Division. He's going to talk a little bit about the updates to the certification criteria as well as the overall updates of the health information rubric which we think of the certification program. Mike?

Mike Lipinski - Office of the National Coordinator for Health Information Technology - Director, Regulatory Affairs Division

Thanks, Elise. Thanks for having me here this morning to talk to you about our rule. I said this at HIMSS. It's been a labor of love getting this out to the public. We're really excited to hear comments on our rule. I'll just reiterate what Elise said. So, right now, you have a version of the rule that's out. It's posted on our website. The only changes that will take place between now and when they publish are formatting changes.

I just want to be clear to folks – there will be no substantive changes between now and when the rule publishes in the Federal Registry. So, our proposals and policies that you see will not be changing between now and when they publish. It's really about formatting to comply with Federal Register requirements. So, that will go on display.

Then from there, it will be displayed at the OFR similar to the way we have it on our website. Then it will actually publish in that three-column document you see and are so fond of, I'm sure. At that point, the comment period will actually start, which will be, as Elise said, 60 days. I just wanted to reiterate the process points that are taking place right now related to commenting on the proposed rule.

So, I'm going to first talk to you about the 2015 Edition and updates that we're proposing. As I do this, I want to go back to the points that Elise was making. First and foremost, we are trying with this rule to, to the best of our abilities and consistent with Congressional intent, implement the 21st Century Cures Act. Then we're trying to do it in a way that achieves that purpose that Elise talked about, which is increasing innovation competition, reducing burden, and advancing interoperability, and obviously

promoting patient access.

So, as I go through this, I'll try to highlight where we've taken those goals and applied it to how we're implementing the Cures Act. So, how we do it has really been in three ways. I'm going to talk about how we're doing it with the certification criteria. I'm going to talk to you how we're doing it with the conditions of certification. That's primarily focused on health IT developers and their products that they have certified through our program. Then I'm going to give it back to Elise to talk to you about information blocking, which is the broader policies to promote patient access and exchange of health information for better patient care.

So, 2015 Edition – the slide you have up now, I don't know if you are familiar with this, but I'd recommend if you have an opportunity to go to this website address. You'll see this icon on it. What we've done maybe about a year or so, maybe longer than that now – we've kind of laid out all the criteria that exists in the 2015 Edition, we give a little explanation of why that functionality – I guess more to the point, what that functionality is included in the criteria and what we would expect the health IT to be able to do that was certified to that criteria.

So, right here, you're just seeing how we categorize all the functionalities, what we think they promote and support, so, whether it's privacy and security or care coordination. So, that's just a little plug. If you want more information about the full 2015 edition, you can take a look at that in your spare time when you're not reading the rule, right? So, let's move to the next slide.

So, again, we tried to focus on interoperability and reduced burden. Here in one slide – if you're familiar with the fact sheets we've been putting out about the rule, we'll be putting out one similar to this slide right here. We'll also have one that goes on the deregulatory actions we're proposing, which Elise alluded to a few minutes ago, but this one right here talks about the criteria.

So, as you can see, it was a very light touch and a focus on interoperability. From a deregulatory perspective, we're proposing to remove certain criteria, criteria that are included in the base EHR definition and some other criteria. A lot of this is because we believe this functionality is ubiquitous across health IT now.

It's either been there since the 2011 Edition or its functionality that has both been there in the certification program that we don't see a developer ever removing from health IT and the functionality itself that we're looking at isn't really focused on interoperability or any specific unique functionality. Really, for example, with **[inaudible] [00:26:04]**, can you record that is really what the certification program is about related to that functionality. So, we're proposing to remove that so focus can be on interoperability.

So, you see here, we made some updates for certain criteria, like e-prescribing. The ones I'm going to talk to you about are like the data export one and the API one. We have some also that we think will improve consent management. So, we'll have data segments from privacy and then the consent managed one you can see over there. Then we have what we refer to as attestation criteria, so encrypting the authentication credential one and multi-factor one. It's really about, "Can your product do that?" So, it's really letting the public know does it do any of these things, not that we're requiring the product do those things. So, let's move to the next slide and dig in.

So, the first big thing that I want to talk to you about is the USCDI, the United States Core Data for

Interoperability standard. This is the standard we're proposing. You may have heard about it previously with TEFCA at the beginning of last year. So, this really just builds on the common clinical data set and establishes a new baseline of data that should always be available for access exchange and use.

What we've done with this proposal is we've added some new data classes and data elements. So, provenance, we're looking there really at timestamped and authoring organization, clinical notes. I think we're proposal up to eight different types of notes to be available. The pediatric vital signs, those were previously optional in the common clinical data set and we're proposing those to be required information that would always be available for exchange, access, and use, then patient address and phone number.

Then the other thing noted here is there would be a schedule for updating the USCDI. Not to get too far ahead of myself, but we'll have a taskforce just focused on USCDI. So, let's move to the next slide.

Okay. So, these are functionalities supporting patient access as well as the exchange of health information, hopefully, innovation, competition, reducing cost. A lot we're hoping can come from some of the functionalities we're proposing. This is one of them. So, this is the EHI export criterion. I'll talk a little bit later about how we tie that back into the conditions of certification for developers.

There are two main use cases we want this functionality to support. That is a provider who wants to change their EHR vendor or health IT vendor. Then if a patient asks for all their data – that's getting back to the Cures, all their electronic data, that is – going back to the Cures, edict to try to provide patients with all of their electronic health information.

So, how we go about this – we give flexibility to the developer in terms of how they – the export standards that they use, you make available ahead of time their data dictionary – so, that will be open for interpretation – potentially, other third-party vendors will develop to help pull that data out or the developer themselves can do that.

The one point I want to make clear about developers themselves doing that – this is where we're tying policies together in info blocking – the use of this certified health IT, we propose that a fee cannot be charged when it's in use.

So, we get into some of the details of what costs can and cannot be charged later on during question and answer, but while there could be charges to the provider for creating the product and rolling it out and implementing it, once they want to say, "I want to switch," we propose that there can't be a fee associated with pulling that data out of your system. A lot of that comes from our research and discussion with stakeholders ahead of time about some of the means that are used to deny access to EHI.

So, we move on to the next slide. So, APIs – I am not going to spend too much time on this particular slide or the next API conditions slide because my colleague, Steve Posnack, is going to give an in-depth presentation on API, the criterion and the condition. The key here is we're going to be replacing the API that we have now that doesn't focus on a standard.

We have some options we propose in the rule as to which version of FHIR we should adopt, whether it's version two, whether it's four – I think we talked a little bit about version three and whether we should be giving functionality and so forth. So, I'll let him talk about that more or you read that in the rule. Two

main use cases supported by this, getting single patient's data and then multiple patients' data. Let's move to the next slide.

Again, I don't want to have to say it every time, but again, we think that's another way of getting all the information out of the system, EHI for a patient. Also, we think this is going to reduce burden in terms of provider getting access to information, improving care coordination. And then obviously, this should significantly promote competition in terms of the third-party apps accessing data on behalf of patients.

All right. So, now, I'm going to go to conditions of maintenance and certification. Again, I just focused on the certification program, the developers and entities that bring products in to get certified. Previously, our focus was just on the product itself and what the product could do and that's who we certified. The Congress, aware of some market failures related to certified health IT – we'll talk about that – and concerns expressed by constituents set forth in the Cures Act specific areas in which they felt that there needed to be conditions and maintenance of certification. So, this rule is hoping to implement that consistent with congressional intent. So, let's start talking about that. Let's move to the next slide.

All right. So, there are seven conditions of certification and maintenance requirements set out in the Cures Act. This rule will implement six of them. The seventh one, as noted there on your slide in light blue, we are not in a place – it's premature to try to propose that now – if you're familiar with it, we went through a process to take comments on the EHR reporting program and we're going through the steps to establish that program now consistent with the statute and how that should be developed. So, let's start talking quickly about each of these six that we're proposing. So, next slide, please.

All right. This one is a pretty straightforward condition. So, not only are health IT developers subject to the information blocking provision – these are health IT developers of certified health IT, to be clear – they have a specific condition required that says that they will not information block. It's as simple as that. They will have to attest to this and then they will be held to that attestation. The HHS Office Inspector General has authority over any false attestations made.

So, let's just move to the next slide. The next slide is even a further backstop to information blocking, where Congress said that we want – this is, again, reactive to potential – at least their understanding of potential market failures – the developers have to meet to provide further assurances to the Secretary that developers will not take any actions that would inhibit the appropriate access exchange use of EHI.

So, if you haven't seen part of the theme here, it's now looking at the business behaviors. So, we're not just looking at the health IT anymore. We're looking at the actions of the developer. I'm going to draw that out.

So, we put forth four proposals, really three – one is request for comment – on how we think developers could provide assurances that they are not inhibiting. One is an attestation that they will be in full compliance with the certification criteria program requirements when they implement the health IT – so, testing doesn't necessarily always test every single functionality, every relevant code set like SNOMED. But what we're going to ask developers is to test that their product can fully conform.

If you're familiar with any of the litigation that's been out there by the Justice Department and so forth, issues have arisen where developers haven't fully implemented the functionality in the field. So, we're asking for an attestation related to that. Here's a tie back in with the next proposal related to that EHI criterion – so, any developer that manages electronic health information stores are managed **[inaudible]**

[00:36:19] manages EHI electronically is going to have to get certified to that functionality.

Then we're also going to require that they roll that functionality out to all their customers within 24 months of the final rule. So, that's a way to ensure that that functionality is getting out into the field, being available to providers and patients.

Then a records proposal – this is really just to ensure the records support the functionalities of a product being certified. This is, again, giving assurances to purchasers and users of certified health IT that you can rely on that certification and that the product does what it says it does and there are records to support that.

Then last, we're asking related to the trusted exchange framework and common agreement whether if developers, one, support interoperability, so this is a criteria, the developers that get their product certified to functionalities that support interoperability – that's that bullet point two – and whether in a situation where they essentially support participation in a trusted exchange, if they should have to then sign on to the trusted exchange and common agreement.

It's just a request for information at this point. There's no proposal because of the current status of the trusted exchange framework and common agreement, but we wanted to get users' thoughts now about how it relates to developers supporting them, users and providers, and whether it would make sense that, from a certification perspective, we required that type of participation on certain developers.

Moving to the next slide, this one, we call it our communication slide. Really, what it is implementing a congressional provision – excuse me, a statutory provision – where Congress said the developers should not prohibit or restrict communications regarding the subjects you see on the screen there. This is really about promoting safety, security of products – I think this is very important in that respect – and usability of these products.

Congress held multiple hearings on this. You have on the record developers and other parties essentially saying that there should be any gag clauses in contracts related to certified health IT. I think we took that legislative history, congressional intent, and put forth proposals that are consistent with it. This is a very broad prohibition Congress put forward.

So, we've actually identified some specific instances where developers would be able to do some restrictions. Those would involve when it's their own contractors or employees, when it would be related to not user-facing aspects of a product in some sense related to IP, but I want to call out here – I'm sure you caught it in some of the press after the release of the rule – that we are saying that screenshots can be shared.

We think that the use of screenshots is fair use under intellectual property law. We do give developers the ability to have minimal restrictions there related to third-party IP in the screenshots as long as they meet some conditions. The altering of a screenshot and then obviously if there's any type of PHI in the screenshot, they would be able to place some restrictions on that. We asked the contractors via proposal remove any contractual provision that contravenes this prohibition.

So, within two years of the effective date of our final rule, we would expect that there would be no longer any contractual provisions that limit the sharing of that information on these subjects. And in the meantime, we're asking them to continually provide notices to their customers that they don't have to

comply with any provision that does contravene this proposal.

Can we move to the next slide? So, API – this is a condition that goes with that functionality and criterion. So, really, there are key pieces here. The permitted fees piece is what is kind of going into detail to a specific type of health IT, here being APIs, related and consistent with our information blocking proposals related to fees. Steve's going to talk a little more about that.

The transparency – this is similar to our provisions that already exit in the 2015 Edition to the transparency. It goes in more detail, but transparency related to the technical requirements and also, business documentation for being able to essentially connect to the API. Then you can talk a little bit about the pro-competitive nature as well. So, I'm not going to spend any more time on this in the interest of time overall. Let's move to the next slide. We'll move to the next slide after that.

I think maybe the only thing I'll mention on APIs – I'm sure Steve will mention this as well – but it's another one where we expect that to be rolled out within 24 months to all users and our customers of developers, that is, so that functionality will be – there will be up to 24 months. It's not that you wait until the last 24 months. Again, Steve will talk a little bit about that, why we took that approach. It's another way of getting patient access and improving interoperability and reducing burden.

So, real-world testing – Congress called this out as well. They wanted to see developers successfully test their products in an environment in which they market it and sell that. So, we've tried to take a balancing burden approach with this. We're asking developers to provide us with a plan of how they're going to do that and then provide us results annually. We focused again on interoperability. So, where this is going to apply is for those developers of health IT-certified to criteria that support interoperability and data exchange. Those are listed on your screen here.

A really unique piece to this is our proposal related to standards version advancement process. I believe that is going to be on the next slide. Why don't we jump to that next slide? There it is. So, as you know, regulations don't always keep up with standards and innovation. Sometimes, they've actually inhibited it because we have evidence and stakeholder feedback where developers and SDOs won't even more to a new version because it would be inconsistent with what's in regulation and therefore, no one either would use it or it would be wasted effort or it would be inconsistent with what is required to be used. That's an instance where regulation is inhibiting innovation.

So, what we're trying to do here is allow developers and users to move to those new and better standards when they're available. We're outlining a process and a rule in which a **[inaudible] [00:44:27]** coordinator would approve a newer version of a standard. So, I want to be clear about this. It's a standard that's already been adopted for use case, but then a new version comes along. We know those come along fast – 1.1, 1.2.

And then users and developers are put in awkward situations, not just the situation I talked about, but where an entity requires use of version 1.2, but you've been certified to 1.0. So, now, you have to go out and get a product that does 1.2 as well because certain programs require certified health IT, but certain public health agencies want you to report with Version 1.2.

So, what we're going to do is set up a process where we can approve version 1.2 for the program. A developer can voluntarily move once they meet certain conditions, including notice to their customers, notice to their certification body to that new version. They would have to show that they can real world

test to that new version. That is going to provide assurances to those who are purchasing and using those products that my product can do that new version too. It's not just a version that got certified originally, but they can actually do the new version.

Then as a certification program for its integrity purposes, we'll be able to hold the developer to that new version as part of the real world testing condition of certification. We're pretty excited about this. We're hoping it helps to alleviate some of our problems that we've been dealing with that I've talked about. We're really interested in comments from stakeholders on this.

Let's move to the next slide. This is really simple. I alluded to in the very beginning attestations. So, all developers are going to have to test all of these conditions and certification requirements. We'll be doing this tomorrow through a web-based process. We're going to be working on – we talk about this in the rule – a bit of a grace period and time to submit this, a lot of the process and procedure to effectuating the substantive requirement. So, if you're interested in that, if you're a developer, you might want to take a closer look at that, how we plan to execute on that.

Let's move to the next slide. I think we're going to talk a little bit about enforcement. This is a pretty straightforward approach here. We can move to the next slide on this. What we're doing is we're going to leverage what we already put in place with the enhanced oversight and accountability final rule, which was a process for direct review of certified health IT by ONC. So, we're going to use that process.

However, there are some unique distinctions between them that we're proposing. One is that ONC would be the sole party responsible for enforcing compliance with conditions of certification. I think we lay out in the rule why we think we're best situated to do that compared to the certification bodies when it comes to the conditions such as communication conditions, for example.

We also propose that we would be coordinated with the Office of the Inspector General in case they instituted an investigation into information blocking, for example and that we propose that in terms of reducing burden and clarity for all parties involved that we could either defer or even rely upon their findings to pursue an action under the certification program.

The other big thing I want to mention – I don't know if it's on this slide. It isn't. So, maybe we can go to the next slide. So, step six – so, this is really just what exists current today – or step four, I should say. Ban, certification ban – so, we're proposing if somehow corrective action doesn't work – that is going to be our emphasis, as we said, in the UA rule, to try to get products back in line and developers back in line.

If it doesn't happen, we think that banning a developer is the appropriate consequence and recourse because as I've been talking about throughout this whole discussion of the condition certification, Congress was very specific as things that they wanted to see developers be held accountable for. So, I think, as I said, it was to address certain "market failures" they found happening. So, we think this is a more appropriate, I guess, final consequence if a developer can't come into compliance with the conditions of certification.

So, at this point, I think it's time to talk about the overarching approach to ensuring access exchange and use. I'm going to be turning it back to Elise. So, we can move to the next slide for information blocking. All right, Elise. Back to you.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy

All right. Thanks, Mike. Next slide – we're going to talk a little bit about our approach to information blocking and some of the policies that underpin that.

So, first, I just want to start off with a couple of key things to note. I'll just reiterate what I mentioned before, which is that the secretary is tasked with identifying the reasonable and necessary activities that do not constitute information blocking. So, in Section 4004 of the 21st Century Cures Act, there is a definition for information blocking as it applies to two sets of actors.

There is one set of actors, which are healthcare providers. We define that in the rule. Healthcare providers have a somewhat different standard in terms of whether they're information blocking or not. It's like a, "Did you know?" standard. Now, the second set of actors are health IT developers of certified health IT. So, they're ones covered by a certification program, health information exchanges, and health information networks. There are definitions for each one of these actors in the rule.

So, that second set of developers of certified health IT information exchanges and health information networks are subject to a different definition, which is more of a known or should have known standard. Under that rubric is where ONC now comes in to identify the exception for if these actors would have been subject to information blocking as per their definition. There may be some situations where their actions were reasonable and necessary and therefore do not constitute information blocking. So, that's the overall kind of rubric of how the policy is laid out and what Congress asked us to do.

So, a couple of other overarching notes before we get into the exceptions – the exceptions that we've developed are based upon a lot of what we heard – now, for any of those who have been around for a while, we have definitely been thinking about information blocking. In fact, Congress asked us some years ago, I think 2015 now, asked us to develop an information blocking report on what we were seeing. We did that and we put that together and subsequent to that, Congress started thinking more about information blocking and what it should look like in terms of statutory provisions.

So, as we are thinking about what are the things that are reasonable, we first have to know what is not okay. That's where we really hinge on the definition that Congress has laid out. The exceptions that we put into place are really thinking about some of the situations we've heard about.

Some things, such as, let's say, if you're thinking about healthcare providers, a hospital system that creates different allowances for the exchange of information, depending upon whether you are a provider that has privileges at their hospital or not or a developer that charges extreme interface fees and changes those interface fees depending upon whether you are a provider, who has their technology – in other words, has their health IT system or not.

So, those are some of the things that we heard a lot about and not once or twice – as Don has noted, he has had many stakeholder meetings who have shared with him concerns about how information practices are used to impede the flow of information that impacts the ability of the patient to get the care that they need and the ability of the provider to provide the care they need to provide. So, that's the overall concept of what we were thinking about in putting this together. Next slide.

So, when we think about information blocking, I highlighted this already in terms of we think about the definitions laid out by Congress and then we think about what are the reasonable necessary activities

that would interfere, specifically looking at the word likely – that are likely to interfere with or present or materially discourage access exchange and use of electronic health information. Next slide?

So, another overarching concept is the definition of electronic health information. This definition we've put together builds upon a definition from HIPAA in terms of protected health information. We note a couple of key components to that definition. One, is the information transmitted by or maintained in electronic media? Does it identify an individual? Is there a reasonable basis that the information could identify an individual? That's important because as we note in the rule, the information blocking provisions are not meant to address de-identified information. That's consistent with 45 CFR 164.

Also, we note that the definition includes past, present, and future health and condition of the individual. So, not just current, not just if you are a patient and you go to a provider, not just that set of information that you would receive at that particular provider, but if there's past information that's available, that would be included as well as future.

Then it also includes past, present, and future payment for the provision of healthcare to an individual. Next slide – I want to talk a little bit on that. We include a request for information in the rule around price information. In particular, there has been a concern that many of us are aware of about how pricing information can have negative impacts on patients, providers, health systems, plans, or across the care continuum overall.

The department is particularly interested in this area as well. ONC, in terms of the definition of electronic health information, thinking about what are the types of information that should be considered price information, how is it defined, what are the electronic means for moving that type of information that may exist already or that would need to exist, and then overall, the department is seeking comment on some of the technical, the operational, the legal, environmental, cultural, and other challenges that might exist around creating a more transparent environment for price information within healthcare. So, there's a request for information in the rule that includes a number of questions related to that. Next slide.

So, thinking about the definition of electronic health information and what we are trying to achieve in terms of identifying reasonable and necessarily activities, one thing to keep in mind is the goal is for these exceptions to be narrow.

The goal and the presumption is that information is being shared appropriately and to the benefit of the patient and the provider who is providing care to the patient. That's an important construct. If that is kept in mind, then what we are then hoping to receive recommendations and feedback is do these exceptions strike the right balance in achieving that? Our goal is to make sure that information is moving and if it's not moving, that there's a really good reason why it's not moving.

So, with that, let's walk through each of the exceptions. So, the first one is preventing harm. This talks about was an action taken by an actor – remember, the actors are the healthcare providers, health information exchanges, health information networks, and certified developers – whether there was an action taken by the actor to not share information because there was a reasonable – that's key – a reasonable belief that the practice would directly and substantially reduce the likelihood of physical harm occurring. If that's the case, then that actor could be subject to an information blocking exception.

The next one is around privacy. The privacy – again, keep in mind, the goal is that information that's

being shared to the benefit of the patient and the provider and if it's not being shared, then there's a clear reason why it's not being shared.

Let me just stop here and note a couple of other things that I should have also noted in the exceptions. In order for your action that you've taken to not share information, to be subject to not be considered information blocking, then you will have to meet one of the exceptions. You can meet more than one, but you have to meet one for that particular action. Each of the exceptions are not just a high-level look at what you've done, what an actor has done, rather. It's an in-depth look at whether the overarching exception has been met. That is accomplished by looking at the sub-components or the sub-exceptions that exist within that.

The privacy one, 171.202 is a good example of that because there are four discreet sub-exceptions that exist and they address specific scenarios that Dr. Ducker and ONC generally are concerned are occurring. So, in order for you to get an exception for privacy-related issues, you'd have to meet one of these four exceptions. They're delineated here.

So, I won't read each one, but you can see they are related to denial of access practices, for example, that are permitted under HIPAA, specifically permitted under HIPAA. There could be some related to pre-conditions that exist under state laws or the protection of information that may exist under such state laws. We want to be inclusive of the state laws that may exist related to privacy or other federal laws that may exist related to specific types of information. With that in mind, think about those sub-exceptions when an individual is thinking about whether they can apply or be subject to one of the privacy exceptions noted here.

The other thing to note here is the policies should be in place. So, one of the things we've heard is, for example, information is not shared with one provider, but it's shared with another. The underlying policies that are in place at that hospital system or with that developer or with that health information exchange or with that network, those policies don't capture the reasons why information would or would not be shared, for example, as applicable to state law.

What seems to be happening in some situations is that the policies change depending upon who is asking. So, if you are asking for information and you are somehow affiliated with that provider, you're in the same practice or hospital, the answer you may get in terms of the request to share information may be different from, let's say, a small provider located halfway across the country in an unaffiliated practice and they're asking for the same information, but they can't get it.

Why is that the case? So, those types of scenarios are what we're thinking about here. So, if there's a policy that is in place and is documented, those are things we would look at or really, OIG, Office of Inspector General, who would implement this would look at. What are the policies that are already in place? Or are you attempting to put in policies once a situation has already happened? Those are the case by case and the factual analysis that would come from any information blocking examinations. Next slide.

All right. so, talking on the same vein as privacy, you have security. Similarly here, we want to look at what are the policies already in place within this particular actors enterprise or practice related to promoting the security of information. The practice that the actor takes part in that would otherwise be subject to information blocking really has to be in place to safeguard the confidentiality, the integrity, and the availability of that electronic health information.

The practice also has to be tailored. This goes back to the overall concept that information should be shared appropriately. If the information is not being shared, then there really needs to be a specific reason why that's not happening. In this case, it has to be tailored to the specific security risk that exists. It has to be implemented in a consistent and non-discriminatory manner.

You're going to see throughout the exceptions that we've laid out language like consistent and non-discriminatory, objective and verifiable, words and concepts like these that support an environment that you are sharing regardless of whether you have a vested interest in that individual you're sharing with. So, whether the provider is under your hospital system or not, whether if you're a developer, whether the requester has purchased your technology or not.

Those are some examples. There are many out there. It's very much a case-by-case analysis. We would be looking at whether the policies and practice you are taking to restrict the flow of information, whether that is objective and verifiable, whether it is non-discriminatory, whether it is consistent across the enterprise that you manage or that you have control over. That is shown here in the security exceptions by that consistent and non-discriminatory.

Then also, in that last sub-bullet, the practice must implement an organizational security policy that meets certain requirements or must be based on an individualized determination regarding the risk and response in the case. We do want to allow for situations where there is a particular security risk that may be individualized but may not be captured in the security policy. How is that identified and is that really based on a reason that's been given not to share information or is it a legitimate reason? Those are part of the case by case examinations.

The next couple of exceptions relate to cost or fees or, in some cases, rent, depending upon how they're referred to in the industry. But for purposes of the exceptions as we've laid them out, let's talk about the responding to recovery costs reasonably incurred first. This relates to the allowance for an actor – remember, that would be the provider, the health information network, the health information exchange, or the certified developer – but the actor can recover costs that it reasonably incurred in providing access exchange and use of EHR.

Things that would be looked at in determining whether that cost is reasonable is – again, you see that objective and verifiable language – are the fees charged on the basis of objective and verifiable criteria that are uniformly applied to all similarly situated persons and requests? Again, that gets to that fairness concept. Are you treating people or requesters the same who are similarly situated?

Also, the costs have to be related to the cost of providing that access exchange and use of information. They need to be reasonably allocated across all customers. We have heard of examples where the development of the interface can cost money. We want to make sure our understanding of the fact that there are costs associated with developing technology, innovating technology, or updating technology.

In some cases, we have heard of situations where the cost of that interface, even though it is the same interface that would be used by different individuals seeking information from that actor that the cost is born by one particular or group of requesters who may not necessarily be affiliated with that actor. Those who are affiliated with the actor, perhaps they are not charged the same interface costs, etc. So, those are things that would be looked at. Is the cost reasonably allocated across all customers?

The fees also cannot be based on anti-competitive or other impermissible criteria. So, again, back to that fairness factor, back to supporting the competitive innovation that should and can exist in an environment supportive of electronic health information moving to where it needs to go.

Then certain costs would be specifically excluded. And then certain costs would be specifically excluded. The one I really want to note here is that where an individual or their representative is requesting their information electronically, through electronic means, that there could be no costs associated with that. I think many of you have heard Dr. Rucker talk about the importance of this, that where the patient is requesting their information that electronically and that the information request is electronic health information, that there should be no costs associated with that. It's a really important component of what we've included in these exceptions. Next slide.

All right. So, the next one is related to responding to requests that are infeasible. So, what do we mean by that? I personally want to make sure that we're clear, again, that the goal of the exceptions, all of them, are that you're sharing information appropriately and that you're sharing information for the benefit of the patient and the provider, but there may be some situations where cost is infeasible. What does that look like? How do folks understand whether they would fall into that or not? So, we've included some clear guidelines for that purpose.

So, one is, just looking at the second bullet, for example, complying with a request most impose a substantial burden on the actor. That burden has to be unreasonable under the circumstances. So, perhaps it's a small provider who is being asked to develop outbound interfaces to support the receipt of information that maybe they normally would not need if not for the request from the requester. In situations like that, maybe that would be considered an infeasible request.

But what's equally important in terms of looking at this and contemplating it is the third bullet, which basically says that an actor must timely respond to those infeasible requests and work with the requester to provide a reasonable alternative. So, it's not just about whether the request was infeasible, but did you attempt to find an alternative means to provide access to the EHI? That is an important consideration as to whether you would be allowed to use this exception to validate why information blocking, you should not be held to an information blocking claim.

So, for 171.206, this one is about RAND terms and licensing of interoperability elements. This, again, relates to the importance of innovation that we know needs to continue to exist in the health IT environment. So, there could be situations where there is a technology that is controlled by the actor that relates the interoperability elements for the movement of electronic health information that should not be considered information blocking. Some of the factors that we would look at in terms of that licensing would be about whether you are licensing on reasonable and non-discriminatory terms.

So, is how you license or the cost associated with the license depending upon whether the requester is affiliated with you or not? That would be a factor that would be looked at. Again, is the ability to license available to those across the health IT spectrum who are requesting the information? You see that language once again here in that last bullet, that the terms of the license have to objective and verifiable and uniformly applied. So, not just simply saying that, "I license these terms on a RAND basis," reasonable and non-discriminatory terms, but really, do the policies you have in place, are there supporting materials that indicate that your licensing plans or procedures are objective and that that can be verified as well and that you've applied your licensing terms uniformly across requesters?

So, those are kind of the overall concepts that we are thinking about. There's one more exception I want to note. Next slide, please. So, this exception is about maintaining health IT performance. So, similar to the security exception, for example, there could be situations where you're not sharing information because something needs to be adjusted in terms of health IT performance. That could apply to a number of different exceptions.

In this one, it's about perhaps let's say you take down your health IT temporarily to address a problem or a flaw that you've discovered. During the time the technology is down, you receive a request for information from a requester and you can't provide that information at the time because the system is down. Would you be subject to information blocking?

This exception could help to address that. But there would be certain things that would have to be met in order for this exception to be claimed, such as did you take down the system for no longer than necessary to achieve the maintenance required? Is the practice for how you take down the health information temporarily, is it implemented in a consistent and non-discriminatory manner, again, using those similar fairness type terms?

In circumstances when the health IT is applied, is there an agreement or some engagement with the customer regarding the unavailability of the health IT? Those are overall the seven exceptions that we've laid out. Again, I think there's going to be a lot of time for discussion of these as part of the taskforce, which Mike will talk about a little bit later. We will also have staff on hand who have worked on the development of these to engage with the taskforces to discuss these further. Let's go to the next slide.

Okay. So, a couple of other things to think about in terms of how information blocking works procedurally. A lot of this would sit with the Office of the Inspector General. I won't speak on their behalf, but I want to talk about the complaint process.

So, the complaint process is something that we are continuing to implement and evolve. You can check on our healthit.gov website for how health IT feedback can be received and there's an ability there for information blocking reports to come in that way as well. We look forward to working with OIG, who would be the main implementer.

For purposes of 4004, if an information blocking complaint comes in, OIG, Office of Inspector General at HHS, would do the analysis and determination of whether the information blocking has occurred. Some of the things they would consider is whether there is an assertion that one of the exceptions should apply to the actor in terms of information blocking being found or not found.

After that, that information blocker could be subject to a number of different enforcement mechanisms. One, if you are a certified developer, health information network, or health information exchange, you can be subject to an up to $1 million per violation fine. That would be determined by OIG. In addition, if you are a healthcare provider, while you're not subject to those fines, you could be subject to appropriate disincentives that are determined by the Secretary. That's something that the Secretary and HHS as a whole are contemplating in terms of what that will look like going forward.

In addition, we've also asked in the rule for additional consideration in terms of exceptions. So, did we hit the right mark? I think that's really important to us. It's really important to Dr. Rucker. It's did the exception, the seven exceptions we've laid out, hit the mark in terms of what is needed to address

information blocking across the landscape? Did we get the right ones? Are there additional ones we should consider? We also welcome comment on that as well. Next slide.

So, that covers information blocking, which was a lot of information and we'll surely have more discussions on that. I want to highlight a couple of other sections in the rule before I turn it over to Steve.

So, on pediatric care and practice settings – next slide – what Congress also asked us to do was to think about, via 4001 of the Cures Act, to think about what are the needs that would support pediatric care and practice settings and particularly, the development of recommendations around that? We took three steps to do that. One, we've developed ten recommendations that are included in the rules for voluntary certification of health IT. So, what are the things that we think are critical for pediatric care providers to think about in terms of health information technology?

Second, we looked at the 2015 Edition, not just what was finalized in the 2015 Edition rule in 2015, but also the proposed criteria that Mike talked about earlier to identify which ones would be supportive of pediatric care and practice settings. So, we looked forward to feedback on that as well. Is our characterization of the 2015 Edition certification criteria beneficial to pediatric care settings and can be used to address the needs that have been identified and in particular the recommendations that we have noted as well.

We also plan to focus on non-regulatory initiatives as well. What informational resources could be useful to pediatric care settings to have on hand when they are thinking about purchasing health information technology or thinking about their support for their pediatric patients. Overall, when we thought about the recommendations that we developed, all of that was done in consideration of a lot of work that has been occurring over many years at HHS, including work around the development of the children's EHR and that was developed with ARCH and with CMS. That's identified and laid out in the rule as well. Next slide.

So, here you have actually what was kind of a one-stop shop of what we did as it relates to health IT for pediatric care. So, we did look at the children's EHR format, which I noted was developed to work with ARCH and CMS. We developed the ten recommendations. You can see that there are very specific components here related to pediatric care settings, such as the biometric-specific norms for growth curves and supporting growth charts for children, thinking about weight-based drug dosage, and also age and weight-specific single-dose range checking. Those are just some, but you can see the ten recommendations laid out there.

Then we also looked further down on the slide at the current 2015 Edition criteria that we think support pediatric care settings. Then over to the bottom right, you see the proposed new criteria. One, the overall United States core data set for interoperability, the USCDI, that specifically we think supports the interoperable flow of information which will benefit pediatric care settings. We also note electronic prescribing and the FHIR-based API as well as data segmentation for privacy.

Now, in the 2015 Edition rule, we had a document level criteria around data segmentation for privacy. In this proposed rule, we have a deeper level at which segmentation could occur. So, that's one component that we think would be helpful for pediatric care as well. Next slide.

So, in addition to some of the areas I talked about already in terms of requests for information, some

others we wanted to highlight in the rule that would be included as part of the care continuum would be this one, which is around the opioid use disorder prevention and treatment and how health IT can benefit addressing the opioid epidemic. So, we include an RFI or request for information specifically on this, including questions around how, for example, FHIR can be supportive of the movement of information in that respect. Next slide.

We also include a patient matching RFI in the rule. CMS in their rule that Alex Mugge talked about a little bit earlier, also included a complementary patient matching RFI as well. In our RFI, we note the importance of interoperability and we want to learn more about what mechanisms that are occurring in the field, what innovative approaches to patient matching should ONC be aware of as part of our work. We also note that GAO recently released their report on patient action, which was called for under section 4007 of the Cures Act. Next slide.

Registries is another RFI that we've included as well, specifically noting under 4005A and B there's a note to interoperability and thinking about registries and how information can flow amongst registries. That could be many types of registries, including clinician registries, could be public health registries across the spectrum, but we're interested in learning more about how some things like the standards-based API that we've included in our rule, how FHIR 4 might help in terms of registries and exchange with registries. Next slide.

This is a timeline. I'm not going to spend too much time on this because I think Mike highlighted a lot of these pieces as part of his discussion of the conditions of certification, but you can see generally from the effective date of the final rule, so when the final rule becomes effective, our expectation is that there would be a two-year timeframe by which any of these requirements would have to be in place.

I would note, however, that at the effective date of the final rule is when the exceptions would be in place, but things such as the API interface with the USCDI, the electronic health information export, those of that nature, there would be a two-year span for which implementation of those could occur. Next slide.

With that, I think we're going to take a quick break if there are some questions and then we're going to turn it over to Steve to talk more specifically about APIs without special effort and the interplay between information blocking and the conditions of certification. So, I know we only have time for a couple of questions, but we did want to take a break. Lauren, did you…?

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thanks, Elise. I do see one hand in the queue, Denise Webb.

Denise Webb - Individual - Member
Yes, thank you very much for that thorough explanation of what's included in the rule. I just wanted to note that last week while I was at HIMSS, a number of CIOs and members have shared that they were really concerned that there was only a 60-day review period for the two rules that came out.

Now, after listening to how extensive the ONC rule is, in particular with the number of multiple RFIs within the rule, I don't know if there could be any consideration given to extending the review period to 90 days. As I said, a number of CIOs requested that and if that was possible so they could do a diligent and thoughtful review and be able to respond to the number of RFIs. That would just be a request that

could be considered.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy
We have heard similar questions at HIMSS as well. We do plan to go out with a 60-day public comment period. That time period has not started yet. So, the rule has been out for a little bit over a week now and the public comment period has not started yet because the rule is not published in the Federal Register as yet. So, there is some additional time before that 60-day clock actually starts. We do think it's important for us to be able to move as quickly as possible towards developing the final. So, we are planning to go out with a 60-day comment period.

What we've done with the HITAC, considering some of the policies that ONC plans to move forward with – Mike will talk a little bit more about this later – we plan to divide the work across four taskforces, which will allow for a more focused but also a more tangible ability to dig deep on some of the particular areas and that will be the mechanism by which the draft recommendations can be developed and then moved up to the full HITAC for consideration.

We'll talk a little bit about the timeline for how we're going to achieve that. I think receiving the comments from the public through the public comment process as well as receiving recommendations regarding the policies from the HITAC in a timely way will help us to move towards the final and to the effective date as quickly as possible.

Denise Webb - Individual - Member
Thank you, Elise.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Aaron, another quick question?

Aaron Miri - The University of Texas at Austin - Member
Yeah, thank you. Elise, you walked over the definition or notion of providers with respect to information blocking, but there's a fairly extensive definition of the term provider that comes from the Public Health Service Act. I think it's counterintuitive for many people who ordinarily think of providers as hospitals and physicians. I thought it might be worthwhile covering briefly what's included in the definition of healthcare provider.

Mike Lipinski - Office of the National Coordinator for Health Information Technology - Director, Regulatory Affairs Division
You want me to take that one?

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy
Go ahead.

Mike Lipinski - Office of the National Coordinator for Health Information Technology - Director, Regulatory Affairs Division
Aaron, that's a good point. Looking back, it might have been helpful to have specified that in the preamble. But we took the definition, just so you understand how we got to that, the definition of

healthcare provider is cross-referenced, but it's specified in the Public Health Service Act, which is what the Cures Act amends to put all these provisions that we're implementing, it makes it all part of the Public Health Service Act.

That already has a definition via cross-reference for the healthcare provider. That term is a very broad term, as Aaron alluded to it and it includes a hospital, skilled nursing facility, nursing facility, home health entity, long-term care facility, healthcare clinic, community mental health center, renal dialysis facility, blood center, ambulatory surgical center, pharmacy, labs, pharmacists, physicians, even those under contract with Indian Health Service, tribal organizations.

If you're not familiar with the Indian Health Service, they do provide certified health IT or tribes purchase it themselves – rural health clinics – some of these are further cross-referenced definitions of these terms that I'm mentioning to you. Then there's even any other category of healthcare facility entity, practitioner, clinician determined appropriate by the secretary. So, we definitely want and seek comment on that definition, whether it's a lack of clarity or whoever you may be or if you think there are certain cross-references that are unclear. Aaron, thank you for noting that.

Aaron Miri - The University of Texas at Austin - Member
Thank you.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
I'm not seeing any other hands in the queue. I think we're going to proceed to have Steve present on the API conditions of certification.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology
All right. Great. How's my mic check?

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sounds good.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology
Super. I know we've got a packed agenda. So, we're going to try to get through this as quickly as possible and keep you all on pace for the rest of the discussion today. Thanks again for the opportunity. I'm going to do a deeper dive on the specific API conditions and certification in the rule and give you a little bit more context about how that intersects with the other conditions in certification and the information blocking-related proposal. Next slide, please.

Here's the big picture, two statutory sections that my colleagues, Mike and Elise, just covered in detail for you. Great job, guys. There are the seven conditions of certification. One of them at the bottom is not currently being proposed to be implemented. It's that EHR reporting program that we had discussions about at the HITAC previously and then you have the seven information blocking exceptions that we propose as well. The highlighted section there about APIs without special effort is going to be the conditions of certification section that we're going to talk about in more detail. Next.

Quick acronym check – so API, again, since we're going to be using that quite a bit, application programming interface, FHIR, which I'm sure many of you, the United States Core Data for Interoperability, and the other new acronym that we've proposed as part of this regulatory slate of proposals called the ARCH, which is the API Resource Collection in Health. I'm going to talk to you about it and its importance relative to our regulatory proposal. Next.

So, we're going to cover the big picture about the API condition of certification and how the API proposals fit together within this larger universe. The first already was covered. We've got the big universe of information blocking. It applies to the four actors, focused on electronic health information, actions covered by those exceptions would not be subject to penalties and disincentives. Click.

We didn't work out our whole rehearsal on the animation here. It will be quite entertaining as part of the webinar. We have the broader API conditions in certification, which fit within this universe of information blocking. As you go through the slides with me today, you'll see a lot of similar language about reasonable and non-discriminatory terms and similar themes that were echoed already as part of information blocking. For the API conditions in certification, we have the statutory condition plus three specific sub-conditions that we've noted as well as maintenance and certification requirements, which Mike and Elise covered relative to the Cures Act's requirements about conditions and maintenance certification. Next.

So, lastly, within the API conditions and certification, we have the new 2015 Edition Cures criterion that I'm going to talk to you in more detail, but as a high-level overview for everyone, we've got a secure standards-based API proposal with a read-only focus, HL7 FHIR as a base standard, and then other implementation specifications to support both provider and the patient access use cases.

So, a number of the slides that my colleagues, Mike and Elise, put together and I have ahead of you are very tech-savvy. We've done that intentionally at least for these presentations so that they are referenceable material. We've digested a lot of the preamble and reg text into these slides and we want to make sure that everyone has a fuller context around which to take a look at the rules, read through all the various sections. They are more tech-savvy than we would normally prefer to present on, but again, as a reference, we wanted to make sure that all of you had this context available. Click.

Okay. So, the who, what, and how of the API conditions certification – in regulatory proposals, it's important to be precise. So, for these specific conditions of certification, we wanted to make very clear who the specific actors were and how they related to each other. So, we chose specific terms, one is the API technology supplier, which is the health IT developer of certified API technology, the API data provider, which will traditional be the healthcare organization that is the one deploying, making available the API, and then an API user which would be persons and entities that the use or create software applications.

This could be third-party patient access applications. This could be third-party service, a population analytics company that a healthcare organization partners with. It could equally be the healthcare organization themselves. We make that clear that in some cases, a healthcare organization that is using its own API may be considered an API user in that context.

With respect to how and what the API conditions, to what they apply, you have the API-focused certification criteria, which we have a slate of in our proposed regulatory text. Practically speaking, though, we're talking about regulating FHIR servers. As a FHIR-based API is deployed, it's going to be

done by virtue of a FHIR server infrastructure. That is what the API conditions and certification apply in the business practices surrounding them.

The other important point to note is how this API conditions and certification applies. In this respect, we want to be very clear – it applies to those health IT developers and the technology that are certified to those specific certification criteria noted above in that section. In contrast, you could, as part of our certification program, see health IT developers that get certified just for, say, e-prescribing, or to do public health interface-related certification. In those contexts, if those health IT developers have products that are not certified to any of these above referenced API-focused certification criteria, these conditions of certification would not apply at all.

So, it's just important, both from a regulatory burden and balance perspective as well as the scope of the API conditions to understand that it applies to those that have gotten certified to the API-focused certification criteria. Click.

So, this is going to build as I'm talking. We have a slate of required capabilities that are the functionality built in the certification criteria. We've attributed proposed specific standards and implementation specifications to support those required capabilities and then we have some additional contexts around which there are attributed or associated API conditions and certifications for certain required capabilities as well as just some additional context I put in there for reference for those of you that want to dig into the details.

Suffice to say, there are number of functionalities that we've broken down here in terms of how a client application would interact with FHIR server, making sure that as we go through the testing processes for FHIR servers that we can appropriately focus on the right conformance test and functionality that would need to be there conformant with the specific implementation specifications or standards.

As part of our proposals thus far – I'll get to this on the last slide that talks about some of these options – we did reference and attempted through our proposals to meet the industry where it was best prepared to deploy these APIs in a standards-based way using available technology. For that, our going out proposals referenced the slate of FHIR Release 2 Argonaut specifications, which is DSTU2 flavor of FHIR.

We did reference some of the newer updates to the SMART Application Launch Framework and the like, but we do solicit comment as part of the regulatory proposals around options for FHIR versions. That being said, the broad suite of implementation specifications, additional FHIR profiles, and the like that were available for a full slate of proposals for the industry to react to were available for that FHIR Release 2 slate. Next slide.

I just wanted to note – earlier last fall, we did release a FHIR testing suite called Inferno. The hyperlink is there. It's available. It's built out right now to test FHIR servers for the FHIR Release 2 slate as well as many of these functionalities that we've proposed as part of this new certification criterion. We will continue to work with industry and welcome feedback. All the code is available open source. I very much would encourage people to go check that out. Next.

The other one I wanted to mention – we put out a blog post last fall about FHIR implementation nationwide. This is a graphic of the percent of hospitals by the hospital referral region where as part of 2015 Edition, as my colleague, Mike, mentioned earlier, we proposed API-oriented certification criteria,

but did not attribute a particular standards requirement to it.

Those of you that are from our FHIR committee duties, you're familiar with the method behind that, but sufficed to say, a majority of the largest market share or attestation share health IT developers that went through this certification program processes used FHIR as part of their API certification requirements and as we've been able to attribute that through our research, we've found almost 87% of hospitals and 69% of MIPS-eligible clinicians are served by health IT developers or products certified to any FHIR version, presumably or right about now, many of them are on Release 2.

It aligns with what, say, Apple is requiring to their health records, app connectivity, and other industry app developers as well. So, as we look to the future evolution, there's FHIR Release 3. There's now FHIR Release 4. So, we have options to support industry comment and feedback. Next slide.

So, when it comes to the US Core Data for Interoperability, here's a full unpacked version. The thing that I didn't reference here and specific is that for each of these data classes and their specific constituent data elements, there are also semantic findings to them, in particular. So, just like what we had with the common clinical data set and its evolution into the US Core Date for Interoperability, we have referenced the specific vocabularies or code systems that are attributable to the particular data classes and elements that we've referenced therein.

So, as Mike covered, we've already proposed to include a few updates to this as we move forward and we have a process called the Standards Version Advancement Process that we hope to use to continue to raise the ceiling above the baseline for certification over time and expand the US Core Data for Interoperability overall. Next.

So, the one important point to remember about the USCDI is that in order to translate the USCDI, which, again, is just data elements, it needs to be referenced in a way and translated into a language of FHIR. That's in FHIR resources. So, we have a lot of experience now for the better part of ten years' worth of regulating standards in understanding what we need from regulatory flexibility and administrative flexibility in order to better work with industry, keeping in mind the context of our standards version advancement proposal.

So, as we look to expand the USCDI and issue a version of that over time, we need a way to translate the standards agnostic from a content perspective USCDI into a FHIR-based way. Similarly, as part of some of our other proposals, the USCDI is translated into the CCDA, as it's referenced in some existing certification criteria.

So, again, just to make sure that the broader audience that's listening has that context behind – there's the USCDI, which is effectively a set of data with some semantic requirements or representation, and then that needs to get translated into the appropriate content standard or standards in which it would be used most appropriately.

So, for the API conditions of certification and the API certification criterion, that's a translation into FHIR. We've identified the applicable FHIR resources that were necessary to support the proposed USCDI data classes elements. So, the way that we do that translation is by referencing what we call the API Resource Collection in Health, otherwise known as the ARCH. You can go to the next slide.

So, this one is going to build. What is the API Resource Collection in Health? It's the 15 specific FHIR

resources that we selected to align to support the USCDI. It starts with the patient at the center, so the patient FHIR resource. Then all of the rest of the FHIR resources that we reference are going to build around that. There's a visual there for you to help remember the acronym. But this is the way that we reference the FHIR resources and then use the existing specifications like the Argonaut Implementation Guide that we referenced to add that additional profile clarity to those resources.

But again, we needed a way to translate from USCDI into FHIR and then leverage existing industry implementation guides to give additional clarity and implementation certainty around those FHIR resources that we need. Equally as important, as we expand the USCDI over time, again, from this translation perspective, there may be data classes that we reference in the USCDI that don't have a particular FHIR resource or profile that's specified in an existing implementation guide.

So, Provenance is a good example. There isn't an industry implementation guide or profile that has yet been developed and published that references Provenance in a way that we could attribute it as part of the proposal. So, where we give the Provenance FHIR Resource life is through the ARCH. We also provide areas where we need to supersede additional or existing industry implementation guidance to make sur that USCDI data policy is referenced appropriately from a conformance perspective in the existing FHIR resources or the conformance requirements for FHIR.

So, another example there would be patient address, if I'm not mistaken, in the existing implementation guidance that's available. It's not referenced as mandatory. So, we use the ARCH as a way to indicate that not only is this required as part of the patient FHIR resource, but it also needs to be a mandatory element of that profile or resource as it gets implemented. Next slide, please.

So, this slide is going to build, again. This is a takeaway slide, high-level overview of the full API conditions of certification and maintenance of certification requirements. The first section here on the slide is the statutory requirement with the noted reference to without special effort. We have the three specific let's call them sub-conditions within the conditions of maintenance of certification for the API condition of certification as well as at the bottom here, the maintenance of certification requirements. I'm going to touch on these very briefly just because this is the only place where they're referenced in detail.

So, we have registration requirements around how apps engage with health IT developers and register their apps. So, there's a maintenance of certification requirement. Again, as we look at the maintenance certification conditions overall, as you look at some of the other conditions of certification, this is an ongoing responsibility that health IT developers have in order to maintain their certificates that are issued to their products. So, once you get certified, there are a certain amount of requirements you need to meet in order to get certified and then as we look forward into the future implementing the Cures Act, there are maintenance and certification requirements as well.

The second one here is important, as we understand, for industry. When we talk about deploying FHIR-based APIs, they have an associated endpoint to which the apps and other services can connect. So, it's important that those endpoints are made available so that various stakeholders can point their apps or services toward what are called specifically service-based URLs but effectively FHIR-based API endpoints and we have maintenance and certification requirements around this because it's an ongoing expectation as more of our customers get their API endpoint stood up that those would be made available and publicly accessible in some manner.

Lastly, as the compliance timeline and implementation for rolling out the new API standards-based certification criteria or criterion, as Mike mentioned, it would be 24 months from a final effective date. We had a choice here about creating an arbitrary certification deadline for health IT developers.

But again, given the experience that we have now implementing the program and numerous rules, we decided to set an overall outcome for industry and then let health IT developers based on different technical architectures that they may have, cloud versus on-premises installations to determine the best cadence and certification timeline that they would need to work out with their customers overall. We proposed the 24-month timeline post a final rule, given the proposals and all the expectations that developers would now have. Next.

So, this first of the sub-conditions within the API condition of certification applies to transparency. I'm going to touch on these really briefly. As many of you know and a good practice as far as many other industries beyond healthcare, when it comes to having APIs, it's important to have the technical documentation available as well as other business documentation so that we operate in an open and competitive marketplace as well as one that allows for proper technical connectivity.

So, we have requirements around the API technology supplier, which in the case is, again, the health IT developer, publishing all of its terms and conditions in a specific enumerated list underneath that. We have a requirement about the fees, which I'm going to go into a little bit more detail, as they are permitted. API technology suppliers need to describe those fees in detailed and plain language. There are variable ways in which fees are calculated. Having access as, say, an API user or an app developer can be able to calculate what you think those expected fees may be relative to the particular customers that you're going to be engaging with.

Then we also have a proposal around a permitted process. If an API technology developer wants to go through a process to verify the authenticity of an app developer, they would be permitted to do so. They're not required to, but if they do implement such a process to verify the authenticity of the good standing of an app developer, they would be able to do so, so long as they're completed within five business days of receipt of that app developer's request to register their software application with the API technology supplier. You can go to the next slide.

All right. So, we're going to dive into the deepest part of the presentation here in terms of the API conditions of certification and an intersection with information blocking. This is really a close intersection with permitted fees. The API technology supplier, which was the circle that was highlighted down below in that left corner, they are the actor that is regulated by the API conditions of certification when it comes to who we have direct authority over from that portion of the Cures Act.

With respect to information blocking, as you all well now know from the earlier presentation, that's a more complicated and bigger umbrella of actors that are involved relative to the relationships that are here.

So, I wanted to depict – we have API technology suppliers that have two different types of relationships, one with their customers, API data providers, and that has both information blocking and API conditions of certification related overlays. And then similarly for API technology suppliers, they may have direct relationships with API users in certain contexts. That equally has API conditions of certification relationships as well as information blocking overlays.

Then lastly, when it comes to API data providers, which would be healthcare organizations in this context, they will have a relationship with API users or others. This could be patients, patient access applications, third-party services, etc. And they will also, because they're covered by the information blocking-related statute provisions, have some type of relationship between their work between API data providers and API users. Click.

When it comes to the permitted fees, we have proposed three categories of permitted fees that could exist underneath the API conditions of certification that would be a deeper and more specific set of proposals that go beyond the broader information blocking-related exception.

So, when it comes to the relationship between the API technology supplier and the API data provider, we have two permitted fees – one around the development deployment and upgrades that would incur fees and costs associated with the API technology supplier as well as API usage costs that would be incurred by the API technology supplier in instances where they are hosting or providing the API services on an ongoing basis for their customers, the API data providers.

The third permitted fee is around what we call value-added services that API technology suppliers could offer to the broader market. I'm going to cover that in more detail on some subsequent slides. You can go to the next slide, please.

So, there are going to be two scenarios – you can click again – that we're going to cover in more detail now about how these relationships apply and the specific proposals underneath. Next.

So, when it comes to the overall conditions that apply from a permitted fee perspective, we had a choice about whether or not to start to list out an exhaustive list of fees that would be allowable and understanding that that would create what I would like to call a perpetual guidance mode for ONC, we decided from a clarity perspective that we would start with a clean slate and say if we were operating in a world where no one could make any money and there wouldn't be any opportunity for research and development, then we would prohibit all fees all together and that would create a no fee world for APIs, recognizing that there will need to be reasonable returns on investment, opportunities for research and development, and innovation.

We started with that baseline of there are no fees that are – all fees are prohibited unless they're otherwise permitted. So, then we kind of work our way upward. So, the opportunity for industry, as they have an opportunity to comment on our proposals, is to identify either where we have not sufficiently made clear or if there are areas where there is ambiguity about certain types of fees that they believe they should be able to charge vis-à-vis their APIs or how they supply them and that we could potentially build in to final rule versions of this or if there's a permitted fee for API deployment or usage, etc. that we hadn't adequately considered and that we should make sure that we clarify as part of the final rule.

So, the onus is on industry to identify where there are more fees that they believe they should be permitted to be able to charge. So, for the broadest aspect in terms of how the general conditions apply to fees, again, piggybacking on the information blocking universe that you understand based on the presentation earlier, there's a lot of repetitive language that we've emphasized here again about the fees being objective and verifiable, that they need to be reasonably allocated among all customers, that they need to be reasonably related to the cost of supplying the API technology and that they can't have a competitive basis upon which the fees are being charged.

So, I'm not going to cover each of these verbatim, but that's the gist of how for any of the subsequent permitted fees, they all need to apply or conform to these specific provisions. Next slide.

So, when it comes to permitted fee number one, which is development deployment and upgrade fees – you can click one more time – the first bullet here is the actual permitted fee. So, an API technology supplier is permitted to charge fees to recover costs reasonably incurred when they develop – so, the actual work to do the engineering, recognize that investment needs to be made, costs are incurred, to develop, deploy, and then upgrade the API technology for the API data provider.

The one thing that we wanted to make very clear in this type of situation, you have the API technology supplier that is upgrading the API technology of an API data provider that then may work with a third-party that they choose for various different services or patient access applications. The API technology supplier can't take into account the API users that their customers pay interact with and subsequently step in front of the API data provider to try to recoup additional fees that would be for, let's say, the privilege of working with their customer, the API user now needs to pay the API technology supplier.

So, we made very clear as part of the proposals that this type of "relationship fee," as I've got there in quotes, would fall into something that would be a prohibited fee and the API technology supplier would not be able to charge API users directly on the basis of the fact that they're just – the API data provider wanted to work with that API user. Next slide.

The next permitted fee is around API usage costs. So, there's a bunch of detail here that I cover. Again, the first bullet here is the actual proposal. So, we recognize that once you get your API technology in place as an API data provider, there will be ongoing maintenance, usage costs, etc. in terms of being able to maintain that API at increased volumes and scale and that there would be charges associated with it if you need to get a better server, something that can handle more scale or volume, better performance, etc., that those would be costs, especially in a case where an API technology supplier is, let's say, hosting or administering that API technology on behalf of an API data provider. We wanted to make sure that the API technology supplier could recoup those costs for providing the hosting and administrative services.

The one thing that I wanted to make clear here as well – again, because there's this three-way relationship that we're keeping in mind, the API data provider is the one that will be making their API technology available to third parties with whom they choose. It could be for their own particular uses. It could be for providing patients access to their health data via an API, but in all cases, the financial relationship needs to be defined between the API technology supplier and the API data provider.

So, if the API data provider were to sign up for a particular tier of API service per month and they exceeded that, then we wanted to make clear that the API data provider, they would need to reconcile whatever those additional costs incurred above their original contract. Let's call them overages, for lack of a better colloquial term. They'd need to square that up with the API data provider.

So, in instances where an API user that an API data provider may partner with for their own internal instances, if they use more bandwidth, for lack of a better example here, then they otherwise originally paid the API technology supplier to provide them, then the API data provider, again, is on the hook for reconciling those charge increases.

The only other one thing I wanted to note at the bottom, just as I'm sure you're reading through, even

though we proposed to allow a particular type of permitted fee for API usage costs, we did not propose or restrict the methodology that an API technology supplier would take in order to engage with services for the API data provider. So, there's no particular fee amount. There's no threshold. There's no methodology.

All that is up to the API technology supplier to determine. We've certainly seen in other industries – mobile, cellphone carrier, telecom industry, where those of us remember the days when we got charged per text messages and then that was unlimited. Then we got charged for video and pictures and now, that's built in. So, there are various different methodologies that we expect to evolve over time. We didn't see the need, necessarily, to propose specific methods that would be the only methods that would be permitted.

That being said, API technology suppliers in determining methods, again, would need to make sure that if there are calculatable ways that needs to be part of their documentation that's made transparently available, that their methodology complies to the general conditions for permitted fees and that it doesn't violate something that would be part of the broader information blocking-related provisions overall. Next slide.

All right. We've got one more set. Keep going. There are some accounting-related aspects to the permitted fees as well, but the one that I wanted to emphasize that we carry through that Elise mentioned briefly – when it comes to patient access, we took a very specific line and said any cost incurred that facilitates a patient's ability to access or change and use their health information cannot be a permitted fee that would be allowed to be charged as part of the API usage cost.

The subsequent bullets that are referenced below are, again, accounting-oriented provisions. Then the last bullet there, I just wanted to reiterate – both of these permitted fees have that same relationship orientation in terms of prohibiting relationship fees from being established and kind of going around the API data provider for the API technology supplier to charge API users based on the relationship they develop with the API data provider. The reason why that point is important is going to be part of the openness and pro-competitive conditions and certification that I'm going to discuss in a little bit. Next slide.

This is the last permitted fee. You can click one more time. There we go. So, an API technology supplier is permitted to charge fees for value-added services that would not be supplied in connection to get something that would be necessary for the efficient and effective deployment and development of such software.

So, if there are above and beyond services that an API technology supplier wants to provide in order to make themselves more attractive for app developers, to provide other market differentiating software, they have the best customer service or level seven technical support, other things that would, as the examples here on the third bullet, make it more attractive for different app developers, co-branded integration, co-marketing arrangements. As I mentioned before, our focus right now is on read-only apps.

So, if an API technology supplier wanted to offer very detailed integration and right testing for an app developer, that could be considered part of their value-added services suite for which they could charge fees. So, that's, again, the purpose of this proposal is to identify where there would be a permitted fee that would not constitute information blocking and wouldn't violate the otherwise aspects of the overall

prohibition around permitted fees.

The one other thing that I wanted to note here at the bottom – we do allow for and wanted to make clear that API technology suppliers would be able to administer their own "app stores," some type of market if they want to, provided that they don't violate this condition of certification and information blocking policies.

So, it's important in this example, as one below, where we noted in the rule, as I basically quoted verbatim, that if an API technology supplier were to use its app store, for lack of better terms, as a gatekeeping mechanism to prevent its customers from being able to use applications that were developed for that API on the sole basis of the apps paying to get listed, then that would create a suspect relationship in terms of the value-added services and would constitute special effort and could raise information blocking concerns and potentially be a violation of this permitted fee for value-added services.

So, again, a lot of the proposals that we have around creating the boundary conditions and clarity and guardrails, as have often been referenced, around which we want a competitive market to exist, transparency to exist, pro-competitive practices to exist in ways that would not constitute special effort for the various actors that are involved in the API ecosystem. Next slide.

I'm going to go very quickly through my last slate of slides here on the openness and pro-competitive conditions. So, this is the last sub-condition as part of the API conditions of certification.

The first main overall proposal that we have is that the API technology supplier must grant an API data provider – so, in this case, a healthcare provider – with the sole authority and autonomy to permit API users to interact with the API technology. So, to say that more clearly, once the healthcare organization has received, been upon receipt of their API technology, this proposal and this language means it's their API technology.

They should be free to choose which third parties they interact with, which other types of services that they want to use – this gets to the pro-competitive conditions in terms of the API technology supplier previously, in certain areas where we've heard concerns that if the API technology supplier has a competing clinical decision support service, that they wouldn't permit their API data provider, their customer, from using a third-party application because that would otherwise compete with the API technology supplier's offer.

So, we want to make very clear that it's the API data provider, the healthcare organization, that gets to choose which services and applications they want to use to access their API technology and so on and so forth. So, when it comes to the API technology supplier, they must provide the technology in terms that are no less favorable than it provides itself. There's some more specific terminology. Again, this is going to be variations of the reasonable and non-discriminatory theme, objective and verifiable criteria.

And then, as I just mentioned, the API technology supplier must not offer different terms of service on the basis of whether an API user with whom an API data provider has a relationship as a competitor – so, this gets to the scenario that I just mentioned before – and also that an API technology supplier must not condition the access on revenue or other value that the API user with whom an API data provider has a relationship may derive.

So, an API technology supplier in other instances or anecdotes that we've heard would prohibit a third party from working with their customer because that third party may have a valuable service that will create revenue or value for that third party and they happen to be a competitor of that API technology supplier. So, you have these anti-competitive practices that pit or put the healthcare organization in the center. So, we wanted to, again, with our proposals make those clear lines and guardrails around which the market could compete. Next slide.

Those were the non-discriminatory terms. To the next slide, we have the rights and access of API technology. So, again, this is similar to the information blocking provision, so I won't focus too much time on it with respect to license and providing the rights that are necessary to interact and use the API technology, specifically to the little section here on the right.

An API technology supplier must not condition any of the rights described on a requirement that the recipient of those rights – so, either the API data provider or an API user pay a fee to license the right like a royalty or revenue sharing arrangement – these are other behaviors that we've seen in the market up until this point that was raised to Congress, raised to us as part of information blocking and as part of what would constitute special effort in the overall context of anti-competitive market behaviors.

So, in order to promote a more pro-competitive market landscape and ecosystem, a number of these sub-conditions are applicable in terms of the various different market behaviors that are available. Next slide.

The last one here gets to the service and support obligations. So, this takes on, let's call it the less sexy, more mundane aspects of making sure that the API technology continues to be maintained, that all the support and services that are reasonably necessary to enable continued effective deployment and use of the API technology continues to be made available. That compatibility as the API is upgraded and changed is maintained in order to avoid disrupting API technology use and production settings.

We know from other industries and market behaviors that as a gateway, as a doorway to data, the APIs are used to cut off access to third parties that may be competitors of theirs, which would be a no-no under these proposals, but also, in non-visible or not visible to the lay public, certain tweaks or subtle changes to APIs can make access to them difficult for third-party services. So, if those types of behaviors were to crop up, we wanted to make sure to have proposals that were leverageable to address either from an API condition of certification violation perspective or from an information blocking perspective as well.

Then we have an exception here at the bottom – if there are excision circumstances, we understand. However, if there are going to be changes, the API technology supplier would need to be transparent and provide notice to its API data providers as well as registered applications that, "Hey, a change is coming. Here's what the change will include." They're on notice then that those changes are coming and they won't be caught off guard by, say, a tweak to the API infrastructure that may otherwise affect their product access to that data. Next slide, please.

All right. Last slide. Thank you for bearing with me and going through this pretty quickly. There are a few opportunities for requests for comment. Very specifically, there are now four releases of FHIR that are out there, three of which are kind of in production in various modes. So, what we've proposed is what is listed there as option one, FHIR Release 2. We have two intermediate options and then the last option there is to just finalize a set of regulatory requirements that would center around FHIR Release 4 and its

accompanying implementation specifications.

There's a more specific request for comment on the document reference and provenance resources, which because they weren't referenced in existing implementation specifications, there aren't clear search parameters like there are as part of the Argonaut Implementation Guide around some of those other FHIR profiles. So, we have comments there about what the search parameters would need to be supported or would be best to support. We have additional comments requested on permitted fees.

So, again, the opportunity onus is on industry to identify where there are permitted fees that should be allowable from an API technology perspective. Very specific for those that are out there technically – the next two proposals there are around reasonable upward bound for refresh tokens, which are part of the OAuth workflow as well as dynamic client registration protocol, which is how apps register to FHIR service to over-simplify things.

We permit dynamic client registration, but recognizing the app developer authenticity verification that we have proposed, there could be other means and mechanisms, so long as they take place in a timely manner that apps could be registered with the different FHIR service.

So, one other thing that I would mention from a security perspective is that just like how patients or other services interact with APIs today, be it proprietary or the ones that have deployed now in 2019 as part of meeting CMS, promoting interoperability program perspectives, the healthcare organizations, in this case, API data providers that will be making the data for which they are the stewards of available in the patient access use case, they have obligations under the HIPAA security rule specifically, but the broader HIPAA universe to make sure that the persons to whom they are disclosing that information have been identity proofed, that they have a verifiable relationship with them.

Often, as our experience is today, we get access to our health information via the numerous portals that our healthcare organizations have made available to us. Our expectation is during these transition years that the authentication credentials that are issued from healthcare organizations to the individuals with whom they have a relationship will be the mechanism by which patients gain access to their health information just like they do today when they go on to a website portal, web-based way. Similarly, if they do that via an application of their choice, they will equally use those same credentials and authenticate themselves to a healthcare organization.

We are not prescribing that username and password be used, but that is de facto, kind of the state-of-the-art right now from a technology perspective that many healthcare organizations have deployed. That being said, we don't have any prohibitions or limits on the types of authentication methodologies that healthcare organizations may use, so that's an opportunity for innovation and expansion over time.

Then equally, when it comes to a healthcare organization, in this context, an API data provider, working with a third-party of their choice for their own business purposes in using their API, that is fully covered in the normal HIPAA paradigm, where they have all of their privacy rules, all of their HIPAA security rule and business associate-related contractual relationships that they would need to establish.

So, these proposals that we have put out as part of this proposed rule don't change that dynamic at all from a security perspective, both technologically as well as from a legal and contractual perspective. All of that still remains in that context and would need to be protected, just as it is today, if they're using a proprietary API to connect to a third-party service.

So, I just want to make sure again – we know that security is often raised as a concern and it's important to keep in mind the various contexts and layers of the security requirements that already apply in the healthcare setting today, the boundaries between healthcare organization responsibility under HIPAA, the patient's right of access, where you do cross today under the laws, once that data gets into the hands of the patient, they became the steward of their own data.

That boundary is ended from a HIPAA perspective as well as just the technical security requirements that they would otherwise have to comply with via a proprietary API or some other interface methodology. We just happen to be proposing a secure standards-based API approach that would be more generally consistent and deployed industry-wide.

So, with that said, I appreciate your time. I know it was a lot to digest just in this one condition of certification. I promise you all of the other ones are as entertaining as this one and very much look forward to your comments and appreciate all of the time that you will spend in advance digging through the rule and giving us the best recommendations you can. So, back over to, I think, Mike.

Mike Lipinski - Office of the National Coordinator for Health Information Technology - Director, Regulatory Affairs Division

Thanks, Steve. Okay. So, that's a good segue about giving us your recommendations. Maybe we can pull up the next set of slides which will talk about taskforce. Okay. So, next slide, please. All right. So, we have set out four taskforces to help you, as members of the committee, provide us comments on our proposals, some you've heard about in depth today, some that we did not even touch on in specificity today.

So, those you can see on the screen. There are four of them. Let's try to take each one quickly. So, why don't we just move to the next slide? I know we're up against it on time. So, those four taskforces will provide you with staff support. So, listed here, you'll have the slide deck if you need to refer back to it for names, but these will be the ONC leads on that. I may even participate in the first presentation on info blocking when we do that. Then obviously, there are some subject matter experts that we'll bring in depending on what specific topic or proposal is under discussion. So, we can move to the next slide and go into each of these.

So, the first one, as you've already surmised, is information blocking. So, the over-arching charge is we're going to be looking at the information blocking proposals, which are almost essentially a rule in themselves, 200-some pages just on info blocking. But you'll also be looking at the associated conditions. So, there's that information blocking and assurances condition that I went over and then we also thought it was important to talk about the communications one as well. That seemed to fit there, so to speak, because it's more based on business practices and policies.

Then last, we'll touch on the enforcement of the conditions and maintenance certification. That's all of them, the process that we have in place. There shouldn't be much time spent on that, as I said. There aren't many unique proposals there other than the certification ban and ONC's role in how we coordinate with OIG, but otherwise, it's the same processes we have in place for ONC direct review of certified health IT.

So, there are some more specifics here on the slide for you. So, we'll look at some of the definitions in terms where we think you can provide us input, such as the network definition or looking at the price

information requests for information. Obviously, the seven exceptions, the complaint process – if you have any thoughts there, we need to set that up per the Cures Act. Then also, we have requests for information rule for the whole department. Same with that price information one, I should say, that's for the whole department regarding disincentives for healthcare providers that are required to be established in rulemaking by the Secretary.

Okay. Let's go to the next taskforce, the conditions of certification. So, we went over those. But this particular taskforce will focus on more of the technical and certification program-specific ones. When I say certification-specific, I'm talking about ones where how you will comply with those attestation requirements, that web-based portal that I was talking about, some of the submissions which would be in the plan. We have our proposals in the preamble and reg talks about what are the certain criteria that have to be in every real-world plan submitted by a health IT developer.

So, you have an opportunity to weigh in on that. You have the opportunity under this taskforce to weigh in on all those specifics that Steve so eloquently laid out to you about our API criteria and condition of certification. And then you also look at some of the other criteria that I mentioned early on that we are proposing. Then some more technical modifications to the program – there's not much there on that. It really is more focused on our certification bodies. Then those deregulatory actions I mentioned in the beginning, there are six of them that we proposed. So, we can move to the next slide and talk about that third taskforce.

So, this is the health IT for the care continuum taskforce. So, primarily, it's focused on or would be focused on our proposals related to supporting pediatric care in practice settings with health IT. That includes the recommendations we put together as well as the criteria that we identified. There are technical worksheets as well that are going in the appendix to the proposed rule. And then particular criteria that support both a pediatric care setting, but multiple settings, behavioral health, long-term, any setting, really, and those are those ones that manage consent. So, that's DSRP in consent management for APIs criteria.

And then as mentioned by Elise, the request for information regarding how health IT can support the treatment and prevention of opioid use disorder – that's in alignment with the strategy the department has set forth for addressing the opioid crisis.

Then last, moving to the next slide, our fourth and final taskforce – this will be focused just on the USCDI. So, you'll be looking at, as a payer on the chart, the specific data elements that are included and then the approach to moving to next new versions of the USCDI.

Okay. I think at this point, we can move to the next slide and turn it back to Lauren to talk about timeline and process.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Yes. Thanks, Mike. So, as Elise mentioned at the top of the call, once the proposed rule is published in the Federal Register, that will the official clock on our 60-day comment period. Sorry, I think we skipped a slide there. We can go back to the timeline slide. Thanks.

So, we just wanted to kind of give you an idea of how the 60-day period will look like over the course of eight weeks or so. So, we're starting today with an overview of the rule and the HITAC charges. Starting

as soon as possible, hopefully as early as next week, we will start each of the taskforce meetings and drafting early recommendations between the second and fourth week.

The fifth week is critical because we want to then present the draft recommendations from the taskforces to the full committee. Of course, there will probably be some updates and revisions and feedback to the taskforces from the full committee with wrapping up final recommendations from the full committee in that eighth week right around the 60-day comment period.

So, again, just emphasizing that although it is a 60-day comment period, at the taskforce level, we'll need to wrap up those draft recommendations right around week five so that we can meet that timeline. So, as soon as we get a date of when it will be published in the Federal Register, we'll present a more finite timeline with the exact dates, but I just wanted to give you an idea of what the next few weeks are going to look like. Next slide.

Okay. So, I know I've been bugging you guys to identify which taskforce you will want to participate in. So, now that you have a little bit more information, please just shoot me an email today, if possible, letting me know which taskforce you'd like to serve on and whether or not you're interested in serving as Chair. Then we will send around a final announcement regarding the taskforce, a list of members, and the Chairs.

I just want to remind the members that you can sign up for more than one if you're interested and available. And if you've participated on taskforces before, you have an idea of how much work is involved at the taskforce level. So, if you can't participate in more than one, you're certainly welcome to listen in on all of the other taskforce calls. Of course, those will all be posted on healthit.gov.

So, with that, I know that was a lot to take in. We've had an overview of the rule and we've now officially established our taskforces. It will be pretty busy from here. So, if you have any questions about the taskforce establishment, just let me know. But do know that in our first taskforce meetings, we'll plan to have a little bit more of a deep dive into each of the topic areas that Elise and Mike and Steve discussed earlier today. There, you have their contact information if you have any other questions on their presentations.

With that, Elise or Steve or Mike, anything else before we transition to our next agenda item?

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy

Well, I just wanted to – just advanced appreciation for all the work that the HITAC has before them regarding helping to inform our policies in these areas. We think it's really helpful. We know that it is a tight timeframe, but we have laid out on that staff lead slide a number of staff who are going to be able and available to the taskforces and the full HITAC to help support whatever needs you may have as you are developing these recommendations.

So, that's my staff as well as some of Steve's staff. Then myself, Mike, and Steve, we are available as well. We really do appreciate the work that I think is about to begin. We do know that there are some tight time windows for this. So, we're hoping that the taskforce structure we've laid out will help in that as well. So, my advanced appreciation and thank you for listening to what was a very long and detailed presentation, but we hope it provides a good overview of what we've included in the rule.

Dr. Don Rucker - Office of the National Coordinator for Health Information Technology - National Coordinator
Yes. I'd like to second Elise, Steve, and Mike's thanks for this. There's obviously a number of details here. We think overall, there is a certain simplicity with this, to be honest with you. We look forward to the taskforce recommendations.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. With that, I think we will transition to yet another very important matter before the committee and that is our first look at our HITAC annual report. So, I will turn that over to our Co-Chairs of that workgroup, Aaron Miri and Carolyn Petersen.

Carolyn Petersen - Individual - Co-Chair
Thanks.

Aaron Miri - The University of Texas at Austin - Member
Perfect. Thank you very much. Appreciate it. Carolyn, go ahead. Do you want to start?

Carolyn Petersen - Individual - Co-Chair
Sure. So, now that we've had a really extensive dive on the interoperability work and the taskforces that we will be going into for the next couple of months, it's time to take a look at where we've been over the last year and get ready to finish up our report and move that on so the National Coordinator can take that to Congress.

So, today, what we're going to do is briefly review our timeline and our process, go through the information that is in the draft report, which was sent out to you on February 8th. Then we will be looking for feedback about the net report and anything that we need to add to it.

Our goal is to address all of those questions and concerns at our next annual report workgroup meeting on March 1st and then to bring you back at the March 20 meeting a report that is complete, addressing all of those points to show you that and to vote on it at the 3/20 meeting. We feel that's important because by that time, the taskforces will be fairly deep into their work and it will be really important that you have as much time available as possible to work on the taskforce matters. So, we wanted to get this out of the way.

So, with that, I will launch into our presentation. If we could have the next slide, please. This is our membership and some of the ONC staff who have helped us. I want to reiterate that they have really been extraordinarily helpful in drafting text for us and listening to our discussions and finding references that support these points so we can provide a good work product. I know my thanks go also to my Co-Chair Aaron and to Christian, Brett, and Chesley, who have also been involved with some really great feedback.

Aaron Miri - The University of Texas at Austin - Member
And I echo that. I absolutely echo the same thing, Carolyn.

Carolyn Petersen - Individual - Co-Chair
Thanks, Aaron. So, our workgroup scope, overarching scope, is that we are informing, contributing to, and reviewing a draft and final version of the annual report that will be submitted to the HHS Secretary

in Congress. So, we are tracking our HITAC progress and we are also providing some input as to what we might do in the coming years. Next slide, please.

Taking a more detailed look at the scope, this has to do with the 21st Century Cures Act. We are providing an analysis of HITAC progress with regard to the target priority areas. We have an assessment of the health IT infrastructure and advancement in the priority target areas, analysis of existing gaps in policies and resources, and ideas for potential HITAC activities. Next slide, please.

So, the next steps and meetings scheduled – next slide – we need to review the report and do some suggested edits today. We will look at reviewing and approving this revised report at the 3/20 meeting. Then HITAC will forward that approved final report to the National Coordinator. The National Coordinator will take the report to Congress and the HHS Secretary. Next slide, please.

So, today, we're talking about the draft. The workgroup will address any of our changes on March 1st. We will bring that back to you in March. Then in a few weeks, we will begin working on the fiscal year '19 annual report. Next slide, please.

We will, again, today look at changes. In March, we will approve, and then that will go forward. Next slide, please. And Aaron is going to pick it up at this point and cover what we've done so far.

Aaron Miri - The University of Texas at Austin - Member
Yes. Thanks, Carolyn. Again, I want to echo one more time my sincere appreciation to ONC and to the HITAC for the fabulous work here. Next slide, please.

All right. So, from a report outline perspective, it's really set up like this. We have obviously the executive summary. There's a forward there from our illustrious Co-Chairs of the HITAC, an overview of the progress we've made in FY 18. We look at the health IT infrastructure landscape analysis. We then do a GAAP analysis on that infrastructure, then recommendations on addressing those gaps, and then suggestions for us to consider for some additional HITAC initiatives and of course, a conclusion in the reference material. Next slide.

All right. So, as noted in Section 4003, the 21st Century Cures Act, we're looking at these four areas in particular – one, interoperability, two, patient access, three, privacy and security, and then four, any other target area related to the above previous three that I just mentioned that the HITAC identifies as an appropriate area we could consider on a temporary basis with adequate notice to Congress. This last one is important because there's obviously a gambit of other dimensionality to health IT. So, it's good for you all to consider are there other things we really want to think about and think through that we may need to debate and consider and propose additional consider for. Next slide.

All right. So, what have we done in FY18? We've had seven HITAC meetings. We've really established a policy framework around that accomplishment of subcommittees. There were nine meetings of the Trusted Exchange Framework Taskforce with 26 recommendations submitted to the ONC. The USCDI taskforce – there were nine of those meetings with nine recommendations submitted.

The Interoperability Standards and Priorities taskforce had six meetings, initially with the priority uses. And of course, this annual report workgroup, we had three official meetings of those and then kicked off interaction with the HITAC and probably a billion emails amongst all of them between each other. Next slide.

All right. So, priority target area – let's look at the landscape analysis here. For interoperability – overall, the interoperability remains fragmented and uneven. HHS has proposed regulations and a trusted exchange framework. Work is underway to identify priority uses of health IT and associated standards and implementation specifications. Related to privacy and security, definitely needed to advance and maintain trust and interoperability and protect the patients. Next slide.

As related to patient access to information, we've noted that it can have a positive impact by supporting shared decision making. We definitely need more information, education, accessibility, and use of application programming interfaces, APIs, as needed, which obviously, the first hour or so of this meeting, ONC did a fantastic job of explaining the importance of that. Next slide.

All right. So, let's look at the gaps. The Cures Act requires an analysis identifying existing gaps and opportunities in policies and resources for achieving the FY 18 objectives and benchmarks and furthering the interoperability throughout the health IT technology infrastructure. Next slide.

All right. So, the Cures Act requires recommendations for HITAC activities to address the health information technology infrastructure gaps. We're going to go into that here in a bit, just in some detail. Next slide.

All right. Let's talk about interoperability. We've noticed a key gap here with a need to increase a level of interoperability. The opportunity, really, is addressing what we're calling the reality gap between the perception of what has been certified for a system and what is truly interoperable in the field. Our recommendation that we'd like you all to think through and talk through are further measuring whether systems are truly interoperable at both content and transport levels after implementation, especially amongst smaller practices and by patients. Next slide.

As related to privacy and security, we noticed the key gap around the implications of the emergence of internet of things as an opportunity we need to consider some appropriate policies for IoT-type devices, healthcare devices, and then our recommended HITAC activity is identify those areas of IoT use that would benefit from guidance and examples of success in the healthcare industry. And as you all see in the news every single day, there are more and more of these devices becoming prevalent. So, how do we start getting our arms wrapped around it and consider all the dimensionality of that? Next slide.

Another item around privacy and security here – we noticed a key gap with the lack of user awareness and education about privacy and security protections. As an opportunity, offer support for an education of technology users regarding privacy and security protections including for health and other information shared on social media. As a HITAC activity recommendation, we can identify educational approaches, technology mitigators, and potential regulatory solutions that offer improved privacy and security protections and really help keep patients and consumers safe and secure. Next slide.

Another item with privacy and security – we noticed a distinct variability in information sharing policies across the states. As an opportunity, we note there could be an increased uniformity of information sharing policies across states. As an activity for us to consider, we should consider the federal role in setting guidelines for the exchange of data across states. Next slide.

Another item around privacy and security is the variability and adoption of cybersecurity frameworks. As an opportunity, offer support for widespread adoption on cybersecurity frameworks and then as a

recommended HITAC activity, consider the impact of nationwide adoption of cybersecurity frameworks and delineate cybersecurity accountability for data by role. As it stands today, there's a number of entities that exchange data and sometimes it's very hard to parse out where does the buck stop when it comes to an item around privacy and security. That's what we mean by accountability for data by role. Next slide.

Another privacy and security area key gap is the lack of user control to share and disclose information. As an opportunity, consider the options for granular levels of consent to share and disclose information. As a HITAC activity recommendation, we could undertake a review of emerging consent approaches and the technologies that underpin them and make recommendations for the improvement of current consent approaches. Next slide.

I'm going to turn this one back to Carolyn to keep going.

Carolyn Petersen - Individual - Co-Chair
Great. Thanks, Aaron. To give you a change in voice here, the key gap that we identified is an unmet infrastructure need for the underserved population. The key opportunity that goes along with that is to support infrastructure needs for underserved populations including exchange costs, the prevalence of electronic equipment, internet access, pharmaceutical services, and use of telehealth services. Our recommended HITAC activity in this area is to measure the impact on the monetization of data exchange. Next slide, please.

Still continuing on patient access, another key gap is accessibility and usability of patient portals and other patient-facing technology continue to need improvement. So, our opportunity is to consider an improvement to accessibility and usability of patient portals and other patient-facing technology. And our recommended HITAC activity is to measure the amount or length of time the portal has been online working properly, patient engagement and/or patient understanding and use of data. Next slide, please.

Another key gap is patient awareness and education about health IT resources. So, for us, a key opportunity would be to encourage patients and caregiver information about health IT resources. Our recommended HITAC activity is to identify use cases demonstrating the value of patient data to the patient. Next slide, please.

So, we've gone through all of the landscape and gap analysis. We've identified some key issues and opportunities and made a few recommendations. Now, we'd like to move into the discussion. Next slide, please.

I think rather than going back through the slide and all of the priority target areas, I think in the interest of time and trying to ensure that we have a chance to hear everyone's comment, we will just take an open discussion with questions, comments, or thoughts about what else we need to add to the report to make it complete. I'll ask Robert to call on people to give us questions and comments.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
So, this is Lauren. I see that Denise has a hand up.

Denise Webb - Individual - Member
Yeah. Thank you, Carolyn and Aaron. I thought the report was really well-written and had some good

details. The one area I do have some questions about, though, was the last part you covered about recommendations for addressing health IT infrastructure gaps. A number of the recommended HITAC activities, like for instance, consider the federal role in setting guidelines for the exchange of data cross-state – I'm trying to envision what consider means.

Are we suggesting that we make some recommendations on the federal role and setting guidelines and that would be the activity of our committee? I would reflect the same similar comments on the next item where we said to consider the impact of nationwide adoption. Again, are we suggesting that we're going to work on that activity to make recommendations? I was looking for some clarification there. Then I have just a couple of other comments. I'll start with that one.

Carolyn Petersen - Individual - Co-Chair
Thanks, Denise. In the preparation of the report and the slides, we came to understand from ONC that there are some terminology standards in terms of the way things are phrased. Consider is one of the ways that the government likes to approach language because it's quite broad and it gives some latitude in terms of what we do.

Really, in terms of the HITAC making recommendations or trying to define its work, we have quite a bit of latitude. We could, for example, do a review of approaches or the ways that various government action is being implemented now and make suggestions. We could take a more focused and prescribing approach, saying we think that ONC and/or other agencies need to do X, Y, and Z.

We really have quite a bit of latitude and that is something for HITAC to talk about and consider what we think is valuable in terms of addressing the work that is laid out in 21st Century Cures and our mandate as well as what would be valuable going forward, taking into account the health IT infrastructure in the US and what we will be doing this year with the NPRM and other work. Do you have thoughts, Aaron?

Aaron Miri - The University of Texas at Austin - Member
No. I think you hit the nail on the head. The other component I would offer to folks is, as we look at it, try to take a step back and see how HITAC can also even bring conversation to the forefront to say hey, we need to think about the implications of not making considerations from a federal perspective, sometimes just the conversations, sometimes even suggestions or guidance can really help set a standard for okay, folks are going to adopt a level playing field of X, Y, and Z so that there's not such a non-uniformity, non-conformity across state lines.

And in the case of privacy and security, you have certain states that are really blazing a trail and going to the N'th degree around the privacy considerations and you have others that are still considering and debating those discussions. So, what happens to the providers that potentially cross state lines or those patients that cross state lines if we don't say something, if we don't make considerations. Just think of it that way.

Denise Webb - Individual - Member
Thank you. I just have one other question under the priority target area under the patient access to information. There's an example under here, for example, measure the impact of clinical-grade data collected by patients on testing costs. What testing are we referring to here in our report? Is this lab testing, procedural testing?

Aaron Miri - The University of Texas at Austin - Member
I'm trying to find exactly what page – what page are you on? I'm sorry.

Denise Webb - Individual - Member
It's under the bullet just before the conclusion or just before suggestions for additional HITAC initiatives. It says, "For example, measure the impact of clinical-grade data collected by patients on testing costs." Is that testing of software, testing of tools? I'm not sure what testing we're referring to.

Aaron Miri - The University of Texas at Austin - Member
Yeah. Go ahead, Carolyn.

Carolyn Petersen - Individual - Co-Chair
I'm thinking that in that situation, we were thinking about tests that might be performed in the lab. For example, there are now some heart rate monitors available to consumers that are actually the same grade as what is used in cardiac rehab lab. For example, a person has a heart attack and they get into a cardiac rehab program and they will wear certain types of heart rate monitors when they go in to do the walking protocol or whatever the exercise training is that's intended to help them build that cardiac strength. There was a time when those –

Denise Webb - Individual - Member
Okay. So, you're referring to clinical testing, then. Maybe we should add the word clinical on clinical testing costs.

Carolyn Petersen - Individual - Co-Chair
Yes, we can make that change.

Aaron Miri - The University of Texas at Austin - Member
Yeah. It was a good suggestion. Also, there were a number of excellent physician stories and others that Brett gave us who was a practicing physician at Baptist as it feeds into this. He noted extensively how this was impacting provider workflow and overall ability to provide care given the variability of costs on the clinical side.

Denise Webb - Individual - Member
Thanks for that clarification.

Carolyn Petersen - Individual - Co-Chair
Sure. We can certainly add additional text there to make that clearer if that would be helpful.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Any other comments or questions or thoughts for the annual report?

Aaron Miri - The University of Texas at Austin - Member
I would offer that I know it's a lot of information and the slide deck doesn't do the justice of the actual report itself that was sent out for you guys to read and read through. Please look it over, send us emails, questions, comments, what not. Several of you already have. I'll say kudos to Steven Lane and others who have. We really appreciate that. Take a chance to really think through it. This is our opportunity to really guide the following years of upcoming work and to really help reinforce what's going on across the

health IT landscape.

Carolyn Petersen - Individual - Co-Chair
And I'd like to reiterate my support for your sending us feedback and helping us to refine this and put into words in concrete the direction that you would like to see HITAC go in the coming year in terms of what we contribute to the health IT infrastructure in the US. The annual report workgroup will be meeting on March 1st, where we would like to start working with the feedback we receive from all of you.

So, I would ask again that you send us by email all your comments and thoughts by the end of your day, midnight, on February 27th. That's a week from now. That will give us a chance to collate all those comments in a chart to ensure that we make changes or respond to each one and then to be able to present that chart showing all of your comments and questions and how we've addressed each one of them in our March meeting.

We realize this is a significant document to read and to process, particularly as we go into the NPRM work, bet we feel it's really valuable for our group in terms of being able to go forward with meaningful activities. We want to be able to bring this back to you in a way that is completely transparent so everyone can see what we've done and how we've worked to address the concerns and really make a document that represents the views, interests, and goals of this HITAC committee.

Denise Webb - Individual - Member
Carolyn, which email address do we send the comments to?

Carolyn Petersen - Individual - Co-Chair
Lauren, what would be the preferred address?

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
It's the ONC-HITAC email.

Carolyn Petersen - Individual - Co-Chair
Okay. Great. Thanks.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
We can send that around with everyone.

Clem McDonald - National Library of Medicine - Member
This is Clem McDonald. I'm a little bit limited in my ability to interact because I'm in a double meeting. I just wanted to say the statement about unstructured, I just want to make sure you don't mean it totally as anything structured. I think you're really just talking about the payload is narrative because unstructured means you wouldn't know who the person was, you wouldn't know the date, and you wouldn't be able to deliver it to anyone. I think just be careful about that word "unstructured" in the document.

Aaron Miri - The University of Texas at Austin - Member
Great point.

Kensaku Kawamoto - University of Utah Health - Member
This is Ken Kawamoto. Sorry, I don't have my hand up. Could I ask a question?

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sure, go ahead, Ken.

Kensaku Kawamoto - University of Utah Health - Member
Great. Could I ask for the privacy and security, whether the Annual Report Taskforce considered the current state of affairs with the FHIR and OAuth specifications just verifying that sending, for example, patient name, etc., when you don't actually need to or providing access to external business associates' lab data, etc., they don't actually need access to is HIPAA compliant. I think it would be very useful if we could get a determination that is, in fact, compliant.

Aaron Miri - The University of Texas at Austin - Member
I can jump in on this one. We did talk in some discussion about some of the previous – remember, we're focused here on 2018, what occurred in 2018. A lot of things were pending by December 31st of 2018 that's now come out.

So, we did discuss some of the work that was done in the previous FACAs and Health IT Standards and Health IT Policy Committee as well as all the recommendations from the API FACA and others, which go right back to your point. I know that OCR and others participated heavily in those. So, there's a lot of documentation there which we do reference in our appendix, but as for our specific question, no.

The reason for that is because the information blocking rule and others had not come out and we didn't want to suddenly go into an area that potentially we'd have to work through when that's really a 2019 report item. That all being said, we're happy to look at that and see if there's another dimensionality we could speak to address that.

Kensaku Kawamoto - University of Utah Health - Member
Okay. If it's more appropriate to discuss in, say, 2019, that's fine. I just want to make sure that what in practice we're doing is covered. I think it probably is, but I have never heard explicitly it is. I want to make sure we were covered in what's going on in practice.

Aaron Miri - The University of Texas at Austin - Member
Got it. We'll look at it. Thank you.

Kensaku Kawamoto - University of Utah Health - Member
Thanks.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. Any other thoughts or feedback on the annual report? Okay. Carolyn, I'll hand it back to you just to wrap up this presentation before we move on.

Carolyn Petersen - Individual - Co-Chair
Okay. Thanks, Lauren. I just want to reiterate our hope that you will share any feedback, questions,

concerns, or fan mail with the Annual Report Workgroup by midnight on February 27th. And again, I want to thank my workgroup colleagues, Aaron, Christina, Chesley, and Brett and to let you know we appreciate being able to bring this to you. Thank you.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. All right. So, I think that just about wraps up our two major agenda items, looking at the proposed rule and the annual report. I know it was quite a bit to digest today. So, again, if you have any additional questions on the taskforce, on the rule, I'm sure those will be addressed once the taskforce activity kicks off. So, with that, I'm going to go for one last call for questions or thoughts before we open it up for public comment.

Kensaku Kawamoto - University of Utah Health - Member
Hi, this is Ken. Just a quick comment – if we are finished early after the public comment, I wonder if the initial discussion on the NBRM, etc. might be worthwhile. Otherwise, I think we'll just do it in our taskforces. It seems like we might be ahead of schedule.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Yeah. We are a little bit ahead of schedule. Robert and Carolyn, did you –

Robert Wah - DXC Technology - Co-Chair
Ken, did you have a comment? Ken, did you have a particular comment you wanted to make about the proposed rule?

Kensaku Kawamoto - University of Utah Health - Member
Sure. I have a number related to the APIs. Would this be the right time or would it be after we go to public comment and see how much time we have left after that?

Robert Wah - DXC Technology - Co-Chair
We have about 15 minutes before we had scheduled the public comment period. I think there's a little bit of room here if you want to start the conversation. We have to break for the 12:45 promise time for public comment, then we can take a break and come back to it.

Kensaku Kawamoto - University of Utah Health - Member
Okay. So, maybe I'll start with one. I noticed the API requirements were around Argonaut and not the US or FHIR profiles. Assuming that was intentional, one comment/question is why Argonaut rather than US or FHIR profiles, since Argonaut is not a public open group. It is membership only and really a closed membership group of a select number of companies and healthcare organizations?

Robert Wah - DXC Technology - Co-Chair
Is Steve still online?

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology
Sure. Yeah. Hey, this is Steve. Can you hear me?

Robert Wah - DXC Technology - Co-Chair

Yeah.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology
Cool. Sorry for latency. Ken, in answering your question, we canvased the ecosystem for the implementation guidance that would be available to support a proposal associated with FHIR Release 2, which is what we proposed. The US FHIR Core profiles, as you may be familiar, were first identified in the HL7 space attributed to FHIR Release 3.

So, because our full suite of proposals centered around where the industry was today, which is associated with FHIR Release 2, we looked at the full suite of implementation guidance that is available and we also look at market-driven consortia standards or implementation guidance that is available and open to the public to use, of which Argonaut specifications are a part for FHIR Release 2.

That being said, we do have a detailed discussion in the rule identifying the various FHIR standards versions that are out at the base standard and the accompanying implementation guidance that's available, for which we request comment. So, we identified FHIR Release 3 was available.

That was one of the options that I covered earlier in terms of if we were to adopt – and I'm paraphrasing what we've referenced in the preamble – if we were to adopt in the final rule FHIR Release 3, we would also adopt the accompanying implementation guidance that would be associated with it, which would be FHIR US Core Release 3 version implementation guidance or profiles, which are the next evolution of Argonaut, just for people to have as a full context.

So, for FHIR Release 2, there were the Argonaut profiles. Then for FHIR Release 3, the Argonaut profiles were folded into what we call the US FHIR Core profiles. So, for FHIR Release 4, our expectation is, since that was just published a month or so ago, there will be a turn of the crank to have updated FHIR Release 4 US FHIR core profiles that will effectively be the second evolution of the original Argonaut profile. So, hopefully, that answers your question.

Kensaku Kawamoto - University of Utah Health - Member
Yeah. I think it will just be a point that we comment on. I think just as a matter of process, yes, Argonaut does lead into US Core, but then it goes into a formal balloting process where people can provide comments. Argonaut really is a members only, where EHR vendors that are not a part of that group, healthcare systems that are not a part of that group have exactly zero say in how that goes. So, I think that would be potentially problematic to set national standards around something that has really no potential for public comment.

Robert Wah - DXC Technology - Co-Chair
Ken, do you have other comments with APIs?

Kensaku Kawamoto - University of Utah Health - Member
Sure. So, another comment/question was I think it's really bold and great to focus on cost only API access. I guess a question around that – it seems very different from any other app store model. For example, I guess it would be the equivalent of the iTunes Store or the Google Play Store, where Apple or Google don't make money based on a percentage of revenue, but it's more the cost of hosting the app. It would be interesting – or maybe just a question – is it based on the interpretation of the information blocking in terms of that's regulatorily required or was it based on any other thoughts?

As a healthcare system developing these kinds of things, that sounds great, but it seems like it could potentially significantly reduce the incentives for EHR vendors to further develop these ecosystems that also potentially have unintended consequences for things like things that people want to make available for free because now, it's going to be on the same costing structure as things that people are otherwise trying to make money on, in a sense, and the current approach is maybe getting subsidized by that so that a public good can be transmitted.

I think of things like if the Federal Government, the CDC wanted to make recommendations and value-add applications available to everyone and make those available for free, it may still cost healthcare systems a substantial amount of money to pay for the API costs because they're on the same footing to install those as a for-profit app.

Mike Lipinski - Office of the National Coordinator for Health Information Technology - Director, Regulatory Affairs Division
This is Mike Lipinski. I will try to provide you a response. I'll just caveat it with I cannot, probably, in my response synthesize all of our laid out justification that took hundreds of pages as to our approach here. I will recite some of what we said.

So, first, starting off with the evidence that we have that we cited in the congressional report to Congress and that we had through stakeholder interactions, including when we were taking information with joint meetings with the OIG to inform this rule making, fees were still the number one way to – I don't say number one way – one of the main ways to prohibit access to EHI. So, Congress – we include fees as our interpretation as a means to information block.

I think as we say in the rule, we see an EHI as not a commodity that can be traded or sold just by the custodians of the EHI just because that simple fact and they have the control and access to the EHI. So, relying on the broad call to prohibition, it's technically not a prohibition. It's saying here's what information blocking is. If you do it, here are the consequences, including up to a $1 million penalty per instance found to be information blocking.

So, with that in mind, we didn't think there should be any fees associated with the access use and exchange of EHI. However, to your points, we believe through our exceptions, we have provided a proper basis to recover those reasonably incurred costs and promote innovation and competition. So, just as an example, building out an API, that is a cost that can be recovered, including profit, as we discuss in the preamble related to that.

Similarly, if you came up with a unique way to do something and then you obtained intellectual property rights in it, we do not say that you can't benefit or profit from that. So, we propose that the approach to that is you would have to license that IP on RAND terms. So, that ensures the access is still maintained to the EHI. However, it is still promoting innovation. It is still allowing the ability to recover a cost to make a profit on innovation. To that point, when it comes to something unique and novel, we say and note that that is something that's considered when determining whether something has reasonable and non-discriminatory terms regarding licensing.

So, we think that we put forth an approach that addresses your concerns. We've found that some of those things like rent sinking royalties to get access were ways to inhibit the access to the information. Again, to our initial premise about it not being a commodity for trading and selling, as we discuss in the

rule, we took this approach. However, obviously, it is a proposed rule. We welcome comments. If you think there is a better way to address the concerns that we've identified related to information blocking, we are, I think, all ears to that and welcome comments. I hope that provides some more insight.

Kensaku Kawamoto - University of Utah Health - Member
It does. I think maybe the simple question would be it would be great to get an example from another industry where the model worked. I personally really like it. I'm just worried about how the EHR vendors will react in terms of their investment into this ecosystem. I think the whole notion of things like smart apps, etc., that arose out of the idea of look at how successful these smartphone app stores are. Let's try to replicate in healthcare.

This would really change that model. I assume there is some other industry where this model has worked and the ecosystem is forced, but I'm just not aware of it. So, I think it would be useful if we have an example we can look at and say, "Hey, this is what we want to do." This approach I think we're heading towards would mean it no longer would be equivalent to an Apple or Google app store kind of model.

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology
Yeah, Ken. This is Steve. Just to add on to what Mike noted and he was saying and I think implied in a way – the important thing to remember as the overall context is that in comparison to other industries, there hasn't necessarily been a law like the 21st Century Cures Act with the definitiveness and specificity of both the actors covered, the types of behaviors that would be prohibited, for which monetary penalties are applied as well as in the API conditions of certification paradigm, a statutory law requirement for APIs to be published and that they be done in a manner for which they can be used without special effort.

There are a lot of unique characteristics of the environment in which we find ourselves from a health IT perspective that is admittedly different in comparison to other industries where they have a different competitive landscape and different business motivators to make APIs accessible and things of that nature. So, I think it's really helpful to look – and we've certainly done so in the past couple years – as we were putting these proposals together. Other industries, how they're being deployed, we look at map APIs, as an example, which is an easy one for a lay audience to wrap your head around and various other spaces.

So, certainly, members of the HITAC have other industry experience where we can take that into consideration. As Mike said, we're all ears. But again, just from a statutory perspective, there are some differences that Congress, as Dr. Rucker mentioned, close to unanimously passed law in both chambers that Congress has specifically provided us to implement and execute as part of the law.

Mike Lipinski - Office of the National Coordinator for Health Information Technology - Director, Regulatory Affairs Division
Just one more point on that that Steve helped me think about and point out as an over-arching thing and Elise did too – you have to always start from the perspective of you should be sharing in all instances, unless required by law not to. That's the way the statute reads. And it's really a likely interference. So, it's not even you had to have interfered. Your action, your practice would likely interfere with the access of exchange and use.

So, our goal was to try to provide – we call them exceptions, safe harbors, where you could do certain actions that would inhibit access exchange and use but would be acceptable under the circumstances. One obviously was we wanted to promote innovation and competition. So, we wanted to be able to recover certain costs related to promoting that access exchange in use, including a profit, as I mentioned, and as mentioned in the preamble. So, that's kind of where we came from to set it up. Again, we did a lot of research. If you don't think this is the right approach, if you think it could have some unintended consequences, we're looking for that comment on that.

Robert Wah - DXC Technology - Co-Chair
Ken, do you have anything else?

Kensaku Kawamoto - University of Utah Health - Member
I don't want to hog the conversation if the others have comments. I have a few more.

Robert Wah - DXC Technology - Co-Chair
I think what we'll do is go right to the public comment period at 12:45 as scheduled and then we'll certainly ask others if they have comments after the public comment. But I wanted to give you one last bite of the apple here before we go.

Kensaku Kawamoto - University of Utah Health - Member
Sure. Did I understand correctly with the one-day verification – so, for example, if we have provider-facing smart apps or whatever is covered that we create, instead of going through the current vendor-based review process for security, etc. that according to these proposed regs, one day later, it must be available to healthcare systems who want access even if it hasn't been vetted by the vendor? Did I understand that right?

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology
I think to help you understand it, it would be helpful to lay out the entire sequence of events because that one-day thing is the end of the sequence. So, this has to do with app registration. If a health IT developer is in the position of registering the apps, they have a choice. They can just automatically register the apps through whatever mechanism they want to do and dynamic client registration protocol is one of those that numerous folks in industry have talked about as a mechanism, where that handshake in registration can just occur in kind of an ad hoc way in – I don't want to say in real time, but for lack of a better word.

In deference to some of the market concerns that we've heard, we've included a permissive process that helped IT developers – in this case, API technology suppliers – saying that they could institute an app developer authenticity verification process. So, you can verify that this is not a bot. This is not some – they can verify who the other person is on the other end. We lay out some examples of the type of documentation that they require.

In keeping with the without special effort construct, we said if an API technology supplier were to have and implement this type of authenticity verification approach, they would have up to five business days to complete that authenticity review. At the point in time when they completed that review, the one-day part kicks in as part of their maintenance and certification requirement. So, we didn't want there to be like a slow walking kind of event where they complete the authenticity review but then they don't – the API technology supplier, for whatever reason, doesn't get the application registered in a timely

manner afterward.

So, that's the one-day thing. Once they complete their authenticity review and the thumbs up, the app should be in the registration listing or what have you within that one day. Does that help? They don't have to do it at all. if they don't do it at all, they're going to have some means of dynamically registering or ad hoc registration at the time that an app comes in.

Kensaku Kawamoto - University of Utah Health - Member
That makes sense. Just to clarify, that is very different from what's currently happening and that's intentional, I'm assuming.

Arien Malec - Change Healthcare - Member
Hey, guys. I just want to comment that we have, to Elise's point, this is a pretty meaty rule and we have four work groups that are going to dive in detail. I'm not sure that we can adjudicate every aspect of the proposed rules before public comment in this session. So, just a suggestion for the chairs.

Robert Wah - DXC Technology - Co-Chair
Yeah. Thanks. This is Robert again. I don't mean to be overly strict about this, but I feel an obligation that since we publicized that the public comment period would be at 12:45, that we honor that promise to them and to anybody who has been waiting patiently to comment would have the opportunity to. So, on the slide, you see the dial-in comment number. There's also an email if the public wishes to email comments in. At this point, I'm going to turn it over to Lauren to manage the public comment period. Is that all right?

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Great. That's perfect. Thank you, Robert. Operator, could you please open the line for public comment?

Operator
Certainly. If you'd like to make a public comment, please press star-one on your telephone keypad. A confirmation tone will indicate your line is in the question queue and you may press star-two if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. Again, that is star-one for public comment at this time.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. Just a reminder for those public commenters, we'll ask you to keep your responses to no more than three minutes. Operator, do we have any comments in the queue at this time?

Operator
We do. We have comments from the line of Mari Savickis with CHIME.

Mari Savickis - CHIME - Vice President of Federal Affairs
Thanks, everyone. This is Mari Savickis with CHIME. A Huge thanks to ONC and to CMS, absolutely an enormous lift. I had questions which I know are hard to answer on a federal advisor committee, but I wanted to find out if there was any information forthcoming regarding educational webinars so we could get that information out to our members. Also, if there's an opportunity for people who are

outside of the HITAC to participate in the taskforce – I wasn't totally clear about that. It sounds like they're getting started next week.

So, if any more information on that could be made available, that would be helpful. Then last but not least, I just want to echo the comment that Denise Webb made regarding the deadlines for the rules. While we appreciate that they haven't been published in final format, we've gotten a lot of feedback from our members that more time will be needed. It's such a meaty rule, especially the ONC one, that we're really going to need a lot of time to get through that. So, thank you very much for taking our comment.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
So, this is Lauren. I just want to be clear in regard to the question about the educational webinars. Is that relative to these materials?

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy
Mari, this is Elise. I'm guessing that's in relation to ONC's general work and not the HITAC, but please clarify and then we can answer either way.

Mari Savickis - CHIME - Vice President of Federal Affairs
Yes, just a general overview for the public regarding the rule. It's not specific to HITAC. But my question around the taskforces is specific to HITAC.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy
Okay. I'll do the webinar one and then I'll turn it back to you, Lauren, for the taskforces. So, in terms of the webinars, yes. As folks know, we always try to make sure there's as much engagement as possible. We will be having a series of webinars for the general public around pieces in the rule. There will be more than one. We're working on finalizing the dates for those, but those should be upcoming, hopefully starting next week. We will definitely publicize those online so folks have it.

In the interim, I just want to reiterate that even though the rule is not included, it has not been published in the Federal Register yet, it is currently on our website at healthit.gov/nprm. If there are any changes to the rule when it's published, it will be small changes. It will not be substantive changes. So, what you have on the website is what ONC is going out with in terms of the proposals. Also, on the website, there are a number of infographics and fact sheets that we've included that lay out different sections of the rule.

As Steve noted earlier, our goal is to provide a quick, relatively easy to read resource for you to take a quick look at the sections of the rule that can allow you to dig deeper at a later time of your choosing on the full depth of the scope of rule, but we will publish the webinar dates and times on that website. I would encourage folks to – those who are interested to sign up quickly because those tend to fill up very quickly.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Great. Thanks, Elise. Just to clarify – on healthit.gov/hitac, on the landing page there, there is a button

for a membership application and that is where you can apply for future taskforces. So, you will see the taskforces that we've laid out today are included in the dropdown menu. I will mention if you've already submitted an application, no need to submit it again. We have it within the database. So, only if you have not completed an application previously.

Operator, do we have any other public comments?

Operator
Not at this time.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Okay. I will turn it back to Robert and Carolyn.

Robert Wah - DXC Technology - Co-Chair
Thanks, Lauren. We have just a couple of minutes left. I appreciate Ken's comments about the API and Arien's also that we're not going to litigate the entire rule in one call, but I wanted to make sure that the HITAC committee had an opportunity to make comments or seek clarification on anything we talked about today in terms of the proposed rule or the annual report. So, anyone who has comments or questions or clarifying questions now would be the time to get them in.

I see some public comments by Clem and Sasha. If you wanted to ask those online, you can do that at this point as well.

Sasha TerMaat - Epic - Member
So, this is Sasha. The comment that I had – and respecting Arien's feedback that we shouldn't get too into the weeds in this context – but as Steve was describing the process for optionally verifying application developers, one question I've heard stakeholders starting to ask is if there is no verification of application developers, is there a clarity around there not being liability for any subsequent consequences that might result from automated or the decision not to perform that verification?

Steve Posnack - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Technology
I think that's a really important point that Sasha is bringing up and something that we would very much appreciate feedback in terms of areas like that where we can hopefully provide clarity as part of the final rule. It may be things that are other federal agencies with whom we need to work to provide some of that clarity to.

Robert Wah - DXC Technology - Co-Chair
Good. Other comments, questions.

Dr. Don Rucker - Office of the National Coordinator for Health Information Technology - National Coordinator
It's Don. We're reaching out to the Office of Civil Rights because they actually do a lot of the HIPAA right of access, which would address that question.

Sasha TerMaat - Epic - Member
Thank you.

Robert Wah - DXC Technology - Co-Chair
All right. Anything else? All right. Well, certainly, Carolyn and I would like to thank the ONC and CMS for relatively quickly going through 700+ pages here for everybody and also, I want to thank Carolyn and Aaron and their committee on the annual report. As was noted, this was a critical report going from our committee. We hope everyone has a chance to review it and will provide their thoughtful comments to us before our next meeting, which is our face-to-face meeting in March. It's also worth noting, as was already said, that the Federal Government closed today in Washington DC because of snow. So, all of our federal members are trying to do this work telecommuting and that's appreciated as well.

Elise Sweeney Anthony - Office of the National Coordinator for Health Information Technology - Executive Director, Office of Policy
On behalf of the ONC team, it's our pleasure. We're happy to do it.

Robert Wah - DXC Technology - Co-Chair
I would say, Lauren, if we could make sure – there was a previous mailing about the taskforces that went out to the HITAC. If perhaps you can re-mail that again now that the presentation has been made, I think that might be helpful for the committee again, the one that outlined the different taskforces that are being stood up and the links as well.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
We'll get that out right after the call while it's fresh in everyone's memory. Robert, you mentioned our next in-person meeting is on March 19th and 20th. We've actually added a day to make it a two-day in-person meeting, which is certainly timely so that we can continue to have these discussions relative to the rule and the report in person. So, if you have not responded to the email concerning travel and accommodations, please do that as well. I will send out the email regarding the taskforces.

Robert Wah - DXC Technology - Co-Chair
Great.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Carolyn, any other closing remarks?

Carolyn Petersen - Individual - Co-Chair
Just a thanks to our ONC colleagues for giving us such a detailed overview of the provisions, of the work we're about to take, and information about the taskforces. As Robert and Lauren have said, I strongly encourage everyone to let us know today what taskforce or taskforces you're interested in as we do want to get the work underway with our 60-day deadline on the horizon. The annual report workgroup looks forward to your feedback about that report and we'll be happy to get together next month. See you all then.

Robert Wah - DXC Technology - Co-Chair
Looking forward to seeing everybody in person.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Great. Thank you.

Robert Wah - DXC Technology - Co-Chair
Have a great rest of the week.

Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Thank you. We'll adjourn. Bye-bye.