The Office of the National Coordinator for Health Information Technology

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

March 18, 2020, 10:00 a.m. – 1:00 p.m. ET

Speakers

Name	Organization	Role
Carolyn Petersen	**Individual**	**Chair**
Robert Wah	**Individual**	**Chair**
Michael Adcock	Magnolia Health	Member
Christina Caraballo	Audacious Inquiry	Member
Tina Esposito	Advocate Aurora Health	Member
Cynthia Fisher	PatientRightsAdvocate.org	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil Jain	IBM Watson Health	Member
Jim Jirjis	Clinical Services Group of Hospital Corporation of America (HCA)	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
Clem McDonald	National Library of Medicine	Member
Aaron Miri	The University of Texas at Austin Dell Medical School and UT Health Austin	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
James Pantelas	Individual	Member
Raj Ratwani	MedStar Health	Member
Steve Ready	Norton Healthcare	Member
Abby Sears	OCHIN	Member
Alexis Snyder	Individual	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem, Inc.	Member
Denise Webb	Individual	Member
Amy Abernethy	Food and Drug Administration	Federal Representative

James Ellzy	Defense Health Agency, Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
Jonathan Nebeker	Department of Veterans Health Affairs	Federal Representative
Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Donald Rucker	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Denise St. Clair	Centers for Medicare and Medicaid Services	Health Informatics Office
Beth Myers	Office of the National Coordinator for Health Information Technology	Deputy Director, Office of Policy
Robert Anthony	Office of the National Coordinator for Health Information Technology	Division Director, Certification and Testing
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Acting Executive Director, Office of Technology
Ryan Argentieri	Office of the National Coordinator for Health Information Technology	Deputy Director of Technology
Michael Lipinski	Office of the National Coordinator for Health Information Technology	Division Director, Regulatory Affairs
Lauren Richie	Office of the National Coordinator for Health Information Technology	Designated Federal Officer

Operator
All lines are now bridged.

Lauren Richie
Good morning, everyone. And thank you for joining today's HITAC meeting. I appreciate you taking the time today and would like to thank the members of the public for joining today and I hope everyone is well. We do have a full agenda today so I will officially open us up starting with roll call. Carolyn Peterson?

Carolyn Petersen
Good morning.

Lauren Richie
Robert Wah? I know he's on the phone. Michael Adcock? I thought I heard him dialing in as well. Christina Caraballo?

Robert Wah
Lauren, this is Robert. I was on mute. Sorry.

Lauren Richie
That's okay. Hi, Robert. Michael Adcock?

Christina Caraballo
Good morning, Christina's here.

Lauren Richie
Good morning, Christina. All right. We'll circle back to Michael. Tina Esposito? Cynthia Fisher?

Cynthia Fisher
Yes, this is Cynthia.

Lauren Richie
Valerie Gray? Okay, Anil Jain?

Anil Jain
Good morning.

Lauren Richie
Good morning. Jim Jirjis?

Jim Jirjis
Here.

Lauren Richie
John Kansky?

John Kansky
I'm here.

Lauren Richie
Ken Kawamoto?

Ken Kawamoto
Good morning.

Lauren Richie
Steven Lane?

Steven Lane
Good morning.

Lauren Richie
Les Lenert?

Les Lenert
Good morning.

Lauren Richie
Arian Malec? Okay, okay. Clem McDonald. Not here. Aaron Miri?

Aaron Miri
Good morning.

Lauren Richie
Brett Oliver?

Brett Oliver
Good morning.

Lauren Richie
Terry O'Malley?

Terrence O'Malley
Good morning.

Lauren Richie
James Pantelas?

James Pantelas
I'm here.

Lauren Richie
Raj Ratwani?

Raj Ratwani
Good morning.

Lauren Richie
Good morning. Steve Ready? Not here. Okay, Abby Sears?

Abby Sears
Here.

Lauren Richie
Alexis Snyder?

Alexis Snyder
Good morning.

Lauren Richie
Sasha TerMaat?

Sasha TerMaat
Good morning.

Lauren Richie
Andy Truscott? Not yet. Okay, Sheryl Turney? Denise Webb?

Denise Webb
Good morning.

Lauren Richie
Good morning. Michelle Schreiber?

Michelle Schreiber
Good morning.

Lauren Richie
Good morning. James Ellzy?

James Ellzy
Good morning.

Lauren Richie
Good morning. Ram Sriram?

Ram Sriram
Good morning.

Lauren Richie
Good morning. Adi Gundlapalli? Okay. Jonathan Nebeker? Okay. And I do believe Amy Abernethy will be absent today. From the ONC leadership side, we have Don Rucker, Steve Posnack, Elise Anthony, Avinash Shanbhag, Ryan Argentieri, Elisabeth Myers, Michael Lipinski, Rob Anthony. And we have Denise St. Clair joining us today from CMS. Are there any other HITAC members that I missed during the roll call?

Clem McDonald
Yes, this is Clem McDonald.

Lauren Richie
Good morning, Clem. Anyone else? Okay. Just as a reminder for those that are not on the Adobe session, I realize there might be technical challenges here of late. Please chime in on the phone and we'll make sure to get you in the queue. At this point, I will turn it to the National Coordinator, Dr. Rucker.

Donald Rucker
Thanks, Lauren. Well, first of all, welcome, everybody. Obviously, these are, as you all know, unique times. I think from an ONC point of view, this sort of pandemic really points out the importance of the work that we have been doing and will be doing in the future with interoperability. And making modern technology enabling things like care at a distance, all these things, I think every one of us has a renewed appreciation for the importance of it.

I, personally, want to thank, on behalf of all of ONC, everyone on the HITAC and, frankly, the public listening for the extraordinary comments that helped us in formulating the rules. Certainly, the ONC rule to be what we think is a good balance of the various interest to the public and getting access to their information, of providers and reducing the burden on them with some of the API tools that will grow out of the rule. We, obviously, talked about some of the things where APIs can help with prior authorization and rethinking the entire business of quality measures and billing documentation. So, the rule sets, I think, advance those causes. We, obviously, want a vibrant EHR vendor community with innovation, both from the current EHR vendors and folks who might enter the app economy. So, we think we have done a good balance there but, obviously, that is for you to judge.

But I want to thank folks for all of their contributions. As you look at the length of the rule, you will see of the 1,200 odd pages, probably 1,100 of them, roughly, are our comments, responses, and interaction to the feedback that you gave us in those discussions. So, hopefully, the thinking there that you have provided is adequately incorporated. So, with that, I am going to turn it over to Steve Posnack, our Deputy National Coordinator.

Steve Posnack
All right. Thanks, Don. Thanks, everybody. Certainly, as we mentioned always thank you very much for your time in attending HITAC meetings. Certainly, with the backdrop of current events, your time is as valuable as possible today. And we want to make sure that we cover all of the updates for you in kind of keeping with our mission and activities.

We're going to cover the Final Rule that was released. Our CMS colleague will also give you an update on that. That will be the largest part of the agenda today. Obviously, in a virtual meeting, we want to make sure that we make the most effective use of everyone's time and keep you doing all the valiant healthcare things that you're doing for the country.

So, thanks very much, again. Thank you to all the healthcare workers out there fighting on our behalf. And I'll turn it over to Robert and Carolyn for the review of the agenda and minutes.

Robert Wah

Well, thank you, Steve, and thank you, Don. This is Robert. We also, as chairs would like to welcome you all to our meeting and, again, appreciate everybody taking their time and talent to contribute to this effort.

I think you have already heard the theme of the day is the Final Rule. As we all recall, we spent a great deal of time providing comments in the proposed rule-making process. I think Don talked about several hundred pages here. I think we contributed a couple of hundred pages of comments to that process. So, I think it will be a good discussion to see the details of the Final Rule and have a chance to discuss it as a group. And so, that's our plan today.

As you know, we'll remind you also we had to move our April meeting to a virtual meeting. So, we'll give more details about that at the end of this meeting. So, with that, I'll turn it over to Carolyn.

Carolyn Petersen
Thanks, Robert. Good morning, everyone and thanks for making time in this very busy and chaotic time to attend the meeting today. We have some really good presentations and I think it will be very enlightening as we think about how to go forward with the Final Rule and the remainder of our work for the year.

With that, I have one announcement that we have transmitted the Annual Report on. So, our work in terms of the fiscal year '19 Annual Report is done. And the workgroup will be starting up later in May with the fiscal year '20 version.

Now, let's review the agenda. We have an overview of the CMS Interoperability and Patient Access Final Rule. Followed by an overview of the ONC 21st Century Cures Act Final Rule and the 2015 Edition Cures Updates. We have the ONC 21st Century Cures Act Final Rule Conditions and Certification Provisions. We'll take a break. And then, we'll return to a review of the ONC 21st Century Cures Act Final Rule Information Blocking Provisions, followed by the Health IT for the Care Continuum Provision. We'll have a public comment period and then, closing remarks and adjourn.

With that, we now need to approve the minutes from the February 19 meeting. All those in favor of approving the minutes, please signify by saying "aye."

Group
Aye.

Carolyn Petersen
All those who do not choose to approve the minutes, please signify by saying "nay." And are there any abstentions? Thank you. It looks like we have approved the minutes from the meeting of February 19. And I will hand the mic back to Robert for any other comments or business before we get into the overview of the CMS Interoperability and Patient Access Final Rule.

Robert Wah
Thank you, Carolyn. And I think we all should thank our chairs, Carolyn and Aaron, on getting the Annual Report done and transmitted and on to the next Annual Report. No rest for the weary. But we appreciate all the work that that workgroup did to get that Annual Report completed. And as Carolyn has noted, it's been transmitted to the National Coordinator at this point.

So, without any further ado, let's move onto the overview of the CMS Interoperability and Patient Access Final Rule. And I think the person taking us through it will be Beth and – oh, no. I'm sorry, Denise St. Clair will lead that discussion.

Denise St. Clair
Hello, everyone. This is Denise St. Clair. Thank you so much for the opportunity to give you a quick high-level overview of the CMS Interoperability and Patient Access Final Rule. We can go to the next slide.

Ultimately, our goal with the Interoperability and Patient Access Final Rule was to get one step closer to our ideal state per interoperability in our healthcare system. And that is a system where we have interoperable healthcare data exchange that will enable coordinated care, improve health outcomes, and reduce cost, improve the experience for patients, provide additional tools for providers to be able to, with less burden, do their best work, and ensure payers are able to facilitate efficient and coordinated care. So, the goal is to get to our ideal state. And this is just the first step. Next slide.

Ultimately, everything that we are doing really falls into this vision of our road map, which is, essentially, built on a strong foundation of privacy and security working through sort of three main buckets of work. One is patient access. Empowering patients. Making sure they have the information they need when they need it, where they need it, safe and secure, and in a way that they can truly understand and make the best use of it. And so, that's a big focus of what we were looking to do in this rule and start down this path.

We're also looking to connect healthcare through data exchange. So, we want to support the value-based care system. And that means we need seamless data exchange across the care continuum. And so, that's the next big piece of the puzzle.

And finally, technology and standards. And that's, obviously, working with our partners at ONC and making sure that we're promoting the use of the latest and greatest technology and standards, that we're getting the data out there and helping drive innovation by providing fuel for what we are looking towards with a very vibrant app community. And there's, obviously, a lot of incredibly smart people out there who can do a lot with this information in making sure that it's available in a safe and secure way for everyone's benefit.

So, this is the overall vision. This is what we were thinking about as we started down the path of the Interoperability and Patient Access Rule process. We got a lot of feedback and we're always looking for more. And I think the most important piece, for us, is really saying that this is just the first step in our current journey.

And there's, obviously, a lot of foundation that has been laid and a lot of work previous to this. And we know there's a lot of work ahead. And so, we're looking forward to that. And we're excited about the opportunities that we have now. And especially, in this moment in time when we are in such a unique situation, appreciating that this kind of work, as Dr. Rucker was saying, could really take us to a better place and ensure that patents have what they need, providers have what they need, and we can support our system together.

So, that's the foundation that we worked with. And then, what did we actually finalize? Next slide.

This is a one-stop-shop of the final policies in the CMS Interoperability and Patient Access Final Rule. And I'll just take you through from the timeline perspective starting at the front here with the first policies that will

be applicable. And the first thing that will kick in will be the hospital event notifications – the patient event notifications.

So, six months after the publication of the Final Rule in the Federal Register and, obviously, we both released, ONC and CMS, released our rules on our respective websites last week. It feels much more than a week ago. But they have not yet been, at least I haven't checked, published in the Federal Register.

So, once they're published in the Federal Register, the clock starts. And six months after that, hospitals will be required to send patient event notifications regarding admission, discharge, and transfer. And this, obviously, will greatly support care coordination and ensure that patients can get that timely follow up when their care team is aware of an event in the hospital. And so, that's the first thing that will come online.

In late 2020, we have a couple of public reporting policies that will be applicable. So, we have one related to information blocking for eligible clinicians and hospitals who are taking part in the promoting interoperability program. If they do not attest to certain attestations that indicate – or attest in such a way that indicates that they may be information blocking then, their names will be publicly reported on CMS websites. So, that's just one way to further show our belief that information blocking is not something that will support our system. And this is one lever we have to be able to shed a light on that and help patients get some view into that piece.

The other public reporting policy is related to digital contact information. So, NPPES includes an optional field where providers can put their digital contact information. And that's been there for a little bit of time now. And what we finalized in the rule is that providers who do not enter digital contact information into that field will also have their names publicly reported. And this is, again, to encourage all providers to get that information out there. We really want this seamless data exchange to happen. And one key piece of that puzzle is making sure people know how to contact each other in a secure digital manner.

So, for instance, direct address is one thing that providers can include so that other providers can find them for care coordination purposes. And we do hope, as we move down the path of application and program interfaces, that providers will also include their digital endpoints there. And those that have them can do that now. So, multiple pieces of digital contact information can be included in NPPES. So, both of those public reporting pieces will be made public at the end of the year.

Now, we get into the application programming interface, the API policies that may be of more interest to folks online. And two API policies that we finalized in the rule are both applicable starting Januarys 1, 2021. The first is the patient access API. And in this rule, we are requiring the health plans that CMS regulates, specifically, Medicare Advantage, Medicaid and CHIP Fee for Service, Medicaid and CHIP Managed Care, and qualified health plans on the individual federally facilitated exchanges. These payers are required, starting January 1, 2021, to implement, test, and monitor a standards-based API that is accessible to third-party applications and developers.

So, this is an FHIR R4 API. And it will need to meet the interoperability technical standards that were finalized by HHS in the ONC 21st Century Cures Act Rule, which you'll hear a lot more about this morning. And what this API must include at a minimum is adjudicated claims, including cost, encounters with capitated providers, provider remittances, enrolling cost-sharing, and clinical data in the form of the USCDI Version 1 if it's maintained by the payer. And, again, you'll hear more about that from our ONC team and partners who are online who can speak to it much more eloquently than I.

So, payers will make this set of claims and clinical data available through the API. For Medicare Advantage Part D Plans, they must also make prescription drug claims available and formulary information. And Medicaid and CHIP Fee for Service and Managed Care Plans must make preferred drug lists available through the patient access API. And all this data will be available so that if a patient finds an app that they like and they want to use it and they authorize that app to ping their payer to access this data, the patients will be able to get ahold of that data in a way that is most useful and valuable to them that they can really understand. And we've seen already through Blue Button 2.0 some of the super innovative and valuable apps that the community has put together using claims data. So, we're excited to see what the community will come up with both the claims and this limited set of clinical data to start.

Obviously, privacy and security are a huge piece of this puzzle. Something top of mind at all times as we're working through these policies. And there's one thing that we did add in the Final Rule as an option based on the comments that we received and the wonderful feedback that we've gotten from the stakeholder community. In addition to something that we proposed and we're finalizing, which is requiring payers to make educational materials available to patients to help them make the best, most informed choices about which third-party apps to think about, what kinds of things to consider when choosing an app to keep their data as safe and secure as possible.

We also are providing the option for payers to ask third-party app developers to attest to having certain privacy provisions in place. And they can then inform patients about that attestation and patients could choose to think twice about sharing their data with an app that perhaps doesn't meet certain privacy provisions. So, 1.) making sure that there's a very easy to read, easy to understand, comprehensive privacy policy available for the patient and they really do understand how their data will be used. What are the secondary uses of data? What are the other data elements on the enrollees' phone if they have an app their phone that might be accessed by the app? Will it be geolocation? Is there anything else? So, just making sure patients are aware of what their actions are, who they're sending their data to, and how best to make that most important decision. So that's something that you'll see in the Final Rule.

And the data that will be shared. So, starting January 1, 2021, the APIs are available. The payers need to make available through the API any data that meets the minimum set required, with the data services, January 1, 2016, forward. So, we, ultimately, need to start somewhere. But appreciate that there is a burden associated with preparing data for sharing via the FHIR based API. So, that initial set of data is 2016 forward.

The second API policy that we are finalizing is the providers' directory API. And this is a public-facing API. And here we are requiring that payers make certain information about their provider networks available via a public-facing, digital API that will be available through a public-facing digital endpoint on their payers' website. And this is so that the API is easily accessible to third-party applications. Provider directory information is, obviously, not PHI and publicly available. So, although the API needs to meet the interoperability technical standards, again, finalized by HHS in the ONC 21st Century Cures Act Rule, it wouldn't include the security protocols related to things like authentication and authorization because we're talking about publicly accessible data.

But no later than 30 calendar days after an update is received or new information is received by a payer, they'll need to make that provider directory information available via the API. And at a minimum, this would include provider name, address, phone number, and specialties. And this applies to the payers that we regulate. Again, Medicare Advantage, Medicaid Fee for Service and Managed Care CHIP Fee for Service and Managed Care. It does not apply to qualified health plans on the federally facilitated exchanges

because QHP issuers are already required to make information like this available in a specific machine-readable format. MAPD Plans will also include pharmacy directory information through the API.

And all of this will be available starting January 1, 2021. And, again, this makes this data available across plans, across players for innovative app developers to really help patients negotiate and understand what their options are. This is just the first step in the provider directory work that we are doing. We appreciate that there's a good deal to do around some things like accuracy of the data and timeliness of the data. So, these are top of mind for the next steps provider directory work. But this is at least a first step in getting the data out there and helping patients negotiate this date in the most valuable ways for them.

Our next policy is applicable on January 1, 2022. And that's the payer to payer data exchange. This policy requires all the payers to regulate to have a system in place to exchange data, particularly, the USCDI clinical data, which they maintain and incorporate that data into a patient's record. So, if a current patient wants their previous payer to send data to their current payer, they can request that up to five years after disenrollment, request their payer to send the data forward and then, the payer would receive and incorporate that data into their record.

We didn't specify a standard method of doing this in this rule. In this rule, we provide the opportunity for the payer to choose. We know many payers work with HIEs. There's also, obviously, the option to use an API, which we strongly encourage. And, ultimately, the goal of this policy is to help the patient create their cumulative health record with their current payer. The ability to, over time, have all your data in one place so that you can carry it with you throughout the healthcare system from payer to payer and provider to provider. And, again, this is applicable January 1, 2022.

Finally, we have a policy in place to improve the dual eligible experience. Right now, as states are exchanging on a monthly basis buy in data and MMA file data with EMS that will become required to happen daily. So, moving from monthly to daily for the data exchange to really help support patients getting the right services at the right time and avoiding some of the duplications that will have to happen if that dual-eligible status, for instance, is not immediately known. That can lead to sometimes additional rework and paperwork and even sometimes for patients not getting access to the services that they should have access to as quickly as they should have them. So, that will significantly improve the experience for patients.

So, that is, in a very high-level nutshell, the policies that we finalized in the rule. And if we go to the next slide, we've provided a lot of information for folks on this website. And so, information to help payers as well as app developers in developing the APIs and the apps. There are links to the implementation guides, reference implementation, a sample that can be used as stakeholders work to implement the policies. There are also some supporting documents. For instance, best practices for payers and app developers as they are working to develop new technologies. And, particularly, for app developers around privacy policies and some of the wonderful resources out there that they can use to really create those true patient-friendly resources.

And also, there is some information for payers who are required to put that education material together for their patients. There's some content that they can pull from to put those education materials together, so everyone doesn't have to sort of reinvent the wheel. But there is some base information they can start with and then, tailor to their patient population. So, the rule is also on this site if you haven't found it yet.

But I strongly encourage folks to let us know if you have questions to review this. And we are excited for the next steps on the road to interoperability. Thank you, Lauren. If there are questions, we're happy to take them.

Lauren Richie
Great, yes. Thank you. We do have a few minutes for any questions or comments for Denise.

Carolyn Petersen
Let's start with Sasha TerMaat.

Sasha TerMaat
Thanks. Hi, Denise. Thanks for overviewing some of the initiatives in CMS's rule. I had a question about the alignment on the USCDI standard for clinical data. I think it's great to see the use of the same standards and technical formats with FHIR in those two areas. But I was surprised to see the difference in timelines between ONC's regulation and CMS's regulation. And I'm concerned that the CMS timelines are adopting the newer version of FHIR in the additional resources that are part of USCDI. It could place a burden on those participants. Do you have any, I guess, background, on why the timelines are not aligned between the two programs?

Denise St. Clair
So, essentially, with the use of the USCDI in the CMS rule, we're, obviously, looking at the payer population. And its data that the payers already maintain. And the resources that are needed in terms of the FHIR resources to be able to share this data via an FHIR R4 API are currently available in terms of one of the links on this site is for the US Core IG. And so, that provides the tools that folks will need to be able to prepare the data and share the data in R4 for the purposes of implementing this API.

So, we appreciate that from the ONC side of the house, the implementation of USCDI within the EHR certification and making sure that certified EHR are ready to share those data is a year later, essentially, than the CMS regulations. But given the fact that we have these payers who are implementing these APIs on the CMS side, we can still make sure we're aligned in terms of the data elements, aligned in terms of mapping those data for FHIR and preparing them for sharing, and appreciate that the certified EHR requirements will come later. But we do still think that there are the tools needed for the payers to be able to implement this by January 1, 2021.

Carolyn Petersen
Okay, let's go to Valerie Gray.

Valerie Grey
Hi, Denise. Thank you for this overview. It's very helpful. I was a little disappointed when is saw that Final Rule excluded a requirement for health plans to connect to, I think what was called trusted networks, trusted exchange networks. Could you talk a little bit about why that was removed in the Final Rule for me?

Denise St. Clair
Sure. We received a good number of comments on this. And, ultimately, what our commenters told us was they wanted to see a mature TEFCA in place to be able to facilitate that trusted exchange network. So, all of the brilliant work that's being done on TEFCA and that is, obviously, ongoing, they wanted that to work through prior to us requiring the payers to be on a trusted exchange network. The criteria that were proposed they felt could be best accommodated by TEFCA. And they were afraid there would be too few

trusted exchange networks that currently met the criteria in the current landscape and just felt it was, essentially, too soon to require it. And so, it's definitely something folks are incredibly interested in, but we just felt we weren't there yet. And we didn't want to get ahead of the work that's being done on TEFCA. So, that was really the decision point there.

Carolyn Petersen
Okay, thanks. Could we go to Jim Jirjis now?

Jim Jirjis
Yeah, hey, thank you. And pardon me if you're going to get to this. But we were keenly reading the timelines because there's work to be done with providers and technology companies to adhere to both the CMS but also, the ONC timelines. With the national emergency of the pandemic, is there consideration on adjusting the timelines compassionately so that we don't inadvertently pull people off of important pandemic work? Is that being contemplated?

Denise St. Clair
Of course, we're in a very, very, very unique situation. And we are definitely thinking through all of the real and incredibly important work that everyone needs to be focusing on right now. So, that is definitely something that is under consideration. Everything is very new. And so, we're assessing the situation and looking for feedback. And we'll definitely, I'm sure, have more to say. But, right now, it's being assessed. It's definitely top of mind and we appreciate the situation so thank you.

Carolyn Petersen
Do we have any HITAC members on the phone who have questions? Denise Webb?

Denise Webb
Yes. Thank you. Hello. I have heard mentioned either in presentations or in light of regs that CMS, as a result of this Final Rule, has talked about payers being subject to information blocking. And I was a little confused by that. I admit I haven't read the CMS rule yet because I'm deep in the throes of the ONC rule and trying to get through that first. But in the ONC rule, payers are not defined as an actor in information blocking. I'm just wondering what sort of enforcement is there going to be with payers? Is CMS applying the ONC rule to payers when it comes to information blocking?

Denise St. Clair
No. As you pointed out, ONC does not list payers as an actor under the information blocking provisions. We, of course, strongly support the information blocking work that ONC has done and think that the spirit of it is something that, throughout the healthcare ecosystem, we should all definitely be attuned to. But it is not something that we are applying to payers.

The one information blocking provision in the CMS rule is related to the promoting interoperability program and the eligible clinicians and hospitals who are taking part in those programs. That's the one specific information blocking piece that we have. In terms of payers making data available to patients that comes down more to our programmatic authority around making sure patients have timely access to their information and are able to use that information in a way to support their healthcare. And so, at the programmatic level of the payers that we regulate, there are already provisions in place to encourage that and to require that access. And this is one way to further encourage that. And, of course, it's also in the spirit of HIPAA in terms of patients' rights to get their own data. So, in the spirit of that as well. But letter of the law, no. The ONC information blocking rule does not apply directly to the payers.

Denise Webb
Thank you.

Clem McDonald
This is Clem. I don't have the machinery to raise my hand. But I just wondered if you could put me on the list.

Carolyn Petersen
Yes, go ahead, Clem.

Clem McDonald
This COVID-19 thing is really a complicated space. This morning's *New York Times* described the teeny, teeny trickle of testing results that we have gotten through compared to every other country. And some of it has to do with regulatory and legal constraints like CDC tests only record the tests of a specimen. It doesn't have any information on patients. So, there's no way to aggregate those kinds of things. In this time of crisis, I wonder if some regulation or some tweaking of our intense concern about individual privacy might be relaxed a bit so that we can find out what's going on and stop people from getting sick. I know it's a touchy subject, but we are kind of at the extreme end of all the countries and the ability to kind of get the testing connected let alone getting it done.

Denise St. Clair
It's appreciated. It's beyond the scope of, obviously, what I can speak to but definitely something we can mention to our leadership as something that was raised for consideration.

Clem McDonald
Okay, thank you.

Carolyn Petersen
Steven Lane and then, Les Lenert?

Steven Lane
Hello, thank you. I really appreciated your comments, Denise, regarding the information blocking and the interface between the ONC rules and the CMS promoting interoperability requirements. You know that I've submitted and others have submitted some questions about that and, specifically, how that plays out in terms of requirements on providers to release information included in the USCDI, specifically, clinical notes, test results, the timeliness of that release, etc. Can you say a little more about that interface and how promoting interoperability, specifically, will help to prevent information blocking?

Denise St. Clair
So, I know that we have some of our CCSQ colleagues on the line. Let me know if you would like to speak to promoting interoperability program, specifically. But I think at a high level, Steven, what we can say is that the intersection of the ONC rule and the promoting inoperability program in terms of USCDI, the requirements for 2015, essentially, will require USCDI to be what is made available to patients from providers, from EHRs when requirements kick in and ONC colleagues can correct me if I'm wrong. But I am pretty sure it is 24 months after the publication of the rule in the Federal Register . It would be, at that time, that providers would need to be able to share the USCDI data with patients via patient access requirements under the promoting interoperability programs using certified EHR technology.

So. as was asked earlier, there is the requirement of EHRs to have the capability to make the data available versus in the CMS rule where we are requiring payers who already maintain this data to prepare the data and make them available for sharing via an API following the minimum data set of the USCDI. The data elements included in the USCDI is the base minimum of data to share. So, that is a super high-level. For more detail, I would defer to our ONC colleagues or any of our CCSQ colleagues who would like to add to that.

Steven Lane
Just so I'm clear, you mentioned 24 months that USCDI would be required 24 months after publication. I guess I was under the impression it was a shorter timeline. We were looking at 6 months after publication of USCDI 2020 for all electronic health information. So, maybe over the course of our discussions today, we can try to clarify that.

Denise St. Clair
Yes. And ONC colleagues, correct me if I misspoke.

Beth Myers
No, it is 24 months. We can talk more about it in the next presentation. I'll actually touch on it with eh USCDI.

Denise St. Clair
Thanks, Beth.

Beth Myers
Yeah.

Carolyn Petersen
Okay, let's go to Les Lenert.

Les Lenert
Hi. I know I'm off subject again but I want to reinforce what Clem said about the urgency of looking at our privacy laws and the confusing morass of state and federal privacy regulations that may inhibit the effect of clinical information during this outbreak. And I know we're off subject. I know this is a distraction that you will take back to your leadership, a parking lot issue. But it is so important that you hear this and bring it back to your leadership that we need to move forward on how to restructure privacy so that there can be frictionless information flow about test results and their clinical meaning across responders, particularly, with our move to new testing strategies and telehealth for screening and drive-through facilities for specimen collection and new laboratories bringing up capacity at an unprecedented rate. We need to have an effective flow of the data to stop the outbreak.

Carolyn Petersen
Thanks, Les. And we'll take one last question from Cynthia Fisher.

Cynthia Fisher
Thank you. Yes, I'm on the Clem and Les theme. In light of this coronavirus, I think as Dr. Rucker kicked us off, is that it's even more imperative that we move faster. And how important these rules – and I congratulate ONC and CMS for this Herculean effort to have these rules come about. And I guess, what is would like to propose to our working group is due to the seriousness of this war against biologic coronavirus,

is there a way that this group can come together, as we've been working so closely with ONC and CMS over the course of time, is there a way that we and whoever else on resources that are needed could look at delivering much faster than the 24 months for all electronic health information?

And I guess I would say to Clem and Les's points, not just testing. But I think we need to look at – we are in an incredible shapeshift of how healthcare will be delivered. And so, just taking care of chronic disease and people in their homes in this new level of remote care and bringing on national access for physicians to be able to do telemedicine and care anywhere, it behooves us to say can we come together as a task force and do better. So, can we do better than 24 months? What can we deliver as an industry without the mandates of 24 months or 6 months? What can we deliver as an industry and can we come together to let these pipes open and flow sooner with standards sooner? And so, I would volunteer my time on such a task force to do so. And I just want to beg the question, what can we do as citizens to deliver on this sooner?

Elise Anthony
And this is Elise Anthony. I just want to clarify one of the points that was mentioned a little bit earlier, at least on the ONC side. It's after six months after the effective date of the rule is when some information would be required. And it would be the type of data that's included that's in the USCDI. So, not the USCDI standards itself, but the type of data that's covered by the USCDI. And then, after 24 months, it would be the full EHR. We will discuss this more as we go through the information blocking section. But just to be clear, six months after the publication date is when you would be required to move some information. And that information would be the type of data in the USCDI. And then you move over, after 24 months, to the full spectrum of what we define as the EHI. But again, Mike will go over this a little bit further later.

Carolyn Petersen
Okay, Thanks, Elise, and Cynthia, Clem, and Les. I think we do have plenty of ground on which to base future discussions and further deliberations. But at this point, since we are running about 15 minutes behind, I'm going to ask that we start the next presentation and perhaps loop back on this during the public comment period if we have time then.

Arien Malec
Hey, sorry. I apologize. This is Arien. Do we have time on the agenda to discuss the COVID-19 response and the role of HIT in the COVID-19 response?

Carolyn Petersen
We don't have any time built-in at this point. But there is space for closing remarks at the end and the public comment period as well.

Arien Malec
I would like to, and maybe you could consider during a break, a way to restructure the agenda. I think there were some urgent topics relating to the use of HIT and information discovery of disease surveillance. And just given where we are, I understand we just dropped a rule, but just given where we are as a nation, I would encourage us to think about putting some time on the agenda to discuss this or perhaps put together a special committee meeting to address the role of health information technology and the COVID-19 response. Thank you.

Carolyn Petersen

Okay. Robert and I will touch base with ONC during the break and see what we can come up with. And now, let's move to the next presentation, the review of the interoperability information blocking and ONC health IT certification rule.

Elise Anthony
Okay, thank you, Carolyn. This is Elise. How is everyone doing? I know, as everyone who has spoken today has said, there is a lot going on in the world today. So, we are definitely thankful for everyone on this call. We understand how tight time commitments are right now and just given the nature of the committee, all that you're doing within the world community to support the COVID-19 response. So, I just want to take a minute and thank folks for that.

Also, as Carolyn noted, we are a little bit behind. So, I'm going to shorten or go a little bit faster on my end because what we've set up today is a series of ONC team members who will talk about different sections of the rule. So, we can maybe cut my section a little bit short in terms of the questions if that's okay with folks. And then, the questions that you probably have fit into either the conditions of certification, the information blocking section, or the care continuum. If there are other questions not related to those areas, I'm happy to answer those now. But just in recognition of Carolyn's point that we are running a little bit behind. All right. So, next slide.

So, just a couple of things to mention. While we make every effort to make sure that the presentations are accurate, we do want to note that it's not a legal document. So, as many of you have already mentioned on the line, you are reading the rule, which is great because that is a document that we do want folks to refer to.

On the website, we have a number of different materials. Please check that out. Healthit.gov/cures rule. Not only do we have our upcoming webinar dates, the next one will actually be tomorrow at 2:00 p.m., but we also have a number of fact sheets and other resources that we think will be helpful.

And also, for the public that's listening, there's a complaint process that is attached to the information blocking section and an overall feedback system that ONC has related to certification program complaints or concerns. And you can find information on that as well on our website. And this presentation was developed at taxpayer expense. Next slide.

Okay, I'm going to present an overview and Beth is going to present some of the cures updates that we've made to the 2015 edition, next slide. All right. So, the purpose of the Final Rule. And as folks have heard me speak before the committee or just generally, I always say the importance of feedback. And we received such a broad array of feedback from across the stakeholder community from patients, doctors, hospitals, developers, and just the public, in general, about what was important to them in our rule. And I do want to take an opportunity to thank everyone for doing that.

And, of course, we received recommendations from the advisory committee. And we want to thank you for all of the time you spent across the different workgroups, the task forces to give us feedback. It has been truly helpful to have all of the feedback from all of the commenters as we were putting together the rule. As Don said, it does account for the number of pages because we want to make sure that we are responsive to the questions that you have raised or the comments that you have raised in each aspect of the rule.

So, in terms of the impact of the rule, this rule is successful when the entire health IT community engages. And there are different aspects in which that happens. And the design of the rule is to support the role of

all of these players in what patients need. So, supporting the ability of patients to have the right to their data, to control their data, to be part of their care team. And I just want to reemphasize that. For the patient to be at the center and part of their care team so that they can help inform their own care as well. And part of that is having the data available to them.

The provisions in the rule also support the ability of patients to be able to shop for their care and to really think about the environment of which their care is being given and more flexibility and options in terms of which provider they want to support them on their journey.

In terms of doctors and hospitals and, generally, the health community, we want to make sure the data is available there. That data requests can be easily and expensively fulfilled so that the information gets where it needs to go to support the care decision. And some of that is also a choice. So, having a hospital system or a provider system that is locked into using a particular platform is not where we want to be. We want to be in an environment where hospital systems and doctors can create the right puzzle of technology to support the care for the patients that they serve. And that's really important. And there may be a particular app platform that benefits the providers' ability to do that. And maybe that can be built upon what they already have. So, that ability to choose and have a choice is really important to the care system and, overall, to the patient's care.

So, generally, we also think about developers. And developers are an important part of this equation. And having developers have the right information of what the government, of what HHS expects will occur, is important. So, a lot of the rule also focuses on here's how you can support the flow of data, health IT developer. So, you'll see that across the different provisions whether it's in the conditions of certifications component, around API requirements among others, or whether it's in the information blocking section as it relates to how information can be moved to avoid an information blocking complaint. Because we do want to make sure information can move, that it can be moved easily, and moved in the way that it needs to move so that it can be used. And some of that is how can you fulfill a request and also, which ways in which a request can be fulfilled is one part of it. But also, the other part of it is when a request does not have to be fulfilled. And we'll talk a little bit about that later as well.

And, generally, to the American public, we are all patients at some point in our lives. And it's really important that information is available and that it can be used by the patient. And that maximizes the ability of the public to have the innovative environment that they deserve and the transparency in healthcare that is necessary. Next slide.

So, a little bit on the history side of the equation. Information blocking, if we go back to around 2015, Congress asked us to develop a report that addressed information blocking. That identified, for example, the type of information blocking that might be occurring and to analyze that, as well as to think through what might be some action items or strategies to prevent information blocking from occurring.

So, we did that in 2015, and we did that from looking at what we were seeing in the industry because we were starting to hear those same complaints as well. After the report was released, Congress was also working on the development of a law to think about health IT. That later became the 21st Century Cures Act in December 2016. That's when it was signed into law. And it includes Title IV, which I have spent the better part of several years focusing on that deals with health IT. Some of those are regulatory requirements. Others are not. But they're all the focus of what ONC is spending their time addressing. Next slide.

So, as it relates to some of the regulatory pieces to support the implementation of Title IV, that's where you find the rule. So, if you think about the rule, as folks on this call particularly know, there are two main sections. You have the conditions of certification, which relate to the health IT developers who are certified under our program. But you also have the information blocking provision, which is broader. There are other provisions. Beth Myers will talk a little bit later about the care continuum support that's included in the rule, particularly, around supporting pediatric settings. But overall, that's kind of the structure of the rule.

And as we were thinking about how to develop the rule and what to cover, we heard a lot from stakeholders. We even held meetings with OIG, the Office of the Inspector General, to hear more about the types of information blocking that were occurring or the types of situations, I should say, where information was being impeded that folks thought or felt was information blocking. And knowing those types of examples helped to inform how we crafted the information blocking section of the rule.

So, through that listening and reviewing the complaints that we had received regarding information blocking that led to our development of the rule. And I should note that not only do I have thank our amazing ONC staff, and it takes really a village to develop a rule, who have helped to draft, to think through the policies for this rule, but I also have to thank our federal partners. Whether it's the Office of the Inspector General, Office of Civil Rights, Federal Trade Commission, just across the landscape, we've heard a lot from our stakeholders. And, of course, CMS, Denise was just on earlier. And they have really helped us to think through what they see on their aspect of healthcare to help us inform how we put together this rule.

So, after releasing the rule and proposed format, we received more than 2,000 comment submissions. Thank you very much. And then from there, we led to the development of the Final Rule, which was released and posted on our website last Monday.

So, getting to this point has been quite a journey and a very worthwhile one, not only because we're very excited about what we have in the Final Rule, but it has helped us to really see what's happening on the ground. And I always say what we developed here in this rule or in any policy we're doing at ONC, we really want to make sure that it works on the ground. So, all of the feedback we received along the way has created a Final Rule that we believe will do just that. Next slide.

And now, we're going to transition. We'll talk a little bit about some of the tweaks we made to the 2015 edition rule in terms of the criteria that are required. So, let me turn it over to Beth Myers, who is my deputy. Beth?

Beth Myers
Thank you, Elise. Thank you, everyone, for joining us today. I'm going to try to make this fast so that we can get closer to back on time. I mostly wanted to take a minute to highlight some specific things that the HITAC has been interested in and, specifically, commented on and also give a high-level overview of what our approach was for the updates that we have made to the 2015 edition certification criteria.

So, first off, in the proposed rule, we did propose that these would be updates to the 2015 edition rather than an entirely new edition of technology. As you all know, having made similar comments, that there were some concerns about that and a lot of discussion about whether it should be a new edition or whether there should be some other pathway that allowed for it to be differentiated so that it wouldn't cause confusion. So, I'm going to talk really quickly about a couple of things that we're doing. And then, later on, you'll hear more about that as the weeks progress because there are specific things outside of the regulation that we'll

be working with developers to do to help mitigate any confusion about what the updates are and how they work in terms of timing.

So, what we did in determining what the scope should be was really try to analyze, historically, what has been the impact of sort of restricting updates to doing a new edition. What has the impact of new edition been both on IT developers and also on healthcare providers? And what should justify an update to the edition versus entirely new edition? Historically, an entirely new edition has been captured and implemented across the industry as an entirely new product. And that is both on the developer side but also on the provider expectation side. Because of that, it, essentially, creates an artificial crunch on an update cycle. That means all of the health IT developers participating in the program and all of the healthcare providers that use the technology to participate in CMS programs are updating wholesale and entire products all at the same time. And we've seen the issues that can create with delays, with significant burden on development teams and on providers in being able to mitigate that cost within their potential system needs and enterprise needs.

So, having just done that with the 2019 year to update to 2015 edition itself, we found it was a pretty high bar to justify another such update that might cause those types of delays and burdens on both providers and developers. So, when we analyzed what we propose and determined what we were finalizing, we determined that it did not, in fact, meet that bar for that type of update but rather should be updates – or that type of new edition change but rather should be updates to the existing criteria. With that in mind, we, specifically, aimed to try to make some common-sense adjustments based on feedback we heard through public comment about how we selected what was going to be updated, how we portrayed what would be updated in the regulatory structure, and how we understand that scope over time in terms of what developers would have to certify to versus what would be an update that is made over time as part of the conditions. And you will hear more about conditions and maintenance of certification aspect of that in the next set of presentations today.

I want to really touch base on a couple of highlights here. Time-limited and removed criteria that is describing, specifically, those things we determined are outdated or needed to be updated with standards or updated to have that standard, essentially, make a replacement to existing criterion. Several of these you will see. On the left-hand side are things that were previously associated with Stage 1 or Stage 2 of meaningful use program – sorry, the HR incentive programs and CMS and the Medicaid version. Some of those are time-limited so they will not be removed until Medicaid participants on the program have sunset so that they're still available to them for those program purposes. I did want to highlight that problem list, medication list, med-allergy list, does not mean that those data elements are going away. It means that the specific certification of how those data elements are captured will no longer be a certification requirement.

And that's really important to understand that those things are still being captured. That data is still absent in the EHR. We're no longer, specifically, requiring developers to adhere to a single pathway in order to capture that data.

So, I want to talk a little bit about the revised criteria. A highlight in there is the interoperability criteria that are being updated with the USCDI. I have a slide on the USCDI so I will touch on that really quickly next. But I did want to point out is that this does include what we're – I made a bucket of the interoperability criteria. And what it does include is the CCDI so the criteria that reference the CCDI. It also includes the view, download, transmit. So, there have been some questions about whether the "patient portal" is included for the USCDI update. The answer is yes, it is. It also includes an update for the CCBA to include the CCBA companion guide.

It's an important point about that that will be mentioned again in the conditions of certification and maintenance of certification section of our agenda today. But I did want to point out, with the 24-month timeline, the 24-month timeline is the end of the update cycle. Essentially, health IT developers can begin doing that update immediately. And, specifically, with the USCDI, we tried to constrain the updates to that data set itself. First off, it's based on the common clinical data set but the updates that we made to the USCDI were aimed to be a constrained set of common sense choices that are largely already existent to try and make sure that it is very much focused on interoperability. And I'm going to talk a little bit more about it in a minute. But to try and allow for that development to begin to happen now, we have put in place that certification can move forward with the USCDI, essentially, immediately. And the 24-month is the endpoint at which everything would have to transition over.

Really quickly mentioning the right side security tags sent and received, that was something we heard loud and clear from the HITAC about the data segmentation for privacy criterion. They are voluntary criteria. But we heard pretty loud and clear that they needed to be retrained because it doesn't solve the whole issue of how to due date a segmentation and, actually, implement segmentation rules based on whether it's a state law or federal law or specific privacy constraints that you might have based on opioid use disorder or issues relating to emancipated minors, those types of things. So, instead, we renamed those criteria to specifically focus on the actual tagging of the data, which is really what that tool does. It allows you to tag the data at a granular level so that other pathways by which you might be implementing rules can be more easily facilitated. And we do, specifically, talk about it as a voluntary criterion and aim to target those specific use cases that I mentioned, behavioral health, opioid use disorder, and pediatric care.

The two immediately below that, electronic prescribing and CQM, both are aligning the criterion to requirements that CMS has for electronic prescribing for Part D. We are aligning with the same standards CMS has already begun implementing as of January 1st of this year. And for the CQM report criterion, that is aligning with the CMS implementation guide for the QRDI. So, it, actually, removes a layer of certification burden on developers by having them just immediately be certifying to the CMS requirement rather than doing a double-layered thing with the QRDI standard itself.

The new criteria, I'm just going to point out two quick things there. First, the electronic health information export. A really important point on this one. I think you're going to hear the word alignment over and over again. And I appreciate the comments earlier that Denise made about alignment. So not only have we aligned the USCDI across criteria, as Denise mentioned, it's in the CMS rule, it's also mentioned in the TEFCA, but we've also aligned the definition of EHI here for this criteria to align with the information blocking definition of the EHI. That was something we heard loud and clear both from the HITAC, as well as from public comment and that alignment was essential for the specific definitions of the types of data sets that we're talking about. So, Mike will, actually, talk about that definition a little bit later on when we're talking about information blocking. But for that criteria, it is specifically aligned to the information blocking definition of electronic health information.

The standardized API for patient population services, I think the big headline highlight there, and I know Avinash and Rob will be talking about that a little bit more in conditions to certification and maintenance of certification, but I get to say the highlights, which is that we are talking about Release 4, which you guys all probably know given that it's been mentioned several times before. But that is the highlight for that criterion. So, we will move on to the next slide.

So, I did want to mention very quickly and then, I think we've officially gone over time, but at least the same amount over time so we'll move on. But the USCDI, a quick thing to note here that we did, again, try and constrain this to things that are sort of common-sense updates. It is based on the CCDS. We have adopted the following new required data classes and data elements, provenance, clinical notes, the pediatric vital signs, and address, email, and phone number. I did want to point those out, specifically, being address, email, and phone number being the things that we identified for patient matching to support patient matching use cases.

So, that is the update to the USCDI. I think we'll probably have some follow up, later on, to talk more about that in more detail. But I did want to reiterate that when we talk about the USCDI within the criterion or within the criteria, I should say, for those interoperability criteria, those updates can be made over the next 24 months. So, it can be certified to the CCDS or the USCDI for 24 months. At the end of the 24 months, it switches to exclusively the USCDI. And that is referring to the certification program and the certification requirements and the specific standards associated with the data classes and the data elements.

Mike will talk a little bit more about, I think, what Elise was also mentioning and what was in Steven's question earlier about the relationship between the USCDI and information blocking, which is separate from the certification criterion that implements the USCDI for the API, for instance. or for the view download transmit criteria that are specific to the certification program of the technology to meet those standards. So, it is the same concept of data elements, but it is a different approach to how it's affected. So, Mike will touch on that later.

I think with that, I will pause so I don't go far past what we've already gone over. And we can try and get a little bit more back on schedule.

Carolyn Petersen
Thanks. In terms of schedule, I see that we are still on a solid 15 minutes behind. And I know we have had a question from HITAC members about getting started on another HITAC meeting or workgroup dedicated specifically to COVID-19. I've been in touch with ONC leadership behind the scenes during this last presentation. And HITAC members, we are going to use the break time to start the conversation and try to hear from you what the top priorities would be to discuss in this next meeting, workgroup venue, whatever that turns out to be. With that, I think we are going to move on to the next presentation now so that we can at least get an overview of all the general areas of the new rule today. And with that, I will hand the mic over to Avinash and Robert and Michael.

Robert Anthony
So, this is Rob. I will start. I will be joined by Avinash Shanbhag who is the Executive Director of our Office of Technology, and also Mike Lipinski who is the director of our Federal Policy and Regulatory Affairs Division. My name is Rob Anthony. I'm the director of our Certification and Testing Division, which oversees the certification program here at ONC. And today, we're going to try and give you a short summary about all that is packed in the conditions and maintenance of certifications bucket. Can we go to the next slide?

So, Congress required through the Cures Act that we establish this concept of conditions and maintenance of certification for the certification program and, specifically, enjoined us to look at these particular areas that had to be covered. And we'll cover each of these on information blocking assurances and so forth. The only section that we're not going to cover here is the EHR reporting criteria, which also is required by the Cures Act but we have deferred to future rulemaking. I think the important thing to understand as we go through this is 1.) we have finalized an approach here where we have an initial certification requirement in

some of these areas for health IT developers or the health IT module. And then, there are ongoing maintenance requirements for continued certification. A developer would have to meet both of those requirements to continue their certification.

And I think it's also important to understand here that we are talking about requirements for developers and/or their certified health IT modules here, especially, as we move forward. It is easy to confuse some of these things and think that they may apply more broadly. But these conditions are, specifically, conditions for ongoing certification compliance for the program. So, if we can move to the next slide?

Sorry, we can move onto the next. This is our overall for conditions. I think this is a great example of information blocking. The first condition of certification where we differentiate where there may be other programmatic requirements. We will cover information blocking this afternoon in a later presentational about how information blocking covers a number of folks that you'll see over here in this right-hand block. It applies to providers. It applies to developers of certified health IT and HIEs and HINs. But what we're talking about here is a specific condition of certification that applies to health IT developers and actions that are taken specific to their certified health IT module. And that is simply that this prohibits any health IT developer who has a health IT product that is certified under our program from taking any kind of action that will constitute information blocking overall. There's not a maintenance requirement beyond continued compliance with that requirement. Next slide.

The second condition of certification overall is the condition for assurances. In many ways, this is not terribly different than what developers are used to in the current program. You are providing assurance as a developer that you can perform to the full scope of certification criteria to which your health IT module has been certified. It is a little bit of business as usual. It's just the addition, I think, of some of the new cures items that are required now. You have to make the full capabilities of what you have available to your clients. You are not taking any action that constitutes information blocking. You are disclosing and attesting what is available to your clients and publicly. There are some maintenance of certification requirements pertaining to record-keeping. But overall, I think assurance really is providing assurance to ONC and ACB that you are meeting the full compliance requirements for certification.

What you will find in this area as you go through the rule is this fifth condition of certification, and we'll talk about this on the next slide, which is related to EHI export. Beth touched on this a little bit. Next slide, please.

Beth talked about this a little bit in the sort of new criteria. This is, for those of you who are familiar with regulatory shorthand, this is the B10 criteria in which if your product of which your certified module is a part, stores electronic health information then, you have to certify within 36 months to the EHI export criteria. You'll see the general requirements on the side. There are two case areas by which you have to certify. One is for single patients' electronic health information export and the other is for patient population, in general. This allows for two scenarios that we, actually, discussed in the Final Rule. It allows patients to fully access and move their health information across systems. It also allows providers to be able to move entire EHI for entire patient populations and migrate between products if they so desire. We will move to the next slide. And here, I will hand this over to Mike Lipinski to talk about the communications condition of certification.

Michael Lipinski
Thanks, Rob. Good morning everyone. I guess I should start off with a caveat that you shouldn't read anything into it that they're asking an attorney to talk to you about this condition of certification. I think it's

more so that I had worked closely with some other staff on this one. So, as a reminder, there were six areas called out in the Cures Act, and you see them on your screen, to which a developer could not prohibit or restrict communications. And the key part is about certified health IT modules as all the conditions are limited to certified health IT. Another key piece, obviously, is anything outside of the six areas can be prohibited and restricted by a health IT developer. In the Final Rule, we answered questions and provided some clarifications regarding some of our interpretations of the terms. But, generally speaking, they remained the same as we proposed our interpretations. Moving on to the next slide.

So, what we did was balance what Congress gave us in terms of prohibitions and restrictions with the rights, so to speak, or interests of health IT developers. We created what are called unqualified protections for certain communications you see on the screen. And then, we had a separate category, and I'll talk to you about that next, permitted restrictions and prohibitions. So, those would be areas where developers would be allowed to put restrictions.

For the unqualified, we identified both the types of communications as well as who the communications are being made to in which we said there would be no restrictions permitted. So, as you see on the screen here, those are them. You can't really say much more about them than what you see. But a lot of our basis or at least one of our bases was the importance of these types of disclosures. But also, that we felt that most developer's interests would still be protected when these communications occurred because as you see on the screen, many of these entities already have in place a means to protect the information that's provided to them and not, subsequently, redisclose that information, particularly, to the public, unless it was in a different form that protected, for example, intellectual property rights.

Let's move to the next screen. And when we move to the next screen, I'm going to pause for a second to make a note of a point that applies to all communications. We made clear in the rule that communications are broad. The statutes provide any definition of communications. So, obviously, they include written and verbal. But we also want to be clear that they include visual communications. And we had talked about visual communications in the proposed rule, particularly, screenshots, which is a form of visual communication similar to like if you took a picture of a Picasso so that you could then highlight on that picture things that you thought were imperfections to prove that it was a copy of an original Picasso. So, we made clear in the rule that those are included as well.

And we also made clear, which we did through examples in the proposed rule, that communication was not limited to the form or medium in which it was communicated. So, putting together what I just told you, a screenshot provided on YouTube could be, potentially, a protected communication, as long as it's consistent with the other prohibitions and restrictions I'm going to talk to you about. So, on the screen here, you see three of them. There were five particular ones that we identified. Developer employees and contractors, non-user facing aspects and, obviously, one of that is any type of source code. So, even as a developer, you should feel confident that no one is putting up, even if it's a security risk, your source code to point out the error in the coding that will allow for malware or a cyberattack. That, however, could be disclosed to one of the entities that we've identified on the other unqualified protection such as a government agency that helps deal with that.

A key to point out here is the intellectual property protection that we've provided, so to speak, for developers. We continue though to maintain – so, they're allowed to put restrictions on communications if they are to protect a developer's legitimate intellectual property, as long as they're no broader than necessary and they are consistent with these other permitted prohibitions and restrictions. And that includes the screenshots and visual communications that we'll talk to you about in a moment. However, I want to point out, again,

that we continue to carve out that if it's under copyright if it's a fair use of the work, see up on your screen the exact language then, they could not restrict such communication, those being the developers. So, let's move to the next screen.

All right. So, as I was alluding to, screenshots and video. So, when I was talking to you earlier about visual communications, video is also a form of visual communication, not just screenshots. So, you'll see that here in the Final Rule now, both in preamble discussion and in reg text. And what we've done is we've continued to limit the sharing of both screenshots and video. And you can see here the video is limited to only where it's the only way to address say a temporal matter. So, maybe a latency issue with how orders are entered on the screen and that could lead to duplicative ordering and, therefore, a safety issue, a usability issue. So, again, the other piece I think worth mentioning is we've not made developers responsible for third-party IP. So, the user is going to have to be aware. But it's not the developer, as we had proposed, would have to figure out what was all the third-party in each of the screens and/or video and then, redact that or try to, as we proposed, attempt to obtain a waiver for its discloser.

And obviously, we pertain to premarket testing and development, as well as one of the potential prohibitions and restrictions. I also want to point out – the next screen really quickly. There's a lot to talk about here. So, the maintenance fees. We received a lot of comments on maintenance fees, including from HITAC asking for more time really to amend contracts. And I think we agreed with that that there would be additional time necessary. And we felt that the notification piece would be a substantial mitigating factor in terms of when the contracts were amended. So, generally speaking, notification about any provisions in the contract that contravene this communications conditions and certification have to be annually provided. So, once in the first year and then, annually thereafter notices to your customers about any provisions that contravene this condition and that they are not enforceable.

What we're asking is we proposed in a reasonable period of time not longer than two years to amend contracts removed from provisions. We're saying now that developers have up until the normal process they use to amend and revise their contracts. So, whether it's in regard to new services provided to their customers and they're going to amend contracts for that or if it's related to, potentially, something state or federal privacy laws. As you all know, there is HIPAA rulemaking in the works. So, if that comes to fruition that there needs to be a change for one of those reasons, we would expect changes to be made regarding this condition and certification at that time. The appropriate ones, obviously.

At this point, it is time for me to turn it back over to – I'll turn it over to Rob but it might be Avinash who is up next though.

Robert Anthony
Actually, it goes to Avinash next.

Avinash Shanbhag
Yes, hey, Mike. This is Avinash. Thank you very much. Again, good morning, everyone. My name is Avinash Shanbhag. I will spend a few minutes providing details about API conditional certification.

First, to reiterate what Rob mentioned earlier, the API conditions of certification apply to practices associated only with API focused certification criteria, which we defined as certified API technology, and do not, generally, apply to other software interfaces. At a high-level, the API conditions of certification established in Final Rule addresses and practices of health IT developers desire common-sense practices such as transparency conditions that talk about requirements of publication of documentation for app

developers to be able to use the APIs efficiently. Fees conditions that talk about what are formative fees and our prohibited fees from being charged by certified API developers so the health IT developers that are part of the certification program. And the business requirements around the use of APIs by app developers so that app developers can efficiently and effectively use these APIs. Can we go to the next slide, please?

As you see, the API conditions are meant to complement the technical capabilities specified for APIs in the Final Rule and seek to minimize the special effort necessary to use API technology. Specifically, these API conditions apply to the developer practices associated with the three previously finalized API functional criteria that we had finalized in the 2015 edition certification in 2015 and the new FHIR released full based API read-only API criteria for single and population services that have been finalized in this Cures rule. It is also worth noting that the scope of EHI is limited to the data elements specified in the USCDI. Can we go to the next slide, please?

I will give you a high-level description of the three conditions of certification associated with API. First is the transparency condition. And here, we have specified and clarified the publication requirements on certified API developers for all their business and technical documentation that's necessary for API users that are the app developers that use these APIs to be able to interact with the APIs appropriately. So, those are things like the documentation and the publication by our publicly accessible hyperlinks that are the responsibility of the API developers.

In the fees condition, we have set conditions and criteria for allowable fees and guidelines for fees that certified API developers are permitted to charge and also to whom those fees can be charged. There are, at a high level, there are three categories of fees that are permitted to be charged by certified API developers. The first one is development deployment and upgrade fees. These are the fees that the certified API developers can charge to their customers, the health organizations that purchase their products. There is an API usage cost that is allowed if the API developers are hosting the services on behalf of their customers so they're able to recoup the cost that they incur. And finally, there's a value-added services permitted fee that can be charged by the certified API developers to the users of the APIs, so the app developers, for services that go beyond what is necessary to use the APIs.

In our rule, we kind of give examples of value-added services, such as additional training, educational materials, or even if you have an app store and if there are some services that enable apps to be provided, maybe a placement in the app store at a position that benefits them so that all which go beyond but are required to support and effectively use those APIs are allowed and are considered value-added services. In general, any fee not permitted by these conditions are prohibited from being imposed. And, finally, we have the openness and procompetitive condition. These are the business requirements to ensure that the API users, the app developers and the health organizations that purchase the product, are given independent ability to use the API technology just to make sure that they have all the rights and abilities to make the maximum use of these APIs to improve interoperability and perform and do innovative activities on top of these APIs.

So, these are the kind of high-level common-sense conditions of certification that are, obviously, details on each of the different conditions that are specified in the regulation. Can we go to the next slide, please? And as we have structured all of the condition certifications, we also have within the API conditions of certification, maintenance of certification requirements, which are the ongoing certification requirements that are to be met by the certified API developers.

We have a set of requirements that are only specific to the new standards-based API. And these are the ones that are highlighted on the screen, which I'll describe briefly. These are the categories of verifying authenticity of the app developer or the user of the API. These pertain to the application registration and the publication of service-based URLs. A certified API developer is permitted to institute a process. So, they are not required but are permitted to institute a process to verify the authenticity of the app developer so long as the processes objective is the same for all the app developers and is completed within 10 business days. Once the app developer is verified, the registration process for the application is required to be completed within five business days of completing its verification. Again, from the NPRM, during the proposal, we had for verifying authenticity proposed five days and for registering we had proposed one day. And based on the responses, we have increased the dates to accommodate the commenter's response.

And finally, certified API developers are required to publish service-based URLs. These are the FHIR endpoints for all the customers of certified API technology that can be used by patients to access that EHI. So, these are the patient-facing endpoints. These are kind of, again, in our rule, we finalized that these are important and necessary ingredients for app developers to be able to use the APIs efficiently. So, it is required as part of the maintenance of certification for certified API developers to publish those FHIR endpoints for all of its customers.

With that, there are a couple more maintenance of certification requirements that talk about timelines for rolling out the API conditions of certifications and also, the overall timelines of when the new API criteria, the standards-based API criteria. need to be provided to the customers. These are all aligned, as was mentioned previously by my colleagues, Beth and Denise, that they are aligned with the overall timelines. And further in this presentation, we have an overall timeline where all the conditions are to be met. And that time, Rob will be covering those. So, with that, I'm going to turn you back to Rob to continue with giving you more details of the remaining conditions of certification.

Robert Anthony
Thanks, Avinash. Can we go to the next slide? So, I think the other major area of concepts to cover in conditions of certification is real-world testing. There's an awful lot to unpack from a regulatory perspective within this condition. But I'm going to focus mostly on the high-level concepts that you'll find here. And from a high-level, it's, actually, I think, a pretty common-sense sort of concept. Congress, through the Cures Act, required health IT developers to, basically, test real-world use of technology for interoperability and in the settings in which it was going to be deployed. So, what we have put together as condition of certification here and the ongoing maintenance is something that will allow developers to verify the extent to which their certified health IT modules deployed in a production environment demonstrate conformance with the full scope of whatever certification criteria they have to comply with within those particular workflows or architectures or type of cares that they are deployed in.

We put some parameters around what things have to be part of that test. If you look at the condition of certification on the slide that is what this regulatory shorthand refers to. The criteria within 315B, for example, are specific functionalities within health IT criteria like transitions of care, which is B1 or B3, which is e-prescribing. So, we outline a number of things that refer to different criteria that would be applicable that relate to interoperability as a whole. If you look at the maintenance of certification, I think that's really where the meat of what this criteria overall or this condition overall really addresses. And this is the notion that developers will submit a real-world testing plan. And they will do that by the end of every calendar year. Then, not immediately the following year but after slightly more than a year of sort of accumulating information, they will submit real-world testing results about the plan they submitted.

We put some requirements around what has to be included in that plan. There are different things related to what standards are applied and the methodologies that they are using and outlining what that detail is. But, essentially, it all comes down to the same thing is that you are looking at what your module is certified to and you are employing a number of different measures related to the real-world application of that technology within the thing as a whole.

That information is made publicly available via a hyperlink. We are, at this point, looking at how we can publish that through the chapel so that it will be easily and publicly available to folks, both the plan and the results from the developer. I think important to distinguish here that these testing plans are not necessarily per individual module. They are per developer and per applicable criteria and per setting of care or applicable workflow. So, it is possible, especially for vendors that have a large number of health IT modules that they'll be able to bundle some of those together so that will not be as burdensome on them to submit.

It is also important, I think, to distinguish because we have started to get this question about the applicability to providers. And, again, I would emphasize conditions of certifications are applicable to developers and to certified products. They are not applicable to providers. So, this is a condition real-world testing that providers should not have to take part in. It should be something that is under the hood, behind the curtain, and will not affect them overall. Next slide.

You will see, as you dig into this section that there are some things that are dependent within this on some of those criteria within the real-world testing plan. So, overall, there will be some requirements to both update certified health IT modules as applicable and also roll out to customers things like the USCDI, things like updates to the newest standards for CCDA, electronic prescribing. There are some other privacy and security things that also depend on this. But, again, this is all on the developer's side. And the reason that it is folded into real-world testing is that there will be a requirement to update this and get these out to the end-user of products within that 24-month period and then, ultimately, after they have been deployed so you have them folded into the real-world testing plan. So, again, you can demonstrate conformance of them in an actual production environment. Next slide.

One of the concepts that you will also find, and I think this is an important concept for moving health IT as a whole forward more nimbly, is this notion of the standards version advancement process. We finalized this notion of allowing the option for developers to advance to a next approved standard in a list so that we can better align with overall industry efforts.

There are many times where the development cycle of a standard may be out of step with what our regulator process as a whole is. And what we wanted to do is provide better alignment for the industry as a whole and more flexibility for the industry as a whole. So, allowing developers, once we approve the use of a newer standard as part of the SVAP, as we're calling it, the standards version advancement process, to be able to select and use that standard for your certified health IT module. You'll see how it works. You would have to, as a developer, you would have to let both your ACB and all of your customers know that you are updating that and how that update will affect you and whether you will support previous versions of it. But in the end, really, what this does is allows people to move forward with newer standards that we think may be ready to be implemented but we have not yet fully adopted as part of the 2015 edition within a regulatory framework.

It is included within real-world testing because, again, if you update in this way as a developer, you will need to demonstrate your conformance to the full criteria certification requirements in that area and you will have to show how this newer standard that has been adopted is being tested in a deployed production

environment overall. This will be a public process, the SVAP, as a whole. And we're releasing more information on that in weeks to come. But it will be a process by which folks will be able to nominate some potential standards for advancements. We will, ultimately, consider them. We will gather some information and, ultimately, the National Coordinator will decide on approving specific standards for advancement and adoption moving forward. Next slide.

Lauren Richie
Sorry to interrupt. This is Lauren. I just wanted to see if we could move along and just kind of wrap this next section up in the next couple minutes, and then we'll –

Robert Anthony
I think that we can.

Lauren Richie
And we'll have Robert and Carolyn adjust the agenda. Thank you. Appreciate it.

Robert Anthony
I probably have two to three minutes left of things to say. So, the final criteria is attestation. This is a very simple concept. You are, basically, attesting to meeting the previous conditions of certification. This is something that the first window will not open until next year, April 1st. But, essentially, there will be attestations submitted every six months. You'll have a 30-day window for health IT developers, again, to submit those attestations to having met those conditions of certification. Again, a requirement of the Cures Act overall. Next slide.

The way that we will enforce this, and I'm not going to dwell on this, but I just going to mention that we are leveraging the direct review process that we already use for overall ONC surveillance. Within that process, there is a way for us to take look at what is happening within areas of certification with product. We may ask for extra documentation. If there is a non-conformity, it results in a corrective action plan. Ultimately, if a developer does not follow the corrective action plan, it can lead to a certification ban. There is a process for that. But all of this is a process that I think developers are already familiar with. Next slide.

If you were to look at the whole sort of timeline of certification, we included this. I'm not going to go into the individual on this, but there are a number of things that I think will take effect in a cascading way. There are deadlines here for when compliance starts with information blocking and deadlines for when the first real-world testing plans and attestations. But this is just meant to describe what that cascading will look like. There will be a number of things that happen over the next 6 months, 18 months, 24 months, 36 months. It's not something that happens all at once. Next slide. And I think that is it for where we are. So, I will break there.

Robert Wah
Thank you very much. Folks, a couple of things. Obviously, we have been challenged with our schedule, as we often are, which is a good thing. I think we have a lot to get through. Carolyn and I and the ONC team have been discussing a number of things in the background during this last presentation. And I think our plan forward is we're going to hold the discussion, even though we've had a number of presentations right now. We want to continue the presentations. And I know that a number of you have some comments and questions. And then, we'll also try to give a sense of where we are in terms of – we heard a lot of interest in talking about health information technology and COVID-19.

And so, what we'd like to do, and I'll give you some time to think about this, is we would like to solicit what you think the priorities should be if we were to create some sort of a workgroup to do this. Obviously, there's a time pressure here. We need to stay very focused on what's doable and obtainable here. We can't necessarily take on everything.

So, what I'd like to do is proceed with the next presentation and give you some time to think about your priorities. I think we'll take a small break in between the next presentation and the final presentation to start soliciting some of those priorities that you feel. And then, we'll try to circle back with a plan of how we can incorporate those priorities into either a working group or another special meeting of the entire committee or a workgroup. And, again, at 12:45, we have a scheduled public comment period. So, as has been our practice, we will take a break at that point and honor our commitment to the public to allow them to comment. We may have a little bit of time extra at the end of our meeting. And that time we will use for a continued discussion of our presentations if we don't have enough time for that, as well as an ongoing discussion of the COVID-19 priorities. With that, I would ask our next presenter to go ahead, and I think that is on our 21st Century Final Rule on the area of information blocking that will be led by Michael, I believe.

Michael Lipinski
Thanks, Robert. I will jump right in. I understand we have a tight schedule. So, I will try to go not too fast but at a decent clip. In that regard, I should mention, yesterday we gave a – sorry, was it yesterday? Monday, I think, right. Anyway, my team can tell me but I think it was Monday. We gave a presentation on information blocking in the afternoon. It was a pretty in-depth presentation. It was an hour and 15 minutes. The slides from that will be made available online, as well as a recording of the entire presentation. And then, obviously, you can continue to reach out to us if you have a question. So, let's move to the next slide. And so, this is the resuscitation here of what we were asked to do by Congress. And we tried to stay true to that throughout both the entire rulemaking and definitely with the Final Rule. Moving to the next slide.

So, this is a slide I used in the proposed rule and other colleagues have used it. And it kind of is information blocking, maybe in some respects, in its simplest form, a type of checklist of what do you have to have to be an information blocker. And we'll talk about a couple of the important ones I'll focus on more today here. Let's move to the next slide. So, also very important, and I know there have been some discussions today about timelines, but what we had finalized is that all actors subject to the information blocking provision, so developers, health information networks, providers, they would not have to comply with information blocking until six months past the publication date of the rule, which, obviously, has not occurred yet.

The other key point that we've pulled out and put on the slide is that the Office of the Inspector General has not yet issued their civil monetary penalties rule, not even the proposed rule yet. That is still under review at OMB. Until they finalize that, they've indicated that there would be no enforcement before the six months. So, at a minimum, you have six months. And what they've said is they will exercise discretion if they were to say, for example, issue the rule another six months after that. Sort of that in-between time, they would exercise discretion as to enforcement.

The other piece worth mentioning, and I did during our presentation, is that there is an executive order out there from the administration back in October. It's 13.8.92. They issued two executive orders at the time. 13.89.1 and 13.89.2, 2 focusing on essentially reinforcement actions. So, we've cited that in the rule. And we've always encouraged self-disclosure and we continue to do that whether it's related to the program or related to information blocking. And once that executive order is fully implemented, there may be an opportunity for advisory opinions as well related to information blocking. So, I just wanted to make you aware of that. Moving onto the next slide.

So, the actors. Obviously, there were four actors identified by Congress. We received a lot of comments I wouldn't say all of them so much but definitely on the developers and the health information networks, in particular. I'm going to spend the most time talking to you about the health information networks. Providers, it was identified in statute who is a healthcare provider via cross-reference of the Public Health Service Act, which Cures amended. So, we've maintained that definition. Developers, we've maintained the definition that we proposed with two things worth mentioning. One is we've incorporated the fact that self-developers are excluded from the definition for information blocking. But they are, obviously, still going to be subject to the condition of certification related to information blocking.

And then, we've also focused on just having – the claim has to be at a time when the developer has a certified product. So, there was a discussion in the proposal, if you recall, and a request for comment as to whether there should be some type of liability for a developer if it no longer had any products in the program but at one time did. We've finalized it where, again, they need to have a product in the program at the time of the information claim for any liability. So, let's move to the next slide and talk a little bit about health information network and health information exchange. It was probably where some of your most discussion was. And, hopefully, you can continue to hear me because I had to make sure my VPN stayed connected there and they asked for my password.

So, health information networks and back to where we were. What we ended up doing, based on comments, is made four changes. The final definition you will see on the screen there. The key one, I think, for – they're all key, in my opinion, but one of the big ones was we received a lot of comments about confusion as to the difference between a health information network and health information exchange. In the Final Rule, we have the same definition for both. We know out in the industry, there are even other terms used for these same types of entities, RHIOs or health information organizations and so forth. That is one key change. Another change is that we have tried to make what type of actions you need to partake in to be considered a HIN. We've tried to focus those more. So, one of the big ones is we removed, substantially, influence in response to comment. There was a lot of concern about that being broad and vague and so we removed that.

We've also focused, and this is, I think, a theme that you will see throughout the whole Final Rule, particularly, when comes to information blocking, is that we continue to focus on alignment with HIPAA because we understand that many of the actors under information blocking provision are also subject to HIPAA privacy and security rules as being either a covered entity or a business associate. So, we focused, again, on, as you see, treatment, payment, and healthcare operations. So, the exchange needs to be related to that. The fourth big change is in the proposed rule, we talked to there being only two entities plus the individual entity that is the HIN needed to be exchanging for there to be a health information network.

Generally, we heard about between all of the things we have whether type of actions they need to be doing and that piece right there and also the piece just focusing on treatment payment and healthcare that we would be covering pretty much everything out there as a HIN was generalized feedback that we received. Between these actions, we feel like it narrows the focus to types of entities we are trying to cover. And to say a little more about more than two unaffiliated entities that are enabled to exchange, so, obviously, that means three or more stated in another way, they have to have the ability as well as discretionary exchange. So, you may have the ability and choose not to exchange in-network, at least on particular use cases and that's okay. But as long as you have the ability and discretion to do so that would count as one of the unaffiliated entities.

And I guess maybe, as an example, what we think prevents an unintentional inclusion of would be like what are, essentially, bilateral exchanges. So, if you had multiple providers sending information to what I will refer to as an "intermediary" or a clearinghouse, and they were sending the information on to registries or government reporting agencies that would not be a HIN because providers are not exchanging between themselves in an intermediary or the receiving entities on the other end are not really exchanging back either with themselves using the services or agreements of the intermediary or exchanging with other parties. We think this definition still achieves our policy goal but is administrable and provides the clarity that stakeholders were asking for. Let's move to the next slide.

EHI, another area where we received a lot of comments about our proposed definition being overly broad. Also, again, going back to actors, so to speak, that we covered under the information blocking rule and also being covered under HIPAA rules, they pointed out, based on definition, there could be the need to segregate data having data that is EHI and data that is EPHI. That was never our intent with our proposal. So, in the Final Rule in some respects, and some comments made by HITAC, maybe not in the way you guys had provided your comments but have, let's say, pieces of thoughts that you were providing.

So, is EPHI found in designated record set? That is what we are focusing on right now, at this time, for EHI. We think that, again, it should be administrable just like HIN definition. Many of our actors that are going to be covered under this information blocking provision have familiarity with information that EPHI found a designated data record set. They're already collecting it, maintaining it, making it available. We believe it's wildly understood. So, therefore, we think it is practical and operational in that respect.
The one thing that you see on the screen here, the HITAC task force had a lot of conversations about this. And we received over 1,000 submissions just on price information. How it would work with our definition that we finalized is that it is not expressly included as you see on the screen or excluded. And if it's it is in the designated record set then, it would be considered EHI. That's pretty much the bottom line on that. Moving on to the next slide.

I want to highlight here, and this is where if you go back to the slide about elements of information blocking, this is a key element and rightfully so. We got a lot of comments on the two things I talked to you about already. All actors, but particularly health information network and then, obviously, the definition of EHI, and an immense amount of comments on exceptions. This element of information blocking is just as important as whether or not you meet an exception. Because if you don't have interference then, you're not going to be an information blocker. Or if you have interference, you still may qualify for an exception and then, you wouldn't be an information blocker.

On the screen, and I encourage you, as we've heard, a lot of you are already steeped in reading the rule, I encourage you to read this part of the rule of information blocking that is in – I'm trying to remember where the page numbers were, 640 and 650-ish, around there off the top of my head. We have other examples of what is an interference. But I highlighted three key ones on the screen here today. Pretty self-explanatory when it comes to the FHIR endpoints. We view that as a technical interference if it wasn't made available and so they should be made available. Delays, we don't set a particular timeframe because, obviously, that's going to be circumstantial. And then, we'll have to look at that case by case. Delays can be considered an interference and have been used. And we've heard from stakeholders they have been used as ways to block access, exchange, and use to EHI.

And another key one that we had in the proposed rule and maintained in Final Rule is that if there is any charging for what is called electronic access, and we have made clear what we mean by electronic access in the Final Rule and I will repeat that for all of you here today. We define it as inter based method that

makes EHI available at the time the EHI is requested and where no manual effort is required to fulfill the request. So, if you are charging for that electronic access then, that is inherently suspect in terms of interference. As I was saying to you earlier and I'll note it again, it's a good discussion of what vetting is acceptable and what vetting would cross the line and be inherently suspect as interference also in the preamble of the rule.

Moving to the next slide. So, let's talk just briefly about what is not an interference. We received a lot of comments, including from HITAC, about business associate agreements. And I think, again, aligning with HIPAA, we are not asking anyone to violate their business associate agreement, particularly, their service level agreements that implement those business associate agreements. However, one key part to this is they can't be discriminatory.

And what I mean by that is if sharing information for treatment and you're sharing it with 10 providers of the patient but you've chosen not to share with a particular provider of a patient then, that's going to be inherently suspect related to why that practice is and why you are being "discriminatory" in nature. And I think the other key point that I made on our presentation about this is that when we or OIG or the department is looking at those agreements, we're going to look, not just at the covered entity as the responsible party, we're going to also look at business associate to see if they've exerted market dominance in getting the covered entity or provider, in our case, to agree to terms where they are not sharing the information with certain providers. And that may be because they're not sharing with a certain provider because that provider has a competitor's health IT and EHR system. So, we're going to look at the whole agreement in those circumstances and both parties to that agreement could be subject to information blocking provision.

Moving on to the next slide. Before I move on really quick, about the education piece. Obviously, we received a lot of comments about that. And we have done our best, I think, in our rule to talk to and encourage providers to provide education about the privacy and security risks associated with sharing your information. I guess I will say, from my perspective, is that there are many laws and many regulations out there. Our job was to implement a particular part of the law through our regulation using the authority that we have. So, we think we have tried to do our best job with what we had in front of us and what we were asked to do by the law.

But as we all know, there are a lot of laws and a lot of regulations because everything is addressed with one law and one regulation. That is my peace on that piece, saying my piece on that part of it, I should say. But, again, we have given some options in the preamble, and I encourage you to look at that, about how you can implement an automated approach to providing your patients, I'm talking to providers now, your patients with information about the apps they're choosing to share or other entities they're choosing to share EHI with. That can include requiring through an automated process an attestation for third-party apps to attest certain privacy practices. We, in Final Rule, have identified some of what we think are minimum practices of third-party developers and privacy practices. But you are free to set an even higher standard from an attestation perspective and "warn" your patients as to whether or not the app they're choosing to share with meets such practices or adheres to such practices.

All right. Now, shifting. There are eight exceptions. I, obviously, cannot go through all of those eight exceptions with you now in great length. I, again, will point you to the presentation we gave Monday. That should be available online soon. You will be able to look at it or listen to it at your leisure and review the slides.

A few things just to mention though on some of them in terms of comments provided by HITAC and just generally by commenters. Privacy exception, we got a lot of comments about the meaningful opportunity piece. And we believe we've addressed that accordingly with what intended in the proposed rule, which is if there needs to be – whoever the entity coming and asking for information, they need to come with what looks to be a clear indication that the patient tried to give them consent or authorization but maybe it is not perfected. In that case, we want the provider to take reasonable steps to try to perfect that consent or authorization by providing the appropriate form, for example, to the patient so they can provide the appropriate authorization or consent.

As some commenters provided, it was not our intent to say anybody can show up and say I want all your – from a recent accident I want all those patients' records. Please go out and find them in your hospital somewhere and give them the opportunity to consent to provide that information to us. That was not our intent and I think we've addressed that in the Final Rule. Infeasibility was another area where the HITAC had provided comments. We tried to provide a lot more specificity there. So, you'll see two key ones, essentially, what we refer to is force major so any type of uncontrollable act like a natural disaster. Those would be reasons not to provide information that responds, so to speak, or fulfill a request for access, exchange, or use.

There are certain requirements that need to be met in doing so, including documenting why you are not doing it. But segmentation is also another one where you are unable to segment the record. Maybe there are certain privacy pieces that can't be segmented out in response to the request. It is another one you could use. Looking at health IT performance, we got comments related to, essentially, when there is a negative impact on the system's performance. And so, we've put in a provision now that allows for, essentially, like metering or throttling if there is a negative impact on the overall performance of the healthcare system. That was, I believe, comments also provided by HITAC, as well as other commenters.

At this point, I think I want to jump in on our next slide and talk about it is a "new" exception. But it really finds its basis in infeasibility exception as well as the EHI definition in the comments we received on the EHI definition. I'll pause for a second to grab a drink here really quickly. I'm getting over the flu I got from my kids. Content and manner. What this allows, first and foremost, is to allow the market to dictate the fulfillment of a request for access, exchange, and use. And so, how does it do it? First and which is key, after the compliance is required and so then, the next 18 months' timeframe, the content, which is the EHI that we are talking about, is limited to that data that is identified in USCDI. So, some clarity on that is that it isn't the USCDI itself with all its associated standards. It's if you have that data that is identified there.

That would include notes if you have them in electronic format. It would include problems if you had them only in ICD10 and not SNOMED. So, hopefully, that provides additional clarity. But any data requested outside of data identified in USCDI would not need to be provided in those first 18 months.

So, the manner first out the gate gives an opportunity for parties to reach an agreement on that. So, if there is a proprietary format in which the requester would like the data, the actor has the option to reach an agreement irrespective of both the fees exception and licensee exception. If they cannot reach agreement on those terms with the requester then, they have the ability to still qualify for this exception through an alternative manner. I think, at this point, we want to move to the next slide so I can get it up on the screen. That is content that I had already talked to you about that. Now, we can move to the next slide, which I believe would be, all right – this kind of lays out the parameters, as I was talking to you about. You can move to an alternative manner if you are just not technically able to meet the request. But what I was talking to you more about was the ability to first meet market terms in providing the data. And if that can't be done,

you move to the alternative manner so that we can move to the next slide. We prioritize the way in which that information should be provided still focusing on the requester.

One key piece though, and I talked to you about delay earlier, it doesn't mean once you're inside of the exception you can delay as long as you want in providing the alternative manner. From a consistency perspective, since you're required to respond, generally, without delay, the same holds true when comes to alternative manner to be able to take advantage of the exception. And so, the order of priorities is, generally, focusing on interoperability, which is also a key component of this rule. So, you start with standards that have been certified, right. We talk in the preamble about both content and transport, but you don't have to have both. So, if the requester says, "I just went into in CCDA. I know you have direct certified," it doesn't mean you have to provide it to me in Direct. I don't use Direct, let's say. I just want it in CCDA. That's permittable under the first priority.

If you're moving into second priority, it is, again, at the requester and, again, under content and transport standards that they may request, and you have available. If you can't do, technically, in the way that they request it then, you would, eventually, move down to three. And the overall goal here is to make sure that the EHI is getting out and is getting to the requester. So, hopefully, something is achieved through one of the other three ways either through the market way, through the certified way, the standardized way. But if not, we still want the information to move. And then, the actor is responsible to provide it in a machine-readable format, including the ability to interpret that EHI as agreed upon by the requester. An example we provide in the rule is the EHI export could be one way of meeting this No. 3 alternative option.

I think that wraps it up. Let me check the next slide. Yes. Okay. I don't know if we are entertaining questions. But I want to hit – that was clearly an abbreviated presentation. But I tried to focus on some of the key policies and proposals that HITAC and other commenters had focused on in the comment and, I think, the key pieces, just generally from a policy perspective, we wanted to emphasize. Thank you.

Carolyn Petersen
Thanks, Michael, for that great and really brief but very comprehensive overview of where things are at with info blocking. Given our situation with time and in consultation with Lauren Richie, we decided to not take questions at this point and, potentially, to revisit this topic in April or at a future HITAC meeting if there is interest from HITAC members. I think we can see pretty clearly today there is a great deal to unpack in all of these presentations and aspects of the rule. And it may be to our benefit to be able to do that in more depth in future weeks as we have a greater chance to look at the rule. With that, I am going to transition to Beth Myers to take us through health IT for pediatric care and practice settings presentation. Go ahead.

Beth Myers
Thank you. So, before we kick-off, I, actually, don't have very many slides for this but I want to thank everyone on HITAC and also on the pediatric care and practice settings task force that was convened last year to talk through our overarching approach for health IT for multiple types of care and practice settings and sort of understand how the work that has been going on, specifically, for pediatric care for health IT supports that has really been going on for the better part of a decade at this point. And it has involved partners from CMS, from HRQ, from other parts of the department, as well as wide a range of public stakeholders, including the number of organizations representing different provider groups. We've had standards development organizations that have been engaged with us. We've had multiple health IT developers, both those who are working on pediatric-specific products and those who are working on broad universal products that need to be implemented in a wide range of spaces. So, I want to take a moment and sort of bank that collective input into this process. We can go to the next slide.

What you will see if you look at the Final Rule is that within the scope of our rulemaking, we adopted an approach that, essentially, took the directives of the Cures Act for Section 4001 of the Cures Act and also looked at what we could do that might be beyond those very specific policies within that law that directed us to adopt recommendations for the voluntary certification to support pediatric care and practice settings. So, we described this a bit in our rule but I also want to talk to it briefly and then, give you a little bit of a teaser of some things that are up and coming that ONC is working on, again, with that collaborative effort across the whole industry, frankly, that folks have been involved and engaged in trying to really promote health IT solutions that are innovative and, specifically, capable of supporting the care of children but also ensuring that, as children transition from setting to setting that the data that needs to be available for providing care to a child outside of the pediatric setting that is uniquely pediatric is also available in those other types of care settings.

What we started with within the rule is, in the proposed rule, we outlined our 10 recommendations for the voluntary certification of health IT. Those 10 recommendations were based on clinical priorities that were identified through a collaborative process with the community starting from things like the children's EHR format going all the way back to 2013, I believe, was the original several hundred identified priorities that were narrowed down over time. And a prioritization process was applied to it to get to a list of 10. We convened stakeholders and met with them about what those 10 clinical priorities really mean and how to conceptualize the development of tools that can support those.

Within the Final Rule, we laid out our approach to doing so ensuring that health IT in the certification program can support those 10 clinical priorities. I do want to point out very clearly because this was an ongoing question that we have developed these recommendations for certification of health IT for pediatric care under the existing program. This is not a separate program track. There is not a separate certification pathway that is just pediatric specific. The reason for that is we heard loudly and clearly from commenters and from the HITAC task force that there should not, in fact, be a layered approach to certification. You don't want a provider who is giving pediatric care to have the technology that is stamped for pediatric and ambulatory and accessing and so forth to create this chain event of these separate and disparate certifications, but rather to have it unified within the overarching program. That is the path that we did take. So, within the program, the criteria that we are looking at, specifically, can be broadly applicable to a wide range of settings and support those clinical priorities.

So, you'll see our 10 recommendations are reiterated within the Final Rule. And we identified some specific criteria that are particularly useful in addressing those 10 recommendations. They include things like the inclusion of the pediatric vital signs within the USCDI, the API itself, which is an essential tool for ensuring that the health data of pediatric patients can move from setting to setting. We know that children with complex care needs are seen in multiple settings by multiple different provider types. So, ensuring that that care coordination has complete records is absolutely essential. And then, we also included things like the voluntary certification criteria related to security tagging to be able to more easily apply security labels at a more granular level, which is a fairly constant need within a pediatric setting to be able to appropriately identify which data element or class might be restricted by a given law or statute within a state or jurisdiction.

So, the other thing that we did within the Final Rule is to identify the current new 2015 edition criteria that support these practice settings based on those clinical priorities. So, you'll see those laid out. I mentioned a few of them just now. But we also describe our ongoing nonregulatory initiative that is attempting to provide the next layer of support to this. We understand that the certification criteria are, specifically, a functionality or a standard that is broadly applicable. We often use the analogy of the floor. So, the

certification program is setting the floor. We want to ensure that people who are doing pediatric care can effectively work with our developers or the developers who are creating a product to support pediatric care settings are able to build the appropriate structure on top of that floor. We have done some work with stakeholders. If you can go to the next slide, these are previews of what we expect to be seeing in the next few months. Some really exciting products coming out that take the next step.

I do want to thank – there are those that I would say in the room but it is virtual, so in the virtual room who have supported and helped provide feedback onto an informational resource that we are currently developing to help take that next layer. So, looking at the certification criteria and how they, specifically, address the clinical priorities but recognizing that in order to be most appropriate for pediatric care needs that might vary, for instance, a pediatric oncologist might have different needs than a pediatric care provider providing care for a teenager who is transitioning and needing to recognize the difference between those implementation specifications or those unique needs for different types of growth charts or whatever else those resources are that that kind of goes beyond what you can capture within the certification program. So, we have been working with partners to do a couple of things.

One of them is not on there yet but soon, you will be seeing on our website the health IT for pediatric care and practice settings page. There will be an informational resource that is available for health IT vendors and developers to see some of these resources and tools that have been developed through pilots, through other federal partners, through standards developing organizations that cover the next phase or the next technical specification needed to more, specifically, address pediatric care needs in a variety of settings.

And we've also worked with a technology team that has been heavily engaged in all of this effort at ONC to update our interoperability standards advisory to, specifically, identify, with a form of tagging, standards that are under review within the interoperability standards advisory for pediatric care. So, those are two pieces of what we have done so far but there is more coming. So, we're very excited about this work. And we will keep all of you informed, including those of you who, obviously, directly have been involved in providing us feedback on these resources as they're being developed. But we'll look forward to engaging again soon about the next steps when that next piece is published, which should be, we hope, this spring. Stay tuned for that. And I believe, at this point, I can pass it off if the chairs want to do questions or have further discussion. I will go ahead and hand it back.

Carolyn Petersen
It looks like we are a few minutes ahead on public comment. And I know there were some questions published about the info blocking So, let's go to questions with health IT care continuum. And then, we'll take Steven's question related to info blocking and then, go to public comment. Any questions for health IT for the care continuum provisions? Okay. Aaron, I'm sorry.

Arien Malec
Yes, sorry. Mine was on info blocking, so I'll just hold for then.

Carolyn Petersen
Aaron Miri, did you have your hand up for a second? Okay. Let's go to Steven Lane and we will go back to Arien.

Steven Lane
Thank you so much. I appreciate the chance to ask for some clarification on information blocking. I have one question I'm going to raise, which is not one of the two that I put in the chat because I think they can

perhaps wait until later. We heard from both CMS and ONC that the info blocking requirements on providers to provide access patients to all data in the USCDI are complex. And they kick in with different timeframes, depending on whether you're a HIT developer or whether you're a payer, whether you're fulfilling the requirements of the promoting inoperability program, etc. I just want some distinct clarification on one point. In my reading of the rules, providers are required to provide electronic access to the data elements in USCDI beginning six months after the final publication of the rule in a manner that is technically feasible, acceptable, etc.

Does this mean that clinician notes, which are not included in USCDI Version 1 must be provided electronically upon request to patients in a manner that they request, including access via the patient portal where that access exists and technical capability exists, which is what some people have referred to as open notes?

Michael Lipinski
I guess that's up for me. This is Mike Lipinski. Before I answer your question, Steven, I'm going to answer a question that wasn't, I guess, specifically asked. Well, it was maybe even by you. But I wanted to offer a piece of clarity that I forgot to do when I was giving my presentation. Why I talked about how we refocused the HIN definition, I want to be clear to everyone it is still a functional definition. There are no particular entities precluded from being able to meet the HIN definition. So, a plan or a provider, if it does everything that we've listed there in the HIN definition then, they would be a HIN. So, I want to make that clear.

But generally speaking, we haven't said like the HIPAA statute and regulations do that say a clearinghouse is a covered entity, a health plan is a covered entity. We are not doing that. But I want you just to be aware that there is still a functional definition.

So, now back to your question. Notes are identified in the USCDI. There are, I think, eight types. If a covered actor – excuse me. I won't call them covered actors. An actor, which would be a healthcare provider, if they had them electronically available in the EHI format and they can be provided through the patient portal or even through an API then, it's EHI. As I showed in my presentation, there are reasons why they may not provide it, right? There could be an exception that they meet. But, generally speaking, they are an actor. They have what would be EHI. So, then you go through the list in terms of whether or not they would be an information blocker and whether an exception could apply. To your main point of asking are notes in, yes. After 6 months if you have notes in electronic format, they would be subject to the EHI definition.

Elise Anthony
This is Elise. Just to add and I mentioned it earlier, I think I started and misspoke and said effective date and corrected it to publication date. Steven, you said it correctly. It's the publication date. But I do want to highlight that it's six months from publication date when information that Mike just described would be required to be made available.

Lauren Richie
Mike, can you mention how the content and manner apply there though?

Michael Lipinski
So, there are a couple of things there, right. If you were requested, you could reach an agreement on costs and if there is a need for a license to get access to that EHI, including the notes. Maybe that is not even necessary, right. Or if you are the requester, you are not going to agree to the terms yourself. You don't want to pay anything for it. So, if they're technically able to, you would drop down to alternative manner,

which is certified health IT. So, a lot of the providers you were aware of have certified view download transmit functionality. If they have VDT functionality and they have the notes in electronic format and that is how the requester is fine with getting them then, that should happen.

Steven Lane
Thank you. That's very helpful.

Michael Lipinski
All right. Great.

Steven Lane
I may have time to slip in one more question for you, Mike, and I really appreciate it.

Carolyn Petersen
No. I'm sorry.

Steven Lane
No, I don't? Okay. I wrote them down.

Carolyn Petersen
No. We're going to Arien's question and we will go to public comment.

Arien Malec
Thank you, Mike. I think this is going to be for you as well. But I have a hard time parsing the between and among standard for exchange and the enable to exchange with each other standard for HIE/HIN and, I guess, more than two are sort of the operative words. In figuring out what dividing line is between an entity that is primarily engaged in doing work on behalf of one party to get information to another party that I'm understanding would not be an HIE/HIN and any that would be enabled to exchange more than one to enable exchange that's between and among more than one party. And I wonder whether if you can help sort of folks who are thinking about this parse through where the operative dividing line would be between an entity of one type that would not be considered HIE/HIN and an entity of the other type that would be considered an HIE/HIN.

Michael Lipinski
So, Arien, I probably even had a little trouble following you. Where were you coming with the between and among?

Arien Malec
Between and among is in the definition of exchange. And the commentary in the preamble, as I read it, kind of looked at both of the definitions of the enable to exchange and then, the definition of exchange as implying between and among. But just that notion of enable to exchange with each other, if you can help me understand what the -- I'm just trying to figure out what is an HIE/HIN and what's not just sort of conceptually so then, maybe we can figure out where the rule applies.

Michael Lipinski
So, without specific -- we were clear in the rule that we weren't going to, specifically, carve out certain entities. We did give a couple of examples of ones we didn't think no longer would meet the definition, such

as I think it was social networking or internet service providers I think was an example off the top of my head.

Arien Malec
We have some entities that are clearly on one side and then, I think there are some entities that are clearly on the other side. And I'm having a hard time kind of painting the line with the language of what is the operative definition where that line gets painted that allows me to clearly divide up entities on one side or the other of that line.

Michael Lipinski
For us, it was the ability of like if you were thinking of it if you had a straight line and I was passing the data through – so, we will try to do a pictorial representation of this verbally. So, if I was on one end and I was passing it through, which "the entity that may or may not be the HIN". And then, they're doing something with data or maybe just providing infrastructure for you to get data to the other entity, whether it's a reporting agency or the government of some sort. That wouldn't be – even if there were like six nodes or seven or hundreds on the one end and there could be one or two on the other end or even hundreds on the other end that wouldn't matter.

For clarity, it wouldn't matter how many nodes are on either end of this. Obviously, you need the three as a basis when we start to get to the HIN definition. What is important is entities on either said are able to exchange with each other. So, if you had all of those providers on one end on one end and all they're doing is funneling their information through to one other entity that would not be a HIN. But if they were able to exchange with each other through the services or the agreement of that entity in the middle then, that would be a HIN as long as there were three of them, right, and it was for payment treatment and operations and meets all of the other parts of the definition. But right now, I think we're just trying to focus on who is exchanging or at least has discussion to exchange.

And then, on the other end, it would be not necessarily -- they should be able to also exchange with the parties on the other end indiscriminately if they so choose. So, it's really about providing the ability for everybody on the whatever you want to call it, either through the agreement or the technological services to be able to exchange information with each other. They don't necessarily have to be doing it but have to have a discussion to be able to do it and to be enabled to do it. Not sure if that is helping you.

Arien Malec
It maybe is. It might be useful having a set of for instances or some FAQs in this area. Yeah. That just would help by way of illustration. I really appreciate your clarification.

Donald Rucker
Yeah. Arien, it is Don Rucker here. Part of what we wanted to do here is not have folks who are, essentially, doing, for want of a better word, clearinghouse functions who are not really distributing it in sort of a classic network sense. For them to not be covered under this concept. That is sort of a hard thing to define. So, this was an effort to define it.

Arien Malec
Understood. Thank you. I really appreciate that.

Carolyn Petersen

Great. Thanks, everyone. I am going to open it up for public comment now. If the operator could please open the line and let us know if we have anyone in the queue.

Operator
Yes, thank you. If you would like to make a public comment, please press star 1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press star 2 if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your headset before pressing star keys. There is no one in the queue at this time.

Carolyn Petersen
Okay. Thank you, operator. Given that we are closing in on the end of our meeting, I will just give you a brief update where things are at with the COVID-19 action by HITAC. We've had some discussion behind the scenes, and we are interested in going forward with some further action dedicated, specifically, to that. We ask a couple of things. First, that you would send Robert and me any comments or questions or topics of interest that you have related to COVID-19 by the close of business or whatever time you wrap up your day on Friday. I will collate all that and send all of that feedback out to the full HITAC membership. As with the Annual Report, we will be completely transparent about all of that. This is just the way that we can move forward in as quick of a fashion as possible. I will be working with ONC with the goal of getting either a call or some kind of a task force thing set up for next week.

In your response, please let us know if you favor a one-time call or you're thinking about something that continues for a longer period like a task force or working group. We will do our best to get something set up for next week. Robert and I will keep you in the loop about that. We do have some federal guidelines about the kinds of notice that has to be given but will be looking into what we can do as expediently as possible. With that, I will pass the mic to Robert for his final comments.

Steven Lane
Carolyn looks like there are public comments trying to come on if you look in the chat.

Robert Wah
I was going to say I think there is a public comment in the queue. Why don't we go ahead and, operator, we can take the public comments?

Operator
Thank you. Our first public comment is from Michael Peters from the American College of Radiology. Please proceed.

Michael Peters
Hi. This is Mike Peters from ACR. This is a question that, hopefully, you can respond to with clarification. The enforcement discretion for info blocking will be exercised until OIG promulgates the enforcement rule. But where this is talked about in the rule is where it applies to CMPs for developers. What isn't clear is if this enforcement discretion also applies to investigation and implementation of provider disincentives. Could someone please clarify?

Robert Wah
I can mention, I guess, clarify to you that there are no provider disincentives at this time. So, to be compliant with the statute, the secretary must identify those disincentives through a notice in comment rulemaking and that has not occurred.

Carolyn Petersen
Thank you. Can we go on to the next comment in the queue, please?

Operator
Our next comment is from Kate DesRoches with Open Notes. Please proceed.

Kate DesRoches
My first question I think was already answered, which is what disincentives are in place ensure that healthcare providers are providing access to patients, specifically, to their notes given that we think that among all of the new data elements that are required, notes are the thing that is going to be a stumbling block for a lot of providers. So, I'm wondering what the plan is for clarifying what those disincentives are. That is my first comment.

Second, I was wondering if there are any plans to move beyond something like a simple attestation to ensure that notes are being rolled out within organizations in a way that is robust and, actually, leads to patients using the notes. We've learned over the years that simply flipping the switch within Epic or Cerner is not enough to ensure that patients know that the information is there and know it is valuable for them to use it. I'd urge you to think hard about developing measures that ensure that patients are actually able to use those notes in a way that is simple and easy for them.

The third is I have looked through the rule. And I am still a little confused about what will ONC's response be to complaints against providers that are submitted by individuals that are saying my provider is not making my clinical notes available to me. I'm wondering what the response from ONC will be. I know that, for vendors and tech developers, there is a financial disincentive but I didn't see that there was anything in there for providers. So, I'm wondering what ONC is thinking about that. Thank you.

Robert Wah
Thank you for that. Due to the interest of time, we will probably move on. Steven, I know you have your hand up. We won't have time to take another comment at this point. I apologize. I recognize that our schedule was way too packed for adequate time for discussion and questions. We always try to accommodate as much as we can. In this particular case, we were not as successful as we have been.

You have already heard Carolyn describe the plan that we have for COVID-19. Please get your comments by email to us. We are trying to be as responsive as we can in this area. I hope you recognize it is a very dynamic situation. We have some federal guidelines that we have to pay attention to in doing this. We work with you and ONC to get this accomplished for you. Again, we always appreciate your time and attention and talent in our deliberations. We continue to ask for your commentary to us as your chairs to make this process better. Again, thank you for your patience and consideration. With that, I will turn it over to ONC for their final comments.

Lauren Richie
Is Don still on? Does he have any final comments?

Donald Rucker
No. I am on. I just want to thank folks. We will look through some of the comments that were made online and try to figure out how to incorporate those. But I thank everybody and I look forward to getting people's thoughts on the HIT parts of the virus strategy.

Lauren Richie
Okay. Thank you. Our next meeting is April 15th, HITAC meeting. We also have a condition of certification and certification of maintenance public webinar on March 19th. The next ICAD meeting is March 24. And just a reminder to everybody, just go to healthIT.gov for more information on upcoming meetings for HITAC. Thanks, everybody. Carolyn?

Carolyn Petersen
I have nothing else. Thank you, again, for your participation today. And HITAC members, please, please send Robert and me your comments regarding the health IT part of COVID response by end of the day Friday. We will collate that and get it out to you and update you about the next meeting, workgroup, or steps. Thank you.

Robert Wah
Thanks, everyone.