National Committee on Vital and Health Statistics Subcommittee on Standards Hearing on Request for NCVHS Review of CAQH CORE Operating Rules for Federal Adoption

Transcript

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VIRTUAL

SPEAKERS

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Alexandra Goss	**Imprado/DynaVet Solutions**	**Co-Chair**
Richard W. Landen	**Individual**	**Co-Chair**
Rebecca Hines	**NCHS**	**Executive Secretary**
Debra Strickland	Conduent	Member
Denise Chrysler	University of Michigan School of Public Health	Member
Denise E. Love	Individual	Member
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James J. Cimino	University of Alabama at Birmingham	Member
Jamie Ferguson	Kaiser Permanente	Member
Margaret A. Skurka	Indiana University Northwest and Principal, MAS, Inc	Member
Melissa M. Goldstein	The George Washington University	Member
Nicholas L. Coussoule	BlueCross BlueShield of Tennessee	Member
Tammy Feenstra Banks	Providence St. Joseph Health	Member
Valerie Watzlaf	University of Pittsburgh	Member
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Name	**Organization**	**Role**
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Presenters		
Name	**Organization**	**Role**
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Sherry Wilson	Cooperative Exchange	Past Chair and Board of the Cooperative Exchange
Hans Buitendijk	EHRA	Chair
Arthur Roosa	HBMA	CEO, SyMed Corporation
Terry Cunningham	AHA	Director of Administrative Simplification Policy
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Robert Tennant	MGMA	Director, HIT Policy
Noam Nahary	Montefiore Medical	Senior Director Health Service Receivables
Stephen Rosenthal	Montefiore Medical	Senior Vice President, Population Health Management
Margaret Schuler	Ohio Health	System Vice President of Revenue Cycle
Gail Kocher	BCBSA	Director off National Standards
Cathy Plattner	Kaiser Permanente	Business Consulting Specialist
Christol Green	Anthem	E-Solutions Portfolio Manager

Welcome, Call to Order

Rebecca Hines: Good morning to members and team and members of the public to day 2 of the National Committee on Vital and Health Statistics NCVHS Meeting of the Subcommittee on Standards. I hope everyone is staying safe and well.

My name is Rebecca Hines. I serve as the executive secretary and designated federal official for the committee. And we, as I said, are on the second day of this two-day hearing regarding the request for the review of CAQH COREs, three proposed operating rules for federal adoption. Today, we will be focusing on the connectivity role.

So let's take care of roll call. You all know what to do. I will start off with our co-chairs, Alix Goss.

Alix Goss: Good morning. My name is Alix Goss. I work at Imprado, the consulting division of DynaVet Solutions. I am a co-chair of the Standard Subcommittee and of the review committee, a member of the executive committee, member of the full committee. And I have no official conflicts, although I will, for perception purposes, acknowledge my role on a national level with the FHIR, Fast Healthcare Interoperability Related Initiatives.

Rich Landen: Good morning. Rich Landen, Standards Subcommittee co-chair, member of the full committee, member of the review committee. And no conflicts.

Debra Strickland: Hi. I am Deb Strickland from Conduit. I am a member of the full committee, member of the Standard Subcommittee, and I have no conflicts.

Denise Love: Denise Love, independent public health data consultant and member of the full committee, member of the Standards Subcommittee, and member of the Privacy Subcommittee. No conflicts.

Jamie Ferguson: Good morning. Jamie Ferguson, Kaiser Permanente, member of the Full Committee, member of the Subcommittee on Standards. No conflicts. However, I would note that we will a presenter today from Kaiser Permanent. So to avoid the possible appearance of conflicts, I will recuse myself from specific discussions with Kaiser Permanente.

Rebecca Hines: Thank you for that clarification. Jim?

Jim Cimino: Jim Cimino. Professor of medicine, director of the Informatics Institute, University of Alabama at Birmingham. I am a member of the Standards Subcommittee and the Full Committee. And I have no conflicts.

Nick Coussoule: Nick Coussoule, BlueCross BlueShield of Tennessee. Member of the Full Committee, the Executive Committee, Standards Subcommittee, and the Privacy Security Subcommittee. And I have no conflicts.

Tammy Banks: Tammy Banks, vice president of Medical Care Strategy, value-based care with Providence St. Joseph, member of the Full Committee and member of the Subcommittee on Standards. I have no conflicts, but just for the matter of perception, I do work with the ONC FAST and Da Vinci efforts.

Vickie Mays: Good morning. Vickie Mays, University of California Los Angeles. I am a member of the Review Committee of Standards. I am a member of the Privacy Confidentiality and Security and a member of the Full Committee and I have no conflicts.

Margaret Skurka: My name is Margaret Skurka. I am a Professor Emerita at Indiana University. I am a member of the Full Committee. I serve on the Subcommittee on Standards and I have no conflicts.

Wu Xu: Wu Xu, retired Public Health State Officials. A member of Full Committee, no conflicts.

Rebecca Hines: Did I call on every member who is here today? I believe so, but please say. All right. Let's move to you, Lorraine.

Lorraine Doo: Lorraine Doo with the Health Informatics and Interoperability Group in the office of Burden Reduction at CMS and lead staff to the Standard Subcommittee.

Rebecca Hines: I just also want to acknowledge we have Marietta Squire and Geneva Cashaw, who are committee management team members with us today. And I believe that takes care of the opening business. Just to note, we do have a public comment period this afternoon. We never know if we are going to be running on schedule. So if you are definitely interested in making a comment, please keep your eyes and ears glued after 1 p.m. and if we have to make any adjustments if we are running ahead or a little behind. So with that, I will turn it over to our chairs, Rich and Alix.

Welcome and Review Agenda

Alix Goss: Good morning. I am going to kick us off this morning based on some coordination with Rich. We are excited to have you back for day 2. It was a really terrific day 1. Lots of great commentary, robust discussion and response to our subcommittee members, questions of our panelists.

Yesterday, our approach was to have each of our presenters deliver seven minutes of high-level remarks synthesizing their written testimony. Then we had subcommittee members provide Q and A facilitation with the panels. And then we round-robined, as time permitted, with additional questions. And ultimately leading us to wrap it around 5 o'clock yesterday.

Some strong themes were really evolved throughout the day, and Rich summarized those at the end of day 1. And that gives us a good starting point for the subcommittee's next planning meeting, where we will start to advance the feedback. But we will also be taking into account today's testimony.

And please note that in addition to these two days of public remarks, we have also received extensive written testimony. And all of that information is available on our NCVHS website for this meeting event. So you can all take a look at the thoughtful well-prepared remarks from your industry colleagues that are available on that website page.

Today's focus on operating rules pivots from prior authorization to the conversation related to connectivity. And we will have a similar approach where we will have panels. We are going to reverse the order, so those who went last yesterday will start first today. And so we will be kicking off with the vendor perspective at 10:15 or once we finish up these remarks. And then

we will have at 11 o'clock, the provider perspective followed by lunch. And then returning at 1 p.m. for the health plan perspective on the proposed connectivity operating role.

As Rebecca noted, we will have time for public comment currently slated. Although, potentially to adjust on the exact time. But at 1:25, I would love to hear from anybody who would like to make public comments. We will then wrap up with some closing remarks and thoughts about next steps. And then adjourn. We suspect likely earlier than the 3 o'clock slated timeframe. But we are scheduled to go until that point. 3 o'clock eastern, I should note.

So if there are any questions from the members, please let me know. Otherwise, what I would propose, while you are thinking about your questions, is that we continue to put the patient at the center of our conversation to think about these operating rules in regards to the larger ecosystem and the balancing act that we have heard is pretty challenging for the industry with so many competing demands. But also the ability for us to tease out the value propositions from all of our testifiers on these extensively developed operating roles.

With that little framing, I will open it up again for questions.

Rich Landen: I think that summarized it and I think we are ready to dive in.

Alix Goss: I think we are. Last I checked, we had at least two of our panelists for the first clearinghouse vendor. I wanted to see -- yes, I see Hans and Paul have also joined us with Sherry and Arthur. And for this panel, Deb Strickland and Tammy Banks will be facilitating our Q&A portion after we receive the testimony and remarks. We can get started a little bit earlier, giving us a little bit more breathing room in Q&A. So without further ado, I believe we could be ready for our first presenter in the first panel of the day.

Vendor Perspective on Proposed Connectivity Operating Rule

Paul Joiner: You can go to the last slide. I am just going to pick up where I left off yesterday. But explicitly with the connectivity rules, and my comments are going to be short because I am going to be pretty supportive. In general, we at Availity also have participation in the connectivity.

There is an ongoing group around, I think, schedule for a vote with CORE in early September around a connectivity version 4 which enhances the sophistication of the operating rule or of the other version 4 which includes an expanse to include higher security. It supports an authentication, authorization methods. It supports the rest in more API frameworks, and it includes the attachments.

So in line with our comments yesterday around the authorization rule, we think we would definitely be supportive in the sense that as long as any recommendation with HHS considers timing and is collaborative like with the X12 comments and some of the payor and provider comments with their organizations around interoperability and the 275 transaction.

With alignment with those timelines and within reasonable commitment to a timeline of making it reasonable for various health plans and other organizations to adopt the rule that we would recommend waiting for the version 4 to come out from CORE, incorporate into any recommendation, to make sure that it is advanced technologies as possible and advanced security frameworks are available for the role and for the recommendation to HHS. So that is

where our general overall on the connectivity and infrastructure rules, that's our feedback and comments.

And then the last thing, I just want to make one comment in relation to yesterday and some discussion around authorizations and as it relates to up times and things like that. I do think that the up time component should be withheld. But I also think we need to take long consideration around some of the smaller health plans.

I think some of the testimony yesterday hit on this. Not everybody has the same resourcing. So putting the right prioritization of what we have to go work on and what order, and doing that with resources or organizations with less resources is important. Especially as various pressures come into the market and different threats of enforcement will modify behaviors too. So I think sequencing of what is put in what order out into the marketplace, and what enforcement communication is put out there is important. I think there needs to be enforcement.

But I think doing it with the right intention to get the right outcomes and that the right technologies are put into place and asked to be invested in in the right order is important because we need clinical connectivity to improve the authorization process. And we need the right security frameworks as well. So our comments are with the right alignment and timing and waiting for the version 4, we would be supportive of the connectivity rules. That is all I have in relation to that topic.

Alix Goss: Thank you. I think we are going to move on now to Sherry.

Sherry Wilson: Good morning. I am Sherry Wilson, past chair and board member of the Cooperative Exchange representing the National Clearinghouse Association, executive vice president and chief compliance officer of Jopari Solutions. And again, we would like to thank you for the opportunity to present testimony today on behalf of the Cooperative Exchange membership concerning the proposed connectivity rules.

The value of the proposed operating rules, we do find they solved the existing challenges of multiple safe harbor connectivity rules by proposing a single and uniform safe harbor connectivity rules. So we think this is going to be a value to the industry with this approach.

As Paul mentioned, we have four concerns we wanted to bring up this morning to cover. And one that Paul has already addressed that the CORE connectivity and security workgroup is actively working on this rewrite of the connectivity rule. And again, our recommendation is that the industry wait for these 2028 CORE connectivity operating rules and come back after they are written to revisit it at that time, to mitigate unnecessary industry implementation (inaudible). So we concur that we wait until these come out before rules are adopted.

We also just want to address that there are existing industry connectivity framework with the National Institute of Standard and Technology. The HIPAA Security and HITECH rules cite National Institute of Standards and Technology, NIST, as the authoritative industry source, not the operating rule authoring entity.

And also, we found the connectivity rules created outside or divorced from the NIST standard guide specifications can create confusion and disparity in the health care EDI standard deployment. So we do have a concern around that and looking at alignment --

The third concern that we have is previous recommendations have not been addressed. The proposed operating rules for connectivity only allows stakeholders one option for authentication on the 509 digital certificate. We also have the concern this limits limiting authentication to only one solution does not provide flexibility to meet different stakeholder business needs. This is really critical. It may even impede EDI adoption.

And then going back to what we talked about yesterday, for prior testimonies by multiple organizations, again the cost of implementing a 509 certificate will be passed on to providers. It won't merely be a shift in the cost in creating additional administrative burden for stakeholders to be able to comply with these operating rules.

And the fourth component that we want to make a note of here is we know connectivity rules limit the inclusion of new and emerging technologies such as RESTful APIs, OAuth authorization and identity services that addresses many of the business issues that propose connectivity rules. Again, we feel that these will be addressed in the new proposed connectivity rules. So we are looking forward to seeing those being addressed.

Just to reiterate, we want to talk about the cost and resources of implementing the proposed connectivity rules. At this point, we see no perceived benefits versus cost and required resource requirement. Again, we see we would be required to implement and support a rule regardless of the usage or current solution. And again, the cost being current of the industry for development and testing. And that aligns with our recommendations.

So we, at this point, do not support the federal adoption of connectivity of the operating rules as proposed. And again, we propose that the industry wait for the new operating rule rewrite. It should be expected by the end of 2020. Again, revisiting any industry concerns as we look at these new operating rules. And we strongly recommend that connectivity operating rules should align with existing HIPAA and HITECH standard regulations that are referenced in the NIST security guidelines.

With that, thank you for the opportunity to testify on behalf of the National Clearinghouse Association.

Hans Buitendijk: Good morning. This is Hans Buitendijk, chair of Electronic Health Record Association. Picking up where we left off yesterday. So we will jump to a couple of slides.

The first one will be slide number 5, I think, on your sequence, so that there are one or two more. Generally, as in the context of yesterday, just to briefly summarize, EHRs are not the primary interactors with the transactions. It is typically done by other systems behind it from a flow perspective, from initiating the prior authorization all the way through to the payor and then back. And so it will be one or two steps further down in the chain where that interaction would occur.

So from that perspective, again there are aspects that we are looking at others to see whether they are sufficient and adequate to increase the value proposition to move forward with these and improve those steps. So looking at connectivity, overall what we see in that current proposal that there is increased focus on secure transactions, that there are steps being taken to fill those requirements. But certainly appreciate the comments made earlier, that next versions would align further with technologies that at least some of those are going to also align closer with what EHRs are starting to use for more interactions with other systems.

But we do not have a specific recommendation to wait for it or not. We primarily look at others to do that. So if you go two or three slides down. In that regard, we really defer to others where it has the opportunity to improve existing processes. But for that last connection and start to have the ability to connect to EHR, bigger steps are needed to enable that.

So when we go to the last slide where we talked about most of that yesterday. And now in context of connectivity, that data transport/access technologies and standards alignment where the technologies used in the administrative financial transaction space and in the clinical space where we are getting connections between those types of systems closer, alignment of technology standards that are consistent, that concepts are defined as the same.

So we don't need to do translations where we really don't need to and make that more efficient, less ambiguous, would be appropriate. And those are all longer-term steps that would be passed this version of the proposed operating rules. And we recognize that is not strictly in the scope of it. But at the same point in time, from the EHR perspective, we are not suggesting that this should not stop or should move forward in its current state.

I think the parties that are directly impacted and involved with that to enhance that part of the exchange are most appropriate to our position to determine is that worth it at this point in time or not. And that is where I will stop remarks for today. And then any comments or questions that you have for me, I am happy to address those.

Alix Goss: Thank you, Hans. It looks like we are over to Arthur now.

Arthur Roosa: Good morning. I am Arthur Roosa. I am representing the Healthcare Business Management Association and CEO of SyMed Corporation.

For anybody that was not here yesterday, HBMA is the National Organization that represents Revenue Cycle Management Companies. And we have clients or members that submit millions of claims per year to smaller companies that submit in the hundreds of thousands. But about a third of the medical billing companies in the country are members.

So we are mostly in support of this operating rule. And we think it has significant savings in terms of the consistent and reliable formatting for data interchange. I think addressing one of the issues that I have heard recently is the fact that although I believe that vendors will pass along the development cost to providers, those development costs drop significantly over time as there would become a consistent way of communicating with different payors.

Currently those costs are passed along at any rate each time that a different type of transmittal or connection has to be designed for a particular payor. And that cost will drop over time. Those costs are not passed along on a payor by payor situation. It is not as if somebody gets an invoice that says that this is for that. But it is a cost that software vendors experience, and those costs will drop with a more uniform rule.

Certainly, the fact that the rule enforces a common envelope does, in fact, help this. As noted on the slide, that the connectivity rule does create that unifying direction. And therefore, it moves us a long to a situation where we are transmitting -- in terms of the connection, consistently with all payors.

We do appreciate the fact that this is an agnostic design. And again, further supported. But we have the same issues as noted yesterday that this will depend on the smaller payors. The larger

payors will implement. Smaller payors may not have the resources to do so or do not have the particular will or motivation to do so.

So in keeping the comments short, the previous speakers this morning have talked about security. We had pointed out in our written comments that we were somewhat surprised that this rule supported SSL. But I was not aware, and we were not aware of, and perhaps we should have been, about the rewrite of rules coming at the end of this year. And perhaps I would add my voice to say that we should wait until that happens before adopting this rule and perhaps this rule will need to be modified based on that.

The enforcement of issues continues to be a concern with the HBMA as the HBMA members interface with a very large number and perhaps even all of the health care payors in the country. We do run into this issue of relatively small payors. When I say small payors, this is small payors nationally. Although a payor could have a significant footprint in a particular market. And therefore, for members that are working within that market or having clients within that market, it is a significant problem. So there needs to be some though into how, if the operating rule is adopted, how it would be enforced.

And also, again timing is an issue. These are relatively busy times. And I had mentioned yesterday in terms of the operating rules for prior authorization, being out two to two and a half years, I would certainly see that this would be a rule that you would want to implement prior to that.

But the timing would be an issue. For our particular industry, we would be looking at probably four to six months. But that probably is not something that would be that short of a timeframe would not be common across the health care industry, I would imagine.

So the primary takeaways, again, the security issue and that may be resolved with a wait until C4 and aligning the rule with that. And then the primary issue of a stronger enforcement once these rules, in fact, are adopted.

And the third recommendation there, was just from a membership standpoint in terms of are members reading the rule and trying to understand it. That the connectivity rule was technical. And for those of us that have that ability or have that inhouse, it is not a problem before most of our members wading through the operation rules for connectivity would be a difficult thing to do. And perhaps something that would accompany it that would be less technical and written for that kind of audience would be useful. And those are my comments.

Debra Strickland: Thank you very much everyone for all of your thoughtful comments. So I have a question. I understand that we have version 4 that is pending, but my question, because we did not have the visibility to that or at least as a group, we did not have that in front of us. Can we safely say that version 4 will resolve all the issues of vulnerability and all the other things that folks are concerned about with the current connectivity rule for those of you who were aware of that new version?

Sherry Wilson: I don't think we can or I can actually conclude that until we actually see what those rules would be. I think that there is definitely -- CORE is aware of that. I think that is why they are leaning towards this direction to rewrite them. They have been very good about getting industry input. So I am very hopeful that it will.

But I think that again our concern is a redundancy and making sure that it does align with an existing standards or framework that we have to comply with, so there is not redundancy. That is really important. We have initiatives with ONC on the Trusted Framework with NIST. The Digital Identify Guidelines with the SP 800-63 series that are coming out that people are complying with, as those are the most current and best practice standards.

So I think we need to make sure we are aligned, mitigate the costs to our industry as we are already moving forward to implement some of these criteria. So there is concern about that. So I think until we actually see what comes out of it, I would hold my comment.

Paul Joiner: From Availity perspective, we have representation in a drafting and are hopeful that it will address a lot of the security and others, especially from the API frameworks questions outstanding out there. In terms of being definitive, I am kind of with Sherry, we have got to see it. But in general, we are very optimistic.

Debra Strickland: So as a follow-up to that, so is version 4 necessary? We have got these other trusted frameworks, and we have got NIST, and we have got these other things, what is the value that this adds to the plate? We have folks that have a lot of work, a lot of things that they have to do. This is just adding another thing to the plate.

Paul Joiner: I think it comes down to enforcement at that point in terms of -- Sherry, what would be your thoughts on that?

Sherry Wilson: I think the concern is that it would be redundant. It would incur additional administrative burden I think to stakeholders, especially from a clearinghouse perspective, where we maintain so many connectivity points and so many different products, different architect. And it had significant impact.

However, I do think the alignment with the national standards, and again, we have a Trusted Framework coming out. There is an opportunity, if they are able to align and coordinate, there could be benefits. But if we are trying to do additional standards on top of what we already are doing today, I think the cost value is not there. It can actually really impede our EDI adoption.

Paul Joiner: Yes. And the redundancy and the technical components of it would occur or would be accrued based off of enforcement meaning if you have to do something versus do you have to build out the framework to have the flexibility that you need to. So in our world, a lot of what has been discussed the last few days, we can react. We have a lot more flexibility in being able to react to various standards.

The issue is, is that health plans and providers have limited resources, and they need to have a clear pathway because they can't be implementing three or four different modes at once.

Sherry Wilson: Paul, just to add to that, I think again it goes back to being mandated, required to implement support regardless of the usage or other current solutions. And something again, that we kind of talked about the prior authorization yesterday, we implemented that and at a great cost with little utilization.

Also from a clearinghouse perspective, we did implement for phase 1 and 2, a lot of the connectivity rules. And what we found, if you Build it, will they come. And that is not necessarily been the case. And that is again one of our other concerns.

Debra Strickland: Agreed. Thank you very much. Tammy?

Tammy Banks: Before I ask that question, I am kind of missing something. Am I hearing that enforcement piece is what makes the CORE connectivity rule different than the NIST? Or is here a specific gap in the NIST security standards that the CAQH CORE connectivity rule fulfills. Can you help me understand that piece or has that research not been done

Sherry Wilson: Yes. It has. Tammy, I think with the new, that really came out in the last year, the NIST SPA 800-63 series on digital identity guidelines, and again, that is referenced with ONC and the Trusted Framework, that they have addressed those on an authentication, on security. And what is very good about that is they took in to different levels to stakeholder EDI readiness to be able to implement that. So they are flexible based on different stakeholder business needs, but still can comply with a framework of security and for connectivity.

And we all are going to be working towards, and a lot of us have already implemented these. And so they already are addressed within that framework.

Tammy Banks: Thank you. Anybody else have any comments? Otherwise, I will go into my question.

Alix Goss: I did. I just want to clarify because, Tammy, I was having the same sort of -- I was trying to link sort of Arthur's comments on enforcements with some of the other comments. And so I was really glad when you asked that question.

And it is nice to get the clarification from Sherry that there is a known redundancy that has already been figured out around these identity aspects. However, I am still trying to loop in how is the enforcement part. And I am wondering if maybe Arthur was getting at the smaller plans. We are going to ask someone to do something. And if you are really going to want to get the uptake and the consistency, the value from the squeeze, so to speak, you really need to have everybody ready to go at the same time.

And so I am inferring, but I need to be corrected here or validated, that Arthur was really speaking to this -- and maybe Paul, this aspect of if you are going to mandate something, please ensure we have the appropriate and robust enforcement programs that help ensure that people are doing the right thing, and that also produce that feedback loop to help us keep evolving lock step as a community.

Arthur Roosa: That is pretty much what I am saying. That, in fact, if you have got half the industry going someplace, and the other half is not, you really don't have the advantage of what you are trying to do by developing these rules. That it is necessary to have essentially the entire industry.

And you have the smaller payors, again, that may be it is a lack of resources or maybe it is simply that they can fly under the radar, that do not develop these things. And unless there is some sort of way to first encourage and then perhaps force that movement, you are not going to get the bang for the buck that you are looking for.

Paul Joiner: My comments on the enforcement piece were this and it is a nuanced point, which is I am assuming somewhere along the line here, you are going to have various bodies putting out various frameworks. But one is going to prevail with the voice of enforcement.

Whichever body that is needs to consider all the other frameworks and all the other messaging out there because whoever carries the enforcement will carry the budget and the investment stick, if you will, long-term. And that may not result to the best outcomes.

So if someone does have the capacity to enforce, they just need to be real thoughtful that these other frameworks or these other avenues and messages out there in that if you do it, just take into consideration those frameworks and be very clear and definitive about what the enforcement is and try to create as much flexibility as possible because you can't serve everyone at once. But make sure the most innovative rules and innovative tools are available to the industry, if you will.

Alix Goss: Help me understand a little bit here around the safe harbor aspects in these rules. So we are talking about enforcement a little bit. And Jamie, you may have a question here around safe harbor. But I am trying to tease out this.

We have got gaps. We have got potential redundancy. I am sorry, not gaps. We have got overlaps with potential redundancies is one thread. We have got this other thread with enforcement and get everybody on the same page.

So I want to kind of tease these out carefully to make sure that things aren't getting conflated within our thinking as we synthesize your testimony.

Arthur Roosa: I am not sure. Could you repeat the question?

Alix Goss: I am a little bit confused, so I need some help, folks. So I think we have got several threads here. And I want to separate them. We have got this conversation around some overlaps within this framework. Let's set that aside for a second and come back to it.

The thing I am trying to get at right now is this enforcement aspect that you have been talking about. And I think, Jamie, you may also be having similar thoughts about how does safe harbor fit in with trying to get to a robust level of security. But I realize the enforcement is from the federal perspective, but there are these carveouts with safe harbors. And I am not linking them well.

Paul Joiner: I think we are talking about a rule that would implement essentially a higher level of security. And yet at the same time, provide a safe harbor for the use of older technologies such as SSL which Arthur mentioned. And also the secure hash algorithm 1 which has actually be deprecated by ONC for EHR certification in favor of high levels of security.

And so I think the question is does the safe harbor effectively undo the enforcement that you are talking about on the higher levels or newer parts within NIST framework by allowing and effectively protecting the use of the older security technologies.

Arthur Roosa: I was suggesting that those older technologies be removed from the operating rule. Whether the safe harbor gets to a point where there is an agreement, an industry agreement, on this is at the lowest level of what everybody can expect to be able to connect and successfully exchange data at.

And that part of that has to be that the data exchange is secure. It would be a modification of the operating rule in that respect to remove the lower level security protocols.

Sherry Wilson: I would concur with you and Jamie with your comments regarding removing those again. The goal here is to get to the highest best practices on security. So I would concur with you, Arthur. And also, with Paul's comment, that there will be, out of all the different frameworks, so maybe come one is best practice industry standards.

And again at this time, when you look at we have to comply with OCR, with the HIPAA high-trust mandates around the NIST requirements, as well as ONC adopting the Trusted Framework and naming these NIST standards within that framework, that will be important regardless of what gets adopted that technology is moving quickly, there is emerging new solutions. You have to look at the cost of maintenance and updating these rules as they emerge.

And again, really keeping in mind the different levels of stakeholder EDI readiness. I think that is what is really important. And again, NIST has been very thoughtful being able to provide flexible solutions based on the different levels of business readiness.

Alix Goss: Thank you, Tammy, for letting me piggyback on your question, clarification. This is good. This is really helpful. It is starting to tease out these separate threads. There is a repeating theme from yesterday. We need a roadmap to sort of sequence our efforts, prioritize what is the bang for the buck, so that we can all appropriately allocate and budget, so we can get to the end game at the same time. But there are some evolving dynamics in the landscape. We need to think through as we synthesize.

Sherry Wilson: If I could just make one more comment. I do think, though, also we applaud CORE for looking at the rewrite. We anticipate or hope that they will look at alignment with these national standards and do some coordination efforts. So again, we appreciate that a lot of these concerns that they have addressed is in the roadmap. So we look forward to anticipation and seeing how those evolve.

Alix Goss: Thank you, Sherry. Tammy, back to you.

Tammy Banks: I have two questions. One is in regards to the safe harbor. Does it protect trading partners from having to implement lower levels of security type of exchange?

Arthur Roosa: As I read the concept, yes, it does. If we are looking at a rule set that says if you will connect at this particular level, whatever level the final rule may encompass. Then the implication, as far as I can see, and I don't know if this has to be codified, but the implication is that if you connect at a lower level, you are not going to guarantee connectivity at that point.

I don't read anything of anybody having a desire to say that some trading partner couldn't separately agree to connect at a lower security level. But just simply that a safe harbor level, it means that if you have developed code which connects at that level, then you are guaranteed that connection. Is that clear?

Tammy Banks: Very. Thank you. Does anybody also have any other comments? Okay. Then my second comment, if you don't mind, Deb, is for Hans. I recognize you represent the EHR Association, but could you give me a better lens.

When I think about connectivity, I think about provider payor rights, so practice management system and the payor or whatever type of administrative system. Can you talk about the touchpoints between the practice management system and the electronic medical record

system. Maybe two standalone, two different vendor companies. How would this connectivity rule impact that?

Hans Buitendijk: If the situation is where we have the clinical EHR in place for a health care organization, practice, hospital, whatever, and the revenue cycle, administrative financial capabilities are done by another system, then you typically will see between those two systems an exchange of data for ADTs, awareness of new visits, either direction whichever one is considered the master for a new encounter, visits, et cetera.

You will see from the clinical system data flowing back into that environments from a charge, financial coding, diagnostic, et cetera, perspective is necessary for claims. But then you see the other system, not the EHR, interacting with the payor either directly or by way of intermediaries, clearinghouses, to get that data.

And somewhere in that line is where the transaction is being transposed from whatever might be used. Sometimes there two in play. There are other things that might be in play, proprietary, whatever, that then gets transposed into the transactions and vice versa. That may be anywhere along the line, but it doesn't sit with the EHR.

So if you then look at the impact of these rules, it is that is really no direct impact on the EHRs or vice versa. I think it is going to be much more of an overall industry and connectivity to be able to create new workflow integration points and connectivity, and move forward with that, and have consistency and processes across the board. Otherwise that there is value in consistency on approach, process levels, security levels, identity providing, et cetera, patient matching.

So that all up and down the chain that we can have the same expectations about the data. So there is value to that. So increased alignment of what the connectivity rule does with auto standards and vice versa. It is always a question which one that is, should you use as the target. But the alignment is important. Not that they need at the same time, always the exact same. But that we see the same progression.

And particularly that we don't see a need to invest in one capability and then very quickly within a year or two, we need to switch. So again, for EHRs, not an immediate impact on what is happening with the proposed rules. It is more for the other parties that are directly engaged with them.

But the general principle of let's not invest in something that we know in a year or two needs to be changed, that we cannot build on top of what we are doing in the next one or two years or three years. In the relatively short term, is that worth it? And it may. But we are not going to be judging that at this point in time on this particular rule.

Tammy Banks: Thanks for that helpful comment.

Alix Goss: To that noodling, I really liked how Hans said sort of this expectation alignment up and down the chain. And he really broke it out into a major set of category, systems, workflow, security, transport, those kinds of aspects. And so we think about some of this feedback that we are getting, so some aspects of disconnects that may exist between what ONC and NIST may be advancing, and then sort of what we are challenged, what we are seeing in some of these operating rules.

So there is an opportunity to start to help bring clarify because I think, heaven help us if we start down a path of wanting to really intersect and converge clinical administrative data and the frameworks. That is going to have a direct impact on all those categories of alignment that Hans said. That is really big.

That takes yesterday's conversation about kind of the balancing act to a whole other level. Because it really starts to speak about these very large threads having to be woven together into a fabric that provides us with a national framework and a trajectory, so that we can continue to invest, to digitize, to capture the data and the workflows, and ultimately bring value in the end to our patients and their outcomes.

And so I think one of the things why I am elevating this point from Hans is we have been talking as a subcommittee about our upcoming vergence project. And I just think his thoughts really fit in with some of those aspects and some of the balancing act that we are going to need to consider our deliberations.

Paul Joiner: And as a clearinghouse, this is Paul with Availity, to support what you are saying as a clearinghouse and as a portal provider. We provide provider portals for health plans to move to a more integrated experience that what you just described is going to have to occur increasingly over time.

Because otherwise, you are going to hit various standards are going to bump up or various progressions of adoptions along the value chain are going to be disconnected, and it is going to force people out of the integrated process to portals or to pick up the phone.

Sherry Wilson: I concur with Paul's comments. I mean, it is creating confusion, disparity and just our health care EDI deployment even now because we are still trying to address all these. So I think you are spot on with your comment that we do need integrated framework to bring clarity to the industry.

Arthur Roosa: My comment is you are touching on an essential problem with the health care system itself. That there are multiple different places and multiple different protocols that we have to deal with. And it is not coordinated and not very well integrated. And so there is a need to create that integration.

But as I see it as a fundamental issue with health care in this nation, I suspect that will be a different thing to do. But I don't think that we should shy away from attempting to do that.

Paul Joiner: You can't wait for everything to line up. So you have to line up as much as you can and go.

Alix Goss: So I appreciate the commentary affirming just how tough of a balancing act we are going to have. But the great thing is, is that this is not the last bite of the apple, and we are all in it together. So Tammy, really thoughtful question there that you asked.

Did you have another questions?

Tammy Banks: That is enough to think about for me. I am still pondering this.

Alix Goss: Are there other questions because we do have a few more minutes within this panel allotment? Okay. What I would propose, folks, is that we could go ahead and start queuing up our next panel which is the provider perspective.

Our presenters today are Terry Cunningham, Heather McComas, Robert Tennant, Noam, and Margaret Skurka from Ohio Health. So I believe Jamie and Nick, you are on the docket for this section. Welcome back.

Provider Perspective on Proposed Connectivity Operating Rule

Terry Cunningham: This is Terry Cunningham once again. Nice to speak with you again. Thank you for the opportunity to comment on this operating rule, the CAQH connectivity rule.

So I will go through a bit of the current landscape. I will go over the value of the proposed connectivity rule. And I will identify an opportunity that this rule could have gone further to address an additional issue. And I will keep my comments brief.

The current landscape, or at least the current situation with the existing safe harbor rules is that safe harbor, which we all know is a concept that enables vendors, providers and health plan security knowing that other parties support their connectivity method. It is established by transaction. And that is an issue for our industry.

Each transaction permits different safe harbor concepts. And these are all, as I think the term was used in the previous slide, these are connectivities of payload agnostic idea. And we should be on the same page across the transactions.

Another issue is that the current connectivity rules allow outdated, less secure authentication methods. Example, this is the basic username plus password. This has been shown to be a less secure method of securing originating connectivity.

And pretty straightforward, how do these operating rules, what is the benefit of these operating rules? It improves security. It utilizes the X509 digital certificate based on authentication. Like I said, username, password, and other older methods that are permissible in some of the operating rules are just that. They are outdated. They are less secure. And especially as we get into transactions, we are going to be carrying patient information, it is extremely important that we do have digitally-secure --

The next benefit of this operating rule is that it streamlines the safe harbor methodology. As I just went through on the previous slide, this operating rule enable the safe harbor concept to apply across transactions. And it would eliminate problematic possibility for variances.

And this was touched on by Hans and several others both yesterday and earlier today. But one thing that the operating rule did not cover, and I think it was a shortcoming of the operating rule, is it doesn't increase the system availability requirements. The system availability requirements are only at 86 percent of the time in order to be compliant.

Again, a point I made on a prior discussion yesterday, but health care is a 24/7 industry. So to allow a system to be down for 14 percent of the work of the week is inadequate and doesn't meet the industry need.

So in closing the HA recommends the adoption of the connectivity operating rule in order to improve security and streamline safe harbor across the transactions. And with that, I will turn it over to the next speaker.

Heather McComas: I am Heather McComas from the American Medical Association. AMA represents physician =s across the country and medical specialties.

As with all of our position-taking at the AMA, we base it on policy created by our house, delegates. And in this case, we looked at policy related to information technologies, standards. And I am not going to read this whole policy.

But actually, the gist is a point that I think is very salient. And I actually can't take credit for it. Terry Cunningham who just spoke, and many of you are that he used to work with the AMA, and he came into my office one day and he said, you know, for physicians and other health care professionals, all these electronic transactions, the revenue cycle work, it is not their main job. We are different than other stakeholders.

A physician's main job is providing care. And certainly, these transactions are very important. We need them, so that physicians can get paid. That is obviously critical particularly during a pandemic when physicians and other health care workers are risking their lives and our families' lives to take care of people.

But this is all ancillary to their main work. Many of our members have reminded me time and time again that they didn't go to medical school to do prior authorization. So this is not their main business. So the gist of our policy is basically physicians want their technology to be easy and seamless and behind the scenes, effortless and secure.

They really don't want to have to spend a lot of time or financial resources on it. They just want it to support their main work of taking care of patients. And so we see in our policy, we support interoperability, and standardization and systems to get that interoperability. Security is very important. Physicians take the role as stewards of patient's health care information very seriously. So it is very important that all transactions and systems are secure.

But costs are also very important to our members. Unlike a lot of the other organizations testifying today that represent multi-million dollar companies, and a lot of our physician members are 10 doc shops or smaller. Some of them are sole practitioners. They don't have millions of dollars to spend on technology. So they need solutions that are affordable and easy to implement.

The AMA participated in the development of the CAQH CORE connective rule. And we do support its federal adoption because we think it will improve interoperability, efficiency, and security in electronic health care transactions.

And we support the rule's adoption because we see some key points of value. First of all, as others have noted, the rule does create a single set of connectivity specifications across transactions. To me, this just makes sense sort of thing. It makes sense that you would have a single set of requirements across all kinds of transactions because connectivity is payload agnostic.

It is not about the content of the transaction. It is just about how systems are connecting. It reduces burden and complexity by creating a single safe harbor across transactions. and we just think it is a logical change that will improve interoperability in health care transactions.

We also would note that the connectivity rule does remove the vulnerable username and password authentication option and requires support of the more secure client certificate-based method of authentication. And this aligns with best practices and information technology and will increase security which we think is really important.

And the final point that I would like to really hit hard on is we see this as a very important steppingstone in progressing to a future version of the connectivity requirements. A lot of folks this morning have been talking about, let's wait for the next version. It is in process. And it will be done soon.

And I really encourage the subcommittee to look at this more closely and perhaps even reach out to CORE to get clarity on their plans for moving forward and recommending adoption of that future iteration of the rule. Our understanding is that although that rulemaking for the next version of the connectivity requirements is in process, that it will not be put forward for federal adoption immediately. There will be an intermediary period.

And we think that this rule that is under consideration right now is a really important step in between what we have now, the different phases that are kind of all over the place. We are getting all the transactions harmonized under one set of requirements. And then moving to this very advanced and more sophisticated set of requirements that get into APIs and the rest. We think this is a really important step to take.

As the provider representatives indicated yesterday, our experience is that vendors do not build out things or implement them without a federal mandate. And our concern is that without a mandate, vendors are not going to update until we get to that future set of requirements if we don't mandate this current set of requirements.

And that would represent a huge implementation lift which would no doubt translate into a much costly for physician practices. So again, we see this as an important step to go in the progress of the future state of the connectivity rules.

Another point I think that is important too, and I think it is a little bit of a nuanced point is that it is very important to get the full value of this rule that it is adopted in exactly the way that CAQH CORE outlined in the recommendation. If you just pick up the PDF rule itself, the what it applies to section does not really align with what the recommendation is.

It is important that everyone understand that the rule is intended to replace the existing connectivity requirements for phase 1 and phase 2 of the already mandated rules, eligibility claims status and electronic remittance device would fall under the new connectivity requirements in this rule. So all the transactions will be harmonized under this rule.

It would all have the same set of requirements. If that is not clear in the rulemaking, it is going to cause mass confusion. There are going to be different safe harbors. But if it is done the way that CORE has recommended, it will have this alignment and efficiency across the transactions.

And then I am going to pick up the thread that Terry brought up in his presentation regarding concerns about system availability requirements. We see system availability to be very much

under the same umbrella as the connectivity requirements. Like the other elements of connectivity, they are payload agnostic. And we feel that it makes sense to put system availability under this broader connectivity rule structure that would be consistent across transactions.

Right now, the existing system availability requirements and the CORE rules are in the infrastructure rules which would enable them to defer between transactions which doesn't make any sense. And as Terry pointed out, the existing system availability requirements are very insufficient. They allow for almost 24 hours of down time per week which is just unconscionable.

And as Terry said, health care is a 24/7 business. I am reminded of this on Sunday mornings when I run by Northshore Hospital on Evanston before 7 a.m. And I see that lien of cars waiting to turn left into the hospital parking lot. People in scrubs, now they have masks on. They are going to work. And I am reminded, it is not the weakened for those people. And the patients that are in the hospital or going to the hospital that day are very glad that those people are going to work.

So we need our IT systems to support this 24/7 business and allowing for that much down time is just not viable in this environments if the intake person at the hospital is checking eligibility, they need it to be available on Sunday. If the urgent care clinic, they need to support an urgent PA which, as we said yesterday, needs to be approved in 24 hours. That needs to have that prior authorization, system availability, on a Sunday evening or any other time of the day or night.

So we would really urge NCVHS to recommend that future versions of connectivity requirements include system availability. Other industries, such as banking and finance, say that anything less than 99.9 percent system availability is incompatible with supporting vital business functions. And I realize that money is important. But at the end of the day, I hope that we all agree that human health is more important than money. And it is wholly unacceptable that we are tolerating such low system availability requirements in health care right now.

So for recommendations, we do really urge NCVHS to recommend federal adoption of the connectivity rule that is under consideration right now. We think it is an important step to take at this time to get us to a future, more sophisticated set of rules. We need this kind of intermediate process to get us there in a way that makes sense and is financially viable for everybody in industry.

We also again urge NCVHS to be completely care about how these requirements should replace existing connectivity requirements for eligibility claim status and electronic remittance advice. And then we again urge NCVHS to push for system availability requirements to be addressed in future iterations of connectivity rules, and that these requirements be at least 95 percent system availability.

And then finally, we also would urge NCVHS and everyone in industry to kind of work together on these issues looking at connectivity requirements. We have noticed that other standards organizations are having requirements and addressing TLS versions and that sort of thing. And it is important for all of our organizations to be kind of mutually surveying each other and collaborating with each other, so we don't have disparate requirements being set and different sets of rules and such. That is all I have. Thank you.

Rob Tennant: This is Rob Tennant. I am director of HIT policy for the Medical Group Management Association. It is a pleasure to join you again today to talk about these rules.

For those that weren't here yesterday, MGMA is a trade association representing than 58,000 practice leaders in all types of medical practices, everything from very small single specialty practices all the way up to the largest multi-specialty institutions in the nation.

In talking about the connectivity rule, I think one of the things that we are very supportive of is, and you have heard this theme, I think, this morning, is making sure that there is consistency with the mandated transaction. So the 270, 271, 276, 835, and now with the 278. We will have alignment on the connectivity side. I think that is going to be critical.

Also, these new rules would build off existing infrastructure for real-time and batch for these transactions. And of course, the 278 assuming those rules get implemented as well.

Obviously, you have heard a lot about the benefits of moving from the existing connectivity standards to the more updated ones including enhanced interoperability and efficiency, security, improved messaging and error reporting, improve commonality. But really the question is how will these be implemented. I think you got a sense from Hans that practices are very dependent on their EHR and practice management system vendors.

Of course, as Heather alluded to, physicians didn't go to school to learn how to implement these rules. So they are heavily dependent on their vendors. And like all of these rules, implementation, when they are accomplished by the larger vendors tend to go better than the smaller vendors. So we have some concerns about the ability of these very small vendors to implement these and other operating rules. And without the support from the vendors, of course, the providers can't gain the advantage of these rules.

But really the question that we asked ourselves, and has been debated here this morning, is should we delay these rules for the next version. And we are kind of torn on that issue. We really believe that version 4 is probably more robust. We will probably do a better job of aligning, as Sherry said, to existing security standards.

But what we are concerned about is if we say we are going to wait, wait, wait another year, two or three years. So I think what we would like to see is a little more outreach to CAQH CORE to find out what their schedule is, how quickly can they move forward with version 4. Because if it does solve the problems that have been raised this morning, it may be worth waiting a short period.

But certainly, we don't want to delay things too much. I think we would encourage NCVHS to reach out to CORE to find out more to see if the rule can be expeditated because there may be ways to incorporate some of the key elements that are missing from version 3. And make sure that the new standard meets the needs of the industry.

So one of the things we have also heard is it is going to be a challenge for the industry to implement these rules. So we would encourage NCVHS to consider recommending a full 24 months for covered entities to implement these rules. I think that is sufficient time to get things done. And if you shorten that timeframe, I think it could have a detrimental financial impact on organizations.

So in summary, we are very supportive of the move forward to enhanced connectivity standards. But again, we would encourage the committee to reach out to CORE. If feasible, I think version 4 is the way to go. But again, we cannot hold off on the other operating rules waiting for the future version of the connectivity rules. So if we are looking at a year or longer, I think as Heather said, we can move incrementally to version 3 and then move to version 4 down the road. Thanks so much and look forward to the questions.

Noam Nahary: Thanks again for the invitation and opportunity to speak with you today. For the record, my name is Noam Nahary. I am the senior director of health service receivables at Montefiore Health System.

As noted yesterday, Montefiore Health System is compromised of 10 hospitals including the Children's Hospital of Montefiore, Burke Rehabilitation Center, Albert Einstein College of Medicine, and close to 200 outpatient care sites. Montefiore Health System has been engaged with CORE since its inception. It has benefited significantly from the operating rules.

I personally have served as the Rules Workgroup co-chair for many years. And our proprietary systems are, of course, certified for eligibility, claim status, and benefits. The CORE process for developing the rules are comprehensive, collaborative, and consensus based. Many types of organizations including a substantial market share of health plans, providers, clearinghouses and vendors contribute to rule development.

Individuals engaged represent business, clinical, technical, and leadership areas from these organizations. CORE always goes the extra mile to consider and incorporate all stakeholder feedback to maximize usability and benefits of the operating rules.

Again, I will note in more detail about the benefits the proposed CORE connectivity rule version C3.1.0 is included in our comment letter, but touch on a few highlights today. Montefiore fully supports the proposal from CORE to federally mandate version C3, 4, HIPAA mandated eligibility, claim status, ERA and prior authorization transactions.

For a bit of history, in the early 2010s, NCVHS recommended and HHS ultimately adopted a federal mandate for connectivity operating rules to support the HIPAA transactions. Recognizing the value of a connectivity safe harbor, that entities could be assured would be supported if requested. But that also allowed other methods if training partners agreed.

CAQH CORE Connectivity version C.1.1.0 is still federally mandated for eligibility, and version C2.2.0 is mandated for eligibility, claim status, and ERA. But initially developed more than 10 years ago, these rules represented cutting edge security and connectivity protocols. However, technology has advanced since that time.

The primary benefits of the version C3 connectivity rule over prior versions are reduced complexity, enhanced security protocols and improved error reporting. Compared to the current state, version C3 will reduce complexity by moving to a single standard augmented security using certificate-based authentication instead of username and password. And improve the communication.

Second and equally significant benefit of mandating version C3 for eligibility claim status and ERA transactions, in addition to prior authorization, is that it will ensure consistent best practice connectivity safe harbor across administrative transactions that can be updated over time.

A single mandated connectivity rule with improved security and network authentication would enable Montefiore to use a single common connectivity method across all EDI transactions, trading partners and health plans. Onboarding will be reduced for weeks to just days as the specifications are normative and used the latest authentication standards.

Again, Montefiore has no major concerns about the adoption of the version C3 connectivity rule. Without a federal mandate, you are concerned the industry will be forced to continue to support multiple outdated connectivity methods, leading providers no option but to connect with trading partners based on their preference for any variety of methods. The federal mandate will accelerate industry adoption beyond early implementers by making investment dollars and resources available for compliance and enable a single industry safe harbor which will introduce cost.

Our second concern relates to the lagging enforcement of the HIPAA administrative simplification provisions. HHS never adopted a health plan certification program for standards. And operating rules as specified in the Affordable Care Act.

So enforcement of the HIPAA provision relies on complaint-driven processes. Montefiore is concerned that even if this rule is federally mandated, limited enforcement may reduce adoption.

To leave you with two takeaways today is that the adoption of the version C3 connectivity rule for eligibility, claims status, ERA and prior authorization will eliminate wasted industry resources supporting multiple connective models across trader partners. In addition, a single connectivity safe harbor across transactions will be easier to update, reduce confusion, and promote industry alignment on the best practices.

Thank you again for your time today. And I encourage NCVHS to recommend a proposed rule set to HHS for federal mandate. Thank you.

Alix Goss: Thank you, Noam. I believe we are up with our next and final panelist in the provider perspective, Margaret.

Margaret Schuler: This is Margaret Schuler. I am the Assistant Vice President of Revenue Cycle at Ohio Health. And again, thank you today for involving us in this hearing.

I have with me Krishna Tummalapalli. He is our enterprise architect. So if the committee has very detailed security questions, I brought him along to answer your questions should you want to ask him any questions.

I want to jump to slide 3. I am going to be brief. My comments are in alignment with Terry, Heather, Rob and Noam. We are supportive of the proposed connectivity operating rule as it is outlined by CAQH CORE.

For the industry, we also agree that this supports best practice interoperability protocols from a single standard and enhanced security perspective. Just to highlight second bullet, again, many of my colleagues have already pointed this out. It is client certificate base authentication removed security vulnerability, username and password resulting in more robust security aligned with industry standards.

Also, with the connectivity rule, moving the ERA, the claim status, eligibility and prior auth, all to the same standards simplify connections. And I think we are all in agreement. When you are on different versions of anything, it adds to confusion and complexity. And so bringing all of the administrative transactions up to the same standard, again, we are very supportive of this.

For Ohio Health specifically, again we are supportive of security. When dealing with PHI, patient information, it is of the utmost imperative to be at the highest level of security. So again, supporting that.

Also, we believe this will drive efficiencies as we, I think, all mentioned today, and connecting with our partners.

Adoption timeline and enforcement, we have talked about this. Typically, HIPAA-covered entities have two years to comply with the standard. Again, very worried, just like yesterday we talked about we are compromising on two days for turnaround time. We should be talking hours.

Same thing with the adoption of these standards. Unfortunately, we are talking years instead of months. So I just want to give a shoutout to us to push the industry to start talking months instead of years on adoption.

The second bullet, Noam already touched on. So again, we need more enforcement around this.

The prioritization resources for implementation are federal mandate. We are supportive of, again, we all need to play -- I used this analogy yesterday in the same sandbox. If we don't mandate it, people are less apt to comply. So we are in agreement with the federal mandate.

And we are dependent on our clearinghouses and our vendor partners in this space. So again, a federal mandate, we find that when it is federally mandated, it goes to the top of the priority list.

Alignment with other industry initiatives, can we continue to talk about there are many, many other industry initiatives around standardization of connectivity. But we can't wait. 3.1.0 would be an incremental improvement. Waiting for 4.0 again is going to lengthen the opportunity for standardization.

I also would like the committee, I concur with my counterparts, I continue to reach out to CAQH CORE to understand their timeline around 4.0 and that roadmap. But 3.1.0, again we can't wait. And this gets us to that common baseline. So when 4.0 is ready, we can easily again move to 4.0.

A final slide just a few comments again for consideration, we do need a single updated connectivity safe harbor standard. Again, this will enhance security for the industry. And a federal mandate really is necessary to move this up on the priority chain.

So those are my comments. Thank you.

Jamie Ferguson: Thank you all very much. I really appreciate it. I will kick off the questions.

We have heard a lot from you about the value of the connectivity rule as an interim step or a stepping stone, even though a new rule is expected potentially in a single digit number of months. But I wanted to ask in that context about the cost and resource allocations for implementing this connectivity rule.

Whether that presents a material burden, especially when you consider the potential burden for serial implementation of a soon following rule as a priority given the public health emergency that we are in. And all the other rulemaking implementations that are going on simultaneously. That is a question for all of the panelists.

Terry Cunningham: I think the key that makes me leery of holding off to the future is that we have seen this play out before. Rules in our industry are often not released on their time schedule. I guess my concern is right now, we know there might be another rule ready at the end of this year. We don't know exactly what it is going to look like. We don't know if there is going to be additional enhancements.

So I would agree with Rob. If CORE can commit to releasing something later this year, and there is something we can adopt at a sooner time frame, then that is one thing. My concern is if we put off on taking any action at this time, and then the industry just festers and not having this enhanced security and some of the benefits of this rule because we are waiting for a rule that may not come for considerable time. I hear your concern --

Jamie Ferguson: Just to clarify my question. We have heard several presenters call for at least 24 months of reimplementation of this connectivity rule. And yet, we are talking about a connectivity rule version 4 that, by all accounts, would come out considerably before that 24-month timeframe, possibly as soon as this year. And so we are talking about now sort of overlapping serial implementations.

Terry Cunningham: I think my comment still holds true in that I have been told that an attachment rule could be coming out any month for five years. I don't know. I am a little concerned with anything that -- there is going to be something coming because I have seen that play out before. If something does come, then yes, I certainly don't think as an industry we want cereal implementations and slowing down, getting in the way of the everyday business providing health care. But at the same time, there are benefits to this rule. And we want to make sure they do get into place sooner rather than later.

Nick Coussoule: Can I ask one more piece to Jamie's question? The practical reality is serial implementations are always going to happen, right? And part of the question is what kind of timeframe between them and how simple are they to get there.

So one of the other things I would ask the panelist to consider in answer to that is getting to one standard certainly makes an upgrade in the future easier than now if you are going for multiple. How big a difference does that make and is the one we would be recommending if we recommend this now sufficient in your mind to allow for that next step without waiting.

Terry Cunningham: My point is I think that is a question you really have to ask CORE. So I really do think you have to reach out to CORE. Is this going to be an easy step to the next version? I don't know enough about the next version. It is not yet developed. So if 4.0 is going to be an easy step, great. If it is not, it is something we can consider. But I think it looks like others are looking to jump in. Again, I think one would (audio breaks up).

Rob Tennant: It is important for us to look at the entire timeline because we are talking here in August. These rules are not going to be implemented in September. We are looking at months probably for NCVHS to come out with its recommendation. And then months later perhaps, CMS will come out with its proposed rule.

At that point, there is another two to three months public comment period. So to Jamie's point, if we implement a rule that is already outdated, there is the two-year implementation period. So now, we are talking probably four to five years before we move to what could be the more appropriate version of the standard.

So I think what I am suggesting is let's find out what the process is from CORE. Let's find out the differences between 3.1 and 4 and make the decision based on the timing. Because unfortunately, we have got more time than we think we do because the process is so slow.

Alix Goss: So if I could chime in here a little bit building on Rob's thought process. Some of us may recall that his superpower is reading the federal register. And he lives very much in the administrative procedures timelines and appreciates the fact that -- and I really want to build upon what you are saying here, Rob, in the sense of we are going to a recommendation.

So let's say best case scenario. That is approved at the November meeting as Rich indicated yesterday. That means that we then send off a letter. So let's say that it lands January 1st for simplicity sake.

So if we take January 1st recommendations land in the federal government, the application unit advances the policy development and then will release a notice of proposed rule-making. Let's be realistic. That could take two years until we get an actual NPRM out.

At that point then, we would then have that 60-day comment period. And then it goes back into the process of the federal government to synthesize the input and to produce a final rule. So I think your four to five years sketch out was spot on.

And in that process, I also want to indicate that while we have all been discussing or having this set of comments be made, there has been background work to clarify getting CORE to come back this afternoon to help us get a little bit more perspective while we are all still gathered. So we are working on that in parallel to your testimony. Thank you, April, for being so responsive.

I think understanding what CORE is going to do on their timeline with their connectivity rules to go from version C3 to version C4 is going to be really critical. But even if we all think that it is worthwhile to wait, there is still not a one size fits all solution we have to approach here. There is some flexibility because they could recommend or speak to C3 and C4 and get industry to weigh tin on that. And that might be able to be overlapped.

So that is sort of the nits and the nats that we need to consider. But we will hear more from CORE this afternoon on what they have planned and in the works for C4.

Rob Tennant: Just to add one more wild card, Alix. There is an election coming in November. And there is a potential administrative change. That probably, at a minimum, will add more time because they are not going to come into office and immediately begin issue regulations that they are unfamiliar with.

So we would potentially have a new CMS administrator, a new HHS secretary. So I think your timeline might even be extended further.

Alix Goss: Well, that is why I gave the two years to get a proposed rule out because that was a wild card. I think we have to be realistic. That may not be the only curveball that we receive because it is 2020, and there has been lots of them this year. So I want to yield the floor back to Jamie and Nick who I think are running --

Jamie Ferguson: I want to get back to our presenters. I think, Heather, it looked like you were about to make a comment.

Heather McComas: First of all, I am very happy to hear it sounds like April is coming back this afternoon because I think we are all speculating what is CORE's plan and let CORE speak for CORE, right? Because I think that is a clarification that we need.

And I totally agree with Alix's point. I think you could do it post facto, but I think it is really helpful for everyone on the subcommittee to hear it at once and everyone on the phone listening remotely to hear it once. I think that is really a great thing.

I also want to say, I think Nick alluded to this, I just want to point out again I think this interim step is valuable and important. It builds that important initial platform or getting all the transactions on the same set of requirements. And it is going to be much easier than to do this job to the next version, which is a big jump.

I mean, we are looking at REST and APIs and a lot more sophisticated requirements than are in the current rule that we are considering. So this is a good base to build on. And I just am concerned that if you are talking -- I mean, if we wait, it is going to be things from phase 1, you are going to be theoretically a huge leap there.

And so I really think it is important to kind of get all the transactions on a same level. And then we can kind of build up to the next version there. And again, I think the clarity from CORE on the plan would be helpful. And I am glad to hear that is happening this afternoon.

Jamie Ferguson: Thank you very much. Let me turn to our other presenters, Noam and Margaret, just to ask if you have any comments or responses to this question.

Noam Nahary: I just want to reiterate or just share some of the thoughts is that it is important to bring existing transactions that are on previous levels up to a more appropriate, more secure level. And then harmonization across the different transaction will reduce cause for providers and sort of establishing a connection, being able to manage one set of standards as opposed to multiple set of standards will really benefit us in terms of the cost associated with connectivity.

Margaret Schuler: This is Margaret. Alix, I like how you laid out the timeline. And I have concerns if we wait for 4.0, is at that seven years from now? And again, I think hearing from CAQH CORE this afternoon is going to help bring some visibility to the timeline.

Just supportive of that of not waiting because there are so many variables. And again, if we do 4.0, we are going to have to go through this entire cycle again with a hearing and public comment, et cetera. So I think it is just kind of pushing out. And we have all outlined there are benefits to version 3 for all of us.

Jamie Ferguson: I want to take the line of questioning in a different direction back to something that was discussed on the prior panel today. And it is about the effect of the not authentication, but the other security requirements in the safe harbor which could have the effect of mandating a trading partner to support older security methods such as SSL or the secure hash algorithm, one SHA-1 which could be deemed to be lacking appropriate security or to expose the trading partner to well-known cyber vulnerabilities.

And so are there adequate protections or what recourse do trading partners have in that case? And again, that is a question for all of the panelists.

Rob Tennant: I think in the last five years or so, I think our members have really been focused on security far more than before. I think if you think of this security rule went into effect in 2005. But because of hackers and ransomware and malware, I think the issue has come to the forefront.

I think we are more aware of the challenges. So I think to your point, if we mandate a rule that has some soft spots in it, we run the risk of impacting PHI. Sol I think one of the questions we can ask April is what does 4.0 do in regard to this safe harbor. And what additional protections are in place with the new version that are not in place with version 3.

Heather McComas: I will admit that I pulled up a two-page cheat sheet here. But I believe that we are talking about the transport security requirement. And I am looking at this. And it says that it requires SSL 3.0 or optionally TLS 1.1 or higher entities that must also be FIPS 140-2 compliant or that requires stronger transport security may implement TLS 1.1 or higher in lieu of SSLs. So I see your point, but I think that the rule is pointing to TLS and even higher versions of it required. So I feel like that does kind of address that concern.

Jamie Ferguson: Just to clarify the question perhaps a little bit. Just under the HIPAA security requirements for covered entities. You have to do, of course, a HIPAA security analysis and review. And it has been reported that many entities have found that SSL to not provide adequate security. So that is really the basis of the question.

Terry Cunningham: I was just going to say I think reiterate what Heather had indicated. In the event that you do have somebody who is identified that for their system, the SSL is an insufficient security method. They would have presumably moved onto a more secure method. And it seems like the rule considered that and permits this enhanced security to move forward without requiring them to the old SSL method.

Nick Coussoule: At the risk of sounding more like a panelist and a committee member, I know we have spent a lot of time trying to eliminate a lot of these older protocols that aren't as secure in our environments, whether it be SHA-1 or the TLS.

And one of the challenges I would see is does the rule as structured and written still permit some of the older models that aren't as secure such that a company like mine would actually have to go in and reimplement something we purposely got rid of to change the security profile. And is that kind of thinking process a consideration, or do you believe that it actually forces a movement towards a more secure model?

Jamie Ferguson: Okay. Well, thank you very much for your responses to that. Nick, do you have any other questions for the panelists in this round?

Nick Coussoule: I think I am good for right now, Jamie, if we have other committee members that have additional questions.

Alix Goss: There was something that Rob said maybe about 20 minutes ago that I want to pick up on because it is actually a theme from many moons ago, Rob, where we have talked about the gaps in the definition of a covered entity, and how that undermines the stitching everything together and making sure everybody is on the same page by not having vendors necessarily in the mix as a covered entity as we do with providers, payors, and clearinghouses.

And so I thought when I heard your remarks, I thought about some of our earlier events, maybe five years ago even with the review committee, on sort of the retrospective considerations of what has undermined our success. And the lack of ubiquitous definition who is a covered entity to make sure we are all playing by the same rules was a theme back then. And so could you give me your thoughts or any of the other panelists on whether they also think that the definition of a covered entity might be a barrier in today's landscape related to vendor.

Rob Tennant: No. It has been a thorny issue for many years as you alluded to, Alix. The challenge for providers in particular is they are heavily reliant on their vendors for compliance which is the reason why clearinghouses missed because they are unable to move data directly to the health plan.

So I think when we are talking about the standards, and they are mandated on covered entities, the fact that the vendor is not required to adhere to the standards. Now, providers may try to incorporate that into their vendor contracts. But in many case, it really depends on the market power of the provider. So a large institution, maybe like Noam's, has a little more clout in their ability to require security protocols in their contracts. Small practices simply do not.

And frankly, they are not really aware of these issues, as Heather said earlier. They are not security experts. They don't know all the protocols. They rely heavily on their vendor to tell them what to do. So I am not sure we are going to see a change in HHS policy. But it is something, I think, the NCVHS might consider in its recommendation letter.

Alix Goss: Or it could also for me, I am thinking about sort of that intersection conversation. And I think that your comments earlier, as well as Hans' comments, about how we kind of tie everything together more effectively as we look towards EHRs and practice management systems being much more effective. And handling clinical and administrative processes is something for us to consider.

Does anybody else have thoughts on this covered entity definition and the implications of vendors?

Margaret Schuler: This is Margaret. I concur with Rob. And when you allow others to have exceptions, again it adds costs. So you can't take advantage of all the standards. So I agree. It is one of those ankle biter items out there. And we always have exceptions now. Well, they are not a covered entity or they are a covered entity. So wherever we can eliminate that variable, that would be helpful.

Terry Cunningham: I would concur in that it is important that whoever is going to be conducting these transactions are required to follow the rules. You would have to talk to HHS, the legal team at HHS, as to whether that needs to be clarification of business associate agreements.

Whether it needs to be -- I can't say specifically as to how the law gets properly situated to cover.

Alix Goss: That is the rub.

Terry Cunningham: I think the intention of these rules is that those who are required to do these processes follow the rules. That is why they included who was anticipated. I don't think the regulatory intent or the legislative intent of the HIPAA regulations, was to allow these exceptions for people to not follow the rules. So whatever may or may not need to be done to ensure that they are brought under the umbrella of required to comply should be considered.

Rob Tennant: If I can add one more point. There is sort of two ways to require or to have vendors meet certain requirements. One is to mandate them. And clearly, that is not one of the arrows that we have in our quiver.

The other is to certify, to allow market forces to play out. And I think what has been disappointing for us is ONC. And they have been very aggressive in a lot of technology issues. But they have been solely focused on the clinical side of health care.

So they have an EHR certification program. They have an EHR reporting program to give providers more information about the capabilities of the software. All of that is fantastic.

But they have shown apparently no interest on the other side of the coin which is administrative transactions. And Hans said it earlier, he said, listen, these transactions are not run through the EHR. They are run through the PM. And so that is another angle here for us to take.

We are not going to get a federal mandate any time soon on these vendors. But if we had a certification process, then that would give a little more assurance to the end user, the provider that the vendor, to Terry's point, was adhering to the standard. And they weren't trying to get around it.

Alix Goss: Good point. But we have got to find other levers than trying to fix congressional statutory language. We have to pick our mountains wisely. And sometimes to take the pass around is easier.

Jamie Ferguson: And just to clarify also, one of the reasons why I honed in on some of that transport security question was because of the ONC certification rules which require significantly higher levels of security than are allowed in this connectivity rule 3.1.

And so in terms of consistency between the different rule sets, the ONC certification program is already at SHA-2 minimum for example.

Krishna Tummalapalli: This is Krishna from Ohio Health. One quick comment piggybacking on what Jamie said. As a technician, when we evaluate products, I have to constantly see as, hey, is this clinical use case, or is it a non-clinical use case.

What I love about it is it is an industry-neutral standard. All the standards, security standards that are being proposed can work for health care and any other application. Because as a health care, we not only have health care specifications. We do have other (?) 1:52:21. So this is really going to help us to say that, yes, this is a common standard across. We had a common evaluation metrics across all the applications we evaluate. And they all need security standards.

Jamie Ferguson: Thank you. Are there any other questions from any of the subcommittee members or committee members on the line?

Heather McComas: Can I ask a question? I am sorry. I forgot. I didn't catch the name of the person who just spoke from Ohio Health. I think that is an interesting point. And I am wondering what you said made me think that if you are saying that you would be applying something across the board, if you had a higher level of security requirements on the clinical side, then that would automatically mean that that is what you are using for administrative transactions.

And so even this rule might have lower security level requirements, then it is required for clinical data by default since you need to have your clinical system on a higher level. But your whole enterprise would be on the higher level of security. Is that sort of what you are saying?

Krishna Tummalapalli: I can give you an example that you all can connect to. So today, if I want to exchange a payload between any other entity, in health care related transactions, we normally default to VPN. Okay. So let's set up a VPN and communicate through TCP.

Now, but this rule is now facilitating, enabling us to communicate through (indiscernible), HTTP, and also it is saying that by using TLS, I am providing, actually I am guaranteeing you the security on that. So now , all of a sudden, I don't have to start looking at VPN as an option for systems. There can be exchange health care information and just rely on the internet for systems that do not exchange health care information.

I have done that in the past because, yes, health care had a specific -- the securities were not the same with our VPN. But today, with this open framework, with TLS 1.2, I think they are good. It is equally secure.

I don't know, Heather. Does it help?

Jamie Ferguson: Thank you. Any other comments from our presenters? And if not, I think we can wrap up this panel about five minutes early. And Alix and Rebecca, back to you.

Alix Goss: I think we are actually able to give every one an additional five minutes for lunch if I am tracking correctly, Rebecca and Rich. We were targeted to return at 1 o'clock to hear the health plan perspective.

Rebecca Hines: That is a plan. Very good. See everybody here at 1.

Alix Goss: So subcommittee members, please also take a look at your email as we are going to try to probably do a round robin to hone in on a few questions we may want to ask later this afternoon.

Jim Cimino: Am I reading the schedule right? We were going to break at noon for lunch.

Rebecca Hines: Yes. It is noon.

(Break for Lunch)

Health Plan Perspective on Proposed Connectivity Operating Rule

Rebecca Hines: So we have our 1 p.m. panelists with us on the open line. So Alix and Rich, take it away when you are ready.

Alix Goss: I feel like I saw Rebecca talking. Were you talking to us, Rebecca?

Rebecca Hines: Yes. So we have our panelists all set to go there on the open line. And whenever you and rich are ready, take it away.

Rich Landen: I am just looking to see how many of our subcommittee people we have got. And it looks like we are good enough to go.

Let's get started with the afternoon panel, the Health Plan Perspective on Connectivity Operating Rule starting off with Gail Kocher from Blue Cross Blue Shield Association, then Cathy Plattner from Kaiser Premontane. And finally, Christol Green from Anthem, and Denise and Margaret will be the subcommittee members who will be handling the questions after the presentations.

Gail, are you ready to go?

Gail Kocher: Again, thank you, members of the subcommittee, for the invitation to speak with you all this afternoon. I am Gail Kocher, director of National Standards for Blue Cross Blue Shield Association.

And just for the record, and for those that may not have been here yesterday, we are a national federation of 36 independent community based and locally operated Blue Cross and Blue Shield companies or plans that collectively provide health care coverage for one in three Americans.

As we talked about yesterday, we do uphold the adoption of operating rules to support implementation of standards that are not supplementing things that are defined by standards, organizations. I think I need to go into the rest of that today. That was more around the piece from yesterday.

In terms of the connectivity rules, we do think there is value to moving to a set of connective requirements for all transactions that apply to all stakeholders. But those connectivity requirements must be sufficient and secure and align with other current industry and other federal security protocols.

We do have a few concerns, some of which you have probably likely already heard earlier today, about the proposed connectivity rule. First of all, plan to anticipate that the connectivity provisions which limit submit authentication to a single method of digital certificates is going to be costly to implement with little return on investment.

The total cost to implement will vary depending on submit or authentication methods, plans already implemented. And we do note that there is, of course, always the cost on the treating partner on the provider side as well. But what we find today is providers still continue to opt for login and password option from earlier phases of operating rules.

The connectivity rules safe harbor provision requires plans to implement the digital certificates even if no provider elects to use it or utilize it, which again creates implementation and resource

impacts, cost, et cetera for something that may never get used or not used as widely as one would like.

And oftentimes, if plans went to push trading partners to that, that can only be done through contractual obligations. And that is not something that we really want to have to do in order to move people to a more secure and better security and better single connectivity.

And while the rule indicates that it will apply across all the transactions for which there are mandated operating rules, there is also a provision that explicitly states that support for prior version C2.2.0 may not be discontinued which again requires supporting multiple methodologies.

So I think this afternoon, three points that we would like the NCVHS to consider as you deliberate over everything that you have heard aver the last couple of days, primarily plans have expressed concerns that the security protocols within this connectivity rule are outdated and considered insecure at the industry level.

Implementing these rules while having to maintain prior connectivity methods as related to safe harbor provisions and the provision I just talked about, as overhead investment with little return. Couple that with the concern around the security protocols that are again considered outdated.

And a requirement to implement this is concerning especially because we are talking about protected health information and exchanging that between our trading partners. And plans indicate that the cost to implement the connectivity requirements as being significant with little return due to again the need to maintain current connectivity method simultaneously.

We heard comments that the cost could be ass significant as implementing the prior phases, at least the phase one with eligibility and claim status. And that is the summary that I have for you all this afternoon. Thank you.

Denise Love: Thank you, Gail.

Cathy Plattner: Good afternoon. Again, my name is Cathy Plattner, business consulting specialist, international EDI business operations. I work for Kaiser Permanent. And just again, as a brief intro, Kaiser Permanente medical care program is the largest private integrated health care delivery system in the US, delivering health care to approximately 12.4 million members in the eight states and the District of Columbia.

I would like to start by addressing a question asked yesterday about a comment that we made on supporting the use of the HIPAA exception process. To clarify, we were expressing our strong support for the need to see an external entity such as Da Vinci to submit a request for HIPAA exception from the current regulations that mandate the use of the 278 for prior auth. So that the industry can implement end-to-end testing of an alternative standard such as HL7 prior to achieve prior auth.

So now onto our comments on the connectivity rule set. Overall, we think it does a good job of increasing the security of the transactions which we strongly support. Kaiser Permanente today is able to support with existing technologies.

However, we did raise two concerns, and I believe they are similar to what have been shared as well. The first one is that CORE proposes to replace old versions of the connectivity rule, 1.1.0 and 2.2.0. Covering transactions for which operating rules have been adopted, namely the payment, ERA, eligibility, claims status. And this new version retroactively to them, as well as get a new prior authorization and referral transaction.

The industry has already established the specific connectivity processes for those existing transactions. And it would need to move to the new connectivity operating room. So it will be important to ensure that the CORE lays out a clear roadmap, as well as a well-defined cost benefit and ROI for the entities required to transition to the new connectivity requirements.

The second one is we also have concerns about the safe harbor and the connectivity standards used in the rule. The connectivity rule attempts to strike balance between the use of SSL 3.0 and the use of newer DSL 1.1 or higher. Now, due to the well-publicized portal, vulnerability and SSL 3.0, this standard has been progressively phased out or rejected in lieu of the newer DSL standards.

So we have concern that if the SSL 3.0 is covered under the safe harbor, and trading partner insist on choosing the SSL transport standard, then entities will be expected to support it consistent with the rules safe harbor condition.

And for reference, the rule states that if the HIPAA covered entity or its agent do not believe that the CAQH CORE safe harbor is the best connectivity method for that particular trading partner, it may work with its trading partner to implement a different mutually agreeable connectivity method.

However, if the trading partner insists on using the CAQH CORE standard, the HIPAA covered entity or its agent must accommodate that request. Thank you. And that is our input on this connectivity rule set. Thank you.

Denise Love: Christol from Anthem is up next.

Christol Green: Good afternoon. I am Christol Green with Anthem. I am an electronic data exchange clinical medical records portfolio manager within our E-solutions Division.

A little bit about Anthem. We experience serving more than 79 million people here. And we also have 41 million within our own family health plans. So we do have a good perspective on how to cover and how to improve prior authorization. But I know we are talking about connectivity rules. Again, listening in today, I think a lot of us have some of the same concerns what Cathy just had spoke to with the SSL and the TSL newer versions. I totally agree, and we agree with that.

The proposed operating rules for connectivity again only allow stakeholders one option for digital certification authentication, the x509. We have concerns around that. We find limiting authentication to only one solution does not provide flexibility to meet our partners' needs. And it may result in additional impacts with our adoption with EDI.

We also, around the connectivity rule. It limits the inclusion of new emerging technologies. We heard much of this yesterday, such as FHIR, XML, RESTful Portal, OAuth and identify services. So that is another concern of ours.

We also, when evaluating the rules, had concerns again as others did with the safe harbor provision that would allow providers to elect a different connectivity methodology resulting in health plans having to maintain multiple methods. And Anthem recommends that the connectivity rule can only be adopted if it is adopted across all of the transactions for which operating rules are in place today.

We have concerns that there would be requirements to implement and support regardless of usage or solutions currently in place. So we do not agree with different transactions that may have different safe harbors.

With that, I think we are pretty much in line with some of the other comments. I don't want to keep reiterating what has been covered. So thank you very much for giving us time today to speak a little bit around the connectivity rule.

Denise Love: Thank you. This has been an education for me because I really don't live in the IT world. So I have learned more than I ever thought I could in the last few hours. So please forgive me if my questions seem a little clueless or whatever.

But what I am hearing, I will just start a question and Margaret will have others, and I may come back with another one. But I am hearing all these tradeoff issues versus moving incrementally. There is some pros and cons to that. Waiting for the newer rules to accommodate these new technologies.

So my question is each one of them has pros and cons and costs. But what is the cost of doing nothing? If we just do nothing and the new rule is way off in the future, what are the implications of that?

Gail Kocher: I think the cost of doing nothing is that we are status quo. So it means we are using the best security protocols that we can. But we have to adhere to the current rules.

So I don't think the concern isn't with wanting to be secure and wanting to do the right thing. The concern is having to implement something in order to be compliant that is outdated. And that technically would apply to some of what is happening today, I believe. I am not the security expert.

So I think if we do nothing, doing nothing may not be the right thing. But to do something just to do something doesn't mean that is the right approach either. If we are going to put money and implement, we need to make sure that the money and resources are implementing the right thing across all the stakeholders. That is my personal belief.

Denise Love: That was kind of part of the question. So in the interim with these new technologies, do you see an appetite for innovations voluntarily as the rest of the regulatory process catches up?

Christol Green: I do. I did hear Cathy speak a little to this, too. I mean, some of the work we are doing at Anthem, like I said, we are moving forward with electronic attachments. We are working with our X12 attachment just because providers have asked for that for quite some time.

But we are also working with the Da Vinci Project and some of their use cases which again emerging technologies. FHIR and end-to-end processing is something that we are truly a lot of

us are looking at to see if this is going to be a better use of our time in completing the transaction. Like we said from the patient to the provider to a payor and back completely instead of using the older technology. So yes, I think we are, and may others are looking at, the new technology and capabilities and starting to get involved in those technologies.

Denise Love: Thank you. Do you have anything to add?

Cathy Plattner: No. Basically, we are in agreement with Gail and Christol.

Denise Love: I will turn it over to Margaret for her question?

Margaret Skurka: I had a question. Could we ask Christol to repeat and elaborate a little bit on her list of tech barriers?

Alix Goss: Could I add in there a little bit, Margaret? Would that be okay? So Christol, you were starting to talk about the technology, limiting technology, and you spoke a little bit about it building on the earlier question. But you said a bunch of stuff like around OAuth and the different types of technologies.

And I think there is some interest in sort of trying to understand especially if you think about the horizon of the intersecting clinical administrative data, some of the commentary from Hans this morning. He listed off a bunch of stuff really quickly. And I just wanted to make sure that were, one, capturing your full list, and two, given you an opportunity to sort of talk about that a little bit more.

So the barriers and being willing to and wanting to innovate, take on new technologies, what that can do in the marketplace and care delivery. But sort of the challenges that you are facing, especially knowing that you have been very progressive in adopting the attachments reg. Especially if you can link anything into that conversation, I would be really interested.

Christol Green: Thanks. No, we were concerned about just having specific types of authentication and connectivity. We are using some other emerging technologies just like some of the other probably EHRs and providers and payors are using. So we just wanted to make sure that with these new emerging technologies such as FHIR, I will choose that one for now, that those are things we are looking at, those are things we are actually using today. And just speak to what we are saying using the X12.

I mean, we need to meet the providers to where they are at. And we do have providers to use the X12 278. But we definitely want to enhance the way we are working as I mentioned and be allowed to submit or be allowed to accept these transactions from our provider or EHR community for the provider to be able to do the end-to-end work. We just feel that limiting these rules are really around the X12 transaction. Gail had mentioned we feel that there may be better use of our money and working with some other technologies.

Margaret Skurka: I went back to my notes at lunch time to review what we did today. And the very first thing I wrote down was that we need to put the patient at the center of all of this. So do any of the three of you want to comment or refocus son how this benefits the patient?

Christol Green: I think I mentioned a little bit yesterday. We have a lot of web portal operations. We have providers being able to get on the web portal to do the prior authorizations 24 hours a day. They can check statuses and all of that.

But we are thinking that we would really like to include the patient in that to share that information through our member patient portals. So that is something that we are looking at. But anything we can do to help the process be a complete process I think is going to help our patients. I know a lot of times these patients are waiting quite a long time just to get the prior authorization completed.

And again, with our current state, I see it. And a lot of us see it as it comes in. A lot of it is manual. That is why we are including right now the X12 275 to assist with getting documentations quicker from the provider. But again, an end-to-end process and using things like FHIR and doing that process would really assist our patient community, our member community.

Gail Kocher: The one thing that I might add is that at the end of the day, all of this is ultimately for the patient to get the patient the information that the provider needs at the point of care as quickly as possible. So if we are expending time and effort and monies to implement things because we have to that aren't going to be used or aren't the most secure, and we are also trying to implement more secure methodologies at the same time, what we are doing is taking time and energy and resources away from focusing on the things that will make a difference in the overall process.

So I think Alix said it earlier today. It is about balancing these needs with the other things that are happening in the industry because there is a lot going on right now. And the more that we can approach them cohesively to ensure that resources are adequately being deployed all our stakeholders, that is when we are going to get the most benefit, I think. And the patient is going to get the right are at the right time with the information that the providers need.

Denise Love: I just wanted to, from my notes, this is kind of a lame question because I think you will all agree that enforcement comes up a lot. So whatever is done, do you agree that enforcement and effective enforcement is needed to bring the whole industry along where we need them to be?

Gail Kocher: I would hope that as stakeholders, that we all implement and we don’t need to have the hammer brought down. But enforcement, you are always going to have the outliers. But it has to be applied consistently. It has to apply to all stakeholders. It can't be just one out of the bunch, one group out of the various set.

Margaret Skurka: Does the rule permit willing partners to choose more advanced connectivity technologies? Is that maybe a necessary provision or maybe that should be explicitly included?

Gail Kocher: I think our interpretation would be that if it is not limiting, but you still have to implement what is in the rule. So some explicit provision that would accommodate something more secure and maybe not require you to implement something that is not going to be used would be helpful. But I think at the end of the day, CORE is the one that is going to have answer what that interpretation or what they believe the provisions actually say at that point.

Denise Love: So it is a floor, I mean, the minimum. And then we will find out if they support innovations.

Gail Kocher: I think CORE is the one that would have to answer that, Denise.

Alix Goss: So, Denise, maybe we -- and Margaret, we can take this question along with the other ones that we were identifying since we have invited CORE to come back and help us with a few Q and A. Rebecca and Rich, keep me honest here. I think we are doing that after public comment which we are slated to do now.

Denise Love: Thank you, Gail and Christol and Cathy.

Alix Goss: I think a big appreciation to all of our presenters is in order. It has been an insightful and interesting day. And so much so that we have got ourselves a little bit of a need for further clarifications as we have noted by inviting CORE back. But I think at this point, Rebecca, do you want to take us into the public comment official stage?

Public Comment

Rebecca Hines: Yes. So for members of the public attending either on Zoom by audio and video, or just by Zoom phone. Greg, would you please walk through the instructions for entering into the public comments space?

Greg Richards: If you would like to submit a written comment, you can do so by clicking the Q and * box at the bottom of your screen and then submitting a comment that way. Otherwise, if you would like to do a public comment with your voice, you can either raise your hand by pressing the participant's button at the bottom of your screen.

On the right-hand side, you will see a list of participants. And you should be able to see a blue right-hand button. Click that to raise your hand and we can call on you. If you are on your phone, you can press star 9 to request being unmuted.

If you do either of these steps, we will see that your hand is raised, and a moderator, likely myself, will call on you, and you will be unmuted in order to give your comments.

Rebecca Hines: You can also use the Q and A box like some folks did yesterday. We will see that as well. So whatever your preferred mode of communicating with a subcommittee, please go ahead and do that. So we have nothing in the email.

So now people are using the Q and A. So David Wilderman (ph.) asking the subcommittee, how does the Predictability Roadmap fit into your consideration of recommending these operating rules? You don't have to answer right now if you don't want, but it is a question for the subcommittee to provide some transparency on, if not now, in the near future.

Thank you, David. Do we have David? Could you type for the record your organization and title, please? I forgot to mention that. Thanks.

Alix Goss: So from a general perspective, I just would like to at least reference that we have had the predictability roadmap as part of our overarching thinking. Because it is part of that view that we take, not only for the value of the operating rules, but also the longer-term view that we take as a committee and a subcommittee, and the various considerations on how to achieve an overarching value from our administrative simplification related efforts.

So I do think that we will be factoring in the predictability roadmap lessons learned, specific recommendations that we have advanced to the secretary. But it is not the only part that we will consider as Rich sort of talked about some of our three-part evaluation criteria yesterday.

Understanding that we are obligated under the statute, sort of the roles of NCVHS, how it fits in with the efficiency objectives and overall value proposition.

But also what is that longer term view of the nation, where are we headed? And so we are also very much also looking at the convergence of administrative and clinical data. So I think the predictability roadmap and the convergence aspects are other things that we need to leave to think about as we move forward in the balancing act.

Rebecca Hines: Thanks, Alix. We have got a number of public comments coming in. We will start with Laurie Woodrow. Laurie, please state your title and organization, and you have up to three minutes.

Laurie Woodrow: I apologize. I did not mean to queue you up. So please move on. Thank you.

Alix Goss: By the way, Laurie did submit LabCorp, so people can see some of their testimony on our website.

Rebecca Hines: Mike, would you introduce yourself, your organization title, and you have three minutes.

Mike Denison This is Mike Denison with Change Healthcare. I am the senior director of regulatory standards and compliance.

I wanted to just basically make a comment that proposed rule connectivity was initially balloted and improved in September of 2015 nearly five years ago. And as many have stated, the known and widely published security vulnerabilities with SSL 3.0, our organization cannot support adoption of the safe harbor connectivity rule that is simply not safe.

While the proposed rule does not require trading partners to discontinue existing connections, section 5 of the rule states that CAQH CORE connectivity rule is a method that HIPAA-covered entity, or its agent, must use if requested by a trading partner. And further states if the trading partner insists on using the CAQH CORE safe harbor, the HIPAA-covered entity or its agent must accommodate that request.

Now, when as stated earlier by Nick, many security-conscious organizations have made significant effort and investment to aggressively sense that SSL connectivity within their IT environments and trading partners. Health care organizations should not be forced via federal mandate to reimplement a legacy connectivity protocol with known security vulnerabilities simply because a trading partner insists, and the rule requirement is that we must.

Rebecca Hines: Thank you, Mike. Next, who do we have?

Greg Richards: That is the last raised hand. We do have a question in the Q and A box.

Rebecca Hines: Okay. We have Ruben Dersing (ph.) from CMS with a question. Alix, is this MIME? Be part of the upcoming rule. It is MIME, M-I-M-E. Or is this going to be discontinued? I think this is a question for clarification more than a public comment.

Anybody else? So just so the attendees know, we are going to ask April, Todd, and Bob Bowman to respond to some clarifying questions in a moment. But we just want to give you one last

moment. Do you have any other input or clarifying questions you would like to get on the record?

Alix Goss: I am unclear about the state of Michigan? Are they asking a question?

Rebecca Hines: So Diane Fuller, state of Michigan, do you have a question for us? Maybe she was responding to my note to the other public commentary.

So I believe this is going to now end the public comment period. However, if you have anything else you would like before we end here today, you can put it in the Q and A or send it to NCVHS mail at CDC.gov, and it will get to the committee's attention as they deliberate in the coming months.

Alix, Rich, back over to you?

Alix Goss: So this is the part where we are not scripted and it is going to be a little squishy for a while because we have decided to add in an additional section at the end, after public comment. And thank you too, April, and I am not sure if Bob Bowman is with you as well, but it is looks like have got CAQH queued up, ready to answer a few questions for us. And so Rich, we had round robin over lunch break to identify a few questions. But we didn't get a chance to talk about how we were going to deliver those questions. Any thoughts on how you would like to proceed?

Rich Landen: I think I can ask them straight out if I can find where I put them. April and Bob, are you with us and enabled?

April Todd: We are. I do have Bob on for any particularly weighty questions. But thank you for the opportunity to come on again. We know you have some questions, and we have also been asked from our participants not invited to present to also highlight and clarify a few things. So I appreciate the ability to come back on.

Rich Landen: Okay. I think we are going to stick with the questions. Let's take the simplest one first. What is the current status and what is CORE's current estimate for the timing of the processes for the updating connectivity rule to version C4? How concrete is that?

You heard a lot of the discussion where several, if not many, of the presenters had some misgivings about one section or other presenters, the connectivity. So kind of get a sense of how definitive is the timing in your estimate or best guess. Obviously not looking for a guarantee.

April Todd: I will reiterate what we said yesterday, and also add on a few more details. So specifically from yesterday, we are very much in alignment with where NCVHS is on the Predictability Roadmap and trying to get incremental out to the industry.

At the same time, we also understand the speed with which this process works. And when we had submitted our letter back in February, before a process in August, we had identified that we were in the process of updating our connectivity rules with the specific intent to help build on the existing rules we were proposing to support clinical data in particular and the intersection between clinical and administrative data.

So in addition to the connectivity rules that are in process right now, we also are in the process of working on rules for attachments, both for prior authorization and for claims. And we also have rules and process and the work related to some VBP things as well.

So the new connectivity rules include a version 1.2 for TLS. It is also includes, at the moment, OAuth 2.0. It includes provisions for REST and for APIs. And our intention is to bring those together with operating rules for attachments and potentially some for VBP as well. Those would come together (inaudible).

In terms of timing, I will let you know that we have just started on our workgroups related to attachments. So we would not anticipate -- the earliest that we would anticipate this rule package coming together would be some time in 2021, depending on when this group could pull that up. It could potentially be 2022.

Rich Landen: And CORE is -- I am reading into what you said here, but I think what I am hearing is that you will move these -- CORE intends to move these three rules forward as a packet, the connectivity and then the two on the attachments you were talking about.

April Todd: And potentially some VPB ones as well.

Alix Goss: Let me just clarify. So the thought is that although we have been talking very much about the connectivity rule being refreshed, the view is it will not stand on its own. It is something you want to bring part forward as a package.

So we have heard a lot about the attachments gap that we have and that we really need that moving forward. And so you are proactively already in motion to address attachments. You are thinking about the larger implications of clinical information exchange for value paced purchasing or VBP. And so you want to bring that three or more rules will likely get ramped over 2021 to come back to this body for consideration.

April Todd: That is correct. We are trying to get unpredictable achievable path for bringing these together. And I will reiterate what Tim Kaja from our board had said yesterday, in that we need to consider these all together. So existing standards, emerging technology, find a way for them to work together and start to build on them. Because if we don't start to make some progress and build on it, we are not going to get anywhere. So that is our intention.

Rich Landen: Any other questions from the subcommittee on this topic? All right. Next question, April. We have had a lot of discussion around safe harbor and several aspects of it yesterday and today.

So the question is safe harbor of connectivity operating rule C4. Does CORE expect that to eliminate optional support for obsolete transport security mechanisms including SSL and SHA-1? And then a couple of follow-on questions. Will C4 align with the ONC Trusted Framework and NIST, I believe already has published a bulletin that specifies TLS version 1.3 for 2024 for federal systems.

Second follow-on, does the CORE safe harbor obligate an entity which has discontinued any particular security mechanism, say SSL as an example, to use that discontinued method with a trading partner who wants to use it.

April Todd: Sure. So let me make sure I get all of those. If I don't, please repeat one of those. There is a lot in there.

So specific to the connectivity rule and NIST, so this rule aligns with NIST where it is applicable. But it also creates more standardization between trading partners to reduce the cost for onboarding and support.

NIST, just as background, covers security at a broad level. The connectivity rule applies to health care trading partners to facilitate a standardized direct connection versus broader flexibility. So for example, as Krishna at Ohio Health had mentioned earlier today, under NIST, you can use VPN, you can use a variety of things, and it is flexible, but it creates a lot of need for maintenance of different ways of doing this.

What the intention of the safe harbor is, is to create one method that is easy to support by all trading partners. That is the expectation that all trading partners will support at least that method to help with (inaudible) connections, to help reduce the cost that is there.

If trading partners mutually agree to do something that is outside of the connectivity rule, whether it is a higher standard or a lower standard, they are allowed to do that through mutual agreement. So the safe harbor is intended to create one base that every trading partner would be required to support. So everyone knows if they want a direct connection, that is how they can connect. That is the intention.

The other thing that I would maybe highlight, and I think Daniel Kalwa from CMS maybe alluded to this yesterday, it is also something that we had recommended in our recommendations on the Predictability Roadmap, is that to make sure that things are up to date with technology related to the connectivity rule, it may be easier in the regulation that goes out to have an active cross-reference to the most recent CORE connectivity rule so that we don't have those gaps in time related to that. So that would be also something that we would continue to recommend that we did with the Predictability Roadmap.

Rich Landen: Thank you. I think that answer addresses the question and the two follow-ons. But because of the degree of conversation we have had over the last two days, let me ask the members of the subcommittee whether everyone is clear enough on the way the CORE has structured the safe harbor for connectivity.

So essentially it mandates a single default method that everyone must support. But allows wiling trading partner agreements to use anything, any other alternative as long as that alternative is mutually agreed by both of the trading partners whether that is an enhanced or, let's call it, an older or obsolescent. As long the trading partners agree. Do we all have sufficient clarity on that? I see some nodding heads. I don't see any shaking heads. Okay. I have got one more, then I will open it up to the rest of the subcommittee.

We heard some discussion about the system uptime currently set at 86 percent. The question is, why that number? I suspect that was some sort of compromise. And then what were the key arguments among your membership for going above that or below that?

April Todd: You are correct. There was some compromise there. There were definitely perspectives from some of the presenters that you have heard today that with prior authorization in particular, the need to have uptimes at a higher level, at 95 percent or higher would be needed.

There are also participants that strongly encouraged us to keep the all-time requirements consistent for all of our operating rules. And that we can consider in a future operating rule related to infrastructure, potentially increasing those across the board.

So we have that out to our participating organizations right now in this survey. We ask our participating organizations and a variety of polls to ask what they would like us to focus on in the upcoming year. That is one of those items that we have asked for them, would they like us to bring this up and to consider this. So that is something potentially on our roadmap to update that across the board.

Rich Landen: Thank you. Alix, questions?

Alix Goss: I think a couple of things are going on here. I realize we have gotten additional public comment that we need to get to. Rebecca, is it okay if we continue with what we are doing now before we read that into the record? I think you have asked a number of my key questions from the lunch time round robin. However, I think there were others on the subcommittee who were interested in asking a question.

Jim, did yours get asked?

Jim Cimino: No, it did not. My question was related to part of the Cooperative Exchanges presentation by Sherry Wilson. There was a slide that said one of the criticisms was the previous recommendation for this rule were not addressed in C3. And the proposed operating rule for connectivity allows only stakeholders one option for authentication, X509 digital certificates.

Second limited authentication (inaudible) solution does not provide flexibility (inaudible) different stakeholder business needs, and they imped EDI adoption. Third prior (audio breaks up).

Alix Goss: I think we lost Jim. He was having audio issues earlier, and he had dialed in on a phone line which I thought would mitigate it.

Jim, we are not getting you.

Jim Cimino: -- authorization and identify services that address many of the business issues that -

Alix Goss: Hey, Jim?

Jim Cimino: -- that proposed connectivity rule with limits. So my point is --

Alix Goss: Jim? Jim?

Jim Cimino: Can you hear me (audio breaks up)?

Alix Goss: No. Barely. We are getting like every other word. And it looks he just dropped from the Zoom all the way around.

Jim Cimino: Can you hear me?

Alix Goss: Yes. No.

Jim Cimino: Can you hear me. Let me summarize very quickly. Those four (audio breaks up).

Alix Goss: Jim, what you need to do is turn off your video and just go audio. Just go audio. Turn off your video because your bandwidth is low. Better. So try now the question, and understand, we didn't get any of it before.

Jim Cimino: I am going to just say that the comment was that there had been previous recommendations for adoption in C3. And they were not adopted. And so my question is, are there plans to address these four issues in C4?

April Todd: I am not sure that I am completely following the question. So in terms of the I think comments related to C3 around flexibility, the purpose of the connectivity rules is to create one common standard that everyone will support as opposed to the connectivity, as opposed to the flexibility (audio breaks up) increases needs for support and maintenance.

But again, those trading partners, if they mutually agree, they can use something different. That is the intention that is there with that particular set. If there were three other ones, if you could repeat what those three are. I heard the flexibility one.

Jim Cimino: I am going to put them in the chat.

Rebecca Hines: We are going to try to bring up the slide. Sherry Wilson's -

Bob Bowman: This is Bob, if I can add real quick, add onto April's comment. It also addresses the concern about the voluntary requirement. Well, this role has been presented previously to NCVHS. And NCVHS sends a letter to HHS for support for the rule. Not for federal adoption, but for voluntary support.

And since that time, we have had many (indiscernible) complete CORE certifications for this level of connectivity, including national health plans, many software vendors and many national clearinghouses. So although it has not been federally mandated, the industry has adopted these transactions with the security and with these connectivity requirements to date. So that is why we are bringing it for adoption because we are actually seeing that tipping point where many of the vendors and clearinghouses and health plans are already adopted it on a voluntary basis.

Rebecca Hines: We were going to just bring up that slide, so that April, you can see if that is still helpful. Is it still helpful, or is Jim's chat sufficient?

April Todd: I am reading through that chat.

Rebecca Hines: Thanks, Kim. Which slide number was that Jim.

Jim Cimino: Number 3. So the question is, are these issues going to be addressed in C4?

April Todd: In C4, for the first few included in there, as we do connect (inaudible), we are wanting to stick towards a minimum number of (inaudible) to connect to reduce costs and maintenance. In some instances, there may need to be more than one there. But our desire there is to remove that flexibility because that does add cost, fi that was the question that was the main question.

Rich Landen: April, this is Rich Landen. I am still quite clear. Is the point that was made in this slide that X509 is the only authentication method allowable that is not a safe harbor approach. It is X509 or nothing?

April Todd: With the entirety of our connectivity rule, the entirety of it is a safe harbor. So if there is an interest for trade, if there is mutual agreement between trading partners to use something else, they are permitted to do that. This encourages and establishes expectation for at least one method from any trading partner opt facilitate those directorate connections.

Alix Goss: Your safe harbor exists as long as you pick one that is in the rule, you are protected. If you do something other than that, unless it is by willing trading partners, you don't have a protection.

Bob Bowman: I would say it this way. That the operating rules allow for predictability, so that any trading partner, provider, who is building his own system requiring one from a vendor or using a clearinghouse or a health plan, they know exactly what the parameters are for that connection. They don't have to go off and build a VPN and set up separate lines. This allows for a web service to be built using SOAP. It is a web service. It allows for very specific connectivity requirement, allows for very specific authentication requirement and a very specific security requirement.

So everything will be prebuilt and prefab and plug and play. I know that is an older term from the '90s. But it really allows that plug and play concept to come in, and trading partners can connect within a week instead of three or four months that it generally can take four connections to be a set up.

So this safe harbor allows for efficiency of build (inaudible) much quicker to build to connectivity.

Alix Goss: I appreciate the value proposition, but I still am trying to get my arms around the nuts and bolts of the rules. So basically, you have got the nuts and bolts, follow this. That will give you a safe harbor. If you don't follow this, then it has to be training partner agreement if you don't do that. If you have either followed the rule or have a trading partner agreement, you have got a safe harbor.

Bob Bowman: Yes, our rule allows for the safe harbor as well as anything else you want.

Alix Goss: So it establishes a floor with a limited menu, even if you don't like the menu. Like if your mom made you eat beets, and you don't really want them, but beets is an option along with peas and carrots. That you can pick one of those or go to succotash if you really want to.

Bob Bowman: Agreed. And there is flexibility and evergreen statements built into the requirements. So we may say, TLS 1.1 or higher. We say SHA-1 or higher. We allow for SHA-2. We allow for TLS 1.3. Those statements allow the rules to have longevity until the next version comes out.

Rich Landen: Jim, did that address all your questions? Are we good?

Jim Cimino: Yes.

Rich Landen: Anybody else have questions for CORE? I am not seeing any. Rebecca, Alix?

Alix Goss: Wait. I am sorry. I think Tammy just spoke.

Tammy Banks: I have a learning curve so the question I have is obviously the secure exchange of this information is critical to any business. And if there is a breach or this information is taken in whatever matter, it is a huge impact on your organization. So can you help me understand the reason for the need for the connectivity rule when the leverage is that voluntarily, these organizations, again I am learning, there is such an incentive for the highest level of security that your trading partner would get to. Can you help me understand that?

April Todd: I think there is a couple of things. One is to highlight, I think, one of the things Alix had mentioned previously. It creates a floor, so that there I at last a minimum that you have that everyone has to comply with. Like any other standard that we have, and operating rules that we have, we want to get as much consistency as possible.

The more consistency that we have, the less that it costs to maintain and support anything that you do. And so those are the two basic underlying reasons for the reason we have done this historically and intend to do that into the future. Bob, if there is anything else you would want to add?

Bob Bowman: I think that is a really important point and is a historical component of federal development. HHS has adopted phase 2 connectivity because it allows for that floor, that base to be built. So we saw an immediate impact for conduct of the transactions when we are mandated for adoption for the operating rules and the connectivity. The eligibility jumped. The remittance advice, the use of the 835 jumped exponentially.

It is really important that when you combine a standard with connectivity and associated business operating rules, that the industry runs to it. It adopts them very quickly. So we have seen this through every other instance where there has been, instead of operating rules, either voluntary or mandated for adoption, and those transactions.

Tammy Banks: To back that up then, so now you established a floor. So anticipating all organizations, well, at least move to that floor or meet the connectivity rule requirement. What enforcement, what is going to make them move? Just because it is mandated or is there an enforcement around it.

Bob Bowman: We have seen even with phase 4, a number of health plans and national software vendors, even the state Medicaid. In Texas, Medicaid is adopted by the connectivity for the prior authorization. So many entities have already moved towards that involuntary adoption because they see the cost benefit. And we have a whole list of all the entities that have completed CORE certification on phase 4 on this particular connectivity.

And so again, I think that is part of why we brought this to HHS because we are at a tipping point when you have two national plans, two national clearinghouses, state Medicaid's and software vendors that are doing this on voluntary basis today, moving in that way. They see the value and perhaps the entire national landscape can see that value as well.

April Todd: The thing that we see from when there are mandates, even under just the existing enforcement that when there is a mandate adoption does increase significantly. Organizations want to be compliant. And in many organizations, that is what frees up funds regardless of what the size of those funds are to become compliant, and that helps the industry further standardize then reduce costs across the board.

Alix Goss: I guess I am curious how, if you are at that tipping point, which is great to hear because I was here in the last round of vetting. And there were a lot of concerns. This has been a different hearing. But also, how much of the industry has already moved to this version?

Like of the overall coverage lives and entities, can you give us better quantifiable sense of how many people are already using this because that also then would aid, I think, our understanding of how much of an ask this is. It almost sounds like you are trying to bring those who are not actively engaged in the national standards development processes or operating rule processes up along with everybody else. And that mandate is need to bring everybody because you have already got a good groundswell happening.

April Todd: I think there are a couple of ways that we are able to maser that. And we are improving some of those actually as we speak. One of those is through our certification program. So we are able to get a sense from a covered lives perspective who is covered through that. From a covered lives perspective, we are around 14 percent that is there. There also are some large clearinghouses as well that would likely expand that. But we don't have a good measurement of how many additional lives that would add on compared to that.

But we are looking at mechanisms through which we can gather more detailed information to get at that estimate. But at this point, we are able to very accurately at least look at covered lives from a health plan perspective.

Rich Landen: I just want to inject a comment. I have trouble thinking of the safe harbor as a floor, I think of it more as a demilitarized zone because there is no negotiation. You don't have to battle with your trading partners if you want to do the prescribed method like the X.509. But if you want to do anything else as a trading partner, whether that is to do something newer, something older, whether you want to try emerging technology or you just want to remain with the status quo, that is a negotiation.

But to think of it as a floor to me connotes that the obsolete, especially when we are talking about the transport layer security, the floor connotes you can't do anything lower. And that is not the case as I understand the safe harbor here. Just an aside comment, not a question.

Anything else from the subcommittee members?

Tammy Banks: Just one more question. I am still grappling with this NIST and the connectivity rule question. And I (inaudible) the connectivity rule is consistent with NIST. I know I am using different rules. So I just need help understanding the value of a connectivity rule, the value of NIST.

And I know you said enforcement really wasn't necessary. It is the mandate that is more important. Can you walk me through that. And I apologize to the committee. I am still struggling with the different regulations on a very similar ask to the industry.

April Todd: So one, we are not saying that enforcement is not helpful. We do think having a stick is helpful. I don't want to have that misconstrued.

In terms of NIST and the CORE requirements, think of NIST as a very broad umbrella that applies kind of across the board to multiple different industries and multiple different players. What we are doing here is that we are compliant with NIST, but we are creating something that is more

uniform for health care industry stakeholders, for providers, for vendors, for others, to comply with something that is more standardized for a safe harbor perspective.

So again, I would reiterate some of the comments previously from Ohio Health where under NIST, you can use VPN, you can use SOAP. You can use a variety of things. But if we can narrow in on one, that is complied within there, that does reduce the support expense and maintenance expense of doing that.

Bob, anything else?

Bob Bowman: I would just add, work connectivity requirements also go down to a level of specificity that trading partners need to have and know. So we went out for metadata within the SOAP header and footer, so you know exactly what version of CORE connectivity you are on, for example. We allow for and require very specific interaction diagrams. So you know exactly what to expect when you send in a transaction real-time or batch mode.

That level of specificity, you won't find in the NIST requirements specifically related to a claim or an eligibility transaction or, in this case, a prior authorization transaction. So the connectivity rules specify things to that level, so that actual application builders can build the application to those specs. NIST, just as April mentioned, has very specific requirements often when it comes to security or authentication. And we include those in our CORE rules.

So we also cite NIST requirements. We cite NIST in footnotes. We include all that resource analysis as well in our discussions with the CORE participants. But that level of specificity is really for your application builders. We include that with the CORE rules as well. So you really can take our specifications and hand it to your programmer or your developer and make him build the connectivity for a real-time 278 prior authorization transaction. They have everything they need right there.

Alix Goss: It is definitely complex stuff. I am glad we have our next planning call to be able to further synthesize all of this. I do think that that we have potentially some additional questions that may bubble up. But while we are all reflecting on this robust discussion over the last half hour, Rebecca, would you like to go ahead and read into the record the recently received question?

Rebecca Hines: Diana Fuller wrote in, I think she tried to get an open line. She is in the state of Michigan. She wrote, we have removed all of the, in quotes, automatic yes approved, end quotes, prior authorizations from the system. And only the prior authorizations that we have left are those prior authorizations that require a manual review of documentation by a medical peer reviewer. There is no quote carveout or out of scope from manual review prior authorizations in these PA rules.

Alix Goss: Thank you. It is helpful to understand the Medicaid perspective and receiving it as Medicaid perspective that these rules aren't going to really help them because their world is already down to the most complex.

Denise Love: And would that also be the case for Medicare Fee for Service? We heard some of that yesterday.

Alix Goss: You heard some of that yesterday as well. Yes. But Medicaid and Medicare fee for service are different payor types.

Denise Love: Fright. But it seemed that fee for service was mostly manual as well, manual review.

Alix Goss: Thank you for reading that into the record. Do we have any further questions from the members?

Lorraine Doo: There was another question that had come in on the chat about MIME. They wanted an answer from CAQH.

Rebecca Hines: Okay, so CAQH, in the Q and A, there is a question, there is a clarifying question. Is MIME to be part of the upcoming rule, or is it to be discontinued?

April Todd: MIME was removed from this most recent version, C3, and not anticipate putting that back in for C4.

Rebecca Hines: Thank you. Any other clarifications while we have our colleagues here.

Alix Goss: I am not seeing any. Thank you April and Bob, for answering our questions. I think at this point, we are ready to move along in the agenda and go to closing remarks. Rich?

Closing Remarks

Rich Landen: I would like to remark that we are closed, but I think I should say something a little bit longer than that. It has been a great couple of days, just really want to extend our thanks not only to CORE staff for helping out, but to all our panelists. They did a ton of prep work, convened a lot of information.

And also to those who submitted public comment letters, very informative. Gives us a lot to think about. But it also provides us the wherewithal that we need to come together as a subcommittee and figure out which point of the compass we head toward.

I guess that is about it. I am looking forward to our next meeting and noodling over these things and beginning to see where we have consensus that will lead to recommendations that we can draft. And again, subcommittee will draft recommendations. Those will go to the full NCVHS. And if approved, or as modified by the Full Committee, then recommendations will go to the Secretary of HHS.

Alix, anything else to add?

Alix Goss: I really think you painted the picture well. There are a number of steps that we need to take and I would imagine that as we progress over the next couple of months, that the Standard Subcommittee will advance something for discussion at the November meeting. So we invite you all back to pay attention to the November, I believe it might be the 17th and 18th, Full Committee meeting. Because there will, if nothing else, be an update on the subcommittee's deliberations and progress related to this work. And so I encourage you to come back to that session.

Rebecca Hines: November 18-19. I think I made an error on a document. It is November 18-19.

Alix Goss: So without further ado, it looks like we are able to give everyone back about 45 minutes of their day since we were slated to go until 3 o'clock. Tremendous effort by all of the

industry in developing the rules, collaborating across the aisle to the standards community, and bringing forth your insights from a policy perspective.

We are taking all of your testimony very seriously, and we will be reflecting on it in the weeks to come. And really, hats off to the subcommittee and their flexibility and tenacity in bringing this effort to a successful delivery. And I think the last two days have been really fabulous.

Rebecca Hines: Thank you. Someone has just asked about the full committee meeting. And I would just like to say that NCVHS.HHS.gov is your one stop resource for all committee work. If you go to the CDC email system, you can Google it and we will add it to our website. You can get on our mailing list. We send out notices before meetings, but you can always find out our meeting schedule at NCVS.HHS.gov.

Alix Goss: And don't forget to sign up for the listserv.

Rebecca Hines: There you go. All right, everybody, a deep gratitude for all of the incredible amount of effort. And Alix and Rich, I think we are officially adjourned.

Rich Landen: We stand adjourned.

(Whereupon, the meeting adjourned at 2:15 p.m.)