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

August 25, 2020, 10:00 a.m. – 5:00 p.m. ET

VIRTUAL

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
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
Frank Pasquale	University of Maryland Carey School of Law	Member
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
Vickie M. Mays	UCLA	Member
Wu Xu	University of Utah	Member
NCVHS Staff		
Name	**Organization**	**Role**
Lorraine Doo	CMS	Lead Staff
Geneva Cashaw	NCHS	Staff
Marietta Squire	NCHS	Staff

Presenters		
Name	**Organization**	**Role**
Dan Kalwa	CMS	Policy Advisor, National Standards Group
April Todd	CAQH CORE	Senior Vice President, CAQH CORE & Explorations
Susan Turney	Marshfield Clinic Health System	President and CEO
Timothy Kaja	UnitedHealthcare	Chief Operating Operator
Cathy Sheppard	X12	Executive Director
Anna Hyde	Arthritis Foundation	Vice President of Advocacy and Access
Christol Green	Anthem	E-Solutions Portfolio Manager
Cathy Plattner	Kaiser Permanente	Business Consulting Specialist
Connie Leonard	CMS Medicare Fee-For-Service	Provider Compliance Group
Gail Kocher	BCBSA	Director of National Standards
Terry Cunningham	AHA	Director of Administrative Simplification Policy
Heather McComas	AMA	Director, Administrative Simplification Initiatives
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
Katie Knapp	Veterans Health Administration	Program Analyst
Paul Joiner	Availity	Chief Operating Officer
Sherry Wilson	Cooperative Exchange	Past Chair and Board of the Cooperative Exchange
Hans Buitendijk	EHRA	Chair
Arthur Roosa	HBMA	CEO, SyMed Corporation

Welcome, Call to Order

Rebecca Hines: Good morning and welcome to 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 and I serve as the Executive Secretary and Designated Federal Official for the Committee. And today the Committee will be hearing testimony regarding the request for its review of CAQH CORE's three proposed operating rules for federal adoption.

Before starting roll call, I just want to note that this is the first meeting for the committee's two newest members, Tammy Feenstra Banks and Jamie Ferguson. Three vacancies were filled in the last month and Tammy and Jamie arrived just in time for this week's hearing. And given their extensive background, we are delighted that the timing worked out for them to take part today.

Let us take care of roll call. Please remember to state your name, the organization you are with, your role on the committee, and any conflicts. Alix, do you want to start off as co-chair?

Alix Goss: I will. Good morning. My name is Alix Goss. I work in the consulting division of Imprado at DynaVet Solutions. I am a co-chair of the Standards Subcommittee. I am a member of the Full Committee and the Executive Committee, and also co-chair of the Review Committee. I have no conflicts and I do not believe any even perceived conflicts in this meeting despite my role nationally as a consultant involved in various FHIR initiatives.

Rich Landen: Good morning. Rich Landen. I am co-chair of the Standards Subcommittee, member of the Full Committee, member of the Review Committee. I have no affiliations. I am retired. I have no conflicts.

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

Debra Strickland: I am Deb Strickland from Conduent. I am a member of the Full Committee, member of the Standards Subcommittee and I have no conflicts.

Denise Love: Denise Love, independent public health data consultant. I am a member of the Full Committee. I am also a member of the Standards Subcommittee and the Privacy Subcommittee. No conflicts.

Jamie Ferguson: Good morning. This is Jamie Ferguson from Kaiser Permanente, a member of the Full Committee, member of the Subcommittee on Standards. I have no conflicts. But to avoid the potential appearance of conflicts, I recuse myself from any discussions of matters related to Kaiser Permanente.

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

Nick Coussoule: I am Nick Coussoule. I am the senior vice president and chief information officer for BlueCross BlueShield of Tennessee, member of the Full Committee, Executive Committee, Standards Subcommittee, Privacy, Security, and Confidentiality Subcommittee. I have no conflicts.

Rebecca Hines: Thanks, Nick. Tammy.

Tammy Banks: Tammy Banks, Vice President of Medicare Strategy, Value Based Care Programs, at Providence St. Joseph Health, no conflicts, member of the Full Committee and member of the Subcommittee of Standards.

Rebecca Hines: Thank you. I think that is all for the members we have on this morning. I want to move over to our --

Alix Goss: Pardon. Do you not want to introduce the other Full Committee members. We do have a bunch of Full Committee members like Valerie.

Rebecca Hines: We do have some members not on the Subcommittee, who has taken the time to join us today. Valerie, would you like to say good morning?

Valerie Watzlaf: Good morning, everyone. I am Valerie Watzlaf and I am associate professor and vice chair of education at the University of Pittsburgh.

Rebecca Hines: And you have no conflicts?

Valerie Watzlaf: And I have no conflicts.

Rebecca Hines: And Wu Xu.

Wu Xu: Good morning. My name is Wu Xu. I am retired public health – I am on the Full Committee only now. I have no conflicts.

Rebecca Hines: Thank you, Wu. I think that is it for members. Frank. Good morning, Frank.

Frank Pasquale: Frank Pasquale, member of the Full Committee, chair for Privacy, Confidentiality, and Security and no conflicts.

Rebecca Hines: Great. Thank you, Frank. Have I missed any other members? It is nice to see you all. Denise Chrysler, good morning.

Denise Chrysler: Hi. I am Denise Chrysler. I am with the University of Michigan School of Public Health and the Network for Public Health Law. I am a member of the Full Committee and a member of the Privacy, Confidentiality, and Security Committee and I have no conflicts.

Rebecca Hines: Thank you. Welcome to all of the members.

Rebecca Goldstein: Hi Rebecca. It is Melissa Goldstein. I am a professor at George Washington University. I am a member of the Full Committee, a member of the Privacy and Confidentiality Subcommittee, and I have no conflicts.

Rebecca Hines: Fantastic. Let us move on to our lead staff. Lorraine.

Lorraine Doo: Good morning. This is Lorraine Doo with the Health Informatics and Interoperability Group in the Office of Burden Reduction and Interoperability at CMS. I am the lead staff for the Standards Subcommittee.

Rebecca Hines: Thank you. I also want to acknowledge Marietta Squire, our Committee Management Specialist is on with us, and I would like to Geneva Cashaw, a Committee Management Assistant. I think that is it for members and staff. I would like to thank all those who took the time and made the effort to prepare written comments as well as those who are speaking here today.

For anyone not on the agenda who would like to speak to make a comment today, there is a public comment period scheduled for 4:45 p.m. Note if for some reason we move along more quickly on the agenda than anticipated, please monitor the afternoon session closely in case we are running early and tomorrow when the focus will be on the connectivity rule, we will open up the floor for public comments in early afternoon currently scheduled for 1:25. With that, I am going to turn it over to our co-chairs. Take it away.

Opening Remarks/Agenda Review

Alix Goss: Thank you, Rebecca. I think I am going to kick us off. For all of us, we will have the support of our technology team advancing our slides throughout the next two days. I would like to go to the first slide. While we are on this slide, I want to set some context about today's events and today and tomorrow's hearing. Ultimately, this is really all about the patient and the multiple layers and dimension that disease affects. If we think about the whole person view of being an engaged and active person in our daily lives, when we are sick, it is hard to be connected to work, family, daily chores, responsibilities to be able to function and to feel well.

This is a large part of the patient experience. It is multi-dimensional and complex as it is ever changing as the disease state changes. The administrative processes that support care delivery add complexity to that patient experience.

In parallel, an aspect applies to all of us in that we all want to improve the health care system and those it cares for, each of us and our loved ones. I am very clear that those presenting today, those who have submitted written testimony and numerous teams that assisted in getting us here today in crafting the Operating Rules are working very hard as health care professionals to make things better. There are so many layers of complexities to address. There are many delicate balancing acts of complexities to positively benefit the whole circle big picture from the patient experience all the way through to the point where the operating rules are used and the lessons and experiences that we learn that go back into our evolution of standards, thus the software and the cycle keeps turning.

These Operating Rules that we will be looking at are some of the final layer of the architecture or structure of our national standards. They are to improve the transaction standards and make it better. These business rules layers hold promise of bringing further value in our administrative transaction processes.

Thank you to all the testifiers over the next two days as well as those who will make public comments and have also submitted written testimony. Your input is critical to infuse the Subcommittee on Standards with many considerations that we will analyze in our deliberations to determine recommendations to the Secretary of HHS on the adoption of the three proposed Operating Rules in front of us.

I am a firm believer that the village is smarter and brighter because of the opportunity to weigh in at various points in the process continuum. NCVHS' portion of the village has grown recently as you have gleaned from our roll call. Our new members are bringing their expertise and

perspectives to not only the subcommittee discussions, but to the overarching decisions made by the Full Committee. I thank those Full Committee members working within the Standards Subcommittee for joining to garner greater appreciation of the work that is underway and will come before you.

For those of you who may be new to NCVHS' efforts, our subcommittee's efforts will vet and wrangle topics with robust industry input to synthesize opportunities into recommendations for consideration by the full body of NCVHS and ultimately that final delivery to the secretary.

We have a super blend of new members, some in the weeds of X12 and CORE with others not. We find the blended approach of not everyone expert in all things health care is a tremendous asset to teasing out the right questions in how to balance the competing perspectives and priorities in our complex health care system.

There are four new members to the Full Committee and several of them, as you heard from Rebecca, are already engaged in our subcommittee work. They have been a part of our subcommittee process and learning the various layers of our NCVHS statutory obligations.

But pivoting back to today, the next two days are just a part of an NCVHS process. Our agenda has prior authorization rules on Day 1 and connectivity rule on Day 2. We will start with level setting on our authorities, scope of proposed operating rules, and the intersection with transaction standards before pivoting to a patient voice. Then we will enter into panels organized by provider, payer and vendor/clearinghouse and providing and providing opportunities for public comment each day.

This is my final hearing as an NCVHS member and as I complete my second term mid-fall, I am honored to have been a part of the NCVHS family for eight years serving the two-term maximum. I am tickled pink by the new addition to the committee and those who continue to serve. It is a terrific blend of people and expertise.

New Proposed Operating Rules Submitted to NCVHS from CAQH CORE

Alix Goss: Without further ado, I am going to provide a bit of a background on NCVHS and the Operating Rules before turning it over to Rich to discuss process aspects including our evaluation criteria.

The role of NCVHS really started with – and related to the Operating Rules started with our responsibilities of defining who should be eligible. Our responsibilities relating to the Operating Rules really started from the Affordable Care Act where NCVHS was responsible for advising whether a nonprofit entity met the requirements to serve as an authorizing entity. We have continued the work related to Operating Rules with holding hearings and assessing for the value for moving forward a set of rules for federal promulgation.

To date, NCVHS has recommended and HHS has adopted Operating Rules for four standards transactions: eligibility, claims status, electronic remittance advice, and electronic funds transfer. We have our citation related to those adoptions and these slides will be available.

In February 2015 and 2016, we reviewed and proposed operating rules for health plan enrollment/disenrollment, premium payment, prior authorization, and claims. We strongly supported voluntary use of these Operating Rules, but we did not put them forward for

promulgation as the value was unclear for the level of effort that would be needed and that was reflective of much of the testimony and the subcommittee's analysis.

In preparing for this hearing, it is good to set some context in that we received in February 2020, a letter from CAQH CORE requesting review of three new operating rules to be considered for recommendation. Two of the proposed rules relate to Prior Authorization standard or the X12 and 278. One operating rule to address connectivity, which would impact all of the adopted-related operating rules for standard transactions.

NCVHS has requested industry input through a Federal Register Notice. We have done outreach to covered entities asking for written testimony and sent invitations to payers, providers, and vendors and clearinghouses and other stakeholders to participate in delivering verbal remarks to this hearing.

Without further ado, Rich.

Rich Landen: Rebecca, I see Vickie Mays has joined us. Do we want to enroll her with the recognition and then the conflict statement?

Rebecca Hines: Good morning, Vickie. Would you like to introduce yourself for the record? Glad you could join us.

Vickie Mayes: Thank you. Vickie Mays, University of California Los Angeles. I am a member of the Full Committee. I am a member of the Privacy, Confidentiality, and Security and Review Committee that is associated with Standards. I have no conflicts.

Rich Landen: Thank you, Vickie. Glad to have you.

Just a few words about how the Subcommittee is going to be looking at the testimony, both the oral testimony today and the written comments that we have received, which currently number somewhere in the 30s, 30 different letters of comments so far.

It is not a straightforward or one-dimensional task. It is not a vote majority rules. It is an analysis. It is looking into the rules themselves, looking into the environment, looking into as Alix so well stated, the value to the patient primarily and secondary then the value to the industry.

The subcommittee will be approaching the value of the proposed Operating Rules in three parts. The first part is do the proposed rules conform to the requirements of the legislation and the citation is on the slide.

Second is do the rules reduce burden in the system. Again, system includes all the stakeholders, the patient, the provider, the health plan.

And then Part 3 is essentially the value question, the value statement. Will the US health care system as a whole be better off with the proposed operating rules to an extent that exceeds the cost of development and/or implementation? Again, we recognize that there are many different stakeholders with many different processes, flows, systems, capabilities, needs in that there is nothing that will work perfectly for every stakeholder and that relative to others in industry. There may be some groups that are more winners than not. That is something we have to take into consideration and yet still make the decision based on the value to the entire US health care system.

From the written and oral testimony we have gotten, we, as members, of the Subcommittee will consolidate the statements, who is saying what, where is there consensus among the industry. We will analyze that input. Then we will go in discussion mode and talk about, deliberate what we have heard and what we have read. Based on those deliberations then the subcommittee will draft a set of recommendations and those recommendations will go to the Full Committee. Hopefully for the next Full Committee meeting, which is November, I believe. And then assuming the Full Committee agrees to the recommendations as presented or as modified by the Full Committee then we will finalize and send the letter from the Full Committee with our recommendations to the Secretary of HHS.

For those of you who want more detail, there is the resources. They are all up on the NCVHS website. It includes both an original request from CAQH CORE for consideration of adopting these rules under HIPAA and an update to that letter because there was some reclassification of the way CORE categorized this.

There are question sets that we posed and then you will be able to see all the written public comments that NCVHS has received.

The process for today, written testimony reviewed to prepare for the oral presentations today. All the comments, as I mentioned, are posted on the website. All the members and subcommittees have seen what has been submitted in writing so far.

All the presenters on the panels today and tomorrow have been asked to follow a template and the key things that we are expecting to get out of the testimony is a sense of that testifier's anticipated value of the proposed rules, any anticipated concerns he or she has about the proposed operating rules, and then in summary, the top three to five points that that testifier wishes the NCVHS to consider in deliberating the recommendations for HHS potential adoption of the rules.

Each of the presenters will be limited to seven minutes of presenting. And after the presentation, there is time for the subcommittee members to ask questions of the panelists. Time and interest permitting, any member of the Full Committee will also be able to participate in that. But it will be restricted to the members of the NCVHS and the Standards Subcommittee. There will not be public opportunity for questions at this time.

Alix Goss: Before you do that, let me just ask to go back to one slide. I wanted to just add a little bit of color commentary to Rich's overview. At six minutes, those who are presenting remarks will receive a time check, a quick auditory note from our timekeeper, Lorraine Doo. And then should someone still be running a little bit long, Rich and I will be chiming in indicating that we will be asking you for your final thoughts so that we can stay on track. I look forward to a robust discussion and the subcommittee's representatives managing each of the panels' Q&A sessions. For the Full Committee members, if you do have questions that you are looking to ask, please let us know either through the chat box or raising your hand so that we can also manage our agenda today. Thank you.

Rich Landen: With that, let us open up the festivities. Our first presenter this morning is Dan Kalwa. Dan is from CMS, Office of Burden Reduction, the National Standards group. And Dan is going to set the stage for us in talking about what it is HHS has authority to adopt as far as Operating Rules under the enabling HIPAA and particularly for Operating Rules, the Affordable Care Act legislation.

Dan, over to you.

Overview of HHS Authority to Adopt Operating Rules

Dan Kalwa: Good morning. Thank you, Rich, and thank you to the Subcommittee for this chance to talk about Operating Rules. As Rich mentioned, I am a policy advisor with the National Standards Group. And we are responsible for the adoption of the HIPAA standards under administrative simplification as well as for the education and enforcement activities regarding administrative simplification.

It is my purpose today to give a very short overview. I do not intend to get into all of the nitty-gritty specifically since this is a very long topic. As Alix already alluded to, Operating Rules were first created as an item in the administrative simplification arena with its adoption in the Affordable Care Act. What I have posted here is an excerpt that contains the specific definition as created in the Affordable Care Act.

I will just take a moment here to note that I have excerpted a lot of language and I would encourage everyone to go back and look at the full language. The references will be on each slide. To the extent that you are interested in seeing the language in context in its totality, I would encourage you to go back and look at the original references.

The purpose of Operating Rules at least as envisioned in the Affordable Care Act was to deal with a hole that the original HIPAA legislation and requirements around adopting the standards for the transaction did not quite cover. Although HIPAA required the secretary to adopt standards for the transactions, in particular, it required the secretary to adopt standards for the data content, for the data format and the code sets. It did not necessarily require the secretary to adopt any rules around the use of those standards so things like what transport technology is going to be used, what are the rules around response times and all those sorts of regular business activities were not originally envisioned in the HIPAA legislation.

To that extent, before the Affordable Care Act, it was left up to the health plans and the providers that work with them to manage these issues in their trading partner agreements or in the companion guides to the standards.

What Congress believed and then imposed requirements for Operating Rules was that this suite or you can call it constellation of different approaches in the trading partner agreements and the various companion guides was not conducive to reducing burden. It did not reduce cost and it did not improve the efficiency for the providers, in particular having to deal with a whole host of approaches and requirements. That is what Operating Rules are for.

The Affordable Care Act specified several things that the Secretary is required to do with regards to Operating Rules. The first is that the Secretary has to adopt Operating Rules and one for each transaction. When we refer to transactions, those are the transactions specified in HIPAA, which I believe most everybody is already familiar with. Examples are the claims transaction, the eligibility transaction, et cetera.

The Secretary is required to adopt a single set of Operating Rules for each transaction. And then it goes into defining exactly what that means. I believe Alix already alluded to some of this. The Operating Rules shall be consensus-based and reflect necessary business rules. That is generally considered to include all of the activities necessary to actually use the standards. And the Secretary secondly develops by a nonprofit.

The Secretary also has very specific requirements around when the Secretary can consider the adoption of an operating rule. The first is the Secretary considers the Operating Rules themselves, but also the Secretary is required to rely on the recommendation of NCVHS and the Secretary is also required to ensure that providers have been consulted either via the vehicle of NCVHS or perhaps directly.

The Affordable Care Act also created the criteria for an operating rule entity is. I will not go through each one of these bullet points. But I would point out that is very similar to what the standard setting organizations were defined as in the original HIPAA legislation, but it does have some differences. In particular, it is not necessary for an operating rule entity to be ANSI accredited, but also unlike many of the SSOs, as we consider them, for example, X12, HL7, NCPDP, the Affordable Care Act did not specify in the legislation any particular operating rule entities. Rather it gave that job to NCVHS to ensure that any of the Operating Rules that it considers and proposes have also been developed and proposed by an entity that meets all the criteria for an operating rule entity.

NCVHS has very specifically given the role of, as we are doing today, soliciting proposals from the authoring organizations reviewing those proposals and if necessary soliciting additional information and then analyzing and evaluating it against all of the various criteria included statute and whatever NCVHS might think appropriate.

NCVHS then recommends to the Secretary. I will point out that one of the roles of NCVHS is very explicitly to ensure that the entities are meeting all of the requirements for an operating rule authorizing organization. I believe we generally assume that that is being done in the process of reviewing the operating rule itself, but it is worth pointing that out as a separate topic for which NCVHS has made the determination.

And then it goes through much like Rich already mentioned. NCVHS is required to determine whether they represent a consensus, determine whether they are consistent with existing standards and then submit to the Secretary a recommendation about whether the Secretary should adopt the proposed Operating Rules.

What I have done for the next several slides is list out merely by phase all of the documents that are explicitly adopting in regulation. It is not my intent to go through all of these specifically. It already has been mentioned. They have been adopted for eligibility, claims response and EFT as well as ERA. The reason I chose to list these out is to point out, one, just perhaps not everybody is aware, just how many have been adopted and how many there are. Each one of these is an operating rule guide with which a covered entity is required to comply. It is these specific guides that the entity is required to implement.

Again, you can see there are many of them. You can see claim status as well as the rest.

Just a final list just for reference, these are the Phase III.

I wanted to point out that in regulation, there are some exceptions to what is contained within the operating rule. I would summarize it as being the requirements around using the acknowledgement standards as included in X12 as well as the certification.

There is no prohibition on using these things. It is merely that we do not consider these as required for compliance with the Operating Rules.

Just as I would ask that the Subcommittee and eventually the Full Committee as you consider what proposals to the Secretary. I would point out some things that would certainly require rule making although this is not a complete list. If you want to change the versions or the Operating Rules specified, even into creating one super guide that includes the rest of the currently existing guides, that will very likely require rule making. Going from the current phase structure to a more generalized or simplified structure would also require rule making as would removing the existing exceptions.

I would also ask that as you consider the adoption or the recommendation for the Operating Rules, if you are contemplating changing the exceptions or asking that they be removed, we would ask that you specify that and to the extent that there has been testimony given, we would like to have that provided.

Just as a final comment, until that regulatory change happens, all covered entities are required to comply with the Operating Rules as enumerated in the regulation and there are no other implementation specifications that would suffice to be considered compliant.

I believe that it is the end of my comments. I realize I went very quickly through a complex topic. If the committee has any further questions, I would be happy to talk about it. If the committee or the public has additional comments or questions, I would ask that they direct them to our official administrative simplification mailbox. That will get you in touch directly with the National Standards group and we will respond to your questions. Thank you.

Rich Landen: Thank you, Dan. Funny you should mention it, but yes, the subcommittee has a question for you and that is can the Operating Rules be used on a voluntary basis by covered entity if there is no regulation for that operating rule that has been adopted under HIPAA or conversely, is there any prohibition against using an operating rule voluntarily as long as that operating rule does not have a requirement in regulation.

Dan Kalwa: That thankfully, Rich, is one I can answer. Very clearly, so long as there is no adopted and this applies for Standards as well. So long as there is no standard or operating rule adopted – covered entities are free to use essentially whatever they would like. It is only once something that is adopted in regulation so once a particular implementation specification for a transaction is adopted or an operating rule is adopted then entities must use what has been adopted unless we are operating under an exception granted for pilot and testing.

Rich Landen: Are there any questions for Dan from the subcommittee or committee members? If so, please use the “raise hand” feature.

Dan, thank you very much for the informative presentation. It is not a small challenge to keep all those requirements in mind, but we will certainly do our best to comply with all that is in the requirements and some of the things you suggested as we complete our deliberations as the subcommittee and recommendations by the Full Committee.

I think we are ready to move to our next presenter.

Alix Goss: April Todd will be next. We are a little ahead of schedule, but that is good. It will give us a little bit of extra time. Thank you, everybody.

Overview of Proposed Operating Rules for Prior Authorization and Connectivity

April Todd: Good morning. Can you all hear me all right? To start off for the record, my name is April Todd. I am the senior vice president at CAQH. I lead the CORE and explorations initiatives at CAQH. Thank you for the opportunity to present our recommendations to NCVHS for the federal adoption of CAQH CORE Operating Rules for prior authorization and connectivity.

I am joined today by Dr. Susan Turney, the CEO of Marshfield Clinic, and also Tim Kaja, the CEO of UnitedHealth Networks at UnitedHealthcare. Dr. Sue Turney is our immediate past chair of our board and Tim Kaja is the recently elected chair of the CAQH CORE Board.

Before we present on the details of the rules, I would like to just provide a brief overview of CAQH CORE particularly for some of the new members that are on the committee. First off, we are a nonprofit industry-led initiative with participants that represent the vast majority of the industry, including health plans, health care providers and associations, vendor organizations, including clearinghouses and EHRs, state and federal government entities, the SDOs, as well as other interested parties.

Our mission and vision are to serve as an industry-wide facilitator to drive the creation and adoption of operating rules that support consistent expectations and adoption of standards that accelerate interoperability and align administrative and clinical data exchange.

As part of our HHS designated rule to develop operating rules, we develop technology and standards, agnostic business rules to help the industry effectively and efficiently use electronic standards.

We also encourage and test this adoption through the CORE certification program, which for a number of HIPAA transactions, has over 80 percent of trading partners that have achieved certification.

Our work is guided by a multi-stakeholder board with members representing health plans, providers, and vendors and advised by government entities, SDOs and WEDI.

We have collaborative working relationships with the SDO, including X12, who will testify today, to facilitate cross-functional alignment, industry education, and ease of adoption.

Today, as was mentioned, we are recommending three sets of Operating Rules for federal adoption. These include Prior Authorization Data Content Rule, which includes requirements for patient identification, error and action codes, and communication of needed documentation, status, next steps, and decision reasons.

Also included, it is the Prior Authorization Infrastructure Rule, which includes requirements for processing modes, response times, system availability, acknowledgements, and companion guides.

And lastly, we have included an updated Connectivity Rule to apply to prior authorization and replace the connectivity rules for eligibility, claim status and ERA to make sure that we have consistency across all the transactions.

As I mentioned previously, we have a multi-stakeholder board that guides the strategic direction for CORE. This slide shows the correct roster of our board members and advisors. Every two

years, we elect a new chair and vice-chair and they rotate between a health plan and a provider. This past July, we elected a new chair, Tim Kaja, who will hear from later in the presentation.

Dr. Sue Turney served as our board chair during the time that the Prior Authorization Rules were developed. She served as a very positive driving force to address one of the most challenging business processes in health care.

I am now going to turn it over to Dr. Turney, who is going to talk about the process to develop these rules.

Susan Turney: Thank you very much for allowing us the opportunity to speak with you and also, I want to thank April for the nice introduction.

As chair of the CAQH CORE Board, I have bene intimately involved in the group's efforts to really streamline the business of health care. I think that everyone understands that no health system can solve the issues that we face as we transition to value-based care. The key here is that we do need to collaborate and work together to make the transition to value feasible, but also it has to be scalable nationwide.

The work that we have done through CAQH CORE is really to address the operational challenges of value-based payment and the value-based payment systems that we see as essential. Especially for those of us who are in care delivery, it is really about the patients. And now more than ever, we have to be able to deliver these efficiencies.

I would ask you to go to Slide 6 please on Operating Rules. As April already pointed out, the CORE participants came together to develop the Operating Rules to really address one of the most challenging health care business processes and that is Prior Authorization. The CAQH CORE Board prioritized this, given the significant list of barriers that we felt we could help to address.

Now on this slide, you can see the highlights of the challenges to really automating the Prior Authorization. Certainly foremost, the lack of detail and the lack of consistency and the use of data content to identify patients, to communicate errors, to specify the needed documentation, to inform on status and next steps, which can create confusions. And as a result – this causes unnecessary provider phone calls, faxes, and it does significantly delay the process.

The purpose and the reason for the CORE data content rules and the reason they were developed was to really address this barrier.

Also, there is lack of understanding of the 278 transaction. You know this, but this standard transaction is federally mandated and particularly among providers. And the CORE infrastructure rules will really create that incentive for providers so that they will be able to use the 278 transaction.

These two barriers that I have mentioned are really related to the fact that there is limited availability of vendor products that readily support the standard transaction. We also know that there are varying state requirements for manual intervention as well as the response times.

As we talk about this, all of these factors really result in varying levels of maturity along the standards and technology adoption curve. One of the problems is that this really does make interoperability a huge challenge.

In order to support interoperability, the CORE connectivity rules create a common connectivity method safe harbor so that all trading partners can really be assured that they will be supported across prior auth and other transactions that we need to complete.

I would say on this particular topic that the lack of federally mandated attachment standards to communicate the clinical information and the associated lack of integration between the clinical and the administrative system is really a barrier to full automation.

The members of CORE and the participants in the organizations have started work on this already. They have started work on the attachment and on the connectivity operating rules so that we will be able to support the exchange of clinical documentation that will then build on the three sets of rules that CORE is going to be presenting on today.

And just a couple of other points I would like to make. This lack of automation really leads to critical delays in patient care. And being the CEO of a large integrated health system, I know that this can drive up the cost for care delivery.

The areas of high volume of PA procedures sometimes need to have dedicated staff just to handle all the paperwork and it takes time. It depends on the insurance and the insurer. It can actually take weeks to get an answer, which if you are the patient and you have that delay, you know that it can lead to worsening of your condition. It can lead to increased pain and certainly more suffering.

Orthopedic procedures are a great example. If someone needs a total joint replacement or a pain procedure or diabetic supplies, the inconsistencies that we see in the PA process can lead to disparities in care. What we know is that some patients have access to needed care while others do not, depending on the insurer or the product that they have.

From a care perspective, development of these PA Operating Rules was not easy. There were a lot of stakeholders at the table. There really was much debate and there was a lot of discussion within the various workgroups at CORE and at the CORE Board itself.

In fact, I have been on the CORE Board for years and have found this to be the most challenging and the most contentious topic that CORE has addressed.

As you think through this and next steps, you will hear comments on items that some organizations wanted included or even excluded from the rules. Many of these items pertain to issues that CORE participants could not reach consensus on at this point in time. But CORE will continue to evaluate the potential rule development for the future.

But the key here is that the CORE participants were able to compromise using an 80/20 approach. In this consensus space process, of course, it is not possible to address every single issue. But the fact that at least 80 percent of participants approved, each rule set at least in my mind is a really significant step to move along the path of improving automation of the prior authorization process.

Now, I would actually ask you to go to the next slide on engagement on Prior Authorization. Now the effort again to develop these rules was significant and there was broad engagement across the industry stakeholders. In fact, the engagement was extremely high.

The participants involved in the development of these rules included some of the following. We had national health plans as well as provider-based plans who cover over 208 million lives. We had a variety of providers and provider associations. We had the state Medicaid agencies, who are responsible for more than 28 million enrollees and vendors, clearinghouses, federal agencies, SDOs, and others.

You can see that the individuals represented a variety of functions across these organizations and all of them collaborated to submit one vote across their enterprise so we could get this across the finish line. Ultimately, each of these rules was approved by at least 80 percent of these organizations.

Now as you think about the rule development process more. I want you to know that we do employ a very robust, a very comprehensive rule development process.

You can certainly hear the opportunities that we have identified through the CORE Board, through the industry surveys, through the advisory groups, and through our environmental scans. At that point, rules are developed and they are vetted via work groups.

During the development of these rules, CAQH CORE held more than 75 work group meetings and conducted I think 35 detailed straw polls and ballots, seeking broad stakeholder input and involvement.

All of the CORE participating organizations that would have to implement rules, including health plans, providers, government, and vendors then did conduct a final vote. Of the three rules that will be presented, each of them received at least 80 percent support on the final CORE participant ballot and approval levels exceeding 69 percent within stakeholder category, and, again, among the plans of providers, government, and vendors.

At that point, the rules were reviewed and then were approved by the CORE Board and now we are at the point where we are recommending to NCVH for federal adoption.

I want to thank you. I know that April and Tim have some additional comments so I am going to turn it over to April right now who will review the proposed rules and I believe we will have time for questions after that. Thank you.

April Todd: Thank you, Sue. We can move to the next slide. I am going to briefly review each of the three rule sets. The first rule I am going to review is the Prior Authorization Data Content Rule. The intent of this rule is to establish consistent data content requirements and expectations, to reduce the unnecessary back and forth between providers and health plans, to facilitate quicker response times and less manual follow-up.

What often occurs with prior authorization today is that providers submit a 278 request that oftentimes results in an error because the health plan cannot find the patient or the provider receives appended response from the health plan with no direction on what to do next. This results in the provider calling the health plan to check on the status of the request and ask what else they need to do and/or the provider sends through fax, email, or through the mail the entire medical record for the patient in the hope that it will satisfy what the health plan needs to approve the request. It takes significant staff time for the health plan to comb through the stack of paper to find the piece of information that they need.

The Prior Authorization Data Content Rules were developed to address these types of issues. Specifically, the requirements in this rule establish patient identification and verification requirements that mirror those of the eligibility operating rule.

It requires specific versus general error and action codes to give the provider more direction on how to fix the request. And as with the Eligibility Operating Rules, the Prior Authorization Data Content Rule requires more specific information to be shared for certain categories. This information includes one or more of the most specific decision reason codes and use of PWK and LOINC codes to communicate what documentation is needed.

These requirements are targeted into the categories of service most likely to require prior authorization and associated documentation and thus provide a stronger ROI for improvements to back-end systems and then requiring the content for all categories of service.

Lastly, the rule requires the display of code descriptions to reduce the burden of interpretation for our providers.

This slide highlights the impact of the Data Content Rules on the workflow along a simplified Prior Authorization process. At the front end of the workflow, the Operating Rules established consistent patient edification and verification requirements – some of the common errors by providing a complete list of demographic data to ensure a better match at the health plan level.

As providers of health plans are exchanging information, the Operating Rules do a few other things. They include the return of specific error and action codes when certain errors are detected. This strengthens the electronic communication, reduces the need for provider manual follow-up.

It also specifies category of service for diagnosis procedure and revenue codes to provide additional information. This enables more auto-adjudication through support of a use case category service approach.

Specifically, you need to return one or more health decision reason codes to provide clear explanation to the provider around next steps so that they are not calling the health plan to figure out what to do next.

It also includes a requirement for use of PWK and LOINC codes to provide direction on what additional clinical information is needed by the health plan. Again, this reduces the need for the provider to call and to send in information because they do not know what is needed.

And lastly, as the health plan is adjudicating the request and providing information back to the provider requires detection and display of code descriptions. This helps reduce the burden of interpretation for the provider.

Within these rules, you will see that the Operating Rules do not specifically apply to how attachments are exchanged. But they do improve the process of specifying what documentation is needed.

As you will hear from many people today, an attachment standard is desperately needed to fully automate this process. You will hear from Tim Kaja later today – CAQH CORE is starting to work on Operating Rules to support the exchange of this clinical documentation. But these rules do help support and inform providers on what documentation is needed.

This slide is regarding the second set of rules, the Prior Authorization Infrastructure Rules. It includes five components. The requirements for a companion guide system availability acknowledgements and processing are aligned with other operating rules that have been adopted for infrastructure.

Specifically, I wanted to highlight the requirements for a response time. These response time requirements have three components. The first one is a requirement of a maximum two business data response time for a health plan to respond to a provider with information regarding what documentation is needed to complete the request.

The second component is an additional maximum two-day business requirement for a health plan to respond to a provider with a final determination once all the documentation has been received.

A third component is an optional component for a health plan. This component is an optional 15-day close-out period where the health plan could close out the request if the documentation requested has not been received by the provider.

These response time requirements must be followed at least 90 percent of the time in a calendar month and do not apply to urgent or emergent requests.

These requirements were informed by a research conducted on variations in various state requirements. Our research found that over 30 states have existing response time requirements, but they vary significantly by how they apply and when the clock starts. It creates burden for health plans to comply with various different requirements from state to state.

The most common requirement that we found among the states, however, was less than three days and that is where we had narrowed in on the two-day response.

What you will see on this slide is again a simple workflow that identifies how the response time requirements and the requirements in the infrastructure rule generally help to support the prior authorization process. Again, at the front end of the workflow, the requirements establish a standard companion guide format, which enables consistent access across trading partners.

In the middle part of the workflow, the rules help to establish system availability expectations. Providers can have an expectation on standard system availability, plus notifications of down time.

It also includes uniform use of acknowledgements. It allows providers to immediately know if the health plan has received the request, eliminating some of that manual follow up to understand what has happened to the request.

The time requirement for initial response, the maximum timeframe of the two days, sets some clear expectations for providers on the timeframe so they know when they will get a response and what else is needed and do not feel the need to make that phone call.

And as we go through the latter part of the process, there is also the response time requirement for a final determination. This enables the provider to receive a timely response and ensuring the safety and appropriateness of medical treatment in the timely way for patients.

And then lastly, as I will talk further about on the next – in more detail around the connectivity and security requirements if we can go to the next slide. The third rule that we are presenting today for federal adoption is an updated connectivity rule that would apply consistently across prior authorization and replace previously adopted connectivity rules for eligibility, claims status and ERA.

A consistent safe harbor connectivity method across all transactions will drive industry alignment and help reduce complexity and cost.

In terms of the details of what is included in the connectivity requirements, it includes a single envelope standard. This will reduce complexity and simplify interoperability through requiring a single SOP plus WSDL envelope standard versus what previously was included as two envelope standards. This will provide uniform support for handling transaction payload for both real time and batch processing modes.

It also includes provisions for increased security, improved security, by requiring digital certificates and removes the security-vulnerable process of username and password. This will help improve security across the industry.

Related to the certificate, required use of certificates, most web-based traffic today uses digital certificate technology and many of the larger certificate authorities offer free digital certifications; therefore, the cost may be lower to incorporate this than using the current username plus password requirement as those requirements often require more administrative support and as I mentioned previously, has less security and may create some vulnerabilities.

Another benefit of the Connectivity Rule is it offers a safe harbor.

The requirements for the safe harbor provide one method with which all trading partners are assured that trading partners can exchange information. It does not require that existing connections be dropped or that trading partners can agree to a different exchange mechanism. But it does create security and expectations that one standard will be adopted and that will help for onboarding of new trading partners.

And lastly, this also improves the messaging and error reporting through updated error codes.

This slide provides a day in the life applicability of all three of the Operating Rules across an example related to imaging. I will walk through how these rules influence that across this process.

First, within this example, this is where a patient presents with abdominal pain and a physician requests a prior authorization for imaging and a CT scan with contrast. The provider would under the operating rules include data identifying the patient, the provider, and the specific diagnosis code for the service. As with the claim, the request would include specific data that the health plan has to accurately adjudicate the request.

Once the health plan receives the request, it will complete the adjudication process. This is where under the rules, the health plan would acknowledge the receipt of the request, 20 seconds for real time and 2 days for batch. The health plan would normalize the patient's name to ensure patient matching. And we with how claims are processed, the adjudication process would allow for member and provider look ups, look ups for eligibility and benefits, specific

procedure and revenue code of analysis and allow many of these steps that are manual today to become more automated to provide a quicker response.

Next, the health plan would determine that the patient based on the review of the data that they have done with their systems that the patient recently had a CT scan without contrast. With this, the health plan would return under the operating rules, specific codes to report anything they found in terms of errors, pends, status, and other processing components and assist the provider in understanding what next steps are needed. In this case, the health plan wants to see what was on the documentation around the previous CT scan.

When pending and requesting additional documentation, the plan would have two business days to return information and what information they need, which is this information around the previous scan.

Next, the provider would receive the response form the health plan. It would have display requirements to enable code descriptions, providing for easier interpretation by the provider. And as with claim adjudication, the health plan would identify specific data that must be supplied and share that with the provider so that they know that they need to provide this other scan.

And as the provider receives this information and then in the last step submits or remits the CT scan without contrast for the health plan review, the health plan would be able to receive that image, complete the review and return a final determination to the provider within two business days. And underlying all of this is foundational connectivity and security requirements that would be expected across all trading partners to help facilitate the exchange and interoperability across these systems.

Now, I am going to turn this over to Tim Kaja, our current board chair, to talk about these operating rules in areas where we are continuing to improve the prior auth process. Tim, I will hand it over to you.

Tim Kaja: I will apologize in advance because I am having difficulty turning on my camera. Unless you guys can do it for me as we proceed through this.

I want to say thanks to April for her leadership and Dr. Turney for her leadership and thanks to the committee for allowing us to discuss the Operating Rules with you.

I have been a member of the CORE Board I think since the beginning when CORE was created. From my view, it is one of the few places in our industry where there are a complete multi-stakeholder representation and I would say complete multi-stakeholder intense interest in advancing the ball of administrative simplification.

If we could go to Slide 18, I am going to talk about the cost savings side of the Operating Rules. And the impact of federally mandated Operating Rules on this industry to date is significant, as you can see here. Using historical data from the CAQH Index and CORE Certification, it is estimated that $55 billion has been cumulatively saved due to automated transactions since the Operating Rules were first mandated in 2013. And about a third of that or $18 billion of this amount is estimated to be incrementally due to operating rule adoption.

The data on the right-hand side of Slide 18 highlights two cases from this analysis demonstrating how Operating Rules drive automation. The first one – in the year following CORE Certification,

one health plan reported a 19.5 percent one-time increase in electronic adoption for eligibility and benefit verification.

For claim status, another health plan reported 37 percent one-time increase in electronic adoption following certification.

As April mentioned, there are many similarities between the Prior Authorization Rules proposed today and the Eligibility Operating Rules that have saved the industry so much time and money that we just talked about.

I have testified to the committee in the past about the significant savings associated with the Operating Rules particularly for UnitedHealthcare.

We know from the CAQH Index that the industry could save $12.31 per prior authorization transaction by moving from manual processing to the 278 transaction. Providers could save 17 minutes on average per transaction.

Right now, the industry conducts more than 90 million prior authorizations annually of which only 13 percent are electronic. The impact that we could have on the industry if the proposed set of CAQH CORE Prior Authorization and Connectivity Operating Rules are mandated as significant, including the resources that would be freed up to support direct patient care, as you heard Dr. Turney talk about.

I am going to talk about case studies on the benefits of automation and the proposed rules. This slide highlights two specific studies that are directly related to the proposed rule set. The first is from Harvard Pilgrim and the second is from the Cleveland Clinic.

From Harvard Pilgrim in Massachusetts, we highlight how the proposed rule requirements create efficiencies for them. Today, 70 percent of Harvard Pilgrim's prior authorization, referrals are conducted, using the 278 transaction, using the CAQH CORE Connectivity Version C3.1.0, as you heard April talk about.

Massachusetts' Harvard Pilgrim's primary market has a state law requiring two business day response for all prior authorizations.

Harvard Pilgrim has adopted its systems. It has adapted its systems and workflows to consistently maintain and meet this requirement, keeping denials at a 1 percent level of all authorizations.

Additionally, with this automation, Harvard Pilgrim has been able to significantly reduce resources by 14 FTEs dedicated to managing prior authorizations.

The second case from the provider side. In early 2020, CAQH CORE partnered with the Cleveland Clinic and their vendor, PriorAuthNow, to measure the impact of automating their prior authorization process. Their solution uses the 278 transaction CORE Operating Rules integrating into the EMR workflow.

Initial results show an 80 percent reduction in staff times, approximately 12 minutes saved per transaction on a prior authorization compared to web portals.

Without an attachment standard, however, submission of the clinical documentation is still manual, but time saved from automating other parts of the workflow through the 278 allow staff to address clinical documentation needs more effectively.

Lastly, in addition to providing time-saving steps, also reported reduction in job stress, which, as you guys know today, is extremely critical.

The data from these two cases highlight the impact a federal mandate could have at a macro level specifically through savings in staff time and more timely delivery of patient care.

All the Operating Rules will drive the use of prior authorization and promote interoperability. Let me again emphasize that they will drive the use of the 278 transaction and promote greater interoperability.

Similar to the Eligibility Data Content Rule, the Prior Authorization Data Content Rule improves member matching and delivers actionable data about documentation needs and next steps between providers and health plans.

Infrastructure requirements incentivize adoption among providers as they can be assured of a maximum response time. We cannot continue to support patchwork, varied response time requirements across states. Trading partners and more importantly patients deserve consistent expectations.

And finally, a single, updated CAQH CORE Connectivity Safe Harbor ensures secure information exchange and quick connections. The Operating Rules promotes standards, adoption, and automation and together these rules will be a major step forward in the industry.

The proposed prior authorization and connectivity rules are an impactful step. As demonstrated by the data I just shared and future efforts will further streamline data exchange. Think of this as a beginning.

To this end, CAQH CORE is already looking ahead. We are very supportive of the NCVHS Predictability Roadmap recommendation to update standards and operating rules more frequently, more predictability in valuable incremental steps.

Over the next year, we will be focusing on developing of new prior authorization attachment operating rules to close remaining automation gaps. Updating our connectivity requirements to facilitate intersection of administrative and clinical data including support for attachments or clinical documentation needs across existing and emerging standards, including APIs and FHIR. This is essential to move this part of the rules forward.

Continued work with industry partners to measure the impact of pertinent and potential future operating rules and continuing to drive implementation of the CAQH CORE Prior Authorization and Connectivity and Operating Rules through CORE Certification beyond the early adopters.

CAQH CORE looks forward to collaborating with NCVHS and the industry as we have in this rule set to work together towards our shared goal of aligning clinical administrative data and improving care delivery by driving automation, reducing waste and efficiencies and enabling a more streamlined and connected health care ecosystem.

Before I close though, and we move to questions, I would like to take a few minutes and I will take my CAQH CORE Board hat off and put on my UnitedHealth Group hat. I have been at UnitedHealth Group for 35 years. UnitedHealth Group is supportive of this Rules package. In particular, we are supportive of the data content rules to help remove common errors in patient identification. We are also supportive of the data content rules to provide more detailed information on required documentation for categories of service most likely to require clinical documentation.

Both of these components of the Prior Authorization Content Operating Rule mirror the requirements of the Eligibility Data Content Operating Rule. As I have testified previously to the NCVHS, UnitedHealth Group has seen significant benefits from similar data content rules implemented for eligibility and benefit transactions when the X12 5010 transactions were put into place.

We are supportive of this proposed Prior Authorization and Connectivity Operating Rules as a significant step to improve the prior authorization process and we look forward to building on these rules over the next few years with operating rules for attachments and complementary operating rules for connectivity to support the intersection of clinical and administrative data across existing and emerging standards.

Starrette Woodley, who was also invited to present at this hearing and I, along with our clinical operations team, are working closely together on prior authorization. We are in the process of implementing these rules now.

At UnitedHealth Group alone, including notification, we process somewhere in the neighborhood of 11 million prior authorization and prior notification transactions a year.

We are quite aware of the need to connect the 278 to FHIR to help solve the challenges of clinical data exchange and the Q&A that has to happen during the prior authorization process. All future but not too distant future things for us to think about and work on.

We are supportive of deploying AI to streamline the prior authorization process with both content and time.

We are actively promoting in the workflow simple displays of when prior authorization is required and when it is not to help physicians and their patients make informed decisions on their health care.

But the entire industry needs to begin with implementing these rules that April just went through and Dr. Turney talked about to reduce the provider burden, improve care delivery, and set the base for how we can improve the flow of health care when prior authorization is required. This is the base for us to build on.

I want to thank the committee for their time as we went through this from CAQH CORE and I will turn it back over to April or we will open it up for questions.

April Todd: Thank you, Tim. We are open for questions. Thank you.

Alix Goss: Thank you. Rich, I think you and I are going to kick us off. We have five minutes available for Q&A. I think we have a couple of questions that we have queued up for this. Do you have a preference on which one we start with?

I am going to dive into I think, what is a little bit more of the challenging question just because we probably only have time for one. What are the implications or consequences of these Operating Rules in light of potential for other standards or new technologies becoming available for prior authorization and the evolution of the connectivity rules sort of kicking up with some of Tim's theme there when he mentioned FHIR and the numerous references of administrative and clinical integration? If you could talk about the implications or consequences of those new standards like upgrades to 5010 or new technologies such as FHIR or new security approaches that would be great.

April Todd: That is a great question, Alix. We have been thinking about this a lot as I know the industry has as well and that is why we are approaching this as a stepwise approach and that is why there are certain components of the rules that are included. In particular, regardless of where the technology moves to there needs to be some common expectations around data content and how do you exchange that information and particularly the use of LOINC codes helps to – expectation.

Also, regardless of technology, there is a need for common expectations around response times. The infrastructure rule and starting to create those common expectations for plans and providers is going to be necessary for our list of what technology we have or may move to in the future.

But also, it is important that we keep in mind that although there may be new technology coming in the future, really our providers and our patients do not have time to waste for that. We need to start with this base and grow from it. And that is why as Tim had mentioned, we are in the process of adding to this and wanting to add to the process for helping to support clinical documentation and some of the connectivity, security components that would be necessary to support that.

Alix Goss: Susan or Tim, would you like to add any comments to that thoughtful response from April?

Susan Turney: No. That is good from my perspective. Thanks.

Tim Kaja: And the same here. I think the general notion of this being a stepping stone, getting similar standards in place around response times, up times, the ability of the delivery system to count on the health care payers to turn responses around and be available is a great first step. That is only part of the rules that I think that April went through. We are going to have to be thoughtful about how we approach the next number of phases all with the intention of taking administrative costs out of the practice through the prior authorization process, almost to the point of trying to make it invisible to the point that you can.

The next number of phases of this I think will be quite interesting for us to work through as an industry. I cannot think of any consequences, to the individual that mentioned what are the consequences. There may be consequences as we think through the 278 and the components of the 278 as it relates to FHIR, but at some point, the two of those end up needing to be married if we want to have a clinical conversation.

Alix Goss: Thank you, Tim. At this point, I think we are going to go ahead and pivot to our next presenter because we have run out of time on this agenda item. Thank you very much, April and Sue and Tim, for setting a good context for the rest of our hearing.

I believe now we are pivoting to Cathy Sheppard, the executive director for X12 to provide input on the Operating Rules. Cathy, are you available?

Intersection of Standards and Operating Rules

Cathy Sheppard: I am. Thank you, Alix. And thank you, everyone, for inviting me to be here this morning. I appreciate the opportunity to weigh in.

If you could advance a couple of slides. Go ahead and move to number four. I do not think everybody needs to see the disclaimer slide.

Most of you know, but I wanted to take a minute this morning to reiterate that X12 is a consensus-based, ANSI standards developing organization. We focus on the development and ongoing use of cross-industry interoperable data interchange standards. Our standards have been enabling electronic communication and business for more than 40 years. We are supported by a strong and diverse membership with expertise in finance, health care, insurance, supply chain, transportation, and other industries. Among that membership, we also represent all the health care stakeholders and we have very active and strong partners working with us as we move forward with our development.

That is all important because the majority of the administrative transactions adopted under HIPAA were developed and are maintained by X12. And specifically, the proposed Data Content Rule that we are talking about today is intended to support X12's 5010X217 and 278 Implementation Guide, which as you all know, is the version mandated under HIPAA.

Before we start talking about the details, I want to make sure that the subcommittee understands that X12 and CORE have a cooperative and collaborating working relationship. We have been working on joint efforts. We are focused on improvements that we can make in tandem or in a cooperative way that will make things easier for the entire industry and all the stakeholders that are represented in the industry.

We completely endorse and support CAQH CORE's information-gathering activities, the industry assessments, their surveys, and the analysis work that we do. Like the rest of the industry, we rely on it to help inform our processes.

I think we have talked enough about what this said. I put it in my deck in case somebody wanted to look at the deck later they would have a full reference set.

I want to be clear that X12 supports data content operating rules and we think that they are valuable and have a place in the ecosystem that we are trying to work in. We believe that they must align with the purpose of the underlying standard or implementation guide. That they cannot contradict or countermand the instructions that are defined in the mandated standard or implementation guide, but that they are a great way to pilot potential data content or data use revisions so that those can be applied in a future version of the mandated standard or implementation guide itself.

We look forward to continuing to use operating rules for data content in that manner so that we can make better decisions that will impact the entire health care industry.

We also support infrastructure operating rules and we know that it is a tough job to consider and balance the diverse interests of the stakeholders. That increasing consistency when the

processes of the implementation base is a very important component of moving health care forward. We know that these infrastructure rules can make a positive impact. And our only qualification on infrastructure rules is that they should not address data content or data use that is defined within the mandated transaction or implementation guide.

X12 also supports connectivity rules with the same kind of reasoning that they are valuable to the industry and they can be used to standardize processes that are outside the scope of the mandated implementation guides. And, again, connectivity rules are outside of data content and they are very complementary to what we are doing over at X12.

As I have said, we generally support data content operating rules and we generally support the data content rule that is being proposed at this time. We provided some written testimony if you want more detail to some of the information that I am going to present this morning.

We do have comments and concerns related to a few sections of the proposed operating rules. I will take this opportunity to run through those.

Section 4.1.1 Patient Identification of the rule that is proposed to you today has generated a lot of discussion with X12 and from outside stakeholders that have contacted X12 directly.

We agree with the stakeholders and the concerns that have brought to our attention that this operating rule does countermand the instructions defined in the 5010X217 regarding the transmission of subscriber and patient birth dates. It does overstep the ACA's definition that an operating rule defines business rules that are not defined by a standard or its implementation specification.

But X12 is not objecting to this requirement at this time, based on a couple of extenuating factors that I will share with you.

Section 1.12.2 of the 5010X217 implementation guide specifically permits a trading partner to require the birth data if necessary. If the entire industry feels that an operating rule can vet this out and help us inform our next decisions that is a good use of an operating rule.

And the second reason that we are not objecting at this time is we are already considering a revision, which would make the birth date required in a future version. We will be able to learn from the industry action and if the operating rule is adopted from the outcomes that follow. As I said, we would like to state that we do believe this operating rule oversteps, but we are not going to object to it at this time.

Section 4.2.2 labeled Consistent and Uniform Use of AAA Error and Action Codes is another area that we would like to make a comment on. We have no objections to the requirement that the most specific applicable reject reason code must be returned. We applaud that.

But we would like to note that there are no general or all-purpose reject reason codes included in the AAA segments of the loops that are named in this section except for a limited number of codes that are already restricted within the implementation guide to situations where no specific reject reason code applies.

Based on this, X12 does not expect this particular requirement will result in improvements in efficiency, consistency, or automation. As I said though, we are not objecting to it because we believe the implementation guide already covers this situation.

In Section 4.2.3.1 Patient Level Event, we fully support the requirement that a health plan and its agent must return specific HCR segment information and either the paperwork or HI information when the review outcome is pended for additional medical information.

We would also note that these instructions are consistent with the current 5010X217 instructions as they stand today.

We do have reservations in this section about the instructions for categorizing the listed types of events. As currently described, the categorization occurs when the request transaction includes one or more diagnosis codes. But diagnosis codes are not required in the request transaction. And the reason they are not is because the information is not always available. We are not sure how effective that is going to be.

In addition, the phrase "that can be categorized" in the requirement leaves open the possibility that a trading partner may determine that they cannot categorize at their discretion and will therefore feel themselves to be exempt from this requirement. It may not be applied as universally as we hope when we look at the intention and the basis of the rule.

Another concern related to this particular section is that there is not a documented general agreement within the health care industry as to which diagnosis codes fall under each of the listed categories. Also, that the first two categories on the list describe a type of service that is represented in a place of service breakdown. These things may cause confusion should this data content rule be adopted and that confusion may result in fewer improvements than we would like from this particular section of the proposed data content rules.

We believe that the current instructions in the implementation guide actually support broader use of attachment information and already referenced the PWK and LOINC use. But since 3.9 of the proposed operating rules specifically states that entities are free to offer more than what is required. We do not object to the limited set of events that are included in 4.2.3.1 nor to the somewhat non-specific instructions that may not be interpreted as strictly as we hope.

We note that health plans who want to provide other attachment information in the segments will be free to do so based on the current 5010X217 instructions. That voluntary transmission of information will not be impacted by this data content rule as proposed.

In Section 4.2.3.2, I am sure you will not be surprised to hear. We have similar concerns about the service level event that we stated above. I do not think it is necessary to go through them again. We all know how the claim level and service level works.

Section 4.2.3.4 about Using Health Care Service Reason Codes. We do not object to these recommendations. However, we would note that the wording "should" does not carry the weight of the "must" requirements that are included in other portions of the proposed operating rule and that "should" is not significantly different than the 5010X217's current instruction that the sender may choose to provide one or more HCSDRC codes at their discretion.

Based on the fact that this is a "should" requirement and not a "must" requirement, we are concerned that this requirement may not significantly increase the number of instances where a health plan provides the most comprehensive information back to the provider.

X12 is neutral regarding the proposed infrastructure Operating Rule and the Prior Connectivity Rule and we have no comment to offer on either of those at this time.

We want to reiterate that should this proposed data content operating rule move forward as a federal mandate, X12 and CORE will work closely together as we have been doing. And X12 will be working in cooperation to assess and evaluate any statistical improvements that arise. We will work with CORE to present simple cross-referenced instructions that ensure implementers understand any modification required to the implementation of the mandate standard based on the proposed data content operating rule.

We will also work with CORE, as we have been doing, to provide education on the intersection of the standards and the operating rules to assist health care industry stakeholders with the understanding what their actions are based on adoption of these data content operating rules.

Regardless of the outcome, X12 and CORE remain committed to our ongoing initiatives that are intended to ensure that data content rules, operating rules that operate in – that result in confirmed improvements in the use, efficiency, consistency, or automation of health care exchanges are considered for inclusion in a future version of the underlying standard or implementation guide.

We will continue to work together to ensure that implementers can view the mandated standards and the associated mandated operating rules in context and that they can easily identify the intersection points and the combined requirements.

We will continue to provide industry-level education that integrates the requirements of the mandated standards and the mandated operating rules and we will continue to do that over time so that the health care industry can remain current as new players emerge or other changes occur.

We will also continue to work with CORE to identify potential data content enhancements that can manifest directly in a future version of the standard or in an operating rule depending on where it is best suited at the time that the potential improvement is identified.

Thank you for giving me time to speak this morning and I am also happy to answer any questions that the group may have.

Rich Landen: Thanks, Cathy. A lot of thought and work went into that. I am very pleased to hear the extent of the cooperation and collaboration between X12 and CAQH CORE. And given the complexity of the transactions, implementation guides and operating rules, it is pretty surprising to see such few concerns that you noted. Thank you for noting the concerns and the Subcommittee will certainly be taking a look at what that means to the industry and the regulatory adoption process within our scope.

Alix, do we have any other questions for Cathy?

Alix Goss: Rich, I echo your sentiments to see the level of collaboration. It was historically figuring out who is on first and which seat at which time for which purpose has been a complex dynamic. And it really speaks to the level of leadership within the organizations to be able to come present such a strong face of support in advancing the use of national standards and corresponding operating rules.

I think there is a general question of interest on my part, and maybe some of our Subcommittee members. As we know that X12 has been working on developing the next round of – let me rephrase that. X12 continues to advance their standards and has a particular set of their work targeted for maybe the next upgrade to the HIPAA mandated transaction standards and implementation guides.

Currently, we have Version 5010 promulgated. There has been a lot of work to produce additional versions since 5010 and ultimately I think there is a game plan, Cathy, that likely you will bring forward in 2021 another set of technical reports or TR3s as they are called in X12 land for consideration by NCVHS.

Can you talk a little bit about that body of work and what might folks need to be thinking about in that horizon for let us say we advance a 7030 or an 8020 version, what might that mean in the face of the operating rules.

Cathy Sheppard: Sure. I can do that quite easily. As everyone knows, when an operating rule is put into place, the intention - for data content operating rules specifically. We will just assume that I am talking about data content rules. The intention is to assess the results and then move a recommendation forward to use that experience so to speak to inform the future revisions. That has occurred and is occurring with the operating rules that have been mandated in the past.

What X12 intends to do as Alix said is move forward a new version for adoption in the coming months. I have no timeline for you, but 2021 seems like a reasonable expectation for that. We will at the time we move something forward indicate to NCVHS whether there any corresponding operating rules and if those operating rules have been incorporated, if not, why, and if so, just a testing that they have been.

The expectation is of course that if an operating rule is not moved forward, there is reason for that and we need to have more discussions before we just arbitrarily say all operating rules roll forward to the new version. When we mandate a new version of the standard, the associating operating rules will have to be evaluated one at a time for impact.

In this particular case when it is possible that we could have new operating rules moving forward for 5010 at the same time that we are asking implementers to start moving towards a new version, I think that we are going to be in a situation we have not been in the past and we are going to need to work together, CAQH CORE, X12, NCVHS and the federal agencies that are involved to ensure that there is a smooth transition that we are not asking people to implement changes that are then only in place for a short period of time before they are seceded by a new version that replaces them.

Timing is going to be something that NCVHS is going to have to take into consideration. That is more difficult right now because CORE and X12 are moving their work forward independently. I can tell you that I have had 50 comments from people in the last six months. Stakeholders in the health care industry who have begged us to please find a way to work with CAQH CORE on timing to ensure that this progression of step-by-step improvements that April talked about occurs in a reasonable and organized fashion. And X12 and CORE do intend to have some discussions about how we can do that moving forward. Does that answer the question?

Alix Goss: I think it gives us some perspectives that you are vowing that there is a really tough act here for us to balance with wanting to move the needle forward while at the same time recognizing that there is a lot in flux right now: the base transaction standard, what might be

coming forward, other competing demands on the industry, even CAQH CORE's own evolution with their connectivity rule and upgrading their own methodology and approach to how they reference their operating rules, their transition in the focus in the categories in labeling of the operating rules. I think that there are definitely some implications there.

We have to really think about the overall value in moving the marketplace forward. Rich talked a little bit bout that in some of his opening remarks. It is just interesting to me if you have any final thoughts on testing or getting other core – I should not use the word core – other critical like attachment regs advanced. Any final thoughts that you may have along those lines?

Cathy Sheppard: We echo everybody's wish for the attachments reg. That would be phenomenal.

There is one more thing that I would like to clarify too, Alix, and that is that whether or not these operating rules become mandated as a result of this effort, we will be evaluating the findings for inclusion in a future version of the 278 implementation guide. As I said, I hope I said it strongly enough. We value the research that CORE does. Whether these operating rules are mandated or not they will be considered as part of the potential improvements to the next iteration of the guides.

Alix Goss: I think you made that point really clear earlier in your presentation. I think the value of their research analysis, consensus brokering, and prioritization of what are the tough nuts to crack and what issues must we address to actually move the industry forward is a huge amount of work. It really will help all of us as we all have precious resources. I am glad to hear that you are factoring those into the work and that there is a life cycle sort of between the technical reports of X12, Operating Rules and the churn will help continue to raise the bar for each work product.

Cathy Sheppard: Yes. Thank you all for having me this morning.

Alix Goss: You are welcome. Thank you for coming and presenting to us, Cathy. I think that we have nicely come to the point where we could all take a break. I believe, Rebecca, we are slated for a ten-minute break to return at noon where we will hear from a patient from the Arthritis Foundation to hear the patient perspective.

Rebecca Hines: Very good. Ten-minute break it is. Thanks. See you all in ten.

(Break)

Patient Perspective

Rebecca Hines: It is 12:01 so I suggest we go ahead and get back into things.

Alix Goss: Awesome. I believe Rich is back as well. I see that our next presenter, Anna Hyde, is queued up and looks ready go so welcome to the National Committee on Vital and Health Statistics. We are very thrilled to have you presenting today. As we started out the session really talking about the patient at the center, we thought it made sense to as a lead in to our covered entity panelist discussions that we would really kick off with the opportunity for the Arthritis Foundation to add the patient perspective on prior authorization and look forward to your remarks. Thank you, Anna, for being here. Please take us away.

Anna Hyde: Thank you so much for having me. I really appreciate the opportunity. This is an issue that is definitely near and dear to us, which I think some of the things I will present will make clear why.

I really appreciate the comments early on about the patient being at the center and how difficult it can be to navigate health coverage, administrative challenges while you are managing your disease. That is really the crux of what I am going to talk about today. My goal really is just to paint a picture of why this matters to patients and why improving the prior auth process is so important to us.

Before I dive in, I will just say that arthritis is a chronic disease. The prior auth process or just health coverage process used can look very different for a chronic disease patient – the average consumer of health care. Arthritis is also degenerative. If there are disruptions in care, it can cause lasting damage.

I bring that up for two reasons. One, just to give a sense of urgency as to why this issue is so near and dear to us, but also to make the point that it is not usually a won and done process for patients. Most of the patients that we talk to have been through prior authorization and other administrative processes multiple times and oftentimes for the same drug – that way.

We collect a lot of data on all sorts of health care and health coverage-related challenges that our patients face. We have done a survey every year, asking for top health coverage related challenges and prior auth has come up every single year as the top challenge, which may be surprising because I think it is not always intuitive that prior auth impacts patients directly as much as it does. It is often thought of as a provider challenge. While it absolutely is without a doubt, the patient is often at the nexus of trying to manage and navigate through. It is a constant feedback loop often via phone between the relevant parties who are involved, the provider, the pharmacist, the payer, whoever else it may be. Needless to say, that is fairly inefficient, and leads to the next bullet point. It just contributes to an overall administrative burden that patients feel.

We asked a question, and these are benchmarked questions we ask every year so that we have been able to develop some trend lines. But 48 percent of the respondents spent more than five hours a month managing their health coverage. And the one that was really alarming to me was that 17 percent spend more than 15 hours a month. It is also the chronic diseases that we represent. Sometimes it is multiple people in a family. You are not just managing the administrative burden for yourself. It could be for your children as well.

We have focus groups that really back all of this up. We do a lot of qualitative research to go along with the survey data. What we hear from them is it is not uncommon for them to really liken the administrative burden to a full-time job. In fact, oftentimes patients have to deputize someone in their family to help manage it so that they can actually keep a full-time job.

A recurring theme that comes up is I might be able to do this. I have the resources to do this. I have a parent or a husband or whoever, but what about the people who do not have those resources and cannot manage it? How many of them are just falling through the cracks and just giving up? We know it happens. We do not know how frequent it happens. Those are the sort of knowns/unknowns that really keep me up at night.

The impact from all of that is probably obvious. Delays in treatment certainly. Just general stress and anxiety. I think that looms really large and we have other – that shows that. In some cases, it leads to abandoning therapy.

And something that I often say is just administrative-driven decision making. When we first started doing focus groups and roundtables on this issue, I was really struck early on at how many patients said that their decisions about what treatments to start are really driven more by how many hoops they will have to jump through than by what is clinically going to be best for them. They want to know right off the bat before anything else how many hoops do I have to jump through. I just think that that is backwards and shows why improving and streamlining the prior auth process is so important to them.

I wanted to put this up because this is some of the quotes that we have pulled from some of the focus groups and things like that just so that you can see it in their own words. Even as early as this week, I had a patient I was talking to who went through a prior auth process for a new biologic. This was just three years ago. It took her seven weeks to get through the process because of such specific paperwork needs. It kept getting kicked back over and over and over again. In that time, there was a lot of confusion about who should initiate and what her role should be and what not. In that time, she developed ulnar deviation. While she cannot necessarily point one to the other, her conclusion was it certainly did not help having that nearly two-month delay and starting that biologic. I think that is a good example of why the sense of urgency is there.

Our policy position around this is really driven by the AMA prior authorization principles, which I will not read through all of these of course. Because it is such an important issue to us, we engage with them in the development of those principles. We were the only patient group to do so. Those have now been signed off on by over 100 organizations. In the consensus statement, I know they will be talking about that later so I will not get into that either, but I just wanted to put that up front.

And then my last slide. I really wanted to just tie this up by saying that the data kind of speaks for itself. What patients want is not going to be a surprise here. A streamlined process with online tracking capability. They often say I can do all of these things online, track my Amazon package or FedEx or whatever. Why can't I do that with my health care? Really that kind of streamlining efficiency is really important to them.

Faster response times. That is really important, too. Like I said, it is a degenerative disease and that continuity is really important.

And then transparency about the process from the beginning all the way through. We engaged a lot with CMS last year as they were doing listening sessions. And one thing – we got asked the question. Do patients even want to know what drugs are being prior auth? The answer is unequivocally yes. And the data here shows what the level of detail that they really want.

My last point I will just say, there is also a trust component, which maybe is beyond the scope here, but I think it is important to illustrate. It is not just that they want to know clear, reasonable explanations for denials. It is also that they want to know clear explanations for why a drug is being prior auth in the first place. If I have been on the same drug for ten years, why do I have to go through prior auth every single year? If there is a clinically sound reason, fine, but tell me. It just feels very much in the dark.

Last point. I think – mentioned earlier that this represents an important first step to build from and I very much agree with that. There is obviously clear value in faster response times. The one recommendation I would have is to conform to the AMA principles on response times, that they should really be measured in hours and not days, the business day piece because your disease does not take breaks on weekends and holidays, and that sense of urgency going back to that again. Our position statement, along with the AMA's position statement, is really around hours and really making sure that there is one for urgent requests that is 24 hours. That is really critical as well. It is something that I would love to see in these recommendations.

I, again, very much appreciate the opportunity to be here and hope to continue to engage with you all and happy to take questions. I will end there.

Alix Goss: Thank you, Anna. I would like to talk a little bit about that business day/calendar day dynamic. We have been hearing some remarks in various places, submissions, et cetera, about the impact there. Could you just elaborate a little bit on your thoughts there with the dynamics related to patient safety in the urgent care setting in particular?

Anna Hyde: Absolutely. I think a good case is – in an urgent case where you have care disrupted for whatever reason and you are on a really complex medication like a biologic, having any disruption in treatment at all can cause major damage. We say 24 hours for urgent requests. Of course, in reality, we prefer it to be immediate, of course. But at least that 24-hour period so that there is not too much of a disruption, but it really is just about preserving that continuity. If it is a Friday, and an urgent request is going to be one business day or two business days, you are talking potentially four to five days without treatment, which can truly cause a lot of damage.

We know and have plenty of evidence that it can land patients in the hospital, which of course drives up health costs, not drives them down, which of course is what we all want is to have health costs driven down. That conversion into hours. It makes it clearer as well. Forty-eight hours no matter what day it is. It is 48 hours. That just makes sense.

Something that we also follow around step therapy. We have seen it in certain pockets with prior authorization in the states, but something that we would certainly like to see standardized across the board.

Alix Goss: It is not just that you are looking ultimately for real time, but if you can't have more instantaneous like within the workflow sort of while the patient is there, moving things along with the clinician or their support team, being able to do that while they are still in the office or in the institution. What you would like to see is the business day values updated to be more of a – do not go into calendar days. Get into this 48-hour kind of would be even a better step than the current rule that you are seeing because of that potential for weekends since health care is 24/7. So we want to see that kind of natural synergy between care delivery and response not being impacted by that holiday or weekend dynamic for being tied to business days.

Anna Hyde: Exactly. It is clear and unequivocal, leaves no room for interpretation.

Alix Goss: Thank you for that. I want to open it up to see if there is any of my colleagues who may have some questions for you because we still have a few minutes in this section of our agenda.

While we are seeing if any of our colleagues have any questions, could you talk a little bit about from your perch of what it would mean to organizations to adopt these rules regardless of the concerns we have talked about. Are there any types of encouragement that we should be thinking about to help organizations ultimately focused on the patient end here with the providers, those care teams? You have talked about deputizing a family member. You have talked about this overall impact. If we think about that end game, we ultimately have to encourage folks to adopt whether it is voluntary or mandated. There is value in these roles. Any thoughts from your part to about how we might encourage folks to pick up and use these roles?

Anna Hyde: That is something that we have been grappling with for a very long time. I am going to go back to the AMA, the consensus statement. We talk about it early and often in any conversation that we have. You already have this cross group of stakeholders who have sort of said these are some things that we can do. Granted some of them are more complicated than others.

I ultimately would love to see let us work backwards. Let us see what is the best way for a patient to continuously stay on their therapy and what needs to be in place for that to happen. However, knowing how complicated the health care system is, incremental approaches like we are going to streamline this. We are going to set the standard around response times or whatever it may be that we can use that as a launching pad to build broader consensus, bring more groups onboard and then just use the momentum from that as really a base of encouragement. And of course, we would love to see that. Then extrapolate it to all plans. And no matter how your insurance is regulated, state, federal, et cetera, we would like to see that continuity and that standardization across the board. I would say just that kind of incremental and that momentum building because the standardization across is one of the more important things and the way to do that – we want to see that done right as opposed to just trying to do it piecemeal.

Alix Goss: Thank you. I really also want to call out the – to me, just a tremendous factoid that you brought to us today, which is the 48 percent of – I think it was patients spend more than five hours a month on their prior authorization activities, but more especially, it was the 17 percent spend more than 15 hours per month. This is within your arthritis community. This is sort of a year over year survey results if I am hearing you correctly.

For our patients that are dealing with advanced arthritis and probably more the ones that have the more complex situation, just shy of 20 percent are spending about a third a week just trying to track down prior authorizations to maintain their continuity of care. That is a factoid that I think not only for us and NCVHS that makes a big difference. But I would love to be able to port that over and use that in our collaborative effort of NCVHS with the Office of National Coordinator's intersection of clinical and administrative data, which a number of us are participating in because I think it is a very poignant statistic. And as we are working on trying to improve prior authorization or identify recommendations to improve that as an exemplar in that larger intersection conversation, that might be a very useful factoid for me to carry forward if you are okay with that.

I am just going to open it up to see if there are any other questions for Anna before we move on.

Rich Landen: This is Rich. I have one. And, Anna, thank you very much for your presentation. It is always good to get the patient's eye view of things. I am interested in particularly how you

presented what Alix just referenced, the degree of management or oversight that the patients are exercising the five or more hours a month. I think it is worth noting both for the operating rules and for the underlying transactions, code sets, and implementation guides of the future that this is an application, the patient monitoring and the patient management that has not been considered in standards, design, and development. This information is both useful to NCVHS and Standard Subcommittee, but also to CORE, X12, and the other standard development organizations. Thanks very much for calling that out.

Alix Goss: I am not seeing any hands raised so I think we are good to go ahead. Anna, thank you again for your testimony and participation today.

Denise, do you have a question?

Denise Love: Yes. Hi, Anna. Thank you so much. This was a wonderful picture of the patient experience. Of your survey that shows the amount of time that people are devoting to this preauthorization issue, how much of that is included like labs and special medical equipment that may not be included in this operating rule? What is that mix?

Anna Hyde: I do not know that exact mix. It is a very general data point. We do not have granularity within that. It is health care coverage irrespective of whatever that coverage administrative time commitment is. It includes prior auth, but it also includes other things as well. It is a data point that we are hoping to build out from in a more granular way because it is something that we want to understand better as well. But it is really just very general. I would caution as well that it is irrespective of if we ask for the patient how much time do you spend. But like I said before, oftentimes a disease like arthritis exists with multiple members of a family so that 15 plus hours could be on behalf of the whole family, not just on the one person. Either way it is still – data point.

Denise Love: Amazing data point – that got my attention. I was just curious what that mix is. Thank you so much.

Alix Goss: Thank you. Thank you again, Anna. I think that that was the last question I see coming in for you. I appreciate your data points and perspectives. It sets us off on a good first step into our panels.

I believe next we have coming up are Christol Green from Anthem and Cathy Plattner from Kaiser Permanente. I think at this point, what I am going to do – Rich, if it is okay with you, I think we will let those presenters proceed and then Deb Strickland and Margaret Skurka are going to facilitate our Q&A for this panel.

Health Plan Perspective on Proposed Prior Authorization Operating Rules (Panel 1A)

Christol Green: Thanks Alix. This is Christol. Thank you all for having the opportunity to let us provide our testimony on behalf of Anthem regarding our perspective on the CAQH CORE Prior Authorization Operation Rule.

I think you guys know about Anthem. Our testimony has been given to the committee. If you want to read the full testimony, it is out there for your reading.

My name is Christol Green and I support Anthem's electronic data exchange as a clinical, medical records portfolio manager. I am within the E-solutions Division here at Anthem. I have

over 30 years' experience in health care, including implementation and integration of the electronic standards. I also work with our industry to drive and deliver new interoperable technologies.

The prior authorization process for us as a health plan plays a critical role in patient safety and protection by ensuring the care being authorized, aligns with the latest evidence-based medical research and ensuring that patient services are covered.

We recognize the importance of prior authorization and how it plays in driving high value care across our health care programs.

Some of our efforts to improve prior authorization. We try to remove, as we can, requirements for certain services when appropriate. And that reduces the cost and the burdens and delivers on our mission of simplifying health care.

We are regularly looking at our processes and our criteria to update to recognize the changes in emerging evidence and our new technologies.

We promote safe and effective care for our patients to ensure that our prior authorizations, providers' choice of drugs, the medical procedures, the treatments and services for our patients are founded on the latest evidence-based, peer-reviewed literature and guidelines.

We ensure that patients do not receive unnecessary tests and treatments and we are looking at again the latest medical evidence particularly in the early stages of diagnostic process for the condition, thereby lowering patients' out-of-pocket costs and avoiding potentially harmful over treatments.

We also promote information sharing between our providers and our health plans, which create opportunities for the health plan to improve care management and care coordination.

Here are some more examples on how our efforts are to improve the overall care provider experience with prior authorization. We have pilot programs that waive the prior auth requirements for some services when providers are taking on risk. These providers when they take on risk such as in value-based payment arrangements, incentives are effectively managed to manage wasteful or duplicative services and they are better aligned.

We also have launched an innovative provider-facing Utilization Management portal tool, known as Interactive Care Reviewer, which allows our providers to submit prior authorization requests to Anthem 24 hours a day. They can also track their statuses without having to call us or fax any information.

We review our prior authorization requirements at Anthem at least twice a year to ensure they are based on the current clinical evidence. We try to identify the services and treatments with high approval rates to determine if a PA requirement should be removed from our listing.

We leverage analytics using stored member data, care provider, and clinical to drive automation to the prior authorization review process.

We participate in emerging technology initiatives with Health Level Seven accelerator project Da Vinci. We work with the Health and Human Services. We also work with the ONC. We are involved also in the FHIR at scale taskforce. With prior authorization, we see that FHIR is an

enabler for providers at the point of service to request authorization by providing all necessary clinical information to support the request and we need that from beginning to end.

We engage heavily with our provider community, also with the X12 278 transaction requests.

Some of the concerns related from Anthem are with what we will be speaking about, is on the connectivity, the data content, infrastructure, and appropriate implementation timelines.

Maintaining multiple platforms across the board to accommodate entities in various stages of implementation for prior authorization is burdensome. All stakeholders, regardless of size, should be given the same implementation time from our perspective.

Adding standards to an updated process does not generate meaningful change to the prior authorization process. We recommend that NCVHS look towards a standards adoption process that will move forward on a continuous basis, bringing all stakeholders along at the same time.

Now with the 278 transaction, which we are conducting today, the ability to request and receive supporting documentation again is critical to our workflow. We see from a lot of the provider community too the lack of adoption of attachment regulation leaves the industry with incomplete prior authorization process.

Some payers and providers will need to manually request and submit supporting documentation as they do today for the 278-transaction process and that sets up some delays. Health care systems and other applications are at varying levels of adoption that we are seeing and maturity to require this support for the critical business function and technical workflow.

Operating rules do not address turnaround times for current business processes that are not conducted electronically end-to-end.

Data content. The standards development. WE are looking at the ownership of the requirements and usage is the sole responsibility of SDOs and not the operating rules authoring entity rules regarding data should be communicated via the data specifications/implementation guides from the industry approved by the SDOs.

HPAA security and HITECH rules cite that NIST is the authoritative industry source. Connectivity rules created outside of and divorced from NIST again is creating confusion and disparity in the health care community in our standards deployments.

Connectivity rule limits inclusions of new and emerging technologies such as FHIR, XML, RESTful, OAUTH, et cetera.

Some of our points to consider in the recommendations again. All stakeholders if this was going to move forward should be moving forward at the same time.

Adopt connectivity rules across all transactions for which operating rules are in place.

We would like to address inconsistencies in the data content rule provision and afford stakeholders the flexibility to use newer business technologies, which would be more efficient for communication exchange between the clinical staff and the health plan.

I think I covered it for you, and I think I am right at my time. Thanks.

Lorraine Doo: I am sorry. Was there anything else that you really wanted to get across for the committee members. I did not mean to interrupt you with a barking dog.

Christol Green: That is okay. We will listen to our next speaker and then we will see if anybody has any questions. I will be talking a little bit tomorrow too. I am good. Thanks Lorraine.

Alix Goss: I believe we are moving to Cathy next.

Cathy Plattner: Good afternoon. For the members of the Subcommittee, I apologize, there is some background noise. It appears my neighbor is having some work done. Sorry.

My name is Cathy Plattner. I am the business consulting specialist in our National EDI Business Operations. I am here to offer Kaiser Permanente's short and sweet feedback on the CAQH CORE proposed set of prior authorization and connectivity operating rules to NCVHS, consider recommending for a possible regulatory adoption. We appreciate this opportunity to provide our input.

Just a brief introduction. The 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 eight states and the District of Columbia. Kaiser Permanente has long promoted the appropriate use of secure technology to coordinate care. We give members and patients tools that allow easy online access to their electronic health information, including a comprehensive EHR, web portal, and mobile applications to securely connect them with their health care teams, their personal health information and the latest medical knowledge.

We also support the larger goals embodied entitled four of the Cures Act of improve consumer access to health information, better care coordination, broader interoperability, and greater information exchange.

Overall, Kaiser Permanente supports the core proposed Operating Rules for Prior Authorization Data Content and Infrastructure, as well as the overarching Connectivity Rule, which if adopted in regulations would supersede current, mandated connectivity support for eligibility, claim status, and electronic remittance advice and also apply to prior authorization.

We have general concerns on each of the proposed rules. First, we want to comment on – we are concerned about the degree to which the prior authorization data content rules could overlap or even override some of the technical report – the TR3 implementation guide requirements included in the X12 278.

We believe that some of the requirements in the proposed CORE prior auth data content operating rules may constrain the data requirements defined in the X12 278 implementation guide.

As we have learned from implementing CORE Phase 1 and 2, the data content rule on eligibility request response X12 278 around the service type codes, such implementation benefitted our trading partners by providing useful responses.

In addition, implementation was a one-time process. It was very helpful to have a testing tool like the one we used.

We had a slightly different experience implementing the data content rule electronic remittance advice, the 835, and the related remittance advice reference codes. Having CAQH and X12 build this code combinations separately, confused our own implementers as well as our trading partners. Unlike the 270/271 service types, the 835 combinations involved multiple updates, which created some redundant work on our part.

The initial testing was challenging without an available testing tool for this CORE 835 operating rule code combinations.

Overall, the operating rules and data content should be incorporated into the X12 transaction standards progressively, perhaps in the front matter, and once they become more stable and widely used. We believe that that approach would ultimately eliminate having two separate sources of standards requirements having CAQH and X12.

Second, the infrastructure rules set focuses on the response time of various transaction options, meaning batch and real time. In our organization, most of these internal processes are fully automated. Thus, we experience no issues with the response time limits for all the varied submissions and response requirements. However, others might have concerns specifically with a two-business day turnaround for batch mode transmissions.

And then the third, the Connectivity Rules Set. It does a good job of increasing the security of transactions, which we strongly support. However, we have two main concerns. The first is the CORE proposes to replace the old versions of the connectivity rule 1.1.0 and 2.2.0, covering transactions for which operating rules have been adopted, namely the claims payments, electronic remittance advice, eligibility claims status and such. And to apply this new version retroactively to them as well as to the new prior auth referral transactions. The industry has already established specific connectivity processes for these existing transactions, and it would need to move to a new connectivity operating rule.

It will be very important to ensure that CORE lays out a clear roadmap as well as a well-defined, cost benefit and ROI for entities required to transition to these new connectivity requirements.

Our second concern is we have concerns about the safe harbor and the connectivity standards using the rule. The connectivity rule attempts to strike a balance between the use of SSL 3.0 and the use of newer PSL 1.1 or higher.

However, due to the well-publicized POODLE vulnerability and SSL 3.0, this standard has been progressively phased out, disabled, or rejected in lieu of the newer PSL standard.

We are concerned that if the SSL 3.0 is covered under the safe harbor and a trading partner insists on choosing the SSL transport standards, entities will be expected to support it consistent with the rule safe harbor conditions for reference. The rules state if HIPAA-covered entity or its agent do not believe that the CAQH CORE safe standard is the best connectivity method for that particular trading partner then it may work with its trading partner to implement a different mutually agreeable connectivity method.

However, the trading partner insists on using CAQH CORE safe harbor, the HIPAA-covered entity or its agents must accommodate the request.

Alix Goss: Cathy, this is Alix. Sorry to interrupt, but please note that you can cover extensively your connectivity comments tomorrow. I believe you may be on the agenda as is Christol to

come back. Today, we would ask you as well as the other testifiers for the rest of today to help us focus on the prior authorization content in infrastructure. That may give everyone a wee bit more breathing room and getting through their testimony today and as such.

Why don't you go and at least take another minute since I just interrupted you? I apologize.

Cathy Plattner: No problem. Thank you. I apologize. And the last slide. The development and implementation of the operating rules, which runs parallel to the process for standards development has been largely accomplished through voluntary industry adoption except for certain operating rules adopted early in the 2000s.

Voluntary adoption of non-regulatory operating rules has provided an important example of how the industry can act more voluntarily and in concert to achieve administrative efficiencies.

We recommend that NCVHS and regulatory bodies consider pursuing increased voluntary adoption of standards, using appropriate programs and incentives and policy levers.

We are also concerned about the degree to which the Operating Rules can be implemented in a scenario where HL7 FHIR standards are used.

To conclude, we want to express our strong support for the approval of a HIPAA exception to allow end-to-end implementation testing of a FHIR-based transaction approach for HIPAA transactions such as prior auth and other transactions that can be achieved using real-time interactive models.

Thank you for your time and attention.

Debra Strickland: Great. Thank you, Christol and Cathy, for your testimony. Very much appreciated.

I have a question I would like for each of you to answer, Christol and then Cathy. If we take a look overall, does this rule go far enough as an intermediate step along the path toward a major improvement to reduce the complexity, improve timelines in the experience of the patient, provider, and the payer?

Christol Green: Again, we do not see it that it is really working to administrative – to really remove the administrative burden that we are seeing. We do talk internally a lot about the patient too. We know this is around the X12 transactions. We see other things that the patient should be able to just like the portal process that we are setting up, the FHIR portal processes under the other rules to allow the patients and the members to see their data, to see what is going on with the prior authorization process. Those types of things we are looking at because really the patient from our perspective – it is around the patient, but we are dealing with the provider mainly.

Really what these rules that we are seeing coming out here around the X12 278 we feel that some of this is outdated. We feel there are probably better ways of closing the gap from the provider – coming from the patient, but from the provider perspective to the health plan to get it a round trip, one type of scenario. It is very difficult today using the X12 transactions. There is a lot of manual processes and we struggle with that. That is why we have been looking at some of the other emerging technologies and being involved in other ways of doing this process that we can have an end-to-end flow, the provider request from the patient, respond back if we even

need a prior authorization – doing the whole workflow. We see that as a better capability for the future with these emerging technologies. We really would like to share that information with our patients via our member portals, our patient portals.

Cathy Plattner: With Kaiser Permanente's integrated model, our current workflows are already automated – inquiries are handled within our modules across our care delivery and health plan.

For our external trading partners, mainly for emergencies and urgent care, the data rule section 3.2 – the rule does not really address that area of our business. We have no trading partner to date that has requested or stated that they have a need to exchange 278 with Kaiser Permanente. I hope that helps.

Christol Green: This is Christol. We do have providers that are on our prior auth programs that we are doing work with like Cleveland Clinic and TriHealth, a lot of different groups, but we are also trying to streamline the process internally also. We have been trying to implement – implementing already the 275 transaction to allow our providers to be able to do that electronically. Without the rule coming out, we had to forward, but we are also working with the Da Vinci piece too to do some of these other types of CDex/PDex work. But in the meantime for the providers that are connected via the X12 278, we are trying to stand up the 275, which we have just done for attachments, but we are going to be doing that also within the next couple of months for our prior auth process.

Debra Strickland: Thank you. Margaret.

Margaret Skurka: Yes. I have one question. Is adopting these rules nationally important enough to start this journey that competes for resources during this challenging time, but we are competing for resources to comply with all the mandates? Either one of you want to take a stab at that?

Cathy Plattner: This is Cathy Plattner. Yes, that is certainty a concern for us. Right now, at least on the health plan side, we are heads down, trying to support the recent final rule published on interoperability. This is a concern that it will tap into those resources that are already taxed out at the moment.

Christol Green: This is Christol. I would agree with that. We have a lot of work going on right now with the different rules that have already been out there working on the interoperability rules. This is a good idea of trying to set up operating rules, but we really need to make sure it is going to work for the long term and being able to update and be able to make changes on the fly if we need to quickly. It has been taking us a long time with the X12 transactions to make changes to get those implemented and we are still waiting for a lot of that. That is why some of us are moving on our own, which again we have to. We need to move forward to allow our providers to send things electronically to us even if there is not a rule.

Debra Strickland: Thank you so much, ladies.

I think we are within our time. Alix.

Alix Goss: Thank you. I would like to ask a question sort of following up on I think a comment that Cathy made at the very end of her presentation. Thank you to both Christol and Cathy for their thoughtful testimony. But this one particular curve ball comment kind of caught me off

guard. The end-to-end testing exception request. I think Cathy made that. Could you elaborate a little bit on your thoughts there?

Cathy Plattner: We are very much in support of any HL7 FHIR-based transaction. That is where we are heading towards. As you may know, we have Epic as our EHR and therefore everything now works seamlessly within our different modules. We are using HL7 FHIR for these transactions. I do not know if that helps.

Alix Goss: I guess I was wondering if you were – because the end-to-end testing exception request to me really refers to the federal regulations that under 162.940 permit our ability to submit a request to HHS national standards and then have that request reviewed so that you can get an exception from doing a mandated transaction. But I was not sure if I was listening with the right filter to which you referred or if it was something separate that you were thinking about.

It may have been just more of a general reference in your perspective, thinking about how – system. Thank you for clarifying that, Cathy. I heard it through a filter of the HIPAA regs. I will retract that filter and thank you for your thoughtful remarks about the HL7 infrastructure within your integrated network as your ability to move data seamlessly and you do not want to use that leveraging or EHR so I appreciate that perspective.

I realize that I am between you and lunch, everyone. I think, Rich, if you have no further comments, I believe we are at that point of being able to head off for an hour.

Rich Landen: Other than thanking Ms. Green and Ms. Plattner, no further comments.

Rebecca Hines: Just I want to remind everyone who is listening, we will have public comment later this afternoon. We welcome your input then if you are not speaking --

Alix Goss: We will see everybody back at 1:50.

(Break for Lunch)

Health Plan Perspective on Proposed Prior Authorization Operating Rules (Panel 1B)

Rich Landen: I think we are ready to resume. We have the second health plan perspective panel starting off with Connie Leonard from CMS, Medicare Fee-for-Service, and then Gail Kocher, Blue Cross Blue Shield Association, and our questions and post-presentation moderation will be handled by Denise Love and Jamie Ferguson.

Connie, are you up and ready? Thank you for joining us.

Connie Leonard: Thank you for inviting me today just to give you guys some perspective about CMS's Medicare Fee-for-Service prior authorization perspective. From a fee-for-service perspective, prior authorization is really in its infancy. Partly that is because we have limited statutory authority so we can only do it in pockets of services, so it is a little different than some of the other payers.

We are certainly supportive of trying to streamline the prior authorization process and make it easier for everyone, payers, providers, beneficiaries and patients, but we wanted to make sure you guys understood how fee-for-service does it. We are a little concerned that some of the unintended consequences could drastically impact the way that we do things.

Right now, when we do a prior authorization request, we actually get the full medical record at the time the request comes in. We have set up our program so that providers know that that medical record comes in with the request, and we do a full medical record review prior to making a decision. So it is very much like what we would call a prepayment or a post-payment review just before the service is even provided. And that is how CMS has just chosen to set up its program, again, because I feel we can do that because we have such limited numbers of cases that we actually take forward.

For us, prior authorization is really a program integrity tool. We are using it to make sure that the right services are being provided to the beneficiaries. That certainly comes into a quality-of-care issue also, but primarily it's a utilization effort to make sure the right services are being provided at the right time with the right documentation and such.

Typically, all of our items are what we call non-emergent. For example, some of the elective surgeries have been most recently some of the times that we have chosen to require prior authorization. Those types of items typically have a lead time anyway. There isn't necessarily a required turnaround time when you have to be backed up in scheduling that type of a visit in the outpatient arena. We do a lot of demi-post durable medical equipment, para-mobility devices, and thinking of potentially doing something down the line on prosthetics. We have announced some of the higher-cost prosthetics, pressure reducing support services. Again, these kinds of high-cost items that are not emergent in nature.

Typically, since we do have this non-emergent perspective from the claims that we choose, our contractors typically have a 10-day turnaround time to make a decision. I will say that today most of them are in the probably five-day window for getting a response back, but we have some concerns with that two-day timeframe decision given that these are non-emergent items. We feel it is possible an exception could be factored in for some of these non-emergency items that a two-day turnaround time is not necessary.

We also always add in an emergency function. If, for some reason, even though we feel like it is a non-emergent item, but the provider feels like they need it in two days, they actually can

request what we call an expedited request. That process has worked really well for fee-for-service, and again, because we have been able to keep our numbers really small as far as the type of services that we are pre-authorizing, we worked really closely with each industry as we rolled it out, and we have actually made changes based on their feedback.

In some of our models we have actually taken away codes where they said no, sometimes that is an emergent service. So we have been able to kind of educate the providers on how it is going to work in the Medicare fee-for-service program, and also do a lot of hand-holding from our contractor perspective with providers, walking them through the process, helping them get the necessary documentation that they need to submit. And we have found that, after the first couple of months, the process gets a lot smoother for providers.

A lot of providers use the Medicare administrative contractor portal to submit their prior authorization requests today. You guys probably wouldn't be surprised at just the number of faxes in the fax lines that are still being used, and that is one of the goals, to get away from that fax machine. The fax machine has no interactive ability, and we certainly are along the same lines of everybody else wanting to increase interoperability that would make it much easier for providers if we had an electronic version that can be shared back and forth. But we are just not sure Medicare providers are necessarily at that point yet.

We have had a process in place for quite some time supporting the current 278 requirements, and we actually haven't had a provider use them yet. Our process may be somewhat cumbersome, and that is certainly what some may say, and we are actually working on trying to identify an easier way for providers to use that process that may make it not so cumbersome for them. We are trying to work with providers and work with the industry to increase that usage. Right now we do it through our ESMD, electronic submission and medical documentation, process.

But the portal and the US mail is still very much used by Medicare providers. Even if we went to some type of new standards and new turnaround time, I think that is the issue that we really want to focus on, is how can we get more providers away from some of those more antiquated processes and into the next big thing, electronic means. It is something that we really have been working towards and struggling somewhat with as we are trying to get feedback.

Being in CMS I was in the unique position of -- not sitting in on all the discussions that CMS had on prior authorization, but I did receive a lot of the feedback that providers and beneficiaries stated about their concerns with prior authorization, and we do try to take those into consideration as we are developing our process.

Our main concern, as I try to wrap up, is that there cannot be a one-size-fits-all, and I understand the need and desire for one-size-fits-all but that may not actually work, and there may need to be some exceptions or some different parameters depending on the type of claim.

I also agree with some of the other comments about implementation timeframe. If this were to go forward as written it would drastically impact CMS's ability from a fee-for-service perspective to conduct prior authorization, and we might actually have to retool our whole entire process, so we would be very concerned. The implementation time would need to be long enough that we could do that and continue doing the prior authorization process.

With that, I will turn it over to Gail.

Gail Kocher: Good afternoon, everyone. I am Gail Kocher, Director of National Standards at Blue Cross Blue Shield Association. I would like to thank the subcommittee for the invitation to present our information this afternoon.

The Blue Cross Blue Shield Association is a National Federation of 36 independent community-based and locally operated Blue Cross and Blue Shield companies, or the plans, that collectively provide healthcare coverage for one in three Americans. On average, we have 150 million transactions that flow through the Blue Cross Blue Shield Association monthly. That is an average of the first six months of this year. Only two-tenths of 1 percent of those are the 278 requests and responds. Ninety-five percent are eligibility transactions. We do conduct the transactions; however, the volume of 278s is very small.

We continue to uphold the adoption of operating rules, especially when they support implementation of standards, and they are not supplementing what is already defined through the standards organizations. Operating rules should not replace either front matter nor conflict with general usage contained in implementation guides.

Regarding anticipated value of the proposed operating rules, plans have indicated that they believe the operating rules in general are likely to increase the reliability and performance of data exchange without affecting the data content of the standards. However, they have some concerns about the operating rules that currently have been proposed.

We believe that these operating rules are likely to add administrative costs not just for plans but also for providers, and feedback indicated that the operating rules as currently published are not likely to add any value to the current workflows. For some plans, they have currently automated prior authorization in which they can conduct final determinations today. They would actually have to revert those to previous pending requests in order to meet the timeframes in the infrastructure rule. Significant systems analysis would need to be conducted to determine if the automated systems could even be revamped to meet the 20-second real-time turnaround requirement.

With respect to the top three to five points that we would like the NCVHS to consider from our comments, plans continue to seek solutions to improve the prior authorization process, including looking for flexibility to use newer technologies to exchange information such as FHIR or XTML through a web portal to accommodate the need for the more iterative process that prior authorizations require. Real-world testing is really needed to document realistic and achievable timeframes, and it must consider all stakeholders as part of that evaluation.

Plans do not believe adoption of these operating rules will increase the adoption of the 278 prior authorization transaction. They continue to report much lower volumes of the 278 from providers, and the value proposition for implementation is very low. Barriers that plans continue to report to adoption are the complexity of the transaction and the lack of an attachment standard. Plans indicate they believe the adoption rates might increase when the health plan attachment standard is adopted.

Finally, we would like to suggest that a reasonable cost-benefit analysis be conducted, and that requires detailed project planning, analysis and review. Blue Cross Blue Shield Association would be happy to work with NCVMS and CMS to develop a set of data points on which such a cost-benefit could be conducted.

Those are my comments. Thank you.

Denise Love: Thank you, Gail, and thank you, Connie. I will start off the Q&A part of this panel. I think Connie alluded to this, and, Gail, you touched on this. This is a question that may be hard to answer. To what degree do you think the exchange of electronic clinical information is a prerequisite for better or more successful 278 uptake?

Connie Leonard: I agree that an increased use if we had more electronic clinical information -- it might be able to increase the usage of the 278 process. It's almost like a circle and there are all these different stops on the circle and we need all this other information to get to the endpoint. If we don't look at all these little points along the way together, if we just make changes to the endpoint but we still don't have all of those other points, then it is not going to happen.

It is kind of like what I talked about with the fax machine and the handwritten medical records. You kind of hear it but you never really think about it, but as we have been trying to talk about structured documents and getting more information electronically and getting things in that format, it's just amazing to us how many providers just are not there yet. I don't know how to get them there, and that is one of the issues that we're struggling with.

Gail Kocher: I think all I would add is that prior authorization tends to be a very conversational type of process. Oftentimes, even if you provide a clear list of these are what you need for X procedure, there is often a give-and-take and a back-and-forth because you need more information out of that medical record. That is why clinical data is important.

Health claim attachments is definitely one way that we can get to that. And yes, there are other technologies that might enable that as well, but not every stakeholder across the continuum is at the same place with respect to newer technologies.

So, as we look at how we can enable the clinical data, we also have to make sure that we are balancing the needs of all our stakeholders and where they are in terms of being able to conduct such an exchange.

Denise Love: I will turn it over to Jamie.

Jamie Ferguson: Thank you very much. I will follow up with another question for both of you. It is reported that the 278 is used just a small fraction of the time when prior authorization is needed, so the question is what proportion of that unfulfilled potential would be achieved by adopting these operating rules. In other words, how much would it move the needle?

Connie Leonard: From a fee-for-service perspective, I actually don't think it would move the needle at all. We have had no providers choose to use it, and I don't think these changes would move the needle. It is possible if there were attachment standards that that might move the needle, as has been mentioned several times. But I actually don't think it would move the needle at all.

Gail Kocher: We didn't pose that specific question to the plans, Jamie, but based on the feedback that we got I would have to say that the plans believe that the operating rules as currently drafted would actually move the 278 forward. We had more than one plan indicate that they would actually have to pull back on some of their automation, and so we think them having to do that might actually further drive providers that are using the 278 to use other methodologies because they might get a response quicker than if they would continue to use the 278.

Alix Goss: Could I ask a clarifying question to read between the lines on Gail's other methodologies? Are you saying that an unintended consequence could potentially be that we drive people more to faxes and portals? Is that what you meant?

Gail Kocher: Yes, those are definitely the other ways that providers are communicating and conducting prior auth with plans today.

Alix Goss: I just don't want to be shortsighted and only thinking about those two and maybe you had a broader perspective.

Gail Kocher: I don't have any other specifics. Most of what we hear is that providers prefer the portal today. I don't have statistics on how much is portal versus 278 versus fax versus something else.

Alix Goss: Thank you.

Jamie Ferguson: I will follow up on that sort of substitution effect, if you will. I think, Gail, one of the things you mentioned was that faster turnaround time requirements might force more of these requests into a pending status initially, if I got that right. So I think the question really is about the two-business day requirement, and is that of sufficient value overall to help improve adoption of the 278.

Gail Kocher: The feedback that we got from plans was that the two-day was too limiting. They would not be able -- because again, there can be a manual piece. There are two things. It is automated but there is (inaudible) that all have to talk to each other. That automation, doing that in that timeframe, is going to be difficult.

The other piece is there is often still some manual intervention because you have got medical directors or clinical staff that are looking at data and trying to do that in two days is tough. I know we had supported the three-day as a minimum. We felt that was a good balance. But through the process, the two-day is what ended up in the published rule.

Jamie Ferguson: Thank you very much. Connie, if I can turn back to you pretty much on the same question, I think you mentioned five and ten-day decision times. What is your take on the two business days proposal?

Connie Leonard: I really worry about a two-day requirement. If we went out with that, it would have an unintended consequence of -- We don't really put a lot of ours in a pending location; we have affirms and non-affirms but they can be resubmitted multiple times. I would be worried that an unintended consequence would be that we would have more denials, more non-affirmations because they need to meet the timeframe but they didn't get to pass it along to the medical director, or they didn't get to do one more piece or talk to the physician or talk to the provider, and they would just non-affirm it knowing that it can come back in with information.

That would have the impact of increasing burden on the physician who is requesting the prior authorization. I don't necessarily know if that is a direction that anyone wants to go in.

Jamie Ferguson: Thank you very much.

Denise Love: I have kind of a wild one, and this may not be answerable. COVID is such a big deal and it is disrupting a lot of things. If the decision goes forward, will that impact the

implementation? Or will COVID spur the need for new innovations and faster turnarounds and kind of up-end the current processes? It could work both ways. What are your thoughts, and is it more philosophical?

Connie Leonard: I will say I have had the same thought that possibly maybe something good comes out of COVID from the perspective of increased interoperability and sharing of records. I feel like there certainly has been a lot of notice of the lack of ability to get the right information to the right provider or supplier at the right time, and I certainly am hopeful that that increased emphasis on the need to have that interoperability is something that maybe will come out of this.

But, at the same time, I am concerned from the implementation time perspective that, because of COVID and everything else that surrounds it, from a claims processing perspective payers would need additional time to implement just because of everything else they are doing because of COVID.

Gail Kocher: I think I would echo Connie on that. There is a lot coming down the pike from federal and state health information technology initiatives, the huge interoperability rules. But it is not like plans have additional staff all of a sudden to work on all of these things. COVID has turned the world upside down in the work environment I think for every entity across this country, and people are having to prioritize and focus on what can be done and how it can be done.

I think making sure any consideration to move forward is evaluated against all the other things that are on everyone's plates, recognizing that resources are competing for other imperatives as we continue to address this national pandemic will be important.

Denise Love: Thank you. Are there any committee questions?

Alix Goss: Hearing none, I am going to ask us to maybe backtrack a little bit in the conversation really quickly to ask Connie a very much more specific question to help me interpret her remarks from a bigger picture perspective more appropriately.

I am hearing you talk very specifically about Medicare fee-for-service and the way the program for fee-for-service operates, and I wonder from your perch if you feel that the experience that you face or spoke to from a CMS fee-for-service perspective is comparable to the rest of the marketplace payers.

Sometimes government programs can be a little bit different than private sector programs, and so this idea of getting the full medical record, the way you handle authorizations in the Medicare fee-for-service program. Do you feel like your remarks are global or very much just tailored to the more unique scenario of the Medicare fee-for-service program?

Connie Leonard: My remarks are really tailored just to fee-for-service. I do want to be clear. I know that other payers have different processes. (Indiscernible) and even the Marketplace, have different processes that they use for prior authorization, so this is really specific to Medicare fee-for-service.

Alix Goss: Thank you. I also feel like Medicare fee-for-service is highly transparent with their medical polices and capabilities for their beneficiaries.

Connie Leonard: We do try.

Alix Goss: I think I am going to turn it to Nick.

Nick Coussoule: Gail, just one question. When you were talking to the other plans or different parts of the system, did you get any kind of overarching indication of what would incent them to move forward or towards the 278? Or do you think there are more of them really waiting for FHIR and that process to come along?

Gail Kocher: Do you mean the plans, what they think the providers are? All the plans are 278-enabled; it's just they are not seeing the uptick of it on the provider community. And it is not that plans don't want to implement the 278 operating rules; there were other concerns in the comments about some of the provisions, some of which we will talk about tomorrow.

I think the plans are willing to implement. The concern is that it is going to, in some cases, have them decrease automation that they have in place, and they don't feel that the cost-benefit, the ROI, for what they would put out is going to increase the provider uptake unless we have the ability to do clinical data.

We deal with plans that would like to move to other technologies, but since this is really about the operating rules, we kind of did go down that path.

Jamie Ferguson: Thank you both very much. I really appreciate your statements and your answers to all the questions. I think now we are ready to move on to the next panel.

Alix Goss: We are. Our next three presenters on this panel are Terry Cunningham, Heather McComas and Rob Tennant, and I believe Tammy and Nick will be managing our Q&A.

Provider Perspective on Proposed Prior Authorization Operating Rules (Panel 2A)

Terry Cunningham: My name is Terry Cunningham. I am the Director of Administrative Simplification Policy with the American Hospital Association. Thank you so much for allowing me to come and speak from the hospital perspective on the proposed operating rules.

Today my presentation is going to go over a general background on prior authorization quickly. You are all familiar with it so I won't spend much time. An overview of some of the problems that from the provider community we have identified, some of the value of how the proposed rules may address some of these problems, and I will go through some opportunities for improvement both in these rules as well as in general in terms of the administrative simplification space.

As you all know, prior authorization is a utilization management method requiring claims for services to be reviewed and approved by payers before services are rendered to patients. AHIP identifies this as it is implemented so that patients can receive optimal care based on efficacy and safety while providing benefit to the patient. Philosophically, the AHA doesn't have a problem with that. Those are laudable goals if implemented properly.

The problems that providers have identified are that the method with which prior authorization is being implemented has been strife with issues that have caused problems for both providers and their patients. These problems are delays caused by inefficient implementation, differences in requirements and submission methods between health plans, occasional questionable

application of prior authorization in circumstances when it probably wouldn't be necessary, and inappropriate denials of prior authorizations that should have been approved.

The reason you see the first two bolded is that I think these are really the two that we will hit on today that are trying to be addressed by the operating rules.

As I said, one of the main problems providers have identified is delays and burdens caused by inefficient implementation. What I mean by this is that for documentation preparation and submission there are a lot of different methods of prior authorization for submitting work, and a lot of them, if not almost all of them, require significant manual work in the provider space, and this requires a significant amount of staff time and resources that could otherwise be spent on clinical patient care. There is also a huge problem with slow processing times that delay patient care and the unavailability outside of business hours.

Another significant problem for providers is the differences in insurer requirements and submission methods for whether or not prior authorization is required for a particular service. Basically, each individual plan has different services that they will require prior authorization on, and it is often difficult for a provider to keep track of and be aware of each specific plan's requirements on prior authorization, whether or not prior authorization is required and what information is needed to satisfy those prior authorization requirements.

Additionally, the method of submission has been significantly problematic. For one, there are just a whole bunch of different ways that are used -- fax, phone call, portal, 278 transaction. Each plan has a different flavor they might require, and because there is no standardization it leaves providers in the space of having to support a whole bunch of different ways of doing it, and I think that has been part of the issue with adoption of the 278.

It's great if one plan might support a 278 transaction, but if for every other plan I am dealing with I have to use a completely different way of doing it, is it worth the time to have this kind of plan-by-plan problem of this 278 works and sort of works on one plan's way of adjudicating things, but I also have to make sure that my staff is prepared to address this with this plan and then is prepared to address different methods of submitting things and satisfying the prior authorization submission process with each.

I want to go through how these operating rules we believe might improve the current state of affairs. Before I go into it, I want to point out if you see my main bullets and they might sound extremely familiar, it is because these are the three same bullets you heard from Anna Hyde earlier. Providers and patients are in lock-step on this. We want to make sure that we can reduce delays, streamline processes and improve transparency. Those are my bullets, and I did not work with Anna in advance, so it's interesting to point out.

As I said, my first point is that we believe that the infrastructure operating rule could reduce delays. The rule as it is written requires plans to respond within two business days of receipt of a prior authorization request; it requires them to request additional information within two business days of receipt and to acknowledge real-time prior authorization within 20 seconds of receipt. This is usually beneficial because there are some processes where providers are longer time, longer than two business days, for adjudication of these things. But more importantly, patients are waiting a long amount of time for this.

Earlier today, Tim said that providers could save 17 minutes on prior authorization as a result of these operating rules. That is great for our providers, but I think what providers will tell you is

the greater benefit is that this would save the turnaround time for their patients. The 17 minutes of administrative work is great, but the fact that the patient is not going to be -- that might not be as easily measured, but it is arguably more important. The patient's wellbeing, peace of mind and the speed with which they can receive necessary care could be improved significantly.

The next thing that I think the infrastructure operating rules do is streamline the process. It streamlines the process in that it does kind of create a more usable 278 transaction which we believe could push more providers to utilize the transaction. There are a lot of issues that they are trying to address with this, and the addressing of the issues may convince providers that this is an actual avenue to address some of the concerns with using the 278.

One of them that we have heard from providers, for example, is there is also this pendant roadblock. What I mean by pendant roadblock is frequently you will submit a 278 and you will get a pendant back because they need additional information, and then you end up resorting to a different way of fulfilling the prior authorization. You will abandon the 278 and move to a different method, but it would be calling them or going through the portal or whatever the other way is. By having at least a two-day turnaround time on the 278, this does address it to a certain degree. I believe there are additional improvements that can be made to make this more streamlined, which I will get to later.

In terms of the data content operating rule, I think this increases transparency and eliminates variability. One of the things that the rule does is it requires plans to use a standardized code set to identify additional clinical information needed for PA requests. This is a huge step. I know there was some concern earlier about the specific way this is being rolled out, and I think, just from the provider community, the use of a standardized clinical code set is extremely important because it makes things more transparent, makes things more uniform so that providers can know upfront what do you want me to do to satisfy this prior authorization requirement.

To the extent that it does need to be expanded to meet the industry needs we would support that as well, but this is a good first step.

It also requires plans to send healthcare decision reason codes -- again, more transparency and more information that the providers can readily use and pass on to their patients while they are developing a clinical therapy.

Opportunities for improvement on these operating rules. The first would be removal of the business day concept. I know you heard this earlier but I will reiterate. Providers are caring for patients 24 hours a day, seven days a week, and to the extent that a plan is inserting a step in this process, which in this case is prior authorization, those same timeframes should be set. The timeframe for the patient care should not be changed because they need to meet a plan's business workday.

The additional is increased compliance requirements. Under the operating rules, plans are required to meet the operating rule requirements 90 percent of the time over the course of a month. If they do that they pass this operating rule requirement. If we are trying to create an atmosphere where a provider can give realistic timeframe expectations to their patients, I think the 90 percent creates kind of a problematic situation in which a provider might be reluctant to say you can expect me to know whether or not this treatment is acceptable within two days.

This just limits the availability because if you fall in that 10 percent it could be significantly longer.

The final -- I don't know if you want to call it the elephant in the room, but it has been said over and over -- is, in terms of NCVHS and the industry, a clinical attachment standard of some sort is extremely important. There is no standard way of sending clinical information on to a health plan, and health plans require clinical information to adjudicate prior authorization a lot of times.

So, if there is no standardized way of sending the information, it limits -- I don't think it completely makes it so attachment is a prerequisite because I do think there is gradual improvement in making the 278 more usable as we try to figure out the clinical attachment process. But I do think that without a standardized clinical attachment process you are going to have a process that ultimately becomes inefficient and manual and you are still using fax, telephone, and mail.

In conclusion, I just want to say that AHA recommends that NCVHS approve the proposed prior authorization rules which establish necessary process improvements, increase revenue cycle efficiencies and improve patient care. I have been involved in this space for about seven years, and this has been the issue since I have been involved.

Really, there has been a lot of talk and a lot of work trying to address this, but it has been the same issue over and over, and from a regulatory space there hasn't been much work done. So I urge this committee to take the necessary steps to get that ball moving so that we can approve this process for providers and, more importantly, the patients. Thank you.

Alix Goss: Take it away, Heather.

Heather McComas: I am Heather McComas with American Medical Association. The AMA represents physicians across the country and all medical specialties of our various areas of work that are highlighted on this slide. I will draw your attention to the item about removing the obstacles that interfere with patient care, and that is right in the sweet spot of what we are talking about today with reducing prior authorization burdens.

I am going to start off with some background and some data that will hopefully ground us in what the prior authorization process is and why we need improvement in this area. The AMA conducted a survey of 1,000 practicing physicians at the end of 2019, and 91 percent of surveyed physicians reported that prior authorization delays access to necessary care. And those care delays translate into downstream problems with care delivery and actually patient harm.

Almost three-quarters of physicians reported that prior authorization can lead to patients abandoning their treatment altogether. Ninety percent reported that prior authorization has a negative impact on clinical outcomes, and nearly one-quarter of physicians indicated that prior auth has led to a serious adverse event for a patient in their care. Also, 16 percent of surveyed physicians stated that prior authorization has led to hospitalization for one of their patients.

If we can somehow put aside the very real human harms being shown by these data, I think it also leads us to question the overall healthcare savings that result from prior authorization. If this process leads to patients ending up in the hospital I don't know if we are really saving the system any money at the end.

Our survey also reported the impact on physician practices. In our survey, practices reported completing 33 prior authorizations per physician per week, and this weekly workload of prior authorization for just a single physician consumes nearly two business days of physician and staff time. These burdens are growing over time. The overwhelming majority of physicians reported that prior authorization burdens have increased over the past five years, and almost one-third of our surveyed physicians indicated they have staff who work exclusively on prior authorization. Obviously, this represents a lot of administrative costs in our healthcare system.

Because of the significant impact of prior authorizations on both patients and physicians, the AMA has been very active on advocating reforms on this topic for the last several years. A very important part of those efforts was a release in early 2018, of the Consensus Statement on Improving the Prior Authorization Process. I want to note that this was not an AMA only effort. My provider colleagues on this panel, AHA and MGMA, also participated in formulating the consensus document, as well as health plan trade organizations, Blue Cross Blue Shield Association whom you heard from just a couple minutes ago, and also AHIP.

This document outlines five agreed-upon areas for prior authorization reforms. Plans and providers agreed on making these changes. Two of the areas are very much in alignment with the goals of the rules that we are talking about today: improving transparency in prior authorization requirements and also improving automation to increase efficiency.

One thing I want to flag is the consensus statement also talks about reducing the overall volume of prior authorization through selective application to just outlying physicians and also regular reviewing and adjusting prior authorization to get rid of low-value prior authorizations, and we think this is a really important and necessary component of prior authorization reform but is not addressed in the operating rules.

Unfortunately, progress on implementing the reforms outlined in the consensus document has been slow, and so the AMA has continued to plug on with our advocacy on this topic. We participated in all of the CAQH CORE efforts and straw polls related to the rules development. I will admit that we were probably a bit of a pest, frankly, in urging them to reopen the infrastructure rule to address the issue of response time to final prior authorization determinations. And my colleague, Rob Tennant, who speaks after me, also was a joint pest, and we thank CORE for taking on this additional work because we think it is really important. The AMA strongly supports federal adoption of the CORE PA infrastructure and data content rules.

Looking at the PA infrastructure rule, we see several aspects of it that will bring value to our healthcare system. First of all, as several people have referenced throughout the day, the rules requirement that prior authorization final determinations be delivered within two business days is very important, given the fact that our *status quo* right now allows -- the accreditation requirements for health plans allow between 14 to 15 days, so that is a significant and meaningful reduction in processing time and will reduce care delays.

We also appreciate the fact that the rule requires plans to return within 20 seconds the additional supporting clinical documentation needed to complete the prior authorization request when those policies and that information is already published. Again, we feel that it is really important to increase the transparency of prior authorization requirements, which we know is a huge challenge for practice staff.

Also -- and this is something that may be a little more nuanced -- we think there is real value in this rule in the fact that it requires plans, after an initial prior authorization request is pended, to deliver a second unsolicited 278 response with a final determination. We think this goes a long way to driving industry towards an end-to-end automated process. Right now, oftentimes when an initial 278 is pended, it drops to a manual process. The physician is directed to a website or to a fax or ordered to call the health plan, and we believe this is really important to keep the whole process of EDI. So this is a real step forward that is offered by the operating rules.

We do have some concerns and I guess a wish list of other things we would like to see in this area. As Anna and Terry both indicated, we are concerned about the processing time being measured in business days. As Anna indicated, the principles that the AMA released with a lot of other supporting organizations several years ago recommended that the processing time for non-urgent PAs be 48 hours. Although these sound the same, 48 hours and two business days, they are really different, particularly when you think about a long holiday weekend. So quickly, two business days can turn into multiple calendar days, even close to a week if you think about the holidays at the end of the year. Again, that is something we would like to have changed moving forward.

Also, we are very concerned that the rule does not include a provision for the processing of urgent prior authorizations, and this is particularly concerning given the fact that non-urgent PAs are -- the requirement for processing time is outlined in business days. And so for that reason we really urge that NCVHS, when you make recommendations to HHS, include a provision for urgent prior authorization processing and that it be 24 hours.

We also see value in the proposed data content rule. As others have referenced, the PWK code and LOINC inclusion in the response to the practice indicates the additional supporting clinical documentation needed to complete the request. We think this is a very important improvement in indicating the transparency of prior authorization requirements to providers. Oftentimes they have to dig through a lot of different sources and manuals to find this information right now.

Inclusion of the Health Care Service Decision Reason Code in the response should bring more clarity and specificity and provide more clear information to the practice about what is going on with the prior authorization. We also think that the rules provisions for consistent use of AAA error codes will help the practice correct and resubmit a 278 if there were problems.

I will admit I think we are all in danger of having PETA come after us because I feel like we are beating a dead horse, but I have to say it again. We really do all need direction on adoption of standards for clinical attachments. This is something that has been lost in the Bermuda Triangle for years and years. It is no fault of the rule itself, but I don't think that the impact of the rule will be well felt or can be fully realized until we have a standard for clinical attachments. So we urge NCVHS to reiterate your previous recommendation on standards for clinical attachments when you make your recommendations regarding these operating rules.

We do see perhaps a glimmer of hope. The federal regulatory unified agenda did show a September 2020 date for an attachments NPRM, so maybe there is a surprise next month that we have something to look forward to. But again, the 278 transaction is not robust enough to carry the clinical data that most prior authorizations need to be processed by health plans.

Here are the main things we would urge the subcommittee to keep in mind as you develop your recommendations in the next couple of months. Again, we urge you to recommend the federal

adoption of the two prior authorization operating rules. We think they offer value, and that value outweighs any potential costs to the industry. I was so glad that Anna participated in today's proceedings because I think this is one revenue cycle process that involves the patient, and this could help us minimize care delays for patients.

We also urge that NCVHS encourage the two business day requirement be viewed as a floor for the industry and that we really try to shorten that processing time moving forward, because, again, two business days could be quite a number of calendar days when we get into weekends and holidays.

We also very much encourage you to add a provision for urgent PA processing, and we would encourage you to set that at 24 hours. Again, that is very important when care needs are more urgent than just regular care. As others have said throughout the day, we urge you to again reiterate the need for a standard for clinical attachments.

My final comment would be I know that several members of the subcommittee are also participating in other discussions going on right now in the industry about prior authorization automation, for example, ONC's HITAC ICAD Task Force, and we would encourage you to kind of think about all of this in a little bit bigger picture and put your recommendations regarding the operating rules in context with recommendations regarding that work and other discussions that are being had right now.

The AMA did present comments to that task force in May, and I included the link there for folks to take a look at.

For some of the neural technologies we think they offer promise, and we think we probably might need some research and piloting to ensure those technologies work as well as we need them to and to be available to practices of all sizes in the near future.

So, again, to take a more holistic view of this and make sure your recommendations on the operating rules fit in with what you might be recommending relating to the ICAD work. Thank you so much.

Alix Goss: Rob, take it away.

Robert Tennant: Thank you, Alix. I am Rob Tennant, Director of HIT Policy for the Medical Group Management Association. In case you don't know us, we are an association with 58,000 members that are leaders in all types of medical groups, everything from a very small, two, three, four-physician, single specialty, all the way up to the largest multi-specialty groups in the nation.

I wanted to build on what my colleagues, Terry and Heather, have talked about because we are talking about very technical rules here, but there is a real impact both on patients, as you heard from Anna, but also on the administration of healthcare, so I wanted to share with you a survey that we did last year.

We asked our members what their most burdensome administrative requirements were, and you can see here prior authorization was ranked number one by quite a substantial margin. If you look at the other burdens, they are all tremendous burdens on practices, but again, prior authorization rose to be number one.

This really dovetails with what Heather talked about. We got about 1,000 responses to the question: are prior authorization requirements increasing over the past year, and 90 percent said yes, so it is a really significant number. You can see here that prior authorization disrupts the continuity of care, it interferes with that very special relationship between the physician and patient, and it causes a lot of costs for practices.

I want to focus on the data content rule. There has been a lot of discussion. There are a lot of positives that we see, and, as Heather said, we worked very closely during the rule development process, a lot of straw polls, and I think you can see that there are a lot of advantages with these new operating rules. For example, receipt and processing of the diagnosis, procedure and revenue codes. Very importantly, consistent patient identification and verification process. We think that is going to lead to a decrease in denials because there wasn't a good patient subscriber match.

Return of the specific AAA error codes and action codes should improve the communication. I think Gail said it correctly that prior authorization is different from other transactions in that it's a conversation between providers and health plans. I think the more we can streamline that conversation, the more we can automate that conversation, the better, frankly, for both sides.

Return of Health Care Service Decision Reason Codes -- We heard about the PWK codes. Again, all of these relate to transparency, and I think that is one of the challenges that we have faced in the medical group world, is simply not knowing what is going on in the process, and I think you also heard from Anna that that results in a lot of frustration for patients. Again, we think that these operating rules will help in that transparency. Providers will know a little bit more, they will have a better sense of what's going on with that conversation with the health plan.

And again, they are requesting additional documentation for a pendant response, which is very important to know exactly what the health plan is requiring so the provider can very quickly identify the data and get it to the plan as quickly as possible.

There has been a lot of talk about whether CAQH CORE should at all be involved in the data content world. Why can't the SDO simply be in charge of that? We would absolutely support a single entity being responsible for data content. However, that presupposes that the SDO will have good and solid input from providers, be able to incorporate modifications that actually improve the use of the transaction, and are nimble enough to act quickly to meet the needs of providers and others.

I don't think those conditions have been met, and I think that is exactly the reason why we have CAQH CORE and why these operating rules are so important. We go a long time between transaction versions.

Alex, you quizzed about the movement at some point to a new set of standards, but that is still a long way away, so we need action now, and I think that is why we commend CAQH CORE for their diligence and professionalism. They run a very tight ship in development of these rules. We don't always agree with the outcome, but we absolutely agree with the process.

Turning to the infrastructure rule, we want to talk a little bit about the positives. I will just run through them quickly, you have heard about them. System availability requirements, absolutely imperative. However, we do note that the rule permits a full 24 hours per week of down time, which we believe is excessive.

Acknowledgements - NCVHS has urged HHS to adopt acknowledgements for other transactions. They are long overdue. We need to know if the plan has received the PA.

Consistent companion guides. Again, consistency is critical here.

You have heard about the two-day additional information request and determination. We do believe that there will be a significant incentive for providers to adopt the 278. I know the current use is about 13 percent, which is abysmal, so we are hopeful that getting a little better information in a more timely manner will convince a practice to say, okay, now it is time to invest in the technology.

But, as you heard from Terry and Heather, we are looking for some enhancements. You have heard about the urgent need. For PAs deemed urgent there should be a maximum response time of 24 hours. You have heard about the business day issue. Healthcare is not a Monday to Friday event, and you can have multiple days if you factor in weekends and holidays.

A little twist here. We are also concerned about the maximum of 15 days for a provider to respond to a plan request for additional information. In many cases the provider may need to circle back with the patient, they may need to order more tests and 15 days goes by in a hurry, so we would like that to be extended to 30 days.

As you have heard from many entities, we would urge the committee to look at 24 months minimum time to comply with these rules. It is a challenging time. I think Gail said it correctly. A lot of regulations, so we need the time to make sure to implement correctly.

In summary, we are supportive of the content and infrastructure rules being federally mandated. We believe these rules will improve the current prior authorization process. We believe the two business day requirement was a necessary compromise during the development process, but we would urge those times to be slimmed down.

Candidly, these operating rules are going to help but they are not going to solve the prior authorization process. We believe that eliminating prior auth for services that are routinely approved and for providers in risk contracts -- and it was great to hear Anthem talk about doing a pilot for exactly that.

Again, to beat the dead horse, getting that attachments standard out, although I will say that it is great to hear that Anthem and also United Health Care are moving ahead independent of a federal mandate with the 275. So I think that bodes well. It shows that the plans see value in this transaction. We need to move forward.

Again, we need to explore new opportunities to automate the prior authorization process. And, finally, for those health plans that are not compliant with the law there needs to be stronger enforcement. With that, I will turn it back. Thank you very much.

Tammy Banks: Thank you Rob, Heather and Terry. We really appreciate your presentations as well as your long-term focus on prior auth. Obviously, this has been a discussion topic for a very long time. I won't even throw out years. I have several questions for you but I am going to try and give a higher-level question so you can expand.

Reading the testimonies and comments, there are a lot of pros and cons. We heard about the patient demographics, we heard about the admission of lab services. I know each of you had mentioned a couple points that are challenging.

In your opinion, does this rule go far enough as an intermediate step to reduce the complexity, improve timeliness in the experience of the provider and practice staff so that will increase their adoption of the 278 and movement away from calls and portals? Could each of you respond and help us understand the value at this point in time?

Terry Cunningham: Sure. While there is certainly room for improvement, which I think we all went through areas where these rules could be improved, I do think these rules establish extremely important protections that improve the process enough to -- I think Rob used the correct word -- incentivize provider adoption of these rules. The fact that you can put a two-day frame on your prior authorization response or a two-day frame on I am going to know whether or not I need to send additional clinical information, that is a game-changer.

It really does change providers from having to be left out in the dark for a long period of time, which is again a huge problem. Oftentimes we will hear from providers saying half the time I don't even know what I need to send them. I don't know what they are looking for. So I do think there are some really important and valuable things in this rule that could improve the adoption of the 278.

All of that is said in the frame of acknowledging that the attachment is an enormous step that is needed down the road, but I don't think not having an attachment should belittle what this rule does accomplish.

Heather McComas: Basically, what Terry just said I totally agree with. Obviously, we all had our own wish list of other things that we want in the rules. But I think, at the end of the day, looking at the current industry accreditation requirements for prior authorization processing, which are 14, 15 days, you can't deny there is a huge difference between two business days and 14 or 15 days. So we really feel like this would move things forward. It would be an incentive to use the 278 if you knew that you would be getting a final decision within two business days of having submitted the supporting documentation.

Again, I think that unsolicited final decision, the second 278 after initial pended response is another critical piece of this. Otherwise -- I have heard before that there is no real reason to use the 278 now because you are never going to get a final decision. When the initial request is pended it's going to drop into another workflow. But that is going to be another real reason that providers will be interested in using this transaction.

I think it really does bring some meaningful change to the industry, although, at some point, if we held this up for every single thing we want, we would never get anywhere. Terry referenced having been working on this for nearly seven years, and he and I are both in the same situation. It is really frustrating that I can pull some of the same bullet points off the slides from five years ago, and I really hope that we can move forward with the rules to improve things for patients.

Robert Tennant: I want to say, first of all, welcome to Tammy and Jamie, great to see you both on the committee.

It is easy for me to say ditto to what they said, but I would just add a couple things. One is you know the success of standard development is when everybody is unhappy with the end result. There is no winner or loser; we all wanted something that we didn't get.

The discussion during the development process had some health plans asking for two weeks' time. Well, that is just unacceptable. While we would like real-time decisions in order to help the patient at the time of service, at least this puts a line in the sand. It is not perfect by any stretch of the imagination, but it is a phenomenal step forward in prior authorization.

I think it's important to recognize that providers want to see this problem solved. And if this adds more transparency and a key word to know exactly what is going on in the process, if they have a definitive timeframe, then that is a very easy sell to our guys to then go to their vendors and say, okay, I am ready to take advantage of the 278.

And the fact that more and more health plans are starting to go down the pathway of the 275 is only going to make that 278 more valuable.

Tammy Banks: Thank you, Rob. Nick, you had a question?

Nick Coussoule: Actually I think Heather was the one who brought it up in regard to ONC's HITAC and ICAD, and one of my questions I guess for all of you, not just Heather, is, clearly, ONC started the mandate on the provider side and certainly in the clinical realm. Administrative transaction is probably more on the payer side in the administrative realm, obviously, and these are coming together, frankly, way faster than most people would have predicted years ago.

But with that kind of work coming, you know, the FHIR task force and the DaVinci work and some of the other work going through ICAD, is this proposed standard enough to go forward with? Do you see it either conflicting or becoming subservient to some degree by some of that other work? How do you view the risk of that or the likely take-up in the provider community, partly because you have got very big providers that can probably deal with all of the above and very small ones who are going to struggle anyways.

Terry Cunningham: I agree that there is a significant amount of work being done at ONC that would address a lot of the same issues or similar problems, the efficiency of this process. I am reluctant to keep kicking the can because we think something is going to be better in the future.

I don't mean to say that so flippantly, but it has been so long that we have been working on this. Six years ago we heard just wait, there is an attachment process that they are figuring out using the CDAR 2.1, HL7. And then when that got finalized, we heard, wait, there is this other new form using this different platform of HL7.

So I think what you say makes sense, but in this space the people who keep paying the price for our delays are the patients who are waiting for the process to become more efficient. So I think any step in the right direction is a good process improvement towards improving -- it is a good step. And do I think that down the line there might need to be additional things to consider? Sure. But I don't think we should put everything on hold until that is addressed, because I think we have already done that in the past and it has left us with really no movement recently.

Alix Goss: Nick, this is Alix and I want to take a little liberty here and ask Terry to add an additional comment to his question and tee up this also for Rob and Heather should they want to ask.

In addition to Nick's question, is there a way that we can actually -- If there such value, is there a willingness to do voluntary adoption even without a federal hammer?

Terry Cunningham: I think the problem with voluntary adoption is the fact that not everybody is going to volunteer. So, from a provider perspective it is great that some people might volunteer, but what that is introducing is differences between each health plan. The real benefit of standards is that you have a consistent way of interacting with plans to solve these issues.

If we have some people volunteering to do things and to a certain extent some people volunteering to do other parts of this and some people not volunteering, you are introducing this variance throughout and it could ultimately result in decreased efficiency.

Robert Tennant: Just to add a few points, and Terry is 100 percent right. When you look at this and you look back, obviously, it has been 20 years and HHS has not issued an attachments standard. Ironically, the only HIPAA standard that was piloted back in 2005 to resounding success was with Empire Blues and Montefiore up in New York. So, even when a standard is piloted and it shows value, there is no guarantee that it will be implemented without a federal mandate.

So, to Nick's point, assume we have this great new solution. Well, it's only going to be ubiquitous if it is federally mandated. If HHS delayed implementation of the 275, which is well established -- I mean, we have gone on with a cornucopia of stakeholder groups, payers, vendors, providers, all saying exactly the same thing: NCVHS has made four recommendations towards that and still nothing.

So, to Terry's point, if we sit back and say, oh, well, FHIR is going to solve all our problems, well, 1,000 things have to happen for FHIR to be implemented throughout the industry. First of all, a national mandate. We don't even know if it works. And how are we going to convince practices, especially smaller ones, to invest in an untried technology when we can't even get health plans to support standards that have been around for a decade?

Heather McComas: First of all, I totally agree with everything that Rob and Terry said. To the point on voluntary adoption, I just don't think it works. Particularly a lot in the vendor community when they look at their development plans they prioritize what is mandated.

In fact, I had on my slide a quote from a major electronic health record vendor from the 2014 NCVHS testimony on attachments where they said that basically there is no incentive for anyone to move until there's a mandate, that they were stuck. And that was over six years ago. And here we sit today, and nothing has changed. So, clearly, we need a mandate for anyone to make the investment in development.

I think Rob is spot on where things are in terms of widely deploying FHIR. I think there is great potential there, and that is why, looking at this in a bigger context, right now the 278 is the HIPAA-mandated transaction for prior authorization. In fact, if you look at the current model for FHIR it includes using the 278 in there, so that the rules would apply to that kind of middle use of the 278 and the FHIR-based prior authorization process while that transaction was mandated. So it fits into that kind of model already.

Again, there is this kind of future-looking technology that I think is very promising and interesting, but I think we really need to do some major calculations about how readily it will be available to all provider sizes and across all service types. You know, a lot of the demos I have

seen are really cool and interesting, but for the same kind of services over and over again. It's oxygen and oxygen. At some point we need to build it out across service types and that is a lot of work, and how long are we going to let patients like Anna's constituents wait for care, wait for another six or seven years before we actually do something in this?

Again, a holistic plan, like how do you implement the rules now and get value now, and then kind of map this out, maybe for the next five to 10 years, what is the overall vision of how this is going to progress.

Alix Goss: Nick, I apologize for adding a question that clearly was a hot potato. I was really just trying to think about how, if hearing such overwhelming support from these associations and knowing that we have written four letters on attachments and not gotten traction, yet industries continue to move with that, if there is value, sometimes the market can move folks there. And even if we make the recommendation, we don't know what will happen on the other side of that submission and how long that will take.

So, to Heather's point, the bigger picture and the valuation criteria that the subcommittee needs to be thinking through will help us thread all these pieces together.

I apologize, I ran us long. Nick and Tammy, on this section, did you have any other questions?

Nick Coussoule: No. I think we have all got about 100, but we do need to wrap up and move on and we can try to circle back to it tomorrow if we have time. Thanks, Alix.

Alix Goss: You are welcome. I bring you good news. It is time for a break. I am going to make it 10 minutes instead of 15 minutes so that we can get slightly back on time.

(Break)

Alix Goss: Deb and Denise, I know that we have several presenters and I believe that Noam and then Margaret, possibly tag-teaming with Randall -- I'm sorry, Noam maybe also may be tag-teaming with Steven Rosenthal, and then Margaret and Randall and then Katie Knapp to bring us home.

Denise Love: Noam, we hand it over to you.

Provider Perspective on Proposed Prior Authorization Operating Rules (Panel 2B)

Noam Nahary: Thank you. Thank you for the invitation and opportunity to speak with you today about the proposed CAQH CORE operating rules. My name is Noam Nahary and I am Senior Director at Health Service Receivables at Montefiore Health System. I have been with the organization for 20 years and my primary areas of responsibility include EDI, training, reporting and cash posting.

Montefiore Health System is comprised of 10 hospitals including the Children's Hospital at Montefiore, Burke Rehabilitation Hospital and close to 200 outpatient care sites. The advanced clinical and translational research at its medical school, Albert Einstein College of Medicine, directly informs patient care and improves outcomes. Montefiore Health System has been engaged with CAQH CORE since its inception and has been benefited significantly from federally mandated operating rules.

I personally have served as a rules work group co-chair for many years and our proprietary systems are of course certified for both eligibility and benefits and claim status. The CAQH CORE process for developing operating rules is comprehensive, collaborative and consensus driven.

The proposed prior authorization rules generate a substantial and meaningful debate among the 125 organizations that contributed to their development, resulting in a rules set that significantly advances the industry's ability to automate prior authorization. It is rare to see such a diverse group of stakeholders come together to address industry challenges.

While not every stakeholder's issue was addressed exactly as they may have hoped, the participants were able to compromise and come to a consensus on a set of rules that addresses maybe 20 of the issues. I commend CORE for such an achievement with the set of rules proposed today, and Montefiore fully supports this rule set.

Historically, Montefiore has seen significant benefits resulting from the federally mandated operating rules for eligibility, claim status, payment and remittance transactions including reductions in claims denials, time and FTE savings, increased collections and an overall increase in transactions conducted electronically.

Montefiore anticipates that the adoption of the proposed CAQH CORE prior authorization operating rules will drive greater automation, increase efficiencies, improve access to timely patient care and significantly reduce our spend on prior authorization. Our comment letter outlines these benefits in detail, and I will highlight a few of these today.

First and foremost, the rules will improve patient experience through the delivery of care across the industry. The current health plan response time to initial prior authorization requests ranges from one to 14 days at Montefiore, resulting in care delays. The proposed requirements in the infrastructure rule will create a national standard for reduced procedure wait times, will improve patient scheduling, create common expectations across health plans and ensure timely delivery of essential patient care. Assurances of a shorter turnaround time with the X12 278 transaction will also incentivize providers like Montefiore to increase adoption and utilize the transaction.

Second, the rules will enable Montefiore to transition away from web portals and manual prior authorizations and implement greater workflow automation via the 278. With the higher volume of electronic transactions that include greater clarity on the reasons for the authorization decision and the additional documentation needs, Montefiore can create efficiencies in its workflows and simplify processes.

Finally, we anticipate a reduction in costs and resources required to support prior authorization. Today at Montefiore we employ approximately 175 staff to manage prior authorization via web portals, phones, and faxes, and that adds up to approximately $11 million in annual FTE costs. Staff spends significant time manually entering data into web portals, making phone calls, and still faxing pieces of paper to address each request. This applies to the initiation, submission, and confirmation of each authorization.

With a federal mandate of the proposed rules, Montefiore estimates a $6 million reduction in FTE costs plus additional savings due to reductions in denials and appeal efforts.

Montefiore's biggest concern with the proposed rule set is that it does not become federally mandated. Industry and patients cannot afford continued use of costly manual processes that

delay care in the hopes of a panacea at some point in the future. It is evident given the current state of prior authorizations that more than just good will is necessary to drive efficiencies and automation today. A federal mandate will accelerate industry adoption beyond early implementers by making investment dollars and resources available to ensure compliance. CORE certification data suggests that federal mandates drive adoption and certification, enabling prioritization and vendor development.

Second, I would like to highlight the need for a federally mandated attachment standard. While federal adoption of the proposed CAQH CORE operating rules will lead to greater industry-wide prior authorization automation efficiency and cost savings, the lack of a common standard for documentation exchange will still inhibit a fully automated workflow.

Additionally, it is important that requirements for acknowledgments are not excluded from a federal mandate, as with past mandates, giving the value to providers of immediately knowing the transaction has been received or not. However, neither the lack of an attachment standard nor the exclusion of acknowledgements should preclude NCVHS from recommending the proposed rule set. These rules are a significant step forward for the industry. Future industry efforts related to attachments will serve to build on the automation enabled by this proposed rule set.

Finally, I want to reiterate Montefiore's support for the proposed operating rules. Adoption of the CAQH CORE Prior Authorization and Connectivity Operating Rules will drive greater automation, increase efficiencies, improve access to timely care, enhance health plan and provider data exchange, and significantly reduce industry spend on prior authorization.

Without a federal mandate, implementation of the HIPAA-mandated 278 and operating rules may lag, resulting in continued inefficiencies and delays and, ultimately, poorer patient outcomes.

Most importantly, I ask all of us to consider the patient. How can we tell our family members who are suffering due to delays in care that we had an opportunity for improvement but did not act? Patient experience is a cornerstone of the care model employed at Montefiore. Delays and efficiencies in the current prior authorization process have a direct negative impact on patient care. The industry must address this change now. Thank you.

Denise Love: Thank you, Noam. Next is Margaret.

Margaret Schuler: Thank you for having me today. Thank you to the committee and to CAQH CORE for bringing these rules forward.

I am from Ohio Health. We are located in Ohio in the city of Columbus, and we are a large health system with 12 hospitals, 35,000 associates. We employ physicians, et cetera. I am the Assistant Vice President of Revenue Cycle, and I oversee the revenue cycle operations from A to Z, and I have been doing this line of work for 23 years for not-for-profit health systems.

Unfortunately, I have been talking about authorizations for 23 years, so I really hope today is a call to action for all of us. We are all leaders in the industry and we are all here with a purpose to solve the issues in the industry. Again, I am going to keep reiterating that call to action.

At Ohio Health we are completely behind the operating rules being brought forward. We have seen directly the impact of standards around operating rules. I am going to share with you a

quick example around remittances. That is probably one of the standards that has been around for a long time now.

Prior to remittance advices being automated, I had over 100 people posting cash manually. Now I have less than 20 people posting cash because it is automated, so there is a direct relationship between automation and reducing costs. With prior authorization we are hopeful that we are going to see - not hopeful. We know we are going to see the same type of cost reduction and, even more important, the patient experience.

Let me spend a moment talking to you about our costs and the impact on our patients. This is very, very important because there is a return on investment for patient care and for the costs of healthcare overall.

Like Montefiore, we have a staff of 70 people -- that is our centralized team -- chasing down authorizations, dealing with faxes and phones and portals. That costs us about $3 million. Patients, because of the confusion up front, many times end up getting the care that they need because we are in the business of taking care of patients. They get the care they need and then we end up appealing the account on the back end because we didn't have an authorization. We spend about $5 million on that process annually. Sometimes we lose those appeals and we write off approximately $2 million a year. So that is $10 million that I easily can quantify.

The costs that are a little more difficult to quantify that are even more important to outline are the costs of the patient. When they think it is going to take two weeks to get an authorization to know if they have cancer or not, they are going to the emergency room. Many times, then they are admitted to the hospital. That is driving the cost of care up for both the health plans, the employers and the providers, and again, the patient is not getting the care they need timely.

Patients can be re-admitted. Anna talked about that need for adherence to medications and the importance of that. When patients don't adhere to their medications because of concerns around authorization and coverage, there is, many times, re-admission. The re-work involved in the denial process and the authorization process -- physician practices have a very nimble staff. They are there, like all providers, to take care of the patient but their margins are extremely slim, and if it's a difference between taking care of a patient or getting an authorization they are going to take care of the patient, so there is a ton of re-work involved.

I have had physicians personally call me up and say, Margaret, I am not discharging my patient because I know the authorization process is going to take too long and I need my patient to get the diagnostic services they need. And so they keep that patient in the hospital for another day or two, rather than discharging them and having that patient receive services in a lower cost to care. So it is absolutely driving up the cost of care without having this automation and, again, the impact to our patients that need the care they deserve.

Value -- I am in agreement with AMA and AHA and MGMA and my counterpart at Montefiore. This is going to be better, faster patient care. We are going to have greater adoption because if it is mandated and it's quick, you are going to see adoption. Earlier on we heard there was only 13 percent adoption because if you send a 278 to a health plan but they don't accept it, you are not going to send it again. You are going to get on the portal or fax over the information necessary.

So we need everybody in the sandbox. We cannot pick and choose, so the federal mandate is really important. And with that automation, you are going to have provider adoption immediately because providers are going to see the benefit.

Higher volumes of electronic prior auth goes without saying. We don't want to waste time with the manual transactions; we want electronic transactions. And what is happening because we are so desperate in the industry, the providers, is there is technology popping up called RPA, robotic process automation, or bots. We have bots now that are screen-scraping portals because we do not have 278 automation between health plans and providers.

That is not ideal. That is a huge Band-Aid, it is not secure at the level it should be. It is middle ware. The screen-scraping is not the way we want to go but we are seeing that pop up because of the delays in adoption around the 278.

I want to spend a second on web portals. Web portals are a step up from fax machines. The health plans traditionally have put all their money into their portals. Unfortunately, though, from a provider perspective, we are then dealing with multiple portals. They are inconsistent, there are no standards. One health plan will want X data, another will want Y. We have to set up training programs just to train on the different portals. When you have turnover with staff, again, you are re-teaching over and over on these portals when if we had electronic transactions that would be a moot issue.

Again, we are supportive of both the data content rule and the infrastructure rule. On the data content, having the detailed information, specific codes, on what is needed. I call it the guessing game about what is needed today, and that delays the patient getting the care they need. Providers want to give the health plan whatever the heck they need to appropriately cover that service, that procedure that their member needs. We don't want to guess.

So, having very specific information, clarity and transparency about what is needed from the provider to give to the health plan to cover that service, we want to get it and have that clarity. This will help. It is just like the bar codes on the remittance advice that helped tremendously. This is the same thing with the data content rule.

Infrastructure rule is all about that timeliness and quick response time. Again, we are super-supportive, like Anna mentioned and many of those who represent providers. We would prefer hours, not days, but this is a good compromise and a place to start.

(Pause. Audio signal was lost)

Margaret Schuler: This is Margaret. Could I jump back to finish up? Thank you.

So these are our concerns. Adoption timeline, again, I just want to reiterate the importance of we have been waiting for decades. We need to get moving, the time is now, and we cannot let perfect stand in the way of good. We need to get moving. That is an important point.

Prioritization of resources. The federal mandate is the only way we are going to get adherence and adoption of the rules. We have seen that over and over. Asking for volunteers is just not going to be effective, so we are supportive of the federal mandate.

Alignment with other industry initiatives. Again, there is great work happening. I am with Terry, though, we cannot keep kicking the can and we need to get started.

Lack of attachments and acknowledgement standards. Our comment here is the 278, I liken it to the plumbing in a house. The 275 will be the water coming through the pipes. You need to get the pipes up, though, in order to get the water running, so the attachment -- I know CAQH CORE has already kicked off the work team to start the attachment rules which will be terrific and we want to keep pushing that forward. But the 278 will be helpful even without -- we will gain momentum even without the attachments available right now.

Finally, seize the moment, *carpe diem*. Let's make this happen. Eighty percent of the CAQH CORE is supportive of moving this forward, which is representative of clearinghouses and providers and health plans, so I think that is a great indication that we need to move forward and folks want to move forward and get away from portals and faxes.

Mandates drive change. You have heard me mention that.

And last but absolutely not least is our patient. Please remember our patient. The mission of Ohio Health is to improve the health of those we serve. The 278 Rule will absolutely improve the health of those we serve.

I really appreciate your consideration and allowing me to express the point of view of Ohio Health and providers.

Denise Love: Thank you, Margaret. Now Katie.

Katie Knapp: Good afternoon. My name is Katie Knapp, and my remarks today represent the Department of Veterans Affairs as a provider.

Given the current lack of uniformity in usage of the prior authorization transaction, the recommendation is that the proposed operating rules should be adopted. As the largest integrated healthcare system in the US, the VA sent and received over 80 million healthcare transactions in 2019 and is committed to implementing HIPAA-mandated electronic transactions to ensure that the benefits of administrative simplification are met across the healthcare industry. These benefits are then passed on to our nation's veterans.

The VA's experience with implementing electronic transactions under HIPAA shows VA is proactive in developing internal software solutions to meet electronic standards. So, until the standard is mandated and ultimately enforced, VA's success is limited. VA's internal prior authorization software was developed and ready to test in 2016, but developing software solutions before final operating rules are in place and before a wide range of payers are utilizing the transaction is difficult.

The VA began first developing a template based on the initial X12 transaction information which hopefully would fit with further clarification of the operating rule. This template was designed to streamline information provided to the payers from the utilization review, or UR, nursing staff.

The intent and purpose of the X12 278 prior authorization transaction and associated operating rules is to reduce administrative burden and provide better and faster care for patients. Currently, with the limited use of the transaction it is difficult to gauge if implementation of these operating rules will positively impact the efficiency of the workflow. However, VA is optimistic that with clear guidelines and increased adoption of the transaction and associated processes the intended benefits can be realized, as they have been under other HIPAA EDI transactions.

Over the past four years the biggest challenge VA has found is uncovering healthcare payers with which to test. There are only a limited number of payers who offer the 278 transaction to providers. Of the nearly 700 payers with which VA exchanges electronic transactions only four payers offer the X12 278 transaction through the clearinghouse. VA could be ready to send and accept 278 transactions, but with so few payers to exchange with, the efficiency is limited.

It also places an administrative burden on UR staff, requiring them to determine which payers accept electronic authorizations and which ones require manual processes. Even for the payers who do accept electronic prior authorizations, UR staff must continue manual follow-up in order to receive prior authorization approval, which negates the potential benefits as implemented thus far.

An area of concern that will prevent VA from being successful in utilizing the 278 is stated in the data content rule. As written, it says that it is not required for a HIPAA-covered entity or its agent to conduct, use or process the X12 278 if it does not currently do so. This qualifier precludes industry adoption and stunts the opportunity to realize benefits for patients.

Currently, of the few payers that do offer the 278 transaction several have delegated authorization for certain specialty services to utilization management organizations, or UMOs. In these circumstances, VA must first exchange a 278 with a payer only to receive a rejection message referring to the UMO for clarification. However, because the UMO does not utilize the 278 transaction, UR staff must complete this follow-up through manual processes.

With this rule, if the UMO is not using the 278 now, there is no mandate to have them use the X12 transaction moving forward. If the rule is not modified to mandate the UMOs to utilize the 278 transaction, the prior authorization process will continue to be disjointed with a combination of manual and electronic processes, which does not align with the intent of HIPAA.

VA remains committed to the benefits of HIPAA electronic transactions and will continue to support the prior authorization transaction and associated operating rules. Any further adoption of this transaction across the industry is recommended and supported, hoping to bring an end to multiple processes to secure prior authorizations for payments for services delivered to our veterans.

I hope these remarks have been helpful and I thank you for the opportunity to submit these comments.

Denise Love: Thank you. Do you want to start off with a question and then I will follow?

Debra Strickland: Sure. To all the panelists, given the known difficulties that we have heard with patient demographics and even the omission of lab services, the rules as written, will they still have a significant value to the overall ecosystem? And what are your thoughts about those omissions?

Margaret Schuler: First of all, I think Terry, Heather and Rob touched on this. This is a great first start, so it will start changing the ecosystem. I like that word you used. It will start changing the ecosystem. Again, I use don't let the perfect stand in the way of the good.

It doesn't have everything. We want hours, not days. We can't send the attachments with it right now, but it will start changing. If we have two-day response and we know exactly what the

health plan wants back, that alone is going to cut down on the turnaround time and get the patients the care they need and help us reduce the administrative burden on the provider.

Katie Knapp: I am going to concur with what Margaret said. It is really hard to gauge how successful, but without the implementation and the mandate behind these operating rules we are not even going to take a step forward. It can't be perfect right now, and we just want to start moving forward.

Noam Nahary: I won't state it again in terms of getting started and the importance of it, but I do want to mention that, in terms of demographics or shortcomings, remember we are building upon a base of EDI. The earlier operating rules around eligibility lend themselves towards providers getting the correct demographics to begin with into the systems, and it's going to be those systems that we are going to use to integrate the 278 as well.

We are building on a base and we want to keep the progress in moving forward towards those automation savings.

Denise Love: This one I think is for Margaret. This is Denise asking Margaret a question. Maybe I am misunderstanding so please help me out.

You mentioned very strongly the federal mandate pushing the standard to be used, and there is the mandate for the 278. So, what will be different? What will make the operating rules be adopted?

Margaret Schuler: Having the content and the infrastructure rules behind it is going to help, and again, we will have that adoption with more providers seeing that, oh, it will only take two days rather than two weeks. You are going to see greater adoption. Also, the content.

Others mentioned about we do need to have a stick out there to help. There's part of it that is federally mandated, but we need help in supporting that mandate. It is important.

But if everyone starts seeing the benefit, again, if the content is rolled out federally mandated, then people are going to gravitate towards this. The idea would be that hopefully we will have the 80/20 rule around the adoption, just like we see with the other HIPAA standards. Unfortunately, many of the other HIPAA standards are also federally mandated and we see health plans and providers that are not adhering to that.

But we have seen movement, like I shared in my example about the remittance advice. Ninety-nine percent of payers and providers are compliant and we have been able to automate and reduce costs. So that is the direction we need to go.

Denise Love: Katie, do you have anything to add?

Katie Knapp: I think Margaret has more experience than I do. It is really hard to gauge with our experience and our office at the VA if it's really going to push the needle forward. We are very hopeful that, when we do get push-back about using it, there is a lot more information out there to help other entities understand the rule and have more context about how to implement it, which is always helpful. All of that together we are hopeful will help start improving adoption.

Denise Love: Thank you. This probably can go to all of you but especially Margaret. You mentioned compliance, so then we get into the E word called enforcement. What I heard is you

expect that with these rules there will be added incentives to support the uptake of the 278, but do you have any additional suggestions for oversight to enforce or assure compliance to the operating rule?

Margaret Schuler: Unfortunately, it is the P word, penalties, and the dollar sign. That would be certainly something we don't want to do, but if it has to come to that -- Just like price transparency, that regulation that is starting to come up, there are penalties associated with it. So people need to weigh the penalty versus -- you know, how much is it going to cost if you don't do it and how much is it going to cost if you are going to do it. Unfortunately, that is probably the only alternative.

But I do see that with federal mandates payers and providers can use that as leverage to say, look, this is law; you need to implement it. The big EMR systems are going to support it when it is federally mandated, the ability to do this. Again, when you have 80 percent of the market marching in the same direction you are going to get more takers.

Denise Love: And hopefully I think what you said earlier, the incentive of the savings and automation would preclude or at least weigh heavier than penalties and dollar signs. But who knows.

That is all I have. Deb, do you have another question on this segment?

Debra Strickland: No, I do not.

Denise Love: I want to thank all three of you. That was very good, and we appreciate the time you have taken to prepare your testimony and present.

Alix Goss: I think we are now moving into our next panel. Jamie and Tammy, you are going to be managing the Q&A on this one for vendor and clearinghouse, and I believe we have already started to queue up our first presenter. After Availity we will have Cooperative Exchange, EHRA and then HBMA and their designated presenters.

Vendor and Clearinghouse Perspective on Proposed Prior Authorization Operating Rules

Paul Joiner: My name is Paul Joiner, and I am the Chief Operating Officer at Availity. For those who may not know, we are a clearinghouse and a gateway and a provider portal that many of the health plans sponsor. We participate in the marketplace between the providers and the health plans, along with many of my fellow panelists.

One thing I would like to say in response to hearing everybody's dialogue today and the conversation is that the debate around authorizations is getting way more focused on a solution in the last two years and a lot less admiring of the problem, if you will. This is an easy thing to describe how difficult it is to solve, but it's really hard to put forward a solution. I think today, as a community on all sides in terms of the patients and the payer and the provider and myself as a vendor and also market collaborator, it is something we all are pushing to solve.

I commend CAQH CORE putting the operating rules forward. I thought they did a wonderful job, and I am going to speak with two hats. I am going to speak as somebody who has been in this problem and experienced it and helped try to solve it both on the provider side and on the health plan side, and who is also an active participant working with health plans and providers week in and week out on both sides. I am also going to speak a little bit from the Availity team.

We met internally a few times and we have a lot of different perspectives because we pull from both the provider and the health plan.

The CAQH CORE operating rules do put forward a lot of gaps in the 278 transaction, and the level of debate is really good, and us being here today is great as well because it is needed. I will get through some of the issues that we have with it, and most of them relate to timing.

In general, going back to the level of dialogue around authorizations, we have seen health plans make an assertive effort to improve the authorization processes, and there has been a really big uptick in the last 24 months. A lot of that is going to require the health plans to change their systems and processes.

There is also another topic that I will touch on in a minute that I am surprised hasn't come up today. A lot of times, when the providers are seeking an authorization they actually end up having to navigate to a vendor of the health plan to obtain the authorization, like a radiology benefit manager, a lab manager and other disease carve-out vendors who manage typically drugs or behavioral are other two common categories. That also needs to be factored into this whole environment in terms of they are a stakeholder and a lot of health plans leverage those vendors.

We have seen health plans pull data forward; we have seen a lot of improvement in the process. We work with one health plan and they just published -- and we could expose -- his auth required rules along with some documentation rules, and we reduced the phone calls related to authorization by 30 percent. So there is opportunity there, and the operating rules definitely frame out the situation and issue with 278 adoption as a means to that end.

With that, I want to move to the next slide. As you can see, the auth is required. It is something that we have worked on a great deal. That just shows you some of the outlines and the rules of content is so important.

The problem with the operating rules we have is it really comes down to there are so many -- I think Nick was hitting on this earlier -- different dialogues around the rules and so many things in flight around other technologies besides X12 at the same time, and so we think some alignment around timing and some of the other things in flight is important to take into consideration in the operating rules.

Also, the time requirements and some of the requirements around the hours or two business days and some of the requirements on the health plan would be difficult for the health plans to adopt, and you are going to have various levels of adoption.

We think the rules and some of those challenges will lead to the plans mixing up the ratio of authorizations and how they deal with UM issues, and you will see an increased level of denials if there is not alignment with some of the other proposals out there and the rules aren't implemented on the right timeframe. So they need to be implemented on the right timeframe.

The other piece is the messages need to be very specific. You have got to be careful about the generic messages and also some of the lack of flexibility but also responding to generic messages. The team didn't recommend linking the rules piece around Safe Harbor rules.

The interoperability and the timing is the key. Overall, we will put Availity's feedback into two or three buckets. Number one, the rules in CAQH are well written and we definitely support them

in general. However, we can't support them at this time because there are so many interoperability -- attachment work needs to be done and other technology standards out there in the marketplace. I was very happy to hear around noontime when the X12 representative was talking about their work in collaboration with CAQH. We think that is critical.

We think there is also the FHIR-DaVinci which I think has been referenced here today. There also needs to be consideration both of resourcing and time of implementation.

The last thing I would say to wrap up is the infrastructure in the vendors -- so there are two things on the vendor side and infrastructure side. It is going to be hard right now, because there are so many interoperability concepts and rules out there, to get the vendors to focus on this specific use case. So I think if the providers -- I do think they are right in that if something is passed or a recommendation to HHS, I do think the vendors are going to have to be brought clarity around what is a priority, and I think interoperability and this generic clinical data exchange will carry and then the authorization work will follow.

So I do think the conversation around interoperability and this conversation around authorizations are inter-related and really important to consider as you put a final recommendation together to HHS.

Sherry Wilson: Good afternoon, members of the subcommittee. I am Sherry Wilson, past Chair and board member of the Cooperative Exchange, representing the National Clearinghouse Association, and also the Executive Vice President and Chief Compliance Officer for Jopari Solutions.

The Cooperative Exchange is the National Clearinghouse Association and we represent the United States healthcare EDI interstate highway system, so we really appreciate the opportunity to be here today to testify, as the proposed operating rules have significant impact on our clearinghouse industry as well as the stakeholders we represent, especially with our role in the industry as connecting across major stakeholders.

I have really enjoyed the discussions today with the testimony from the different stakeholders. When we look at the value of the proposed operating rules we definitely find there is industry value in having a standard infrastructure and EDI transaction response timeframes. In addition, as we have heard throughout the day, we find the rule enhances workflow automation and business processes and can really help to drive the industry through a partial automated process, so we really applaud CORE and the industry efforts to at least start moving the needle forward.

However, we want to touch on three major concerns about the proposed operating rules. Our major concern is that, after numerous testimonies and industry efforts, the same critical business processes and technical workflow still have not been addressed. It has been over 20 years-plus, as we have heard from many people today, and we still have an incomplete 278 transaction set, again, without the adoption of attachment regulations, and industry is left with an incomplete prior authorization workflow, and we feel that does not meet stakeholder business needs.

The other concern is the data quality content. Although there is value in standard turnaround requirements, the question still remains does the quality of the response meet stakeholder business needs for authorization. Our response -- if the answer is no, which we think it is -- is we then have not really moved the barrier to discontinue traditional methods of verification needed

for timely patient care and we continue to see the use of the phone and more manual processes (inaudible).

The second concern that I think we have talked about throughout the day is we believe the operating rules involving data content should be coordinated with the SDOs. Our industry experience has found that data content rules created outside of or divorced from SDO guidelines and data specifications creates confusion and disparity in the healthcare EDI standards development.

As Paul stated, it was very pleasing to hear today the testimonies from the SDOs working together, and we definitely encourage the operating rule authoring entities to continue to effectively partner and align their efforts with the standards development organizations and peers to address these business concerns. So it was very exciting to hear about the progress being made on that front.

We want to address the cost-benefit analyses as we do not believe they can be determined due to gaps in automation, and we speak of this from firsthand experience throughout industry. Twenty-plus years ago, after considerable cost to our industry, we invested to comply with the HIPAA mandates to support the 278 transaction. After we had done this, as well as other payers, the supporting evidence to our concern is reflected in the current level of implementation of prior authorization across the industry which still remains extremely low.

So, needless to say, not only about our industry but we are concerned about the implementation cost to the industry as a whole. It is not proven that adopting these operating rules without the necessary gaps in automation being filled will increase industry adoption; however, we strongly recommend the implementation and maintenance costs from proven pilot studies be evaluated for ROI prior to regulatory adoption. This, of course, is on the CAQH CORE roadmap, and we highly support this initiative.

In summary of our recommendations, we do not support the federal adoption of the prior authorization infrastructure or data content operating rules as proposed. We do see value and again applaud the industry and CORE for their efforts; however, the transition we believe is still missing information necessary to automate the complete business process and achieve the business purpose.

Again, redundantly, as other testifiers today have said, without the adoption of the attachment regulations, the industry is left with an incomplete prior authorization workflow that does not meet the stakeholder business needs. I don't need to be more redundant, but that is definitely a concern.

In closing, we would like to ask the committee, how can we as an industry, better support your initiatives? NCVHS serves as our vehicle for our industry and stakeholder voices to be heard at the HHS decision-making table. As we reflected preparing for this testimony back to all the different testimonies, our concern is that, despite numerous concise NCVHS letters of recommendation to the HHS Secretary backed by industry consensus, the urgency of our business requirement needs, the focus on prior authorization, there continues to be minimal measurable action or change.

In addition, the collective stakeholder investment costs incurred over the years with minimal or no realized progress or ROI is of really great concern.

So we ask how can we as an industry support the NCVHS effort to help drive administrative simplification with HHS. We value everything the industry has done and your efforts, but we ask you how can we be more effective having our voices and your representation heard with HHS. Again, I applaud the efforts with CORE and all the things they have done, the very opening of today's testimony. The efforts were, while we all try to make this move forward without HHS's support, how effective are we really going to be?

I would like to thank you again for the opportunity to testify. If you have any questions I am willing to take them now.

Jamie Ferguson: I think we are going to take questions at the end of the panel, so I think Hans is up next.

Hans Buitendijk: Good afternoon. My name is Hans Buitendijk. I am currently Chair of the Electronic Health Record Association, and we really appreciate the opportunity to talk today about some of the proposed operating rules and the context in which they are being further developed.

A little bit about the EHR Association. It is an association of about 30 members covering hospitals, post-acute, ambulatory, a variety of settings, specialty based EHRs across the United States. Our main focus is to help collaborate across EHR vendors and the industry, our clients and industry at large to improve on the quality and efficiency of technologies where they can work together and where we overall can provide increased value together.

A little bit of backdrop around EHR and the overall context in which we are talking, which is not totally limited to 278 although that is certainly the focus for today's session. Clearly, we recognize with our users and our community that prior authorization overall creates a burden, both for the providers that initiate and the staff that need to follow up and work on collecting data and otherwise.

There have been efforts to date to integrate prior authorization into the workflow, but there have been some challenges. There is quite a variety of variations between payers and how do you integrate that into the EHR better with the user. The need for human intervention to collect data that might not be electronically available, and clinicians are not necessarily going to be the first ones to include the data or find the data that might be elsewhere. And there are inadequate capabilities and response times to really make it interactive and make it more integratable, deeper into the EHR.

So, as a result, EHRs, where the real focus is on the use of clinical documentation around that and then interaction with administrative and financial systems -- might be the same system, might be other systems, but from an EHRA EHR perspective, the primary focus is on the clinical user. That has been a challenge to get that deeper into it. So, EHRs typically do not implement either of these transactions in the flow back and forth and the content. It is mostly done by intermediaries, by fax, phone, other solutions, portals that sit next to or behind an EHR elsewhere, but not directly from an EHR.

Looking at that, there are certainly a variety of promising approaches that are included. Some of them have been talked about today. HL7 DaVinci, trying to include it in the clinical workflow; DME activities to tie the ordering with prior authorization. And there are three major steps: is there a need for the authorization so that as the ordering party, as the initiating party you have already a good idea whether it is needed or not, whether you can progress or not; completing

the supporting documentation as automated as possible based on existing data on record; and then submitting and receiving the authorization.

In the last step, there is at this point in time until another standard is allowed, clearly, there is the X12 278 and then talking about 275 as well. But again, to emphasize that that is typically not done with the EHR so the goal here is how can we tie everything together and make it work across.

A variety of EHRA members are active in these initiatives to help bring prior authorization closer to its end goal and so that we can have the loop from provider to request to response, authorization or denial, and the follow-up steps that can be much quicker and much more efficient with the least amount of effort by everybody.

When we look at the proposed operating rule we are going to actually be looking at them from a little bigger distance than others in the discussions today. Overall, today, data content and infrastructure, we certainly appreciate the clarification on patient identification fields and helpful and necessary capability across the systems to match patients better, faster and more accurately. We also appreciate the clarification improvements on response time, but we have a couple notes around that. We will skip connectivity until tomorrow.

Looking at 278 data content, highlighting again the patient matching and identification is a challenge for any clarification that is there. Any step forward that we can make to improve upon that is welcome, and we continue to work with everybody to further improve upon that.

Longer-term but aligning with some of the earlier comments, as we get into FHIR APIs as they are being exposed, more data will become more easily available for supporting information to complete the data necessary to submit an authorization, to interact with the systems, to initiate, et cetera. So, aligning with that in some fashion as we move forward is important, as well as with e-prescribing, because it is another part of the puzzle that prior authorization is needing across the board.

We recognize these are not in the current scope for what we are looking at, but that needs to be taken into account to ensure that steps taken today lead us and continue to lead us to that ultimate goal of much tighter integration closer to the provider rather than the lengthy time that it currently can take.

To enable that deeper integration and get us closer, we want to recognize that the suggested 20-second response time and the 86 percent up-time for that goal is not sufficient as much as it creates an improvement from where we are now. I am not going to put this as do not progress with it, do not take the steps, but where the goal is to improve the overall prior authorization, it falls short of what will be needed to really create an integrated solution with the EHR. Until that point in time, it will be integration with solutions behind that.

A holistic approach is essential. This can provide a step towards that, but that is not enough to achieve where we need to be so that we can reduce human involvement where data is actually electronically available, where automatic evaluation of the rules is available, consistency is available, sub-second response times are available and that it is 24/7 because clinical care does not stop and we do need to make progress continuously.

That is how we are looking at it. Again, EHR is part of the overall workflow but not in the middle of the current prior authorization process because of some of these challenges that exist.

From a recommendation perspective, the operating rules as proposed reflect a step forward to further clarify, and that is essential for interoperability to make it easier to adopt and we support that, we appreciate that. But we also see continued need for harmonization of terminology across the entire flow as we are trying to tie clinical and administrative data flows together.

Also, automatable authorization rules so that we can reduce the amount of involvement and speed up the time to get resolution to the authorization request, whether it is on an individual item or on a much higher level of care for certain patient categories. Also, that we can get the supporting documentation more easily and that we can transport the data more quickly and efficiently back and forth, with the least amount of steps in between.

Those are the steps that we look forward to and continue to work with everybody to be the ultimate connection point and starting point where this all begins and ends, from can I continue with this activity, this service, this procedure, and, if so, when I get the authorization did I know about that and can progress, so that we can shorten the time and make that as efficient as possible. So we are looking forward to that. Thank you.

Arthur Roosa: Good afternoon, everyone. Thank you for the opportunity to present to the committee. My name is Arthur Roosa and I am presenting on behalf of the HBMA, Healthcare Business Management Association.

A quick word about the HBMA. We are an organization mostly composed of revenue cycle management companies. We have members that are very large, those that are more small and middle-sized. We have some members that submit millions of claims per year. I am the CEO of SyMed Corporation. We are one of those mid-size companies and we submit just short of about two million claims a year in the process. Our primary goal is the education of the members along with advocacy and collaboration, and hopefully we are doing that part today.

My comments today will be relatively short. I am also the last speaker today so I am sure that will ring well with everybody on the call.

The proposed infrastructure rule is something that we believe is a good first step. We spend about two hours or so of staff time per provider per week doing prior authorizations, and it does vary greatly by specialty. When you cost that out, it is about $11,000 per provider per year in chasing authorizations. So, anything which works towards getting that process more fluid is something which we would support. We will get into later some of the issues that I have heard today that will say that this may not be a good way to go, but I do believe that it will be impossible to create something which is perfect before we move on anything at all.

As technology moves forward, something that could be decided this week will not be the best thing that we could possibly do in three weeks' time, so it is important that the committee makes a decision on this is something that we can accomplish now and to move forward with that, recognizing that ultimately there will be an improvement on that, and that improvement will come actually sooner rather than later. But if we keep waiting for the sooner, things will never happen.

Also, one of the problems that we certainly deal with is that there are 1,000, or just short of 1,000, insurance companies and payers within the US, and the larger payers certainly are those that have presented today and have talked about their ability to accept the 278 transaction. Many of the smaller payers do not. One of the impediments to this is being able to bring those

folks along. Although they are smaller payers and they don't represent a very large portion of the claims that are being sent, there are a lot of them, and so they actually present a significant cost in development.

An interesting thing that I heard today was from Kaiser. I think Cathy Plattner mentioned that Kaiser doesn't really see it as an advantage in the fact that their trading partners have really not asked them for the 278 transaction. A reaction that I had was I didn't know they supported it. So Cathy can expect that they will get a call from us saying, if you support the 278 transaction, let's talk about how you do that and perhaps how can we implement that.

Basically, it has been our experience over time that actually many of the administrative simplification requirements are implemented and implemented well by the larger payers, but the smaller payers are the ones that create an additional impediment to getting there.

Again, one of the problems is the small payer issues. I mentioned within these slides companion guides a few times, and it is about how they are used; it is not about what they are. Again, their misuse is by smaller payers who tend to use companion guides to identify a non-compliant interpretation of a particular data element. But that is not really the problem with the companion guide; that, again, is the problem of consistency and, as others have talked about, enforcement.

In terms of enforcement -- and we have brushed on it today and nobody really wants to focus on this so I will take the plunge -- a question that we often ask our CM companies is, if we create new rules, who will enforce them, and what will be the penalty if somebody does not follow them. Historically, there has been no penalty and folks have not followed the rules or they have made slight variations in the rules.

Since I used Kaiser before I will use Kaiser this time. Kaiser was not returning data in the 835 that was necessary to return, and it took a little bit of effort to get them to make the change in their software to do that. It is that type of noncompliance which does drive up the cost and makes the acceptance of any new operating rule difficult because there is no enforcement in back of it.

The main things we would like to mention today are there needs to be -- well, we do support the operating rules for both data and for infrastructure. We suggest that if they are adopted that they are in fact enforced.

Our second bullet point is really about enforcement and the use of companion guides in a non-compliant way. Also, in our reading of the data rule and the infrastructure rule there was nothing specifically said that if somebody does meet the minimum requirements and data structure requirements for those rules, a trading partner is guaranteed that their transaction will be accepted. When I say accepted, I don't mean approved. I mean that it will be taken in to be processed. If that is the case, then I believe those rules should be changed such that the floor that is being established is a safe harbor where, if a trading partner met that level of compliance, they could expect their transaction would be at least processed by the trading partner.

I believe that concludes my comments.

Jamie Ferguson: Thank you all very much. Let me lead off with a question for all of you to address. I am going to modify a question that we asked to a different panel earlier.

It has been reported that the 278 is only used a small fraction of the time when a prior authorization is needed. And at the same time now, there are a lot of other rules and priorities, and obviously we are in a public health emergency, so there are a lot of competing priorities. The question is how much improvement in adoption of the 278 in terms of that unfulfilled potential would be occasioned by the adoption of these operating rules. And does that make this rise above other competing priorities for resources?

Arthur Roosa: I think it is a matter of timing. If you are creating a rule that you're saying you have like a year to implement that, I believe that is going to really interfere with other things that are going on that have a higher priority.

I think, though, if you are able to provide a significant amount of time -- and when I say significant amount of time, probably around 24 to 30 months for the adoption of the rule, I think the other priorities, one would hope, would be mostly resolved by then and the focus could then shift to 278.

Jamie Ferguson: Thank you very much. Other responses?

Paul Joiner: I will add one comment on the 278 in relation to the operating rules. The 278 transaction for notice of submission I think is more widely used by some of the larger health plans, but when it comes again to procedural services like high-end radiology and other service lines, there is so much additional clinical information, I thought it was said earlier, around conversation. That is why alignment with X12, and the other standards bodies is important because this is not like a remit or claim where it is very encounter-based. You would think it would be, but it is a very chatty, conversational type interaction. I thought that was used earlier and it was good. That is why some of the technology standards mentioned earlier are important.

I think the rules frame out the problem well and frame up the opportunity and the issues of the 278 well, but as far as solving the problem, I think it has to have the 275.

I think also I agree with the timing. It has to give the health plans an opportunity to respond and create the right response so every 278 doesn't get pended.

So it's about the timing if you will, and coordination with the other bodies.

Sherry Wilson: I would just concur with your comments, Paul. I think that without that 275, again, 278 is an incomplete transaction. So, looking at industry evidence support is that we have had this 278 mandate for a long time, and because we haven't solved without that 275 being able to complete that business process, we have continued to use these manual and ineffective processes. So we strongly believe that until those issues are resolved we do not see it increasing adoption. Again, 20 years later we are not that farther ahead in the industry.

Jamie Ferguson: Hans, anything to add to that from your perspective?

Hans Buitendijk: Not specifically because, as I indicated before, the adoption of 278 and where it would be able to take us with the next step is not necessarily where EHRs are going to be starting to integrate. I think from the EHR perspective looking at effort to take it on, they are not looking at an effort to take it on at this point in time. Plus, clearly, over the next 24 months they are going to be very busy with a number of other rules that are out there.

But I don't think that is the primary target to take it on at this point in time, not until we can get to capabilities that enable integration and flow much more tightly so that the user experience that we need can be achieved. And it is too early for that. I don't think EHRs as EHRs are going to look at that. Administrative and revenue cycle capabilities and others have a better shot at starting to improve on what they have.

Jamie Ferguson: Thank you very much. Tammy?

Tammy Banks: I would like to ask a little bit more tangential question. We understand that the statute requires operating rules to accommodate acknowledgements and that earlier operating rules require use of acknowledgement standards. However, HHS excluded these requirements because standards had not been adopted for acknowledgements at that time.

The proposed operating rules also require use of acknowledgements. What are the implications of having the acknowledgement requirements excluded again, and should these rules be recommended for adoption?

Sherry Wilson: I feel very strongly, to your point, Tammy, that the acknowledgement transaction is a critical key to adoption and that HHS needs to look at including it as part of the rulemaking process.

What we have learned that has really helped enhance EDI adoption among stakeholders is that they know that transaction has been received, is not lost in the mail, and there is an audit trail to be able to expedite that communication. So it is a critical key to the success. Without having it as part of that transaction set I do not see the effectiveness or full value that can be achieved.

Paul Joiner: Yes, you are going to have to have acknowledgements so that you don't have black holes and you also don't have confusion. Lack of clarity drives phone calls and drives provider frustration up, so anything that -- response is important.

Arthur Roosa: I concur, and that is an easy concur.

Paul Joiner: One thing I would say is that the acknowledgements need to be clear. Vagueness, again, drives phone calls up.

Tammy Banks: Hans, do you have anything to add?

Hans Buitendijk: No. I think, generally, without acknowledgements interoperability gets very challenging.

Tammy Banks: Arthur, I think the other presenters are quite clear in their position, but feel free to chime in if I misunderstood. Overall, does this rule go far enough as an intermediate step to provide value to your membership in order to do adopt and utilize this transaction?

Arthur Roosa: Well, it misses -- There is a need for data content, and either you are needing the 275 or you are needing a truly expanded and robust dataset in the 278 in order to actually make it useful.

My concern is, in this development, if in fact we will be focused on the 275, then I believe that this particular rule does go far enough as far as the creation of the 278 transaction and the

response that you would get back. And although I am hearing certainly different ideas about the response time, in our particular industry those response times are adequate.

Tammy Banks: From the vendor perspective, who is missing at the table? What perspectives do we not have represented here?

Hans Buitendijk: I think, since these efforts typically happen in the administrative business office setting in support of the request, some of those systems might not be in play that are more directly closer to the place where the transactions are actually going to be created and transposed into and out of. So those might be one to consider. EHRs a little bit further away. The next step is admin and revenue cycle, and then you get into the intermediaries and then you get to the payer.

Paul Joiner: In my business, in Availity, we have kind of the health plan side and the provider side, and on the provider side we have about 300 resources that call and try to obtain the authorizations for various providers across the Southeast. I still think this group should consider and have a discussion with not only the other standards bodies, but also, you know, health plans have put a lot of people between them and the provider on authorization processes, and specifically, I think you should have a conversation with some of the radiology benefit managers and some of the other firms, and I think they would have interesting insight.

A lot of providers do process the 278, but some of the larger health plans are only told to call somebody else. I know these firms are doing their best to try to improve that experience. I know health plans are putting a lot of pressure on them and providers want to improve that experience, so, getting an idea of what their input is on this would be interesting and would be enlightening I think as well.

Sherry Wilson: I would just add to that, too. When you look at who is missing, I think we have good representation, but I think really the voice of the patient. We are trying to solve increase in healthcare, and obviously, being a patient advocate, this really comes down to the care, the quality and the timeliness.

So I would say hearing more from our customers, the real people, at the beginning of this process and how it's impeding their life. I mean, we have a lot of the stories of HL7 on how the impact on prior authorization is affecting healthcare in this country.

So I think more patients, and hearing the users of the outcomes we are trying to achieve.

Paul Joiner: Any voice from the quality community would be good as well. That would be one other area. My theory is it would be the benefit managers and the quality arena.

Speaking of quality, one other thing I think is important, data quality and consistency to drive the automation is going to be a challenge, and that is where the EHR conversation and some of the newer technologies may help. But I think someone was referencing that earlier regarding testing. I think that is an important piece of the puzzle as well, which probably we will hit on more tomorrow.

Jamie Ferguson: Paul, you mentioned radiology. We did receive testimony from radiology service providers.

Paul Joiner: I'm sure they call the benefit managers a lot.

Jamie Ferguson: If there is no more discussion at this point, I think, Rebecca, we are back to you for public comment.

Public Comment on Proposed Prior Authorization Operating Rules

Rebecca Hines: Thank you. Public comment instructions are coming up. Those of you who are on the Zoom, the instructions are there. If you are calling in by phone the instructions are there and I will ask Greg to review them for people.

Greg Richards: If you would like to issue a public comment please raise your hand. If you are on your computer you can do so by clicking the Participants button at the bottom of your screen and then navigate over to the right side where it lists participants, and at the bottom life you should see a little blue hand that you can raise.

If you are on your phone and would like to make a public comment, please press star-9 to request being unmuted. If you raise your hand via either of these methods, we will call out either the last four digits of your phone number or your name once we have given you permission to speak.

Rebecca Hines: Or you can always email us at ncvhsmail@cdc.gov. Thus far I don't see any public comments coming into the email.

Greg Richards: No one has raised their hand in chat, either.

Rebecca Hines: If you would like to go back to Q&A we can do that and revisit to see if anyone has reached out in the next minute or two, or we can just sit here and wait for another minute while Alix and Rich gather your thoughts for moving towards your summation for the day.

Alix Goss: This has been a fantastic afternoon of testimony. I know we are waiting for a few public comments, and I thought while we wait to see how that process pans out, if there is anybody who was in the afternoon panel who would like to chime in on Tammy's question around who is missing at the table. We certainly heard the opportunity to engage a little bit more on several fronts. If there was any category of stakeholder that may not have been brought up yet, please feel free to chime in and let us know.

Rebecca Hines: I think something has come in. There is a comment on the Zoom written by Laura Caldwell. Her comment is, "Just an observation. I would say one other missing participant are state Medicaids." She is with GDIT with New York State Medicaid.

Do you all want to speak to why that is the case, because it is not for lack of trying. And we also did get some written comments.

Alix Goss: Well said, Rebecca. We have reached out numerous times. I say hats off to Lorraine and also the support of CAQH CORE for helping us extend our typical outreach to Medicaids. We typically have had the national Medicaid EDI group, NEMI, come participate with us.

We are very sensitive to the challenges with the advanced budgetary and lead times that state Medicaid's often have in being able to pursue mandates, so we have actively reached out and asked for their input. We did get a little bit of submission. Thank you for making sure we check that box. It is definitely important.

Rebecca Hines: I just want to encourage everyone if you haven't already, most of the public comments are posted. The late arrivals are not quite up yet but they are on the meeting page over in the right-hand side in the box. There is a cover sheet with all the organizations who submitted, and you can scan through the pdf.

I think at this time we can say comfortably that public comment is done for the day. Just note we will have an open time again tomorrow after the discussions on connectivity after lunch.

Alix Goss: Rich, wrap-up time for day one.

Closing and Adjourn

Rich Landen: I think we have gotten just tremendous feedback. The focus today was on the prior auth rules rather than connectivity, which we will get into tomorrow with roughly the same organizations as presented today. But we heard a lot about possibilities but no guarantees on adoption.

We have heard some complimentary views and some conflicting views on what the incentives might be to the different parties. We have heard some concerns about rule promulgation timeliness relative to whatever else is going on within the ecosystem, whether they be other rules that compete for resources or COVID-related.

We have heard comments about length of time on any possible implementation timeframe. We have heard interesting comments about how the different systems, the EHR and the revenue cycle systems all have to work together to accomplish the automation. That I think was centrally focused on by all our presenters and that the more we can automate this the more efficiencies we can capture, the better service and turnaround time we can have for the patients and providers.

But we have also heard that there are types of prior auth that are more conversational than we typically think of in terms of what EDI handles with a kind of once-and-done claim or remittance advice. So we have an awful lot to think about.

We have some competing views, we have some agreement that the 80/20 rule may be operative here. There is no such thing as perfection. And, as we reflect in some of our subcommittee questions to the presenters, where does the value lie. Is there sufficient value knowing this can't get us all the way to the absolute end? Does this move the needle sufficiently to support a recommendation to adopt, even though we know that there is a very complex and dynamic ecosystem spinning all around us?

That is my sense of today. All the panelists I want to compliment for the work they put in and the clarity of their presentations, staying on point, and just really helping the members of the subcommittee and NCVHS get the wherewithal to help interpret what they read in some of the letters that have been submitted to date, and the opportunity to ask some questions to kind of flesh out the nuances here.

Alix, anything to add?

Alix Goss: Great summary. I am looking forward to those notes that you so eloquently read from. It has been a lot of great content. The industry's voice is coming through even if it is a little

bit not in tune with one another, but that is what we need hear, and that gives us a lot of good input as we take on deliberations after these few days of hearings.

I feel like it has been a really successful first day and glad we are able to wrap up actually early. I'm sorry we won't all be able to convene afterwards for discussion at our usual watering spot. I will open it up to see if there are any subcommittee members that may have thoughts or comments before we call it a day.

(No response.)

I guess we get to give seven minutes back to everybody. Rebecca, for those of us who are convening tomorrow do you want to just dust us off on some of the logistics?

(Discussion regarding logistics)

Rebecca Hines: I want to applaud our co-chairs for your superior agenda management. I think we all appreciated it, and it would be great if we could start on time tomorrow at 10:00 a.m.

I also want to say from behind the scenes there was a ton of prep work and I heard some comments that it looked really smooth today, and I just want to say that wasn't an accident. So I just want to thank everyone for your hours and hours literally of labor, and especially to our two new members who clearly have already jumped the learning curve and are right in the pool with everybody else.

Alix Goss: I think the Saturday additional prep session that everybody participated in, and even from people while they were driving across the country. We have asked a lot, especially of our West Coast folks. You have been up bright and early, compiling things late at night, and it is definitely a team effort. Thank you for your service.

Rebecca Hines: With that we are adjourned and will see you all in the morning.

(Whereupon, the meeting adjourned at 4:55 p.m.)