Health Information Technology Advisory Committee

Transcript
March 20, 2019
In Person Meeting

SPEAKERS

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

Raj Ratwani	MedStar Health	Member
Steve Ready	Norton Healthcare	Member
Patrick Soon-Shiong	NantHealth	Member
Sasha Termaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member
Prior Auth Panel Speakers		
Name	**Organizations**	**Role**
Andrew Robie	Anacostia Community Health Center, Unity Health Care	Family Medicine Physician
Heather McComas	Administrative Simplification Initiatives, American Medical Association	Director
Daniel Kalwa	Division of National Standards, Centers for Medicare and Medicaid Services	Policy Advisor
April Todd	CAQH CORE, CAHQ Index Data Report	Senior Vice President
Anthony Schueth	Point of Care Partners	CEO
Margaret Weiker	National Council for Prescription Drug Programs	Director of Standards Development
John Kelly	Edifecs	Principal Business Advisor
Robert Dieterle	EnableCare, Program Management Office HL-7 DaVinci Project	CEO
Kate Berry	American's Health Insurance Plans (AHIP)	Senior Vice President Clinical Affairs and Strategic Partnerships
Melanie Combs-Dyer	Provider Compliance Group, (Medicare Fee for Service) Center for Program Integrity, Centers for Medicare and Medicaid Services	Director
Sagran Moodley	Clinical Data Services, United Healthcare	Senior Vice President
ONC Speakers		
Name	**Organization**	**Role**
Lauren Richie	ONC	Designated Federal Officer
Donald Rucker	ONC	National Coordinator
Elise Sweeney Anthony	ONC	Executive Director, Office of Policy
Thomas Mason	ONC	Chief Medical Officer

Andrew Gettinger	ONC	Chief Clinical Officer
NCVHS Speaker		
Name	**Organization**	**Role**
William Stead	NCVHS	Chair

TRANSCRIPT

HITAC Members

Operator
All lines are bridged.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thank you. Good morning everyone. Welcome to the second day of our HITAC meeting and welcome to the first day of spring as well. I would also like to extend a warm welcome to our guest presenters today, and our NCVHS members that are joining us here today. We will officially call the meeting to order starting with a roll call. Carolyn Peterson?

Carolyn Peterson – Health Information Technology Advisory Committee – Chair
Good morning.

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

Robert Wah – Health Information Technology Advisory Committee – Chair
Present.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Michael Adcock?

Michael Adcock – Health Information Technology Advisory Committee – Member
Here.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Christina Caraballo?

Christina Caraballo – Audacious Inquiry – HITAC Member
Here.

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

Federal Officer
Tina Esposito?

Tina Esposito – Advocate Health Care – HITAC Member
Here.

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

Cynthia Fisher – WaterRev – HITAC Member
Present.

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

Brad Gescheider – PatientsLikeMe – HITAC Member
Present.

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

Valerie Grey – New York eHealth Collaborative – HITAC Member
Here.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Anil Jain?

Anil Jain – IBM Watson Health – HITAC Member
Good Morning.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
John Kansky?

John Kansky – Indiana Health Information Exchange – HITAC Member
Here.

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

Ken Kawamoto – University of Utah Health – HITAC Member
Here.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Steven Lane?

Steven Lane – Sutter Health – HITAC Member
Good morning.

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

Leslie Lenert – Medical University of South Carolina – HITAC Member
Present.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Arien Malec? Not yet. Denni McColm?

Denni McColm – Citizens Memorial Healthcare – HITAC Member
Present.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Clem McDonald? Oh, wait. He's absent. Aaron Miri?

Aaron Miri – The University of Texas at Austin – HITAC Member
Good morning.

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

Brett Oliver – Baptist Health – HITAC Member
Here.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Terry O'Malley is absent as well. Raj Ratwani?

Raj Ratwani – MedStar Health – HITAC Member
Here.

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

Steve Ready – Norton Healthcare – HITAC Member
Present.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thank you, Steve. Patrick Soon-Shiong? Absent. Sasha Termaat?

Sasha Termaat – Epic – HITAC Member
Here.

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

Andrew Truscott – Accenture – HITAC Member
Present.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Sheryl Turney?

Sheryl Turney – Anthem Blue Cross Blue Shield – HITAC Member
Present.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Denise Webb? Thank you. And also joining us with our ONC leadership we have Elise Sweeney Anthony, Executive Director of Policy; Andy Gettinger our Chief Clinical Officer; and Tom Mason, our Chief Medical Officer. I will now turn it over to our National Coordinator, Dr. Don Rucker.

ONC and NCVHS Speaker

Don Rucker -- Office of the National Coordinator for Health Information Technology – National Coordinator
Good morning, everyone. One of the important charges for HITAC is working on interoperability. As we have been sorting through that, that is a core mission for ONC more broadly. As we have been working through that, we have identified what looks to be a large and important opportunity for the country in interoperability. Some of this was teed off by our work on provider physician burden, led by Andy Gettinger and Tom Mason. We identified in our burden report where we were working with our colleagues at CMS that the whole prior authorization process really is broken. I think all of us as clinicians and any of us who have had to deal with patients know this is not exactly a secret. In looking at it more closely, it turns out that the fundamental disconnect here, there is a long history to it, but the fundamental disconnect may be that we are taking financial data off in the X12, Electronic Data Exchange, the EVI data and that is uncoupled from clinical data. This is very important when we are looking at not just prior authorization, but also things that have a very similar computational payload. So, a fair amount of clinical detail, a fair amount of if you will, rules, logic that need to come together to do a prior authorization evaluation. That is also, it turns out to be similar to the computational payload you need to give an accurate price to a patient prospectively, not retrospectively, but prospectively. It also turns out to be very similar to the payload in terms of a fair nugget of clinical information with a fair nugget of business and clinical logic that you need for CVS hooks and clinical decision support.

We have a number of approaches around this. I would like to kick it off for a couple minutes of reflection with a longtime leader in the field of medical information. Professor Bill Stead from Vanderbilt. He has a long and distinguished career which makes you wonder how he did all that in one life. Most importantly, he is the chair of NCVHS. NCVHS along with CAQH are under the HIPAA law required to provide advice to CMS. Dan Kalwa is here (maybe, Dan, you can raise your hand) from the CMS standards group. They have been working on problems for a long time. Bill, if I can turn it over to you for a couple minutes of reflection here on all of this, it would be most appreciated.

William Stead – National Committee on Vital an Health Statistics – Chair
Thank you, Don. It's a real privilege to be here. Let me start by introducing the colleagues that have joined me. Alex Goss is the cochair of the Standards Committee. She is Vice President and Senior Consultant from Imprado, which is a division of DynaVet Solutions. She brings a wealth of experience from the health standards interoperability world, health information exchange governess, and HIPAA and Hitech compliance. Raise your hand.

Then across from me is Rich Landon, another member of that subcommittee. He brings in-depth experience with interoperability of administrative and clinical systems, patient safety, regulatory compliance, and standards developments from the perspective of healthcare operation, the insurance industry, and the electronic health record vendors. Then Deb Strickland is another member of the Standards Committee, and a national EDI expert. She served five terms as cochair of the ANSI X12 Insurance Electronic Remittance Advice Workgroup and as cochair of the WEDI Electronic Data Interchange Workgroup. I am also joined by Rebecca Hines who is the Executive Secretary and Lorraine Doo who is the Lead Staff of the Standards Committee.

To frame what we are trying to do, I believe, is pretty simple. How might we align administrative and clinical standards so that the clinician's information system may submit a request for prior authorization of a service to a payer and the payer may adjudicate the request with an electronic conversation that does not require manual effort? When Don and I were chatting, that is really the end goal of this session. With that, I will try to keep it that short unless you have a follow-up question, Don.

Don Rucker -- Office of the National Coordinator for Health Information Technology – National Coordinator
No. I think you have framed the problem. This is the issue as we go through the search for value as a country in paying for healthcare. How do we better tie clinical and financial data? Clinical being what we get and financial being what we spend to get it. Put bluntly, I think prior authorization is the tip of the iceberg, but I think it is a global problem.

William Stead – National Committee on Vital an Health Statistics – Chair
Let me add just a smidgen of color commentary to that. I am the generalist in this space. What I have learned as I've been working with the Standards Subcommittee is the disconnect between how the administrative systems even think about the problem and the clinical systems. CAQH, which has some of the best data on the industry use of the prior authorization standards, calculates both the cost savings and the potential benefit based on the labor of the transaction itself, transmitting it. They exclude the cost of getting the information out of the provider's systems to be able to transmit it and of absorbing that information into the payer systems because they assume that the historic divide between revenue capture systems and cycle systems and EHRs will not change. Therefore, the work will not change. That is the disconnect between a few hundred million dollars in opportunity and the several billion-dollar opportunity that AMA thinks might be available given burden on physicians. That is the chasm we are

trying to figure out how to breach.

Don Rucker -- Office of the National Coordinator for Health Information Technology – National Coordinator
Yes. As we work really hard to get the application programming interfaces and getting this into the hands of consumers, that chasm has to be put together if you will. I don't know if that is the right metaphor. That divide has to be undone at the patient end as well. Let me turn it over to Carolyn and Robert for our next speakers.

HITAC Members

Robert Wah – Health Information Technology Advisory Committee – Chair
Good morning, everyone. Thank you to our national coordinator and cochair from NCVHS. Just a couple of administrative remarks. We could not start the day without another batch, this morning. So, those of you who have not checked your email, there is another batch. I don't think there are too many more batches coming out of the oven, but we are hoping that will take care of that and we apologize for the late arrival. Some materials were not able to be sent out previous to that. We are very excited about this discussion about prior authorization. I'll put on my AMA hat just for a second and say this is a major topic for physicians and our patients. I think we all have antidotes of where this is having a major impact on physician practices, not just from the practice side, but how our patients have to deal with this as well. Let's not forget all of that. We have added some new verbiage to the conversation. Computational payload and hooks will be a major topic today. We are looking forward to that. To start us off we have a panel on Patient and Clinician Perspective. We are looking forward to that. I think we have everybody that is going to speak seated. We have Andrew Robie and Heather will join us from the AMA remotely. Daniel will join us after that, I think. So, with that, I think we have our speaker table down there and I will turn it over to them to kick us off with Patient and Physician Perceptive. Thank you for joining us.

Prior Authorization Panel Speakers

Andrew Robie – Anacostia Community Health Center, Unity Health Care – Family Medicine Physician
All right. So, I guess I am first. I am Andrew Robie. I am a family physician with Unity Health Care which is a large federally qualified health center here in the District of Columbia. I also happen to serve as the CMIO. I became interested in getting involved in health IT because technology is such a powerful tool for increasing the efficiency, safety, and equity in our healthcare system. The prior authorization is one area ripe for IT intervention. It is a privilege for me to be here and play a small role in supporting the important work ONC is doing in addressing administrative burden and especially prior authorizations. I wanted to thank you all for the work you are doing on behalf of me, my colleagues, and especially, our patients. We appreciate that.

I have been talking to colleagues, over the last week especially, about prior authorization and what it means to them. It may not be surprising that physicians react very strongly to those words. We generally, as a group, do not like prior authorizations. I talked to one colleague yesterday who is Mother Teresa. She is and Internist. She works at a homeless shelter here in town and deals with clinic flooding with bedbugs, and patients struggling with addiction and chronic mental illness and a lot of really challenging things in her work environment. She said to me, "Unequivocally, the worst thing about my job is prior authorizations." That kind of lets you know where a lot of us stand on this issue and what the impact is.

Why is that? There are two things. One is the amount of time and resources that prior authorizations

consume. The nurse on my team spends at least 10 hours a week dealing just with medication prior authorization issues. The three physicians that she supports also spend a few hours each dealing with these issues. That does not include the case manager who is dealing with a lot our durable medical equipment prior authorization needs, care coordinators who are dealing with a lot of the prior authorizations for advanced imaging. It all adds up. This is time that the nurse could use doing population health work, calling people about cancer screenings that due, educating patients about diabetes and other health issues, and doing case management work. Just a lot of important work that is not being done because of the time spent doing these authorizations. Probably more importantly is the potential for patient harm in delays in getting necessary medications and medical equipment and testing. I do a lot of work treating opioid use disorder and prior authorization for buprenorphine, for example, could be the difference between a patient being successful in their recovery and relapsing and dying of a Fentanyl overdose in the couple of days that they have to wait for their medication. For our patients, especially those with social barriers and limited health literacy, often a prior authorization could be the difference between them getting a medication they need and not getting it at all because of communication problems and other challenges. It's pretty common that I will prescribe medication for a patient for uncontrolled diabetes and I will see them three months later or whenever they wander into the clinic again and find out they didn't get that medication and we are back at square one.

What I want to do today is focus on medication prior authorization because that's what impacts me the most on a day to day basis as a clinician. I will walk through the typical cycle from prescribing this and then finding out we need a prior authorization or maybe not finding out, submitting the paperwork or the information to the payer, and finding out if the authorization was approved or denied, and the patient filling the prescription. Hopefully, we will set the stage and understand some of the challenges and inefficiencies of the system. We will highlight areas where IT could be beneficial in solving some of these problems.

We will talk about Mr. Jefferson. This is kind of an amalgamation of patients, not a real patient. None of this scenario is unrealistic at all. We saw him a couple of weeks ago. He has uncontrolled diabetes. He has a couple of medications. He really needs to start insulin to control his sugar. He is resistant to the idea of an injection but agrees that he is worried about his sugar. So, he agrees to start insulin. What I do first is search my EHR for a medication. Lantus, for example, is a long-lasting insulin that is pretty commonly used. A lot of times formulary information is available in the EHR. The best-case scenario is that I search for Lantus and it pops up. There's a green smiley face in the case of our EHR next to it and that usually means it is on the formulary and I can prescribe it. There aren't going to be any problems. Sometimes the green smiley face lies. I talked to a colleague yesterday who prescribed a medication that was green in the HER. When they called the insurance or submitted the claim it was not formulary so there was an inaccuracy. Sometimes you will see a red dot next to a medication that means it's not formulary. That's okay, you try again. What happens more frequently is two things. You see either an orange or yellow face with a flat mouth. You can't really know what those guys are thinking. Sometimes it means it is a step therapy medication. Sometimes it means it needs a prior authorization. Sometimes there could be a quantity limit that isn't a big deal. Sometimes it seems like every face that pops up is yellow and you don't know what that means. Maybe even more often than that you just see a question mark next to a medication, which means that there is no formulary information available. In that case, you have to go to the insurance website and search for the formulary. Some of them are great and they make the formulary very easy to find. Some of the websites seem like if they were trying to make it hard to find, they could not have done a better job of hiding it.

If you happen to find the formulary information on the payer's website, then you need to look through 40

different plans and hope you pick the right one. Sometimes patients know their plan or have their card. More often they don't, and you need to do some guesswork. There is a clear opportunity to do things better here with technology and make sure we have well integrated formularies in our EHRs or at the very least formularies that are transparent and easy to find online. In this case there was no formulary information available in the EHR so I poked around on the website for a few minutes. Mr. Jefferson got impatient and I ultimately ended up just sending a prescription for Lantus because that is often covered. I kind of had my fingers crossed. That prescription was e-prescribed to the pharmacy. The pharmacist gets it, runs the claim, and finds out that an authorization is required. This is not done until the patient is there at the pharmacy waiting to pick up his medication. The pharmacist lets the patient know and then something has to be done to alert the provider, to let me know that I need to do a PA or pick another medication.

The best-case scenario is some of the pharmacies work with a third-party prior authorization resource. It is a little bit incredible to me that this cottage industry has grown up around making PAs easier. I'm thankful that it has. From what I understand, some of these services can be integrated with EHRs. That's great. In our case it is not integrated. What usually happens is I get an email from CoverMyMeds, a service a lot of our local pharmacies use, to tell me a claim was rejected. I click a link in that e-mail that takes me to a secure website that is outside of our HER. I go to a web browser. I select the patient and it will pull up the medication that needs the PA. Usually the PA form is an electronic form to be filled in. Often a lot of the patient and provider information is automatically populated, which is great. I get excited about that little time-saving. Usually there is additional information I need to fill in manually. Then I hit the bottom and it electronically sends that information or often faxes an image of the form to the payer. Once that is processed, sometimes the website sends an email that says they have responded. Very often it doesn't. More frequently than using a third-party resource is I get a fax from the pharmacist saying a claim has been rejected. It takes a couple days to identify what is needed. Usually there is a number on that form to call for prior authorizations. The nurse has to take the time to call the company, stay on hold for a while. Sometimes you can give the information over the phone to get the prior authorization and that is great. Often, they will fax you a form to fill out that you will then fax back to them and wait for a response.

The worst-case scenario, which is often the most common unfortunately, is the pharmacist tells the patient to let the provider know they need authorization. If you have tried calling a physician's office lately, sometimes we don't answer timely. That is inconvenient and challenging for patients. A lot of my patients don't have a phone that works, so just making a phone call can be tough for them. They have to go over to the clinic. When a patient tells me that something needs authorizations, that could mean a lot of different things. They could need a PA or they might need a refill. It might mean they are trying to fill the med early and need an authorization for that reason. Usually this requires another phone call to clarify what is going on, just time spent trying to get to the end goal. Once we know this, we need to search the same confusing website to find the form again and often the patient has no idea of their insurance especially patients with Medicare Part D plans. They can be challenging. What also happens is the patient just never relays the message because they have too many other things, work and other things going on in their life and I don't find out that they didn't get the medication until the next time they are in the clinic.

So, the opportunity here is creating standards for communication electronically regarding the need for authorization which I don't think should be too difficult to do. So, the next step is figuring out what I need to do. In this case for Mr. Jefferson, I found the formulary. I looked for alternatives and found the alternative was an insulin that he had been on in the past and it caused a rash. I needed to do the prior authorization for this other insulin. The nurse made a call to the payer about prior authorization and got transferred around a few times. Ultimately, she gave up and she looked online and found what we thought

was the right form. Now, we need to print this form and fill it in by hand. This is probably just about the only paper we use in our clinic, these PA forms. We fill it in and it asks for things like demographics, diagnosis, medication directions, allergies, all these things that are structured data in our HER and could easily be sent in another way to the payer, but we are writing them in their form.

Then we fax the form to the payer and wait for response. The obvious opportunity here for improvement is standardizing the information that is required by payers on prior authorization and improving interoperability and allowing exchange of information between HER and payer prior authorizations. Now, we wait for a response. That can take anywhere from 24 to often 72 hours. In the meantime, Mr. Jefferson is anxious. He has called a few times asking about the medication. Best case in terms of getting a response to a PA is when a third-party service that is involved notifies me through email, and I log into the portal to check on the status. They also notify the pharmacy and the pharmacy usually contact the patient to pick up the medication. More frequent things that happen are a fax to the provider, which takes a couple of days to identify the fax and know this is a PA that has been authorized. We need to call the patient, if we can get them on the phone, and let them know. Sometimes the payer notifies the patient but not me. I'm let wondering and that ends up being an okay outcome but may generate more phone call. A lot of times we don't get any notification. We end up needing to make a follow-up call to check on the status.

In this case the form we found on the Internet was the wrong form. We filled it out, faxed the form to the payer, and they sent us a fax back that said, "Sorry, this is the wrong form. Would you kindly fill out this very similar correct form and send it back to us?" So, we filled out another form with the same information and sent it back to them. We waited a few more days and got our response. The opportunity here is to create standard communication about approval and rejection and notification to patients. I think a lot of these PAs are no-brainer. They get reviewed and approved. Those are almost automatically done. Some payers have algorithms to automate this process and allow instant approval or rejection. So, Mr. Jefferson got his insulin. It took about seven days. In that seven-day period, he called the clinic 4 or 5 times because he was worried. That consumed additional resources. That created a lot of worry for him. He had one avoidable Saturday emergency room visit because he was worried about his sugar being high. He ended up going to the ER because he didn't know what else to do. So, we got where we needed to be, but it is a convoluted process that is not patient or provider friendly. I hope all of you can agree that we can make this better and we can make this easier. Again, I appreciate all the work that is being done here to make my life better and my colleague's lives better, but also make this system safer and better for my patients. Thank you.

Robert Wah – Health Information Technology Advisory Committee – Chair
Thank you very much for that. Your very detailed description of that doesn't even begin to capture all of the headaches that your office went through as well as your patient. We do appreciate the high detail of that experience. I think next, we will hear from the AMA and Heather who is on the phone. Is that right? Heather? Oh great.

Heather McComas – American Medical Association – Administrative Simplification Initiatives Director
Yes. Can you hear me okay?

Robert Wah – Health Information Technology Advisory Committee – Chair
Yes. I will turn it over to you.

Heather McComas – American Medical Association – Administrative Simplification Initiatives Director
Great. Thank you so much. First of all, thank you for the invitation to the American Medical Association to

participate in this discussion today. As both doctors Wah and Robie have indicated, this is a usually concerning issue for physicians. We are glad to be included in this discussion about prior authorization. On a personal note, thank you for allowing me to participate remotely. I very much would prefer to be there in person, but I had foot surgery last week and can't travel at the moment. Thank you for that. Let's advance to the next slide please.

This is an overview of what I will cover today. I will start off by sharing some survey data that quantifies the impact of prior authorization on both physicians and patients, and then I will try to put a human face on this problem, which I think Dr. Robie has already done a good job of. I will just provide a little more detail on that. Then I will be discussing some prior authorization and form initiatives that have been going on in the industry for the past couple of years, and then conclude by summing up where we are today on progress in improving the prior authorization process for all of us, whether we be representatives of health plans, providers, or patients. You can go two slides.

So, as you have heard, prior authorization is a huge concern for physicians. As an AMA staff member, I hear concerns about this topic all the time from practice staff and physician members. We feel it is important to have hard numbers to back our advocacy ricks. To that end, we conducted a survey of 1000 practicing physicians at the end of 2018, 40% primary care physicians and 60% were specialist. Go to the next slide, please. One important concentration areas of the survey was capturing the patient impact of prior authorization. We can all agree that there are many administrative burdens facing clinicians today, whether they be reporting functionalities, revenue cycles, transactions. I think prior authorization is unique. The reason we spend a lot of time talking about it is because it impacts patients. It is a process that needs to take place before care is delivered. That is what is so different about this process, and why this is getting so much attention.

We asked physicians in our survey about the average PA response wait time. 65% reported that they wait at least one business day for a prior authorization decision from health plans and over a quarter reported waiting at least three business days for a prior authorization decision from health plans. That is time that a patient could be in pain or anxious about their condition and they are not getting the necessary care that their physician ordered. Go to the next slide, please.

It is not surprising that an overwhelming majority of physicians, 91%, report that prior authorization can delay delivery of care. It is important to note that we are not just talking about the inconvenience of waiting. Obviously, in today's society we are really annoyed if we have to wait for anything because we are used to everything being so quick these days. This can impact patient health and their clinical outcomes. If you turn to the next slide, we can see an example of this. 75% of the surveyed physicians said that prior authorization can lead to treatment abandonment. This is exactly what Dr. Robie was talking about earlier. When he sees a patient three months later that he ordered a medication for and they are not on that medication because prior authorization was required, and the care delivery process broke down. This is very concerning. When patients abandon treatment, there could be a clinical repercussion for that. If you go to the next slide, we can see that 91% of physicians indicated that prior authorization can have a negative impact on patient's clinical outcomes. That is very concerning.

The next slide was the heart stopping moment from this year's survey results. We asked physicians if they have had a patient in their care experience a serious adverse event as a result of prior authorization requirements. I want to point out that we were very specific about what we meant when we said serious adverse event. We basically mirrored the verbiage in the FDA’s definition and gave examples such as death, hospitalization, disability, life-threatening event. We are obviously talking about something very

serious here. Over a quarter, 28% of physicians report that they have had a patient in their care who has experienced a serious adverse event resulting from prior authorization. We are talking about major clinical harm. This is really concerning from a human perspective, from a provider perspective. This is very upsetting. Even if we could somehow put that human aspect aside, which is hard to do, and just think about this from an economic perspective. All of these serious adverse events lead to increased healthcare costs. Dr. Robie was talking about a patient who can't get their insulin and ends up in the ER. Think about the expense to the health plan. It would have been cheaper to pay for the Lantus in a timely fashion versus having that patient need to go to the ER to get that treatment. Obviously, the cost control goal that is cited for prior authorization is not working.

In the next slide I highlight data that captures the practice burden of this process. 86% of physicians describe prior authorization burdens as high or extremely high. As we go to the next slide, we see that these burdens are growing. 88% of physicians report that prior authorization burdens have increased over the past five years. My final slide from the survey data captures a picture of what a prior authorization looks like for the average physician practice. On average, practices report completing 31 prior authorization per physician per week. This workload for a single physician consumed almost two business days of physician and staff time. We talk about administrative costs in our healthcare system and this is clearly a major contributor. It is not surprising that well over a 3rd of practices report employing staff who work exclusively on prior authorization. As Dr. Robie was discussing, there are more valuable things the staff could be doing like care management, taking care of patients versus doing paperwork. So, go to two slides in, please.

Those are the numbers that I think are important to quantify this problem. For the next couple of minutes, I would like to put a human face on prior authorization. If you remember nothing else that I say today, I'm hoping you will remember the next couple of slides. I think this is really important. Ultimately, healthcare is about people, about patients. That is what AMA has been trying to address through our Grassroots Advocacy efforts that are based off our online hub, six-part authorization, sixpartauth.org. The website has both physician and patient facing tracks. The website describes the issue and verbiage understandable to different audiences. The tracks add to a common call to action a share your story. Since the launch, we have captured over 500 patient and physician stories about how prior authorization can impact care delivery. I encourage you to go to the site and look at the story gallery to see these stories. There are powerful stories from physicians and patients. We have an associated social media campaign that has been very effective. We have over 10 million impressions thus far. We also have a petition that allows people to contact their congressional representative and ask for prior authorization reform. Please, go to the next slide.

This slide captures a very few of the many powerful stories and the story gallery. I won't read these, but I wanted to highlight a couple of these on the screen for you. Look at the top left story from Kathy M. She is a mother whose daughter suffered from ALS and was scheduled for a PET scan that had to be delayed because the prior authorization was incomplete. By the time the scans could be rescheduled, her daughter had passed away. That is a tragic story.

Looking way to the right, we have a story of Don C. who is a cancer patient. His chemotherapy treatment was delayed for three weeks due to prior authorization requirements. Very concerning, particularly for an oncology patient. If we look at the bottom left of the screen, this if the story of Beverly. She is an emergency room nurse and she talks about how she frequently sees patients who have been ordered to have an imaging test by their primary care physician and they have been waiting weeks for the test. She sees them coming to the emergency room to get the test because prior authorization is not required in

the ER. They might be in pain or anxious about their condition and they just want to get the scan. From a sheer cost perspective, this is not accomplishing what the prior authorization process was supposed to do. The ER visit is very expensive, and we have made that patients suffer and wait for weeks to get that imaging test that was ordered by their physician. As we continue our discussion, I hope we can keep these patient stories in mind. Go to the next slide.

There are three other people I would like for you to keep in mind as we go through the discussions. First is Linda Hollier. She is the mother of Collin Hollier who died at the young age of 28 from melanoma. During the course of his illness, he was supposed to have scans every three months to check the progression of his disease. Those scans were always late because of prior authorization requirements. Sometimes up to four weeks late. Late in the course of his disease treatment, he also had drug treatment delayed due to prior authorization. Linda is now left to wonder if the scans had been done on time, maybe things would have been caught sooner and if the drug treatment could have saved his life if it had been delivered on time.

Going to the next slide, I'd also like for us to keep in mind Candace Myers. She is a patient who requires multiple medications to function well. When her husband changed insurance a couple years ago due to a job switch, she suddenly could not get the medications that she had been on and had been working well for her for several years because of prior authorization requirements. She says she missed doses and she felt everything broke down for her. Finally, go to the next slide. Let's also keep Katherine Johansen in mind. She is a patient that suffers from multiple myeloma. She had prior authorization denied multiple times by her insurer for a simple treatment that multiple oncologists recommended. She said she had to wait for the insurance company to give their approval. She might have been in a position where any oncologist would have said, "No, there is nothing we can do for you now." So, I hope we can keep these patients in mind while we discuss this topic today. Go to the next slide, please.

Hopefully, I have convinced you that this is a big problem like Dr. Rucker said. The whole prior authorization process has been broken down, we can agree on that. There have been a lot of conversations in the past couple of years about reforming the process. And important landmark in these reform conversations was the release in early 2017 of a prior authorization annualization reform principal by AMA and a coalition of 16 other organizations representing patients and providers. The underlying assumption of this document was that prior authorization would continue to be used for the foreseeable future. We just want to improve it in a way that it is not a burden to physicians, a waste of healthcare resources, and to not delay patient care. For these 21 common sense principles are grouped into five broad categories: Address areas of clinical validity, continuity of care, transparency and fairness, timely access and administrative efficiency, and exploring alternative ways to address utilization management that don't delay patient care. Go to the next slide, please.

An important outcome of the release of the principles is that they triggered conversations between the provider and health plan communities about prior authorization reform. A little over a year ago in January 2018, the AMA and 5 other organizations representing providers and health plans released the consensus statement on improving the prior authorization process. The organization to bond this document, along with the AMA or the American Hospital Association, the American Pharmacies Association, Medical Group Management Association, AHEPP and Blue Cross Blue Shield Association. It is important to note that providers and health plans agreed that prior authorization needs to be improved and similarly to the principles document, there were five bucket areas addressed by the document. You can see some overlap in themes between this consensus statement and the original principles. Both documents address improving transparency in prior authorization requirements. Something that we heard from Dr. Robie is

it is hard for physicians to determine what requires prior authorization. Another overlap was improving and protecting continuity of care. We need to increase automation and get away from manual processes. Two categories in this consensus statement address reducing the overall volume of prior authorizations. We think this is really important.

The document talks about health plans regularly reviewing their list of drugs and medical services requiring authorization and reducing those lists. It doesn't make sense to require prior authorization for those services that are almost always approved. It is wasteful on both the plan and provider side to require prior authorization. The document also addresses and encourages plans to selectively apply prior authorization requirements. In other words, don't require prior authorization of every single physician. Instead, target those physicians who, perhaps, don't have prescribing habits that align with their specialty. I can go one. Please, move two slides forward.

A natural question here is, with all these reform activities and discussions, where are we? I get asked this question all the time. The consensus statement has been out for over a year. What is going on and what improvements have we seen? Unfortunately, from the physician's perspective progress appears to be disappointingly slow. In our 2018 Prior Authorization survey, which I shared the data points from earlier in the presentation, we included some questions that address each area of the consensus statement. Here on the slide you can see the question that addressed prior authorization transparency. Seven in 10 physicians report it is difficult to determine whether a prescription or medical service requires prior authorization. This aligns with Dr. Robie's story about looking at his HER and having this cryptic little face smiling or frowning. What does that mean? It is very hard for physicians to determine what services and drugs require preauthorization. That is the fundamental breakdown of this process. That is something that people will be talking about later this morning. I think it is really important.

Going on to the next slide, we asked physicians about automation. I would say in my conversations with health plans that this is the area of the consensus statement that they are prioritizing in their reform efforts. They are most interested in automating the process. Even here, though, we see that progress is slow. Most physicians still report phone and fax as the most commonly used method to complete prior authorization for both medical services and prescriptions. Another data point that I want to point out is 21% of physicians report that their EHR system offers electronic prior authorization for prescription medications. As Dr. Robie talked about, his EHR system does not offer that functionality. While there has been a lot of great work and energy surrounding electronic prior authorization for drugs, it has not reached prime time yet in physician practice in a way that is meaningful. The AMA thinks that automatization of prior authorization is very important, and we fully support the innovation in automating the process through electronic transactions. We think it is only a piece of the pie. If we only focus on automation, we really aren't going to improve the situation for patients like Candice, Katharine and Linda's son, Collin. Let me head to the next slide.

We think it is so important to also address the overall volume of drugs and services requiring prior authorization. As you can see, an overwhelming majority of physicians report that the number of medical services and prescription drugs requiring prior authorization has increased over the past several years. We are not seeing volume reduction as we had hoped. Going on to the next slide. Looking at ways to reduce volume, 8% of physicians report contracting with health plans that offer programs that exempt providers from prior authorization. So, things like gold carding programs are not being widely offered right now by health plans. Finally, we also asked about continuity of care. Go to the last slide. An overwhelming majority of physicians report that prior authorization can interfere with continuity of care. This is very problematic. I would like to bring this back to the patient. We're talking about treatment being disrupted

and negative clinical consequences for patients and patient harm. Even if we had the most perfect automated process, there would still be the potential for care disruption for patients who have been doing well on a treatment for a period of years. Perhaps they change health plans. Perhaps their existing health plan changes their coverage requirements. Now something needs to have a prior authorization. There could be potential for care to be disrupted and that can lead to patient harm. With that, I will end. I encourage everyone to think about patients today during this discussion. Thank you so much and I look forward to hearing everyone else's perspectives.

Robert Wah – Health Information Technology Advisory Committee – Chair
Great. Thanks, Heather. We hope your recovery from your surgery is good. We are going to turn it over now to Daniel from CMS. That is our next speaker.

Daniel Kalwa – Centers for Medicare and Medicaid Services – Division of National Standards Policy Advisor
Good morning. Thank you for having me. I want to thank this committee for this opportunity and the members of NCVHS for attending. I can't tell you how important we at the Division of National Standards think this dialogue is. I really do honestly believe that this is probably the best way to resolve some of these issues with prior authorization. My comments will, I hope, offer some food for thought and some questions for consideration as the committees move forward with their recommendation to the Secretary and to Congress. I have heard some things this morning that I am hoping my comments might shed some light on. I have heard the problems in prior authorization described as a disconnect or a chasm. I believe that is probably very true. At least part of that is due to the structure of how we have been adopting standards and at least some of that is related to how regulation and the statutes work. I will cover some of that this morning. I hope the committees will take that information away with them as they develop solutions for prior authorization and the technology that they might recommend. Next slide, please.

The Division of National Standards is within the office of Information Technology at CMS and it has been delegated the authority to deal with HIPAA administrative simplification as well as the changes that were included in the Affordable Care Act. What that means substantially is that we have three tasks. We are to make and clarify policy with regard to administrative simplification, that includes the rulemaking process. We would be the ones that adopt the standards and operating rules under HIPAA. Our other tasks are to educate on this topic. Also, to provide some regulatory guidance to the industry where necessary and when it is asked for. Finally, we are required to enforce HIPAA policies. There is language in HIPAA and the ACA around requiring compliance from covered entities, which are essentially healthcare plans, healthcare providers, and clearing houses. So that, if they are unwilling or unable to perform the transactions mandated by HIPAA, we are supposed to be intervening. We do not deal with the Privacy and Security sections of HIPAA. I want to make it clear that our authority is narrow in this process and only with regard to the HIPAA administrative simplification area. Next slide, please.

So, I am particularly glad that NCVHS is here today. I have shamelessly stolen some text from their website because they worded it well. They are a statutory advisory body which makes them responsible for advising the Secretary on the transactions included in HIPAA administrative simplification. More importantly, the Secretary is required to rely on the recommendation of NCVHS with regard to those transactions. I bring that up because HIPAA doesn't cover all the steps of prior authorization. The comments earlier by Dr. Robie have made that abundantly clear to me. Thank you. It does cover some of the steps. Therein may lie some of our problem. Next slide please.

I have helpfully listed all the transactions. This is not all that NCVHS is responsible for but for this discussion

I thought it was what was important. There is a whole list of transactions, and I will discuss this a little bit more in depth, but at least 3 of them impact prior authorization but don't cover the entire process. The first one might include eligibility. The other two would be the referral certification and authorization transaction which is down near the bottom of the list. That is the literal prior authorization transaction as it exists in HIPAA today. Then, of course, attachments. HIPAA refers to it as health claims attachments, but I think it would be reasonable to conclude that attachments would apply to prior authorization in so much as medical records or supporting information might be required for a prior authorization. So, I bring this list up because these are specifically the recommendations that NCVHS would make to the Secretary and then the Secretary would delegate action to us on these transactions. So, the Division of National Standards would be responsible for developing any regulatory actions and ensuring that the education around the adoption of the standard and the operating role, should it exist, is done. Next slide, please.

I have radically oversimplified prior authorization just so I can structure my discussion here. In the broadest steps one can imagine that the healthcare provider must know that the patient they will see is eligible under their health plan. That is considered under HIPAA. There is an electronic transaction, and it is fairly well used, just to determine the eligibility of the patient under the health plan. Some steps have already been described. The healthcare provider needs to check that a preferred service is even covered. They also would need to check the prior authorization requirements. I did not include price clarity or anything like that in, but presumably that could be included steps two and three. Then, after some handwaving, the physician or healthcare provider has collected all the information that the healthcare plan needs, including any clinical documentation. Then they submit that to the health plan. HIPAA does imagine that. The currently adopted transaction as well as yet to be adopted standards for attachments would support that process electronically.

One thing you will notice here, it is not envisioned anywhere under HIPAA is the concept of transferring this information between healthcare providers. Dr. Robie, you particularly mentioned the issue with prescriptions and knowing that prior authorization is needed, and you may not always get that information back from the pharmacy. I can imagine, I'm sure everyone can imagine many issues around imaging and diagnostic testing and various other services where multiple healthcare providers are included in this process. It is important to note that is not envisioned under the current healthcare HIPAA standards and perhaps that is one place where we could certainly do some work. Next slide, if you would.

I have already mentioned that HIPAA has adopted a couple of standards related to prior authorization. The step one that I described above is in 45 CFR Subpart L. I can tell you it is riveting reading, but it is there. Steps 4 and 5, at least step 4 where the actual prior authorization is sent electronically from a healthcare provider to the health plan, is covered under 45 CFR Subpart M and that is the referral certification and authorization transaction. The Health Claims Attachment Standard and any associated operating rules have not been adopted at this time. As HIPAA envisions it, at this time, there is a magical handwave in between eligibility and then the provider sending in prior authorization. There seems to be a presumption, at least as it exists now, that they would know that prior authorization is required and what the requirements for that prior authorization are. I think this clearly illustrates the disconnect or the chasm just with the most basic aspect of prior authorization in getting from I have a patient and I know they are enrolled in a health plan, to I am submitting a prior authorization and all the steps in between have not been covered. As both of these committees move forward, I hope you will keep in mind the current landscape and tailor your recommendations to show us what needs to change within the bounds of HIPAA and the ACA authority and the interoperability authority. Next slide, please.

I also want to mention operating rules. This gets a little bit more into the technical details. Historically,

the way the HIPAA transactions have been adopted and because of the way the statute was written, the Secretary is required to adopt standards that are very specific to those transactions that I have listed earlier. We have done that by having implementation guides specific to that transaction. That means the Secretary is unable to adopt broad-based standards. There is a necessity for guides that specifically tell the covered entities how to implement the transactions that HIPAA specifies. Beyond that, the ACA realized that there was a lack because the implementation specifications only cover the data content and format. They do not cover things like the network security requirements or transfer protocols or the error checking and acknowledgments around the business of moving these transactions around. That is where operating rules come in. I bring this up because, to the extent that recommendations touch on HIPAA transactions, I think it is important for the committees to keep in mind that there may also need to be operating rules, if they do not exist, and the standards do not support those activities in the guides. As you make recommendations, it would be very useful to structure them in giving particular recommendations or advice with regards to which transactions are being modified or updated and what operating rules are needed where and if they exist or not. Next slide, please.

I have packed this slide with a bunch of questions. The general idea is that we ask, as you go forward with your recommendations, to consider where in the prior authorization process you are making recommendations, and to consider under what authority those recommendations may be put in place. I have already mentioned HIPAA and ACA. The authority that ONC is being operating under is different from those. As you make recommendations, it would be useful and helpful to be clear about where the changes are being made and under what authority. I also suggest the committee consider as you are making recommendations, are you replacing the standard? Adding one to be used in parallel? Are you modifying an existing standard? There are probably other options that I have not covered. My point is that it is important to be specific because prior authorization is so complex. My other thought is, are different standards going to be used depending on the service? I can imagine many different permutations, whether you are doing a BME service, or a lab service, or a pharmacy, or something far more complex like lower limb prosthetics where there is multiple back and forth between healthcare providers. The idea would be to, to the extent that you can in your recommendations, I'm sure that's not always possible, to use supporting documentation. What is the business use case that you are proposing these changes under and how broad is the change? To what extent does it affect the industry? That is really the point of all of these questions. I have to say again that we are very supportive of this process and particularly of these committees and everyone else working together to come forward with proposals to revise what is prior authorization in general and what is clearly lacking as a useful and efficient process from the electronic space. Next slide, please.

That is essentially the content of my comments. I hope that as you move forward and as the Division of National Standards continues to support this process that we can find effective and implementable operational steps to improve this process so that healthcare providers and patients can essentially see this as a transparent process. That should happen in the background in an ideal world where the physician is making clinical decisions based on their knowledge of the coverage of the health care plan and any subsequent steps would happen in the background. That way, once the patient reaches the other services that is being authorized, everything has already happened. That would be the ideal outcome from all this. I look forward to working with the committees in the future and I am here to see what sorts of recommendations you end up generating. Thank you for your time.

Carolyn Peterson – Health Information Technology Advisory Committee – Chair

I want to thank our experts for some excellent presentations this morning. We will now start the discussion with the HITAC members. If you could signify questions by putting your table card on end, we

will get started.

HITAC Members

Carolyn Peterson – Health Information Technology Advisory Committee – Chair
I see Arien has punched in first.

Arien Malec – Change Healthcare – HITAC Member
Yes. This would be unusual. So, I am in an interesting position with respect to this. Let me mention a couple of things not from the perspective of trying to talk about commercial capabilities but from the perspective of demonstrating that there are a whole set of capabilities that are array able against this problem. We have some industry ecosystem issues that make it harder for us to array those resources against this problem.

In my day job, I run R&D and oversee the operations of our clearinghouse businesses. We do about 12 billion administrative transactions per year. We do 11.9 billion of them are EDI-based following the ANSI X12 standards. We have a utilization management division support content organization called InterQual which is an adjudication of appropriateness of care, setting of care, capabilities. Just yesterday we saw a technical proof of concept about the ability to take a 278 transaction, the referral authorization transaction, bounce that against the appropriateness of care content and auto adjudicate some utilization management on the medical billing side. We have some structural impediments at this time. I think Bill Stead put it really well when he said that we have an approach that assumes the administrative work flows and clinical work flows are inherently and always will be disconnected.

Notwithstanding the HIPAA authority provided to CMS, nothing in that authority says that the relevant standards have to be EDI standards. I think about EDI standards as good workhorses. They have proven their worth in large-scale transaction volume. They are inherently disconnected. It is really hard for me to think about doing an eligibility transaction and then with respect to the same eligibility information subsequently doing a referral authorization or an EPA transaction. In the context of that transaction doing an attachment and in the context of that also adding the potential claim information and adjudicating that claim in anything close to real time. In the pharmacy space, we can adjudicate information in real time, but we can't hook al those systems up. I'm sure we will get to pharmacy a little bit later. So, as a perspective, I think it would be helpful to – we are geared up for 7030. The experience we had, for those that don't know, the X12 transactions come in major numbers. We had 4010. We did the big transition to 5010 and now we are gearing up to 7030. It is a really good time right now to consider whether a 7030 refresh is the right approach for the US healthcare system or whether we want to embrace the work that we have done in patient access in terms of electronic interchange and start to think about a more API driven ecosystem. In particular, start thinking about HL-7 FHIR in conjunction with the ANSI X12 in creating a higher variance of these transaction sets.

Our experience is that the innovators of healthcare, the people like CoverMyMeds and other kinds of innovative startups have a hard time consuming EDI. They work with us to consume API based transactions. There are no standards for those API-based transactions so, in some cases we have made them up. It would be useful to have a standard there. The value that we get in moving to an API-based approach is a better ecosystem for innovators to plug their work flows in. A better ecosystem to think about taking a smart on FHIR or CDS decision hooks workflow and plugging it into eligibility and referral authorization workflows. The ability to contemplate, for example, as we stand up information exchange under the TEFCA, to contemplate attachments as opposed to being a standalone administrative

transaction. To contemplate that they would call back into the EHR and retrieve information for payment. So, maybe just a perspective at this time, but I think we have a lot of it across the US healthcare system. We have many pieces to array against this problem. We have an ecosystem issue. We need to coordinate payers, and providers, and pharmacies, and PDM's, PDPs, etcetera at the same time. I do think that we have a core standards problem in that we are inherently asking for a world that, as Bill Stead describes, assumes that administrative and clinical transactions are completely separate and will never cross. A little bit of hope that I think we can take a big swing at this. There is about $300 billion of opportunity across the US healthcare system for improving administrative workflows. We have heard stories about the administrative and clinical burden that is associated with these workflows. Also, we have a perspective that now is a good time to contemplate a different approach to administrative transactions and ways to make administrative and clinical transactions harmonize better. Thank you.

Carolyn Peterson – Health Information Technology Advisory Committee – Chair
Thanks, Arien. Les?

Leslie Lenert – Medical University of South Carolina – HITAC Member
Just a quick comment. I think we have already seen evidence that this is an example of the worst application of the Golden Rule. That is to say that he who has the gold is making the rules. That is the insurance companies who are making the rules for transfer of information. It is time to completely reconfigure the system. We need to focus on delivering the maximum value for patients. There is ample evidence in the literature of harm from those two patients from this prior approval process. There is minimal evidence of impact on cost of care in a positive way. I did a quick literature search this morning and I could not find anything that shows this is a realistic process. I think it is just cost shifting. The insurance will save money, the healthcare providers will take on the cost of meeting their data requirements because of the Golden Rule. In this situation, I think we should be reengineering and focusing on the data sources, as Arien says, either with FHIR. Why not just say that the CCD is what you get to make the adjudication decision from? You have this much time. Otherwise, the patient is harmed by this process.

We have standards already for moving the stuff. I think we need to look at what is the most efficient process for the patient that delivers a safe system that allows the provider to do a clinical review of whether drug is indicated, but not to delay a drug unfairly in order to reduce the number of doses or have other economic benefits that really come on the backs of patients.

Carolyn Peterson – Health Information Technology Advisory Committee – Chair
I'm seeing no other table tags up at this moment. I will take this opportunity to indicate my support for Les's comment that we need to come up with a process that puts the patient at the center and focuses on making things work for the patient. We really are here to serve those individuals. Are there any other comments for this panel or questions for these panelists?

Daniel Kalwa – Centers for Medicare and Medicaid Services – Division of National Standards Policy Advisor
I apologize. The CDA is a proposed standard for attachments. As Daniel notes, we haven't been able to get out of our own way even with respect to attachments workflows. I think you put this well. I'm not sure I would go so far as to say there is no compelling case for utilization management or for workflows to check appropriateness of care. Those processes can and should be so much simpler than they are arrayed right now. It is very clear that we don't have the right standards and technology model that enables – Heather put it really well. There were two parts

to this. One is reducing the overall burden of it is easy to put a PA workflow in place and harder to take one away. Even in cases where there is appropriateness for some of the checks, we could do so much more to take out the administrative cost and burden and we are clearly stuck at being able to assemble all the capabilities out there in the US healthcare system. They could be appropriately simple to really reduce both clinician and patient burden. Thank you.

Robert Wah – Health Information Technology Advisory Committee – Chair
If there are no other – Oh. I'm sorry. Steven?

Steven Lane – Sutter Health – HITAC Member
Les, I want to follow up on your comment. I think what you said is that this is so broken that rather than going through all of the effort to get this to work on FHIR and get the detailed information back and forth and find the standards, I think you said let's just send them to CCD and let them do the best they can with that and be done with it. Is that what you said?

Leslie Lenert – Medical University of South Carolina – HITAC Member
That is a sweeping generality. I said if today I had to reengineer a system to be patient oriented, I would say, "Here is the CCD. You have so many minutes, hours, or whatever to process it. Make your decision. If you can't make it on that basis then release the drug."

Steven Lane – Sutter Health – HITAC Member
Based on the data available, we would be no worse off and perhaps better off from a clinical and financial outcome?

Leslie Lenert – Medical University of South Carolina – HITAC Member
I think that would be my initial reading of it. I would love to see a systematic study of the impact of, on a pharmacy level, the benefits, and harms of this sort of process. Particularly when the rules are focused more on the finances than they are on the clinical benefit.

Robert Wah – Health Information Technology Advisory Committee – Chair
It is a novel and radical suggestion. I think it is great to hear in this form. We have some tremendous expertise in the room. Is there anyone from the insurance side or anyone who thinks that this suggestion is out of bounds?

Arien Malec – Change Healthcare – HITAC Member
Maybe I will jump in and provided perspective here. I know that a number of people have taken a crack at this with respect to, can we switch from using, for example ICD 10 and CPT as our core terminology in the facts adjudication and can we flip to SNOMED CT as our core terminology for adjudicating transactions? John and maybe Bill Stead put a very compelling paper out a while ago while we were thinking about doing the ICD 10 transition arguing for this point. The perspective, I would love to see such a world, the perspective that we need to have with respect to a transition like that is a perspective that recognizes that the maximum, the actual adjudicators for Medicare transactions, the Medicaid payers, and the commercial payers, and even the PBM has built a huge set of assets. Many of them run on COBOL, some are in a back room. They do adjudication. The cost to transformation for that adjudication would be significant. It is something that we should contemplate and consider.

We should also understand the taxpayer cost to that transition and make sure that at the end of

the day it will be a congressional authorization for CMS to spend money on rewriting adjudication systems. That is the actual constraint. It's not the notion that somebody thinks that this terminology is better for administrative transactions than that terminology. It is the perspective that says we have this deployed asset on adjudication that needs to be rewritten and there is a significant one-time cost for that rewrite. I wonder if, Daniel, you have a perspective on that or if it's just something you want to stay the hell away from.

Robert Wah – Health Information Technology Advisory Committee – Chair
Real quick, just to remind the group, the way we frame this is that we have a patient and clinician perspective first. We are then going to talk about some industry standards and then we have a segment talking from the payer perspective as well. I want to make sure you see the landscape of where we are heading for the entire morning as we have this discussion. I do want to cut this discussion off in any way, but I just want to frame the morning so you understand where we will have the discussion points before I go on to the next two speakers. Daniel, if you have a comment that you want to make, then we have two more comments from our members here.

Daniel Kalwa – Centers for Medicare and Medicaid Services – Division of National Standards Policy Advisor
I only wanted to comment to the extent that Melanie Combs-Dyer will be speaking later this afternoon and she can offer the perspective of Medicare fee-for-service on that topic. Thanks.

Robert Wah – Health Information Technology Advisory Committee – Chair
Andrew?

Andrew Truscott – Accenture – HITAC Member
Thank you, sir. I must admit that it's moderately amusing to watch Arien's face when both Les and I put up our signs at exactly the same moment while you were talking. I will be interested to hear Dr. Robie's view. Coming out from where Les was outlining, which is in some sense some fairly fundamental shift as clarified by Dr. Lane as well. I'll be interested to know from a talk place, you are living this day in and day out. You see both sides of it. You see the upside and the downside of what they suggested. You see the impacts to common processes and procedure upon patient outcomes and administration of the system. What you think?

Andrew Robie – Anacostia Community Health Center, Unity Health Care – Family Medicine Physician
What do I think about Les's suggestion? I think any system that is going to reduce manual work and take the administrative burden out of my hands, I'm all for that. I think it certainly, as a physician working in health centers, we see the need to potentially sometimes require authorization to do some utilization management. There is a limited pool of money in Medicaid, for example, to provide care for a lot of patients. I feel that I need to be a good steward of those resources. A lot of the authorizations I see are either not really clinically relevant or not going to improve a patient's outcome or not make a significant financial impact. One $500 is preferred as opposed to the other $500 insulin. I'm not sure where the math goes with that one. I think putting some of the components on the payer to pull the information and make these decisions with the information I have in my EHR sounds good to me.

Andrew Truscott – Accenture – HITAC Member
Thank you. That is helpful.

Leslie Lenert – Medical University of South Carolina – HITAC Member
I would just like to add that with the advances in deep learning available now, that the issue of being able to take an extensive text document with different data types and other things and predict whether an authorization should or should not be applied based on application of neural network with precision is not a difficult task. We could be rethinking this process rather than using a rule base implementable COBOL strategy. We need to move forward to a modern architecture and design an approach based on existing data. But computational burden should move to the people who benefit.

Robert Wah – Health Information Technology Advisory Committee – Chair
Cynthia?

Cynthia Fisher – WaterRev – HITAC Member
Thank you. Yes. As someone who is looking at this from an innovator standpoint and a consumer standpoint, Leslie's idea is substantial. It is like Netflix to Blockbuster. When we look at the opportunities with AI and the abilities to catapult us forward, I think having a revolutionary idea to overcome – as an outsider looking in at the multiple steps of this adjudication, it looks like information blocking itself in the many ways of keeping protectionism for status quo. We are in this moment where I believe it behooves us to open the pathway and clear the pipes and allow the conduit for innovation to go directly to the patient and physician interaction such that substantial time is saved and risk is mitigated and physicians can go back to practicing medicine again and patients will live safer and healthier lives. Thank you.

Robert Wah – Health Information Technology Advisory Committee – Chair
Thanks. Thank you to our presenters with the patient and clinician perspective. We appreciate your input and hope you will be able to stay for the rest of the conversation. We are going to switch now to industry standard perspective. We have a series of presenters here you see on your agendas. We will start with April Todd. Is that right? I think there is going to be a quick change of the signs and we can ask our resents o come forward onto the table. I'll turn the presentation over to April

Prior Authorization Industry Standard Perspective

April Todd – CAQH Index Data Report, CAQH CORE – Senior Vice President
Good morning. Thank you for the invitation to speak to this committee. I want to give a little bit of background around CAQH to give a little perspective on where we come from. Please, go ahead to the next side.

CAQH is a nonprofit organization with the mission of working to simplify and streamline healthcare business processes. There are three component pieces of CAQH. We have a national utility around provider and member data and there is a component of our work called ProView. This is where the majority of providers in the U.S. do their credentialing. That is shared with all health plans within the U.S. and we are also starting work on provider directories to simplify that process as well. In addition to what I will talk about today which is around the CAQH index which is done under our explorations arm, there is a third area that I wanted to mention particularly picking up on Daniel's comments around operating rules. At CAQH core, we are the national operating rule author for HIPAA transactions and have been working on those rules since 2005. We started with the eligibility and benefit transactions. This is the most heavily transacted

transaction right now in the industry. We are currently working on three sets of operating rules related to prior authorization, attachments of clinical information, and rules related to value-based payment. In particular, I wanted to note that related to prior authorization we have a set of rules that went out for industry vote last week. That will soon be coming to the industry for consideration for mandate across the industry.

If we can go to the next slide, I will cover what the CAQH index is. The CAQH index is a survey that we have been doing for the past six years. This is a benchmarking survey and we are tracking adoption of electronic transactions and the cost and time associated with performing those transactions. This is a way for us to track progress within the industry and locate where more effort is needed to continue to make progress and identify where there are barriers. The CAQH index is a collaborative effort. We have a multi-stakeholder counsel that advises on the work of the index and they have experts across the industry that provide guidance on how the survey is conducted. This is a survey that is directly informed from information from providers, health plans, and the vendor community. Please, go to the next slide.

The index tracks transactions across the administrative workflow. This is from when a patient visit is scheduled through when a provider is paid and there is remittance advice or information about the payment that is communicated to the provider. There are a variety of different transactions along this flow that we track. Not all of them are we able to report. There is a very good reason for this. Some of the transactions for which we ask for information are not transactions that are easy for providers or health plans to report on. In some instances, the transaction has very low volume. In other transactions, it is hard for them to disentangle a specific transaction from their workflow. Please, go to the next slide.

There are a few definitions I wanted to highlight for the information I am about to present. One is around transaction costs and I will add on to what Bill had mentioned earlier around what it is that we track. I think this is very important. We track the cost and savings estimate associated with the transaction itself and transmitting the transaction. We are not looking at IT or technology costs. We are not looking at the cost to gather information or the follow-up information or to transmit information from clinical system to administrative system. There's a good reason for doing this. First, it is our experience in the interviews that we have done that there are few systems connecting this information. It is difficult for health plans and providers to report on the cost and time affiliated with connecting that information. This year we are undertaking a time and motion study with NORC at the University of Chicago to help us understand with plans and providers how this is working in their workflow between clinical and administrative information so that we can ask for in depth questions to understand what is happening with that flow of information.

There are three definitions that we use very commonly within the index. This is where we categorize how a transaction is done into three buckets. One is an electronic transaction. This is an automated transaction using a HIPAA standard. Second is a manual transaction. This is one that is done end to end involving human interaction through a phone, fax, email, something that involves manual intervention. Third is a partially electronic transaction including web portals or IVR systems. Go to the next slide.

I want to give background on who participates in the CAQH index. In our 2018 index for health plans it included 49% of covered lives within in the U.S. through the health plans that submitted

information for this survey. That is on the medical side. On the dental side for health plans, it is about 44% of covered lives in the dental industry. It is a very large representative sample that participates in the index. In terms of healthcare providers, the survey represents a broad range of specialties. This aspect of the survey is conducted by NORC at the University of Chicago.

At a very high level, I wanted to highlight what we have seen in terms of trends related to volume of transaction that are occurring in the industry as well as potential cost savings that remain from converting from manual to electronic transactions. As demonstrated on the left side of the chart, we have seen a large increase in the volume of transactions that are occurring between providers and healthcare plans. One of the highlighted reasons for the increase is related to eligibility and benefit transactions. These transactions by far cover over half of the transactions that occur within the industry. We have seen a large increase in that over recent years. What we have heard in the interviews we conducted is that this is the result of an increase in complexity of the healthcare system, the types of benefits plans, and types of information needed and requested. So, providers have told us that they are requesting information on eligibility and benefits during multiple times along the patient's care journey.

On the right side, what you will see there is the potential cost savings that remains in the industry by moving to electronic transactions. I will remind the committee that this is just for the transaction itself. It is not for the other costs that can surround that. For the first time this year we saw a reduction in the opportunity savings that exist for the industry and what you will see on the next slide is where that is coming from. We have reached a tipping point related to electronic adoption of some of the higher volume transactions. That has resulted in that decline. On this slide you will see these are the transactions for which we reported in 2018. You will see there are three transactions where we had very high electronic adoption. That is really eligibility and plan benefit verification, claim submission and coordination of benefits. There are other transactions that we have seen a routine increase in over time as well. That second area is prior authorization. Over the last six, that area of adoption has been very and has bounced around little bit. There is very low electronic adoption within industry. Go to the next slide, please.

There are a variety of reasons for why prior authorization adoption has been low. First off, related to prior authorization, what we have seen in the industry and this matches what we heard from the AMA, we have seen an increase in the volume of electronic prior authorization transactions. This increase has been 12% since the last survey we conducted. It is still one of the lowest volume transactions that are occurring between providers and health plans. In terms of how the information is transacted, there is a very low volume done electronically. We have seen some bouncing around and mid-level use of web portals for transacting this information, but again, the vast majority of this is communicated through manual means, phone, faxes, manual communication. When we do the index, we conduct interviews with health plans and providers that submit information to understand more background as to what is going on with those transactions. There are common things that we hear as to why the adoption of the transaction is low.

First, we hear from plans and providers that there are really no vendor systems to use for prior information. There is a low offer of systems that can support communication of that information. In a survey we did with vendors, that bears out. Only 12% of vendor systems are providing services to facilitate electronic transmission of the prior authorization. The second thing that we hear, this is one that is the most common response that we hear. There is a lack of an attachment

standard to support transmission of clinical information that is needed related to prior authorization. This is by far what we hear most often. It is hard to go end to end with a prior authorization if you can't communicate clinical information and do not have a standard. The vendor community is loath to create technology if they are using a standard that is not going to be supported. Lastly, some states have certain laws that require part of the prior authorization workflow to be conducted manually. Some states require a consultation between a plan and provider, a telephone conversation. Others require that a final determination, particularly a denial, be communicated by mail or fax. So, there is that reason as well. We can go to the next slide.

What you'll see on this slide is highlighting one of the points I made earlier around vendor systems and those that support different types of transactions. What you will see here in the second and third column is that there is a correlation between the adoption of electronic transactions and availability of systems to support those transactions from vendor systems. For those that are offering that service there is higher adoption. As you will see here prior authorization is the lowest supported service in the industry.

The last thing is I wanted to make a few points around attachments. As I mentioned this is something we hear very frequently. It is also a topic that we are working on related to operating roles. As was mentioned earlier, electronic attachments in HIPAA even though it references a claim attachment. They support claims as well prior authorizations because clinical information is needed to support prior authorizations. What we found in the 2017 index, we did not receive enough information in the 18 index to be able to support this. What we heard from our survey respondents was that 6% of them are using an electronic method to transact attachments. We have also, as part of the work for KOHR in our environmental scan have been collecting additional information related to attachments that should be of interest to this committee. We have been working with our participants to understand a bit more how they are communicating and attaching information. What we have heard is that 12% of them are communicating some attachment information via EDI. It is something done in pilots. This is not something that is done on a routine basis. Another 18% use web portals to be able to communicate this information. The vast majority, 70%, this is done via mail and fax.

The lack of an attachment standard is driving action or lack of action within the industry. When we ask why they are not using electronic means to communicate clinical information, the three top reasons that we've heard is first, 44% of our respondents say the lack of regulatory direction. That is delaying their work. The second is 23% reported that the lack of industry direction is delaying their efforts. Lastly only 9% say this is for budget reasons that they are not taking this up. A last point related to attachments is that that lack of attachment standard is impacting prior authorization. With that, I am open for questions or we can move on to another member of the committee.

Robert Wah – Health Information Technology Advisory Committee – Chair

Thank you very much. I think we will move through this. I also want to make the point that everyone recognizes we put no breaks in this schedule. Take personal brakes as you need. We thought this was a jampacked morning with great information, so we filled it up with that. Our next two presenters are Anthony and Margaret.

Anthony Schueth – Point of Care Partners – Chief Executive Officer

Thank you. My name is Tony Schueth. I am the CEO managing partner of a consulting company called Point of Care Partners. I was the leader of the prior authorization workflow to transactions task group for 14 years from 2004 to last year. I have been at the forefront of electronic prior authorization for very long time. Please go to the next slide.

I've given lots of presentations on electronic prior authorization and one of the things I like to start with is just the way I view the world. People have talked about different buckets. I think April talked about those. I bucket prior authorization into three categories. As a consultant we like to – One of our core competencies is to break things down and people like things in threes. The three that I like when I look at the broad set of types of prior authorization are drugs, devices, and procedures. What Margaret and I are going to talk about today are going to be drugs. I think some of the other panelists will be talking about devices and procedures. To clarify, April's numbers in her index were prior authorization for more devices and procedures than for drugs. The volume of electronic prior authorization transactions in pharmaceuticals is a little bit higher. We don't have percentages like CAQH has. It is significantly higher. To connect the dots and go back to Dr. Robie this morning, he was talking about electronic prior authorization in the pharmacy world. That is what I will talk about. Please, go to the next slide.

Here is a road of history that begins in 1996 with the passage of HIPAA. HIPAA is widely known and has been discussed today as a privacy, security, portability of insurance law. It also named and directed that certain transactions be named and about 2000 is when they named certain standards, including prior authorization, or as Daniel said earlier, a standard for referrals and authorization. That is what the 278 from X12 was designed as, a referral or authorization form. There was discussion, Arien is not here anymore, but Arien was talking about the difference between clinical and financial. There he is. I couldn't see you.

The 278 was and is a financial and administrative transaction not a clinical transaction. In 2003, the MMA passed. That's a Medicare Modernization Act. That created part D. In that act or law, they asked for NCVHS to have a series of hearings about electronic prescribing. Standards would be named. Where there were none, they authorized and conducted pilot test. In 2004, we began to look at all this and seeing where all this was going, and we formed a standard development organization task group. That is the organization I became the lead of. That was a multi-standard development organization task group. In other words, X12, the owner of the 278, HL-7, the owner of the attachments and NCPDP which is the, Margaret will talk more about this, but the predominant standard development organization for the pharmacy world. We all came together, and we said, "Let's figure out how we can use the 278 to support prior authorization for pharmacy. This is in the ambulatory environment." In 2005 we began to have hearings and in 2006, we had pilots. In these five different pilots, 4 of them tested electronic prior authorization. We tested the 278, but we had to have other enhancements to it.

The task group, the very first thing that they did was look at the prior authorization forms out there in the industry. What they discovered and what we found was that there was clinical information required for an insurance company to decide that could not be transmitted in the 278. What we decided to do was use the attachments that April talked about. We were going to use the attachments, we learned that you could not attach it to a 278. We were going to then attach it to a 275 and use that as part of the pilots. The findings from those pilots were that it does not work very well. It is redundant information. It is kludgy. This was in a report to Congress. So, four of the five pilots tested prior authorization. It went into a report to Congress and the

recommendation was that we create a new standard. The report to Congress went out in 2007. This is public information. Not a lot happened in the area of electronic prior authorization between the end of the pilots and 2008.

Then what happened was AHRQ, the Agency for Healthcare Research and Quality. John White, who is now at ONC, came to me and said we have to move things forward and get things moving forward. Let's form an expert panel to figure out how to move things forward. So, what I did was I dusted off the report to Congress. We identified some of the pilots and other key stakeholders. We came together, got a room and we put together a five-year roadmap. The first thing this expert panel decided that we should do is to create a standard, at lease for pharmacy, that was outside of the 278. We chose to create it within NCPDP and use the script standard. In our view and vision, prior authorization was a part of the electronic prescribing process. That is an important point that I am going to go into more detail on as I proceed with my presentation. We chose to use the NCPDP script standard for prior authorization for drugs. Moving forward, the next thing that happened was that Minnesota passed a law that was a driver and then in 2011, CVS Caremark decided they were going to do a pilot. Actually, I went back to John and I said look, we have been working hard to come up with the standard within script. Can we do a pilot and test it like we did in 2006? At the time he was supportive, but he had his hands full with something called meaningful use. Maybe you've heard of it.

What Caremark said was, “We don't need government money, we will do it.” They involved all scripts, Iscribe, NaviNet, and CoverMyMeds who has been mentioned before in this pilot. We pilot tested this new script standard. With the learnings from that, we modified the standard. There was actually a challenge to using the script that came from the industry. Someone came along and said isn't it the X12 278 the HIPAA named standard? Shouldn’t we use the same standard for everything? We had a big long meeting and we had a debate where both sides got to represent their points of view. And the industry, this is the important point, the industry chose to continue with the script. Not CVS Caremark, the industry chose to continue with NCPDP script. They felt that was the way we should proceed. That's what we did. The new standard was published in 2013. Implementation began in ‘15. We are now implementing it with EHRs. I'm going to get into some more detail. Everything that Dr. Robie said is true. I'm going to give more color around his experience as I go through this. Let's go to the next slide, please.

Okay. The vision for electronic prior preauthorization on the pharmacy side is that it is part of the electronic prescribing process. I wanted to walk through the slide, which is the slide I give often on electric prescribing. I want to point you to the lower left side of this. That is the formulary database. What happens today in electronic prescribing is that payers use another NCPDP standard called formulary and benefit. They gather that information to push this out to an intermediary, Surescripts. Surescripts aggregates all of the formulary information from all of these different payers into one large file which they push out to EHRs in the marketplace. There are over 700 EHRs right now today that are certified by Surescripts to do electronic prescribing. I have sat down during a football game and done the tally myself. What these EHRs do is they get this information and then they have it stored in their system. Then, going up at the top, the night before the patient is going to come in to visit the doctor, an eligibility transaction or request is sent electronically through an intermediary, in this case, it is Surescripts, to a PBM. The response back includes the identifiers that connect that patient to the accurate formulary.

When Dr. Robie talked earlier about sometimes I see a green smiley face and sometimes I don't.

Sometimes I don't see anything. He wouldn't see anything would probably be because they did not identify the patient accurately. Surescripts uses five data elements to identify a patient which I don't want to get into because I don't have a ton of time. They might not have accurately identified the patient through the eligibility request. That would be why there was a question mark. They could also get this information back and the information that comes back connects to the right formulary information. That is supposed to, the vision in the very beginning was that that would include a prior authorization flag. The doctor would know if he is writing a prescription for Lantus and prior authorization is required, he would know that before the patient even left his practice. Go to the next slide, please.

This process that we envisioned from day one and that is driven by eligibility informed formulary and a prior authorization flag, we call prospective PA. That is on the right-hand side. So, Dr. Robie knows that patient Mr. Jefferson requires prior authorization. The idea was we would extract the information from the EHR, pre-populate that in the request, send it electronically to the payer, and the payer would send a response back that authorization is approved or not. I know some of you are physician advocates. We want to reduce the burden on doctors that could also be a process that is done by a staff member. It doesn't have to actually be the doctor that does it. The whole idea is to be a completely automated prospective process. When the patient left the practice, they knew exactly what they were going to get when they went to the pharmacy.

Too often what happens is this. Can you go backward, to the previous slide? Too often what happens is this. The doctor doesn't know that prior authorization is required. So, what they do is they send the prescription electronically to the pharmacy. The pharmacy then, on the right-hand side, imagine there is an arrow between the pharmacy and the PBM. They submit a claim to the PBM. The claim is rejected. In fact, we know how often it is rejected. 11% of the time it is rejected. Of that, 67% of the time it is because prior authorization is required. So that kicks off, let's go now to the retrospective slide. Yeah, that one.

That kicks off what we call retrospective PA. That means that a claim is rejected. It goes back to the pharmacy. Now the pharmacy has an easy button nor code that they put in that sense the prior authorization electronically to the doctor through a different channel. Unfortunately, the patient is gone. He doesn't have all the information that they need, and it is outside the workflow. At least that is a catch. At least somebody has caught this, and it is now electronic, and it does meet our standard. It is a retrospective process that we now follow. The pharmacy submitted to the prescriber. It can be in their workflow, sometimes it is in the task list or inbox. In his case, he described that he would press a button and go out to a portal. The information would be included in the portal. That is the way this retrospective process works today. They fill out the information, get the response back, and then they send it back to the pharmacy. It is cumbersome. It is suboptimal. I will tell you what it does. CoverMyMeds is the one that actually has this process. There are no advocates for it. In fact, if you look at it, they just put out a report card. It shows that patients get therapy 13.2 days faster if it is prospective rather than retrospective.

The other issue is when you have that rejected claim. I said, 11% of the time it is rejected. Of that, 67% of the time it is because prior authorization is required. Of that 67%, 37% of the time therapy is abandoned. They just give up on it. Here is a percentage from CoverMyMeds. Today, 65% of the transactions are retrospective and 35% are prospective. The majority of the volume is retrospective. It is a sub-optimal process. As I get a little further in this, I will get into why it is like that. Let’s go to the next slide, please.

Let's talk about what the problem is with formulary. First and foremost, anyone who has ever done a survey or talked to a physician – Dr. Robie mentioned it this morning. Actually, Dr. Robie was kind about this. He said sometimes he sees the formulary and it is great because he sees a smiley face. He said that sometimes it is not accurate or wrong. That is true. Part of the problem is that eligibility driven flat file formulary process that I described is a snapshot in time. Things may have changed. It might've changed from the time the information was cut and transmitted to Surescripts and sent to the EHR. Sometimes EHR does not update the information on a regular basis. It is not a problem with the EHR but it is the practice's problem. It depends on how they are all set up. There could be errors and problems.

I can tell you what I think the two biggest problems are with formulary. First and foremost is that the formerly information -- by the way, we as an industry designed that process because in 2006, 2004, and 2000 when we created it, physicians did not have high-speed Internet. They could not do a real-time transaction like they were doing at the pharmacy. Things have changed. What we needed to do was get the formulary information out to them in a way that would not slow the doctor down. Trying to do some real-time request response when all they had was dial-up was not going to work for a physician. This whole process was created at the time, given the circumstances that existed in the office. Things have changed. The way it works is the information included in this formulary standard, which is, by the way not the problem. I'm not just saying this because Margaret is sitting next to me. The formulary standard works just fine. It is great.

The problem is, the information is at a plan level not an individual patient level. Let me explain what that means. A plan would be General Motors. There is a group level between plan and a patient. The group level would be General Motors hourly employees in Toledo. The individual patient level is John Smith or Jane Smith. The formulary information is at the plan or group level, not the individual patient level. Sometimes when the doctor looks at the information it looks like it is wrong, but it is not. Instead, it is at the wrong level. The other problem that we have comes from a study that the AMA did. Too often the commercial plans do not include the prior authorization flag in the formulary. It gets better. It shows we get better from 2014 to 2016 but in 2016 only 33% of the time when formularies were analyzed, did it contain a prior authorization flag. I can tell you that almost all plan designs have prior authorization. It should have been closer to 90% and it is at 33%. That is part of the problem. Commercial plans are not including the prior authorization flag. On the Medicare and Medicaid side, they do. It happens. It can be done. They are just not doing it in that case. Let's go to the next slide.

I'm going to pick up the pace because there are a lot of other people to hear from. Everything is primarily retrospective today. Go to the next slide, please. I am going to finish up because I know we have a number of other presenters. Where are we going with all of this? First and foremost -- there was one other. There's a solution to this formulary problem. Unfortunately, I added the slide and it did not get included. There is a solution to this prior authorization challenge we have and the formulary information not being at the patient level. It is called the RTPBC, the Real-Time Pharmacy Benefit Check. CMS has put out an NPRM on the RTPBT, Real-Time Pharmacy Benefit Tool. We as an industry are developing what is called a real-time pharmacy benefit check. This is a real-time transaction that is being implemented in the industry by innovators and early adopters. I will give credit to ONC, to Steve Posnack's group, a woman who is no longer at ONC named Tricia Lee Wilkins who put out an RFI, request for information saying, "Why can't we have the same information at the point of care that we have at the point-of-sale. Like at the doctor

have the same information at the point of care that we have at the point-of-sale? Why can't the doctor at the point of care have the same information that we have at the point of sale?" This RTPBC is designed to fix that and provide that same patient-level information at the point of care.

There are other pieces to it as well that our valuable and important. One is it can provide patient out-of-pocket costs, so transparency. If it is not approved, then it can provide alternatives. It can tell you where the pharmacy should be. It is a solution the industry is working on bringing. So, where we going with RTPBC? We are starting to implement RTPBC more in the marketplace. It is another NCPDP standard. We will see it more tightly integrated within the electronic health record. There is going to be an elimination of unnecessary PAs.

There is one more slide. Lauren, if you can go to the last slide? I am going to make a couple of points. One of the things we have learned is that all of this that we did on the pharmacy side was driven by stakeholders saying this is what we want to do. I would say what is needed in the industry right now to get us to the point where Dr. Robie has a positive experience with every situation he encounters is first we need to make sure -- Right now HIPPA has named the 278 as the prior authorization standard. On the pharmacy side, the industry has moved forward with the script. We need to have that as another alternative. Arien talked about his company is using the 278. There are some using the 278. It is a small volume in the pharmacy. People are using the script and one thing that would really help with payers that have not participated is to understand that it is allowed under HIPPA. Another thing that would really help with formulary is broader adoption of the RTPBC standard. The third thing is making sure that the commercial payers use the formulary and benefit standard that exist today. The last thing I would say that would be helpful is the vision, in the beginning, was that the information could be automatically extracted out of the EHR and included in the prior authorization request. In 2004 and 2003 we were talking about using an HL-7 standard called Jell-O. It does not exist anymore. Using CDA, using FHIR to get information out of the EHR including the prior authorization request would be exceptionally helpful in terms of reducing physician burden. I am going to leave it with that and I apologize if I went over but this is something I have been living for the last 14 years. Thank you very much.

Robert Wah – Health Information Technology Advisory Committee – Chair
Great. Thanks. To finish up the medication workflow, we're going to move to Margaret.

Margaret Weiker – National Council for Prescription Drug Programs – Director of Standards Development
Thank you. I am Margaret Weiker. I am Director of Standards Development at NCPDP or the National Council for Prescription Drug Programs. Next slide. We are a not for profit ANSI accredited standards developing organization that has over 1600 members that represent virtually every sector of the pharmacy services industry. Our members drive our solutions. They bring their perspective to our forum and using our consensus-based process, we develop standards as well as education and other types of guidance such as the safe use of acetaminophen, milliliter dosing, and other types of education. We also have data products that were developed by industry for the industry that augments our standards development process. Next slide.

More than half of all pharmacy electronic prior authorizations are not sent electronically. They are done via the manual process. A fax or a phone call. I'm not sure that we have too many interactive voice response systems that do this, but I guess it is a possibility. It is a manual process.

As Tony alluded to, that leads to a 37% of that prescription volume being abandoned. It is a very inefficient system. 37% is a lot. If we look at it from an electronic point of view, this can be automated. A person goes to their physician. The physician determines that they need a prescription. At this point, it comes to a decision. One is done prospectively, and one is done retrospectively. If we do it prospectively, I have done an X12 270 eligibility request and received a response back. In that response, I get what I will call pointers or hooks into the formulary as well as containing other information that can be used. If I have the formulary and benefit standard incorporated into my EHRs or some process, then I can use the hooks to determine the formulary and what are the requirements for that drug. That file is generated by the health plan or processor. Typically, it goes through an aggregator which takes all of them and transmits them to an endpoint. In most instances that update is not done in real time, it is a batch process. Is it done at night? How frequently is it done? Is it an automatic update or does someone in the office have to press a button to do the update? A lot of times that file does not get updated.

Let's say I trust the formulary and benefit information I see before me as a prescriber and it says prior authorization is required. So, if I am going to do that prospectively I would send NCPDP script EPA transactions to the payer. There are eight EPA transactions. The first is, if you do not know the criteria of what is required for that prior authorization, you can initiate a request and say tell me what is needed. In some instances, the response will come back and say you do not need a PA because the formulary file was not updated. Or it will come back with a set of questions that need answers, many of which can be extracted electronically from the health record. Once I obtain the prior authorization, I use the script standard and use the prescription ordering transactions in that standard and send that to the pharmacy. The pharmacy processes it and creates a claim that uses the HIPPA adopted NCPDP telecommunication standard. They get a response. I pay my co-pay and I'm out the door with my drug.

If it is done retrospectively, the prescriber would send the order pieces of script to the retail pharmacy. The pharmacy would submit the claim and they would get back a reject 11% of the time. That is for over 4.5 billion claims a year. 11% of that is rejected. As Tony said, 67% is rejected because of requiring prior authorization.

There are instances named in HIPPA. The telecommunication standard does have prior authorization transactions. Those transactions and that standard is only used if the pharmacy is allowed to do the prior authorization. There are very few health plans that support that. They are primarily Medicaid and do so with a limited set of drugs. In most cases, the pharmacy either picks up the phone and calls the physician or faxes something. The script order transactions do allow a return from the pharmacy to the prescriber letting them know that the prescription requires prior authorization and is not going to be filled until that is obtained. However, not all pharmacies support that transaction. There are many electronic health record systems that do not support that transaction as well. The processing is also an issue. There was a study done by CoverMyMeds that says if the prior authorization is done prospectively the patient gets their drug 13.2 days sooner than if it is done retrospectively or manually. Next slide.

The script EPA transaction mimics today's PA process. It allows for a standard structure for exchanging the PA questions and answers set. While allowing the payer to customize their questions. When we had the multiple STO panel, we were looking at all of EPA forms. Back in the day, Celebrex required APA. We had many health plans that required a PA in order to get Celebrex. When we started evaluating the questions, there was a one-word difference. Would

they change? No. I need to have my question my way. There was a rheumatologist and their professional society sponsored a rheumatologist to go through every health plan in this country and gather all the requirements for prior authorization for a particular drug that is most commonly prescribed and come up with one answer set. She did it, but no health plan would adopt those because it wasn't their questions, wasn't worded the way they wanted their question worded. We accommodated that flexibility in the standards which allows the customization of those questions by the health plan or payer.

In addition, the transactions do support the automation of the collection of data that can be gathered from the EHR without someone manually doing it. If I need the results from an A1c test I would send the code for a particular date and say give me all the test results for the A1c for this time period. That can be extracted or sent back to tell me the results and go back to the health plan. That can be done automatically, and we have accommodated for that. The transactions can be used in a solicited or unsolicited model. A model where I will ask you to give me information and the other model is, I will do it prospectively before you tell me. Then it does reuse many of the data elements or structures used when you send an electronic prescription. Next slide. There are eight –

Robert Wah – Health Information Technology Advisory Committee – Chair
I don't mean to interrupt you. I just want to make sure we are fair to our other presenters. We're covering medication transactions with yours and Tony's presentation. Looking at the slides, there are a number of overlaps between the two. Can I ask you to start summarizing because I want to give adequate time for the other transactions we are dealing with in prior authorization? I apologize I'm coming down on you particularly but just trying to keep this equitably devoting time to all subjects. Thank you.

Margaret Weiker – National Council for Prescription Drug Programs – Director of Standards Development
There are eight electronic transactions and scripts listed on the screen. I'm not going to go through them. Tony went through history, but I do want to point out that NCPDP did follow what we believe was the correct process at the time. This was to go through the HIPAA process and to submit a designated maintenance organization request and go through NCVHS. Back in 2014, NCVHS did recommend the 2013101 version be adopted using the best method to do so and that has not been done. Next slide. Today, where are we? We would like to have the script standards 2017071 for pharmacy benefits adopted. It would streamline and standardize across the board. Many pharmacies, 70%, have implemented it and it is used to expedite therapy. We are listed in the 2019 ISA. On the next slide, I go through the benefits of script standards. So, we'll just go right on. Next slide.

I want to point out that in the CMS 4182 final rule, they received many comments in their proposed rule about adopting the script EPA transactions. Their response is we would like to but it is covered under HIPAA and until HIPAA changes our hands are tied. Next slide is recommendations. First and foremost, we recommend adopting 2017071. We need EHR vendors to incorporate these transactions into their software. That has been a big issue. It needs to be integrated into their workflow. In many cases, there are third parties that provide solutions but outside of a prescriber's workflow. We also need processors to support the transactions. Not all of them do and not all support the full set. Also, we need to review requirements about what needs a PA and what does not and incorporate analytics into that. From an NCPDP point of view,

we need to complete enhancements to the formulary and benefits standards as well as the development and release of our real-time pharmacy benefit standards. I hope I got us back on schedule.

Robert Wah – Health Information Technology Advisory Committee – Chair
Thank you very much. Now we can turn our attention to nonmedication workflow particularly durable medical equipment referrals and imaging. Our next speaker is John Kelly.

John Kelly – Edifecs – Principle Business Advisor
Thank you. We are talking about standards and a big part has to do with language precision. Because WEDI has EDI in its name, I would like to make a statement that EDI, electronic data interchange is an activity. X 12, HL-7, FIHR, XHTML are standards and methods. I want to be clear in a precision way when we talk about WEDI who we are and what we're doing that we're not just talking about the world of X12. Next slide.

We as a workgroup for electronic data interchange convened a Prior Authorization Council in response to a call from its members and its leadership to assess the industry progress toward the adoption of electronic methods of prior authorization. WEDI represents a broad industry perspective of providers, clearinghouses, health plans, vendors, and other organizations in public and private sectors that partner together to collaborate on industry issues. WEDI is named as an advisor to the Secretary of Health and Human Services under the health insurance portability and accountability act. We take an objective approach to resolving issues. Next slide, please.

That approach is grounded in the experience of our members, the deep subject matter expertise of our workgroup participants, and the broad industry representation made possible by the constitution of our leadership and board of directors. Next slide, please.

We hope the perspectives we offer will help HITAC members and ONC leadership be successful in formulating policies that will help advance the goals of the CURES act. Next slide. I would like to start by describing what the Prior Authorization Council is not. Next slide, please. The PACs charter specifically excludes any attempt to build industry consensus about national policy, procedures, or specific technology in order not to duplicate the work being done by other industry groups. Rather the goal of the PAC is to build across stakeholder view prior authorization in the United States and develop recommendations to adjust gaps relative to the critical components of any plan to provide feature industry direction by WEDI or HHS that would significantly reduce the administrative burden generated by the prior authorization process. Next slide, please.

Prior Authorization Counsel is comprised of a broad set of constituent groups. It includes the Blue Cross Blue Shield Association, CAQH, the Cooperative Exchange, the Healthcare Administrative Technology Association, HIMS, HL-7, Medical Group Management Association, National Council for Prescription Drug Programs, WEDI, and X12. Each member of the PAC had an opportunity to present a comprehensive review of their initiatives and activities associated directly and indirectly with the US healthcare prior authorization industry policies and procedures. Each presentation provides an opportunity for all PAC members to engage in a thorough question and answer dialogue. Next slide, please.

After we have the opportunity to share details of all the major known initiatives, we correlated

the body of work that we went through to establish a common understanding of prior authorization in the US market. This was a subjective exercise but the industry as a group is quite deep and we believe findings to be grounded and relevant. A number of areas of focus emerged but one gap related to lack of any industry effort aimed at solving the problem of provider burden. Next slide, please. Next one.

We believe it is relevant to take into account this identified gap, the lack of any directed effort devoted to automating the point-of-care burden on providers associated with prior authorization. In order to establish the significant of this finding and its relevance to the topic of today's meeting, I want to refer to a finding from the AMA prior authorization physician survey. This survey has been repeated the last three years. During that period, the hours of physician office time devoted to prior authorization has consistently remained at between 14-16 hours. And the number reported in 2018 was 14.9 hours. Now, there are a lot of estimates surfacing that purport to calculate the financial impact and degree of physician burden associated with prior authorization. The estimate considered most relevant by the council was that the 14.9 hours per physician per week, multiplied by the 1 million physicians in the country, multiplied by the average national hourly rates for healthcare workers put the cost of PA at over $25 billion a year. For every person covered by health insurance in the US, roughly $100 each year is devoted to paying for prior authorization. Next slide.

Whether this cost is offset by any financial or other quality benefits to the industry is a topic for another meeting. Regardless of whether prior authorization is a beneficial component of US healthcare, the burden of the process can be reduced by reducing the physician office cost and the office cost can only be reduced if we achieve what the PAC white paper called single action order entry. By this, we mean that once a provider puts in an order for service into the EMR an active documentation required for the provision of care and recorded as part of the normal workflow, machines should be able to manage the rest of the PA process. If the industry can settle on common processes, standardized communication models and transaction, and the acceptance of a B2B model for the end-to-end prior authorization process, it may be that a single year cost of $25 billion for PA, if it is invested in transition to a automated model, may eliminate the cost of year over year into the future. If we eliminate the burden associated with the current PA model, we may be able to implement a more robust system of delivering appropriate care. Next slide.

I want to elaborate on a single action order entry. The act of ordering an order creates a message in the EMR such as an HL-7 message. This act could trigger a sophisticated machine-based workflow that determines if a prior authorization requirement exists and if so what information is required to be provided to the payer of record in order to fulfill the PA requirement. After that, it can request the authorization from the payer. A more detailed description of single action order entry is provided in the PAC white paper on prior authorization and distributed to the HITAC members. Next slide. Next one.

[Speaking Dutch] is a Dutch phrase that translates as "appropriate care". And in this version of value-based care **[Speaking Dutch]** is a principle that implies that an approach similar to that adopted by Toyota and Ford when they transformed automobile manufacturing in the last century. That principle is "Manage the quality and the cost will take care of itself". Now, whether the results of this approach yield in healthcare what we saw in auto manufacturing, it is difficult to predict. With a fully automated prior authorization process, the US version of appropriate care

may begin to mimic what is occurring in the Netherlands. CMS is in the process of ramping up its appropriate use criteria program for high-cost radiology. CMS.gov states, “The protecting access to Medicare act of 2014 section 2018B establishes a new program to “increase” the rate of appropriate advanced diagnostic imaging services provided to Medicare beneficiaries.” If your typical commercial payer program that implements prior authorization to view the use of imaging by network providers, if you look at it, it would never have a goal of increasing utilization of high-cost services. So, if you consider that the core of the CMS AUC program is the direct incorporation of CDSM, clinical decision support mechanisms, into the care workflow, that implies the scenario wherein CDSM my not just evaluate whether the order should be done but what alternative procedure might be appropriate given the patient's presentation. This is not unlike the manner of E-prescribing applications build “advice” into ERX workflows. With CDSM, an informed PA process, we would not just be asking should I do the procedure, we may be asking what procedure I should do. If we take the provider burden from the 14.9 hours a week to virtually nothing by automating documentation processing and incorporating CDSM's, we create an opportunity for lower administrative costs and increasing quality. Whether that ends up actually increasing the cost of services delivered is a question for another meeting. It’s important to note that the lack of point of care workflow automation described above is not the only major issue with prior authorization.

The huge variation across all payers regarding medical billing and payment policies is a significant hurdle to burden reduction. The timeliness of the entire process of prior authorization is frequently cited and the lack of information stored in patient records, and the variation in how that information is stored and accessed within each EMR vendor’s software also introduces significant challenges. The lack of consensus in general on the real value and appropriateness of payer medical necessity review inhibits the general commitment of resources to effectively implementing such programs. An interesting perspective is if you accept the premise unnecessary services and procedures are being delivered, it does not necessarily flow that payment reform is placing providers at risk for cost and quality will illuminate the need for someone to be performing a medical necessity review. Under such scenarios, the job of implementing prior authorization processes falls to another party. Next slide, please.

While these issues are being considered by the Prior Authorization Council, the Government Accountability Office released a report to the US Senate Committee on Finance in April 2018. That determined that CMS should take access to continue prior authorization efforts to reduce spending in Medicare. Consequently, in the view of the Prior Authorization Council some form of pre-review of medical services appropriateness will continue to be an integral part of the US healthcare system and therefore every possible effort should be extended to automate the process. The importance of this automation was reinforced by the repeated observations of the GAO it that difficulty in obtaining documentation was the major barrier to expanding prior authorization. Toward that end, the summary recommendation of the PAC was that some entity or coalition of entities needs to create the incentives or pressure to cause the major EMR vendors to make the research and development commitments to bring about single action order entry. Next slide.

To be clear the Council does not underestimate the scope of the effort that will be necessary to bring this about. Perhaps a misnomer associated with reducing physician burden is the phrase “administrative simplification”. These processes are complex and cannot be made simple. In a former role, I worked at Harvard Pilgrim Healthcare New England. Almost a decade ago, HPAC

invested in a major effort to automate their prior authorization processes by using provider portals and the HIPAA X12 278. The fundamental finding and a premise of the project was if you want to automate prior authorization, then the plan policies need to be automatable. HPAC embarked on a business process redesign initiative to identify policies that can be automated or cannot be automated and if the services covered were generally authorized upon review made sense to eliminate the policy. The remaining policies were reworked so that they could be automated using the data elements available in the X12 278. For a significant period of time, over 90% of prior authorizations were electronic and over 90% were adjudicated in real-time. Unfortunately, as years passed, life and healthcare get more complicated. HPAC is finding the need to incorporate a request for additional information, attachments, and decision support software into its prior authorization process using the 278 transaction. Instead of simplifying the administrative process, we need to get better at automating complexity. Towards that end, the Council suggested the industry learn from a change adopted by CMS. CMS has rebranded meaningful use and advancing care quality programs as promoting interoperability. To begin to address the mindset change needed to solve the PA problem, the council suggests that the industry should consider promoting the term administrative automation in place of administrative simplification. In doing so, they would be accepting the fact that we need to get really good at the complexity and then provide the tools required to support that approach. Our cellphones do that for us every day. Why not our HIT? Next slide.

Another major finding was it is critical that we avoid standards wars. The harmonization FHIR, CDA, and X12 standards development efforts need to be a joint priority among the stakeholders. The successful and rapid adoption of end to end automation will be predicated on the ability of the industry to create a sustainable pathway for innovation while leveraging the billions of dollars already invested in technology assets created to comply with existing law. These assets represent a fully functioning digital highway connecting payers and providers and represent a low-cost glide path for sustainable change. The exception processes to the compliance requirements should exhibit a commitment to a minimum bar as a floor with additive capabilities to support innovation among willing parties and early adopters. Next slide.

They debunked the myth about humans only using 10% of their brains but it is not a stretch to say we only use 10% of the capability inherent in the X12 278 transaction. The common version of the transaction is rich in data elements around which payers and providers can build very effective care and payment processes. The fact that adoption has been poor is related to many factors. Not the least of which, as stated before, is that many policies cannot be automated as they are currently written. REST OAuth JSON will not change that. FIHR is the technology answer to the question of how to talk to an EMR. FHIR is the right answer regarding how one requests data elements from a clinical data repository or how one packages those data elements so that they can be interoperable in supportive care plans, quality reporting, or the determination of medical appropriateness. That said, how data payloads are enveloped for transport from machine to machine processing and how metadata elements are communicated for routing addressing business process automation. Those are questions that have multiple equally adequate answers given how much current infrastructure supports X12, CCDA, NCPDP, and other deployed HIT frameworks. These frameworks are fully capable of interoperating. The reality is the provider adoption of the 278 is low but payers and stakeholders other than providers have generated huge operational efficiencies by leveraging the HIPAA transactions including the 278. These stakeholders invested a lot in reusable infrastructure to support those efficiencies. Next slide, please.

There was a marvelous piece of collaborative work that was done by WEDI, X12, and HL-7 to produce a joint implementation guide that laid the groundwork for the much-anticipated attachments rule from HHS. HHS should provide guidance on collaboration as it relates to the work underway at ONC and HHS. Cell phones are perfectly capable of allowing you to hear music, compose documents, and watch the video without you knowing what format standard was being interpreted for a particular attachment. HIT can make the complex simple and backward-compatible. During the course of the work of the Prior Authorization Counsel, HL-7's DaVinci project emerged as an industry collaborative that shows great hope in addressing a number of issues cited above. My colleague Bob Dieterle will speak in more depth on the topic of DaVinci. I only raise it here to say that the formation of the Council predated the creation of the DaVinci project. Our white paper was informed by the good work they were doing, and the major gap cited regarding EMR vendors addressing single-action order entry is a high priority use case for the DaVinci project. The consensus of the Council is that the industry still requires the application of some carrots and sticks to all the stakeholders, not just EMR vendors if we are going to make significant progress in eliminating the degree of manual interrogation of providers required by the PA process and currently observed in the industry and reported by the AMA. I want to thank the HITAC and ONC for presenting us with an opportunity to speak today. I also convey our continued commitment and support of the important initiatives underway and contemplated by the ONC.

Robert Wah – Health Information Technology Advisory Committee – Chair
Thank you very much. Just to let you know, we are a little bit behind schedule. I take responsibility for some of that. If we could move to the DaVinci project and then we have our own HITAC member talking about CDS works at the end. We will run a little bit longer than currently scheduled but I would ask you to try to keep your time close. We are going to take a few minutes off of your previously agreed to 15 minutes. Thank you very much.

Robert Dieterle – EnableCare Program Management Office HL-7, DaVinci Project – Chief Executive Officer
My name is Bob Dieterle. I'm a member of the Program Management Office for DaVinci and a co-lead for the prior authorization support use case work we're doing at DaVinci. Next slide, please. We'll talk a little bit about the implications of the HIPAA requirements on the work we're doing. We will spend a bit of time giving an overview of DaVinci and our use cases and talk specifically about prior authorization support work that DaVinci has been doing for the last several months. Next slide, please.

The environment we are in is a complex one. We have providers and payers trying to communicate information related to procedures or treatments that will be performed or ordered. Using a number of technologies, fax, the telephone, portals, electronic exchanges, trying to communicate medical records to support those requirements. Next slide, please. Under the HIPAA requirements, we have to have a request for prior authorization. In the ANSI X12 and 278 standards, what we're showing on this slide is the anticipation that we may need the documentation in the 275 standards. At some point between the provider and the payer, we have to meet this requirement. On the other hand, we do not have that requirement between clearinghouses and individual providers. Next slide, please.

One of the problems we have had is trying to integrate the technologies that have been approved

whether it is the X12 standard or any other method into the EHR to extract the information in real-time to automate transactions. Next slide, please. Even when we wind up looking at the use of the patient management system where we typically have integration with the X12 transactions, one of the problems is in getting in real-time information out of the EHR to support the prior authorization. One of the statistics reported earlier is only 12% of prior authorization transactions as of CAQH index report 2018 are automated end to end. Less than 6% of the attachment's transactions were automated end to end on the 2007 report. I believe the number was so low on the '18 report that they did not report it. Next slide, please. What we are focused on is trying to enable using FHIR, the ability to reach into the providers EHR and extract the information necessary to support the prior authorization transaction using supporting documentation. On the payer end, to the extent, they are establishing FHIR-based clinical support systems and convert that information back to use the emerging technologies. Next slide, please.

DaVinci was formed as a project under HL-7 about a year ago. The goal was to use a multi-stakeholder funded environment consisting of providers, their supporting EHRs, payers and their supporting technologies to implement FHIR-based solutions for value-based care. The goal is to automate the exchange of information to support value-based care between providers and payers and providers and providers. Ultimately, creating implementation guides, reference implementations, and pilot projects to prove that these standards work. Next slide, please.

As we shift from fee for service to value-based care, we have to need to improve our ability to communicate in real-time, information necessary to support these processes. That is where DaVinci's efforts are focused. Next slide, please. By the end of this year, we will have completed use cases, implementation guides, reference implementations to support major transactions between payers and providers focusing on prior authorization and documentation requirements and the ability to free up payer data to make it available to providers. This is addressing quality reporting and gaps in care and real-time and being able to support medical record exchange from providers to payers to meet various value-based care requirements such as risk adjustment or quality program management. Next slide, please.

DaVinci consist of 30 members. We have 12 of the largest payers involved. Four of the largest EHR vendors and nine supporting technology vendors for payers and over 12 provider organizations. Across the board, we support 70% of covered lives and about 70% of physicians using certified EHR. This is a partial list of our members. You can find a full list on the HL-7 DaVinci website. Next slide, please.

These are the 12 use cases we are working on. The process that DaVinci uses is to define requirements for a use case; clinical requirements, technical requirements, along with business requirements, and testing departments. From that, we create an implementation guide that we ballot through HL-7 so it can become a formal standard. We create a reference implementation intended to exercise that implementation guide. It is a unique thing for DaVinci. We have the ability to simulate a provider's interaction and payer's interaction and prove that the implementation guide actually works. At the same time, we create test suites to validate that the exchange is compliant with the implementation guide and the underlying standard. We get to the point where we bring this out to pilot and have tested it extend extensively using the test suites that we have developed. We have connections that the implementers can hook up to so you can verify that their end is working. What you see in the upper left-hand corner are two use cases we have completed. They took them to the ballot in September of last year and we're going

through the process of resolving them. In both cases, we're going back to the ballot for updates on the FIRE release. The data exchange framework for quality measures will be talked about more extensively.

The pale boxes are the data exchange framework for quality measures, and coverage requirements discovery, which we will talk about more extensively. The next one is documentation templates and coverage rules. The ability to get information that exists in a payer's environment into an executable form in a providers environment. The three boxes below are related to the ability to free up clinical information and make it available to other providers or payers in a standardized restful way. The same thing with payer data. The ability to provide that information back to providers so they have a complete record of what has happened to their patient even if they do not provide care. The prior authorization support we will talk about more. It builds on top of the prior use cases. We have additional work we're doing on gaps in care, on patient cost transparency which I believe Ameldi Consvair will talk about a bit more, and on things like chronic illness documentation and risk adjustment. Next slide, please.

The relevant use cases for the work we're talking about today are coverage requirements discovery which uses CDS hooks to connect into the provider's workflow enabling the provider to ask a question of the payer and exchange information. Then documentation templates allow us to take payer rules and make them executable in the provider's workflow. Health record exchange and clinical data exchange is our ability to package up the data collected on the patient that is necessary to support the determination of medical necessity for a particular service or device undergoing review for prior authorization. And prior authorization support where we bring together the three other use cases to enable the end to end exchange of information. Next slide, please.

We use CDS hooks as a way to initiate these transactions. I am not going to go into this in detail. Dr. Kawamoto will be going through some of that in a minute when I am done. Broadly, we use the ability to trigger in the clinical workflow the assembly of information and exchange with a payer organization's clinical decision support system. To initiate a conversation that ultimately results in information return that can be any number of things. We will talk about that on the next slide. Next slide, please. We use it as part of the coverage requirement discovery to allow the provider to ask the question at the point in time when planning treatment or ordering service or device. Is there something I need to do to ensure that whatever I am doing now is covered under the payer's contract? It could be as important as prior authorization. It could be the fact that specific documentation is required to support medical necessity determination for that particular service or treatment. The return information is called a set of cards. Those can be purely informational or say that nothing is required for this specific service or something as complex as saying not only is prior authorization required, we have the ability to help you assemble that information and provide the ability to launch FHIR application that can guide the provider through not only assembling the information but asking for anything that's missing.

Robert Wah – Health Information Technology Advisory Committee – Chair

I'm sorry. We need to have you summarized. Ken is going to talk about the CDS hooks in just a minute and I really want to give him adequate time to do that. I apologize I'm being tougher on the people later in the panel than the beginning. I'm really going to need to have you go down to one more slide if you could.

Robert Dieterle – EnableCare Program Management Office HL-7, DaVinci Project – Chief Executive Officer

Next slide, please. Next slide. Melanie Combs-Dyer will talk about this in a moment. This is the foundational use cases we're using for prior authorization. It is what has been implemented by CMS as documentation requirements lookup service. Next slide, please. This is the approach we're taking to prior authorization support. By using the ability to have the provider use CDS hooks to initiate an action to transfer information to the payer where the payer can evaluate that information on what procedure, device, or treatment is being ordered. And then they can decide whether or not there is a need for prior authorization. They can return the information and the fact that there is a need and have the provider invoke a smart FHIR application that could pull down the payer's rules. We're working to go and get the standard definition for those rules in clinical quality language, CQL, and have those executed in the context of the provider's environment which pulls information directly from the clinical record. Assuming it is complete, it can be submitted immediately for prior authorization without any interaction from the provider. If more information is needed, it could use standards that we are working with, structure data capture, to ask the provider for the additional information, capture it, then initiate the prior authorization transaction. As we indicate that transaction would be implemented with translation into and potential out of the X12 standards to meet the HIPAA requirements. Next slide, please.

There are two other possible approaches to prior authorization that come out of the work that we are doing. One is to focus on a provider or payer only effort around prior authorization. If we go to the next slide, you will see that. The ability of CDS hooks to exchange a token giving access to the patient's record can be utilized to have the payer check the records see if the information is necessary to support prior authorization and do nothing but issue the prior authorization number. The fact that it has been approved denied or additional requirements needed then return the appropriate card with a link to the app. The other choice is to do most of this on the provider side. Rather than return rules that assemble information, to populate a prior authorization transaction going back to the payer. Rather have all the rules necessary to evaluate the information sent to the application on the provider side. Have that application evaluate the information that currently exists and any information that need to be collected. If all requirements are met, issue the authorization within the context of the clinical workflow and communicate the fact that it has been approved within the provider payer's rules back to the payer. That would give the payer documentation.

The number of possible workflows that these technologies allow us to implement that are – As we see on the next slide. I apologize. So, by using these new technologies, FHIR, CDS hooks, smart on FHIR, CQL, it is possible to take previously labor and time-intensive tasks and automate them within the clinical workflow within real-time. It is possible to acquire the clinical information while the patient is still in the provider if that is necessary. It is possible to obtain prior authorization in real-time so we can meet the one critical reason we're doing this which is to minimize the burden on the provider. The second is to improve patient care and patient care experience.

Robert Wah – Health Information Technology Advisory Committee – Chair

Thank you very much. We have already run out of time for this section. We are going to cut into the next one and going to lose our discussion time, but I want to give Ken adequate time to talk about CDS hooks. I apologize I came down hard at the end of the panel, not at the beginning. That's the way it worked out.

HITAC Member

Ken Kawamoto – University of Utah Health – HITAC Member

I'll see if I can go really fast. I'm going to give an overview of HL-7 and CDS hooks. This is a technology that can be used across the use cases and would be attractive from the perspective of not having a variety of different standards being used for similar use cases. Next slide, please. This is what we have already talked about. CDS hooks is a vendor diagnostic remote to send support specification being standardized in HL-7. Next slide, please.

The general notion is that from the EHR use the notion of a hook to invoke these standards. Within the service it can do whatever it would like, whatever logic and how it specifies it to evaluate that data which is retrieved in FHIR and returns results as what is known as cards. Next slide, please. Obviously hooks a very important but what are these trigger points in the EHR? The key thing to notice is the only hook that EHR vendors have started to adopt is the patient view. This is when the patient chart is open. There is a lot that is being discussed right now, but that is the current state.

The next priority ones we are looking to implement are the ones for order select, which is the notion use set. At this point, I want to order Atenolol or order sign when you have filled out all the SIG information and said, "I'm ready to sign this." Those are an active element. Next slide, please. This is the overall workflow example. For example, you're about to prescribe medication and that sends a hook to a service that can pull data from the EHR FHIR servers and return back information, suggest alternatives, and request that you open a smart app. Next slide, please.

This is the notion of where the data comes from. There are several places. One is hook context data where you push data. The only key part is data not available from an FHIR server. Orders that are about to be placed may not exist in physical memory in the database and available through FHIR services. Otherwise, there are multiple approaches. If you can have the data supported in FHIR in an EHR, you can pull it for use. Next slide, please.

This slide shows a variety of organizations involved in this project. Next slide, please. This is what CDS hooks is focused on. A lot of the focus is on releasing 1.0 specification in HL-7 with a focus on the patient view hook and the production pilot. EPIC is the first EHR vendor to release production support for this with the patient view hook. Cerner is about to do the same. Some have implemented this a little earlier using custom middleware. We have done that and had a variety of things running on CDS hooks at the University of Utah. Next slide, please. Skip this, please. Next slide. Next slide.

These are some references. Next slide. I just have a few slides from here. This is showing the big picture of what it can look like. I'm going to walk you through a quick example on prior authorization. Let's say Humira, which is a very expensive medication that requires prior authorization. The clinician is but to order it. At that point, when it is selected it will invoke a service call to the insurer and that insurer can use the FHIR tokens to pull additional data. Some of it will you allow it to automate it but inevitably you will pull additional data. This is where Bob was talking about these go to the smart on FHIR app and provide information to complete the process. Next slide, please.

This is showing the exact same interaction can be used for price transparency. You're going to prescribe this and the patient's co-pay will be these many dollars. The notion is the same. Next slide, please. This is showing another use case with clinical and financial. Let's say someone is a heavy smoker. You can invoke that service and it detects that the patient is a 30 plus pack smoker and should be considered for lung cancer screening. Go to the app to identify and address the issue that lung cancer is the leading cause of cancer death but only has a 6% screening rate or less right now in the US. The next slide is the final one. Here I listed a few key needs that we need to address. One is that all of this really depends on the data you can get. If you have all of these hooks that is great but unless the data is encoded and available in the structured form, you'll have to ask the user to enter it. We need to expand the EHR FHIR support for needed such as to hear the detailed smoking history. We need to expand and specify the order of these hooks because a lot of these use cases are based on orders. To be clear, it is not yet standardized or implemented in vendor products.

The next one is regulatory guidance from the HIPAA perspective. I have discussed these many times, so I am not going to bring this up again. We need to make sure what we're doing is HIPAA compliant. There is a notion of EHR trigger cards. A lot of these hooks are generic. You open a patient chat and are about to place an order. You will quickly overwhelm the system and the provider will wait a long time if we start asking for checks on every order placed. As a practical matter, EHR vendors are providing locally specified logic for when particular hooks are specified. This is currently done completely off spec and we need to start bringing that in spec. There is also a need for greater support for asking users questions to enable orders to be placed. And finally, we need to apply this to important use case and prior authorization is an important use case. Other important use cases include things like advanced imaging. Thank you.

Robert Wah – Health Information Technology Advisory Committee – Chair
Thank you, Ken. Thank you to the entire panel. Clearly, there is a lot of work being done and a lot of opportunities. If I could ask the next panel to get ready to come up. Just to tell you where we are on the schedule roadmap, because of the panel running over we had to take out the discussion about standards. We will have another discussion period at the end of the payer and perspective that we will have now. As you all know I have a strong commitment to the public comment scheduled at 12:30. We will work around that, but we will honor the commitment to the public to allow them to comment at 12:30 regardless of where we are in the discussion. Thank you all for your patience and understanding. We will move to the public and private payer perspective starting with Kate Berry.

Public and Private Payer Speakers

Kate Berry – American's Health Insurance Plans (AHIP) – Senior Vice President of Clinical Affairs and Strategic Partnerships
Is it on? Thank you for including AHIP in the discussion and thank you to ONC and the committee for looking deeply at this issue. I appreciate the opportunity to be here. Next slide, please.

America's Health Insurance Plans represents all of the health insurance plans across the country such as Medicare Advantage, Medicaid managed care, individual market, employer-sponsored insurance, etcetera. Next slide, please. We are very focused on market-based solutions and addressing affordability, quality, and access. Next slide, please. Our values are about a partnership with government and providers, and focusing on patients and consumers, and to

really address patient needs. Next slide, please. I guess I missed one. There should be one more in here. We are missing a slide. I want to highlight that some of the data for why prior authorization is necessary. This is a tool validated by public and private purchasers for a long time and is intended to address areas where there are potentially patient safety issues. There are wide variations in practice. Roughly 30% of healthcare services is potentially unnecessary and harmful. That is acknowledged by physicians and other stakeholders such as the Institute of Medicine. There is a wide variation in care. That is the reason that prior authorization is in place. There are a number of safety issues. It is a tool to improve safety as well as when other things are equal, addressing affordability. Next slide, please.

Some of the things to keep in mind is that these policies are based on evidence and includes input from clinicians. All of the services that require prior authorization routinely are reviewed by the health insurance plans annually or twice a year. They make the information available in multiple ways. Next slide, please. We can skip this. Go ahead to the next slide. I want to focus on some of the ways we are working across the industry to improve the process. Automation is obviously a really big opportunity. What we have been working on is a potential demonstration project we will be launching later this year to automate prior authorization. The goals here are to look at multiple different approaches, different clinical domains -- potentially prescribing or hospital-based transactions, looking at multiple different technologies. Looking at standards-based scalable solutions. Making sure these are payer agnostic approaches and as integrated as possible with practice workflow. These are the objectives of our planned automation process.

What we have gone through in order to figure this out has been a very rigorous process. We issued an RSP last year to 12 or 15 different vendors that offer automation solutions. We received 8 or 10 proposals and have reviewed all of the proposals and brought in the top four of the vendors. Just in that process alone, we have learned a lot that reinforces some of what you have heard today, which is that there is no perfect solution. There is a lot of potentials. Automation can potentially dramatically reduce the phone calls and faxes that go back and forth between provider offices and health insurance plans. However, there really are no perfect solutions out there. A number of folks have said that. There is great potential but not any vendor out there that can solve the whole problem. We're in a place where we need to recognize that we need to build on what is available, make progress in this direction, and recognize that there are no simple perfect solutions.

As part of this, we are planning -- we have brought in the top vendors and have selected a few vendors and are in the process of scoping the details of the demonstration project. What specifically will the use case be? Who will payer participants be? Who will provider participants be? Very collaborative very detailed process just to specifically scope the project. We are planning to have a relatively short-term demonstration. We will have independent evaluator to show the impact on the patient, impact on the practice, and hopefully, the impact on health plans as well. We're targeting to launch the demonstration later this year. We will probably run it for 6 to 9 months and have the evaluation performed. One other piece I do want to mention is in addition to the demonstration project we have been working with America's Physician Groups, which is the large medical groups, on a continuum of value-based care and functions that need to be performed as part of as risk-based population health. We also working at another level to think about under what circumstances in performance-based contracting is it appropriate to delegate functions to medical groups taking on responsibility for the population. I think it is an important piece to think about how we share responsibility for getting these necessary functions

completed. That is another parallel effort related to reducing the volume of prior authorization and having groups take on that responsibility themselves in performance-based contracts.

In summary, I would say there is tremendous potential. We have learned a lot in doing this. The health insurance plans are highly committed to improving this process and streamlining prior authorization for all stakeholders. This includes the patient, providers, and plan. Thank you.

Robert Wah – Health Information Technology Advisory Committee – Chair
Thank you. I'll give you two minutes on this but you skipped over the gold card. Can you talk very quickly about decreasing the volume of requiring prior authorization?

Kate Berry – American's Health Insurance Plans (AHIP) – Senior Vice President of Clinical Affairs and Strategic Partnerships
Yes. I do not like the term gold carding, but the idea is selective application of prior authorization for physicians who perform very well. This is something that people have a lot of interest in and we have explored quite a bit. Some plans do have programs in place. What they have learned is that different positions perform differently on different types of services in terms of the approval rate etcetera. There is the dynamic where if you know there is oversight you might learn how to document appropriately or not to request if the request is not supported by evidence. What we have seen is that performance tends to slip when the provider is gold carded. Oftentimes, you have to monitor and adjust. Not all providers perform the same even within one group. Different providers may have different track records around prior authorization. There are some state laws that restrict the ability for different enrollees or patients to be treated differently, for there to be different rules that are potentially discriminatory. There are a lot of issues around this.

Plans are doing this, especially in risk-based arrangements. We do not think it is a widespread solution. We think automation and electronic prior authorization has a much greater potential to dramatically reduce the phone calls and faxes that go back and forth and streamline the whole process. If 80% of prior authorization the tool can be in place but transparent to the practice. It all happens behind the scenes. 70% or 80% can occur without any manual intervention. There is great potential there to streamline.

Robert Wah – Health Information Technology Advisory Committee – Chair
Thank you. And thank you for cutting back a little bit on time. Next, we will go to Melanie.

Melanie Combs-Dyer – Provider Compliance Group, Medicare Fee for Service, Center for Program Integrity, Centers for Medicare and Medicaid Services – Director
Thank you. I believe that Dr. Rucker was right when he started the meeting by saying that the prior authorization process is broken. I also believe that prior authorization is an important tool for payers to have in their toolbox to assure compliance with the payer's rules. I believe that we, here in the room today, collectively must find a way to fix the broken prior authorization process.

I am Melanie Combs-Dyer. I am the Director of the Provider Compliance Group at the Centers for Medicare and Medicaid Services in the Center for Program Integrity. That is the part of CMS that deals with waste, fraud, and abuse. I particularly work in the Medicare fee-for-service program. Next slide. Today I will talk about the Medicare fee-for-service program prior authorization system and what it looks like. Then I will talk about new industry efforts to try to reduce provider burden in the prior authorization. Next slide.

I think it is important to understand how the Medicare fee-for-service program defines prior authorization. Prior authorization does not create any new documentation requirements. You may have heard from the physician this morning, Dr. Robie, about how some health plans may require medical necessity forms or certifications. CMS does not have any of that in the Medicare fee-for-service program. We only require the same documentation in the prior authorization that we would require during a regular prepayment review audit or post-payment review audit. The rules are the rules are the rules and it does not matter if when we apply them. It is the same if applied before the service was rendered (as in the case of prior authorization) or before the claim is submitted in a pre-claim review, or prepayment review after the claim has come in and we request and receive medical records or post-payment review. Maybe the claim was paid years ago and now are we requesting and receiving the records for review. The rules are the same and no documentation requirements are different at any of those points in time. One benefit of prior authorization is that it does allow the provider and supplier to address issues with documentation before rendering the service and submitting the claim. That means they can go back and forth with the Medicare Administrative Contractor a number of times until they get the documentation right. Doing this could help completely avoid the appeals process. If we apply the rule after the claim has been submitted then if the provider gets it wrong and the documentation does not support that the rules were followed, then the provider has to enter the appeals process to get that claim paid. We think avoiding that is a big benefit to the prior authorization program.

I wanted to quickly address one of the issues Heather McComas from AMA raised earlier today. She showed some very compelling photographs of patients who had been involved in very tragic cases where their perception was that the prior authorization prevented them from getting care. The fee-for-service program and Medicare ran a home health pre-claim review program in 2016. We paused it to make structural changes to the program. When we restart it, we are planning to allow the provider to request multiple episodes of care. The way home health is paid in 60 days segments. We will allow the provider to request multiple episodes on the prior authorization request and let the nurse reviewer approve multiple episodes. We think that may help fix the problem. Next slide.

We are listening. I have been out on a listening tour with several folks from ONC such as Dr. Mason and Dr. Gettinger. We have heard a lot from providers about how it is too difficult to find out when prior authorization is required. Once a provider figures out that they need to do a prior authorization, it is too hard for them to do it. Next slide. I am happy to talk to any standards development organization that wants to try to fix prior authorization and make it better. Today I want to highlight a couple of projects that we have going with the DaVinci team. You heard Bob Dieterle talk about DaVinci and I will be highlighting a couple of those today.

First, what we call a documentation requirement lookup service or DRLS. We will also talk about the new FHIR standard emerging for attachments and the new FHIR standard for prior authorization requests. Next slide. We think DRLS is cool because it will allow the provider, at the time of service and in the EHR or practice management system to be able to discover whether prior authorization is required and the documentation rules. We think this will help reduce provider burden, reduce appeals, and improve the improper payment rate. Next slide. This is a picture of what the DRLS will look like. This is Dr. Robie in the upper left-hand corner, or any provider, interacting with their EHR using CDS hooks as a trigger perhaps in the order or perhaps when the patient is being scheduled. They will be prompted to ask two sets of questions. Are

there prior authorization requirements? The second set of questions is to show me those prior authorization requirements or show me the documentation templates. And if you have patient cost information, show me that. This depicts that transaction going out and pinging the appropriate payer's repository.

In the upper right-hand corner, you see the Medicare fee-for-service repository of rules. Today our prototype is sitting ARC CDS Connects platform. You heard Tony talk about how the ecosystem in the drug formulary world is revolving around the repositories of rules. I believe that this ecosystem may be able to do the same thing for all the nondrug stuff. This prototype was demonstrated at HIMSS and I think it was one of the most popular booths in the interoperability showcase. The Medicare fee-for-service program is planning to pilot test the use of this DRLS system and is beginning to plan to move out of prototype and build a permanent DRLS system.

This next slide shows a picture of what the provider might see coming back into the DRLS system. Here are the rules and this is what the thing you are considering ordering will cost the patient. Next slide. You heard Bob Dieterle talk about the process for each standard coming out of DaVinci with implementation guides, reference implementation code, and launching pilots. We are planning to move from a prototype to our permanent DRLS system. You may have noticed that the CMS interoperability rule dropped last month. In the preamble, it talks about the DRLS system and how the Medicare fee-for-service program is using it and encourages all other health plans, especially Medicare Advantage, Medicaid, and qualified health plans, to build a similar system. Next slide.

These are all the DaVinci use cases Bob talked about earlier. The two in the upper right are the two that make the DRLS system work. They are called coverage requirements discovery and documentation templates and rules. I would now like to move into the new FHIR standard for attachments. Next slide. This particular use case, in the DaVinci world, is called clinical data exchange or CDEX. We believe this standard may be able to be used for provider to provider exchange of medical records but also a provider to payer exchange of medical records. Next slide.

We are closely monitoring the HL-7 workgroup that is creating CDEX standard. There are some links you can follow if you want to participate in the process. Next slide. Attachments are important to us because we have a huge volume of medical records. Next slide. We request lots and lots of medical records even though it is only 1% of the claims we receive. Next slide. Our ESMD system, or Electronic Submission of Medical Documentation System, is the way we receive electronic medical records from providers. It is based on the connect standard that ONC developed 10 years or so ago. It encouraged federal payers to consider using it. We have adopted that in our ESMD system. Unfortunately, today most of the transactions coming into the ESMD system are PDF record. We wish we can get to a world where CCDAs were coming in or the CDEX standard were coming in. I will tell you that the ESMD system has the ability today to accept an X12 278 and a CCDA but unfortunately very few providers are using 278 in our world. Very few providers are submitting CCDAs in our world today. We are beginning to explore enabling FHIR in our ESMD system. I will keep you posted on that in the months to come. Next slide.

The new FHIR standard for prior authorization request is on this slide. They should look like a familiar layout of the DaVinci use cases. Now I have circled the prior authorization support standard. This is one we're watching carefully. NCVHS report recently recommended that HHS should promote and facilitate the testing and use of new standards and suggested that this prior

authorization standard would be a good one to use. We currently have a pilot test in the plans for DME e-prescribing. That is an ordering physician sending in an order for DME (probably oxygen or CPAP) along with the needed supporting documentation requirements found in the rules and sending that to the supplier and the supplier sending back a response that it was received and delivered to the patient. We are exploring whether we can add a test of prior authorization mechanism. Next slide.

The prior authorization support standard that is being developed in FHIR is one that we are closely monitoring. You can see the links for where they are being developed. If time permits, I would love to hear more about the proposal that someone made around the table earlier (maybe it was Les) about physicians just being allowed to submit CCDAs. I wasn't sure if that was a proposal just for those situations where the payer has a prior authorization program and just wants to submit CCDAs for those prior authorization items, or if that was a suggestion that was for all claim services. I wasn't clear if you meant get away with the claim altogether and just submit a CCDA. I also want to make a quick comment on the comment that someone made about artificial intelligence in the EHR and can this decision making, and actual application of the rules be more automated. We are thinking about three places where that could perhaps happen.

One is at the MAC, the Medicare Administrative Contractor. We are already in dialogue with all of our contractors about the use of computer-assisted review of documentation. Those systems that they can program to read the CCDA or read the CDEX transaction that is coming in. It would read that medical record and apply the rules and automatically give approval for the ones that meet the criteria and flag for a nurse review of the ones that do not. Secondly, we think there may be private sector companies out there who are beginning to try to take the payer rules and apply them to the medical record. I call those medical record self-checking services. I think they started with the old companies like InterQual and Milliman. I think they are growing. We are interested in hearing from more of those kinds of companies and learning about what they do. I would love to hear from providers on if that is something they would be interested in utilizing.

Finally, we think the ultimate would be what Kate Berry suggested. Could you take those rules, actually embed them in the EHR making it automatic so the provider could somehow almost as TurboTax tells me when I filled everything out correctly and I am ready to submit. Maybe the EHR could do that and automatically tell the provider when the criteria had been met and everything was ready for submission. Thank you, very much for inviting me today. I'm very excited about the prior authorization improvements that may be possible in the future. I really am thankful to the leadership at ONC for putting today together and for their leadership in trying to fix the prior authorization processes. Thank you.

Robert Wah – Health Information Technology Advisory Committee – Chair
Thank you very much. Our last speaker is Sagran.

Sagran Moodley – Clinical Data Service, United Healthcare – Senior Vice President
Can you hear me okay?

Robert Wah – Health Information Technology Advisory Committee – Chair
Yes. Can everyone hear?

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

Federal Officer
Be a little louder, Sagran.

Sagran Moodley – Clinical Data Service, United Healthcare – Senior Vice President
How about now?

Melanie Combs-Dyer – Provider Compliance Group, Medicare Fee for Service, Center for Program Integrity, Centers for Medicare and Medicaid Services – Director
Much better.

Sagran Moodley – Clinical Data Service, United Healthcare – Senior Vice President
Great. Thank you very much and my apologies for not being able to travel and be there in person. I appreciate the opportunity and I am happy to participate be it remote. In the interest of time, I will be brief. I am Sagran Moodley. I serve as Senior Vice President of United Clinical Service within United Healthcare. Within clinical services, if you think of the engine room of the things we do in the health plan is relative to CMDM. Prior authorization is very, very core to a lot of the cost of care affordability management if you will.

I want to make a provocative statement to say, pay is typically from the UM spectrum often being on the perspective of utilization management, in some case reduction. I cannot stress enough that with triple aim as our compass, improving patient experience vis-a-vis quality satisfaction, improving health outcomes, and reducing per capita cost in healthcare spend is absolutely critical for us. In that, the administrative burden is shared across all spectrum. Most critically and detrimentally, it can delay care. To those things I talked about vis-à-vis the health outcomes, it does not help serve our goals of better outcomes and better cost with better patient satisfaction.

Prior authorization when it comes to payers is often referred to as the tax law with us owning the tax code not sharing the tax code with those who have to abide by the tax code. We often hear providers respect to it if they could tell me what the rules are and consistently adopt it, we could abide by it. In fact, be better placed to support it. I cannot stress enough, as I said earlier, the narrative has changed and evolved. Our commitment to bringing and exposing those guidelines, be it benefits or medical necessity, into the workflow into the decision, or enabling decision at the point of care is absolutely front and center for us. I am honored and privileged to serve as the chair of DaVinci and one of the commitments by United to serve in this capacity and participate in the important initiative is exactly that. It is supporting and promoting the adoption of standards accelerated into interoperability and really driving down provider administrative burdens while increasing outcomes.

Many have heard me say this before. I like to use the analogy of the Travelocity of prior authorization. Imagine a world where Travelocity of PA. If you think of all the airlines being forced to expose their rules vis-a-vis the reservation systems so that Travelocity can present to consumers in real time what those options are. Imagine a world where there is a Travelocity of PA. By the way, our consumers, millennials, and others will demand this. It is no different than the experience they accept and demand in the e-commerce experience in other industries. This Travelocity of PA needs to be health plan agnostic. It needs to be enabled in real time at the point of care. You saw from Melanie and Bob, through the work of DaVinci and documentation lookup service, enabling that at the point of care is absolutely where we want to go.

It does open up the opportunity for us as payers to think about other things. All too often we ask for information we already have. For example, claims data such as surgery abdominal imaging for cancer patients. Why would we ask why this is necessary? Why do we ask what the medical necessity is for it? The earlier speaker talked about gold carding. We think about it in terms of the triple P. Gold carding at the procedural level, gold carding at the provider level, and gold carding at the patient level. There are patients that fall into certain super-utilizers or high-risk categories that we based on medical evidence we know they are going to experience and have needs for certain services. We are also trying to advance cancer journeys in the case where we know there's a small cell lung biopsy being ordered and before the result can we clear the barrier and clear the runway for all the things we know typically follow based on that unfortunate outcome that they indeed have cancer. Imagine the conversation goes today like this. The oncologist will talk to their patient and say, "We are waiting for United to approve your services (be it radiology or chemotherapy or surgery) and as soon as we get it done, we will let you know." Imagine the conversation goes like this, "Your payer is behind you. They're going to support you and have provided all the support you needed. They have made it easy by clearing the runway for all the services you need to get through this most traumatic time."

An example of knee arthroplasty. We know there is imaging, surgery, DME, and physical therapy. Why do we need to know what the medical necessity is for DME or physical therapy post knee arthroplasty? Sleep studies that are work-related is another example. Last but not least, we collect data, be it for different reasons like A1cs, and then turn around to ask for A1cs for the prior authorization of an insulin pump. So, there's definitely opportunities where we can harvest and leverage data we may have. I will tell you the North Star for us as United and payers is we want to quickly get beyond the benefit check and medical necessity because soon we will realize that is just a commodity and table steak. What we really want is to get to site to service, site to care and cost transparency. Yes, that is covered for that knee arthroplasty. Yes, it is medically appropriate. Can we ensure we get to keep cost down for consumers, keep out-of-pocket cost down? Can we make sure it is happening in the most optimized cycle of care, be it an ambulatory surgery center where we have evidence of high outcomes and high quality and better total cost of care? As opposed to the inpatient facility? Cost transparency for consumers is absolutely important to help ensure that happens.

Today prior authorization is not a guarantee of payment. That fine print to every PA often causes a lot of frustration for providers. We get millions and millions of prior authorization for services that do not require a PA. For example, a back brace. The reason we get it, despite how often we would say no PA is required, providers would not buy into that because the last time they did not get paid on it. That nonpayment may have something to do with benefits and not PA, but yet, they will want to understand and demand we provide that prior authorization and go through the burden that we put on them to ask for evidence for that back brace. When I talk about this caveat to "Yes, it's approved, but we cannot guarantee payment," when we think of prior authorization, we went running that claim all the way to the claim's engines. That way we not only say, "Yes, it is covered, but yes, this is how it will pay."

I really believe with this Travelocity of PA it forces all payers, including us, to expose their rules. I will tell you, we are thinking about this very aggressively. We think of prior authorization in the context of RAIN, Referral, Authorization, Inquiries, and Notifications. We know it has to support automation of prior authorization. We have different benefits and different medical necessity criteria for the same procedure and the same members. We know it has to support duplicate

checks because very often providers submit the PA on the portal and follow-up with a phone call and request the same PA. Supporting of bundling. Supporting of complex benefit roles like bariatrics. Premed MAC so we can bounce out of the medical necessity when we know there is not a need for one. Or postmed MAC so we can drive better cost transparency and inform the consumer about better choices. And support prior authorization for things that are not just service or medical, like post-acute care transition, oncology, and step therapy, and genetics.

We have as part of United deployed last year a pre-check my script to really advance this work. I am pleased to announce that we have now over 30% of adoption of pre-check my script which provides prescription options at the point of care. Evidence has shown that we have reduced over $25 per PA. We reduce time by 30+ minutes per successful account we have saved over $80+ dollars on prescription for consumers. We are committed, motivated and excited about the opportunities. We will pause at this point in time. Thank you very much.

Community Discussion on Standards and Payer Presentations

Robert Wah – Health Information Technology Advisory Committee – Chair
Thank you. So, we have a few minutes for community discussion. I will open it up for standards presentations as well as the payer presentations we just had. I appreciate everybody's patience while we get this back on track. Comments, questions for the payer panel? Also, as I said any questions you have for the standards group as well. I don't see anybody. Arien, go ahead.

Arien Malec – Change Healthcare – HITAC Member
I am getting a reputation. Les is right behind me, though. My head is sort of spinning about this discussion. It is fantastic. I think the discussion that Tony started on formulary benefits –I implemented that in 2004. We did all the very careful work to link PA formulary status in with hyperlinks, for example. You could go straight to the EPA site to fill in information. Yet we discover that there are ecosystem issues related to availability formulary. My understanding is the availability formulary limitations are more prevalent on the patients of most need. My understanding is that the large commercial PBM's by and large have implemented more of the formulary standards. Tony is nodding at me. The Medicaid, I'm not sure where Medicare BDP and MADPs are with respect to data availability. The reason I bring this up is that as we talk about a future world where PA and potentially other worlds can get adjudicated based on CQL statements that are published by payers. I am mindful of the comment – I apologize I forget which panelist from WEDI who noted that adjudicating in a rule-based manner requires payers to publish in a rules-based manner and it requires that the complexity of adjudication is reflected in things that can be automated.

We have a classic ecosystem problem. I have got to plug the EHR into the workflows. I think we have got good technology there with CDS hooks, FHIR and a whole bunch of workflows that can take away some of the complexity. But then we have got an ecosystem problem in terms of the intermediary who may not be adjudicating these rules. Most particularly on the payer side, the ability of payers whether the MACs or Medicaid's or commercial payers to be able to publish their rule sets that some might consider proprietary or trade secrets. I know that Medicare does not. Perhaps make them publishable in ways that can be adjudicated. I wonder if the combination of the payer panel and the standards panel, we might get at these ecosystem effects and ways of addressing the ecosystem dependencies.

Melanie Combs-Dyer – Provider Compliance Group, Medicare Fee for Service, Center for Program Integrity, Centers for Medicare and Medicaid Services – Director

One thought on that, Arien. Thank you. I do you think with automating prior authorization like the beginning of electronic prescribing, you have to go piece by piece. Ultimately the system needs to move forward in an organized way. A lot of the conversation there are lots of standards. You know there are old standards, new standards. There's an opportunity to move forward. The challenge for everybody is like, who is going to lead? How do we make it as transparent as possible, so we can make progress? I will say even in exploring the pilot, as I mentioned the demonstration project, we learned that there is no easy answer. There needs to be enough clear direction that there can be government, private sector, EHR, intermediary, PBM, payer, etcetera, moving forward on multiple paths.

Aaron Miri – University of Texas at Austin – HITAC Member

Good morning. Aaron Miri, University of Texas at Austin. A question for you and a comment on one of the presentations. I don't remember which. There was a lot of material, which is great. The degree from a provider perspective when I query my clinicians and what really is the most painful component of prior authorization – I was actually double checking with my clinical leads and chairs just to make sure I wasn't missing the boat – the number one thing that they came back to me was checking the PDMP. In Texas, it is a manual process to the degree that they have to do this for prescriptions for controlled substances. That seems to be the biggest hang up in a lot of things. Is there a way you can recommend to us some sort of stair stepping approach? I appreciate your prior comment, Kate. You may have said that you have to take it piecemeal. Maybe potentially automating that component and making that component be automated, checking PDMP other stuff like that. Are there steps like that that we could look at as a committee to help streamline this automation? And then doing what Melanie mentioned using AI or machine learning down the road? Are there steps you recommend to us, so we put it on our list to look at and consider? Thank you.

Kate Berry – American's Health Insurance Plans (AHIP) – Senior Vice President of Clinical Affairs and Strategic Partnerships

I think there are a lot of issues with the prescription drug monitoring program. I would not have thought of that as an electronic prior authorization. There are a lot of issues there in usability and interoperability across states. I think they are an important tool. You know, to help address excessive prescribing of controlled substances and opioids. Getting those integrated with the provider workflow through the EHR. That's the direction that needs to happen. I think there are a number of barriers there. Maybe others want to comment.

Margaret Weiker – National Council for Prescription Drug Programs – Director of Standards Development

NCPDP has a standards-based facilitator role around PDMP that is based upon our standards, the NCPDP script standard. That's the standard that would be used for the EPA and prescribing. It has the capability to do the text so to speak. Then also would feed into the telecommunication standard which is the claim standard. That also would support that as well. From the adjudicator point of view.

Anthony Schueth – Point of Care Partners – Chief Executive Officer

If I could respond to that, Arien, as well. So, there are a number of efforts I think that are relevant to this area. One includes an effort to define the standard way using FHIR to pull PDMP directly.

There are state health departments piloting that, right now. In terms of retrieving the PDMP data and for example as a smart FHIR, it's already in progress. The other part is knowing when to you need to check the PDMP. That is also part of the ONC effort to do clinical distance work based on the CDC guidelines, which include checking PDMP. I'm engaged in a project with ONC on that right now. We will be piloting the that as well. There are ways these can be hooked in to make it work. The biggest challenge now is no FHIR implementation guide for PDMP and other prescribed meds and that needs to be addressed.

Robert Wah – Health Information Technology Advisory Committee – Chair
I'm going to give the microphone to the national coordinator.

Don Rucker -- Office of the National Coordinator for Health Information Technology – National Coordinator
Yeah, Arien. So, the PDMP I think turns out to be a fairly different. There are some similarities but there are some big differences in terms of the heterogeneity overstates, across states. So, it will require some fairly different solutions. We have, as Kim mentioned, a number of projects working with other folks at HHS to try to understand. Part of the problem is every state has a different PDMP. She's nodding her head. DHRA have been helpful in pointing this out. So, there are other problems here. They will not be solved, unfortunately by the discussion we have today.

Robert Wah – Health Information Technology Advisory Committee – Chair
Right.

Leslie Lenert – Medical University of South Carolina – HITAC Member
We need to make sure this system for prior authorization works for patients. I am wondering, the extent to any of these pilots include patients from representative organization to make sure pilots are actually producing systems where the patients get the feedback they need and have a system responsive to their needs. Hold on to that question. I want to comment what my you know, whatever it is, it's a simple suggestion. The suggestion was that there should be one comprehensive summary statement of the electronic medical record. Similar to a CCDA but it is transmitted for prior authorization purposes.

Let's not do the computation on it that we did when I was a post-doctorate at Stanford in 1980 whatever using rules. Let's use deep learning methods. Let's require that you make the adjudication based on the CCDA or whatever summary document standard that we agree on and that you do it within a certain number of seconds of computation. Then, let's move on to manual processes. Let's make sure you documented in evidence-based fashion that your precision of appropriate application of the rules has adequate performance. That it is 90% sensitive and 99% specific as far as identifying somebody who should receive the therapy based on that. At that point, we can move on and resolve the remaining cases as best we can. Let's get a standard document. Let's use the best technology we have now to rapidly do this. Then, set a limit on the time of computation. I think that's really the key issue that you have in this kind of thing, to make it a transparent process. Those are my thoughts. I want to know the extent of which patients are involved in any of the pilots that are going on.

Robert Wah – Health Information Technology Advisory Committee – Chair
I realize this is not going to be a two-minute discussion, but I feel strongly committed to the 12:30public commentary. At 12:30 we are going to open it up. We can come back to this

discussion, but I want to make sure everyone knows my plan. I've done these many times before. We will come back to this. If there is a quick response to Les's proposal about a standardized format that gets used for adjudication as opposed to individual forms, you have to fill out for adjudication?

Margaret Weiker – National Council for Prescription Drug Programs – Director of Standards Development

I will briefly touch on our way involving patients. I have a stakeholder workgroup in my BME prescribing world that brought together physicians and other prescribers, BME suppliers and other people that support them. I begin to describe what my pilot was like. The very first question from the Frank Opelka of the American College of Surgeons was, "Where is the patient in all of this? Where can the physician learn did the patient get the CPAP machine? Did the patient put it in the corner, and they haven't used it or is the patient compliant with the physician's order? Is the CPAP machine helping the patient's symptoms or not helping the patient symptoms? Can you please involve the patient?" I've been reaching out to the CARIN Alliance and others, to find those patient facing apps that may be able to be part of the pilot. Thank you for the question.

Robert Wah – Health Information Technology Advisory Committee – Chair

All right. Why don't we move to the public comment period? As I said, I appreciate everybody's indulgence with the commitment that we have for the public. We publicize the time of the public comment period and we want to stay to that because many of them have made schedules around that commitment. Lauren, why don't you take over?

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

Sure. If there is anybody in the room that would like to provide public comments, please come to the presenter table, and state your name.

Okay. I'm seeing no one in the room. We will go to the phone. Operator, can you please open the public line?

Operator

Yes. Thank you. If you would like to make a public comment, please press * one on your telephone keypad. The confirmation tone will indicate your line is in the queue. You may press * 2 if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the * keys.

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

Thanks. I think we will leave the line open for a minute or so to give folks time to dial in. One more quick call anybody in the room? Operator, do we have anybody dialing in at this time?

Operator

Not at this time.

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

Okay. We can go back to the discussion. Operator, I will check in after another couple of minutes

or so to see if anyone has dialed in.

Robert Wah – Health Information Technology Advisory Committee – Chair
Okay. Thanks for everybody's patience on this. Are there any other comments anybody else would like to make in response to Les's proposal in terms of this standard out bound information that would come from providers as opposed to providers having to meet individual and selective payer requirements of information sources? I think I summarized that right, Les. Is that right? Just for the panel down there, the microphone system is set so only four microphones can be on at a time. So, after you finish speaking if you could just turn your mic off that would be great.

Ken Kawamoto – University of Utah Health – HITAC Member
If I could respond to Les. I think he is definitely onto something. I have been having a number of conversations, especially with Cerner about the notion that we are human beings. When we were created somebody put an 8 x 11 page in our head and said that is how we are going to communicate with each other when we are not talking. When we are in the world of machines, I think back to experiences in clinical operations, physicians presented a patient to another physician to get advice or a consultation. So the notion that if the information is structured in an EMR, then we should be able to come up with a method, and FHIR certainly has some elements that could work, to have a machine present a patient. If you give key of a diagnosis or procedure or condition or timeframe, have the machine then assemble a presentation that is a set of data, an array of data. Pass that to the other machine that is trying to make a decision. That does not eliminate the need for people to be involved in the key decision processes. When you consider the deep learning aspect of AI, you need to think about this. If a payer's decision support system gets 100,000 arrays of data about patients and it can establish a history of which ones were approved and which ones were not, you almost away from the idea there is some core set of questions that are supposed to be asked. It is more I have a presentation of a patient I'm putting out there. Then based on statistical analysis, the payer can probably get to the point very quickly with AI, to say with this presentation this should be approved.

It gets more like, when you have the response of the physician presenting to another physician. Their gut and experience come into play. They say, "I've heard this presentation before. I think that's appropriate." Is it correct? That doesn't come into consideration because we are moving to the point where it is the presentation of data as opposed to I have to have a data model that defines the document that I have to populate. That bounds the conversation, as opposed to saying, "Here is what is happening with this patient." And then having another set of algorithms respond to that. We are not technologically at that place. But I know Hans from Cerner calls it a letter. In his kind of orientation is a provider sends a letter to another provider that says, "Here is the patient. What do you think?" It's not bounded by any defined structure of a document. Here is my impression. I do think, Les, you are definitely onto where this ends up, whether it is next year or five years. That is where we are going to be.

Robert Wah – Health Information Technology Advisory Committee – Chair
I'm going to call on Sheryl as another payer source.

Sheryl Turney – Anthem Blue Cross Blue Shield – HITAC Member
Thank you. First of all, I want to thank everybody for coming forward and speaking today. For me it has been enlightening as well as I have taken a number of actions items I need to have discussions on. I represent Anthem and we are part of the Blue Cross Blue Shield Association. We

participate in the WEDI standards group as well as the DaVinci project and the demonstration of the DRLS that was discussed today. It is one of the things we have been working hard to try to implement. So, I am very happy to be working on this type of activity. One of the things I wanted to say is it is not an easy problem to solve, as everyone has stated. I'm very interested in Leslie's suggestion. Definitely, that will be a topic we will take back.

I actually am also at going to a Blue Cross Blue Shield Association meeting where I help Anthem represent HL-7 and DaVinci. We will discuss this in a few weeks. It would be wonderful to be able to bring things like that back to talk about them. But at that end of the day, we cannot forget the patient in all of this. That is really centric. There are some practical issues we need to solve. We have been working with the care quality forum. Some of the obstacles we have when we work with providers, in terms of requesting data, and documentation, getting a response to some electronic transactions. Today, we would like to have some of those discussions overcome. There is a definitely, not the overwhelming support, when we are doing provider contract in wanting share clinical data. Quite honestly it is a constant struggle to work with providers. Maybe not everybody is as open as the people that spoke today, in terms of wanting to solve some of these challenges. It will be a collaborative effort that we need to participate in. I know, for one, I hope to be able to bring them back and help the payer community lead that change.

Robert Wah – Health Information Technology Advisory Committee – Chair
Thank you.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Robert, if I can check again. Operator, do we have any comments on the phone?

Operator
Yes, we do. We have a comment from Shelley Spyro with pharmacy HIT.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thank you. Go ahead, Shelley.

Shelley Spyro – Pharmacy HIT Collaborative – Executive Director
Good afternoon my name is Shelley Spyro. I'm the Executive Director of the pharmacy HIT collaborative representing over 25,000 members of a majority national pharmacy associations Including pharmacy education, and accreditation. Our members include key pharmacy organizations involved in health IT, including the National Counsel for Prescription Drug Programs CNPDP, who we heard from today. We have 13 associate members representing and prescribing health information networks, transactions, processing network, pharmacy company system vendors, pharmaceutical manufacturers, and other organizations that support pharmacist services. Pharmacy HIT Collaborative's vision is to assure US health IT infrastructure will better enable pharmacist to help optimize person-centered care. Our mission at the leading authority of pharmacy Health IT, the collaborative advances and supports the usability and interoperability of health IT by pharmacist to help optimize person-centered care. Our major focus of the collaborative and pharmacists in all practice settings, community health systems, hospitals, managed-care, behavioral health, and long-term care integrate into the national infrastructure.

On behalf of the pharmacy profession, the Collaborative over the last nine years, have dedicated our efforts to define and promote the use of standards within clinical documentation systems used by pharmacist. The collaborative supports the NCPDP electronic prior authorization standards, within the electronic prescribing standard script. The collaborative supports the DaVinci project prior authorization use case and supports the efforts to ensure pharmacist providing clinical services are included in any electronic prior authorization process for medications, devices, and services provided. Thank you, I appreciate the time.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thank you, Shelley. Operator, do we have any other comments at this time?

Operator
No. No other comments at this time.

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
Thank you.

Robert Wah – Health Information Technology Advisory Committee – Chair
Why don't we go ahead and resume the conversation? I will go to Steven.

Steven Lane – Sutter Health – HITAC Member
I wanted to supplement what Les said. When you made your initial comment you mentioned the idea of sending a CCD and having that be analyzed and computed using machine learning to evaluate. In your secondary comments, you mentioned CCDA, which is the larger group of potential document templates. I wanted to point out that there have been other use cases or challenges we face. We been able to develop special purpose CCDA documents. One of the complaints we hear from providers about CCDs and their uses in clinical care is that there is too much information. You can pack lots of information into a CCDA document. And again, I think your novel approach is really quite intriguing.

If we look at the individual rules that are set up by insurers, these pieces of information to approve this or what have you, we could literally pile all of that information that might be needed, into a giant CCDA document. This document would have all the data necessary for 99% of the prior authorization processes that need to occur. That does not need to be pleasantly readable by a human being. It could be sent off into the insurers system. They can do the analysis that you described within a matter of seconds that would spit back an answer that would be at least as accurate and helpful as the slower human or even back and forth FHIR-based process at looking at one element at a time. I want to second your proposal. I would say that we could in rather short order, create a document that includes all the relevant history, medications, allergies, procedures, etcetera that have been performed on a patient the day it was available in the EHR and send that off. It would be a prior authorization specific CCDA document type that would be custom created for this purpose.

Leslie Lenert – Medical University of South Carolina – HITAC Member
You would get a level of temporal analysis that would be unlikely to be achieved in a guideline specific language processing application. I will leave Ken to comment on that if he thinks he can

do better.

Robert Wah – Health Information Technology Advisory Committee – Chair
Cynthia.

Cynthia Fisher – WaterRev – HITAC Member
Thank you. I would like to commend Les for his idea. You know, I am thinking about the patient experience. A lot of the prior authorization system, if you look historically, it is built upon payment, right? It is payment authorization for approval for modality. If we flip it on its head, rather than looking at the architecture at financial optimization of each of the players in the queue, we flip it on its head to look at the patient's experience along with that physician interaction and the determination of care path forward. Using a model like this novel model that Les proposes, think of it even further about how the decision support real-time impacts the patient's not only their physical and mental health, but also their financial health. Be that as it were, in that real-time moment if you're looking at authorization for say, a brace for ACL or you are looking at or device, or you are looking at a planned surgery for a hernial repair, real-time as we go to optimizing not only the authorization but we optimize that experience that both physician and patients can look at what is prescribed and what is the next step in the competitive pricing modality too. Looked at what is realistic and affordable and nearby and take the entire financial health into that patient's decision-support.

For instance, we have patients that tell us they've been authorized to get a certain medical device, or a brace system. After they get it down the hall from the doctor's office, they get home to search on the Internet they could've gotten it for 1/10 of the price. Okay, so if you think of what that means when you have a family of five children and you are paying twelve hundred dollars more for certain brace, that starts to erode at your options of care. And impacts other facets of your life. I will give you another example I've heard from the Senator who he himself needed a hernia repair. He gave the example that his health insurance would pay six times more of what he was authorized to get within the system, he could go with the very experience quality care to get it for 1/6 the price but had to do so in cash not to be covered because it was the right thing and it was the best surgical option for him.

You think of these types of examples that as we look especially at so many of our employees both small and medium-sized large businesses we look at options of being self-insured. If you think about the dynamics and the effect of having this uberization of our choices in that physician to patient interaction and transaction at the future options for their care. As a self-employer, we look at the total overall cost of our health plan. If our employees have options to save 1/10 of that cost, that is an amount we take from the whole FTE equation, the full-time equivalent equation of their welfare and their wages. So, economically looking at taking an idea like Leslie's, broadening it from the pricing side, uberizing it and looking at what it means to our society as a self-insurer. If our patients and our employees can get something for an option of 1/10 of the price, that drastically affects the welfare portion of their wages. That is what we reserve is a self-employer for their healthcare. Think about it. Those savings that we have can go to increasing wages of our employees.

Ultimately, we have seen wage stagnation because of the ever-increasing prices of health plans and RTPAs almost 7% to 9% a year it increases. If we could drastically give that patient the option, the patient physician experience, we will impact dominos across the board. Economically it will

be a stimulus to keep the money in the wallet of employees and patients as well as being able to expand the attack on the tax deficit that a runaway cost in healthcare has cost us.

Robert Wah – Health Information Technology Advisory Committee – Chair
By the way we are scheduled to finish at 12:45 to a wrap up and probably finish completely at 1:00. I think this is a good discussion and we will let this go a little bit. Then Bill Stead and the clinical team from ONC have some final wrap up comments. Andrew?

Andrew Truscott – Accenture – HITAC Member
Thank you. I will be brief. I hear everything you are saying. I think we are being disingenuous to ourselves if we try and say the standards are at fault. We plenty of standards. We have more standards than we can shake a stick at. We've got CDA, HL-7, FHIR, whatever you want to do. The implication of what Les is suggesting is a shift of onus. It's a shift of onus away from a provider seeking permission to a payer the ownership for them to say, "Well, hang on a second, have you thought of…" When you mentioned about compute time, I think what I was hearing was, "It's up to you to get back to me by the time I push this out the door." Is that? Yes, okay. Which is a fundamental shift in how we actually handle the psychology of prior authorization. It's almost become prior notification. I'm not going to seek permission. I'm going to seek etcetera. That is what you are suggesting. We should stop sitting here focusing on new ways of implementing standards to address the process we would like to change the process of.

Leslie Lenert – Medical University of South Carolina – HITAC Member
If I could comment back and forth one thing on this. Now, I have the record on here. I have downloaded on Apple healthcare or whatever. I have used the Google equivalent. Now, I could get prior authorization. Why not? I could check five different things and different prices. All I need is a summary document that can read my record here and have an interface that allows that and then the patient can lead healthcare decision-making at the level equal to the doctor because he knows what the insurance company will cover or not when they go in to talk to the doctor. That would change things, wouldn't it?

Robert Wah – Health Information Technology Advisory Committee – Chair
We need to leave promptly at 1:00. I'm going to give Bill the microphone for one minute or two and make sure we get his input. His committee, as ours, is vital in this process.

ONC Speakers

William Stead – National Committee on Vital and Health Statistics – Chair
Thank you, Robert. I will try to sort of summarize what I have heard as I have been at this firehose briefly. First, I hear total agreement in the question we posed at the beginning. I hear a second equally important question which is how do we establish curb zones that prevent delays in the patients receiving care and that keep the patients and clinicians informed? We now have two equally important objectives, one around having the question be resolved without manual intervention. The other, putting curb stone that make sure the patients get what they need when they need it.

I think there is a pretty clear mandate for change. I came in thinking the path forward would be to basically recognize that with a paper form, we have to request everything that we might need at one time. In our current digital ecosystem, we have a possibility of mirroring a very streamlined

administrative transactions with conversational FHIR or API-based approaches to getting the additional information you need targeted at the decisions. I've heard we have really an embarrassment of riches in the number of prototypes, pilots, and partial solutions that are underway. They are in fact showing what is possible. As somebody said, it may have been Melanie, we've got to step back with both committees to figure out how do we become both agile and planful about how we identify one or two alternative paths that might well work together? What are the key steps in each? What are the standard components we have or gaps? How do we pilot actually working that so we know they work together?

I also hear that we need to have an element of revolution. Treat the fact that some of our current practices are in fact analogous to information blocking. The suggestions that Les has made, in particular, mandating that people come together and agree on the key questions etcetera, so that there is no way we can provide standard exchange if everybody is asking the questions slightly differently. So, I think an agile, planful for way of thinking about the system as a whole, complemented by one or two key revolutionary curb stones maybe, might be a path forward.

The end game is probably obvious to all of us. That will be downstream, probably a number of years. The business of the fact that that both the idea of CDM enabled prior authorization single order, again what you really want that to do is help the clinician know what to recommend, and help the patient know which choice to accept. That's the landscape I am taking from this that NCVHS and I hope HITAC can think about together.

Robert Wah – Health Information Technology Advisory Committee – Chair
Thanks, very much Bill. As we noted, the National Coordinator had to depart. I want to make sure we hear from the clinical team at ONC as well. I will give the opportunity to Andrew and Thomas to make comments on this as well. They've been very focused on this as we wrap up.

Thomas Mason – Office of the National Coordinator for Health Information Technology – Chief Medical Officer
Sure, thank you. I want to start by thanking the presenters for being here today. They really delivered an outstanding overview of the complexity of the landscape. I want to thank them for their time and providing their testimony. I also wanted to thank all the HITAC members for sparking this robust and very stimulating discussion about, what are some of the solutions related to addressing prior authorization. I wanted take one quick step back.

Andy, Don, and I were thinking about the vision of this session, really working closely with NCVHS. I was to thank Bill and the standards committee of NCVHS as well for having this joint session to think about where is the intersection between the administrative transactions and standards, versus the clinical standards? Where can we work together from our perspective at ONC? As you mentioned, how do we bring together the two committees? We really wanted to present the landscape. What are the issues, challenges, and think together in terms of solutions around prior authorization? This is a first step. I think we accomplished that. It has been great to see how all of the different presentations have come together, to stimulate the discussion here. I want to do again, say thank you to everyone that has been a part of this. Any other comments, Andy?

Andrew Gettinger – Office of the National Coordinator for Health Information Technology – Chief Clinical Officer
I join Tom in thanking all of you. I also want to thank Tom and Robert. We gave you an impossible

job. We squeezed too much into the timeframe. I apologize to you. I want to go back to how this started. It started with the very careful review of the clinician burden and we heard loudly and clearly from a variety of stakeholders this really is a problem. The work we are going to do together with NCVHS and HITAC will have a huge impact on clinicians downstream. I will stop there. Again, thank you all.

Robert Wah – Health Information Technology Advisory Committee – Chair
Again, thank you. Other comments from the committee? I know the smell of jet fumes becomes quite loud about this time in the meeting. Again, thank you, all for your indulgence. I want to thank the panelists. I agree. We tried to put 10 pounds of wool in a 5-pound bag. We appreciate you bringing all the great information you did and the dedication of the work you are doing. We hope we can all work together to make things better for our patients and practitioners. We are looking forward to the opportunity to use the technology and the policymaking levers we have to make this better for patients and clinicians. Seeing no other comments. I will say our next scheduled meeting is in April. I will give it to Lauren to do statistics and logistics and tell us when the next batch of cookies is coming out

Lauren Richie -- Office of the National Coordinator for Health Information Technology – Designated Federal Officer
We will always have cookies for you. Nothing more than we will see you in three weeks at the same place. Safe travels and we are adjourned. Thank you, everyone.

Robert Wah – Health Information Technology Advisory Committee – Chair
Safe travel, everyone. Happy Spring.

[Event Concluded]

Duration: 264 minutes