Interoperability Standards Priorities (ISP) Task Force

Transcript
June 11, 2019
Virtual Meeting

SPEAKERS

Name	Organization	
Kensaku Kawamoto (Co-Chair)	University of Utah Health	Co-Chair
Steven Lane (Co-Chair)	Sutter Health	Co-Chair
Andrew Truscott	Accenture	Member
Anil Jain	IBM Watson Health	Member
Arien Malec	Change Healthcare	Member
Clement McDonald	National Library of Medicine	Member
Cynthia Fisher	WaterRev, LLC	Member
David McCallie	Individual	Member
Edward Juhn	Blue Shield of California	Member
Leslie Lenert	Medical University of South Carolina	Member
Ming Jack Po	Google	Member
Raj Ratwani	MedStar Health	Member
Ram Sriram	National Institute of Standards and Technology	Member
Ricky Bloomfield	Apple	Member
Sasha TerMaat	Epic	Member
Scott Weingarten	Cedars-Sinai Health System	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Tamer Fakhouri	Livongo Health	Member
Terrence O'Malley	Massachusetts General Hospital	Member
Tina Esposito	Advocate Aurora Health	Member
Valerie Grey	New York eHealth Collaborative	Member
Victor Lee	Clinical Architecture	Member
Mark Roche	Centers for Medicare and Medicaid Services (CMS)	Member

Lauren Richie	Office of the National Coordinator	Designated Federal Officer
Margaret Weiker	National Council for Prescription Drug Programs (NCPDP)	Guest Speaker
Ryan Howells	Creating Access to Real-time Information Now (CARIN)	Guest Speaker
Dr. Andrew Mellin	VP Clinical Informatics, Surescripts	Guest Speaker
Ryan Hess	VP Product Group, Surescripts	Guest Speaker
Viet Nguyen	MD	Guest Speaker

Operator
Thank you and all lines are all now bridged.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Good morning everyone. Welcome to the ISP task force meeting. We have a very full agenda today so we will get started with a quick roll call. Ken Kawamoto?

Kensaku Kawamoto - University of Utah Health- Co-Chair
Here.

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

Steven Lane - Sutter Health - Co-Chair
Good morning.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Anil Jain? I believe he said he is going to be absent today. Arien Malec? Absent as well. Andrew Truscott? Clem McDonald? Cynthia Fisher?

Cynthia Fisher - WaterRev, LLC - Member
Present.

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

David McCallie - Individual - Member
I am here.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Edward Juhn? Terry O'Malley? Les Lenert? Jack Po? Raj Ratwani? Ram Sriram? Ricky Bloomfield? Sasha TerMaat?

Sasha TerMaat - Epic - Member
Present.

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

Scott Weingarten? Sheryl Turney? Tamer Fakhouri?

Tamer Fakhouri - Livongo Health - Member
Here.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Tina Esposito? Hi. Tina? No? Valerie Grey?

Valerie Grey - New York eHealth Collaborative - Member
Here.

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

Victor Lee - Clinical Architecture - Member
Here.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Is anyone else on that I have not announced? Okay. At this time, I will turn it over to our co-chairs Ken and Steven for a few words before we get started.

Steven Lane - Sutter Health - Co-Chair
Great, well, thank you, everyone, for showing up this morning we really appreciate it, both our task force members and all the members of the public that – who we can see who are on the line, many of whom are friends and some of whom I've never met before. So, really appreciate people's interest in this topic.
This, of course, is the Interoperability Standards Priorities Task Force and as you can see from the agenda we're going to be talking about medication data, specifically in the area of formulary, benefits and price data, this is a piece of a journey that we are on, trying to dig deep into the standards and implementation specifications related to the interoperability of medications data. So, we have Margaret Weiker from NCPDP, Ryan Howells from CARIN, we have a team from Surescripts and Dr. Nguyen from DaVinci. All of them are going to take us at breakneck speed through what they are doing and what they perceive as the standards challenges that they are facing. And then we'll have time for a discussion and public comment. So, Ken, would you like to add to that?

Kensaku Kawamoto - University of Utah Health- Co-Chair
No, look forward to everyone's insights into this topic.

Steven Lane - Sutter Health - Co-Chair
So, if we go on to the next slide just to remind all of us on the task force as well as our visitors that the charge of our task force pretty much directly from 21st Century Cures, is to make recommendations on

priority uses of health IT, and the associated standards and implementation specs that support these uses. So, we have done a fair bit of work in this area. If you go to the next slide, you will just see quickly who is on the task force and what organizations we each represent. And remember that these task forces are simply **[audio distortion] [00:03:45]** to the HITAC and subsequently to the ONC, and we don't really have any power unto ourselves. Though it's a great opportunity to provide input. On the next slide, next couple of slides, you will see a little bit of what our journey has been, just to put you in, orient you to our timeline, we started last summer.

We spent some time figuring out what directions we wanted to go in, what the priority areas we wanted to focus on. We spent quite a bit of time looking at orders and results and developed some recommendations that were then shared with the HITAC. We then went on to discussing referrals and care coordination, and similarly, finalize the recommendations. On the next slide, you can see where we have been this year, and really decided to focus in on medications and medication data as the third major area that we're going to be looking at and we are due to develop and present on the recommendations back to the HITAC in the September, October timeframe.

So that's where we're at and we are focusing in on medications today. So next slide is really just to orient us to this phase of the medication work, we did do quite a bit of work already, looking at the issues related to discrete sigs, challenges related to medication reconciliation, have developed some draft recommendations that have been shared with the HITAC regarding price transparency and access to PMP data, data standards required to support prior authorization and again some of the challenges related to free tech versus discrete sigs. One final recommendation that we developed has to do with E prescriptions that are sent to one pharmacy and then need to be forwarded to another pharmacy due to availability or some other – you know, patient convenience, etc. and looking hopefully to NCPDP to help us with determining where standards are needed or implementation guides to be able to support that kind of a work flow.

So that is kind of where we've been and as I said at this point what we want to do is take advantage of our guests, the first of whom is Margaret Weiker, who comes to us from NCPDP and for each of these brief but meaty presentations, our focus to really understand the organization that's being represented, the work that they have done and how it has been informed by the standard or lack thereof related to medication data and how we as a task force might be able to make recommendations, weigh in regarding standards that need to be implemented, expanded, developed, etc. to help move this corner of the industry forward.

Ken, do you want to add to that before we turned it over to Margaret?

Kensaku Kawamoto - University of Utah Health- Co-Chair
No, I think this group has done a lot of great work, and they're doing a lot of great work, so we look forward to hearing about it.

Steven Lane - Sutter Health - Co-Chair
So, Margaret, thank you again for joining us, and if you can introduce yourself to the group and you now have 11 whole minutes to take us through an introduction to NCPDP.

Margaret Weiker - National Council for Prescription Drug Programs (NCPDP) - Guest Speaker
Great. Thank you. I am Margaret Weiker, I'm the director of standards development and NCPDP. Next slide.

NCPDP is a not-for-profit, multi-stakeholder form for developing and promoting industry standards and business solutions that include patient's safety and health outcomes while also decreasing costs. The work of the organization is accomplished through its members who bring expertise and diverse perspectives to the form. As an ANSI accredited standards development organization, NCPDP uses a consensus building process to create national standards for the real-time, electronic exchange of healthcare information. Through our collaborative problem-solving form, we also develop and standardize best practices for product labeling, dosing instructions and patient communication and education and other practices important in safeguarding patients. Our data products developed by industry for industry help support the important work of our members. Next slide.
NCPDP has a standard called the formulary and benefits standard. It is a widely used standard in the industry and it's mandated for use under Medicare. The formulary and benefit standard provides a standard means for the pharmacy benefit payers to communicate formulary and benefit information to prescribers via technology vendor systems. Next slide.

A formulary is a list of prescriptible drugs and products published by a health plan, a benefits manager or a payer. Each product within a formulary is assigned a formulary status and a numeric preference level. The formulary status has three aspects for each product, is it reimbursable? Is it on the formulary? And is it more or less preferred than other products on the formulary? The numeric preference level provides additional detail within the same formulary status. Coverage information qualifies the condition under which the patient's pharmacy benefit covers the product. For instance, a product may be covered only for patients under a certain age or of a certain gender. Other products may be covered up to a certain quantity.

Payers can communicate the following coverage factors: prior authorization flags and routing processors, step therapy flag and explicit list of step therapy products, age limits and gender limits and quantity limits. Products exclusions specialty product benefit indicator and messaging are also included. Co-pay information describes the cost to the patient. The extent to which the patient is responsible for the cost of a prescription. The specification supports multiple ways to stake this cost, including a flat co-pay or dollar amount, percentage co-pay, a combination of flat and percentage, a co-pay tier, minimum and maximum co-pay, days supplied per stated co-pay, co-pay differences by type of dispensing pharmacy, minimum and maximum retail allowances, quantity based co-pay, benefit stages, minimum and maximum age limit co-pays, approximate total cost range which refers to the combined total price that the plan and patient must pay to purchase a product and also there is a capability to list a co-pay specific text message.

There also is a place to provide an alternative as well as then, their formulary status, numeric preference level coverage information and co-pay information. The formulary and benefits standard is a batch standard which means the file is transmitted onto the vendor partner which then, in turn,

uploads it or has the provider incorporate it into their practice management system. Also, formulary and benefit standards are not patient specific. Next slide.

The other current standards that can list pricing transparency is telecommunication standard. And that standard is adopted under HIPAA and widely used today as well. It is a standard format for the submission of a drug claim or other transactions between a pharmacy provider, and a PBM or insurance carrier or CPA, that is standard, also have transactions for eligibility, prior authorization, and information reporting. Next slide.

The telecommunication standard version D-0 is the one that's currently adopted under HIPAA, this will tell the pharmacy how much they are going to get paid and then it also provides patient pay amount information. Such as the amount of co-pay coinsurance, deductible, sales tax, any amount that is attributed to product selection, such as the patient prefers to have the brand versus the generic and the differences associated with making that selection. It also can provide information in regard to the provider network, coverage gap, as well. Next slide.

Version F 2 of the telecommunication standard is the one that NCPDP has asked to be adopted under HIPAA, but we are still awaiting the NPRM from HHS on that. For this standard, there are additional patient pay components that we have added since version D-0, and that has to do with the changing landscape of products and offerings in the industry today. For example, there is now a grace period, a catastrophic benefit. We have also added other patient payer responsibility amounts and spend down, as well. There are additional formulary alternatives that are returned in the version D-0. It basically does provide the formulary alternative, but it basically gives you a drug name, a description, and an amount, for the version F 2, it provides benefit tiers, reason codes of why this alternative may be better than the one that the physician prescribed. It also can provide therapy, time, duration, maximum and minimum age and maximum and minimum amounts that they supply. Next slide.

NCPDP is in the process of bringing forward to balance what we call the real type prescription benefits standard. We expect the standard to go out to ballot after our August workgroup meeting which is the first week in August. This standard was developed to meet two industry needs, one to facilitate the ability of the pharmacy benefit payers or manager or processor to communicate the formulary and benefit information to providers in a real-time mode, as well as patient specific and of course any standard is created to insure a consistent implementation throughout the industry. Next slide.
The real-time prescription benefits standard obviously contains coverage indicators, alternative pharmacies, estimated patient pay components, therapy time duration and period. Maximum and minimum age and as I said the amount and it does provide very detailed alternative product information. Next slide.

One of the challenges that we are facing in regard to the real-time benefits standard is whether to include the – what's called the full negotiated price. In the CMS final rule, they determined not to mandate the use or the inclusion of a full negotiated price. As you can see there was a lot of opposition and there is still a lot of opposition in regard to including that amount in the standard. At this point in time, we are going to include that field in the standard, and we are most likely going to make it either situational or not used, that is still being discussed. But we felt that by adding the field now, if changes

are made either to CMS or other means, it would provide the field in the standard and we would just have to go in and update the situation or actually make it used from not used. So that is the information that CMS included in the final rule around the full negotiated price. Next slide.

The other challenge has to do with the ONG rule, and it has to do with the safe harbor and chargeback and rebate. NCPDP did comment to this rule and we proposed three approaches or methods to support their definition of chargeback and how this could work in the industry. And this does impact patient savings, as well as than how it is reported as well as how the pharmacy handles the chargeback or rebate. So that – we're waiting again on that final rule in regard to any changes, you know, do they adopt one of our approaches, do they go a totally different way, or do they adopt some combination of our approaches? And based upon that, that will determine which way we go. We have already placed in the standard some qualifiers that can support this based upon the approaches that we proposed, but we may have to remove them or make additions to them depending on what their final rule is in regard to that.

So, there are a couple of challenges waiting on this particular one, a final rule, as well as then do we go ahead and include the full negotiated price and the real-time benefits standard? So that concludes my presentation. And there is my contact information.

Steven Lane - Sutter Health - Co-Chair
Margaret, thank you. Thank you so much, that was very thorough and exactly on the mark for what we asked of you. And what we're going to do is we are going to hold questions until the end. So that all of our presenters have a chance to contribute. So next up is Ryan Howells, who has become a good friend, working at the CARIN Alliance. A lot of people do not know that CARIN stands for Creating Access to Real Time Information Now, which I think is a really cool acronym. Ryan, are you on audio?

Ryan Howells - Creating Access to Real-time Information Now (CARIN) - Guest Speaker
I am, can you hear me, Steve?

Steven Lane - Sutter Health - Co-Chair
We can, yes, please, enlighten this group about what you guys are doing and how it relates to medication benefits and price, and the access to that data.

Ryan Howells - Creating Access to Real-time Information Now (CARIN) - Guest Speaker
Sure, so Ryan Howells, I'm a principal at Levitt Partners. We help lead a group as Steve mentioned, called the CARIN Alliance, which is a group of about 50 multisector organizations that are working to ensure that patients could have digital access to their health information using APIs and third-party applications. We have about as I mentioned about 50 multisector organizations participating, and providers and plans and pharma companies, platform companies and EHR vendors and others, all with that express desire to find ways to ensure that individuals can have more digital access to their data. So, as it relates to the pharmacy, in particular, we are actually -- we are working on developing a FHIR implementation guide that has to do with extracting specifically a consumer facing real-time pharmacy benefit check standard and I will talk about that here in just a moment. First, I wanted to talk about policy drivers. Margaret mentioned a few of those, the CMS final rule on real-time benefit tool that

was out there as well. I want to mention another one, there is one called the patient's right to know drug prices act, which is actually a piece of legislation that was signed into law in the fourth quarter of last year. It has to do with the ability for a patient at the point of prescribing to be able to be told whether or not the formulary price or the cash price is less and so that essentially removes the gag clause that pharmacies have been under for an individual patient to receive that information.

There has historically really been no significant way to operationalize that for the pharmacy to actually have that information in their system or for the patient for example to have that information on a mobile device or on a third-party application. And so, we wanted to find a way where we could actually help to be able to operationalize that piece of legislation. As Margaret mentioned the real-time benefit tool final rule as well is out there as well. That is primarily focused on business-to-business interchange, which is outside the scope of what CARIN is trying to accomplish, we are solely focused on business to consumer interchange and there is also the CMS NPRM that is out there as well around patient access and interoperability that also mentioned disability for access to formulary and benefit information.

So what we are doing as I mentioned is leveraging the good work that NCPDP has actually, is looking to accomplish here with their balloted standard in August around real-time pharmacy benefit check and all of the things that Margaret mentioned, formulary and benefit information, out-of-pocket costs information, therapeutic alternatives, and the other key pieces of information that is found in that standard and mapping that to a fire API standard so that third party applications on behalf of consumers could access that information digitally and aggregate that at the point of prescribing or at the point of dispensing. And our hope is that patients, along with their providers will both have the same information at the same time. And that will allow them to make a mutual decision as to what is specifically best for them and what's most efficacious as well as potentially most cost-effective for them at that point of prescribing.

In addition to those core data elements that are found in the real-time pharmacy benefit check standard that NCPDP is putting together -- we're also including in line with the patient right to know drug prices act an ability for patients to see their cash price alternative. We are using grid RX on the open API that they have made available to help make that happen, and that provides an ability, good RX has about 10 million individuals that are on their platform today and about 70 percent of them actually have health insurance already and so they go through a formulary process to make that happen and 50 percent of the time the cash price is actually less than the formulary price are so, our hope is that providing the individual patients with both cash price alternative as well as the formulary price, they can make a decision that is best for them as it relates to the drugs that have been prescribed to them in a mutually beneficial way between them and their provider to make that happen.

From a timeline perspective, I'll end with this Steven, we have received approval from a project scope statement perspective from H07 to move forward with this, that happened a few weeks ago and our hope is that we can be able to move this to ballot sometime in February as long as the stars align and we can move forward in a deliberate way and obviously piggyback on some of the good work that

NCPDP has done. Our group hopefully can be able to take that and map that to that FHIR API standard so that we can have third party access to the information as well. So, thank you, Steven.

Steven Lane - Sutter Health - Co-Chair
Thank you, Ryan, that was fabulous. The work you guys are doing is really quite impressive. I'm sure we're going to have plenty of questions from the task force. Let us take advantage of being a couple of minutes ahead, if the team from Surescripts is ready to go, I see some of you on the line here. Who is going to be leading this presentation?

Dr. Andrew Mellin - Surescripts - Guest Speaker
Hi, this is Andrew Mellin from Surescripts. So, we'll get started if you want to pull the slides up for us, please.

Steven Lane - Sutter Health - Co-Chair
And Andrew, welcome, I'm glad you're here. I know Andrew from a couple of meetings, and he is a physician and deep in this space so glad you're here with your team.

Dr. Andrew Mellin - Surescripts - Guest Speaker
Okay, great, well, I will be co-presenting with my colleague Ryan Hess, who is vice president of product innovation and supporting the medication information services. Just very briefly on Surescripts, Surescripts is the nation's largest interoperability network within our network, the Surescripts Network Alliance, we connect virtually all electronic health record vendors and pharmacy benefit managers and pharmacies and clinicians, to support over 1.6 million healthcare professionals and 258 million patients in our network. Last year in 2018 we processed 17.7 billion transactions supporting care throughout the United States. So today we will be talking a little bit about our process to support the prescriber with formulary, real-time and electronic – real-time benefits information and electronic prior authorization. Next slide, please.

So just to give you a general overview of the services we provide to support the providers, it is really multi, multiple sets of data that come together to support the provider at the point of care and the point of decision-making. The first part of that is eligibility and formulary, so we do a real-time electronic eligibility check to determine the plan that the patients are on and what benefits they have signed up for. We align that with the formulary that is part of every electronic prescribing module so that formulary process gives the provider the first level pass about what is on the formulary for that patient and what is at the different tier levels.

The next thing we do is after the prescriber prescribes or provides specificity around what they are going to prescribe, we will do a real-time prescription benefit check to determine that patients out-of-pocket pay as well as potential alternatives. My colleague Ryan will go into that in a little bit more detail. And then, for those drugs that do require prior authorization, out of this process will trigger an electronic prior authorization process to complete the process to get the medications dispensed. Next slide, please.

And specifically, on real-time description benefits, we are focused on giving that provider as precise of information as possible so when that patient arrives at the pharmacy, they know what they're the out-of-pocket cost will be and to give those provider alternatives. Now our model and our philosophy are to give that patient the information as defined through their pharmacy benefit plan. We leave it to their insurance companies, the pharmacy benefit plans, to determine the price, to determine the alternative in a specific way for that patient, based on their co-pay, based on where they are in the plan for the year and we present that unaltered to the provider at the point of care. The health technology vendors, the EHRs then present it within their prescribing process. With the goal of improving provider satisfaction and reducing overall administrative costs. Now I will turn this over to Ryan for further details.

Ryan Hess - Surescripts - Guest Speaker

Great, and if you could move down one slide. So this gives a snapshot of where we are with adoption on the EHR side of the network and on the PBS for Health point side of the network so what you can see on the far left-hand side, about 80 percent of prescribers are on EHR's that have signed on for real-time benefit. That gives you some idea. The second number there 77 percent is for electronic prior authorization. And then the third number the 76 percent is the flipside of the network, so this is how often a PBM or health plan or how many of the PBM and health plans have signed up to deliver this information to the provider. So, 76 percent of patients are under a health plan or a PBM that have signed up to deliver this information to the provider.

The one service that's not on here is eligibility and formulary, Andrew already talked about that. That is fairly ubiquitous so that would just be close to 100 percent on both sides. A provider sees it and a health plan or a PBM is delivering it. Go down one slide.

A couple of insights that folks may appreciate around each of the services, so this is eligibility and formulary, this is the first service that Margaret had talked about, which is a standard -- sorry. This is some survey data from an eligibility and formulary survey that we had done from providers a while back. This service has been out there for quite a long time, as I mentioned, so it is well adopted providers, it is well utilized by providers, it's something that they are accustomed to seeing in the workflow.

If you go down one slide, real-time subscription benefits and this is the newer service that is fairly well adopted at this point, it's been fairly rapidly adopted. It gives a little bit more depth in terms of how this works, so for real-time benefit obviously, the physician selecting medication and pharmacy. We start there because there is actually, they need to have selected the medication, the strength, the dosage, the specific pharmacy for the PBM and health plan to return pricing information. So that is, they need to have a fair level of detail in terms of what it is that is being prescribed for this specific service. This happens in real time. So, the physician writes it, in real time they send the request to us and we, in turn, reach out to the relevant EBM or health plan. We bring that back or bring that information back in real-time and it gets displayed, so literally as the prescriber is sitting in front of their computer, they type this information in, within, sub two seconds is the goal, what we're doing most of the time, this information will come back and be displayed on that screen in front of them, and

then that gives the opportunity for the physician to discuss with the patient as they are writing the prescription what should be the right prescription.

If you go down one slide, these are the pieces of information that are coming back so coverage alerts which are age, quantity limits and anything that requires a prior authorization, channel options, retail, mail order, and specialty pharmacy, member pay details, so this is the specific price that the member would have to pay, is what's most often presented. We can carry through the remaining deductible as well and then alternative drugs. So, for whatever the prescription was selected, we will carry back the prescription that was selected, the price for it, the price for the multiple channels, any coverage alerts, and then we will do the exact same thing for the alternatives that the PBM has supplied, so if there are three alternatives for that medication that was selected, each of those alternatives will have a price, the coverage associated with it, an option for retail and an option for mail order.

Go down one slide. And then it was asked as we came into this meeting that we talk a little bit about some of the features that are in development around these services. So, I put the three different products on the slide on the left-hand side. On the top left you can see the real-time benefit, and we continue to roll out the service for more and more PBMs and health plans, often times they have tweaks in the scheme, so this is something that we are working through. The next thing that we're doing is we're bringing real-time to other market segments. So, I just talked through what it looks like from a provider perspective. We have a similar service that we are rolling out now for the pharmacist. So, when you show up at your retail pharmacy what does it look like? And then there's a couple of other market segments that we are working on, bringing this data to, as well.

And then the last part I mentioned here is the integration of additional price of benefits information. You may recall when I was further up, I had talked about bringing in the remaining deductible, elements like that as we get deeper into the service, the different pieces of information, the different people want to see, that as the service evolves, and more people may come under ACO's that – different things that a provider in ACO wants to see so we are working through what should be displayed and what scenario. Going to the right-hand side eligibility and formulary, I was spending a fair amount of time on patient matching, which I think we've talked about with some other groups. And then, we're spending a fair amount of time moving into the medical drug as well.

So right now much of what we talked about is under the pharmacy benefit plan, as I say, a number of drugs that are covered under the medical side as well and we are integrating that information in and then on the bottom under electronic prior authorization, we talked about a couple of different things, we've talked about bringing the service to the pharmacy so we're trying to improve that pharmacy to pharmacy EHR pharmacist to provider interaction. We're doing a little bit of -- not doing a little bit, we're actually doing a fair amount of clinical data extraction from the EHR and then for prior authorization, often necessary, as well. We're moving into the medical drug space so again those drugs that are covered under the medical plan, as well as potentially the pharmacy plan. So that is the end of our presentation.

Steven Lane - Sutter Health - Co-Chair

Thank you so much. I'm very, very impressed with how you fit that all into nine minutes. So, thank you, thank you very much. And again, I would like to take advantage of what a great job all the presenters are doing. And let Dr. Nguyen talk to us a bit about DaVinci and how they're putting this data to use. That's going to give us a little bit more time for our discussion and Q&A. I am very much hoping that all of the presenters are staying on the line and will be available to respond verbally to questions that the task force has and I'm sure that people are jotting these down furiously as I have been. So, Ken are you comfortable if we go ahead with Viet?

Kensaku Kawamoto - University of Utah Health- Co-Chair
Sounds good.

Steven Lane - Sutter Health - Co-Chair
Great. Dr. Nguyen?

Viet Nguyen - DaVinci Project - Guest Speaker
Good morning, thanks for inviting us. My name is Viet Nguyen, I'm the technical director for the DaVinci Project. I'm an **[inaudible] [00:37:34]** and a physician. And my role is to help shepherd our use cases through the HL-7 process. DaVinci is a collaborative formed under the auspices of HL 7, we included the major payers in the US including CMS, a large number of providers, as well as Health IT vendors. Our process is to have our community identify specific use cases that they would like us to address around value-based care and administrative process treatment and clinical information exchange and from that list of use cases, we prioritize them and then develop project scope statements and put them through the HL-7 process.

And with the goal of using the HL-7 and FHIR process to develop FHIR implementation guides for our use cases as well as reference implementations so that developers and the community can see what the FHIR standard would look in one implementation and our work is around quality measures and gaps in care as well as clinical data exchange between payers and providers as well as process and improvement around prior authorization. One area related to this discussion that we have been working on is a FHIR representation of drug formulary and these came from similar drivers that were discussed before by Margaret and Ryan and what our use case has done is to take as a starting point, the formularies released through the qualified health plan, and represent them as FHIR resources and APIs, and so we have drafted an implementation guide that was actually just approved to go to ballot in an early Hl 7 ballot beginning in a couple of weeks.

And in the implementation guide, we do a couple of profiles on a list resource to represent the coverage plan. That will provide the links to the information about the plan and formulary and contact information, descriptions of drug tiers, and associated costs. And we have another profile on the FHIR medication knowledge that represents a formulary drug. And along with that we have two primary API queries that allow an application to query a drug plan or drug tier and with this, we expect that we'd be able to have a FHIR method of having an insurer represent their formulary through FHIR and then applications being able to query against a plan and be able to retrieve the formulary information and be able to have the client know whether or not there are requirements for prior authorization or if it's step therapy.

And we envision one use case might be about – a patient may want to do some shopping and be able to compare prices on different plans and coverage on different plans. And so we have this implementation guide that I will send to Dr. Lane and Dr. Ken Kawamoto to share and then we also have a reference implementation, because that is one of the things we do, and DaVinci's do demonstrate this in code for developers and so we will make that available and it is being hosted by the health services platform consortium.

I apologize and I don't have any slides to share on this, but we'll send out the link to all this information discussed and implementation guide. Thank you.

Steven Lane - Sutter Health - Co-Chair
Thank you, Viet, that was very helpful. So, we were successful in getting a tremendous panel of presenters here, all of whom really took seriously the challenge to boil down their message. And we really appreciate the effort that was put into this. So thankfully this gives us 45 minutes to have a discussion of this material and to think about it again very specifically in the context of the charge of our task force which again is to make recommendations to the HITAC and to ONC regarding priority uses of health information technology and the associated standards and implementation specifications that support such uses. So, I think that what I would like to do is take some more of our presentation time that we planned and ask each of the presenters, in turn, to respond to a couple of specific questions.

And the first one that I would have is what do you need? Our task force is in a position to make recommendations, and to suggest to ONC and then ONC could suggest to CMS or to other bodies within our ecosystem what needs to be done with regard to standards, requiring them, advancing them, implementing them more consistently. And this is up to and including making suggestions about conditions for the patient under CMS, etc. So, if we could, going back to Margaret, first, what do you need? If you were sitting on Santa's lap and asking for what you wanted for Christmas, with regard to standards or their implementation, what if anything and maybe nothing, would NCPDP need to really move us to the next level?

Margaret Weiker - National Council for Prescription Drug Programs (NCPDP) - Guest Speaker
Well, since you asked, I think a final rule around the Safe Harbor and chargeback the OIG proposed rule that came out, having a final rule, sooner than later, would be beneficial in regard to what changes we may make in not only real-time benefits, proposed standard but in our other existing standards. And then since I can ask for anything, I'm going to ask that maybe CMS commit to once the real-time the NCPDP real time standard, the benefit standard, is completed, that they commit to actually naming that in a rule where in the current rule they didn't name a standard. They said they would look to do that in the future once it is a standard was balloted and approved. But having that commitment, so to speak, would be beneficial.

Steven Lane - Sutter Health - Co-Chair
Great, that's fine. Ryan, and feel free as other people are speaking, to think about other aspects and I'm sure we will have another chance. Next step then would be, let's see, who was next? Ryan, in your

world, coming at this from the patient side, what does CARIN really need to catapult forward on your path?

Ryan Howells - Creating Access to Real-time Information Now (CARIN) - Guest Speaker
Well, I would agree with the points that Margaret has made, and obviously, support those. In addition, I think that we would have liked to have seen the patient being named a little bit more prominently in the real-time benefits rule, final rule. It did not necessarily happen. There was some discussion in there about the fact that they wanted to postpone that to some degree and I think it was largely due to the fact that the standard wasn't necessarily finalized yet, and so the hope would be that as the standard is finalized, as hopefully Margaret has her wish, that it is named in the final, in an upcoming rule process that there will be opportunities to also discuss the need for patients to also receive the same information that the physicians are receiving, either at the point of prescribing or in advance of the point of dispensing. And so, I think that is one hope and then in addition, as we leverage the work that DaVinci's done on the implementation guide for F&B.

We also can expand that to look at additional ways where we can provide additional data to the patients, and the hope is that if we develop our kind of implementation guide over the next few months, that also could also be named in the future, regulation that allows for individuals to then again get additional access to the information that they are looking for similar to what their physician has at that point so that they can again make that mutual decision together. So, I think those are some kind of high-level points, we definitely do not want to lose the idea of the cash price component as well. As you mentioned, it's in law now, and we want to try to find ways to operationalize that so finding opportunities where we can work together with industry partners as well as our public sector partners on making that available I think that would be very beneficial.

Steven Lane - Sutter Health - Co-Chair
Great. Let me sort of supplement my request to each of the presenting, or presenters, or presenting groups, that you actually send us a little write up, sort of your wish list specifically related to the standards and their implementation guides. And their meaning in the rules and please include as much detail, as you would like, about which specific rules at CMS, etc. again, because this group has not gotten into it quite is deep as each of you is. And if we are going to craft meaningful recommendations, we want them to be as implicit and specific as possible.

So, Surescripts, you guys are in a little bit of a different situation, of course, you're a private company, you've got a product, you've got a customer base, you know, there are all kinds of issues related to that and we really appreciate your sharing with us your functionality and your development direction but of course, you also have competitors, or at least we hope, in America that you do, and – so, I think you have a different perspective that you bring to this discussion. But similarly I think where you guys have really pushed this quite a long ways within your product line, where do you feel that standards need to go and need to be implemented differently so that what you are attempting can be made available really across-the-board to all patients, all providers at each appropriate point in the process?

Ryan Hess - Surescripts - Guest Speaker

Sure, this is Ryan Hess, I will take the question. So, for areas that are well developed eligibility and formularies, the best thing there is to continue to have the reinforcement of standards. That is kind of a foundational service whether it's from us or anyone else, that many of these other services are built on top of. So continued reinforcement of that as a foundational service that also adds a supporting, and recent legislation around prior authorization, has been helpful. So more reinforcement of providers and PBN self-plans, utilizing electronic prior authorization is helpful similarly, for real-time benefits, whether it is the two standards of an NCPDP, so for the standard within NCPDP, the standards within NCPDP reinforcement of the adoption of those would be very helpful, those are well tested and thought out transactions.

And then, you know, they ask for things like medical drug coverage, so if the drug is covered under the medical benefits as a pharmacy benefit, it is a little bit too early for there to be standards we think. We're all exploring multiple ways of blending that in including through to the prior authorization, there are multiple groups trying to come up with standards that might work. So it is a little bit early for us to be asking for standards there, but a tipping of the hat, that is an area that the government has been pushing forward, that's a pain point in the industry and that, once we all figure out what the best standard will be that will get pushed forward and that would be helpful as well. Thank you for asking.

Steven Lane - Sutter Health - Co-Chair
Great, and yes, from your perspective, obviously, DaVinci's moving along quickly and looking at balloting, but any help that might be needed? From ONC or CMS and others within the government to help this move forward more quickly?

Viet Nguyen - DaVinci Project - Guest Speaker
Yes, I would agree with the previous speakers, that we do need to come up with a shared standard, especially that utilizes the open APIs and makes this formulary drug information more easily accessible on the stakeholders. Since I'm a terminologist, I'll jump down just a little bit to the layer of some of the things we discovered, in working on this IG, I talked to the use case leads, and a couple of things that they identified that would be beneficial in this work that is sharing the formulary information, from the comparable cost plan where is they found there was a need for additional controlled medical vocabulary, some concepts that were inconsistent across plans that they looked at were things like the pharmacy type and relating between retail pharmacies versus mail order pharmacies.

Concepts around the co-pay options, and concepts around what it means to be a – the difference between – some plans using 30 day dispense versus a month dispense so I think these are things that are definitely tractable but developing that controlled vocabulary so when a client application tries to compare across plans, the information is directly comparable because it filters on the controlled medical vocabularies there. That is some policies, that is what I would recommend.

Steven Lane - Sutter Health - Co-Chair
Great, again I'll ask each of you to write that up for us and give as much detail, links, references, as possible so we can put that together. So, that brings us right on time to our discussion with the task force and Sasha TerMaat has sort of thrown out the first question. Sasha, do you want to ask that verbally?

Sasha TerMaat - Epic - Member
Sure. So, the question I put in the chat, is that I was listening to the presentation about the work being done by HL 7 FHIR, and I was just trying to clarify if the resource was delivering a patient specific result or just information about the plan? And if the question does not make sense, I can give an example.

Viet Nguyen - DaVinci Project - Guest Speaker
At this point a plan level data that would be part of – we had envisioned part of a formulary service that would add additional information that would be patient based, but that wasn't the scope of this IG.

Sasha TerMaat - Epic - Member
So, it would not include information about like deductibles that the patient had already paid or not and how that might factor into the cost?

Viet Nguyen - DaVinci Project - Guest Speaker
I don't – I'll be honest, I am not the author of this IG, but it does not appear that is part of this initial iteration, this first draft.

Sasha TerMaat - Epic - Member
Thanks.

Steven Lane - Sutter Health - Co-Chair
David McCallie, you have your hand up. And I invite other task force members to utilize the **[inaudible] [00:54:53]** feature.

David McCallie - Individual - Member
Yes, hi. This discussion gives me a good opportunity to bring up the standard joke about standards, that they're so good because there are so many to choose from. We have a plethora of standards here. What would help me understand it would be a picture, and I'm not sure who is able to draw that picture, that shows sort of the sources and control of the various bits of data and how various standards are used to flow that data between the entities that process it. So it does not do much good for example to have a FHIR standard that is FHIR friendly for consumers to access if there is no one to host the data and that may be a function of the fact that there's no one authorized to actually have that data or no one who currently has that data who is willing to authorize access to it. So, I think the gaps that in my mind exist here, is not that there are missing standards, but that there are overlapping standards and really unclear data flows.

Now, we have heard pretty cleanly that there are some blockers to moving forward that are based on regulatory language, and that is useful to know and that is obviously something that we can feedback to the HITAC committee, the OIG and CMS rules that were brought up. I suspect also what we have not heard a whole lot about is what are some of the business blockers, in terms of who is willing to share data and who is not, who does not want to share it. So, maybe in the subsequent discussions, we could get a little bit of a clue about what are the market or potential market failures here that are prohibiting

progress? So, I don't necessarily have a specific question for anybody other than just wondering if there is some place where we could get a picture of how this all assembles together? Because I don't know who's going to host those FHIR APIs for example or whether the NCPDP standard maps to the FHIR standard cleanly enough, and who would do that – that translation and mappings, etc.

Steven Lane - Sutter Health - Co-Chair
Thanks, David. Does anybody have a response to David's questions, comments, musings?

Viet Nguyen - DaVinci Project - Guest Speaker
At least, this is Viet. At least for the IG that we're putting in the ballot, it is intended to be implemented by insurers to allow client applications to look at their formulary, so that would be the expectation there. Currently, they can go to **[inaudible] [00:57:55]** and get that.

Steven Lane - Sutter Health - Co-Chair
So, all that current information is in the PBM to manage that under contract to the payers, would the assumption be the payers would pull that data out of the PBM then serve it up themselves or would they just route it to the PBMs?

Viet Nguyen - DaVinci Project - Guest Speaker
So, I will use the standard FHIR responses, there's going to be implementation considerations around architecture and how that flows through the third-party stakeholders because we know that that is prevalent throughout the whole ecosystem. So I do not have a specific answer but I would imagine the PBM in conjunction with the payers would have this information but how it is served up, I think it is part of looking at the broader infrastructure around directories and end point, you know, finding endpoints. So, I would have to defer for the moment, that specific answer to that question.

David McCallie - Individual - Member
That's interesting, like the one group that we have sort of seemingly solved some of these problems is GoodRx. I wonder how they've done it. Maybe we should've invited them to the call to explain how they get their data because they – they come as close as anybody to have actually delivered this capability.

Steven Lane - Sutter Health - Co-Chair
We certainly do have time, David, to invite them, if the task force thinks that would be helpful.

David McCallie - Individual - Member
I would be very interested to know how they get their data and how they solve some of these problems because it's quite impressive what they have done.

Steven Lane - Sutter Health - Co-Chair
Terry O'Malley, your hand is up.

Terrence O'Malley - Massachusetts General Hospital - Member

Thank you, first of all, Ken and Steven, thank you for inviting an incredible group of presenters, and to the presenters, thank you, this has really been informative and cannot thank you enough for laying the groundwork for all of us. I would like to rip a little bit on Dave McAuley's point and it is really an issue around coordination, so who has the big picture of the sort of where we are going, and who has a picture of what pieces are in place? And part of that I guess is to what extent are you all coordinating your activities? Or is this really a series of work streams that do not necessarily overlap consistently? I would appreciate a sense of how tightly coordinated are you three groups with your end goal of moving pharmacy data?

Margaret Weiker - National Council for Prescription Drug Programs (NCPDP) - Guest Speaker
This is Margaret with NCPDP, and we have agreed to coordinate with Ryan and with CARIN with regard to the patient facing real-time benefits check and we also have been participating in the DaVinci Project around the formulary and benefit APIs. Excuse me. And then –

Terrence O'Malley - Massachusetts General Hospital - Member
Yes, I would agree. Go ahead, Margaret.

Margaret Weiker - National Council for Prescription Drug Programs (NCPDP) - Guest Speaker
Sorry, and Surescripts, just to bring them in, is actively participating in NCPDP and in our task groups in regard to their formulary and benefit task group, the real-time benefit checks, in fact, one of the co-leads is an employee of Surescripts and then for the prior authorization as well.

Ryan Howells - Creating Access to Real-time Information Now (CARIN) - Guest Speaker
Margaret, it is Ryan and I want to echo your comments. Terry, there is a high degree of, I think, behind the scenes, you know, coordination that's going on as Margaret mentioned, HL-7 and NCPDP are working very closely together on this, CARIN and DaVinci are working closer on this so we are not overlapping in implementation guides that we're running parallel processes that are adding to, rather than duplicating specific work streams and then Surescripts is a member of CARIN, I think they're also involved in DaVinci as well. So there is a lot of -- it appears as though some of these are overlapping and if you want to get into some additional detail about how they're individual work streams that build on one another, from the standpoint of folks working on specific implementation guides, building on implementation guides that are in flight or will be published soon and then implementing those implementation guides, that that is something that we think talked about and happy to bring you up to speed on. Or others if needed.

Dr. Andrew Mellin - Surescripts - Guest Speaker
I can confirm Surescripts is actually one of our founding members of DaVinci. They coordinate quite a bit, working with that.

Ryan Hess - Surescripts - Guest Speaker
This is Ryan Hess, from Surescripts, I can confirm we are members, founding members of DaVinci as well and we work intimately with NCPDP and we work with CARIN and we use all of the standard elements and then some, so we primarily work between providers and pharmacies and PBM health plans. We do not do as much with the patient facing but we use FHIR standards in our work, we use

NCPDP standards in our work, we actually use ANSI standards in our work, as well. And we blend them. So, even within the same service, we could be using three different standards, from three different bodies, to execute what from a provider perspective or pharmacist perspective is one workflow. We weave them together. We are happy to, if it helps, there's an incredible amount of complexity here and if it helps we are happy from our perspective, from the provider pharmacy PBM health perspective, we're happy to create a diagram of where we are checking information from for each of the different services and then what standards are being carried and if that is helpful.

Steven Lane - Sutter Health - Co-Chair

That would be very helpful, I really appreciate that offer. Part of the trick in this discussion is – you know, it's awesome that Surescripts has so many smart people and is involved in all these things, and is able to deliver the services but again I mean, you're a private company within – working in a competitive marketplace, so I guess the question is, how do we go from the secret sauce that you been able to develop to an ecosystem where these kinds of services can be made available, competitively to everyone who needs them? So, I mean, sort of an open question I'll leave out there. Cynthia Fisher has her hands up, for those that do not know her, Cynthia is an entrepreneur and real great patient advocate. Sorry, Ken, go ahead.

Terrence O'Malley - Massachusetts General Hospital - Member

No, it's Terry, I just had a quick follow up question. So, I suspected as much so thank you for confirming the fact that you guys are all coordinating. Is part of your message that the issue is not so much around building standards or kind of filling gaps? It is really around leveraging powers that be to help them enforce the standards that are in place for at least choose a standard. Is that a correct conclusion about where you all want help?

Steven Lane - Sutter Health - Co-Chair

I think that is a key question, Terry, I don't hear anyone chiming in but that is a kind of input that we love to hear from you, in your Christmas list, is if the standards are moving along a page and the coordination is happening appropriately, is there a need or an opportunity to enforce standards or require their use differently. And certainly one question that is come up for me in listening to these discussions is whether or not there is really a need to perhaps require that through the HR certification for example that EHR's connect to the real-time pharmacy benefits services, that they connect to electronic prior authorization services, or if there is a need or if it would be appropriate to require that PBMs make available their list the pharmacy benefit data to the EHR's, and you saw the slide showing 76-80 percent adoption which is pretty darn good but it leaves a significant chunk yet unserved, do we just let the market do that? Or should art task force suggest to ONC that they need some help mandating that? So, again, Cynthia, I think your hand was up, would you like to take it?

Cynthia Fisher - WaterRev, LLC - Member

Yes, thank you. Good discussion. I would like to just weigh in representing patients, employers, you know, innovators, that support having the likes may be a follow up meeting of GoodRx so that we can also learn what would be important in the standards so that innovators like GoodRx could, I like your word, catapult, even and I like your word catapult, even catapult us further into the future, efficient and convenient and transparent delivery of information, to both consumers and employers? So, I think

from an innovation angle I think that would be great. And I would also put to the committee on the openness of the data, the PBM data, as it relates to – interfaces also with the HER, all sort of look at creating that open standardized API architecture so that innovators too would have access to that data that might provide other health and combine medical services for us.

And then final point, I think, is as we move into consolidation of so many of the players in the industry vertically integrating, how do we as a committee make sure and I would ask to you all, and maybe this is the likes of some tech companies or innovators, to sit at the table, how do we make sure that we have the types and the dataflow accessible without restrictive covenants such as giving percentages of companies or percentages of revenue flow in order to get access to this important data for patients? As new apps and new technologies can get delivered? So, I think that is another question is how do we make sure that we keep the open pipes and we do not have restrictive covenants that prevent innovation for the future? That is a consolidated industry.

And then finally, last but not least, is for Margaret, just for my understanding and then maybe some others on the committee, you mentioned some language regarding safe harbor. Could you just elaborate on that a bit about where is there Safe Harbor or where's the request for Safe Harbor? And just enlighten us on that with respect to the CMS rule or ONC's rules.

Margaret Weiker - National Council for Prescription Drug Programs (NCPDP) - Guest Speaker
Okay, well the office of Inspector General – issued a proposed rule entitled fraud and abuse, removal of Safe Harbor protection for rebates involving prescription pharmaceuticals in the creation of new safe harbor protection for certain point-of-sale reductions in the price of prescription pharmaceuticals in certain pharmacy benefit manager services. That is quite a name of a proposed rule. And no, I did not memorize it, I had to read that. What is in the rule is to have those charge backs actually be pharmacy and or consumer facing, so if there is a rebate being paid from a manufacture to the plan or rebate to the pharmacy that instead of having the plan have the rebate or even the pharmacy, to actually reduce the patient's cost based upon that rebate. In other words, take that rebate and apply it to the patient's out-of-pocket cost, versus to the PBM, versus to the pharmacy.

Now how that is all going to work is still up for – we proposed three approaches and of course we have no idea which one will be picked or if it will be a combination or approach totally different, but the goal of that proposed rule was to have those rebates, Safe Harbor charge backs, be more consumer facing and actually apply to the consumer's out-of-pocket, versus to the pharmacy or to the PBM or payer.

Ryan Howells - Creating Access to Real-time Information Now (CARIN) - Guest Speaker
And then Margaret, on the other question, I could maybe address a few of those, they're very thoughtful, I don't know if I've captured all of them, but you asked about how innovators can gain access to the information, I think that is one of the reasons that obviously NCPDP is doing their work and we are doing DaVinci and CARIN are doing their work and trying to make that available via the FHIR APIs that allows for innovators to use modern technologies to be able to gain access to the API endpoints, which has the data included in it. There was some discussion and obviously, all of that is open APIs, meaning that they are nonproprietary, and they are available for anyone to use and our anticipation and our hope is that we will have multiple industry partners be able to adopt that scale.

The other point on GoodRx, Steve, and I'm happy to make an introduction with you on that team with the folks that we're working with there, just a little bit of more color there. Part of the concern is that when an individual patient goes to a pharmacy and decides that the formulary price may be too high and they just want to pay cash, and they use GoodRx or they use other services, GoodRx is not just the only one out there doing this but if they use another kind of discount card type services, the problem exists is that health plans don't know whether or not there's medication adherence that's occurring at the point of dispensing. So that lack of understanding about whether or not the individual has actually been able to take the drug and using the drug, you know, it's difficult for them to capture some of that information.

If the person pays cash there is no systematic way to capture that and so our hope is that if we can put it in a similar API as what is occurring with real-time pharmacy benefit check and some of that information, hopefully will flow back to the regular systems to help health plans and others ensure that from an adherence perspective that folks have it decided that they want to take cash versus formulary price and that can get into the regular flow of the workflow itself from an adherence perspective. So I think it helps both parties, long-term, helps the patient, it helps the plan, it helps the providers as well to know that their patients are actually – have received the drug whether they paid cash or whether they've gone on the formulary for it. And I think the final point was around -- and those of the major points that you had mentioned, but I guess one other point on GoodRx, which is they do have a solution.

I wouldn't say, I mean, certainly there are some agreements that they have with specific PBM's to David's point earlier, to actually access this information, but I want to be clear and other presenters on the phone can correct me, but this information as it relates to real-time pharmacy benefit check has been around for quite some time. And the idea that in fact, there are health plans that have put this into production already and are seeing significant benefit from it. And so, I think this idea and it is an open standard although what MCTP is doing is actually balloting the standards, so it becomes more formalized. Some folks actually got ahead of that a little bit with either proprietary standards or, which with just their own kind of flavors for those and that's grateful to see us kind of getting our arms around how we can publish this in the future and so hope is that we'll have more of a consistent way of doing this on an open standard that involves both EDI which is mainly how the pharmacies exchange the data, and APIs, which is mainly how the apps will be able to adjust the information.

David McCallie - Individual - Member
Hey, Ken, can I comment on that?

Kensaku Kawamoto - University of Utah Health- Co-Chair
Yes, David, your hand is up next.

David McCallie - Individual - Member
I just want to respond to Ryan because that is a great point but to make a subtle distinction, that an API itself can be open as in the standard is publicly available for free but the service that hosts the API could charge for it even if it is using an open standard so the open standards this kind of step one but

the real question to me here is what are the business blockers that make this data either too expensive or too expensive to flow or is just competitive forces inhibit it from flowing? The fact that the standard is open is great, but if there is nobody who is willing to serve the data up for a reasonable market driven price, the open standard will not be useful. So, we need that dataflow diagram, but we also need to know what are the business blockers or the incentivizers, depending on how you want to look at it, that either facilitate the flow or inhibit the flow of this information.

Kensaku Kawamoto - University of Utah Health- Co-Chair
Yes, David –

Ryan Howells - Creating Access to Real-time Information Now (CARIN) - Guest Speaker
I think -- you make a really good point, David, that perhaps where policy may need to a change is really focused on the PBM's themselves. Or the insurers to make sure that that data is being made available not only to providers but really to consumers directly via the APIs. We are on the time to go to public comment. I heard a voice trying to chime in there so take that one comment. We will switch over.

Dr. Andrew Mellin - Surescripts - Guest Speaker
Just reacting to David's comment briefly, is that David, I don't know how this will be operationalized and terms of a business model perspective but certainly -- and I am not speculating either on this, so, to be clear, at least in terms of what ONC and CMS has already published in their proposed rules, they've made it extraordinarily clear that patient access to their own health information should be made free and openly available. So again, I do want to speculate on future standards and how that would actually operate, but that's obviously been made clear through the proposed rules that of already been published.

David McCallie - Individual - Member
Yes, I agree and that's encouraging so what are the roadblocks? Why is it not happening? That's the kind of thing that might be helpful for us to dig into a little bit because clearly, that is the right endgame but how do we get there?

Cynthia Fisher - WaterRev, LLC - Member
This is Cynthia, I thank you for the thorough responses to my questions, and support that, you know, I do think it would be helpful for the committee to understand, perhaps from some of the tech innovators that sit on the other side, and have had had some onerous business practices requests that have prevented them from providing their technologies, so that we get a better understanding of what is happening today that is preventing it from happening. And we get to the free delivery and readily available access to this wonderful plethora of information that is going to revolutionize care for the patient and quality and price reduction, and the only way we can get there is if we allow innovation to allow it to be delivered and happen. So I do think it is an important role of the committee and Steven and Ken, I think it would be great if we could go that next level and have some of these questions brought up further and delved into to see what if anything we can do to keep those pipes open and let them flow and allow for innovation.

Steven Lane - Sutter Health - Co-Chair

So, with that, let's go to public comments.

Operator
Thank you. Oh, excuse me, I'm sorry.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
No, go ahead.

Operator
Thank you, if you would like to make a public comment press star, 1 on your telephone keypad and the confirmation tone will indicate your line is in the queue. You may press star 2 if you would like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Thank you, and do we have any comments in the queue?

Operator
Yes, we have a comment coming from Shelly Spiro.

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

Shelly Spiro
Thank you, my name is –

Steven Lane - Sutter Health - Co-Chair
Shelly, can you start by, yeah, introducing yourself.

Shelly Spiro
Certainly, my name is Shelly Spiro, I'm the executive director of the pharmacy HIT collaborative, and an active member of the NCPDP and HL 7 efforts. And the efforts of the pharmacy HIT collaborative are focused on pharmacists that provide clinical services and how those services are exchanged in an interoperable manner. We've worked on several projects, in collaboration between NCPDP and HL-7, especially around the pharmacist electronic care plan which includes a FHIR implementation guide. These are important for pharmacists to – especially those pharmacists that are involved in value-based payment models, and able to measure information.

I know that this task force in with this session, has been focused on the pricing and the dispensing of medications but I just wanted to make this task force aware that pharmacists do provide clinical services and we are working on those standards to make sure that we are or that we have codified

information where we can measure outcomes on the encounters that pharmacists are providing with those services, which also includes information to make sure that the patient can afford the medications that they're taking, social determinants of health and other areas in relation to the care of the patient. And I just wanted to make the task force aware of that.

Steven Lane - Sutter Health - Co-Chair
Thank you, Shelly.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
Operator, any other comments?

Operator
There are no additional comments at this time.

Lauren Richie - Office of the National Coordinator for Health Information Technology- Designated Federal Officer
I'm sorry you said –

Operator
There are no additional comments at this time.

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

Kensaku Kawamoto - University of Utah Health- Co-Chair
I think I have a few minutes and maybe Terry, you have your hand up and then I would like to follow up on one of David's comments, but Terry, please go ahead.

Terrence O'Malley - Massachusetts General Hospital - Member
Just a question, it sounds like everyone's working really hard on standards, are there any information needs, any sort of standardized vocabulary that is missing from your deliberations or would help them?

Viet Nguyen - DaVinci Project - Guest Speaker
This is Viet, we will send this up in a write up, but we did identify some controlled terminology needs. I think another one that I did not mention was the drug class that if we're going to be making some of this information to patients, like understanding pain versus analgesic, and a lot of the terminology that we use is fairly technical or healthcare focused, so if we're going to be offering this information to patients, we need to – some terminology to help them understand how to read this formulary information. But we'll write this up and send it in to you.

Terrence O'Malley - Massachusetts General Hospital - Member
Thank you.

Kensaku Kawamoto - University of Utah Health- Co-Chair
This is Ken, just to follow up on David's comment, I would like to ask the presenters to comment a little bit more on his notion of what are the market issues and the business issues that are potential barriers and from a health system perspective, for example, we have been really wanting to implement the patient co-pay estimation capabilities at the point of prescribing, and have found that we are still at a point where we would only have about a third of our patients, so to speak, coverable by that. Looking at other health experiences, they seem to indicate that they are not being able to see, say like 80 percent coverage, what hopefully we would be able to get. Maybe folks would comment on, you know, are those temporary issues? What are the issues given the standards from the specs that are available that are now preventing that? So, a comment on that from the presenters would be appreciated.

Margaret Weiker - National Council for Prescription Drug Programs (NCPDP) - Guest Speaker
This is Margaret, and in regard to the standards, I mean we provide the vehicle, the highway, so to speak to report that type of information, and why that data is not being populated from a PBM or payer perspective, I cannot answer that question.

Ryan Hess - Surescripts - Guest Speaker
Yeah, I can answer, this Ryan. So, as you point out, 76 percent of the number we use, the missing 24 percent varies greatly by region. It really depends on your health plan. And there are some health plans obviously, and PDMs that are represented by that are not in there. The biggest driver that we see is that the health plans and the PBMs have different weights of emphasis in terms of the changes that they are looking for from the perspective of the real-time benefits. So, what they want to achieve is different. So, some of them are focused on total drug spend, some of them are focused on PA avoidance and some of them are focused on drug utilization review. And it is not one-size-fits-all. So, when we, Surescripts went out we had three or four different big PBM's that we were talking to and we were trying to listen to everybody, but not everybody agreed on what was the most important thing to be presented to the provider and thus driving change. So that is why some folks are trying, you know, some folks go different routes. Because they feel like they can get their ultimate goals that are implemented.

Kensaku Kawamoto - University of Utah Health- Co-Chair
Thank you. You've been very helpful.

[Inaudible] [01:27:12].

Steven Lane - Sutter Health - Co-Chair
Yes, we don't have a lot of time but I did want to comment to Ryan's point about the value of dispense information in terms of knowing about adherence, that sort of also challenged by the fact that some patients choose to pay out-of-pocket for meds, so that information is not available to their payers or even some or all of their providers. So, there some privacy issues there. But thank you. So, this again has been wonderful. Again, we are asking each of the presenters to send us their wish list related to standards and their implementation and where you think our committee might be able to make

suggestions to ONC in particular, who could then potentially work with CMS and others. Thank you all for your participation. This is been a great and very informative meeting. And the task force is going to be meeting next on the 25th in two weeks and will probably, Ryan, I'd love to take you up on your offer for an intro to the folks at GoodRx. It sounds like that would be a valuable addition to our contemplations here.

Ryan Howells - Creating Access to Real-time Information Now (CARIN) - Guest Speaker
Sounds good.

Steven Lane - Sutter Health - Co-Chair
Anything else, Ken?

Kensaku Kawamoto - University of Utah Health- Co-Chair
No sounds great, thanks, everyone.