



Interoperability Standards Priorities (ISP) Task Force

Transcript
October 08, 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
Lisa-Nicole Sarnowski	Office of the National Coordinator	Acting Designated Federal Officer

Operator

Thank you and all lines are all now bridged.

Lisa-Nicole Sarnowski - Office of the National Coordinator for Health Information Technology- Acting Designated Federal Officer

Good morning. Welcome to the ISP Task Force meeting. My name is Lisa-Nicole Sarnowski and I will be serving as the Designated Federal Official for Lauren Richie on today's task force call. This meeting is officially called to order. Let's start with the roll call. I have Steven Lane, Ken Kawamoto, Tamer Fakhouri, David McCallie, Terry O'Malley, Sheryl Turney, Cynthia Fisher, Edward Juhn, Ming Jack Po, and Ram Sriram. Is there anyone else I missed?

Sasha TerMaat - Epic - Member

This is Sasha TerMaat.

Lisa-Nicole Sarnowski - Office of the National Coordinator for Health Information Technology- Acting Designated Federal Officer

Great. Thank you. Okay. That completes our roll call. I will now turn the meeting over to our co-chairs to begin today's agenda.

Steven Lane - Sutter Health - Co-Chair

Excellent. Thank you so much, Lisa-Nicole and welcome to our call. Thank you for stepping in today for Lauren. We most appreciate that. We're going to be briefly reviewing our schedule, brief though it may be. We are going to jump into our draft report, focusing primarily or initially on the medication and pharmacy data section and then we will have time for public comment, as always. Next slide.

As a reminder to taskforce members and a number of additional folks who have joined us, as we can see on the call, the charge of our taskforce is to make recommendations or priority uses of health information technology and the associated standards and implementation specifications that support such uses and the specifics are here for your review and we are in the home strategic of finalizing our report that we will be delivering back to the HITAC next Wednesday, the 16th of October, for their review and comment. Remember, the HITAC did see the draft of this at their prior meeting, made a number of comments, some of which we will be looking at today. Next slide.

These are the members of our committee. Thank you for those of you who have been able to make the time to join us this morning. This has been a long haul of over more than a year now. We really appreciate everybody's input and comments. Next slide.

So, this is a view of our timeline and where we are. You can see we're now up to October 8, which is our second-to-last review of our recommendations report. We did introduce an extra meeting.

Cynthia Fisher - WaterRev, LLC - Member

Ken? Does this go until noon?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes. The somebody who asked if the meeting goes until noon is unmuted.

Cynthia Fisher - WaterRev, LLC - Member

Thank you.

Steven Lane - Sutter Health - Co-Chair

So, we did introduce an additional meeting this Friday if needed. I'll be surprised if we don't end up needing it, but it should be on all of your calendars. As was just mentioned, today's meeting was calendared for two full hours. We'll see if we can stand up that long. Then Friday's meeting is scheduled for 90 minutes starting 30 minutes earlier.

That, again, is for us to bat cleanup and go through and capture any secondary comments. There have been a number of secondary comments where folks have gone back to the earlier sections and made additional comments that I think we'd like to work through. At the end of the day, you're going to need to rely on your Co-Chairs to do some of the final cleanup of the draft report before we present it, but it's going to remain available for all of you to review online.

We've spent quite a bit of time addressing comments that have come in to date. We did get some input from other HITAC members who have viewed and offered a number of minor editorial and grammatical and punctuation comments that we've managed offline so not to belabor those with the larger task force. Any questions about our timeline and where we stand in that?

Just for an operational note, we will attempt as usual to use the hand raising feature in the Adobe Connect meeting. Between Ken and me, we'll try to keep up with that. We also welcome public comments entered in the chat. Please identify yourself and perhaps what constituency or organization you're representing and we'll try to address those as time allows. During the course of the meeting, we also do capture all of those and publish them with the official record of our meeting, both audio and written. So, public members who are joining, you definitely have a chance to chime in and have your voice heard.

All right. Let's go on to the next slide. Perfect. So, Ken, do you have anything you want to add before we jump into the document?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. I think my main suggestion is to see if we can go as expeditiously through these comments as possible because we can always come back. So, if it looks like we're going to go interactable discussion on a topic, I suggest we note it and come back to it. Also, if there are items that are especially out of scope, as in we haven't really discussed it previously, I suggest we create a parking lot item for that for what needs to be addressed in the future.

If it goes into more elements that are more policy than standard, especially if we hadn't discussed it too much earlier, I also suggest that unless we can come to a fairly quick resolution, we park it, try to get back to it during this week if we can, and if not, put that into the list of things that needs to be considered for the future.

Steven Lane - Sutter Health - Co-Chair

I'll just share that we had a number of task force members come back to us with the request that we add that in the beginning. I think sometimes our conversations tend to find themselves charting new territory. As appealing as that is, this really isn't the time in our lifecycle to be adding whole new topics. We really need to make sure we get our recommendations right. Again, they should be focused on standards and their implementation. That's really our primary charge.

So, having said that, we're going, as we said, to jump in with the medication and pharmacy data. For those of you following along at home, this is the top of page 33 in our 50-page draft report. And as with all the other sections, we started with an illustrative story. Last time, we spent a lot of time thinking about the story. This has been up here for a while for folks to comment on and I don't think we've received a lot of comments.

So, we can just pause here and see if anyone has anything to add or say about this. Again, the attempt was to try to put this into really, a first-person patient context as we start in to each of the sections, not assuming that the story will touch on everything that follows on the subsequent observation recommendations, but it's meant to set the stage.

Kensaku Kawamoto - University of Utah Health - Co-Chair

And I see here we have a generic recommendation which we've tried to follow. First, it was from Sasha, to stage recommendations to determine which standards make the most sense, then require them, not if you don't know, don't require them. It certainly makes sense. David had certainly described the needs from two perspectives, providers and patients. I think by putting in the stories, that certainly helps. By putting the patient-centered items first, we've also done that. So, I'm just going to go ahead and resolve it, but let's keep that in mind as we go through.

Steven Lane - Sutter Health - Co-Chair

Great. Thank you, Ken. So, moving on down, we, as routine, have split our recommendations into tier one and tier two. We have so much discussion about the importance of price transparency that this was brought up towards the front and really highlighting the patient-facing items. People should just be aware that has been done. Then what we're going to do is go through this.

This first change that I made was in response to some feedback from Sasha, which you can see here, regarding what happened at the August NCPDP work group meeting. Anyone who was there or is more in the know about that is welcome to chime in. We made some changes in regard to your comment there, Sasha.

Sasha TerMaat - Epic - Member

Thanks.

Steven Lane - Sutter Health - Co-Chair

We'll go ahead and resolve these. So, this, again, just to be clear, we're talking about real time prescription benefit checking and the importance of knowing the true out-of-pocket cost from the

patient's perspective, number of observations. With regard to our recommendations, here, again, Sasha made the point that we shouldn't be too quick to require functionality as part of the EHR certification program.

So, there was a suggestion to soften this recommendation from require to encourage EHR vendors to provide functionality and real time patient-specific prescription benefit checking into prescribing workflow. Any questions about this? Does anyone have concern about softening this recommendation just a smidge? Great. Thank you for that. Denise really was –

Kensaku Kawamoto - University of Utah Health - Co-Chair

Clem, do you have your hand up?

Clement McDonald - National Library of Medicine - Member

Yeah. We have two years to do it and this is what I thought everybody really wanted. I don't know how far the standards are for doing it. So, that's the only hesitation I would have. It's one of the things we talked about a lot and one of the things that's really popular to help patients.

The only other thing I'd add is I thought there was an interest in at least keeping in the light the idea of the total cost so that the patients might worry about their insurance rates going up if they always pick the mightily expense choice. I thought that was also something we'd heard in a previous discussion. I'd just hate to soften it too much. Two years is a long time.

Steven Lane - Sutter Health - Co-Chair

So, Clem, we do have above here the true out-of-pocket cost. We've tried to be clear about that as we've gone along. If there are concerns about excessive softening in our recommendations, we can certainly do as we've done in the past to encourage now and when ready require the functionality.

Clement McDonald - National Library of Medicine - Member

Okay. That would be all right. But I was actually arguing for not just the out-of-pocket cost because that was discussed a bit. I thought there was a couple of people who wanted to have also the actual cash cost or the real cost somebody is paying behind the patient's scene, mainly like the insurance companies may have to pay. They would have to pay if they didn't have a good coverage. Some of them are monstrously higher.

Steven Lane - Sutter Health - Co-Chair

You're right, Clem. We have touched on that in other sections and I don't think there's anything wrong with adding it here.

Clement McDonald - National Library of Medicine - Member

Well, I wasn't really caring if it's here, for sure. I just want to make sure it's brought up somewhere. You don't have to change anything now.

Steven Lane - Sutter Health - Co-Chair

Well, I popped in a suggested change here. I see a number of hands up. Cynthia?

Cynthia Fisher - WaterRev, LLC - Member

I agree with Clem. Also, thank you for adding both cash – it just popped off my screen – cash and I would put the total price for the expenditure as well as Clem mentioned earlier, not just the cash price. Sometimes the cash price is 40% lower than a negotiated rate. To Clem’s point, we’ve gone through this before in other venues that the only way you can lower the 8% to 12% increase for businesses and employees a year in their premium cost or in their coverage cost is to get at the total cost and drive those costs down and enable steerage.

So, I think it’s important because to get to the out-of-pocket cost, you have to know the whole price and see it broken down as part of the explanation benefits. So, that being said, I think we need the real cash price, what the real cash price would be and what a negotiated price or out-of-pocket cost would be as well. All of those prices need to be conveyed to the patient for choice.

Steven Lane - Sutter Health - Co-Chair

Ed, do you have your hand up?

Edward Juhn - Blue Shield of California - Member

Yes. I agree with the folks regarding the total drop cost and patient cost distinction. Do we want to add a piece in here regarding the price transparency for both new and existing medications?

Steven Lane - Sutter Health - Co-Chair

That sounds to me like a whole new section.

Cynthia Fisher - WaterRev, LLC - Member

I think that’s a really good idea. I’m sorry to jump in here. I think that’s a really good idea because so many diabetics have come to us with the changes in insulin formulary and how it has set them back substantially and to look at a comparative price to what their classic drug regimen was. It isn’t until after they’ve paid the costs and the price of this inordinate change of a prescription that they then have to go back to the doctor and try to go back on their old formulary. I think that’s a very good idea.

Steven Lane - Sutter Health - Co-Chair

Okay. I’ve captured that for future consideration. If we can get back to it in the four hours now remaining or three hours remaining, we will. For now, we’re going to parking lot that. It is a nice idea, the idea that instead of having to attempt to re-prescribe a medication to see all of this cost and physician support data that it would just be suddenly there for all of them. It is already on a patient’s list and the idea of being able to run interaction checking on a standing list of meds as opposed to having to rely on the alerts as they are prescribed. I think it’s a great idea, but we should hold off on it. Cynthia, your hand is still up.

Cynthia Fisher - WaterRev, LLC - Member

Yes. I also just want to make sure that we allow for an open API structure here on this application area of the standard because I think in the step back, this is a function of your EHR. There are other innovative tools, mobile apps, GoodRx, MDsave – there are other tools that may want to compete and

provide better innovative opportunities. I just want to make sure that we're not creating a standard that narrows the field of participants.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Cynthia, the next recommendation is that, the next section. So, it's covered. Yes. We have that explicitly covered in the next block.

Cynthia Fisher - WaterRev, LLC - Member

Okay. Thanks.

Steven Lane - Sutter Health - Co-Chair

We could also include just a simple reference to it here except now we've got the require – yeah, it's probably too many things to throw in together. So, again, we have some minor suggested changes on the language that have come from our discussions right here on the recommendations, incorporating the cash and total cost retail cost along with out-of-pocket costs and the softening here that one would only require this functionality for EHR vendors and when standards are sufficiently validated. Any objection to those changes?

Cynthia Fisher - WaterRev, LLC - Member

Steven, how do you do the change where a vendor isn't an EHR vendor?

Steven Lane - Sutter Health - Co-Chair

Well, we're about to get there.

Cynthia Fisher - WaterRev, LLC - Member

They don't have to go through EHR.

Steven Lane - Sutter Health - Co-Chair

As Ken said, that's in our next section. Let's get down there. I just did want to publicly acknowledge the careful review that we received from Denise Webb, who really added some refinements to our document and this was one of them. All right. Ken, you just added a comment. Do you want to mention that?

Kensaku Kawamoto - University of Utah Health - Co-Chair

That's for later. It's just noting there's often a charge for doing these kinds of checks on a per transaction basis. Maybe it's \$0.25. Maybe it's \$0.50. The patient has 15 medications. That's like \$8.00 just to check. I think we just need to make sure that we don't have onerous requirements of always checking constantly for things that aren't being changed or refilled, etc. But since it's on a parking lot item, I'd say we just move on.

Steven Lane - Sutter Health - Co-Chair

Great. All right. So, Cynthia, again, thanks for highlighting the importance of patient-facing APIs to support real time pharmacy benefit checking and pricing information. So, again, we've spent a lot of time on this already. We have observations, recommendations, and, in this case, policy levers. I will

point out that this latter section of our recommendations, we didn't get as deeply into policy levers. Part of it is because our policy work has been busy doing other things.

But anybody who would like to offer policy levers for some of our recommendations is more than welcome to. I think if we have time to work on this week, we probably have time to review them when we meet on Friday. I'm not seeing any hands up. Again, this section, I think, is pretty complete. We'll just pause for a moment and give people a chance to look at it. Again, some minor linguistic and grammatical and punctuation changes may have been made since the last time you saw this.

Sheryl Turney - Anthem Blue Cross Blue Shield - Member

Steven, one thing I would – I don't know if this makes any difference, but we use RTPBC just to be consistent with Da Vinci and others, it's RTBC. That's real time benefit check. It would be applied to pharmacy. I don't know if you want to make it consistent.

Steven Lane - Sutter Health - Co-Chair

We can do that. So, calling it real time benefit check, RTBC, for pharmacy data. Is that what you're suggesting?

Sheryl Turney - Anthem Blue Cross Blue Shield - Member

Yeah. So, the RTBC is the acronym that they're using and it specifically aligns to pharmacy.

Steven Lane - Sutter Health - Co-Chair

Okay. Does anyone object?

Kensaku Kawamoto - University of Utah Health - Co-Chair

I don't think we need to do it in particular since NCPDP refers to this as the way we do it. If there are multiple competing ways of referring it to the industry, I don't think we have to use one or the other. I think it's okay. It's clear what we're referring to. So, for example, NCPDP, this is their preferred term, it looks like.

Sheryl Turney - Anthem Blue Cross Blue Shield - Member

All right. Thank you.

Steven Lane - Sutter Health - Co-Chair

I agree. I think people can figure it out. I don't think we're too far off there. All right. Great. We made it through that section painlessly. As we walked through this for the first time, we realized there was a fair bit of overlap between these various checks and transactions. We got some great feedback from some real subject matter experts in their area, but we have separated out the benefits checking and, in this case,, the eligibility and formulary checking, which is the next section.

Why don't you scroll down on the display here? I'll make sure we're in the right place. We want to be in the eligibility and formulary checking on the bottom of page 36. There we go. Thank you. Okay. Here again, we made a number of observations focused on the standards that exist and their implementation, and a number of recommendations, here we did not.

Scroll down to the recommendations here. Most of these took the form – let me just get us through here. Most of the recommendations take the form of encouraged/incentivized. I think we’ve modified our use of language a number of times as we’ve run through this. In here, none of these things say that it would be required. That section, again, has no comment. But we do have Cynthia with her hand up. So, go ahead.

Kensaku Kawamoto - University of Utah Health - Co-Chair

You’re muted, Cynthia, if you’re talking.

Cynthia Fisher - WaterRev, LLC - Member

Hello? Did someone just call me for my hand up?

Steven Lane - Sutter Health - Co-Chair

Your hand is up, Cynthia. Yes.

Cynthia Fisher - WaterRev, LLC - Member

It was up for when a statement was made earlier, which was unbeknownst to me that there was a \$0.25 charge or there’s a charge and I’m not sure if that’s an EHR vendor that’s charging or where the charge lies and who pays the charge for searching on these prices. Where is that? How do we make those fees transparent?

So, my question is I can put GoodRx on my phone as a patient and I get that for free and get to use coupons or see where the prices are different. How does that compare so that I as a patient know if there are fees to search on prices within my EHR? How does that affect and who pays, ultimately? Is it usually the patient?

Kensaku Kawamoto - University of Utah Health - Co-Chair

I’ll put that in the parking lot of transaction costs or pharmacy-related interactions should be further reviewed and discussed. I’m not an expert in this. I just know that for certain interactions, like, for example, for billing or what not, it does cost us. I know this because in order to get a **[inaudible]** **[00:26:42]** cost, we oftentimes have to put in what’s known as a test claim, where we say, “Hey, we plan to fill this. How is going to look?”

That’s where the health system pays – I believe NCPDP – sorry, not NCPDP, Surescripts – the cost. I’m not an expert on this. I think if we go into this in detail, it could be useful, but I suggest we parking lot and come back to it. I don’t know what the range of costs are, but obviously, these folks do it for a business model, right? They’re not just going to provide all these costs and checking, etc. for free. Somebody pays. I believe that will become an inhibitor, right?

Cynthia Fisher - WaterRev, LLC - Member

Well, it’s interesting because in other business sectors, you don’t charge to show your customer your prices. Healthcare is unique. So, I think it’s just to have transparency if there are hidden fees for even

searching to find out what you're going to pay, ultimately, it hits the consumer. It would be helpful to understand where those transaction fees are and how much they are so the consumer is aware.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Let's come back to it.

Cynthia Fisher - WaterRev, LLC - Member

We can just put a note to that.

Steven Lane - Sutter Health - Co-Chair

We got it. We've captured that. If you want to look, there's a whole series of comments now. Capturing this is something that we may come back to when we have time.

Cynthia Fisher - WaterRev, LLC - Member

Thanks.

Steven Lane - Sutter Health - Co-Chair

All right. I think we are down to prior authorization specific to medications, which I believe is on page 37 at the bottom there. Thank you. Sasha had commented that we talk about prior authorization in a number of places in our recommendations because it certainly applies to orders, as we've seen, to referrals, and to medications. So, we just clarify that this is for medications. Sasha made a suggestion to update the header. We did that. Are you comfortable with this, Sasha.

Sasha TerMaat - Epic - Member

Yeah. Thanks.

Steven Lane - Sutter Health - Co-Chair

Great. Here again, under prior authorizations, we have a number of detailed observations that we've made. If we can scroll down to the bottom of 38, Ram made a comment that this needs to be put into a patient-centric perspective and a little back and forth. Ram, are you on?

Ram Sriram - National Institute of Standards and Technology - Member

Yeah. I'm here.

Steven Lane - Sutter Health - Co-Chair

Great. Do you want to comment on this?

Ram Sriram - National Institute of Standards and Technology - Member

As I mentioned in my email, what happens is it kind of implies that these distinctions are made because insurance, they want to make money on something like this. So, we want to put it in a positive way. That's all I said. I think you made some changes.

Steven Lane - Sutter Health - Co-Chair

I just tried to clarify the language here. Now, it says there are business incentives on insurers to reduce the use of expensive medications and other clinical services. I don't know if that is clear enough.

Ram Sriram - National Institute of Standards and Technology - Member

Yeah. That is more positive. Then maybe if you want – I'd say the problem is that – did I get my point right straight on that. do you understand what I was trying to say? The initial thing – what it means is there's a limit on prior authorizations because insurers think that it's expensive and they want to make money. Is that the truth?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes.

Ram Sriram - National Institute of Standards and Technology - Member

If that's the truth, then we can leave it like that.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think for sure. Insurers are – right? I mean...

Ram Sriram - National Institute of Standards and Technology - Member

What I said as, “[Inaudible] [00:30:49], due to certain business policies followed by the insurers.”

That's a little bit ambiguous. Do you see what I'm saying there? You say there may be a limit to which payers can be made easy and I think due to policies of the insurers or something like that. That's what I said. Steven, do we have the statement that I sent you via email?

Steven Lane - Sutter Health - Co-Chair

Yeah. It should... Sorry.

Ram Sriram - National Institute of Standards and Technology - Member

Let me check my email on that.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I feel like the way it's stated now sort of conveys the point. I'm not sure we need to go back to find the exact wording.

Ram Sriram - National Institute of Standards and Technology - Member

Okay. Yeah. I'm fine. Thank you. I have no problem.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Perfect. Cynthia?

Steven Lane - Sutter Health - Co-Chair

Cynthia, your hand is up.

Cynthia Fisher - WaterRev, LLC - Member

Sorry. I meant to take it down from before. No comment.

Steven Lane - Sutter Health - Co-Chair

Okay. Great. Thank you, Ram, for that. Our next section is on alternative therapies. This is toward the middle of page 38. Here again, we made a number – this is another transaction, another opportunity for decision support for the patient and/or prescribing clinician.

We talked here about a number of different sorts of alternatives that can be made clear to folks and then we make some specific recommendations to encourage and incentivize health plans and PBMs to freely share this data. Any thoughts on this one? I see no hands up. Again, folks are welcome to review these at their leisure and provide comments. We welcome that.

The next section, medication reconciliation on page 39. We talked at some length about this and the challenges, the number of observations, recommendations in this case, some policy levers. Sasha, you had a comment on the recommendations, where you say we have seen challenges with similar approaches internationally and would be hesitant about this direction. It certainly should be researched carefully for pros and cons.

The directions that you're referring to is our statement to investigate potential approaches to centralized or coordinated medication-less stewardship. And then Ken, I think you've added some clarifying language here. You want to comment on that, Ken?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Just Sasha's comment – Sasha, does that look reasonable?

Sasha TerMaat - Epic - Member

That does. Thanks, Ken.

Steven Lane - Sutter Health - Co-Chair

Terrific. All right. Good. Thank you both. And then under policy levers, we do highlight that Argonaut, USCDI, ONC for additional support – I guess this is meant to say they should provide additional support to US Core FHIR profiles for provenance and reconciliation history. That's a bit of an unclear sentence, to me, at least. I think we're saying these groups, Argonaut, ONC, USCDI, which is – what does this mean to say?

Kensaku Kawamoto - University of Utah Health - Co-Chair

I believe the intent was the US Core FHIR profiles in the FHIR domain, information on what was happening with regard to reconciliation, the fact that this medication came in from external health system B and was reconciled as the patients actually taking – all that is kind of lost right now, where it's not required to be part of what's provided in the US Core FHIR profiles. I believe that was the recommendation to say, "Hey, if we're going to do this reconciliation thing, we should actually track the results of those reconciliations and what happens." Otherwise, it has to be done over and over again.

Steven Lane - Sutter Health - Co-Chair

Okay. So, I just added a verb there in an attempt to clarify that. Is that still comfortable?

Kensaku Kawamoto - University of Utah Health - Co-Chair

So, that was a clarification. I think the question for Sasha is it seems like you're getting into NCPDP script. Can you clarify your comment a little bit more about what you think should change?

Sasha TerMaat - Epic - Member

So, I think that we were trying to clarify, when I was talking to my colleagues, what the gaps – we were referring by work on a different standard that there were perceived gaps in NCPDP. Maybe that's now the case, in which case, it might be helpful to just make that clear. We thought that the NCPDP script standards would meet the needs that were identified above for doing this type of reconciliation and didn't know if there was a perceived gap because of the suggestion to work on other standards.

Steven Lane - Sutter Health - Co-Chair

I don't know that the NCPDP script really provides the tools to clinicians to efficiently reconcile medication lists. I think that's what we're getting at is those standards are great and they're making progress, but medication reconciliation still is a major hurdle and one which is not being done sufficiently or accurately across the care spectrum. I think that's what we're getting at here.

Sasha TerMaat - Epic - Member

Sure. No standard is going to provide those tools, though. They just make sure the data is accessible.

Clement McDonald - National Library of Medicine - Member

I think through reconciliation, what we really need to get to is a total list of what they could be on. That doesn't exist. It could exist. Surescripts almost has it. Then it's easy. We did that in Washington. When you're just talking and asking and guessing, it's always going to be hard. That might need a standard.

Steven Lane - Sutter Health - Co-Chair

I think, again, our charge is to identify the standards that are in use, which I think we've done, and their implementation, and then identify opportunities for enhancement. I think what we're really getting at here is there's clearly an opportunity. I can tell you. As someone who reconciles med lists every single day, there are opportunities for better standards, better tools, better implementation. I think that's what we're getting at here.

Sasha TerMaat - Epic - Member

I think Ken's comment addresses our concern, if that works for others.

Steven Lane - Sutter Health - Co-Chair

Terrific. Any other comments on this language? I see no hands. We will proceed. Everyone is being very well-behaved today, I'll add. Our next section is on discrete structured medications, Sig information. We're on page 41. Again, we've made a number of observations, including the existence of the structured Sig task group at NCPDP. We've made some recommendations here. Sasha and Ram, you each had comments. Sasha, maybe you can comment on this. It's a long comment.

Sasha TerMaat - Epic - Member

Yeah. I think I have a grammar error in it. Sorry. So, this goes maybe to some of the policy levers or recommendations. Our software has supported discrete Sigs for some time, but it's frequently not implemented because when a healthcare organization does implement it, when they send it to a pharmacy, then they don't get back discrete Sigs in a meaningful way that incentivizes it and makes renewals easier.

So, it's like limited benefit to implement until the pharmacy echoes it back from that perspective. So, it seems to us that the most effective way to incentivize use of discrete Sigs would be to encourage the pharmacy systems to implement so that they would send it back and then providers would naturally see it as having more benefit.

Steven Lane - Sutter Health - Co-Chair

I couldn't agree more, Sasha. This is actually looking more like an observation than a recommendation, Ken.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I'll put that up top.

Steven Lane - Sutter Health - Co-Chair

Perfect.

Kensaku Kawamoto - University of Utah Health - Co-Chair

It's already up a little bit above. Can we scroll up a little bit. We had that discrete Sig information. Even when documented by prescribers, it can be lost in translation or get filled, refilled, etc. In particular, even when an EHR sends discrete Sigs, pharmacies need to turn refill requests [inaudible] [00:41:35].

Clement McDonald - National Library of Medicine - Member

Well, this is Clem. I've weighed in a couple times. I think we're going the wrong direction requiring physicians for more clicks to put in complicated discrete Sigs. There are a lot of ways to do it easier and nicer. Let pharmacy turn it into discrete things.

Steven Lane - Sutter Health - Co-Chair

Clem, you've made this point a number of times. We have captured that in the second to last bullet under recommendations, "Consider developing public good resource for converting pretext Sigs to structured Sigs, leveraging available resources such as Apache, natural language processing, etc." I don't think anyone disagrees that we want to minimize the burden on prescribers. Having said that, we want to capture and leverage and maintain and interoperate the discrete big data. We're trying to strike that balance there, Clem.

Clement McDonald - National Library of Medicine - Member

I think once you do that, the hospitals will insist doctors use it because it makes less work for the people they pay for, the pharmacists. I really think it's the wrong direction. I really don't think it's necessary. It

really helps pharmacy. Pharmacy calls if they can't figure it out. There's no safety issue with that. Now, a single TID/BID, that's only there, I think. That's a given. That's easy. When you start to get something like declining doses and all, where people want to say what they want to say, I think that's a bad idea. I'd just like to get that asserted.

Steven Lane - Sutter Health - Co-Chair

You have, Clem.

Clement McDonald - National Library of Medicine - Member

Okay.

Steven Lane - Sutter Health - Co-Chair

I think – let me see if we need an additional observation here. We definitely want to avoid undue burden on providers. As a provider that enters both simple and complex Sigs routinely and an EHR system that facilitates that and allows me to set up defaults and preferences, I can tell you it's really no big deal.

We definitely want to make sure that everyone has it be non-challenging. But the benefits, which we've attempted to call out repeatedly, are the opportunity to get dose-specific decision support to calculate total lifetime dosage, to look at dose-specific warnings and interactions, which can only be done if at some point in the process with Sig is made discrete and available for analysis and calculation. So, again, it needn't be on the backs of the entering providers. We want systems that make that as easy as possible, but getting the data still has real value.

Clement McDonald - National Library of Medicine - Member

Well, for someone who's done decision support for like 40 years, I don't think you're getting anything about drug interactions at the present time. But let me just stop. I've made my point, I think.

Kensaku Kawamoto - University of Utah Health - Co-Chair

It's been reflected now on the last bullet point there.

Clement McDonald - National Library of Medicine - Member

Okay.

Steven Lane - Sutter Health - Co-Chair

Thank you, Clem, for being such a great champion of the doc in the streets.

Clement McDonald - National Library of Medicine - Member

I think a thorn I think, but that's okay. Thank you for being patient with me.

Steven Lane - Sutter Health - Co-Chair

So, we've made a number – folks should look at the language changes that have been suggested.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Could we scroll down the screen a little bit so we can also see the changes made to the recommendation, just a little bit of a scroll down. That's perfect. Yeah.

Steven Lane - Sutter Health - Co-Chair

Any other comments on this? Great. Sasha, thank you for adding detailed suggestions.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. Steven, do you want to accept all the changes?

Steven Lane - Sutter Health - Co-Chair

I'm just going through and checking, making sure there are no concerns here. Okay. So, Sasha, do you feel like we've resolved your comment here?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes. Thank you.

Steven Lane - Sutter Health - Co-Chair

Awesome. All right. Then Rahm, you had mentioned the task group and we had captured that before. Thank you for that. All right. Sasha, you had a comment at the end of this recommendation. The recommendation was for Argonaut to provide additional support to the US Core FHIR profiles. I think this was the thing we already talked about. Are you comfortable with this?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Isn't the last bullet point already assumed by the one above it? I'm trying to see what the fifth bullet has that the fourth bullet doesn't have.

Sasha TerMaat - Epic - Member

I agree with that point and that might help clarify the confusion that we saw in the fifth bullet.

Steven Lane - Sutter Health - Co-Chair

Okay. We can just get rid of the fifth bullet and go like. Is everybody comfortable with that?

Kensaku Kawamoto - University of Utah Health - Co-Chair

And just a small minor note, Sasha, up top where we said pharmacies can provide users incentive to provide structured Sig, I just said better incentivized because there may be other incentives already. It's easier to click over to the default structure adoption.

Sasha TerMaat - Epic - Member

That's a great point. Thank you.

Steven Lane - Sutter Health - Co-Chair

On the next section, medication administration and dispensing history, there's a comment from Ram on the wording – dispense versus dispensing. Is there one word that's used more commonly? Either one seems fine to me.

Clement McDonald - National Library of Medicine - Member

Isn't the purpose here to facilitate de-duplication? It's a mess when you get all these.

Kensaku Kawamoto - University of Utah Health - Co-Chair

The purpose of this part, Clem, is that we all – in addition to what we prescribed, we want to make sure we know what actually was administered or dispensed.

Steven Lane - Sutter Health - Co-Chair

And I can tell you when you've got this data, it's fabulous. It really is a huge benefit. So, again, just the wording – dispense versus dispensing. If no one objects, we'll take Ram's suggestion.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Sure.

Steven Lane - Sutter Health - Co-Chair

Okay. Great. Very good. We're working cross-purposes there. So, we've got a number of observations and recommendations. Sasha, you had a suggestion about the recommendations. We aren't talking about a certification condition here, just a criterion. It still already exists in the eRx criterion. So, I don't know that the first half of this is relevant.

Clement McDonald - National Library of Medicine - Member

Can I just add a twist. Is a dispensing history going to be separate from the prescription list or the order list or a flag on it? I think it's going to be –

Steven Lane - Sutter Health - Co-Chair

I think the idea, the way I think about it is that for any given medication on the patient's list, current or historical, you can go back and look at when it was dispensed at the pharmacy and/or administered in the hospital or home care setting.

Clement McDonald - National Library of Medicine - Member

All right. Ignore what I said. That's clear.

Sasha TerMaat - Epic - Member

So, a couple thoughts – first of all, it said an EHR condition of certification before and it wasn't a condition of certification, which has, I think, already been corrected. However, I do believe the Rx fill component of the NCPDP certification already includes this in certification. So, I think the challenges are around implementation and uses with pharmacies. I don't think the certification piece is a gap.

But if someone wants to clarify how it is a gap, I need more details. It is accurate that it's not part of promoting interoperability to do it, though, I don't know that that's a correct component because it's not so much under the control of the participants in promoting interoperability, the providers. As far as I understand it, the ability to receive Rx fill is there. I guess the question is whether it happens falls, in my understanding, to the pharmacy and the network.

Steven Lane - Sutter Health - Co-Chair

So, shifting this to be a recommendation to require this of the pharmacies.

Sasha TerMaat - Epic - Member

That is my perception of the current gap, unless I'm misunderstanding.

Steven Lane - Sutter Health - Co-Chair

No, I think you've got as much knowledge of this as anyone on the call. So, we're going to go with your suggestion. Ken is really good at doing this real time editing to capture people's comments.

Sasha TerMaat - Epic - Member

That looks good, Ken.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay.

Steven Lane - Sutter Health - Co-Chair

I would separate those out, Ken. The first one is on the pharmacies and the second one is on EHR.

Kensaku Kawamoto - University of Utah Health - Co-Chair

This part is EHRs, right? So, the first phase is for the EHRs to be able to query for and make use of it. The second phrase – so, it's EHR, pharmacy, EHR. If we want to separate it, we should separate it like this.

Steven Lane - Sutter Health - Co-Chair

Clem, you can go on mute, perhaps. Thanks. I think Sasha, your point was the EHRs are already required to do this.

Sasha TerMaat - Epic - Member

Yes.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Clem, your mic is unmuted. Does this work? If we're sure it's not there, we can delete it.

Steven Lane - Sutter Health - Co-Chair

I think what you're saying, Sasha, is that bullet three isn't required because that is already in there.

Sasha TerMaat - Epic - Member

I think if we want to preserve the context we discussed, we can keep bullet three, but really, it seems extraneous to me because the Rx fill component of the current e-prescribing certification includes it. The real thing we need is the new bullet four.

Steven Lane - Sutter Health - Co-Chair

Okay. I don't think there's any harm in leaving that in. Are you comfortable with that, Sasha?

Sasha TerMaat - Epic - Member

Yes.

Steven Lane - Sutter Health - Co-Chair

Wonderful. Okay. Let's go down to your question about PDMP data. What did we mean there? So, again, we're talking about medication administration dispense history. I think what we're talking about is that this should also apply to controlled medication and the data that is maintained in PDMPs, which today, in my state, I can see past dispense data in the PDMP, but that may not be universally available. I think, Ken, that's what you were getting at. I think you introduced this bullet.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I don't believe exactly the history, but I believe the idea here was when we talk about dispensation and administration history, that includes PDMP data for controlled substances.

Steven Lane - Sutter Health - Co-Chair

So, just so I understand, the PDMP should also be a recipient of that data from the pharmacy or the PDMP should also supply that data to EHRs?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. So, when we query a source of – so, the intent here is just like we can query pharmacies or pharmacy benefit managers to get dispense info, we should also be able to query a PDMP to get their data with the caveat that it has to be allowed by state regulation.

Sasha TerMaat - Epic - Member

Yeah. Maybe we could clarify and just say that PDMPs should also be queryable as a source of administration and dispense data.

David McCallie - Individual - Member

This is David. Just a slight pick on that. The PDMP structure is kind of an artifact of the way we do things today. The goal here is to get dispense information about controlled substances. I don't know that we would want to require that the PDMP approach be the future, necessarily.

Kensaku Kawamoto - University of Utah Health - Co-Chair

No. It's just saying if it's there, we should be able to access it.

David McCallie - Individual - Member

Just make it clear that the goal is dispense information should include the controlled substances. If the physician has to go to look two different places and try every time in two different places, that's going to be an undue burden.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Similarly, pharmacies, other sources of controlled substance data, pharmacy benefit managers should also enable this data to be queryable, where allowed by relevant – or which they were not prohibited. Is queryable a word?

David McCallie - Individual - Member

I think so.

Steven Lane - Sutter Health - Co-Chair

I think we've made it one. I think it's understandable. Does this work, David, Sasha?

Sasha TerMaat - Epic - Member

It works for me. Thank you.

David McCallie - Individual - Member

Yeah. I think it's wordy, but I think it's got the spirit right. So, I'm fine.

Steven Lane - Sutter Health - Co-Chair

All right. Anything else on medication administration and dispense history? Great. I want to really congratulate folks. This is going very well today. The next section is on translation and mapping between RxNorm and MDC codes. This is an area that David and Ricky spent a lot of time thinking about and helping us to evolve our language.

I don't see any comments, but I just wanted to give people a chance to appreciate their fine work and see if there's any feedback on this. Great. I want to, again, invite the public, who are listening in, if you want to chime in, feel free in the chat box. It's been very quiet today, but you're welcome to join the discussion.

All right. That brings us to the end of what we considered our tier one, medication and pharmacy recommendations and now, we'll go on to tier two, where the first thing we tackle, again, specific to medication and pharmacy data is provenance. Jack, you jumped in with a comment here. Is that something you wanted to take up now? Okay. Ken, don't we have provenance called out as a cross-domain issue already?

Kensaku Kawamoto - University of Utah Health - Co-Chair

I don't know if we do, actually. I don't think we do, actually. We do not, I don't think. We do have specific discussions of provenance in other sections. In particular, I believe in orders and results, we have it. We have results exchanged between HIT systems that may not include sufficient provenance metadata and in medications, we talk about provenance here. I don't know. We could try.

David McCallie - Individual - Member

What's the question? I lost the –

Steven Lane - Sutter Health - Co-Chair

The question is whether we should call out provenance as a cross-domain issue. I think it really does vary by data type and the observations that we've made were very specific to the data type. I don't object to the way we have it split up presently. There are a number of things we address in different sections.

David McCallie - Individual - Member

That seems okay.

Clement McDonald - National Library of Medicine - Member

Are you responding to Jack Po's comments?

Steven Lane - Sutter Health - Co-Chair

We're trying.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Trying to.

Clement McDonald - National Library of Medicine - Member

He's right in the hospital, if you take it as a history, you can't get all that. We should recognize that.

David McCallie - Individual - Member

But that doesn't rule out that if it's an electronic exchange and that information is available, that it should be a part of the standard.

Clement McDonald - National Library of Medicine - Member

We should make that clear, though.

David McCallie - Individual - Member

Sure. If the patient gives you a straight history, that's the best you can do. The provenance is by history.

Clement McDonald - National Library of Medicine - Member

Well, it doesn't say that. That's all I worry about. I think he's got a point. I think it may create tangles and knots for these developers.

Steven Lane - Sutter Health - Co-Chair

I think what you're getting at, Clem, is the idea that patient-reported data, the fact that I know this because the patient told me, is that item should ideally be captured and transmitted with the data, here again, getting back to your earlier point, which is without creating undue burden on the clinicians that are capturing the data.

I know the system I use does have a function where for patient reported data, that is captured and it's maintained and it's done fairly automatically. When the patient, for example, comes on the portal and

says, “Oh, I’m really taking this medication,” that is captured. I think that’s what we’re talking about is if that data is captured, it should be maintained and transmitted.

Ram Sriram - National Institute of Standards and Technology - Member

I agree.

David McCallie - Individual - Member

Or said a different way, patient reporting is a kind of provenance. That is the provenance of that particular item.

Clement McDonald - National Library of Medicine - Member

I still think you ought to make some distinction in the wording. This becomes regulatory or encouragement, it will be misinterpreted by some.

Kensaku Kawamoto - University of Utah Health - Co-Chair

What about this, if we say we’re already collected and available? We’re not asking now when the patient says, “I’m taking this,” to have to integrate them to say, “Where was it first prescribed? Who was the prescriber?” It’s just saying where already collected and available. How’s that?

Clement McDonald - National Library of Medicine - Member

That’s good.

Steven Lane - Sutter Health - Co-Chair

Also, I’ll note that I think Terry O’Malley, who helps to Co-Chair the USCDI Task Force is on the call with us. There’s been a lot of discussion in that task force about what are the components of provenance and how should they be captured and transmitted? I think there’s a nice overlap here. Of course, both of those task forces lead up to ONC, who often is in a position to make the rules. This is a good addition.

Clement McDonald - National Library of Medicine - Member

Well, also, be aware – there’s a full definition of provenance in WC3, which is very sophisticated.

Steven Lane - Sutter Health - Co-Chair

WC3, what is that?

Clement McDonald - National Library of Medicine - Member

That’s the internet task force.

David McCallie - Individual - Member

World Wide Web Consortium. It’s probably overkill.

Clement McDonald - National Library of Medicine - Member

No, it is, I think. But just be aware. It’s lurking.

Terrence O'Malley - Massachusetts General Hospital - Member

This is Terry. I think Sasha made a recommendation at USCDI that we recommend that patient provided data be able to be marked as a provenance. So, it's not called out in the initial recommendations. So, it's sort of in the wings.

Steven Lane - Sutter Health - Co-Chair

I think of that in relation to allergy data in particular. So many times, we capture and document an allergy based on a patient report. Occasionally, we actually will see an allergic reaction. At least the system that I use does not allow you to clarify that. Seen by a clinician, though, if it's reported by the patient – I think that would be a nice addition.

Kensaku Kawamoto - University of Utah Health - Co-Chair

And then Sasha had a comment about whether medications could be modified by anyone other than the prescriber. I don't know if you want to comment further on it, but I agree with your comment.

Sasha TerMaat - Epic - Member

Sure. So, my colleagues and I were just worried that if it were expected that recipients obey an obligation to not modify a medication, it would have really significant workflow implications. You couldn't refill it, update it with information about how the patient is actually taking it. That seems bad, from my perspective, when it sounds like you agree, Ken. I don't know if we had really seriously considered that.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I don't think it's typically in there anyway and if we know who the original prescriber was, then that oftentimes clinically can look at it and say, "Oh, okay, this is a cardiology medication prescribed by the cardiologist. They have an appointment coming up. We should just have them manage it." This isn't something that's typically captured anyway, right? That would violate also our requirement to not ask people to collect things they're not already collecting.

David McCallie - Individual - Member

No one, I don't think, provenance constrains what you do in the future. It's just information about how you got to where you are. I can't imagine anyone would interpret it as constraining what you can do in the future.

Kensaku Kawamoto - University of Utah Health - Co-Chair

That is what we had suggested. So, I think we should delete it.

Steven Lane - Sutter Health - Co-Chair

I agree. I think that would be dangerous. If you think about practice, I'm always changing the Sigs that someone else prescribed. That's routine. If you maintain the provenance of the prescription and you can see it's been originally prescribed in such and such a way and now, it's been taken in another way, that's helpful. I think we've captured that.

David McCallie - Individual - Member

In my mind's eye, that's what you want is a linked set of steps that got you from some starting point to where you are now so that you can make decisions about how to proceed. That's what provenance tracks, the handoff of a particular piece of something between parties over time. That may be overkill for what we can do with prescription standards, but that's sort of the long-term goal. I should know the history of this intervention in the patient and how it came to my attention.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. I think that change history would be nice if it's already captured, right?

David McCallie - Individual - Member

Yeah. If the systems are handing off data, it should be fairly straightforward to say, "This is what I got. I'll track it. Now, you change it if you need to, provider." We're going too deep here.

Clement McDonald - National Library of Medicine - Member

I was going to say that. We're going to make a complicated thing and we don't really have the time or maybe the expertise to develop this huge thing we're talking about.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I'll just note this change history is, for example, in our EHR, in FHR, it will tell you if you originally started with a prescription and updated, it will tell you the original one is this and this is the current one and the dose has been increased. I don't think we're being theoretical here to say if it's available, it would be good to have change history.

David McCallie - Individual - Member

I agree. The thought here is a standard that would allow that kind of data, which all the EHRs capture internally to be handed off across an interface so that we don't lose it. But anyway, we're too deep for this discussion. The key point is registered. It's a benefit to know the history of evolution of a particular prescription called provenance.

Steven Lane - Sutter Health - Co-Chair

So, I wonder how this relates to the true out of pocket cost. Maintaining this history of the provenance is important, but do we need a history of the costs related to a medication? I think this is more a history of the medication itself. I would suggest we could take out this piece.

David McCallie - Individual - Member

I would agree. Take that out.

Steven Lane - Sutter Health - Co-Chair

All right. So, anybody have any persistent suggestions, further suggestions? I think we've made a number of useful changes here.

Cynthia Fisher - WaterRev, LLC - Member

This is Cynthia. I'm sorry. I can't raise my hand. I'm just on my phone now. I would just like to add to give the option to see the price trail. If someone was paying X for insulin and then it all of a sudden

went up to 5X, having a provenance of having the history of not just out-of-pocket – again, the total cost – and this is really important because the only way employees and employers and people can drive down their coverage and their premium is through them being empowered with transparency of knowing the real prices that they have paid and they are paying. So, if that information is there, having the provenance of that is very helpful to being able to have a voice.

Steven Lane - Sutter Health - Co-Chair

I can appreciate that it would be helpful. I think we are a long way from there.

David McCallie - Individual - Member

Yeah. It's going to build an infrastructure that you can't afford to build. You've got to get started with the simple stuff.

Kensaku Kawamoto - University of Utah Health - Co-Chair

We have a fill history.

Cynthia Fisher - WaterRev, LLC - Member

Not necessarily. If your billing history is there, it's sort of like having a receipt from your restaurant. The hospital has it. They have the billing history. I think this information exists. It's a matter of having options. I'd just like to flag the option for consumer empowerment.

Steven Lane - Sutter Health - Co-Chair

So, Ken added that. I like the way you did that Ken. We're talking about data where already collected and available. He added parenthetically including costs. I think that captures it sufficiently.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. For example, this kind of data, I know as long as – in some cases, we have this data. It's available. Because we have the caveat, again, we're saying potentially include where already collected and available, I think there's little harm in something that says potentially include where already included and available and include things that should be considered. This is almost like a parking lot item.

Steven Lane - Sutter Health - Co-Chair

Any further comments on this. Great. Okay. That was provenance. We're going on, remembering that we're in our tier two issues for medication and for data. Going on to prescription drug monitoring program data, we actually have kind of two items here, which have to do with PDMP. The first is highlighting the fact that access to PDMP data can be cost-prohibitive. That has been suggested through observations and recommendations.

Cynthia, you've had a comment here on the recommendation. The recommendation was to streamline PDMP regulation across states, for example, via federal regulation or perhaps model straight regulation and I think your comment was that this is a non-starter.

David McCallie - Individual - Member

Unfortunately, that may apply to more than one policy recommendation that we have in here.

Steven Lane - Sutter Health - Co-Chair

Cynthia, do you want to comment on this?

Cynthia Fisher - WaterRev, LLC - Member

Hang on just one minute. I just think that we need to just look at the empowerment of a federal trumping stage regulation. We can come back to it. Does anybody else have any comments?

Steven Lane - Sutter Health - Co-Chair

The way we phrased it is we recommend streamlining of PDMP regulations across state, for example, via federal regulation or perhaps model state regulation. So, that's not too strident, I don't think. I think your comment acknowledges the challenges that have been faced and the history of the PDMP regs, but is there anything about the recommendation itself that is either faulty or in need of clarification.

Cynthia Fisher - WaterRev, LLC - Member

I'll just leave it. I just think it's a big reach.

Steven Lane - Sutter Health - Co-Chair

Denise Webb also said that she agreed to trying to get federal regulations to change would be very difficult.

Kensaku Kawamoto - University of Utah Health - Co-Chair

So, I guess the question is what we want to change.

Steven Lane - Sutter Health - Co-Chair

Ken, wouldn't we want to put that down under a policy lever?

Kensaku Kawamoto - University of Utah Health - Co-Chair

These are approaches.

Steven Lane - Sutter Health - Co-Chair

Maybe down at the bottom there. Yeah.

Kensaku Kawamoto - University of Utah Health - Co-Chair

If feasible, streamline unified regulations in this area and then CDC, SAMHSA grants, incentivize... How's that? I think the operative word is, "Providing, if feasible..."

Steven Lane - Sutter Health - Co-Chair

That looks great.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Then there was a separate comment from Sasha of why it would become cheaper if providing access to PDMP data at low cost directly through state PDMPs. My understanding is it's because then you just

get it directly from the source rather than going through the vendor that acts as the middleman here and charges fairly high fees.

Sasha TerMaat - Epic - Member

It seems like a strange approach to develop a standard to solve that policy problem. I don't know.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Well, ONC is already working on this. I don't know if anybody who's working on it could comment. But the idea here is, as I understand it, there is no current open standard to do this and you basically have to go through the vendors.

Sasha TerMaat - Epic - Member

I guess our feeling was that NCPDP provides a standard that might be appropriate to do this. If it's not widely supported, then it seems like our recommendation would be low-cost, widespread support for the existing standard. If we see a gap in what NCPDP would provide with exchanging and accessing PDMP data for history of medications and so forth, then I could see recommending standards work, but I guess that was the background.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. This sort of relates to – if Ricky's on, he could comment as well, maybe Jack – the idea here was – we have a high-level on this as well – when there are multiple different, I guess, tracks of standards that could do this, it's an issue, right? So, for example, if we could get lab data through HL7 Version 2 messages or what not or CDAs, does it mean we should not support it in FHIR? I sort of view it similarly here. I think it's a good point to say if there are other non-FHIR-based standards that support it, we need to call that out, but I think it's also the case that having a non-FHIR-based way to get some data doesn't necessarily mean that we should not build it into FHIR.

Sasha TerMaat - Epic - Member

Yeah. I think it would be appropriate to recognize both standards. Then if we have a separate concern about cost, I think I would just break that out from the standards. We think there is an appropriate standard for this today. FHIR might also be an appropriate standard with further work. There's a pilot. Third, we have, independent of standards, concern about the cost.

Clement McDonald - National Library of Medicine - Member

Well, it's not totally independent of standards if there's no field to send it, it's not going to happen. You've got to have a place for it if you're going to do it.

Kensaku Kawamoto - University of Utah Health - Co-Chair

David has his hand up.

David McCallie - Individual - Member

Just zoom out and help me with my ignorance – is there PDMP data that's relevant above and beyond the kinds of dispensing and provenance data that we've already been talking about? My naïve assumption was that the PDMP part is simply because it's restricted data by state laws but that

otherwise, existing standards ought to be adequate if you could just use them. Is there additional data that's not covered in the current standards?

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think the data is there. A big part of this particular PDMP focus is regulation and cost. So, there are regulations that say, for example, you may not bring in the actual data into the EHR and there are cost issues where it can be fairly expensive to try to get access to this data.

David McCallie - Individual - Member

But my point is that it's the same data that we are getting for not restricted drugs and the artifact of these expensive middlemen is a regulatory artifact, not a standards gap. To Sasha's point, why aren't we just using existing standards or the ones that we've called to be enhanced as above.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I believe there are also some state regulations that require you to go through the PDMP.

David McCallie - Individual - Member

That may be. That's a regulatory gap, not a standards gap. I'm saying the standard – why do we need a new PDMP standard?

Clement McDonald - National Library of Medicine - Member

Well, let's clarify – are we saying we should not make it in FHIR, which is sort of the direction everything is going?

David McCallie - Individual - Member

No. But it isn't where we get prescription fill information, dispensing information. No one is suggesting that we rip all the NCPDP out and replace it with FHIR.

Clement McDonald - National Library of Medicine - Member

Well, that actually has been hinted.

David McCallie - Individual - Member

Well, sure. Maybe someday, we'll rip out D2, HL7 also, but probably not a high priority.

Clement McDonald - National Library of Medicine - Member

Okay. But we have to be thinking about it. There's no reason NCPDP could send their stuff in a FHIR structure.

David McCallie - Individual - Member

Yeah. I thought Sasha's point was we may not need a new standard here. We just need to clarify regulatory access using the existing standards. We've created this artifact of middlemen who are exploiting the regulatory complexity, but we don't need a new standard for that, I don't think. I don't know. Over my head.

Steven Lane - Sutter Health - Co-Chair

So, please, everybody, take a look at what we have here. Perhaps, if we can scroll up a tiny bit, we can see the full section on the screen. That would be good. How do folks feel about the language as it's presented?

Sasha TerMaat - Epic - Member

Just watching what the rest of Ken is adding.

Kensaku Kawamoto - University of Utah Health - Co-Chair

This is addressing David's comment.

Sasha TerMaat - Epic - Member

I think this is clearer now. I like the edits that have just been made.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think we're getting pretty close to public comment time, I believe. But we have a few minutes.

Steven Lane - Sutter Health - Co-Chair

Okay. Public comment is at 11:45. We've got time. So, that was PDMP data. I'm seeing no hands. We will proceed to the next PDMP item, PDMP query and reporting transactions. Here again, we have some observations. Sasha, you had a comment here.

Sasha TerMaat - Epic - Member

So, I think this may have been edited since I made the comment. There's a distinction between getting the information from the PDMP and reporting back to the PDMP. I think I was trying to draw that in the comment. For example, NCPDP provides the ability to get the medication history, which we just were talking about, but if you have to report back to the PDMP that certain things were reviewed or certain actions were taken, that isn't necessarily reported.

So, I think the question is when we say here prescribers report to PDMPs, in most cases, it's actually the pharmacy that sends the medication data to the PDMP. The prescriber gets information from the PDMP to see the med history. So, I was saying our thought is what prescribers report to the PDMP like I review this, that's not actually supported by NCPDP. If our thought is we're really talking about the initial reporting of the medications, then it's actually happening from the pharmacy to the PDMP in most states, not from the provider.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. So, should we basically delete this one and edit yours?

Sasha TerMaat - Epic - Member

Yeah. I think we [inaudible] [01:28:23] this as an important distinction piece if we're rewriting. And then in the next one, we could probably just narrow it like...

Kensaku Kawamoto - University of Utah Health - Co-Chair

How's that?

Sasha TerMaat - Epic - Member

I think that looks good.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Recommendations – we need to probably update recommendations, right?

Sasha TerMaat - Epic - Member

Oh, good point. Yes. And then the second recommendation, I think, exists with NCPDP, which is what we mentioned earlier.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. Do we not this because it already exists?

Sasha TerMaat - Epic - Member

I think it exists with NCPDP, but if there are gaps we discussed, we could clarify what they are.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think this is good.

Steven Lane - Sutter Health - Co-Chair

All right. Anyone have any further comments on the suggested changes? We will go ahead and accept those and move on. The next section has to do with the detection of adverse drug events, an area that we've spent some time reviewing. We have some comments here from Sasha.

Sasha TerMaat - Epic - Member

Yeah. So, our first bullet point recognizes that health organizations routinely do this in another system, but then some of our recommendations seem to imply it's desirable to more of this into health IT, like the electronic health record. My comment, I guess, just calls out some of the considerations for why that doesn't happen today. There are protections afforded to healthcare organizations to encourage reporting without punitive consequences to a patient safety organization.

So, the best practice for doing that is to use a risk management information system because that helps take advantage of the protections offered for PSO reporting in a very specific way, incorporating and reporting directly from the electronic health record would not offer the healthcare organization the same protections. So, I think we need to kind of reconcile that with our recommendations.

Steven Lane - Sutter Health - Co-Chair

I think that this whole thread of our discussion came out of an acknowledgement that the current processes are probably capturing only a small fraction of the adverse drug events that actually occur and that many of these could be identified in a more automated way to allow for more comprehensive reporting, management, and ideally prevention of adverse drug events.

So, I think that we are, in our discussion, challenging the current state and the relative lack of transparency that exists out of an understandable desire to avoid liability. I think it gets in the way of us actually wrapping our arms fully around the patient safety issues here. That's what we were trying to get at.

Sasha TerMaat - Epic - Member

We have some of the bullet points that certainly recognize that, like new approaches to address the liability concerns, for example. I think the piece that maybe was missing was maybe the current role of a risk management information system.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. So, if we add it. If we do the addition below where it says instead of saying we will communicate to FDA, we say relevant entities such as PFOs. It doesn't preclude the FDA, but it also explicitly allows – your main point, Sasha, is yeah, if it goes directly to FDA versus PSO approach, basically, it's saying let's not disincentivize people from reporting things because they think they're going to be punished for it.

Sasha TerMaat - Epic - Member

Right. As we do things like this vision of one-click adverse event reporting, the documentation that goes into that one-click adverse event reporting, healthcare organizations will want that to be protected and if it's in the EHR, it may not be extended those protections. I think that's kind of the balance that has to come up.

Either that is dependent on some of the policy clarifications we request later, like make sure the current protections are extended to those types of workflows or that that flow is actually interoperability between an electronic health record and a risk management information system so that the analysis and reporting is also still part of the protected records, even though it may originate from documentation in the medical record.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think the updated wording addresses these. Can you take a look and see if it does? I also made updates below.

Sasha TerMaat - Epic - Member

I'm reading the updates. Those look good to me, Ken. Thanks.

Steven Lane - Sutter Health - Co-Chair

Other comments. Very helpful observations. Thank you, Sasha.

Cynthia Fisher - WaterRev, LLC - Member

Steve, I have my hand up.

Steven Lane - Sutter Health - Co-Chair

Now I see it. Thank you, Cynthia. Go ahead.

Cynthia Fisher - WaterRev, LLC - Member

I have a concern about the adverse events being reported outside of the EHR and not in the EHR itself. Let me give you a specific example of a penicillin family of drugs allergic reaction that take place in a patient within a known system healthcare provider, major hospital system and is administered, even with the family advising that the children – now an adult – the local children’s hospital has the adverse event reporting from previous allergic reactions and the list of drugs that were acceptable to that patient, tolerable, not able to be obtained in emergency situations.

The patient then is administered a penicillin family of drugs. It’s not put in the EHR. Then a second round, a second round is tried. Anaphylaxis takes place. That’s not reported in EHR. Then a second drug is administered also within the penicillin family. So, one is you can prevent by having that allergic reaction to penicillin shared across EHRs. The very problem of interoperability was just exemplified by a patient that reported to us.

Then two, while in house, two adverse events that were caused even though the patient disclosed that they were allergic to penicillin. None of that was found in the EHR in their portal, noting there was allergic reaction to adverse events that caused complications. So, how do we – this is really critical patient information. Multiple hits at an error and avoidance of information doesn’t make for a positive response. How do we remedy that? My concern is this language seems to protect the hospitals from liability.

Kensaku Kawamoto - University of Utah Health - Co-Chair

If you can see what I typed in, I updated the observations so they note that in any case, any allergies to medication should be separately documented in the EHR. I think that’s common best practice. If someone is anaphylactically allergic to penicillin and somebody doesn’t record into the EHR, that is no way what we’re recommending here. That’s crazy.

Steven Lane - Sutter Health - Co-Chair

But I think that Cynthia makes a good point that allergies are a special case of adverse drug events and as we’ve discussed and as you highlight here, there are standards for documenting and reporting and interoperating allergy data that are not new.

Sasha TerMaat - Epic - Member

I think we should show the difference between allergies and contraindications, which would have an important place in a patient’s record. I think we all agree those should absolutely be in the EHR and shared between systems interoperably. From information that might go into a PSO report like the root cause analysis that would be separate and not as related to the patient’s medical record, specifically.

Kensaku Kawamoto - University of Utah Health - Co-Chair

We’ve updated the text to reflect that. It’s a good point. I certainly had no intention that this meant you don’t actually document an allergy because that would be just bad.

Cynthia Fisher - WaterRev, LLC - Member

Okay. Thank. What about documenting adverse drug events with the patient as well to root cause? It could be the adverse event of two-drug interactions. For instance, let me give you one – if the administration of morphine and vancomycin in a very short time duration, if they're both pushed in an ER setting and you don't know if the event of response – I forget what you call it, where the head feels like it's on fire, but the adverse response you don't know if it's related to the morphine or it's related to the vancomycin or related to the two administered together to short and too intensely.

I've understood this from a couple of heads of ERs that this is something that can happen and it takes vancomycin out of your arsenal when it was how it was administered along with morphine.

Steven Lane - Sutter Health - Co-Chair

Thank you, Cynthia. That's a very true clinical observation. We are closing in on our public comment time. We have three more items here in the section we want to review quickly. Thankfully, only one of them has any comment. So, just quickly, we've got medication prior authorization as a medical benefit that we've called out with some observations and recommendations that seem to be non-controversial. I'll just pause there to ensure that there's nothing we're missing there.

Then the next section where there were some comments is medication information, where we have made a number of observations and Sasha, you had some comments on our recommendations. We can maybe start this and then we'll pop over to public comment and come back.

Sasha TerMaat - Epic - Member

My colleagues and I were just commenting on the recommendation to consider using ICD-10 for exchange of indications. If there's an associated diagnosis for a prescription, then ICD-10 would be an appropriate way to convey the diagnosis, but if the indication is taken for pain, ICD-10 is not going to be an applicable standard for that. I didn't know we should update our language to capture diagnosis or not be thinking about ICD as the real standard here.

Steven Lane - Sutter Health - Co-Chair

Ken just captured some additional language here sort of differentiating that. Sometimes, as you say, ICD-10 is perfectly appropriate and other times something more pretext might be preferred.

Clement McDonald - National Library of Medicine - Member

I'm worried, again, about more clicking. First of all, certain drugs, the indication is sort of implied pretty much absolutely. If you're going to have an indication and a diagnosis, it's just going to take physicians more time.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Clem, due to that, we have the second from the bottom bullet point, where we said new requirements should be informed by the desire to avoid undue provider burden related to capturing this data. I think the tension here is we're thinking this does provide value to know why something was prescribed but we also don't want it to become an undue burden.

Clement McDonald - National Library of Medicine - Member

It's a slippery slope. Once it's written down, you've got to do it. People will think this is absolutely important and doctors are heinous beasts for not recording it and they better, by golly, do it. One, I always used to write it as part of the Sig for diabetes. That's not going to be allowed.

Steven Lane - Sutter Health - Co-Chair

So, let's pause for public comment here and we'll come back to this discussion.

Lisa-Nicole Sarnowski - Office of the National Coordinator for Health Information Technology- Acting Designated Federal Officer

Thank you. It is now time for the public comment portion of our agenda. We will now open up the meeting for public comment. Operator, can you please open the public line for comment?

Operator

Thank you. If you would like to make a public comment, please press star-one on your telephone keypad and a confirmation tone will indicate your line is in the queue. You may press star-two 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 key.

Steven Lane - Sutter Health - Co-Chair

Do we have any public comments in the queue?

Operator

There are no public comments at this time.

Steven Lane - Sutter Health - Co-Chair

Thank you very much. Do let us know if some public comments pop up. Let's go back to the discussion then. Clem was very appropriately identifying the challenges of potential provider burden, if there's a requirement for documentation of the indication for medication. I think here, again, this is one of those things kind of similar to the discrete Sig, where EHR vendors could provide functionality to standardize this.

If the endocrinologist is always prescribing metformin for diabetes frequently and a gynecologist is frequently prescribing metformin for polycystic ovary syndrome, then that can be captured and thus reducing the burden. However, the reason that a medication has been prescribed can be very valuable to the patient, to their caregivers, to the pharmacy, for them providing counseling and to other providers downstream who may be receiving that data, home care, etc.

So, like you, Clem, for my entire career, I've been capturing this data, whether we do it in Sig, whether we do it as associated indication or diagnosis, there are all sorts of different ways to do it. What we have endeavored to call out in our regulation is that this is valuable data. It's valuable data to capture. It's valuable data to interoperate, especially for the patient who's receiving the medication. So, we want to do that with an acknowledgement of the various ways it might be captured as well as the need to avoid burden.

Kensaku Kawamoto - University of Utah Health - Co-Chair

David has his hand up too. Maybe we can do David and then Clem. David?

David McCallie - Individual - Member

You've got the point about the research that's ongoing on the topic up in the observation, but you cast it as a recommendation. I would suggest maybe move that into the recommendation, the last bullet point there. I think the tradeoff there between value gained and burden on clinician is something that you have to go study. Work is being done to do that.

Clement McDonald - National Library of Medicine - Member

I didn't see that comment, but that's a good one.

David McCallie - Individual - Member

The last bullet in observation. It's the Gordy Schiff work that I mentioned in one of our previous calls, AHRQ grant.

Kensaku Kawamoto - University of Utah Health - Co-Chair

You're saying bring that into the recommendation?

David McCallie - Individual - Member

Yeah. It is a recommendation, the way it's written. I would suggest moving it in. Take that study into account. That will help clarify the value.

Clement McDonald - National Library of Medicine - Member

That's a good idea. I think if you gave opportunities to do a free text and then use a study because it may turn out that it's always implicit and there's hardly any new information passed by it. You've got to visit diagnosis.

David McCallie - Individual - Member

Gordy Schiff would disagree violently with you. I've had this conversation with him. It's worth a study.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Again, I don't think we have time to resolve how this should all shake down. I think we just have time to state that it should be looked at. I think we are in agreement that having the reason that a medication is prescribed would be a good thing. We also agree that we don't want this to be burdensome. I think we have the right balance here where we say we should consider standards and at the same time, avoid undue provider burden.

I can imagine a case where for common medications an EHR might provide, you're giving lisinopril. Here are the two, three main reasons why you do it. You can click on one of them. Or if you want to put something in free text, you could. I think it's not for us to decide right now. I think it's for us to recommend that work be done.

Clement McDonald - National Library of Medicine - Member

All right. I'm okay with that.

Steven Lane - Sutter Health - Co-Chair

And Sasha, do you feel comfortable with the language change that's been made here?

Sasha TerMaat - Epic - Member

Yes. Thank you.

Steven Lane - Sutter Health - Co-Chair

All right. Well, I want to acknowledge that we got to the end of our three sections of recommendations. As I said, there were some comments that have been entered in the first two sections that we are going to come back to when we meet on Friday. At the end here, we have two final sections that are rather brief. One was drafted by Terry O'Malley regarding continuation of the functions performed by the ISP Task Force, which I think was nicely phrased. If folks haven't had the time, I'll just give you a moment to look at those.

And then our last few paragraphs are phrased or presented as the conclusion, clarifying that there were three areas that we focused on in our report. We kept this patient centric. I then added some additional language here about the discussion that we had about trying to reach out to the FDA and identify opportunities for collaboration and coordination.

Interestingly, the FDA just recently made some announcements about their desire to collaborate with the ONC among others to improve interoperability. So, I think I was just attempting to acknowledge that. Then Sasha, I think you made the good point that this isn't so much a conclusion as it is sort of a next step. Perhaps it goes under the section before.

Sasha TerMaat - Epic - Member

With the next steps section in six, it would seem like some of the language in the conclusion might better belong there. Even the second paragraph about additional areas that didn't have time to be explored might belong nicely in the continuation section, keeping the conclusion more about the summary of the work that was able to be performed.

Steven Lane - Sutter Health - Co-Chair

Moving those last two paragraphs to the section above, do you think?

Sasha TerMaat - Epic - Member

That works nicely, from my perspective.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Steven, do you want to move it?

Steven Lane - Sutter Health - Co-Chair

Yeah. I'm just thinking about the logic of – paragraph three, for sure. Let's move that. Paragraph two does sort of follow on paragraph one. So, I'm just thinking whether that should move as well.

Kensaku Kawamoto - University of Utah Health - Co-Chair

We can put the second paragraph at the very bottom right before conclusions. Maybe we just leave that in conclusions. Maybe we just add a sentence right after it, “We recommend that these that work on additional priorities...” I feel like it’s kind of generic and gets the point across. We worked on three things and we still have three more things we think someone should work on.

Steven Lane - Sutter Health - Co-Chair

I have a thought. We can move the conclusion up above the continuation. The continuation is what comes after we make our conclusions. That might put it into a better order.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Maybe we’ve got summary and conclusion.

Steven Lane - Sutter Health - Co-Chair

Okay. Yeah.

Kensaku Kawamoto - University of Utah Health - Co-Chair

If you go up, I moved it up top.

Steven Lane - Sutter Health - Co-Chair

Does that feel like we’ve got the order correct?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. I like it.

Steven Lane - Sutter Health - Co-Chair

All right. So, we don’t mind ending a few minutes early. Again, I want to thank everyone for your tremendous engagement and participation and collaboration. We do have a number of outstanding comments in the earlier sections that have come in since we went through those the first time. A number of them were entered on Clem’s behalf by Liz Amos. We’ve responded to some of those here. We will go back to the top and work our way down, again, at our final meeting on Friday.

We have been reminded by our ONC team that we need to get materials out to HITAC for their review and they would like us to be able to get that done by Friday. So, we did leave ourselves, I think, 90 minutes, starting pretty early here on the West Coast on Friday morning to work on this and we look forward to as many of you as possible joining us for that final meeting as we put the final polish on this document that will go back to HITAC next week. Any comments from anyone before we close out today?

Clement McDonald - National Library of Medicine - Member

Well, I’d like to comment on your remarkable patience, Steve, both you and Ken.

Steven Lane - Sutter Health - Co-Chair

This has been a great experience. It really has. Thank you, Lisa-Nicole for stepping in for the ONC today. Your help is tremendous. So, everyone have a good day and we will hopefully see most of you back on Friday morning.

Lisa-Nicole Sarnowski - Office of the National Coordinator for Health Information Technology- Acting Designated Federal Officer

Thank you, everyone. From the public listening in, you can find a calendar of all HITAC meetings as well as all of the meeting materials on healthit.gov. A couple of friendly reminders before we adjourn – this team will meet on Friday, October 11th from 9:30 a.m. until 11:00 a.m. Eastern time and our next full HITAC meeting is on Wednesday, October 16th. With that, we will adjourn for the day. Thank you all once again for your thoughtfulness and insight. Have a wonderful day.