

Transcript
July 23, 2019
Virtual Meeting

## **SPEAKERS**

Name	Organization	Role
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
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
Lauren Richie	Office of the National Coordinator	Designated Federal Officer

#### **Operator**

Calls are now bridged.

# <u>Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated</u> Federal Officer

Good morning everyone. Welcome to the ISP Task Force meeting. Of the members, we have the two co-chairs, Ken Kawamoto, and Steven Lane. We also have David McCallie, Edward Juhn, Terry O'Malley, and Sasha TerMaat. Are there any other task force members that have dialed in? Okay. Hearing none, we'll circle back a little bit later. At this point, I'll turn it over to Ken and Steven.

## Steven Lane - Sutter Health - Co-Chair

Great. Thank you very much, Lauren. And welcome, everybody. And thank you for joining us. We are going to be talking a little bit about the upcoming schedule for the task force, which has been somewhat modified. And then we're going to dive right into a discussion of our current draft recommendations around medication data. We'll have some time in the end for public comment, and we have a number of members of the public who have joined us today and hopefully some of them will have some ideas to share with us at the end. And anything to add to that, Ken?

## Kensaku Kawamoto - University of Utah Health - Co-Chair

No. Sounds good. Let's get into it.

## Steven Lane - Sutter Health - Co-Chair

Excellent. With regard to the schedule, Lauren, or Denise, did you want to talk about how that is being modified?

# <u>Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated</u> Federal Officer

Sure. So this is Lauren. So for the task force members, you may have noticed that we sent out a few additional invites beyond September of this year. And that is only just to allow ourselves a little additional time to finalize the annual report that's due from this group. So we're anticipating starting that around September and hopefully wrapping up in October. So it will be kind of finalizing the recommendations from this set, but also, finalizing the full report. So I didn't want to alarm you too much there, but that is the reason for the additional meetings.

#### Steven Lane - Sutter Health - Co-Chair

Any questions from task force members about that? Great. Hearing none, we'll jump right in. Next slide, please.

So we have put together a set of draft recommendations, you will recall at our last meeting, regarding the medication data domain. We separated those into priority one and priority two as we have in the other domains where we have been working. And we then presented those to the full HITAC a couple of days after our last meeting and did not get any significant pushback. So just as a high-level review, starting out, these are the subdomains that we have discussed within medications.

The issue of being able to access administration and dispense history. The importance of eligibility and formulary checking. Alternative therapies. Real price data. Support for prior electronic authorizations, specifically utilizing benefit data, EPCS. We've extensively discussed discreet sigs. And I don't know if Clem has joined us yet, but Clem continues to speak out about the challenges of discreet sigs and his views on that. So we may get to discuss that again. The challenges related to med rec. All of these seem to float to the top as the highest priorities in this domain.

On the next slide, the areas that we've identified as priority two include the importance of being able to transfer prescriptions between pharmacies. The need to be able to query and report transactions related to PDMP. The cost of accessing PDMP data. We spent some time, you'll recall, discussing opportunities to improve the detection and reporting of adverse drug events. We've had some lively discussion about Rx norm codes, their availability and use. And I want to particularly thank David McCallie and others for the work that they've done trying to help us clarify this. Ricky Bloomfield also spent a lot of time thinking about this. And we'll talk more about this, hopefully, today. EPA related to medical as opposed to prescription benefit. And then, the question of public access to standards that are required by federal programs.

So we have for each of these subdomains, broken things up into observations, recommendations, and proposed policy levers or institutional responsibilities for trying to address these. And what we're going to do today, and I suspect well into the next meeting, is kind of go through these in detail, and ensure that the specifics are an accurate reflection of the position and views of the task force members.

A number of you have had the chance to go into the document that we are keeping on Google Docs and make comments. And we will want to go through those today in detail. Ken, do you want to add to that?

#### Kensaku Kawamoto - University of Utah Health - Co-Chair

No. That sounds good. Let's get right into the details and try to get them into something that we can submit.

## Steven Lane - Sutter Health - Co-Chair

Perfect. I see Val Grey has joined us. That's great. And again, we have quite a number. Have other task force members joined us since we took roll call at the beginning?

## Victor Lee – Clinical Architecture – Member

Yes, this is Victor Lee.

## Steven Lane - Sutter Health - Co-Chair

Hey, Victor. Welcome.

## <u>Tamer Fakhouri – Livongo Health - Member</u>

Hi, this is Tamer Fakhouri.

#### Steven Lane - Sutter Health - Co-Chair

Tamer, good morning. All right. I see it looks like Ram is here, which is great.

## Ram Sriram - National Institute of Standards and Technology - Member

Yes, it is Ram Sriram from NIST. I am here.

#### Steven Lane - Sutter Health - Co-Chair

Super. Thank you, Ram. All right. Let's go ahead and dive in. And I think we'll just take it from the top. We have done a little bit of reorganizing these items to try to put like items together. Again, we are open to input from task force members regarding all four columns here. The assigned priority, observations, recommendations, and policy levers. And again, we have a couple of comments that have been added to the document. So let's just dive in and see how far we can get.

The first one, and again, within the priority one and priority two, I don't think there is any sense that there are sub priorities. That one thing that is listed as priority one is more important than another. But rather, we kind of lumped them together.

So I am actually going to do a little bit of reading just to make sure that we're all on the same page here. So we observed that medication reconciliation is a challenging and burdensome process, that typically requires the time-consuming engagement and input of clinicians. That this should ideally be performed consistently at transitions of care and prior to prescribing. That the demands of the current workflow lead to a situation where this may not be completed prior to the time of prescribing, leading to missed opportunities to improve patient safety. That similar medication data entered by different users and different systems may be difficult to reconcile due to lack of standard data formats. That there may need to be updated to patient medication lists based on changing formularies as insurance coverage changes over time. That there's no incentivization for med rec. And that there may be opportunities to automate steps in the med rec workflow to decrease the time and effort that clinicians must dedicate to this process to improve both efficiency and safety.

So just pausing there for task force members. Again, please feel free to use the hand-raising feature. That allows us to sort of see who wants to jump in. But does anyone have any input, additions, subtractions, modifications, to the observations that we have made around med rec?

#### Kensaku Kawamoto - University of Utah Health - Co-Chair

I see Terry first and then David. Terry, do you want to go first?

#### Terrence O'Malley – Massachusetts General Hospital - Member

Sure. So, great summary. One of the challenges as a clinician for med rec is there is no source of truth. And so, every time you get a medication list, you almost have to go back and rebuild it unless you have some highly reliable source that you can tap into and then edit, essentially.

So one of the observations I would make is that there is no source of truth. And one of our tasks might be to find one or assign one or designate someone as the responsible party for the source of the truth. And I'm not sure what that format would look like. Whether it is a repository, the patient as we allude

to, or whether it is a designated clinician that has that responsibility. But I would expand that piece. My only addition. But otherwise, it's great.

## Kensaku Kawamoto - University of Utah Health - Co-Chair

David?

#### David McCallie - Individual - Public Member

Yes. So leveraging Terry's comment, I would say it is not always clear who the responsible party is. So in some settings of care, HMO like models where there is a clear-cut primary care physician, one would assume that is the responsible party. But a whole lot of care gets delivered outside of that kind of a context where it may not be really clear who is responsible for medication reconciliation.

So I think that is part of what makes it challenging and burdensome. That we mentioned our point number one, and it is related to the non-incentivized point later down, it may not be clear who is the responsible party. So there can be an issue at that level, which is not a technology problem at all.

I also agree with the comment that there may not be a gold standard or truth for the current medication profile of a patient. That's just a sliver of the larger problem that there isn't a gold standard or truth for the entire medical record. So work being done under TEFCA and other approaches to try to address access to the federated records that a patient could have spread across the places where they get care, obviously should include medications as a key focus on that. But medications are no different than the rest of the record in many ways.

## Steven Lane - Sutter Health - Co-Chair

Thank you for that observation. And thank you, Ken, for trying to encapsulate that in one additional observation. So let's move on.

The recommendations that we have come up with around med rec include exploring solutions that capture identifiers for medication data reconciliation instances and results. so maybe we should add to that the idea of actors. That is who performed the medication reconciliation in a given instance. So maybe, Ken, since you are editing, or Tomer's in there, we can add actors there under the recommendations.

To investigate potential approaches to centralized or coordinated medication list stewardship potentially owned by a specified primary care provider, patient's preferred pharmacy, or the patient herself. Really getting at some of the comments that were just shared.

Explore and encourage pilots to incentivize medication reconciliation of both individual medication and full medication list level, either as a specific task or as a part of the patient management fee. To support analysis and pilots of the automation of medication reconciliation workflows, including utilizing A.I. and machine learning.

And a recommendation, which actually looks more like an observation. Patients have the right to access to their medication lists but amending or correcting the medications is cumbersome and

sometimes virtually impossible. There is a significant patient safety risk from inaccurate or out of date patient lists remaining in the EHR. And patients are the only ones who have knowledge about the actual medications that they are taking. Patients should be able to always have the same view of the medication list as their providers. And providers must implement an easy, efficient, timely, and user-friendly process for patients to amend and correct their medication lists.

So, wow. That's a mouthful. And I can just imagine who offered up that edit.

## Kensaku Kawamoto - University of Utah Health - Co-Chair

I'm just going to split that up into two pieces. Keep the same content, just move it, so the observation goes under observations.

## Steven Lane - Sutter Health - Co-Chair

Perfect. I was going to make the same suggestion. Thank you so much, Ken. So now we have observation and recommendation split up. So let's pause there. Again, feel free to use the hand-raising feature, and I want to collect any suggestions, edits, recommendations related to that.

And again, if task force members can kind of stay out of the cells that we are actively working in, so Ken can get in and out and do the edits, that would be awesome. I don't know that you can have two editors in there at once. Any thoughts on the recommendations? I think they are pretty solid. All right. We'll move on then. I see no hands to the policy levers and responsibilities here. We have added the least, generally, in that area. So perhaps folks will have some new thoughts. Oh, Terry, I see your hand up now.

#### Terrence O'Malley – Massachusetts General Hospital - Member

Just a quick suggestion. Maybe we want to be a little bit more explicit about what some of the possible models are that we want to have investigated. So we call out the patient as the steward, the specialist/doc as a steward. Other approaches might be like immunization repository. Should there be a medication repository? Who would manage that? And then sort of any other structures that we already are familiar with that might be able to be repurposed for med rec. Anyway, suggestion.

## Steven Lane - Sutter Health - Co-Chair

You know, one thought, we already do have the notion of looking at the patient as the owner with the fire-based ability for patients to download their data onto an app of their choice via APIs. Certainly, that seems to create an infrastructure that allows the patient to be the official owner. I could imagine, too, that for different patients, it may be different. There may well be patients where the patient herself wants to take charge. Others where a PCP or a clinical pharmacist or an A.I. app. It may be that there is a need to identify medication list owner as a new concept and data item, that then could vary across the population of patients. David, your hand is up. You know, I can just go back and forth between Terry and David routinely. Go ahead.

## <u>David McCallie - Individual - Public Member</u>

Hello.

#### Steven Lane - Sutter Health - Co-Chair

David? Hello? Oh, boy.

#### David McCallie - Individual - Public Member

Hello?

## Steven Lane - Sutter Health - Co-Chair

Oh, there are. I can hear you, David. Can you hear me?

## <u>David McCallie - Individual - Public Member</u>

Yes, now I can. I don't think they had me in speaker mode, I'm sorry. I dropped off due to user error and had to reconnect, so sorry about that. I may have missed a comment or two, so if I'm repeating somebody else, I apologize.

They explore solutions point, number one there, I think we might want to add the phrase, business models. I think solutions emerge when there is a business model that supports that. And some of that list that you rattled off a minute earlier about it might be the PCP, it might be the pharmacist, it might be a private entity that the patient engages via apps. But for things that are expensive and take a lot of time to perform, there needs to be a business reason to do it. So we can make all the data available through these APIs, but there has to be a sort of an unstandardized way for somebody to say this is worth my while to do this hard work, above and beyond the patient themselves, who may not be qualified to do it. So just add business model would be my suggestion.

#### Steven Lane - Sutter Health - Co-Chair

Yes, good. Ken captured that. That's great. Good suggestion. All right. So with regard to the policy levers, we have identified that the Argonaut, USCDI, ONC, for additional support to the U.S. core fire profiles. I don't know what as above means there, and I'm not quite sure what this means exactly. I think there is a general sense that U.S. core is critical to this, so it needs to evolve. But anybody who might have suggested this wants to flush out the idea here so we can get it into a full sentence.

#### Kensaku Kawamoto - University of Utah Health - Co-Chair

I think it might have been from me, but whoever did it, please.

#### David McCallie - Individual - Public Member

This is David. It didn't come from me, but I can imagine specifically the work on provenance is critical to understanding where did a particular medication statement come from? If there is a need to go find out why it is there, you need to be able to chain backward and say who originated this. So maybe that is a specific U.S. core urgency, the provenance.

#### Kensaku Kawamoto - University of Utah Health - Co-Chair

So maybe that goes in the recommendations section. The importance of tracking the provenance of medication data.

#### <u>David McCallie - Individual - Public Member</u>

The tricky part about provenance, it's another one of these things that is expensive to do. So it may require some policy levers to make it actually happen in the real world.

#### Steven Lane - Sutter Health - Co-Chair

Okay. We have the suggestion that federal agencies support investigations into better approaches for med rec. Again, a little vague. ONC work with CMS to explore multiple billing reimbursement codes that could be used to reimburse clinicians or other actors I would think for a partial or full reconciliation of a patient's current med list. But I think I might have thrown this in. The idea that this could be done by primary care, by specialty, by a pharmacist. I mean, it could be done by advanced practice clinicians who are not physicians as well. So we might want to add APCs there. Any other thoughts? I see no hands. Yep?

## <u>Sasha TerMaat – Epic – Member</u>

Sorry, this is Sasha. I am not in the hand-raising. But there are current quality measures that focus on having current documentation of medication. If those aren't furthering the goal, that stuff could be an angle for perhaps different measures or revised measures that would be an incentive for appropriate quality programs like MIP for reconciliation.

#### Steven Lane - Sutter Health - Co-Chair

So, perhaps there is a recommendation that quality measures related to medication reconciliation be reviewed to assure that they incentivize the kinds of behaviors and processes that we think are of a high priority.

## <u>Sasha TerMaat – Epic – Member</u>

That sounds good.

#### Steven Lane - Sutter Health - Co-Chair

Okay. I'm leaving the editing to Ken.

## Terrence O'Malley – Massachusetts General Hospital - Member

Or maybe say that the first step is to identify who the steward will be. Make that a quality measure, yes or not. You've identified the responsible party for maintaining, for managing the med list.

## Steven Lane - Sutter Health - Co-Chair

Well, I think, yes. If or when we decide that that is really part of the solution, yes, that would make sense. Okay. Let's leave that. Again, this document remains available to members of the task force, and we invite you to submit comments. Terry, you did have a comment, specifically that you added to this cell. You said specify requirements for a patient managed process. Do you want to say more about that?

## <u>Terrence O'Malley – Massachusetts General Hospital - Member</u>

No, that says it all. If we laid out the requirements, so what do we need to make sure all the pieces are there. Whether it's data or process or standards or whatever.

#### Steven Lane - Sutter Health - Co-Chair

Does this go under recommendations?

#### Terrence O'Malley – Massachusetts General Hospital - Member

Maybe. Just really a deep dive into what it would take for the patient to be the steward. What are the tools that that person would need?

## Steven Lane - Sutter Health - Co-Chair

Okay. Well if you can think of additional language, maybe, that could go into the recommendations section, let's share those.

Okay. Let's go on, then, to the next row and we'll just sort of work our way through this document for as much time as we have today. This is getting at the discreet structured medication SIG information. Again, an area that has engendered a fair bit of discussion. I think just to channel Clem since he's not here, his thought continues to be that this is more trouble than it's worth. That free text parsing should be able to take care of this. That he sees a real challenge with complex SIGs such as ramping and tampering, etc. Notwithstanding the fact that some of the major EHRs have figured out how to do that pretty simple and put that all into structured fields. But I don't know that that structure has been standardized so that ramps and tapering doses can be interoperable. But I think that's something we can talk about.

So, you'll notice here the crossed-out text. We had initially suggested that this needed to be added to U.S. core fire profiles, and then Ken did a bit of a deep dive and realized that that was already there. So I think we can just delete that crossed-out text to unclutter these a little bit. But again, just the observation here is that the discrete structured medication SIG information provides multiple benefits, including a more consistent display of medication information, support for clinical decisions, support, and analytics.

We have the example here of calculating opioid morphine milligram equivalents. The observation that free text SIGs are prevalent in ambulatory EHRs. And that those systems also need to parse and interpret that data if they want to support animation analytics and decision support, which of course is somewhat error-prone. The discrete SIG information, even when documented by prescribers, can get lost in translation, as medication orders are filled, refilled, etc. That is to say that EHRs and pharmacy systems, any prescribing systems lack standards so that discrete information is efficiently and accurately moved between them. And that neither EHR vendors nor providers are incentivized to utilize discrete SIGs.

So any other observations or corrections to those that people would like to share?

#### Kensaku Kawamoto - University of Utah Health - Co-Chair

This is kind of stated there, but I think to avoid multiple times people having to reconcile the same thing with data coming in that has previously been reconciled, I think it is quite useful to have the structured SIGs then too to be able to tell that they are in fact the same SIGs as well, the same prescription.

## Steven Lane - Sutter Health - Co-Chair

Great.

## Terrence O'Malley – Massachusetts General Hospital - Member

Just a question. And Ken, what's the process you see into achieving that? Is that a provenance issue, or is it an infrastructure?

## Kensaku Kawamoto - University of Utah Health - Co-Chair

I think if you see two prescriptions or two details on prescriptions that are the same down to the SIG level, then you can pretty confidentially say they are the same prescription. There's really no need to reconcile, especially when it comes to external. Whereas if it's free text, someone has to visually say that, yeah, these are actually the same thing. So this one's a duplicate.

#### David McCallie - Individual - Public Member

Ken, I'll point out – this is David. I'll point out the obvious thing that just because they're the same doesn't mean they reconcile to the truth. It should be maybe something that should be discontinued.

## Kensaku Kawamoto - University of Utah Health - Co-Chair

They could both be wrong.

#### David McCallie - Individual - Public Member

Correct. That was my point. But step one is to say, are they describing the same event? And if you don't have a provenance tracker that can make that obvious answer, the same prescribing event, let's call it for ambulatory, then your next best thing is the structured SIGs that line up perfectly. But I would again connect may be the higher priority should be the prescribing event. It's a provenance ID that can be used to say these traces back to the same prescribing event. And therefore, we know who was responsible and exactly what's going on here. Not exactly, but you have a better clue. So it's provenance again.

#### Steven Lane - Sutter Health - Co-Chair

All right. And then we have some recommendations here, identifying the potential failure points for discreet SIG data to get lost and correct them, whether throughout standards refinement or improved standards compliance. Encourage the HIT community to identify and share best practices regarding how to capture structured SIGs when possible, such as ramp tamper regimens. Facilitate and incentivize the use of discreet structured SIGS wherever feasible. But do not prohibit pre text SIGs because this could place an undue burden on providers. I think that was really Clem's concern. Forcing people to do things that would take them more time. But of course, we always need to balance the value proposition. Sometimes providers do need to a little more work for the patient to get the benefit.

Encourage the maintenance and discreet SIG information as part of the medication SIG, as data moves between providers, payers, PBMs, pharmacies, and patients. Consider developing good public resources for converting free text to structured SIGs. And this could build off an open-source resource

develop for CDC/ONC project to parse opioid SIGs from more free mailgram equivalents. Any thoughts on the recommendations?

Very good. And then thinking about the who might be responsible and what policy levers could be utilized. The NCPDP, reviewing current standards, and identifying and addressing gaps. I think we have some NCPDP representatives on the call. So perhaps they could offer some public comment about this. Is there really a role for NCPDP here to help us capture and maintain this data as it moves between actors?

ONC to coordinate an effort to identify best practices for capturing the structured SIGs. That seems like an appropriate place for that. Consider funding for a publicly available tool for converting free text SIGs to structured SIGs. For those of you who haven't lived through this, I know in our organization when we went to e-prescribing and spent years going back and forth about free text and structured SIGS we actually built a huge table of various free text SIGs and how they would map the structured SIGs, and I forget. It was tens of thousands of lines long, the idea that every organization shouldn't have to do that themselves, or every vendor, I think that's a good one.

Here again, Argonaut, USCDI, ONC, consider expanding U.S. fire core profiles for medications to include the input, output metadata. Requirements to enable market base but an interoperable competition on such parsers. Wow, that's a mouthful. Maybe, Ken, that came from you?

## Kensaku Kawamoto - University of Utah Health - Co-Chair

I don't remember if I did, but that sounds like a good idea, anyway.

#### Steven Lane - Sutter Health - Co-Chair

And then, maybe that last one is redundant. I'm not sure that adds anything to the fourth one. Any thoughts on the responsibility and policy levers?

## David McCallie - Individual - Public Member

Steven, it's David. On the recommendation, I'm jumping back one, I've just been thinking about it as we talk about it. And maybe our NCPDP colleagues, if they are available on the call later, could comment on this. But is there a way to track a dispense event, I'm thinking ambulatory here where most of these problems occur, back to the original prescribing event in a robust fashion?

So provenance but now specifically for medication events. And does the standard allow this and it's just not being used or does the standard need to be expanded. So, it seems to me that every dispense event should be traceable back to a prescribing event, which should be traceable back to an individual. And that should be doable in a standardized way across all systems. So that if there is a question, you could go back and find the original intent, whether it's still relevant and so forth. So I don't know if that's issuing in the standard, or it's just not used, or if it is used and it doesn't work. I think that's a precursor, maybe more important than structuring the SIG if I think about what's going on.

## <u>Steven Lane - Sutter Health - Co-Chair</u>

I think you make a good point. And it also makes me think of the fact that we have this challenge, which is that medications are often prescribed with one set of instructions and then are actually taken differently. And the notion that there is the prescribed SIG and there's the manner of actual consumption, and sometimes those may each need to be documented discreetly. I don't think we've captured that. I wonder if that would be adding as an observation, Ken. That it may be valuable to structure both the recommend and the actual manner in which the medication is being taken.

## Kensaku Kawamoto - University of Utah Health - Co-Chair

I see. You mean, patient-reported?

#### **Steven Lane - Sutter Health - Co-Chair**

Right, right. Exactly. Okay. Seeing no hands, let's go on to the next row, which has to do with medication administration and dispense history. And the importance of being able to access this data. So the observations here, clinicians, patients, and payers can benefit from access to patient's medication administration and dispense history. Medication dispense history should be traceable to the original prescription. That's a good addition. Thank you for that. Relevant historical information includes inpatient, outpatient, and mail order pharmacy data. Medication dispense information is especially valuable for controlled substances when this information is integrated into EHR systems in real-time, it can beneficially inform the prescribing process. This information may be available from several sources, including payers, PVMs, pharmacies, and PVMPs. Information is not universally available nor integrated into EHR workflows today. And that med admin dispensation information is currently missing from U.S. core fire profiles. So any thoughts on those observations?

## <u>Terrence O'Malley – Massachusetts General Hospital - Member</u>

It's Terry. Do we want to call out the data elements required for that process specifically? I mean, you're going to need the prescriber and all the issues around identifying the prescriber. The issues around medication identification. Something we haven't mentioned, indication or reason for prescribing. I'm just saying, would it be worthwhile calling out the discreet data set for that?

## Steven Lane - Sutter Health - Co-Chair

It certainly seems reasonable. Does it belong here in terms of the dispense history?

## <u>Terrence O'Malley – Massachusetts General Hospital - Member</u>

It probably belongs where David was talking before, about the provenance. In a sense, it's a provenance. More related to provenance.

#### David McCallie - Individual - Public Member

This is David. I think it is tied to that. But I was triggered by your use of the phrase indication. I think there's been some work done on the value of understanding the intent of a prescription in helping downstream figuring out what's going on. And there's not a structured intention or indication field that I'm aware of. That's an issue that we might want to track. Someone has done a big study on that recently, and I'm completely blanking on their name. It will come to me in a few minutes, at Mass General.

#### Steven Lane - Sutter Health - Co-Chair

It is a very good point. It probably warrants its own row, the challenge of indication or associated diagnosis, again, is something that in our organization we've done a lot of work on over the years. I, personally, feel that there is real value in having an associated indication or diagnosis. But again, you can tell from the way we're using the terms, whether that is an ICD 10 code or some other list of codes or free text is not at all standardized. And having a discreet indication for medication can be very helpful if you're thinking about indication-specific decision support. And we all know, that the classic cases, like med foreman, which can be used for polycystic ovaries or diabetes, for SSRI, that can be used differently for depression or anxiety or pain, it is very helpful.

So, I don't know. Do people feel that we should add this as another row, with the observation that this data is not captured consistently and there are no standards for how that data might be maintained with medication as it traverses the ecosystem?

## <u>Terrence O'Malley – Massachusetts General Hospital - Member</u>

Eye.

#### David McCallie - Individual - Public Member

I think it makes sense. It's Gordy Shift who I was thinking of, who has done a bunch of studies on this topic.

## Kensaku Kawamoto - University of Utah Health - Co-Chair

I'm adding this on the very bottom as priority two. If folks want it higher, I can put it up there too.

#### Steven Lane - Sutter Health - Co-Chair

Great. Thank you, Ken, for starting that out. Maybe when we get down there, we'll look at how that language has been crafted. All right, with regard to the administration dispense history, the recommendations, hopefully, we can get them back up on the screen here, are to support pilots of the automated real-time query for medication administration dispense history from all available sources. To support pilots that integrate medication administration dispense history information into routine prescribing workflows. To continue in the future requiring the capability to query for download, integrate and utilize medication administration dispense history as a condition for EHR certification as an incentivized metric under the promotion interoperability program. To encourage the further profiling of medication to dispense resource within Fire and the development of the U.S. core fire profile for medication dispense. Which could build off the U.S. implementation guide for med dispense, and we have reference there.

## <u>Terrence O'Malley – Massachusetts General Hospital - Member</u>

It's not showing. Yes, we're not showing the spreadsheet anymore.

## Steven Lane - Sutter Health - Co-Chair

They said they are working on getting it back up again. So I'm going to go ahead and keep reading. Then there's a recommendation to reconcile these with NVC versus Rx norm codes. And we have a whole item on that, so this might be redundant here. But it goes on to say the server should send

whatever codes they use in their system, usually NVC if it's a dispensing organization. Okay. So the idea that there should be coded data to go along with this dispense information. And it says adding a requirement for Rx norm codes would be beneficial. Again, I think this is fine here, but we do go into this in greater detail later.

#### Kensaku Kawamoto - University of Utah Health - Co-Chair

Steve, I don't know if you want to pause, but Sasha has her hand up, too.

#### Steven Lane - Sutter Health - Co-Chair

Oh, okay. For some reason, I don't see that. Oh, there I see it. Sasha, jump in.

#### Sasha TerMaat – Epic – Member

Oh, sorry. So I just had a comment about the certification recommendation. Because there are some NCPB standards for receiving dispense information from a pharmacy in current certification expectation. And so I'm not sure that the certification component is the gap unless there is other information like we were talking about previously around some certain data element, like indication, that is important or if it more a usage thing.

## **Steven Lane - Sutter Health - Co-Chair**

Sasha, if you have a reference to sort of where that NCPDP requirement is built if you could add that maybe under the observations, so we capture that here?

## Sasha TerMaat – Epic – Member

Sure. I'll take that as a follow-up.

## Steven Lane - Sutter Health - Co-Chair

Great. Thank you so much. And then there's a final recommendation here. Consider requiring API based availability, medication dispense info from pharmacies, PBMs, and health systems that dispense. So all pretty solid recommendations. And then seeing no hands, I'm going to go on to the policy levers. Again, sort of a broad notion. Argonaut project proposed for additional support. Again, not quite sure the specifics of what that means. Same under USCDI. ONC to facilitate inclusion in HL-7 core file profiles for USCDI prioritized items.

It's interesting to hear the discussion, within the USCDI, I mean, we have one of the USCDI task force co-chairs, Terry, here. Thinking about how we might incorporate this into USCDI and how that would be brought forward given the current notion that additions are going to be sponsored by stakeholders. Kind of thinking about who would push that forward is an interesting thought.

ONC ensure that relevant data holder is engaged and can effectively share appropriate data, including PDMPs. We probably only have to say including PDMPs once or twice in here. Clearly, we want to include PDMP in this discussion.

And then there's a comment that the Karen Alliance may be interested in helping drive the implementation development process for med dispense, as they are currently part of the HL-7

accelerator program and doing the same thing for fire claims. And the evidence of benefits data. So again, another potential actor here. Any other thoughts on this row?

All right. Seeing no hands and hearing none, we're going to go ahead and talk now about eligibility and formulary checking, which are used together to inform the initial prescribing selection. ENF checks are a foundational part of e-prescribing. It's embedded in nearly every EHR. Eligibility identifies a patient and their associated pharmacy benefits manager. There's an NCX-12 transaction standard, sports eligibility checking. Formulary displays, group-level formulary, for example, which drugs are on and offplan, which ones are preferred, which ones require PI, etc. And NCPDP formulary and benefit 3.0 transaction support formulary checks. ENF checks are proven to impact the patient in three ways positively. Drive more cost-effective prescriptions through formulary compliance. Drive higher patient pickup adherence at the pharmacy. And decrease the number of prescription changes required between the prescriber and the pharmacy.

So these are our observations about the value of and the standards supporting eligibility and formulary checking. We have recommendations. I see a hand up. David?

#### David McCallie - Individual - Public Member

Yes. Are we making the distinction between the payer independent – well, let me call it the patient bin and insurance information independent eligibility and formulary checking versus the information necessary to actually figure out the cost of the prescription? And the reason I'm asking, my memory from some of our presentations and from when we worked on this in the past, when I was back at Cerner, that the ENF checking, if you're just going against the static database, that doesn't take into account the patient's actual bin and their coverage, that you get information that is sometimes so generic that it's not really specific enough for the physician and the patient to make a complicated decision.

So I guess I'm asking, should we mention the fact that existing ENF checking is sometimes not granular enough, and maybe we should always be going down to the price level. Am I being clear?

#### Kensaku Kawamoto - University of Utah Health - Co-Chair

I think so. You're saying that ENF checking is often viewed by providers as unreliable and not useful.

#### David McCallie - Individual - Public Member

Correct.

#### Steven Lane - Sutter Health - Co-Chair

We do have a whole section on out-of-pocket pricing. But I think that's worth adding as an observation, Ken.

## Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes, I'm adding it now.

#### <u>David McCallie - Individual - Public Member</u>

If you could put aside the technical constraints, if you could replace the ENF scoring of tier one, tier two, tier three, with an actual price, why would you need ENF?

## Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes. I will add that as an observation.

#### Steven Lane - Sutter Health - Co-Chair

It's a really interesting point, David, because, in some sense, ENF really came first before we started talking about having actual price data. And at the end of the day, what's going to drive the decision is the price as much as the formulary data.

#### David McCallie - Individual - Public Member

Right. ENF was a workaround for the fact that real-time pricing was too expensive to implement. So it was a static snapshot of high-level plans. But it's so high level, and there are now so many specific constraints and prior authorizations and other constraints that I wonder if maybe the goal should be to replace it with real-time for everything.

#### Steven Lane - Sutter Health - Co-Chair

So perhaps the observation that over time, like real-time pricing data becomes more available, that as you say, there may not be as much need for EMF. So it seems like having it all is probably the ideal, right? Knowing what is eligible, what's un-formulary, and what the costs would be, I think as a prescriber, would be most beneficial.

## David McCallie - Individual - Public Member

Yes. You could imagine a system that shows at a high level by saying drug class or category, what they're eligible for. And then a drill in that fetches real-time price information. There is a variety of ways to stage it so it could be a hierarchal set of queries so that you don't waste resources computing completely unfeasible drug choices. But it's clear that ENF is not sufficient in many cases. Otherwise, we would not have had a big debate about actual pricing.

#### Steven Lane - Sutter Health - Co-Chair

And I think that your point is captured in the recommendations where we suggest continuing to support the use of existing transaction standards for ENF checks until such time that other standards prove themselves superior and are fully integrated into the prescribing system.

So while this is imperfect at this point, it's still worth doing. I don't think that we are suggesting that it should be tossed out pending some other solution. To encourage and incentivize health plans and PBMs to freely share ENF data with all vendors who utilize this data to prescribe EPA services to prescribers. Here again, I think one of the challenges is that not all vendors or not all stakeholders are sharing this data freely. To encourage and incentivize EHR vendors to support the integration of the NF checks in their e-prescribing platform. To encourage and incentive providers to implement and utilize the checks for all prescriptions. To encourage and incentivize the development, implementation, and use of fire-based ENF transactions. And then there's recommendation eligibility, and formulary data must be accessible to the patient as well as providers.

Here again, a nice addition to the patient perspective. And I'm afraid Cynthia's not here to get credit for what I imagine were her additions there. And we don't have any specific suggestions under the policy levers and responsibility here. I think it sort of goes without saying, we would imagine ONC could support this. That NCPDP could help support the standards, and that here again, I think the same comment that we made about dispense history, that Karen may have a role to play, in terms of ensuring this data is exposed to the patient-facing apps.

So I don't know, Ken, if you want to sort of creating some of that or copy some of it from the row above.

#### Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes, I can do that.

#### Steven Lane - Sutter Health - Co-Chair

You're on it. Great. So Gary Dolan, thank you so much for your public comments. Gary has provided some links to a number of HL-7 Fire standards around the medication resource, medication dispense, medication request, administration. And he points out that U.S. core has not yet incorporated all of the above. So we, again, appreciate your input, and we'll be sure to capture of the public chat and comment on our meeting minutes that will be published.

And good. And Ken's capturing some of this. So the next row then, rows six, we are going to talk about prior authorization. This one, I think, we have a hard time fitting all of this onto the screen. So we'll start at the top. What we may need to do for the purposes of visualizing this is actually split this into two rows. Maybe we can do that quickly. I don't know, Ken, maybe I'll let you do that. Just thinking if we split the observation into two rows, we might be able to get it all to show. Or here, I'll try just extending the column width. Doing the column width will probably work too. There we go. That's coming along.

So with regard to the observation, prior authorization transactions are required before coverage is allowed or approved for certain medications. Medication PA can be a time and labor-intensive process that frustrates prescribers and patients, leading to delays in treatment and unfilled prescriptions. Traditional PA workflows are retrospective, that is the need for prior authorization is identified at the pharmacy. And require clinical staff to utilize telephone, fax, and/or log into a portal to complete a series of questions used by payers/PBMs to determine whether and how the medication will be covered.

Electronic prior authorization can reduce the number of times that PA requirements interrupt the clinician and their staff. EPA queries and responses are currently supported by both X-12 administrative transaction standards for eligibility claims, etc., and NCPDP standards, which are spelled out.

The NCPDP scrip EPA standard has been gaining industry adoption since 2015, with providers in all states utilizing the service to process PAs under the pharmacy benefit. The NCPDP scrip EPA allows the

need for PA to be identified during the e-prescribing process. The provider can either choose a drug that does not require PA or initiate and process the PA electronically and the EMR prior to sending the prescription to the pharmacy.

A number of vendors have developed and implemented EPA functionality which integrates with EHR based e-prescribing workflows to allows clinicians to view and respond to PBMs PA requirements in near real-time. The workflows provide only partial automation and often require clinical staff to collect data from the EHR and manually respond to questions. The value of EPA services depends on which payers and PVMS are represented by each vendor. Not all EHRs and providers have integrated EPA integration. Payers, PVMs utilize custom question sets to determine whether or not a given medication should be approved within a specific patient context. Many questions rely on free text as opposed to structured responses.

There's currently an active CMS MPRM for EPA for pharmacy benefits for Medicare Part D members. API based data access and exchange could further streamline the EPA process, reducing burden and delays. And Fire-based clinical data exchange, use cases, and implementation guides are being developed under the auspices of the DaVinci project to automate EPA transactions. So lots of observations about prior auth and electronic prior auth. Anyone want to add, subtract, or modify, related to our observations? And I think it's fair to say that a lot of this came from some of the presentations that we received from vendors that are involved in this space. So I think we want to make sure that these observations are meant to be vendor-agnostic but certainly informed by actors in the industry. David?

#### David McCallie - Individual - Public Member

I think that list is good. I just want to remind folks, at least my cynical view anyway, that the friction created by prior authorization is there in some cases on purpose, and there's a certain degree to which the friction can't be removed because if you removed it, that friction would just come back somewhere else. And that payers and PVMs are trying to control the use of prescriptions for incentive reasons that may go beyond just the clinical care of the patient. I don't know that we need to document that, but there's some degree to which you're never going to take the friction away because that's part of the purpose.

## Steven Lane - Sutter Health - Co-Chair

Interesting observation. Anyone else? Does anybody see any of this as redundant? We tried to narrow it down, though it's a pretty long list.

Okay, looking at the recommendations, encourage, incentivize health plans and PBMs to freely share prior auth requirements with all vendors who utilize this data to provide EPA services to prescribers. I think today there is a bit of an arms race going on to see who is collaborating with whom and who can make what data available. And I think the idea is it should just all be freely available.

To make this work, we will need PBMs to create coded PA forms that can be incorporated into EHRs. It's a little bit different than the data availability. I'm not sure why we have that one indented. I think its sort of a different recommendation, so I'll just change that real quick.

Encourage, incentivize EHR vendors to support the integration of EPA services in their e-prescribing platforms. Encourage incentivize providers to implement and utilize these services. Encourage, incentivize the development, implementation, and use of Fire-based EPA workflows.

ONC should invest in testing existing standards and appropriate workflows in the field, developing implementation guidance for stakeholders. And here again, the patient observation. Patients often bear the burden of ensuring that providers and plans are communicating to obtain prior authorization so they can receive their needed medications. Therefore patients should be notified electronically of prior authorization status in real-time. So I think that's, again, a combination of observation and a recommendation. And maybe, Ken, if you can split the observation off into the appropriate field, that would be preferred.

And then in terms of policy levers, we've got NCPDP reviewing the current standards and identifying and addressing gaps. ONC is coordinating efforts to enable widespread PA for prescriptions at the point of choice.

You know, we don't have a lot here about CMS in our policy levers. Clearly, CMS has the opportunity to acquire things as conditions of payment, as much as ONC has the ability to require them as certification requirements. Again, those seem to be the bit levers that we have available to us. I think NCPDP is more of a facilitator than a responsible party. So I think as we go through these, we might look for opportunities to join CMS to support some of this.

Any other thoughts on PAs? This is obviously a wide and a deep area that we've spent a lot of time talking about. I want to remind everyone that all of these recommendations are going to be turned into prose, commentary, and as we do our writing of our report back to the HITAC and the ONC.

Seeing no hands, we can move on to the next row, which is the out of pocket costs. And we can talk about here the observations. If in the display, you guys can go down to the next row, that would be great. So I'll just go ahead and read off the observations.

Patients and physicians need to know the truth out of the pocket cost of their prescriptive care. And desirable information includes the net negotiated price, the patient's personal share of the pricing be it from the deductible, percentage of share, or out of pocket costs. The unavailability of price data contributes to problems with medication adherence since patients don't realize they can't afford a drug until later at the pharmacy, the also embarrassed when they cannot fill the prescription due to price issues and may not tell their doctor about the situation.

And then we have a reference to a Harvard blog post on this topic. And there may be specific pain points in the workflow, such as prior authorization or eligibility checks that need to be worked out in order for this use case to work.

So those are the observations about out of pocket costs. David, I know that you earlier identified this as related to the formulary and eligibility checking. Any thoughts about those observations that people want to share or add? David, your hand's up?

#### David McCallie - Individual - Public Member

Yes. Nothing to add other than to point out that there is a tremendous amount of overlap between these several rows that we have been working through. Between formulary prior authorization, real-time benefit checking, and true out of pocket cost. And the challenge might fall to the co-chairs to try and coordinate and synthesize this down a little bit because there's an awful lot of overlap here. It's a huge space and a complex problem. So maybe the complexity is justified. But I get a little confused, like what's the difference between real-time prescription benefit checking and true out of pocket cost information and formulary benefit display for the provider trying to make a responsible decision for a patient who has financial constraints. Those are so similar that maybe we can simplify it once we've enumerated all the bullets.

## Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes, there are some subtle differences, right, because they are different levels. Real-time benefits tell you how much it would cost from this particular pharmacy with my insurance. Whereas the true out of pocket cost might include, wait, if you use this coupon here and paid cash, it would be this much. So that's one level deeper. And then there is knowing the general formulary and such. Yes, it's a good point. We thought about it. Part of it's just logistical. If we try to merge them all, it becomes a gigantic row, which becomes hard to display on the screen while we're talking literally. But it's a good point. Yes, these are obviously highly related, for sure.

#### David McCallie - Individual - Public Member

But I mean, maybe a description of an idealized state would be useful for people to envision how it would work if it was optimal. So, for example, the physician in making a prescribing decision has a display that indicates the out of pocket cost for this particular patient for the drugs that are most likely to fit the prescribing decision. Maybe that would say it does not take into account coupons or something because that information is under the control of the patient. It would also flag, for example, this drug would cost X, but prior authorization is required. I mean, you could imagine a workflow that weaves these together into some kind of idealized state. Maybe that's what's missing. It's just hard to sort of figuring out where's the term of each of these recommendations. And if you achieved them, would it solve the problem.

I'm not criticizing the work. I appreciate how incredibly difficult space is. That's part of the reason why there's maybe been less progress than one would have thought.

## Steven Lane - Sutter Health - Co-Chair

Yes, I think you make a really good point, David. And the folks at NCPDP and ONC who have been trying to move us forward down this path, there is this overlap and interaction between each of these transactions that have to be sorted out. I kind of like your idea of telling the story of how it would ideally work, and maybe we could include that in our report, writing that up as a component of this set of observations and recommendations.

Seeing no more hands, I want to go on to the recommendations related to cost. Providers, health plans, and health IT vendors need to collaborate on standards and workflow to make price data availed in the EHR at the point of care and in real-time via open standard API. So here, really getting at the point that both the patient and the provider should be seeing similar information in their own user interface. Ultimately allowing for open API and application access to affordable alternatives is the goal of providing the patient and physician choice. It affects the patient's financial choice and their ability to afford compliance of care choices. I'm not quite sure what all that means. But certainly, I think again, the idea that this data should be accessible via API to both the patient and the provider.

Proprietary approaches are beginning to be offered. That's definitely not a recommendation, that's an observation. So we can maybe move that if we think it's worth keeping. It may be that standards already exist from organizations such as NCPDP in which case ONC should invest in testing these standards and appropriate workflows in the field, developing implementation guidance for stakeholders, and considering such standards for inclusion in future EHR certification.

Here, again, I think we want our recommendations to be more specific. And I think we do want to capture what standards actually do exist from NCPDP as opposed to just sort of imagining what may be. So perhaps commenters who are aware of specific NCPDP things, we can add additional observations if we can identify these standards. David, your hand's up again.

#### <u>David McCallie - Individual - Public Member</u>

I want to make a comment in this context similar to the one I made earlier for the one about clarity around the business models. So these APIs have to be hosted by someone. If there is nobody to run the service that responds to the API call, you haven't gotten there. So those services are beginning to emerge. So the comment proprietary approaches are beginning to be offered. That is a business model aspect of it that needs to be called out. The API itself is not sufficient. There needs to be clarity around who will, in fact, provide this service.

## Steven Lane - Sutter Health - Co-Chair

Good point. Going on to the policy levers, here again, calling out NCPDP. Reviewing the standards. Efforts to enable whites to read price transparency and Karen already had some work going in this area. That was on out-of-pocket costs. We can then move on to real-time prescription benefits.

Here again, acknowledging the earlier point that all of this is really quite related. but there are barriers to broadscale adoption of real-time prescription benefit checking that limit access to this functionality for both prescribers and patients. RTPB is a key component to knowing the true out of pocket costs. So sort of calling out the relationship between these two items.

RTPB is used to confirm the price of prescribed medication, and provide appropriate patient-specific benefit alternatives, should price or availability be an issue. There is an NCPDP standard that is being balloted next month.

Prospective EPA using NCPDP scrip standard is driven by information from NCPDP formulary benefits as well as real-time prescription benefits, which again, I think, speaks to the interactions that you've identified, David.

Both these standards allow for the identification of the need for prior authorization during eprescribing so that the provider can either choose to peruse the original drug or switch to a more preferred alternative. Actually maybe a more cost-effective alternative would be the better way to say that. Consistent integration of RTPB checks and health IT systems in e-prescribing applications using either available standard would support cost-effective prescribing and patient choice.

So I think the key here and one of our key challenges is to identify the standards. And this was one of those transactions where multiple standards can be used. And we got feedback from participants that this isn't the time to pick winners between these standards. That it would make sense at this point to continue to support both of them.

So the recommendation, to require payers and PBMs to make RTPB information including true out of cost data freely available to both prescribers and patients. I think you're picking up a motif here in our recommendations. Initially, this would be based on the pending NCPDP standards for content and transmission of the queries, but in time, this should be made freely available via Fire-based APIs.

To require EHR vendors, and Sasha, I'll forward to your comment here, to provide functionality that integrates RTPB checking into the prescribing workflow, including decision support tools. To facilitate the selection of cost-effective alternative medications. To incentivize prescribing providers and patients to implement and utilize available HIT functionality to select cost-effective medications and treatments. And to support the development of standardized clinical questions and responses to support the PA process.

You know, this may belong up under PA. For example, prescriptions tried and failed, patient-specific data, demographics, vital signs, lab results, diagnosis, and medical history. Yes, I think that probably belongs up on the PA row, rather than the RTPB row.

And here again, in the policy levers, we've called out ONC to include requirements for RTPB formulary and benefit checks in conditions of certification for EHR technology. For CMS to incentive prescribing providers to utilize real-time formulary and benefits checking at the time of prescribing.

Here again, I think, Ken, we can probably pull this CMS one out of the RTPB row and put it up in the formulary and benefits checking row.

ONC and USCDI to support the development, eventually require, the use of Fire profiles to support real-time formulary and pharmacy benefits checks. And here again, I think your point, David is really appropriate here. That real-time formulary and benefits are checking really kind of go together. And we might want to just move this one up in the spreadsheet so that prescription benefit checks and formulary checks are juxtaposed. And again, the observation that Karen is also working on this from the patient perspective. So a couple of hands up. Sasha?

## <u>Sasha TerMaat – Epic – Member</u>

So, just a question. Why is proposed as a condition of certification rather than part of a certification criterion? To me, it seems like we would, once there is a standard defined which is maybe the later step of the Fire profiles piece, it would simply be a certification criterion not a condition of certification.

## Steven Lane - Sutter Health - Co-Chair

I think your point's well taken. I think we sort of pulled that language perhaps out of some CMS recommendations we've used. I also sort of stumbled on that. So I think, maybe Ken, you can change that to a certification criterion.

#### Kensaku Kawamoto - University of Utah Health - Co-Chair

Sorry, I'm a little bit behind. What do you want me to change?

## Sasha TerMaat – Epic – Member

On the policy levers.

## Kensaku Kawamoto - University of Utah Health - Co-Chair

What to change here?

Take out conditions of certification or just conditions of and say include it in certification. Conditions of certification are really business requirements, and this is the functional requirement for a system that would achieve certification.

The other piece I would say is it seems we have some steps that are about determining which standards would be used, and some steps which are about implementing the standards. Practically, we all acknowledge the standard determination should happen prior to the implementation. It might make sense to clarify that in our recommendation. For example, I don't want us to implement a certification requirement before we determine which standard is appropriate for this purpose.

## Steven Lane - Sutter Health - Co-Chair

David?

## <u>David McCallie - Individual - Public Member</u>

Basically, I think, be repeating what you said before you turn it over for comment, so bear with me for a second. I think clarifying the use case for the provider point of view and the use case for the consumer/patient point of view, with respect to the terms we are throwing around here, is something that would help the reader of this summary to understand. So, when the provider is making a decision about what to prescribe traditional using formulary and benefits, we would now say it should be supplemented with either and or real-time prescription benefits or true out of pocket cost. We should get clarity on what the provider sees, or we think we should see in some ideal future state. and likewise for the patient actor, when they are making their decisions, what do they see and in what

context? Factor prior authorization into that as well. so maybe a use case flow explaining these terms and how they relate to each other would be helpful to understand the recommendation.

#### Steven Lane - Sutter Health - Co-Chair

Good suggestion. All right. We are coming up on our time for public comment. Again, I invite the public, and there are many of you on the call who have comments to be ready to dial in for that. I am just going to take the one minute and start in on our review of the next row. Which is the lack of patient-facing APIs for Realtime prescription benefit and pricing information? which I again, is an extension of what we were just discussing. This is really a continuation that a fire-based API would allow a single prescription alteration experience to power both prescription benefit as well as claims access. and an example via Blue Button 2.0 or the upcoming care in Blue Button implementation guide. and for accurate pricing, specifying the following information would be needed. Dispense is written status, full plan, patient identification, etc. So again, I think just more specifics, I think, David, you offered up some of these. Let's go to public comment now, and if we have time, we will continue on.

## <u>Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated</u> Federal Officer

Thanks, Steven. Operator, can we open the line?

#### Operator

If you would like to make a public comment, please press star one on your telephone keypad. A confirmation tone will indicate your line is the queue and 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 keys.

# <u>Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated</u> Federal Officer

Thank you, operator. Any comments in the queue?

## Operator

Yes. We have comments from the line of Margaret Weiker with NCPDP.

## <u>Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated</u> Federal Officer

Thank you. Welcome, Margaret.

#### Margaret Weiker – NCPDP – Public Commentator

Thank you. A couple of comments. There was a question in regard to having the capability to track the dispensing events to the prescribing event. This script standard has a message called RX fill that performance that functionality. However, that transaction has not been widely implemented, but there is one available.

You also mentioned about the structure and codified SIG. We have a specific task group within NCPDP that is responsible for the structured and codified SIG that is used in the script standard. So as always,

if any gap has been identified or you would like to discuss it further, we can to coordinate a time to meet with the task group or had the task group leads come on a call or whatever may be needed. And in fact, any of these recommendations where you are evaluating the NCPDP gaps, we would be more than happy to participate in any kind of gap analysis you may have.

#### Steven Lane - Sutter Health - Co-Chair

That is great, Margaret. With regard to the structured task force, would you say that there are standards that have and fully developed to manage the structured sig? Especially related to some of those ramps, tampers, and complex SIGs that Clem and others have identified as challenging?

## <u>Margaret Weiker – NCPDP – Public Commentator</u>

We believe it does. But if there is something specific that you want us to look at, I can take it to that task group. But it has been developed over many, many years.

## <u>Steven Lane - Sutter Health - Co-Chair</u>

Great. Good to know.

# <u>Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated</u> Federal Officer

Okay. Thanks, Margaret. Operator, any additional comments?

#### **Operator**

Not at this time.

## <u>Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated</u> Federal Officer

Okay. Steven, back to you.

## Steven Lane - Sutter Health - Co-Chair

Great. Thank you so much. In the last seven minutes, I would just like to finish off row 9 here initially. So I read through those observations. I think to David's earlier point; we have an opportunity to tighten some of this up. We want to make sure we captured everything, but we will look for opportunities to edit this down a bit.

Recommendations support efforts to make RTPB available to consumers. Pricing returns should include a lot of specific data elements here. Price under the plan is covered, as well as cash price. FSA, HRA amounts that are separated out, so the consumer sees the actual cost. So a lot of specifics here.

Then in terms of responsibility, looking at ONC, potentially adding data RTPB data elements to the USCDI. An interesting thought, Terry. CMS considering requiring the availability of information from federally sponsored health plans, similar to the reason requirements to make available patient-facing fire APIs. So multiple opportunities to support this. Any thoughts about that? If not, we do have time to shift our focus from the pricing to alternative therapies. which clearly some alternatives will be driven by price but others by other factors.

So the observation on row 10 that prescribers and patients desire to be informed of alternative therapies at the time of prescribing. This may include trade versus generic options. Alternatives in the same therapeutic class, and alternatives for the same condition from a different therapeutic class, as well as alternative therapies, even nonpharmaceutical that may be helpful for the patient's condition or diagnosis.

Recommendations here to encourage incentivizing health plans to share data with all vendors utilize this data freely. To encourage incentivizing HR vendors to support the integration of alternative therapy data and recommendations in their e-prescribing platform. To encourage and incentivized providers to implement and utilize this data at the time of prescribing, and to encourage and incentivized developments and imitation of fire-based transactions.

So this list of recommendations has become pretty standard. We need the payers and the PBM's to share the data. We need HR's to implement the tools, and we need the providers to use the tools, and we need to encourage the development of fire. So I think, here again, nothing too new here. Any comments? David, your hand is up again.

#### <u>David McCallie - Individual - Public Member</u>

Yes. Just visualizing that last set of recommendations. One way to think of it is analogous to planning a trip. When you query the airlines for your choices to get from point a to point B, and you can see an array of choices where direct, convenient time may cost considerably more than the one-stop or to stop less convenient times and make the right trade-offs. Where the information that the consumer and the physician need, does the physician presumably know what to indicate it's for the treatment desired, the consumer may wish to weigh in on the convenience factors. I'm willing to take a less expensive drug twice a day instead of the more expensive drug once a day. Hopefully, it is clear what the bullet list of recommendations is trying to accomplish, but maybe making the analogy to planning a trip would be useful to readers.

## Steven Lane - Sutter Health - Co-Chair

Good point. Yes. We should not presume what the driver will be. It will not always be cost. There may be other considerations.

#### David McCallie - Individual - Public Member

Or trade-offs between cost and other considerations.

## <u>Steven Lane - Sutter Health - Co-Chair</u>

Right. I think we have within our sights, getting through the priority one items here. So that was row 10. We will move on to row 11, which addresses some EPCS. Well over 90% of retail pharmacies are unable to receive electronic prescriptions of controlled substances, only 32% of prescribers are enabled to send them. That is a gap for sure. EPCS is legal in all states and DC, and 15 states have enacted laws that mandate it. Does this support act require it for part D programming beginning in 2021?

So the recommendation here to encourage and incentivize provider adoption utilization for all controlled substance prescriptions, obviously if that can be done in 15 states, it can probably be done in the rest of them. To encourage reporting rates of ECPS by providers and pharmacies and to set progressive annual targets for the rate to advance the use of this. Obviously, this touches on the opioid epidemic and ways to combat that. Any thoughts or suggestions about this observation and recommendation?

All right. And then, Ken, you captured here the content of the original describing event is not defined.

#### Terrence O'Malley - Massachusetts General Hospital - Member

Actually, that was me. I snuck that in.

## Steven Lane - Sutter Health - Co-Chair

Oh sorry. You want to speak to it, Terry?

## Terrence O'Malley - Massachusetts General Hospital - Member

Just getting back to David's point. It seems to be at the heart of a lot of these processes. So maybe if we look at the content, we can use that content to drive a lot of these other processes.

#### Steven Lane - Sutter Health - Co-Chair

All right. We are on time. I want to thank everybody for your participation. We got through the priority one items. Your co-chairs will burn a little midnight oil and try to tighten this up as best we can. We do invite people, task force members to jump in and add comments at the cell level, probably better than just editing. Because sometimes, I think the edits, we end up having to move them around a bit. and in terms of our next meeting, it should be in two weeks, I believe. Is that right? Three weeks, August 13. Same time, same station. We will move on to the priority 2 items at that point. and hopefully, we are hoping soon to have a structured outline for our report from ONC colleagues that we can use to start looking at what our report back to HITAC is going to look like? Any final thoughts?

## Kensaku Kawamoto - University of Utah Health - Co-Chair

No. Sounds good.

## Steven Lane - Sutter Health - Co-Chair

Thank you all for participating, and we will talk to you again in three weeks.

## <u>Lauren Richie - Office of the National Coordinator for Health Information Technology - Designated</u> Federal Officer

Thank you, everyone. Bye-bye.