



Interoperability Standards Priorities (ISP) Task Force

Transcript
August 13, 2019
Virtual Meeting

SPEAKERS

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

Good morning, everyone. Welcome to the ISP task force, where we will continue our discussion on draft recommendations to date. Just do a quick roll call of the members. We have Ken Kawamoto, Steven Lane, Anil Jain, Cynthia Fisher, David McCallie, Edward Juhn, Ram Sriram, Tamer Fakhouri, are there any other task force members that are on the phone?

Ricky Bloomfield – Apple – Member

Ricky Bloomfield.

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

Hello. Anyone else

Ricky Bloomfield – Apple – Member

Good morning.

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

Okay. With that, I'll turn it over to our co-chairs to get us started.

Steven Lane - Sutter Health - Co-Chair

Excellent. Thank you, guys, so much and thank you, everyone, for showing up this morning. As Lauren mentioned, we are going to be working through the rest of our medication and pharmacy data recommendations. And trying to clarify and gain input into those. The ONC team has already begun an initial draft of our final report. And we've been working with them to sort of put a structure together and start to figure out how we are going to incorporate the recommendations we have settled on to date.

We're thinking that today is probably, if we're successful, the last day our focus is put on the recommendations themselves. But of course, as we put them together into report form, I think inevitably there will be a discussion about just what we meant, etc. But I think, at this point, we're no longer going to be bringing in subject matter experts or diving into new domains. Though there may be specific observations and recommendations that pop up as we go along. Ken, do you want to add to that?

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think that sounds good. We are really trying to go into the report ready mode soon.

Steven Lane - Sutter Health - Co-Chair

And then, as part of that, we wanted to talk about the schedule for the remainder of our time together. So, I think we can kind of go through our initial slides here. Here is the proposed schedule. So we met on the 23rd. We're meeting today. And then we have another meeting scheduled later this

month. Two full task force meetings in September and then one at the beginning of October before we make final recommendations to the HITAC. There is going to be a HITAC meeting next month, in September, where we will have some opportunity to present some draft recommendations. I don't think we have really dug down really deeply into the medication/pharmacy data recommendations.

So I don't think we have really determined what we are going to be focusing on in the September 17th in-person meeting. But clearly, our final report will need to be done by mid-October and delivered.

Any questions from folks about the schedule or anyone have any concerns about that? Great. Well, again, thank you all for coming. And I think, Ken, do you want to walk us through the med priorities, and I'll try to take notes as we go?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. That's great. If we can go to the spreadsheet. And we were just discussing where we left off, I thought it was after the cost information. I don't remember if we went through the non-cost priority one recommendation. But we can just briefly go over them.

So, the first one you see there, is on having alternative therapies, so not just cost on what you are about to prescribe, or wanting to prescribe, but what other options are there and information around there. And just as a note, I think it was David, I think, who had commented, we should take a lot of our related recommendations around things like price transparency and prior authorization and try to merge a lot of the related recommendations. We did attempt to do it in the Google spreadsheet format but realized it just becomes unwieldy, just because of the nature of the way spreadsheets work. So our plan is to merge them together at the point of converting these to our report format. And as a part of that too, we are drafting, I think another person recommended coming up with stories to kind of put these recommendations into perspective in kind of a use case personal format. So we have started drafting some of those up for medications and others, and we'll plan to incorporate those for feedback as well.

So if you have any comments on these, let us know. Otherwise, we'll go fairly quickly through these remaining party one. The other one was around row 12 around electronic prescriptions of controlled substances, that is still fairly limited and needs to be increased. I do see in content 1A, the content of the original prescribing event is not defined. I don't remember who or when we added this, but perhaps we could get a little bit of clarification on it. At least for me, it was a little bit unclear on what we were referring to here.

Steven Lane - Sutter Health - Co-Chair

I think Terry added this. And he is not with us this morning. But I think it really had to do with provenance. And the point that when you receive a prescription on a med list from another organization, that you really don't know where that came from, how did they get it? Was that a med they prescribed? Was it a med they heard about through the patient? that they imported from Sure Scripts or another provider or from a claim, for example? It is not clear what the source of that original prescriber was.

Clement McDonald – National Library of Medicine – Member

I agree. This is Clem. It's confusing because if it's the original prescribing event, there isn't any ambiguity. And I think we should require people that want to put in there to be much crisper than this. This will lead to nothing but confusion. And we already have the provenance in other parts.

David McCallie - Individual - Member

But it's not transmitted reliably, Clem, I don't think. I think med reconciliation is difficult in part because it is difficult to know where the medication originated from. If you wanted to track it back to the source.

Clement McDonald – National Library of Medicine – Member

Well, maybe he is just maybe it is just semantics, but what we want to know is, the item you had in your record came from, if it really is the original, that's what you wanted to know. Where it came from. I may be talking semantics, but regardless, I don't think this is actionable the way it is.

Steven Lane - Sutter Health - Co-Chair

I don't think it is just semantics. I think that it is one thing to say. You know, who started this. I'm on an anti-hypertensive. It was originally prescribed six years ago by a PCP in a town where I no longer live. Since then the dose was modified by a cardiologist, and then it was stopped, and then it was restarted at a different dose. Are we really talking about the entire history of a given med? I don't think we are. I think it would be unrealistic. Or, as Terry said here, the original prescribing event. Who started it, when, you know, and the details about that, as he said? Patient, author, organization, times, medication dose, frequency, duration, indication, you know, that information from the original. I don't think any system is designed today to capture and maintain that as metadata to a prescription. Is that something we are interested in promoting?

Clement McDonald – National Library of Medicine – Member

I think it needs a lot more analysis of what we're really trying to do.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think this relates to the notion of a care plan, like who is managing this medication, for example? Now we want also to avoid burdens, unnecessary burdens going on it as well. I mean, I can imagine if when you order a prescription, there's another checkbox that says, please don't modify it without my knowledge, have that being there you have to check, that sort of thing.

David McCallie - Individual - Member

Yes. No one is asking for that. I think it is just a question of making sure that particularly as information about prescriptions flows across system boundaries, that the receiving system has some way to determine where this original medication came from. Just a simple handoff consistently.

Steven Lane - Sutter Health - Co-Chair

But are we talking about the original original, or simply the one that they are receiving? That is really the question. Are we really asking for a whole new category of metadata that should somehow stay with the prescription as it transmits across boundaries? I don't think we are prepared for that.

Ricky Bloomfield – Apple -- Member

I think you have the original substance and you also have the original dose or the original route. Or would any of those be considered a new prescription, or an old prescription? And then you have a concept of clinician responsible for managing, which can be incredibly ambiguous, for example, if prescriptions are written while inpatient for discharge, it could be written by a resident who is not going to see that patient ever again. Yet the primary care physician might not agree with that prescription and doesn't want to be managing it. And so I think there is a lot of complexity built in here and it has been noted.

Clement McDonald – National Library of Medicine – Member

Here here.

David McCallie - Individual - Member

Well, the problem to be solved is that.

Clement McDonald – National Library of Medicine – Member

Well, this needs to be questioned by someone who's not on the line or speculating about what was meant and how to deal with this. I think it's a fool's errand, right now.

Steven Lane - Sutter Health - Co-Chair

Terry is not here to defend this. Should we sort of gray it out until we can discuss it with him?

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think it is clear sort of what he meant to include things like designation, whether a modification can be modified by anyone other than the prescriber. But I think it is okay for us to sort of mold it to what we think while we are on as reasonable and he can review it. It is not like we are finalizing it now, right? There is the opportunity, these will all get molded as we go into recommendations.

Clement McDonald – National Library of Medicine – Member

Not only that, the industry will push back too.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. I think the question is to focus this more on what should be consistent across the exchange of information. This is a real issue, right. So when we get external data, a real issue we run into is that when we import it, or reconcile it, like it, then just all the providence gets removed. It is as if, for example, we say as of today when we reconciled it, patients state there on this medication because we reconciled it with them. It doesn't say because it came from our neighboring health systems record.

Clement McDonald – National Library of Medicine – Member

But, Ken, if we have providence in all the prescriptions and the receiving system can keep it and deal with it as they wish, the key here is having the provenance and I think we already have asserted the provenance.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I know.

David McCallie - Individual - Member

Isn't that what is being asked for?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes, that is exactly what I am asking for.

Terrence O'Malley – Massachusetts General Hospital – Member

This is Terry. Hello.

Ricky Bloomfield – Apple -- Member

I think this is beyond providence.

Terrence O'Malley – Massachusetts General Hospital – Member

Sorry to interrupt.

Steven Lane - Sutter Health - Co-Chair

No, please jump in. I think this is yours and welcome.

Terrence O'Malley – Massachusetts General Hospital – Member

I think the question is providence. And what can we attach to the original prescribing event as Ken says that let us know where it came from and where it has been.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I agree. Is a separate issue of whether the EHR decides whether they want to show it or not, etc. But at least the data should be consistent. We are running into issues where after reconciliation, it is not even in the backend where we can see it and make use of it.

Steven Lane - Sutter Health - Co-Chair

In terms of a recommendation, it seems that all we can recommend is that this is explored. I mean I don't think we have time to sort of say, of Terry's list of potential items to include, which ones are most important. But, really, that this is an area that should be looked into.

Clement McDonald – National Library of Medicine – Member

Let me just say, we did this study with Sure Scripts and we got all the prescriptions for the last three years, and we presented it in a flowsheet, and there was no problem with figuring out stuff. But we had it all. And it's there. Actually, Sure Scripts has it all, most of it anyway.

David McCallie - Individual - Member

But it's not passed across interfaces like that. That is what is being asked for here.

Clement McDonald – National Library of Medicine – Member

I did not hear what you said.

David McCallie - Individual - Member

I don't think that information is available across interfaces and typical settings today. You know.

Clement McDonald – National Library of Medicine – Member

It's probably in Sure Scripts. You have to pay for it. It's available as an H2, as a D2 HL7 prescription message.

David McCallie - Individual - Member

Asking Sure Scripts to solve the problem is not the solution, I don't think.

Clement McDonald – National Library of Medicine – Member

I'm not proposing that. I'm only pointing out that if we get all the data, we're not going to have problems with any of this stuff. And I think that's what she would be getting.

David McCallie - Individual - Member

Isn't that what we are asking for here?

Clement McDonald – National Library of Medicine – Member

Well, I don't know. I shouldn't be commenting.

Anil Jain – IBM Watson Health -- Member

This is Anil. The description that is written on the Excel sheet, or the spreadsheet is more than just providence. This is trying to get into the head of the prescriber and the person who changed the prescription and for what reasons they changed it. Whether it went from brand to generic, this is beyond the technical provenance, but more of a clinical sort of thread as to the decision-making about a prescription. I do think this is beyond just simple provenance. At least the way I see this on the screen.

Clement McDonald – National Library of Medicine – Member

I agree with that. I think that will be a lot of work for a lot of clinicians.

David McCallie - Individual - Member

I think it's a workflow issue when you start. But when you're making the original prescription, it's not a big deal to indicate who you are, what you're doing, what you did. And I think that information that's often lacking and why medication lists are so terrible is that no one takes responsibility for managing the lists in part because they're not sure who is managing each individual med. That one piece in there that says can I change this medication. Or who is the only one to change it or don't change this unless you are me? That becomes really critical for people on very bad medicines that have a lot of bad clinical outcomes if they're not managed correctly.

Clement McDonald – National Library of Medicine – Member

You can do that within an institution, there's an agreement about it. I don't know how you do it across the world.

David McCallie - Individual - Member

You make a standard list of what you expect and have someone write the prescription.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes. My suggestion is there are two separate issues. One issue is if there is information that is available, and people are capturing how do you make sure that doesn't get lost during the reconciliation process or import process which is I think an issue distinctly. And then there is also the issue of you know, there is a lack of information currently captured that is important for clinical decision-making, but I think that is a separate issue and that is probably more like a USCDI to tackle the issue, someone to propose. because it is something like, right now, in many systems, it is not required for you to actually specify why you are prescribing a particular medication, like to treat something or prevent something. If we say for example that is required, that is a fairly substantial change that would be, you know, we would need to weigh, what does it mean if it is not voluntarily. For example, you could put in if you want to, but you must put in. I mean not as you know, maybe the benefit is worth the cost, but that is not something that I think we can decide in five minutes here.

Steven Lane - Sutter Health - Co-Chair

I have added language in the spreadsheet for people to consider. Sort of trying to clarify this as an observation and some recommendations to consider this. I guess the responsibility would really be to ONC.

David McCallie - Individual - Member

Isn't it our goal to suggest areas where we think additional work needs to be done? We are not supposed to solve the problem. We are supposed to prioritize the areas where additional standards work is needed.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think that is fair. I mean, I you know; we did put higher up medication reconciliation is a problem. As a priority one. I think of it might've been our first priority. I think it is reasonable to say that it is a part of that issue, sort of elaboration that part of the reason why it is very difficult to do reconciliation and to you know make sense of it is you know, these two issues. The data from the source is sometimes just like not carried through, and information that is later needed for reconciliation in making decisions on it is oftentimes never documented and hard to access.

David McCallie - Individual - Member

So you have at least provenance, which is a technical question, and then you have provider intent, which is a broader clinical question amongst others. Those two could be called out. Lots of studies have been done on capturing provider intent. It was Gordy Shift who did the large studies that completed not too long ago. I think if we were in the motive still getting input, he would be a good person to solicit for what they learned about capturing clinical intent.

Steven Lane - Sutter Health - Co-Chair

And we have a separate item for a reason for prescription indication, associated diagnosis. We have already said that it is valuable. Those really are the two key pieces here, and this one just simply gets that maintaining that metadata and sending it for medication information.

Clement McDonald – National Library of Medicine – Member

Be aware that for some drugs, it is obvious. You don't really need to say it.

Steven Lane - Sutter Health - Co-Chair

Yes. That is clear. And yet saying it does improve the completeness of the record. You may need to say to the patient. Again, providing the prescribing providers are not the only people who need this information. A lot of my patients don't necessarily know the Tylenol is for their headache.

Clement McDonald – National Library of Medicine – Member

Yes. That actually that is a good reason to put in the prescription. So it shows on the label.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes. It does bring up this other USCDI process too where it fits really nicely, right. Like the questions become things like what's the benefit of it? Which includes if the patient actually knows why they're taking, that might actually increase their compliance. You know, other doctors, the poly pharmacy could be reduced, etc. And if there are places that are actually already doing this with different EHR systems, then that can be listed. It seems like the kind of thing that is a natural use case for the separate USCDI process which would adjudicate these kinds of issues, I think.

Steven Lane - Sutter Health - Co-Chair

I invite everyone to look at the language as I have modified it and see if this is capturing the meat of our discussion.

David McCallie - Individual - Member

Do you want to list intent? Prescribing intent, and your ...

Steven Lane - Sutter Health - Co-Chair

I put an indication.

David McCallie - Individual - Member

Okay.

Steven Lane - Sutter Health - Co-Chair

That is fine. I can add that in.

David McCallie - Individual - Member

Indication or intent, I don't know. Indication is...

Clement McDonald – National Library of Medicine – Member

Are we talking about the two fields? Indication and intent?

David McCallie - Individual - Member

No, Clem, I'm saying those are the same thing. But just intent is a stronger word.

Clement McDonald – National Library of Medicine – Member

Right. But indication might be better understood by the world, I don't know.

Steven Lane - Sutter Health - Co-Chair

I have just added some clarifying text. Again we are not going to solve this problem today. We are just saying someone should look into this. And it's probably the ONC.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes, okay. I think these look good.

Steven Lane - Sutter Health - Co-Chair

Does anybody feel that we need to return to the hand-raising feature? That was a little loose for our standard discussion.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Sounds good.

Steven Lane - Sutter Health - Co-Chair

It was efficient, but I want to make sure everyone had a way to contribute. I can watch the hands, Ken, as you are leading the discussion.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Sounds good. I think we have discussed one this one fairly well unless anyone has objections as indicated by raising the hand, let's move on.

Okay, let's move onto the priority two, ones. Let's see, this is row 15. These get into the kind of secondary recommendations. So one is around PD MP data. The issue is that it can be getting access, it can cost prohibitive. We know that fees may be required to download data into Behr's. And data access is dependent on a lot of patchwork of state regulations. For example, some don't allow you to incorporate the data into your ERHU. You can only view it with no ability to make use of it in the system.

Recommendations we had. Streamline regulations across states either via federal regulation or perhaps model state regulation. Provide US core fire profiles Is to support access to PD MP data at low cost directly through state PD MPs. And there is an ONC project on this currently called I think RX check. Explorer is making PDMP data available for third-party apps to download and transmit to support innovative services. And policy levers responsibility we had was on to HHS Congress state legislator streamlining unified regulation from this area. And ONC and state PD MP providers continue support for enabling direct low-cost fire-based access to state PD MPs. Thoughts on this one?

David McCallie - Individual - Member

You want hands or not?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes, let's do hands.

David McCallie - Individual - Member

I am posting talk raising my hand. I think this is all good. The one word that is missing is privacy. At least in the states that have had big battles about this, it is being cast as a privacy issue. And so this explorer making the middle column third point available for third-party apps to download, that is a red flag for privacy concerns, you need to put some kind of qualifying language in there.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah, so maybe services, comma, where privacy can be assured, or you know that kind of thing.

Clement McDonald – National Library of Medicine – Member

What about approved service, public health has got to get it by law.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes. Sorry. After this one, let's do hands. But yes. With appropriate privacy controls. Or when you know, the apps are you know, from authorized stakeholders such as designated public health organizations or something like that.

Clement McDonald – National Library of Medicine – Member

Yes.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. Anything else on this row 15? I'm going to go ahead and add that.

Steven Lane - Sutter Health - Co-Chair

Sorry, Ken, I was thinking it actually belonged in the observation as opposed to posting a recommendation. But that is fine.

David McCallie - Individual - Member

While we are pausing here, if any of you have not seen the Washington Post series on the uses that the federal prescription narcotics database is being put to in terms of the opioid crisis, it is fascinating to read. And it is an amazing example of what data can do. And the fact that it was hidden away and took a years' worth of legal wrangling to get it exposed is a sad commentary.

Clement McDonald – National Library of Medicine – Member

David, is it good or bad? I didn't read it.

David McCallie - Individual - Member

Well, it is good because it explains retrospectively, what was the causes, or I will say what was the early warning signs of this opioid crisis. A small number of pharmacies in most states have over 75% of opioid prescriptions. They had all this data and stuck it in a database and kept anybody from looking at it. And in retrospect, it was just seismic warnings of what was going on, in plain sight, for 10 years. It's stunning reading. Read it.

Clement McDonald – National Library of Medicine – Member

Okay. Thanks.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. Let's go on to the next one. Adverse drug events. We have row 16 ADE detection is presently in the emerging manual process. Due to viability concerns, health organizations routinely document ADs and weighted patient safety events in IT systems that are separated from other EHR and other HIT systems. Work is underway by ARC to automate portions of the chart review process in an effort to identify and characterize potential ADEs.

It would be beneficial to have a one-click adverse event reporting function where a clinician could click a button, and it would snapshot the patient's current medication profile and pop up a question on what the adverse event was and communicate that to the FDA for subsequent analysis.

Recommendations, explore the data standards and specs that would be required to further automate the AD documentation analysis and reporting of AD. Explore the technology and data requirements necessary to support A.I. enabled real-time utilization of population-based AD data in conjunction with individual patient data to inform clinical care and population automatically related to all state medication usage. Support coordination between AD-related work being done by ARC, FDA patient fit modernizations, EHR vendors, pharma, and other stakeholders. And explore and encourage new approaches to address liability concerns on the part of provider organizations which limit the transparency of AD event data.

So that's what's there. Thoughts, David?

David McCallie - Individual - Member

I thought we had a discussion about putting this in the context of broader patient safety events. But I don't remember exactly what we landed on. It seems odd to carve out a specific subset of patient safety for recommendations.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think this is our medication sort of topic and I think that is why. We could make a note that you know, you know, similar approaches should be identified for other types of safety events.

David McCallie - Individual - Member

Well, that context may be more around -- the barriers are typically going to be legal, and so you might as well deal with all of those in a complacent way. Reporting and adverse drug event versus some

other adverse event that will fall into the same legal frameworks. It should be seen as part of broader safety. Focus.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. And I think we want to say something about – do we say and not for anything about legal aspects that we should probably I mean it is probably implied.

David McCallie - Individual - Member

You reference patient safety organizations, which are fundamentally a legal construct. It doesn't say it explicitly, so I think what we would call for would be consistency. So that there is a standard way to respond. Without undo, concerns of liability and one set are radically different from liability in another setting, which would inhibit you from reporting.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes. Okay. That sounds good. It looks like Steven is typing some more things there.

Steven Lane - Sutter Health - Co-Chair

Sorry, going on and off mute so as to not make you listen to my typing.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes. That sounds good. I think that is perfect. If anyone has anything else, please raise your hand. Okay, let's move onto the next one.

Row 17, PD MP query and reporting transactions with providers and pharmacists are not standardized. Standards 2017 include prescribers reporting to PD MP using the existing med history transactions that are currently integrated into e-prescribing workflows. Okay. And recommendations here is to adopt using these and to encourage the element of a standard query and reporting.

David McCallie - Individual - Member

Maybe that could be merged into the earlier one.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes. Maybe someone has a little bit more insight into this? What is the -- why is the query reporting transactions being considered separate from – query and reporting different from just trying to get the data? I am trying to understand this and the one-two rows above. The one above, the ONC work is fire-based and this one is saying use NC PDP.

David McCallie - Individual - Member

Maybe call for the reconciliation?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes. I am not familiar with this NC PDP standard. Maybe what we should do is...

Steven Lane - Sutter Health - Co-Chair

I think this came from our discussions with Sure Scripts, and the acknowledgment that this is working, and there are standards in place. And there was a sense that you know, moving too quickly you know that we want to optimize our use of existing standards. At the same time, we are also looking at new opportunities to leverage any technology, such as a fire.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think that falls under probably a generic recommendation not only for meds, and really in every area. Which we tend to have multiple sortable sorts of historical and current standards, and we also have I guess multiple competing approaches. And I think we want to foster innovation without a sort of ignoring and unnecessarily sort of replacing existing-working standards. I think that is the generic issue, right? That we have to sort of work through across all of these domains. I'm not sure we have enough information, and I think in the prior sort of deliberations, I think the general consistency was for example for you know, referrals with direct, etc., is that we don't feel like we can declare a winner and so you have to choose the source. But there needs to be you know this issue of having multiple competing standards and platforms and needs just to be addressed. I don't know how much more we want to get into that.

Okay. Why don't we move on? Unless folks have comments on this row 17 PD MP query and reporting transaction? Other than we should merge it in, and I think we can merge it in at the report writing state, with the other PD MP one.

Okay, row 18. It is difficult for a patient or provider to specify that a prescription that has been sent to a particular pharmacy be transferred to another pharmacy should the provider-patient desired have they prescription fulfilled elsewhere. The NC PDP script standard prescription transfer transaction support this. They also support notifications of the prescriber. This is a recently finalized standard which is mandated for use under Medicare part D beginning January 1, 2020, and is not widely implemented at this point.

And we had encouraged and incentivize implementation use. Although I am wondering like do, we actually need to encourage incentivize people if this is going to become mandated in 2020 by Medicare, which I assume would mean it would change the industry? I'm just trying to see...

David McCallie - Individual - Member

I was the one who I think originally raised this, and I was not aware of the impending – well, I wasn't even aware of the script standard much the less of the impending rule change for part D. It sounds like this one has been addressed. I would de-prioritize it if it was just me.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Steven?

Steven Lane - Sutter Health - Co-Chair

Yes, I think David, I didn't remember whether it was you or somebody else. But this did come up in our discussion as an important need. And then in the further discussions with SMEs from NC PDP, we learned indeed that this was being taken care of. So perhaps we could drop it.

Clement McDonald – National Library of Medicine – Member

Let's do that.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay, this one will be dropped. Let's move onto the next one. Some medications are covered under a patient's medical benefit as opposed to the pharmacy benefit. So meds covered under the medical benefit often requiring prior authorization and/or the documentation of clinical data, which makes the prescription process more complex.

A determination, whether it is approved or covered under the pharmacy or the medical benefit is not standardized. That is left up to the payers and PBMs. The technology standardization of these processes lags behind the benefits verification, authorization process for medication covered by pharmacy benefits, medical benefit. Queries and responses typically are X12-278 transactions. The medium-term solution to streamline is standardized. Prior auth process may involve a combination of multiple technical standards similar to how today's pharmacy benefits, verification process blends a combination of X12 and NCPDP. Multiple initiatives have spun up around the medical benefits verification authorization and use under the space of H12, NC PDP, and the DaVinci project.

So recommendations are supported multiple pilot approaches to the automation of prior authorization for medications and services covered under the medical benefits, with the goal of standardizing integrating these processes with other EHR workflows. Steven, did you still have a comment?

Steven Lane - Sutter Health - Co-Chair

Oh, sorry. No. I dropped my hand there. But I will just say, I was the one who sort of took these discussions and turned it into this language and that is true for a number of these. I just want to be sure that everyone feels comfortable with both the observations and recommendations as they are stated. This is a great chance for you guys to keep me honest.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Any comments? I think it makes sense. It is the right level to say hey you know there is a lot of ongoing work and ONC should keep supporting this. And I think it will, as evidenced by ONC's real focus on prior auth in general, right, and the insurance industry with DaVinci working on it.

Steven Lane - Sutter Health - Co-Chair

I think this is another example to David's earlier point, where this applies to the medical benefit prior auth process generically, not just the medications that happen to be in the medical benefits. The other thing we might have included as a recommendation, and I will just throw it out there, is the observation in item – just the fact that the determination of which items fall under the medical benefit versus the pharmacy benefit is up to the payers. And it would seem that if that in itself were standardized, these things fall under one category, these fall under the other category, that would streamline the processes. So everyone's playing with the same set of rules. This is the second bullet on the observation. Do people feel we should have a recommendation to standardize that or consider standardizing that?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Anil?

Anil Jain – IBM Watson Health -- Member

I want to make sure I heard that right. Are you suggesting, Steve, that we standardized how payers decide what is filled under medical versus pharmacy benefit?

Steven Lane - Sutter Health - Co-Chair

Yes. That is what I am suggesting.

Anil Jain – IBM Watson Health -- Member

I am not sure that that is an interoperability problem or an informatics problem. I think if we start to get into the business models of how payers may determine certain therapy as being covered under what plan, I think that might be a little too much. My perspective on that.

Steven Lane - Sutter Health - Co-Chair

And I think the counter to that would be that you know, if EHR and other HIT systems are building workflows around this, at least being able to predict, you know, if it is payer A, I have to have one workflow, if it's payer B I have to send out by another workflow. You know, or service providers want to step in and develop services, APIs, etc. to help support this. Again, not having certainty about which one is covered under which, seems like it adds friction.

Anil Jain – IBM Watson Health -- Member

Yes. I would just argue that we already have a little bit of uncertainty, even if you knew what category it would be under, whether it would be covered or not covered. Perhaps instead of figuring out whether it is consistently covered under medical or pharmacy benefits, that the transactions that lead to a preauthorization or lead to a benefits check come back and tell us, tell the system what it is under. As opposed to trying to get the payers and the purchasers to all agree on how they are going to cover this. Again, I think that there is only so much you can do with standardizing the way the information flows. The rest will have to be this business model of payers and purchasers.

Kensaku Kawamoto - University of Utah Health - Co-Chair

And David has a comment.

David McCallie - Individual - Member

I think the simple answer might be to say regardless of whether it is a medical or pharmacy benefit, the standards dealing with prior authorization should be the same. So in other words, we are not weighing in on what should be which, but that they both should be handled with similar standards and we have got a split now that makes it really cumbersome. Right?

Clement McDonald – National Library of Medicine – Member

I don't agree with that.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Maybe not necessarily the same, but like under recommendation, we can say faster in approach to both types of prior authorization that is seamless to the end-user, or something like that? Because there may be different data needed. Some may need to use different standards. But I think as long as the methodology allows for a seamless user expense, I think it is okay. You can imagine the initial one is a call to service that checks which of these paths I should go to, and then you make another call. Like there is a variety of potential technical solutions, but you know. Anil?

Anil Jain – IBM Watson Health -- Member

That is exactly what I was trying to say. Sas that we could use the information transactions as a way to figure that out as opposed to having people change business models. So, yes, good.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay.

Steven Lane - Sutter Health - Co-Chair

What do you think of the language I just put in there?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Could we change similar to coordinated or something like that? Just because the information like it very well might be like I don't know, there are different queries, and I am not sure if that means it is sufficiently similar? I guess it is a vague enough word, but I think the main thing is that the two approaches are coordinated, not necessarily that they are the same.

Clement McDonald – National Library of Medicine – Member

Well, why couldn't they be the same? Why couldn't the same message content be there despite different formats? You are going to have to see the indication, there will be 50 variables or 20 variables. Whatever it is. I can picture how they can be parallel. So that the systems that deal with them don't have to guess a lot of things.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. Well, maybe. I don't know.

David McCallie - Individual - Member

I mean there are ways to do the standard so that it could truly a don't care. But that is not the direction they are headed right now. So you know I think there is a reconciliation of different approaches that should be factored into how hard the standards are developed. Could they be consolidated?

Clement McDonald – National Library of Medicine – Member

There is going to be a problem anyway with the difference between both of them in terms of drug delivery.

David McCallie - Individual - Member

Right. You know and maybe the case that some prior authorizations are simple enough to be so standardized you don't need flexibility in the interaction with the clinician. But I suspect over time more, and more benefits will require actual interaction with a clinician and I'm afraid that some of the standards are being approached today are not going to be flexible enough to deal with that. But that is a deeper concern, sorry.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think Stephen's comment was perfect. Although it disappeared on my screen.

Steven Lane - Sutter Health - Co-Chair

Somebody deleted it.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Who deleted it? I did not do it.

Steven Lane - Sutter Health - Co-Chair

Let me see if I can go back. There it is. Maybe it was me.

Kensaku Kawamoto - University of Utah Health - Co-Chair

I see it now. Okay. I guess. Specifically, I think the way Steven wrote it, I think captures our comments, does anybody have any like qualms about the way to specified now? Okay. In the interest of time, let's keep moving, and we will always have, all of these are inevitably going to be slightly reworded, etc., when we put it into a narrative format, I think. So we will have another chance to review. Let's go on to the next one.

This is interesting that we have this listed as a party one. We will need to verify if that was intentional or not. We have observations, not a single standardized coding system for medications. RX codes are used by health systems, EHRs, and other e-prescribing systems to define the prescribable product, e.g. a brand name, a semantic brand of drug or a generic semantic clinical drug as well as the amount or duration to be dispensed. NDC codes are used by pharmacies and PBM's, to manage inventories of the individual manufacturer's product. There are use cases which require translation mapping between RX norm and NDC codes usually for a consumer refer for the price of a specific prescribed medication. RX codes could be used to define the brand name or generic prescribable product as well as the amount or duration to be dispensed. The pharmacy of PBM would map that to a representative NDC that would be used to query the inventory and pricing info.

Recommendations we have here, continue to support the use of RX norm codes to describe medications within fire APIs. The complex mapping between RX norms, SBD, SCD codes and representative could be cataloged, should be cataloged by the NLM working in conjunction with NDC as they do for other private code mappings like multimap and FDB. The translation from RX norm to specific NC inventory, that item should be performed by the PBM or pharmacy rather than by the consumer software. The consumer will often only have access to the RX norm code delivered via a fire API. Consider incentives to pharmacies to make medication dispense available via patient-facing API. These medications would likely be coded with NDC plus-minus RX norm.

Policy levers responsibility continue to work to catalog mapping of RX norms to NDC. ONC remains steadfast, and recommendations stood here to fire plus USCI for consumer APIs plus the use of RX norms for US core.

I believe a lot of this came from Ricky, but do folks have a comment?

Clement McDonald – National Library of Medicine – Member

This seems really complicated. What's the bottom line? I mean, we had the [inaudible] [00:50:15] that prescriptions will be, for brand names, are almost always more expensive. I mean, there are cases where they prefer the brand names, do they need to get to NDC?

David McCallie - Individual - Member

This is David. Ricky and I worked on this together. The issue was the mapping question. Well, it was the vocabulary question for fire APIs, when consumers interact with either pharmacies or PBM's. What nomenclature should be used?

Clement McDonald – National Library of Medicine – Member

So when consumers are interacting?

David McCallie - Individual - Member

Right.

Clement McDonald – National Library of Medicine – Member

What you see is the brand name and the generic. On the label.

Steven Lane - Sutter Health - Co-Chair

But again. I don't think this is just about brand and generic. This is really about the codes that are behind it and the fact that different pieces of the process, the ecosystem utilize different codes, and there is a need for mapping between them. It is not about brand and generic.

Clement McDonald – National Library of Medicine – Member

I had written generically for my whole life. And I never had any problems. I am having trouble...

Kensaku Kawamoto - University of Utah Health - Co-Chair

We can start with a little bit, I think this foundational issue, for example, is if you, you know, even if you just wanted to prescribe you know, I don't know like lisinopril 10 milligrams or something. There would be an RX norm, in that case, code for it. I think that would be an SCD code that says lisinopril 10 milligrams oral tablet or whatever, capsule. And then but when you are trying to get to the dispensable for example to see you know, what the cost would be for this medication, those systems oftentimes deal in terms of all the different NDC codes which could be the one that has 30 pills, the one that has 60 pills in a pack, the one that is in red packaging, the one that last month got a green streak in the packaging and they all have different NDC codes, right?

Clement McDonald – National Library of Medicine – Member

Have you looked at any of these webpages that give you low-cost prescriptions or over cost? They don't mention an NDC code anywhere.

Kensaku Kawamoto - University of Utah Health - Co-Chair

No, but I think in terms of the actual transactions was – so for example, I mean to be very explicit. For example, when we try, when we have a question about how much the medication is going to cost, the failsafe proof way to do it is actually trying to dispense one of those and go through NCPD an interaction. Right? And to get that, yes, this medication would cost \$3.75 after insurance has been in place and then cancel it. Because that is the level at which those transactions are done.

So perhaps, and you know, this recommendation is saying for example in those transactions, there should be a resource that translates from a publicly available resource that translates from you know, an RX Norm code down to a representative NDC code. So that is a specific proposal that is given. You can imagine there could be other approaches, hey, PBM's, etc., please accept an RX norm code with the duration, etc. and use that as the basis for identifying the best cost and what the alternatives could be.

Anil Jain – IBM Watson Health -- Member

There is a very real and specific use case that came up related to this issue that surfaced, some of the work that has been going on in Carin right now, looking at real-time benefit checks where there is the interaction of the consumer and the potentially the health plan or the pharmacy. And currently, the recommendation for Argonaut, for patient-centric receipt of medication data, is that the RX norm code is provided. That is what is provided every time.

Of course, in most situations, the NDC code can't be known because at that point, when you are receiving something from a list of medications in the EHR, it has not yet been since. So there is no way to know that. So the consumer might get RX Norm codes from their providers, but yet when they want to interact with the ecosystem that requires NDC codes, someone has to give, and there has to be some mapping there. And so, it is trying to ease this integration of a world where consumers are interacting with both sides which are relatively new, I think, but we are seeing use cases now where it will be required.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Terry has his hand up next. Sorry, Clem, because Terry had his hand up, let's go to Terry first.

Terrence O'Malley – Massachusetts General Hospital – Member

Just to echo the fact that this is really about real-time benefit checking. It is the fact that the system is so complex right now. And there are several different ways to get through it. I think this is reflected in this line item. More of the system issue than a particular code. The system itself is just very confusing.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Go ahead, Clem.

Clement McDonald – National Library of Medicine – Member

I am not sure what I think about the NDC codes. I don't know the full details, but I think they come from the knowledge vendors and they allow them putting those things together. I don't think they distribute them. I am not positive about that.

Kensaku Kawamoto - University of Utah Health - Co-Chair

[Inaudible] [00:55:59] for example, does have a mapping between RX norm codes and NDC codes. The issue here is that it gives every possible NDC code associated not a representative one.

Clement McDonald – National Library of Medicine – Member

The system is a mess, as you well know. If somebody re-labels another drug, it gets a new NDC code. So every pharmacy that labels their own drugs has separate NDS – I mean, CVS has its own NDC codes. It's a mess. There is no central file that has them all. The closest they come is the first data bank collection from everywhere. So I worry about depending on building a big system when if you knew where to find the cheapest drug, you could find the cheapest drug. I do it today with low-cost drugs.

Kensaku Kawamoto - University of Utah Health - Co-Chair

So, one suggestion – oh, go ahead Anil.

Anil Jain – IBM Watson Health -- Member

I guess maybe I am overthinking this, but it sounds like the biggest problem is we don't have a national repository of NDC codes because that is the only way – and I always thought that was under the privy of the FDA. But if there is a recall or if there is a manufacturing defect at the package level, the NDC code is the only way to track it. So why wouldn't our recommendation be that the appropriate agency, in this case, the FDA actually manage a national database of NDC codes and keep it up to date?

Because at least in my prior experiences, the databases that FDA would manage would be out of date, very quickly. There didn't seem to be that much of a need. But now, with all the consumers, and happening, and what I think is sort of a safety nightmare right now in the medication space, I think we ought to make the recommendation that there ought to be a central database that is managed and kept up to date. Therefore when CVS or Walgreens or anyone else decides to have their own dispensing packets and create a new NDC that there is some central – I thought it was always the FDA but that there is some central authority that will do it.

And then whether it is a vendor or an EHR, I mean an EHR vendor or third-party or consumer group, they can use this to figure it out. There is always going to be one too many from RX norm to NDC, given that the NDC's are going to be more specific about packets and dispense amounts and things like that. I guess I'm advocating for two things. One is a central repository that is going to be leveraged by all the stakeholders, and the second is to recognize that there will never be a one to one between RX norm and NDC.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. I didn't quite realize that the FDA list wasn't complete. I guess another issue I have heard is that NDC codes oftentimes recycle. So if that still is, in fact, the case, we should obviously make a recommendation that that really bad terminology practice not being done. David.

David McCallie - Individual - Member

Yes, I was going to point out the conversation in the chatbox in case people aren't looking to it that that NDC codes are available freely and without restriction from RX mix, the API source for RX norm codes. That issue got clarified.

But I think we have sort of two separate proposals here, both of which are important. One is the notion that we should have a standard way to keep the NDC codes up to date, be that via the federal agency or not. And then second, is we would consider the consumer-facing APIs continue to speak in RX Norm space, where you're talking about the non-inventory-based specification of medications. Whereas the others you know, of necessity, have to deal with inventory, which means NDC space. So that we do need to maintain a consistent mapping between those two. Is certainly not one to one, but it needs to be maintained regardless. And Clem, it is an API question not a human reading webpage question.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Steven?

Steven Lane - Sutter Health - Co-Chair

Yes, I was just, so Clem, this first bullet under the responsibility where it calls out in NLM in particular. Are you objecting to that?

Clement McDonald – National Library of Medicine – Member

No. I am not objecting. But I just they can't always do what they are requested to do. And I was wrong about – I still think there are some constraints about dumping them all out, but I may be completely wrong. It is just that I'm not authorized to say no one can do it. I just want to be cautious. They may have other barriers or cost or limitations or some agreement with the FDA. I am just saying, yeah. I am not saying we shouldn't do it, or they shouldn't do it. Let me retract all that.

Kensaku Kawamoto - University of Utah Health - Co-Chair

And I think a key issue is it is not really just consumer-facing. It is any group that has and deals with medications on in RX Norm-based approach because that is the level they have, should be able to interact with other systems at that level. If you think about it, it seems very artificial when a provider or patient says I am taking you to know, let's say, you know, this particular inhaler. And I want to find the cheapest way to get this medication. Or you know this type of an inhaler. And then to have to like in order to communicate with another system to get that, to say I'm going to use the system to convert it to a representative medication that can be dispensed that somebody has determined, because who knows if that representative medication is the one that is cheapest for my insurance, right?

And it seems like these systems, for example, that offer alternatives or cost or you know, say what it estimated should be able to accept the intent of I want to order this kind of medication and maybe be smart enough to know that as long as it is in that drug class it is okay to potentially switch and do all the magic behind that. Does that make sense?

Clement McDonald – National Library of Medicine – Member

When would the patient ever even know of typing in the whole NDC code? I have trouble seeing that. It's always a class of some kind they are asking about.

Kensaku Kawamoto - University of Utah Health - Co-Chair

That's exactly right. But I think their way the recommendation is stated, I think it is basically saying as you know, the process should be a group to identify what a representative NDC is for medication. And all the interactions around things like price checking to happen at the level of the representative in NDC. And I'm questioning should that really be the way or should it be in fact that these systems take the RX norm code, and sort of the other things like I want to dispense 60 pills worth or whatever, and then from that, it does things like mapping and a representative NDC may be one of the approaches. It may be to check every single NDC that is stocked in pharmacies in their geographic area, mail order pharmacies and check which comes out cheapest for example.

Clement McDonald – National Library of Medicine – Member

I am for that.

Steven Lane - Sutter Health - Co-Chair

Cynthia, you may need to go on mute.

Clement McDonald – National Library of Medicine – Member

I think the representative NDC code is an artifact of some limitations otherwise. It wasn't you didn't want to say you didn't know the generics. I think I thought that is what I got.

David McCallie - Individual - Member

They were a pre-RX Norm attempt to solve this problem.

Clement McDonald – National Library of Medicine – Member

Oh, okay. Yeah. I think what Ken said is what you're going to do. You're going to ask in some generic way, and then you might get back an NDC code. But what you're asking will be for some category, and let the system optimize the code for that category.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Clem, I think that is what I am proposing should be done. I don't think that is actually what is done right now. How the standard actually works.

Clement McDonald – National Library of Medicine – Member

Oh, okay. Okay.

David McCallie - Individual - Member

And the categories, the broad ways of specifying, particularly for consumer-facing, we think they should be RX Norm. And the inventory managing systems have to be prepared to deal with translations to and from. With respect to those transactions where that make sense. A consumer asking for how much does this drug cost. They should be able to specify that in terms of in RX Norm generic for a

clinical drug and get some choices back. And the receiving PDM would have to be able to understand the SCD code, and map it to their inventory choices, and provide some information.

Anil Jain – IBM Watson Health -- Member

Those are the use cases that I think Ricky was wrestling with. He had to drop off so maybe you should revisit this one when Ricky is back with us.

Kensaku Kawamoto - University of Utah Health - Co-Chair

How about for this one, let's just park it a little bit and put a comment that we will reformulate based on this discussion. And then of course for review by everyone you know later. But I think it is really getting around the notion of like we have two different worlds and terminologies discussing these, and we need effective ways to sort of bridge that gap, right? And currently, these recommendations are already going out of one potential solution path, and I think it is perhaps too early to do that. I think we can point out this is a potential solution path, but I don't think we should say this must be the solution path everyone implanted. Maybe we can do that and priority -wise, it is currently labeled as A1 and A2. This seems like a fairly high issue because it is tied very closely to the other priority one recommendation. Things like real-time benefit checking and all that, it is highly tied. I recommend we ship this up and keep it as a 1.

Okay. Let's move on to the other ones. Row 20, National Library of Medicine RX norm API does not return RX norm codes for discontinued drugs so it can create gaps in prior meds analysis. Recommendations, support pulling of archived RX norms, and NLM archived APIs. NLM is aware so that this would be a matter of resourcing prioritization. NLM recommended priority is completing the work. ONC may be provided on with a contract to complete the work.

This is probably just a generic recommendation too. Like, you know, when we say a group should do it, what that actually means is somebody, say the government, should pay and make sure that there's sufficient funding to do it, right. Because unfunded mandates are basically not something that gets priorities.

Okay. And thanks, Rob. Rob is saying row 20 is a priority. Yeah, I'm aware they're working on it. The implication of that not being there is that if people use to say the RX norm APIs assuming that it gives you current ones, it will do things like if you want to say hey, I want to see whether a patient has had this condition by checking to see if they've been on these medications. As it turns out, if they were on the medication five years ago and two years ago the medication got discontinued and is no longer available on the market, your system would falsely infer that the patient has not been on a medication for that condition, because you know, if it's not on the market, it doesn't pull a path now.

Steven Lane - Sutter Health - Co-Chair

Are you comfortable than leaving this to the priority two or did you want to move it to one?

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think it is a priority two. Because they are aware of it. It is a matter of can somebody please maybe prioritize it or give it a little bit more money.

Steven Lane - Sutter Health - Co-Chair

But we agree that the one above it on row 19, that should be priority one and moved up, correct?

Kensaku Kawamoto - University of Utah Health - Co-Chair

I think so. That is a foundational issue of we need to figure out how NDCs and RX norms are going to talk to one another and where the routes where the responsibility lies. I think currently it's assumed that the responsibility lies in the EHR and patient-facing systems to somehow make the conversion to the dispensable level for use in these transactions. And really, like for example, in EHR a patient is not going to know what the PBM is going to know, of like you know, like which one happens to be cheapest for their insurance?

Steven Lane - Sutter Health - Co-Chair

Okay. I have moved it up.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. Let's move on to row 21. Some IT standards required by federal programs are not publicly available. There is a strong benefit in public availability of health IT standards required by federal programs, including HR certification to ensure public review and compliance. For example, BP standards with support the interoperability of medication pharmacy data should be freely available to the public, including providers, pharmacist, and technology developers. It has been NC PDs business model for the last 20 years to allow only members access to PD MP standards. Most ani accredited STUs either charge for the standards or only allow member access. HL-7 does provide some of the standards for free. When a standard is referenced in NPRMs, a displayed copy of the standard must be available to all for the purpose of commenting. Each government agency determines how the displayed copy will be available. The displayed copy is removed once the comment period closes.

So the recommendation here is essential, we rely on these standards, right. So we should support public availability of the health IT standards required by EHR certification criteria. So the policy lever suggested here is ONC potentially in partnership with federal organizations such as CMS or NLM consider paying for US license to standards required by HER certification criteria similar to how the US government currently pays for national [inaudible] [01:10:40] license. To avoid perverse incentives, i.e., penalizing those standards development organizations that have already opted to make their standards openly available. Support not only standards that are currently publicly available but also those that are not currently available now. Especially not doing so jeopardizes the future availability and maintenance of those standards.

And just as a disclosure, I drafted this row and I'm an unpaid board member of HL-7, which is obviously implicated in this as well.

But a big-picture issue is I think standards that are only available for a limited time during commenting is — I think that is an issue, right? Because you know, it is when you are actually using the standards that issues oftentimes come up. And then, this notion of I think the standards are really public goods and should be supported. I will note for example, from HL-7's perspective when they made all their

standards publicly available, it had a dramatic impact on membership and revenue. that threatens future longevity and just the ability to keep the organization alive.

Clement McDonald – National Library of Medicine – Member

Threatened, because of other organizations, they are one of the few that do that, and it's hurt them.

Kensaku Kawamoto - University of Utah Health - Co-Chair

It is a big deal. It has been a precipitous decline in membership, which means that there's a real risk that a group like HL-7 might go bust, and there is no organization left to maintain the standards. Okay. So let's make sure, go ahead.

Cynthia Fisher - WaterRev, LLC - Member

This is Cynthia Fisher. I am sorry my plane was delayed, and I couldn't get on the call earlier. I don't know who is leading this discussion. I was just wondering if you could provide your name and please repeat the last couple of sentences about your concerns. It would be helpful.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes, Cynthia. This is Ken Kawamoto. You want me to reiterate sort of the last row's issue?

Cynthia Fisher - WaterRev, LLC - Member

Yes. You had a concern about the data and the impact, could you repeat that?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes. Sure. Okay. I will reiterate this one. So the notion here is that we are basically, through different programs, like HR certification referencing and requiring standards, a lot of them, except for the comment period, are not available to the public. So, otherwise, you basically have to pay to get access to them. And the recommendation overall is let's make sure that standards that we are requiring for people to use are actually available to the public. And also when we do that, let's not have perverse incentive where people who have groups that have kept their standards not available to the public are supported whereas groups that have publicly made their standards available to the public to the detriment of their membership and ability to maintain their organization are not penalized. David, do you have a comment?

David McCallie - Individual - Member

Yes, I just want to speak in support of this recommendation, and I think we have a precedent with the funding of SNOMED. This is not an unheard-of thing now. The government can, in fact, fund standards development if the government is willing to spend billions of dollars prospering interoperability through meaningful programs, it seems silly that they can't afford a tiny fraction to actually support the development of the standards that make it possible.

Steven Lane - Sutter Health - Co-Chair

Yeah.

David McCallie - Individual - Member

I like that.

Steven Lane - Sutter Health - Co-Chair

I think we have nailed this one. Let's see if we can get through the last one before we go to public comment.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. The last one is medication indication is oftentimes not captured. This is actually directly related to what we talked about with provenance. Medication indication may be entered as free text rather than the standardized approach. There could be a substantial value from both unstructured and structured medication, including indication available.

And then this has to be balanced against the added provider burden for capturing this data. And we have already sort of discussed that. I think we just incorporate this into the other comment we had about what is the information about a prescription that should be captured and transmitted and kept, as well as what are information that may not be currently being captured at a wide scale that should be. And we had commented earlier, this kind of thing would be perfect for a USCDI process. Because there is, I think the high value in, for example, documenting why we are prescribing the medication that we are prescribing.

Steven Lane - Sutter Health - Co-Chair

One thing that comes up and I have been through this a lot, over the years, is the question of whether this data should be captured using the same diagnosis codes that we used for billing, or whether it should be a separate code set. I know that some HIT vendors have a whole other set of options that could be used because of the sense that providers find it difficult negotiating the ICD structure to find these. I think like Clem, you know for my entire 30 plus year career, I have associated every medication with an ICD diagnosis, and it hasn't been much of a burden, it is just kind of what I do. I am treating hypertension. I am giving them this. Is pretty straightforward, and it actually facilitates real-time diagnosis-specific decisions and looking at the total cost of care, etc., etc.

But, do we want to weigh in on whether this should be done using the diagnosis codes that we are all familiar with or whether it should be left up to the vendor? I mean we say it can be free text, which I totally get that. Some people – there are real reasons to do free text, and I suspect Clem would argue that having that argue decreases provider burden. But do we want to weigh in on the code sets and whether it should be free text or ICD, or whether we need to encourage the development of another entire standard for this data.

Clement McDonald – National Library of Medicine – Member

Just to weigh in on that...

Kensaku Kawamoto - University of Utah Health - Co-Chair

Alright, Clem, David had his hand up. So let's do David then Clem then Anil – oh, actually, maybe David and then we need to go to public comment, and then let's go back to Anil and Clem. David?

David McCallie - Individual - Member

Yes. Just to repeat, AHR2 paid for a major study of these exact questions and Gordy Shift ran it. I think we should not make steep recommendations without hearing from what he learned.

Clement McDonald – National Library of Medicine – Member

I agree.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Great, let's move on to public comment and then we will go to Anil and Clem. Lauren?

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

Great, operator, can we open the line?

Operator

Certainly, if you like to make a public comment, please press star one on your telephone keypad. A confirmation tone will indicate your line is in 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

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

Thanks, I want to do a quick check. Have any other members joined late, since the start of the call? I know Sheryl and a couple others.

Sheryl Turney – Anthem Blue Cross Blue Shield -- Member

Yes, Sheryl did join.

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

Thank you. Any others?

Terrence O'Malley – Massachusetts General Hospital – Member

Terry O'Malley.

Cynthia Fisher - WaterRev, LLC - Member

Cynthia Fisher did join.

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

I have you guys, okay. Operator, any comments in the queue?

Operator

Yes, we have comments from the line of Katie Talento with KFT Consulting.

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

Thank you. Please go ahead with your comment.

Katie Talento – KFT Consulting – Public Commentator

I appreciate everything you're doing and really and supportive of the work that you do. I wanted to speak up now about an issue that was not discussed on this call. That I understand you are all in the midst of considering developing recommendations on it. And that is on the definition of electronic health information and if it should include pricing information as a form of compliance with the definition, with respect to the past, present, and future, payments for healthcare services.

I think it is really important that we include pricing information in that definition. Because it is actually more important to clinical decision-making than past information, like claims information. It is far less important to clinical decision-making by doctors and patients than future payment information that includes pricing.

So if I am going to make a decision about a certain drug or a certain cost-benefit analysis as a patient, then I think it is really important that patients have access to pricing information. Not just for list price but the negotiated price, total negotiated price, as well as out-of-pocket costs that include my deductible spend, and other cost-sharing especially coinsurance, hospital admissions, etc.

I just hope that you all will consider that. I know it is sort of radical. It is not what has been considered in the past. But it is a very common sense. But it is what the American people support. I know there was a recent poll that suggested 88% of Americans would support full price transparency in this way, including over 60% that would support it even if it temporarily raised prices. I appreciate your considering this. I know it was off-topic, but I wasn't sure I would be able to make future meetings, and I wanted to get that comment in. Thanks so much.

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

Thank you for your comment. Operator, any other comments in the queue?

Operator

Not at this time.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Great. Maybe we can go back to the spreadsheet. And thanks for that comment, by the way. We are dealing with party two recommendations, what you are described were actually the bulk of our priority one recommendations we've gone over the past several weeks. So it's definitely on our radar. Anil then Clem.

Anil Jain – IBM Watson Health -- Member

A couple quick comments. Like Steve, I generally make associate diagnoses with the medications I prescribe. But a couple little caveats. One is that I think we have to start thinking about when clinician start to do that, what is on the label, off label prescribing meaning downstream? And the second is that the medications transcend that single encounter, there is going to be a challenge when we already have problems with the problem list if you will. What happens when we have inaccurate diagnoses that tend to flow with the medications. We all know there is inaccuracy in the record.

So, just two quick comments. I'm not saying we shouldn't sort of have some sort of program to require some diagnosed with certain types of medications, but perhaps we ought to be thinking about this with the consequences. And also, as we think about prior authorization, there may be other ways to get at the indications for those drugs that really matter. I will leave it at that.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Clem.

Clement McDonald – National Library of Medicine – Member

I just want to clarify; I never coded my diagnoses and prescriptions ever. And I think I just said the name. For diabetes or for hypertension or blood pressure or whatever their current complaint was. And the words I used with the patient. If we put ICD10 codes in there, I don't think the patients will know what they have the time. So if you turn them into the words, I see looking better. Just beware of that. I am not for putting codes and, but I am for saying it.

David McCallie - Individual - Member

I don't think we should jump to the conclusion that you have to actually code it by a medical disease code associated with capturing intent. There are ways to capture useful and meaningful intent without going to that level of granularity. I think that is what Gordy was studying in his AHRQ grant. What is the right level of granularity to improve safety and compliance without necessarily burdening the clinician?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay, we are about five minutes to the bottom of the hour. Any final comments from folks before we transition to what is next? Okay. So, Steven, should we maybe sort of discussing where we are, and you already covered it towards the top, but what is to come in the next few months?

Steven Lane - Sutter Health - Co-Chair

Well, I think maybe we can ask Lauren to comment on that or Denise. Or maybe we can go back to the slide that showed the schedule that we have coming up. I think our hope is to get a draft report and it will be a very rough draft. I want to assure you. So you will see the format, and how we are, how we are probably proposing and translating our spreadsheet into prose for the report. But I think if we, Lauren if we can get the broad structure and some chunks fairly well fleshed out, I think the plan was the team was going to get back to me and Ken and perhaps Terry so we can work on it, and get it out to the larger task force. I would love to see us get that out for folks to be able to really chew on before our 8-28 meeting.

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

Yes. That is the plan, Steven. And then thereafter we would like to incorporate feedback from the full task force in time for the September 10th task force meeting, talk through any outstanding issues and perhaps maybe share a draft, a final draft of the report with the full community on the 17th. We will have to see whether it is you know, in a good enough place to kind of discuss openly with the group or just kind of have it in their back pocket as we are talking through the final recommendations. But that is the plan to try to finalize the first draft by September with a complete final report in the October timeframe.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Okay. Well, thank you, everyone, in a finding any final comments before we close today's call.

Steven Lane - Sutter Health - Co-Chair

Just one quick one. I don't know if we can pull back to the spreadsheet. I added some language while we were talking. I was trying to capture some of what was being discussed earlier. Can you screen share, Katie? There we go, thanks. I just added to that third or fourth bullet under observation. Patients may benefit when the indications subscribe medications are included in the prescription label and other systems. Does that help capture some of what people were saying?

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yes, I see you put Anil's comment on the off label, or I think it was Anil's, or David's. About off label usage and the recommendations, too.

Steven Lane - Sutter Health - Co-Chair

Yes. Our recommendations are not very specific here in terms of what needs to be done. That I don't know whether somebody wanted to suggest, are we suggesting that EHR systems routinely have the ability to capture and maintain medication indication in either free text and or structured fields? I think that is what we are saying, but we have not written that down yet.

Kensaku Kawamoto - University of Utah Health - Co-Chair

Yeah. It may also be that we are recommending that for example, this becomes a supported effort in terms of moving through the process, right? Anyway. Okay. Thank you, everyone. Have a great week, and shall we close the call?

Clement McDonald – National Library of Medicine – Member

Thank you guys.

Steven Lane - Sutter Health - Co-Chair

Thanks so much.

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

Bye-bye.

Kensaku Kawamoto - University of Utah Health - Co-Chair
Thank you.