



Interoperability Standards Priorities (ISP) Task Force

Transcript
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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
Mark Roche	Centers for Medicare and Medicaid Services (CMS)	Member

Lauren Richie	Office of the National Coordinator	Designated Federal Officer
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GUEST SPEAKERS

Name	Organization
Kim Boyd	CoverMyMeds
Ryan Tarzy	CoverMyMeds

Operator

All lines are now bridged.

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

Good morning, everyone. Welcome to the Interoperability Standards Priorities Task Force. With us today, we have our two Co-Chairs, Ken Kawamoto and Steven Lane. We also have Anil Jane, David McCallie, Edward Juhn, Terry O'Malley, and Ricky Bloomfield. Are there any other members that are on the phone at this time? Okay. I'd also like to welcome our guest, Kim Diehl-Boyd from CoverMyMeds.

And I will turn it over to Ken and Steven to get us started.

Steven Lane – Sutter Health - Co-Chair

Great. Ken, do you want to kick us off or would you like me to?

Kensaku Kawamoto – University of Utah - Co-Chair

No. Please go ahead. Sorry, I've been out for vacation in Japan but got back and looking forward to this discussion.

Steven Lane – Sutter Health - Co-Chair

Excellent. Well, welcome, everyone and thank you to those of you who have made the time to come on the call this morning. We are proceeding with our discussion of medication and pharmacy data and we're really looking forward to starting to dig into our draft recommendations.

We also did make a connection to the folks from CoverMyMeds, who, like Surescripts is a key vendor in this space and has done a lot of great work in evolving functionality and utilizing the standards that we've been talking about. So, we're going to give them a chance to share their perspective on standards and how they might be advanced to better support these workflows.

On the next slide, we have just a review of the charge of our taskforce. I like to always bring this up and remind people why we're here, especially our visitors, and that is to make specific recommendations on priority uses of health IT and the standards and implementation specifications that support the uses.

So, we've been through a process of identifying priority uses for our focus and have worked through a number of those. We're actually probably coming to the end of our deep dive into these areas and we're going to be starting to work on putting together our report back.

On the next slide, there is actually a partial list of our taskforce members because the slide is not optimally formatted and doesn't actually show us the last couple of rows, which include Sheryl Turney and Scott Weingarten and Mark Roche. So, apologies for that, but these are the folks who are here. We'll go ahead.

So, all of you hopefully received the emails from the ONC team inviting you to go and look at our spreadsheet, which we have up on the Google docs, where we've been evolving our observations, recommendations, etc. This is kind of the approach that we've taken to our prior domains, where we've dug in and then we've tried to develop specific recommendations within those domains of opportunities to advance or further specify the implementation of standards.

So, on these next two slides, I'm going to briefly take you through the areas where we've gelled around some observations and recommendations. This will be a quick tour. Then we will invite our friends from CoverMyMeds to make their presentation. We thought this would help set them up, understand where we've been. Then we'll come back to these lists, open up the spreadsheet, and start to go through in greater detail because really, what we want to do is go from these high-level concepts into much more specific recommendations of what we think should be done to advance within each of these specific areas.

Any questions before we go through the list? I know some more people have been coming on the call. We've got a lot of folks here now. Ken, anything to add to that before we run through this?

Kensaku Kawamoto – University of Utah - Co-Chair

No. Sounds good.

Steven Lane – Sutter Health - Co-Chair

Awesome. So, again, as Ken said, he's been away for a little bit. So, I took the list that he really started on when we went into this domain and have tried to parse it out based on the presentations that we've received, the subject matter experts that have been with us and the specific comments, both on our calls and into the documents that the taskforce members have been making. So, I really want to thank everybody who's taken the time to dig into this and hopefully, everyone will.

So, I took the liberty of separating out our observations into Priority 1 and Priority 2 areas. Of course, we can change the priorities. We can upgrade things, downgrade things as the taskforce sees fit as we're going through this process. But just to remind people of the big chunks that we've been moving around or the big pieces we've been moving around the board – we've talked a lot about medication reconciliation and the challenges of that and perhaps the opportunities for standards to support moving that from the challenging process that it is today to something that might be semi-automated in the future.

We've talked about discreet structured medication sigs, both their challenges and their opportunities, and we'll dig through that in a little bit greater detail. We've learned about the importance of transactions to get medication administration and dispense history data and have talked about how valuable that can be to both patients and providers and how it would be beneficial to see that be more interoperable and specific.

We've spent a lot of time talking about real price data from medications. This has clearly been a motif of our discussions throughout the work of our taskforce, the importance of price transparency, and getting that data into the workflow so that patients can make choices and providers are fully informed.

The eligibility and formulary checking – clearly an important step in medication prescribing and one that has a number of standards that are supporting it today and may have some opportunities to advance with the continuing ascension of FHIR and new approaches. EPA for medications covered under the prescription benefit is something where a lot of work has been done. I think we'll be hearing from our friends from CoverMyMeds about this and how the existing standards are supporting real life applications for EPA.

Alternative therapies – of course, a key piece of information that is helpful for patients and providers and payers involved in this, suggesting and supporting the use of alternatives. And then EPCS – we have not dug into deeply, but do have some recommendations that we've prepared there. So, it's a long list to say that these are all top priority, but I think based on our discussion that's sort of where we are.

Let me go through the next slide, which are sort of the Priority 2 items and then we'll turn it over to our friends from CoverMyMeds. So, here's the second slide, where we have specified the other issues that we've been discussing, which include the challenges of cost for access to PDMP data. These are not in the particular order within the priorities. So, don't feel that something on the top of the list is more important than something at the bottom here.

Adverse drug event detection – we spent a bit of time talking about that. I was certainly impressed by how manual that process still is. Transactions for querying and reporting to PDMP databases – we, I think, discussed some opportunities for improvements there. The transactions for transferring prescriptions between pharmacies – we learned from our friends at NCPDP that this actually is covered by their existing standards, though, it's not well-implemented. So, here, we're going to be talking more about the implementation specifications as opposed to the standards themselves.

We have talked about EPA as it relates to medications and other products and services covered under the medical benefit, which is quite different than the processes for those covered under the pharmacy benefit. Ken, I think you raised the challenge that RxNorm codes are not routinely available for discontinued drugs and that can make it hard for systems to deal with historical medications. So, that was an identified opportunity.

We had some discussion about the availability of NCPDP standards in the public domain. I actually got some feedback from NCPDP that they do post those standards publicly during the public comment periods, but then they take them down again. But there was some concern, especially on Clem's part, about whether or not there should be more general public access to those standards. So, we could talk about that I think at the end of that discussion, which was held largely offline. Clem was satisfied with the response, but we'll see whether that stays on our list.

And then I've had a chance to do some deeper dives with some of the vendors and some other subject matter experts and I've learned a little bit about the REMS challenges that are out there with collecting data for high-risk meds and managing those. We can decide whether we want to wade into those waters at all or leave that off the list for now.

So, those are kind of the areas, those subdomains, if you will, that seem to have floated to the top in our discussions of medication and pharmacy data so far. Any comments or questions from the taskforce before we hand it over to CoverMyMeds to tell us about their journey?

Great. I will take a break and we'll hand it over to Kim Boyd and her colleague from CoverMyMeds and hear a little bit about how they fit into this space and where there might be opportunities to advance standards based on their experience.

Kim Diehl-Boyd – CoverMyMeds - Guest Speaker

Thank you so much. This is Kim with CoverMyMeds. Ryan and I really appreciate the opportunity to be present here today with this taskforce and talk about some of the things that we've seen that work well, utilizing standards and protocols in the industry to not only surface patient pricing, but also facilitate the prior authorization process.

Just by way of background, I know we only have a little bit of time, but I've been an NCPDP member for 19 years, was a prior member of HL7 as well. So, I've been very familiar with the standards process and what you're looking at through the ONC lens around improving the healthcare system. With me is Ryan Tarzy, who is our VP of Strategy. When he gets into the pieces, I'll let him introduce himself. We can go ahead and move forward with the next slide but thank you again.

So, CoverMyMeds – our core mission is to help patients get the medications they need to live healthy lives. We started in 2008 to try to improve the prior authorization process for patients, providers, pharmacies, and payers. You can go ahead and forward as well.

To date, we've touched to scale 142 million lives, utilizing the standards and protocols that we have in place at CoverMyMeds to expedite the prior authorization process so patients can get on their medications quicker and live healthier lives. Go ahead. You can forward, please.

We've done that by creating the largest network in the healthcare space related to these transaction types. We have over 700,000 providers, 500+ integrated EHRs. We are connected with 96 percent of the pharmacy industry as well as 200+ life science brands and 94 percent of the payer market, representing 94 percent of the prescription volume. So, as you can see, CoverMyMeds has gone from being this small startup to this large organization that can facilitate the exchange of electronic transactions to improve patients' lives. Go ahead, please.

We did have a huge year in 2018 by helping providers and patients through the prior authorization process. We've processed over 41.7 million total PA streams the year of 2018 and utilizing the average median wage of a nurse practitioner, we've been able to save

practitioners and prescribers 10.4 million hours and time associated with reducing their call time and their faxes and \$343.4 million to the system as well. You can go ahead and...

But what we really wanted to talk to the taskforce today about were the newest technologies that are out in the industry, which I know you did have a presentation by another vendor a couple of weeks ago. We're very appreciative of their time in providing to this taskforce some of the challenges they've seen, why this information is starting to be surfaced now, why it's important to have this information. So, we'll kind of pivot to real time benefit check or what we call our patient pricing transparency tool. You can go ahead and forward.

One of the reasons for the difficulty in not only prior authorizations but in pricing transparency in general is the F&B file. While the F&B file is a standards-based file and it's information that can be provided in real time, it is not information that's always in real time.

So, providers today do not always trust in the formulary and benefit through their e-prescribing systems and for prior authorizations as well. What we found through a study is that over half of those providers did not trust the F&B file to give them accurate information about patient assistance, about their coverage information for their patient. Go ahead and forward, please.

We do know that prescribers are talking about medication costs with their patients. We surveyed providers and 70 percent of those prescribers had indicated that they are having frequent conversations. I'm sure this is probably not information you're not already familiar with, but we just wanted to home in on that. Go ahead and forward, please.

One of the interesting thoughts that we found very helpful to us making the decision to move forward with a pricing transparency tool was that when we surveyed some patients, we found that 52 percent of patients that we surveyed said that they did not get their prescription filled because it cost them too much money. They had sticker shock when they got to the pharmacy counter. And 75 percent of those patients reported that they actually received a prescription that cost them more than what they expected them to pay when they did get to the pharmacy counter.

So, our **[inaudible] [00:16:38]** is to try to mitigate that sticker shock, that price shock when they get to the pharmacy counter and we feel that that's what the pricing transparency tool should do is inform the prescriber and inform the patient about what their options are at the lowest cost out-of-pocket for that patient. Go ahead.

So, we're trying to empower as an industry providers and patients to make those decisions about their medication therapy before they actually finalize that prescription, before they get through the prescribing process. Go ahead, please.

What I'm going to do is I'm going to turn it over to Ryan Tarzy now and he can talk to you a little bit about RxBenefit Clarity. But he will home in on the standards and protocols that are being used in the industry today to help facilitate this exchange in real time.

Ryan Tarzy – CoverMyMeds - Guest Speaker

Thank you, Kim, and thank you, everyone, for your time. My name is Ryan Tarzy. As Kim mentioned, I'm Vice President of Strategy at CoverMyMeds. Prior to CoverMyMeds, I've had a career working with digital health startups around the themes of empowering patients and have, like Kim, been involved in NCPDP, but earlier than that with HL7, was founder of one of the first personal health record companies, and involved with HL7 and the ONC and CCHIT for the early days around standards for CCD and HL7.

So, this is a topic that's near and dear to my heart and I'm very excited about what's going on with FHIR and HL7. I think it's really a tremendous opportunity in combination with the other existing standards.

So, a little bit about RxBenefit Clarity – just to give you some context because I think it is different – it is different than the way we're approaching the market. From the way you might have heard about it from Surescripts, from our perspective, the way we're taking to the market is learning from our lessons of what worked in EPA.

It's important to, in our view, incorporate all stakeholders and all opportunities to provide true transparency and affordability options to the patient, to truly be patient centered. For that reason, we focus on calling it not real time benefit check, but true price transparency solutions. And fundamentally, as I said, transparency is just a means to an end. It is not the end itself. The true problem we're trying to attack is the problem of affordability for patients and economic sponsors in the market.

So, with RxBenefit Clarity, what we're doing is determining the accurate patient pay amount at the patient's preferred pharmacy and, of course, whether or not a prior auth is required. We do that through connecting to multiple networks, which we'll talk about in a little bit here, so that we're able to actually deliver the same information as if the patient was sitting in the pharmacy right now and pull that forward into the prescribing workflow so that the patient and the provider can have an informed discussion about all their options and not just their options of what they're going to get through their insurance benefit.

The key here, of course, from a value, as you've seen, is to eliminate prescribing barriers that – obviously, all stakeholders will get hurt when we have situations where a patient didn't know the cost of a medication before they show up at the pharmacy and then therefore don't end up getting the medication because of affordability.

That leads to pharmacy callbacks. That leads to the provider getting callbacks, which they don't want to hear, and ultimately that will undermine the trust in the system. This is why it's so important that we make sure that the price that is shown is an accurate representation of what's going to happen in the pharmacy versus just what's on their formulary and benefit file. Next slide, please.

So, that's why it's so important that we tap into the pharmacy network. We at CoverMyMeds have partnered with RelayHealth, which is the largest provider of pharmacy switch and

adjudication of benefits in the market. By doing that, we're able to pull forward the processing of the claim in the form of essentially exactly the same information that would happen at the pharmacy.

This is something that, again, if you just look narrowly in a benefit response in a standard and the way it's described in some places that I've seen – of course, this is a developing standard as we go – you would think that the only answer is to return the formulary and benefit information.

What's critical with combining the connections to the payer PBM as well as the pharmacy network is we're giving all options of what the actual price is going to be and we're increasing the chance that we're going to be able to deliver a response to the provider that they can trust. What we're seeing just from real time in the market or where the market is at right now is that solutions that are relying strictly on payer connections are responding at less than 10 percent of the time.

Therefore, we're seeing these solutions getting turned off when you can only trust it for that percentage of the time. So, it's important that we look at all options as well as ideally leverage the opportunity to see what's going to actually happen at the patient's preferred pharmacy versus routing them, for example, towards mail order if that's not a good option for them.

The other important component of leveraging the power of the pharmacy network is the patient benefit lookup. One of the critical gaps that we have right now in the real time prescription benefit model, if you go down that pathway, is that the EHRs don't, most of the time, have the patient's eligibility information. They focus on the medical benefit, not on the pharmacy benefit, the front of the card versus the back of the card. Even when they do it, they usually just scan the card and don't have the pharmacy eligibility information in a machine-readable format available to these APIs.

So, what we're doing by leveraging the pharmacy network is being able to save a large number of transactions that would have not been able to give the benefit of transparency to the prescriber by using information to match this eligibility from a previous claim that's happened in the last 90 days to the patient and be able to return that benefit information. That's allowing us to deliver response rates closer to 50 percent versus 10 percent.

The other thing that's been critical to take into account is patient assistance programs. This can be something that is viewed as a dirty word for certain stakeholders, but fundamentally, we believe this is critical to solving the affordability program. If we truly believe in price transparency, we need to actually deliver an accurate representation of what's going to happen at the pharmacy and that includes e-voucher programs which are going to be automatically applied and e-coupons to know that the patient is given every option and that it's reflective of what's going to happen in the pharmacy. Okay. Next slide.

So, how RxBenefit Clarity works – it's a little bit different again. So, we are working now with EHRs that represent half a million NPIs. We have the most NPIs live in the market right now,

150,000 that are actively pinging our solution at the level of 5 million unique patients a month. What we're seeing that's really delivering for them is the ability to ping multiple different opportunities here.

So, essentially how it works is the EHRs will ping CoverMyMeds through a rest API using protocols that are well-established on restful APIs. That's not an NCPDP standard. It is a typical rest API that is well-established across multiple venues. It could be – and we actually do have a couple that are live using SMART on FHIR. That's our preferred methodology of where we are pushing most EHRs to go with us is to connect with us through a CDS hook, which is a substandard of SMART on FHIR.

Unfortunately, most of them are not there yet. So, this is, I think, a critical part in any kind of standards building is that you give a bridge time period to push towards a SMART on FHIR standard, but right now, we have essentially a bridge solution that uses a standard restful API and then we use SMART on FHIR on the back end internally so that we're ready for those that are ready on SMART on FHIR.

So, we have a restful API, which it's our SMART on FHIR API. Then from there, we route the information to multiple connections. We have direct connections with a number of PBMs and those are growing. They have their own restful APIs. Some are using script. Some are using the restful API. Some want to use standards looking back at the E1 or B1 standard that's typically used in pharmacy or D1 standard.

So, there's quite a variety. I think that's another important theme, since I know how focused this group is on standards. There is no one standard to approach the market right now. There are multiple established pathways to deliver this information. As we look towards this from a regulatory and from a standards perspective, creating perspective, it's important that we don't essentially stop the innovation or slow down innovation by requiring one standard pathway.

So, moving on to the next slide – a common theme here is to allow multiple methods not only of getting the information, but recognizing that in the real world right now, patients don't get their medication through one way. We've all heard about the companies like GoodRx and the issue of noninsured in the market right now.

What we're seeing is that about 33 percent of the time, a patient actually benefits from using cash or coupon or a direct-to-pharmacy discount like we've all heard of the Walmart \$4.00 generics programs or discount Tuesdays. About 33 percent of the time, the patient is going to benefit by not using their benefit. That's actually what's happening in the market and growing even more.

So, when we think about the way a patient is getting medication and when we think about a real time price transparency solution, we need to deliver a solution that is going to both leverage the PBM benefit as well as the direct-to-pharmacy and cash and coupon benefits.

So, CoverMyMeds, this is the approach that we're taking. As we mentioned in the technical

diagram, we're connecting to right now pharmacies directly through their benefit processors to get their prices that include those \$4.00 generic prices, those cash and coupon programs, and also, layering in e-voucher and e-coupons into that price so it truly is accurate and represents all options for the patient.

In addition, we are connecting to the PBM, which has the information more comprehensive around payer alternatives, which was mentioned earlier. So, we really want to have the best of both worlds, where you can show the alternatives that the payer prefers, show the clinical alternatives that are established through groups like First Databank and Multum, well-established clinical alternatives, but also show the patient affordability options and the real time cash networks. Next slide, please.

Ultimately here, it's also important that you deliver it in a way that delivers speed. Right now, where our average time is 0.25 seconds and it's critical that whatever standard or solution that we develop going forward, we recognize that speed is of the utmost and we don't go down a pathway that is going to require a long time or it's not going to be used. Patient providers want to read and move on. Next slide.

So, I just wanted to give you what's actually happening in the market. This is a case study. Again, we've partnered with EHR systems that have over 150,000 providers live and over half a million that are now coming on board, so, another 350,000. We've had over 130 million individual searches in our time. Through the case study that we did across that population, we found that the patient pay amount returned was 97 percent accurate. Again, we mentioned it was delivered in 0.25 seconds.

This is really where we get excited, though. Patients whose providers used RxBenefit Clarity were 19 percent more adherent to picking up their medications. Cheaper alternatives were shown in 2.5 million of those transactions, helping providers give more options to their patients. Same day pickup, which as we know, convenience is another part of the value proposition for patients as what they're looking for, being more consumers – 84 percent of the time, that was available and 61 percent of the time they were available within one hour.

So, again, the advantage to the pharmacy connection is we can determine what is actually there in the pharmacy versus just what's on the benefit. Just to give you kind of a sense, providers ran an average of four transactions during a single patient visit. So, they are out there and shopping for their patients.

Steven Lane – Sutter Health - Co-Chair

Ryan? Sorry, can I just jump in here.

Ryan Tarzy – CoverMyMeds - Guest Speaker

Yes.

Steven Lane – Sutter Health - Co-Chair

These are wonderful outcomes. Can you try in the rest of your time, just because we have

some limits here, to focus on the standards issues and where you think standards need to go to be able to bring this kind of functionality to everyone across the industry, appreciating you guys have done this already?

Ryan Tarzy – CoverMyMeds - Guest Speaker

Yeah. I'm sorry. I tried to bring it to outcomes and speak to, with our stuff here, where we've seen the critical components around standards. Let me re-address those specifically here and go off slides. I think the important thing, as I alluded to earlier, is we fully support the development of the NCPDP real time price transparency standard. What I encourage the group to think about based upon what we're seeing in the field right now and the level of innovation and speed of adoption, which is really unheard of.

I mean, it's happening at five times the rate of what EPA was adopted in seeing how many people have adopted these standards and how many EHRs have brought it into their solution is that we don't stamp out that innovation or slow down that innovation by requiring a single – there are multiple protocols that are being used that are well-established, such as HL7 and FHIR. I would encourage us to continue to lean in on the FHIR standard and encourage more EHRs and stakeholders to adopt FHIR and particularly CDS hooks and the care resource documents components of the 4.0 standard as a methodology for delivering real time benefit check and as a protocol for delivering real time benefit check.

There will continue to be members of the stakeholders, for example, on the pharmacy side, but also on the PBM side that are going to use the V1 B1 telecom standards as a way to means. That is a well-established, very secure, very fast way of delivering benefit information. So, I encourage all of you to consider multiple pathways of delivering the benefit information or a better word for it is the price and related coverage and affordability options.

But I also encourage you to consider that there will be times where a rest API is still the right way to deliver information because there is no established standard, for example, of how to deliver cash information or coupon information through any other means other than rest API protocols that have been used across many different industries and can still be delivered through a smart front end that is going to deliver you the security but still go down that pathway.

With that, I'll open it up to the questions.

Steven Lane – Sutter Health - Co-Chair

That's very helpful. One of the things that your friends over at Surescripts did was after our discussion, they went back and sort of wrote up a short, bulleted list of just those pithy observations about the standards and actually made some of the same points about the need to embrace different standards. Given that you guys are so much deeper into this, it's really helpful if you can – I've been furiously scribbling notes and we're going to transcribe your presentation.

But if you can say, "At this point in the process, these are the standards that we think should continue to be supported. This is where more specific standardization may be beneficial. This

is where it's good to allow the use of multiple standards and which ones." That kind of input is really helpful.

Ryan Tarzy – CoverMyMeds - Guest Speaker

Yeah. I think in addition to standards, I think one of the things we should be thinking about – I was at the CHIME Advocacy Summit two weeks ago. One of the conversations that Don Rucker and members of Congress were talking about were the issues of open standards and removing information blocking from the standpoint of health systems that are creating those siloes.

I think the other thing I would consider the group to think about is making sure that all this information is available openly to the patient when the patient is asking for it. So, a lot of this is not just about developing a standard of a way to do it, but it's also about making sure the patient has access to that information from wherever they're requesting it, much like we're asking for health systems to release APIs, open APIs for patients to download information from a health system. I would encourage us to try to develop standards to allow patients to have the rights to access their eligibility information.

Steven Lane – Sutter Health - Co-Chair

Very helpful. Thank you for that presentation. This is a good time for taskforce members to ask any questions. We also have the public chat window for those who are not in the taskforce if you have pertinent questions. Sometimes we can repeat those and bring them into the discussion or you can wait for the public comment period.

David McCallie – Individual - Public Member

Steven, I don't know if you're doing the raise hands thing but –

Steven Lane – Sutter Health - Co-Chair

Yeah, David. Go right ahead. You're on top. Yeah.

David McCallie – Individual - Public Member

Okay. Kim and Ryan, thanks for the clear presentation. One thing that you left out or I might have missed it is sort of what your business model is. At the high level, I'm interested in what the incentives are that make an expensive network like this actually work. So, can you just describe who pays you and why?

Ryan Tarzy – CoverMyMeds - Guest Speaker

Sure. So, our solutions are delivered free to patients and pharmacies, which are the primary users of the network that are enabling this for patients. Our economic sponsors are payers, for whom we create a lot of efficiency and ultimately improve appearance and pharma, which benefits from patients being more adherent to their medications. That's for our EPA standard.

On our real time benefit check network, which of course is newer but growing faster, the primary economic sponsor that we see in the market going forward is the payer because they

do benefit from either being able to help avoid prior authorizations or switch medications to a more affordable medication is often the outcome presenting transparency, but in addition to that, pharmacies are benefitting and are economic sponsors for us as well because they're avoiding restocking and patients not getting their medications. Then finally, pharma is, in a small way, participating so far through their patient assistance programs.

David McCallie – Individual - Public Member

When you say payer, you typically would be talking about a PBM?

Ryan Tarzy – CoverMyMeds - Guest Speaker

That's correct. Right now, the existing real time benefit check solutions are [audio cuts out] [00:39:54] retail pharmacy benefit primarily solutions, so, yes, they are for the most part PBM-sponsored. That's correct. We'll see that probably change over the next year or two.

David McCallie – Individual - Public Member

I think you said it in your answer, but just for clarity, you have a direct to consumer exposure as well as something that the EHR is exposed to providers? Is that correct or did I miss that?

Ryan Tarzy – CoverMyMeds - Guest Speaker

Yeah. So, the by far predominant means that we are delivering the real time price transparency solution is in the EHR at the point of prescribing. But we do have a solution in the market that delivers to the patient a solution that puts them in control of understanding all their options, including which pharmacies, which method to use cash or coupon or to use their benefit.

David McCallie – Individual - Public Member

Okay. Thanks.

Steven Lane – Sutter Health - Co-Chair

Ricky, I think you're up next.

Ricky Bloomfield – Apple - Public Member

Great. Thanks. Great presentation. I had a quick question about the eligibility. You mentioned how key this was in getting the information in a structured way to increase your ability to return information. Are you using a standard for that such as the FHIR coverage resource or are you just capturing that in your own format?

Ryan Tarzy – CoverMyMeds - Guest Speaker

That's a really good question. I would love if we could get a faster pathway to FHIR 4.0 standards with the coverage resource documents. That would be a tremendous way to solve not just the PBM or pharmacy benefit but also to make improvements towards medical PA and price transparency for medical benefit. So, we've been serving on those taskforces and are very encouraged by early developments with Da Vinci and so forth. The reality, though, in the market is nobody has that live.

So, we're relying on – I wouldn't even call them standards. There are components of NCPDP that talk about these data elements. So, there is a structure, in a way, in the existing scripts standards that talks about this. But the reality is a lot of times the information is incomplete or, as I said, a non-machine-readable format. So, we're using the patient information and their PBM information to research back into previous claims to match the patient to their benefit so that we can return the proper information for that patient.

Ricky Bloomfield – Apple - Public Member

Got it. That makes sense. Are you engaged at all with the CARIN Alliance, who is also thinking about some of these things?

Ryan Tarzy – CoverMyMeds - Guest Speaker

We are aware and engaged. We haven't formally joined at this point, but it's something that we are looking at as well as Da Vinci. We're informally involved in taking part in HL7 task groups. We're not a paying member of Da Vinci, but we're involved. We're also looking at EHI. So, these are all things that we're aware of, but not formally a part of.

Ricky Bloomfield – Apple - Public Member

Great. Thank you.

Steven Lane – Sutter Health - Co-Chair

Great. Next hand up is Terry O'Malley.

Terrence O'Malley – Massachusetts General Hospital - Member

Hi, thanks for the great presentation. Actually, a comment and two questions – I gather from what you're saying that you don't think there is an absence of standards of what you'd rather see as a coalescence around existing ones. Is that correct?

Ryan Tarzy – CoverMyMeds - Guest Speaker

That's right. I think that's an accurate description. We're not being held up by a lack of standards at this point. A coalescence of standards around, for example, the care resource document of FHIR 4.0, around the existing standards coming out of NCPDP around SMART on FHIR and CDS Hooks, but also factoring in older standards such as the B1 and D1 standards in pharmacy, coalescing those and making sure that the information is actually open and available to the patient and their provider.

Terrence O'Malley – Massachusetts General Hospital - Member

Great. The other question – I'm going to steal the ISP Taskforce time to ask you a USCDI question – you alluded to data that's not available in the standard format. Could you come up with a list of things that are missing that would be nice if they were part of certification?

Ryan Tarzy – CoverMyMeds - Guest Speaker

Yeah. We can do that as a follow-up. We'll gather that as part of our follow-up bullet points.

Terrence O'Malley – Massachusetts General Hospital - Member

Thank you.

Steven Lane – Sutter Health - Co-Chair

Great request, Terry. Thank you so much. Just for my own notes, you mentioned the need to coalesce around the care resource document in FHIR 4.0, the NCPDP work with SMART on FHIR and CDS Hooks, and then you mentioned some older standards that you say are still helpful to support this. What were those older standards again?

Ryan Tarzy – CoverMyMeds - Guest Speaker

So, these are old telecom standards that have been used in the pharmacy world for adjudication for many, many years. They would be called telecom and those are the B1 and D1 primarily.

Steven Lane – Sutter Health - Co-Chair

And who owns those standards? Are those X12?

Kim Diehl-Boyd – CoverMyMeds - Guest Speaker

The telecom standard is owned by NCPDP.

Steven Lane – Sutter Health - Co-Chair

Very good.

Kim Diehl-Boyd – CoverMyMeds - Guest Speaker

The telecom standard is for telecommunication.

Steven Lane – Sutter Health - Co-Chair

Thank you.

Kim Diehl-Boyd – CoverMyMeds - Guest Speaker

You're welcome.

Steven Lane – Sutter Health - Co-Chair

We know just enough to be dangerous.

Ricky Bloomfield – Apple - Public Member

And just to clarify, when you say the care resource document, are you referring to the care plan resource, just so we understand what you're referring to?

Ryan Tarzy – CoverMyMeds - Guest Speaker

No, it's a little bit different, although that's helpful as well when you're talking about transfers of patients. There's a specific HL7 standard called – I hope I'm not getting the words

wrong – but I know it’s called CRD and I believe it is –

Kim Diehl-Boyd – CoverMyMeds - Guest Speaker

Clinical resource –

Ryan Tarzy – CoverMyMeds - Guest Speaker

Clinical resource – is it clinical?

Kim Diehl-Boyd – CoverMyMeds - Guest Speaker

Clinical resource document.

Ryan Tarzy – CoverMyMeds - Guest Speaker

Yeah. Okay. I think that might be it.

Ricky Bloomfield – Apple - Public Member

Got it. So, something outside of FHIR, a separate HL7 standard that you’re referring to.

Ryan Tarzy – CoverMyMeds - Guest Speaker

No, it actually is part of FHIR 4.0.

Ricky Bloomfield – Apple - Public Member

Okay.

Steven Lane – Sutter Health - Co-Chair

Ricky, maybe when you dig into that, you can shoot us back some information about what you find just so we’re all on the same page.

Ricky Bloomfield – Apple - Public Member

Yeah. I’m looking at it right now on the HL7 page. I’ll let you know. Thanks.

Steven Lane – Sutter Health - Co-Chair

Ed Jun, your hand it up.

Edward Juhn – Blue Shield of California - Member

Yeah. Thank you so much for the presentation. Just a question of clarification – does your service address both new prescriptions as well as existing prescription? And the follow-up is the delivery mechanism to get that information primarily through Surescripts or some intermediary RTBC service or is it via some type of EHR app or API?

Ryan Tarzy – CoverMyMeds - Guest Speaker

Yeah, really good question. It does serve for both initial prescription as well as follow-up prescription, as well as primarily delivered at the point of prescribing in the prescribing workflow. It is at the same point in time in which right before, in fact, you would send the

script through Surescripts most likely as the monopoly in the market, but the actual call is done through a rest API, sometimes through SMART on FHIR, but it's not in any way going over the Surescripts network. It's a direct connection between the EHR or e-prescribing software to CoverMyMeds.

Edward Juhn – Blue Shield of California - Member

Thank you.

Steven Lane – Sutter Health - Co-Chair

All right. So, as always, David has his hand up again. But David, if you're willing, I'm going to flip-flop and let Jack Po go first and then we'll come back to you.

David McCallie – Individual - Public Member

Absolutely. Fine.

Ming Jack Po – Google - Member

Thank you. I was just curious – you mentioned a number of statistics earlier around how many of the meds are actually cheaper sometimes on cash versus getting it through the PBMs or through some other insurance coverage way, as well as you mentioned that you guys can get pricing from the PBMs. Do you guys also get deductible information and is that true after taking into account deductibles?

Ryan Tarzy – CoverMyMeds - Guest Speaker

Yeah. So, the information we mentioned where about a third of the patients would benefit from using – because of high deductibles or because under-insurance, that's really the driving factor. So, deductible and coinsurance is factored in when we're talking about that, absolutely.

In terms of when we are returning the price, it does incorporate deductible into the benefit price for the patient, yes. So, it's not just this would be your copay if they haven't hit their copay or deductible. It's what they actually are going to experience and write and check for, put in their credit card for at the pharmacy.

Ming Jack Po – Google - Member

I see. I'll just ask one more quick question before I hand it to David. I forgot who mentioned – someone asked about the fact that you guys also have a consumer solution. Is the consumer solution free or is it also a paid solution that they somehow access as an app or on the website?

Ryan Tarzy – CoverMyMeds - Guest Speaker

I'm not sure I understand. Are you asking the name of it or where are we doing it? What's the question?

Ming Jack Po – Google - Member

How do consumers access it and do they have to pay a fee to access it?

Ryan Tarzy – CoverMyMeds - Guest Speaker

So, it's absolutely free to the patient. It is available via either download of the app or going to the mobile website or via solutions with our partners like through a patient portal that the health system or EHR provides. Those are the primary means right now. We also have some employers that are interested in providing this type of transparency tool for their employees.

Ming Jack Po – Google - Member

Thank you.

Steven Lane – Sutter Health - Co-Chair

David, back to you.

David McCallie – Individual - Public Member

Yeah. I'd like to come back and have you say a little bit more about the tradeoff between – I think you used standards versus innovation – and understand a little better what the competitive landscape looks like here in terms of which – I would call them standards competing for airtime and how that affects the market.

So, for example, we've heard numerous people mention the NCPDP standard. You mentioned that you support it but you were encouraging us not to stifle innovation. I'm not quite sure I understand that tradeoff. Could you just dive in a little deeper to that to the degree that you're comfortable?

Ryan Tarzy – CoverMyMeds - Guest Speaker

Sure. Let me start with kind of an example. We're pulling from a lot of what we've seen happen in e-prior authorization and trying to apply those lessons of what has worked in e-prior auth and bring that forward into – it is a very similar network with very similar stakeholders for this market.

So, for example, while the script standard has been very important to the development of EPA and the adoption of EPA, there are a number of examples where – I'll give you an example of attachments. So, we had a situation over the last couple of years where in order to get a prior auth approved, there was required documentation by the payer to be able to get that approved – lab results, for example. Well, the version of the standards at the time didn't allow for attachment.

Now, it does, but that's an example where there is like a two-year gap in which it would have stifled the adoption of electronic prior auth. So, the way we handled that is by supplementing the standard with rest APIs that enabled for a solution by the provider to be able to attach that and send it through parallel pipes to the standard, if you want to think of it that way.

In addition, there are field limitations often and character limitations in the standards that sometimes they're not full cooperation from all the different players around that. So, the

option there is you require the standard and you wait two years before everyone comes along or you start working with what you have to deliver value to the patients. That's one example.

So, if you carry it forward in the real time benefit check world, the reality is that PBMs are at different levels of sophistication, readiness, and financial capability to adhere to, say, building a real time API for the script standard. They're used to using the telecom B1/D1 standards because they have to live with that right now.

If we were to force all PBMs – this includes small little Medicaid plans, regional Medicaid plans, which still deliver a lot of care for the most vulnerable of our patients – if we were to require that without funding it and even if we did just based on the sophistication, we would be limiting the availability of these price transparency and affordability programs. Does that make sense?

David McCallie – Individual - Public Member

Yeah. That's very helpful. I appreciate that. That fleshes out your thought, in my mind, a lot better. Thanks for that example.

Steven Lane – Sutter Health - Co-Chair

Great. Ken Kawamoto?

Kensaku Kawamoto – University of Utah - Co-Chair

Yes. Thanks. I have two questions – first question, from a coverage perspective, if you have, say, a patient in a health system and you wanted to check this API for cost, about what percentage of an average prescription would have the coverage information? So, not only the out of pocket costs, but if they're insurance, has that insurance cost available?

Ryan Tarzy – CoverMyMeds - Guest Speaker

It's a complicated question to answer. Right now, we are able to return a response nearly 50 percent of the time and we expect that to be closer to 70 percent by the end of the year. When I say return a response, that can be a variety of responses. It could be the price or it could be PA needed or it could be that this drug is not covered, which is a valid response in certain cases.

The rate in which you're able to return is dependent on a ton of factors. I mentioned the eligibility, but it's also quite regional. Depending on the payer who's dominant in a given area and whether that payer or PBM has the real time APIs available – it's a complicated question.

The market is ranging from less than 10 percent response when you're dealing with a purely PBM connection and you're in a market that has, depending on the PBM, up to north of 80 percent response if you are able to leverage the pharmacy and you have a payer that's in that market that is sophisticated, that is dominant.

Kensaku Kawamoto – University of Utah - Co-Chair

That jives with our actual health system experience. What do you think we could recommend from this taskforce's perspective to get that closer to 100 percent?

Ryan Tarzy – CoverMyMeds - Guest Speaker

That's a really good question. I think the biggest thing you can do is release the eligibility information because, as I said, that is the single-biggest limiting factor in us being able to respond. If you don't know who the patient is, you don't know who the benefit is, and we don't always know who to hit even if the API is available. I think that's the single-biggest thing you do.

On top of that, I would say being able to move more quickly the EHRs towards the 4.0 FHIR standards would more quickly break down the barriers to be able to ping information and bring that in the real time level to the provider.

Kensaku Kawamoto – University of Utah - Co-Chair

That's the EHRs, you say?

Ryan Tarzy – CoverMyMeds - Guest Speaker

That's right. Right now, the standard they're enforcing is 2.0, I believe. I'd love to see us move quicker to 4.0 and move up that timeline.

Kensaku Kawamoto – University of Utah - Co-Chair

Maybe just to follow-up on that – specific recommendations we might be able to make are have this pharmacy coverage information a required US Core Data for Interoperability data point is available and move towards FHIR 4.0. What do you think, in the name of avoiding information blocking, encouraging PBMs to enable this kind of information to be provided if they're made an API request call to see what the cost is.

Ryan Tarzy – CoverMyMeds - Guest Speaker

You said it better than I could say it.

Kim Diehl-Boyd – CoverMyMeds - Guest Speaker

This is Kim. We commented on the information blocking rule as well as the interoperability rule from CMS. Those were some of our prime comments in those comment letters is about the openness to your point on the PBM side and also on the FHIR resources 4.0 on the EHR side.

Kensaku Kawamoto – University of Utah - Co-Chair

Thank you.

Steven Lane – Sutter Health - Co-Chair

Ricky Bloomfield?

Ricky Bloomfield – Apple - Public Member

Yes, thank you. On that point right there – the Argonauts group this year is actually working on an upgraded guide to R4 that the EHR vendors are engaged in. It does include the same data elements as the Argonaut 1.0 guide, which is currently what they've implemented. There are a few additional resource types there, but to Ken's question, I think the important piece is having the EHR vendors move to R4 means different things to different people.

So, it would be helpful for us to give very explicit recommendations in terms of the data types that are there. That may be additional work on top of the current Argonaut work that's happening. Then the other thing that I would mention is in line with the CMS proposals and the proposed rule earlier this year, the CARIN Alliance is working on an API to extend the blue button claims API to private payers and MA plans as well, which sounds very similar to what you're asking for. That is also FHIR R4 and it is a guide that is almost complete.

So, if you have feelings or input into that, I'd recommend reaching out to them because that's also ongoing work. I did want to mention I'd followed up on the care resource document from before. I did not find any care resource document, but I did find within Da Vinci there's a profile called the Coverage Requirements Discovery, which I'm assuming has to be what you're referring to there.

Ryan Tarzy – CoverMyMeds - Guest Speaker

You got it. Thank you for making sure for posterity we're getting it right. That's the one. To follow-up on your point – first of all, thank you, I think even more encouragement for us to get involved with CARIN – I think there is a nuance there that I haven't said that is critical, which is maybe it is heavy-handed to require full 4.0.

Getting to the specifics of what parts of 4.0 are needed for this area specifically, it is as CRD that is probably the most critical **[audio cuts out] [01:01:48]** and pieces that are already in 2.0. So, a possible task here, as I'm thinking about it, is not require a speeding up of the full 4.0 standard, which maybe is a bigger lift, but identify the specific elements, for example, CRD, that need to be pulled forward faster to enable this specific problem to be solved. Maybe that's actually the right approach.

Ricky Bloomfield – Apple - Public Member

That's exactly right. The reality is no one in the near future will implement all of 4.0. What it means for the EHR vendors to implement the Argonauts guide of 4.0 means only those specific resources that have been profiled as part of that initiative, which is a narrow but valuable set of resources. I just wanted to make sure that was clear. That's exactly what we're asking for here is how do we prioritize what those are so that work can happen. That's not going to happen unless we explicitly state that it's part of some initiative like that. Yeah, you're thinking about it exactly the right way.

I did have one final follow-up questions, which is building on Jack's question from earlier on the patient-facing piece. One last question – is there an API for that that third-party apps can use? If so, is it FHIR-based? Could you talk more about that? Or is it only accessible via your app and the website?

Ryan Tarzy – CoverMyMeds - Guest Speaker

Right now, it's only accessible via our – well, that's not exactly true. It is available for patient portals. So, it's essentially embedded into the patient portals and calling our information for it. We're also bringing it forward into the EHR now. It is being accessed via API. It is primarily being accessed through the app and the website, but we have started to bring it forward via API, but not through any kind of standard, just through our internal API.

Ricky Bloomfield – Apple - Public Member

Is that documented anywhere or is that something that you would give out if companies approach you?

Ryan Tarzy – CoverMyMeds - Guest Speaker

More the latter. We're being selective at this point of where we release it until it's further established.

Ricky Bloomfield – Apple - Public Member

Thank you.

Steven Lane – Sutter Health - Co-Chair

So, again, thank you so much for that presentation. We obviously chose to continue the Q&A because that was so beneficial. Again, I would like to ask you to go back to your cave and put together a list of very specific suggestions, requests, aspirations, vis-à-vis the standards, what's in, what's out, where things need to go that we might consider. It's very helpful to have your perspective on that as we formulate our own recommendations back to ONC.

Obviously, we've been talking about Argonaut and CARIN and Da Vinci. ONC is clearly involved in all of those. Even if ONC is not the ultimate actor that would need to carry out the recommendation, I think it can still be very valuable for us to weigh in and provide direction to ONC as to where they should be investing their energies.

Ryan Tarzy – CoverMyMeds - Guest Speaker

Thank you so much for the chance to participate and for the feedback. I think we landed in a really good place there.

Steven Lane – Sutter Health - Co-Chair

With that, what we'd like to do is use the rest of our time to prepare for our presentation to the HITAC.

Kim Diehl-Boyd – CoverMyMeds - Guest Speaker

Thank you.

Steven Lane – Sutter Health - Co-Chair

We are on the agenda for a brief update to HITAC in a couple of days. What I'd like to do, given where we are in our time here, is to go back through these kinds of priority one and

two areas just to kind of review these with the taskforce and get your input. Do we have the right high-level areas for our focus? Are we missing any? Are any of these really not appropriate for our inclusion.

So, something we need to add, something we need to subtract, or something we need to move from Priority 1 to Priority 2 just because I think this was the level of detail we'll be able to present to HITAC. Then what we're going to do between now and our meeting in two weeks is really invite people to go into the spreadsheet and start looking a very detailed way at our observations, our recommendations, and the recommended policy levers and responsibilities that we've identified.

I think this was kind of a first or second pass on these things and we want to be sure to get taskforce input and then we'll probably spend all or at least the majority of our meeting on the 23rd digging down into those observations and recommendations to fine-tune those.

So, back to the question – within Priority 1 – again, there are quite a few of these – hopefully, some of you have had a chance to look at the spreadsheet. I don't think we have time to go through this spreadsheet in detail, but at a high level here, does anybody see anything here they think needs to be removed or changed or downgraded at all? You can chime in or raise hands if you see fit. Someone at least say at looks like we're on the right page here. I'll take positives or negatives.

Kensaku Kawamoto – University of Utah - Co-Chair

I think we're on the right page here.

Steven Lane – Sutter Health - Co-Chair

Okay. Let's go down to the Priority 2 slide. Here again, some of these we've talked about. Some of these may or may not need to persist. Again, the public access PDP standards – Clem is not here to speak for himself, but he might have been satisfied by that – Ken, I think you raised this question about RxNorm codes. We haven't spent a lot of time talking about RxNorm Codes. I don't know that that's an area we need to dig into in greater detail.

I know that we've had some issues within my organization recently with trying to look at the accurate interoperability of allergen data between systems and we've found that RxNorm codes are not used consistently by, say First Databank and Medi-Span. Our vendor at least has suggested that if they were, they would be able to more accurately exchange data between systems that are utilizing different third-party vendors for their allergen file. I'm tempted to throw that into our recommendation to incentivize or require the use of RxNorm codes, at least for allergens. But I'm curious if other people have thoughts about that.

Kensaku Kawamoto – University of Utah - Co-Chair

This is Ken. Yes. I think there are other cases where there are appropriate RxNorm codes but it's not actually made available. A good example is self-reported meds oftentimes don't have – even though there are corresponding RxNorm codes that are structured and use medication knowledge vendor mappings in the backend for some reason don't have RxNorm

codes attached to them.

So, I guess along the general lines of are there ways we can strengthen the degrees to which medication data and medication-related data like medication allergy data actually get RxNorm encoded. I think that would be very useful. Otherwise, you end up having to do things like string matching or likely just ignoring the data.

Steven Lane – Sutter Health - Co-Chair

Does anyone have a counter-opinion to that. If not, I think it would be nice to make a recommendation about incentivizing or requiring mapping of RxNorm. Do people know of any reason why that would not be a good idea?

David McCallie – Individual - Public Member

This is David. I missed the absolute beginning of the discussion. There are obviously things reported as allergies that don't actually map to medications, per se. I'm not quite sure what the boundaries are of when you need an RxNorm code. Are you saying all potential allergens and un-tolerated substances should be considered RxNorm? I don't think that works.

Kensaku Kawamoto – University of Utah - Co-Chair

I'm assuming the recommendation is if there is an applicable RxNorm code, it should or shall be mapped. Obviously, if there isn't an RxNorm code, then it makes no sense to say you need to have an RxNorm code for it. For example, it's not a medication.

David McCallie – Individual - Public Member

Yeah. Then you have medications and medication classes. There are RxNorm codes that correspond to classes, but that's another distinction that you have to be careful about. People will say, "I'm allergic to penicillin," not a particular penicillin.

Kensaku Kawamoto – University of Utah - Co-Chair

Yeah.

David McCallie – Individual - Public Member

Allergies is a mess. Anybody who's worked on it knows what a quagmire.

Steven Lane – Sutter Health - Co-Chair

Right. I guess the question on that one, David, is do you feel like we know enough to formulate a useful recommendation or do you feel like we should reach out to the folks who own RxNorm and hear from them about where they see the opportunities? I think we may have time to make one more outreach.

David McCallie – Individual - Public Member

I certainly agree that if it is a medication or medication class, RxNorm is the right code set to use, but I don't feel comfortable that that's a sufficient statement. I don't know what that might not allow for. It would really be more, from my perspective, less from RxNorm's

perspective and more from people who implement allergy transactions' perspective – the EHR vendor community that wrestles with sharing allergies in a standards way. They may have issues that say RxNorm doesn't address our concerns here.

Ricky Bloomfield – Apple - Public Member

Are you referring to allergies specifically or is that an example you were using about a need for RxNorm generally?

David McCallie – Individual - Public Member

I thought that was the context that we were discussing with this particular RxNorm potential gap is in allergy reporting. There may be broader issues as well.

Steven Lane – Sutter Health - Co-Chair

I mentioned the challenge that I'm experiencing with allergies and then Ken mentioned the need to also look at the need for mapping for meds and the classes. I think those are all potential areas for us to weigh in on.

David McCallie – Individual - Public Member

Got it.

Ricky Bloomfield – Apple - Public Member

The only thing I would add there is Argonaut has taken the position of RxNorm as the preferred coding system for medications as well as substances within allergies. So, I think having a recommendation to extend that to other use cases would be appropriate. The only other thing I would add is generally RxNorm doesn't work for every use case. This has come up as part of the CARIN conversation that the pharmacies, PBMs, and payers have a preference for NDC codes, a very strong preference because that is what is given at the point of medication dispense.

So, it has raised some interesting issues in that they would prefer to receive an NDC code from any inbound party no matter who that is, when the reality is that a sending party might not have the NDC codes. For example, if it's a patient, they might have received their information through a FHIR API where they only have RxNorm and you can't really resolve an RxNorm to an NDC code unless you know the specific brand of generic or brand name medication.

So, it's not a mapping that can be done. There is a broader need for the RxNorm to NDC mapping to be standardized on the server side for a lot of these transactions to occur. I don't know if that's something that we want to take a position on or discuss in our recommendations.

Steven Lane – Sutter Health - Co-Chair

Ricky, I would really invite you to write up what you think would be an appropriate recommendation for us to consider in that regard. Feel free to add it to the spreadsheet or send it to us as an email and I could add it. I think you're on to something really important

there and you clearly have visibility to the key issues through your work with Argonaut and CARIN. Please put that together for us.

David McCallie – Individual - Public Member

It might make sense to ask someone from FDB or someone who deals with that on a daily basis. It's a really complicated space. NDC is serving a completely different purpose. It's a bad code space. It's got duplicates. The faster we can move away from NDC, the better, but you're not going to because it's what drives inventory management in the pharmacies. So, they don't want to give up.

Steven Lane – Sutter Health - Co-Chair

Exactly. That's exactly why the problem needs to be solved. Those two worlds are coming together now.

David McCallie – Individual - Public Member

Well, they've been coming together for a long time. At Cerner, we did NDC mappings to FDB, to Multum, to RxNorm, and it's complete. It's messy. It is a problem. Maybe talk to somebody from FDB or Multum and make sure we get the full scope of the issues.

Steven Lane – Sutter Health - Co-Chair

David, before we transition to public comments here, if you have contacts or can identify folks at those organizations that you think might be helpful for us to speak to and certainly if you and/or Sasha would be willing to join an offline discussion with them to see if there's value in bringing them to the taskforce, that would be helpful. In the meantime, if you and Ricky could clearly have deep understanding in the space, you could at least draft some observations and potential recommendations, that would be really helpful.

So, we are going to transition to public comment right now. You want to make the announcement on that?

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

Sure. Operator, can we open the line?

Operator

If you'd 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. You may press star-two if you'd like to remove your comment from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

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

Thank you, Operator. Any comments at this time?

Operator

None at this time.

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

Okay. Steven, back to you. If we get any comments over the phone, we'll let you know.

Steven Lane – Sutter Health - Co-Chair

Great. Thank you so much. That leaves us with ten minutes. Our immediate next task is to prepare our report back to the HITAC. If we can pop back to the slide with the Priority 2 recommendations, I'll just again ask the taskforce – are there any on this list that we should not bother with? We haven't really talked about the risk evaluation/mitigation strategy data issues. Perhaps let's pop over to the spreadsheet for a moment if you can. I know you guys have that teed up for us. Maybe if you can scroll all the way to the bottom row, which is going to be row 19 – perfect.

Okay. Again, this did come up in a sidebar discussion. I don't want to assume it's appropriate to our taskforce unless people agree. I certainly learned a lot in doing some deeper dives here about how this works that the absence of standards regarding the documentation required for REMS, the variable processes for data collection, the potential opportunity for standardizing this and just came up with this very broad recommendation or initial recommendation for the development of standards to forward this area.

I'm curious whether taskforce members feel that this is appropriate given that we haven't spent a lot of time on it or whether this should be dropped. Any thoughts one way or the other?

David McCallie – Individual - Public Member

I don't know enough about it.

Steven Lane – Sutter Health - Co-Chair

In the absence of enthusiastic support, my tendency would be to drop it because we've got plenty of other things to weigh in on. Ken, do you agree?

Kensaku Kawamoto – University of Utah - Co-Chair

Yeah. That sounds good.

Steven Lane – Sutter Health - Co-Chair

Okay. Working our way up the line, this issue about access to NCPDP standards – again, Clem raised this. He's not here to speak to it. We had a sidebar email back and forth with the folks from NCPDP to understand where this really stands. Does anyone feel that this needs to be kept in here or is it satisfactory that NCPDP, like other standards development organizations do keep their standards private for the most part or are we okay from our taskforce perspective not wading into these waters or is this something we should be commenting on?

David McCallie – Individual - Public Member

This is David. I have felt strongly about this topic for years, but in a much broader sense than just NCPDP. The thinking in my head is if the government requires the use of the standard in a regulation, then the standard should either be freely available or the government should make it available by purchasing a license, etc. That's done for some of the standards, like SNOMED, where the government actually pays SNOMED for US rights to use SNOMED, but it's not done consistently across all the standards that are, in fact, required.

That's a huge big policy issue. It would actually be money well-spent compared to some of the things we spend money on. I think the only way to frame this in broad strokes, if it's a required standard and it's not freely available, then the government should subsidize exposure of that standard to those who need it to fulfill the regulation.

Steven Lane – Sutter Health - Co-Chair

I think that's really what Clem was getting at. I concur. I think that probably is the better way to rephrase this, not have it being specific to NCPDP. Do others have comment on that?

Terrence O'Malley – Massachusetts General Hospital - Member

Agree. Well-said. To generalize it is probably a better idea.

Kensaku Kawamoto – University of Utah - Co-Chair

Yeah. Maybe also in general, I think one thing to note is that we don't want to set up perverse incentives of if you keep your standards behind a paywall, then the government will pay you to make it available, just from the HL7, for example, that when HL7 decided to make all of its standards available openly.

That had some financial consequences for HL7 as well and maybe it's in general, not just making standards that are open available, but insuring also that standards that have been made available continue to be made available. Just this notion of the government supporting open standards, which may not only entail paying folks who have things behind a paywall, but for folks who made it available openly to keep supporting that.

David McCallie – Individual - Public Member

I think the perverse incentive point is a good one. It's always a good one. I was specifically thinking of standards that are, in fact, required for regulatory compliance, which limits it to a tiny subset of the full complement of available standards. But otherwise, considerations of perverse incentives is a good one. But it's a small amount of money, even if there were perverse incentives, compared to what we spend money on flailing in this space sometimes.

Steven Lane – Sutter Health - Co-Chair

Ken, can you take responsibility for rephrasing this observation/recommendation later today? Do you have time for that?

Kensaku Kawamoto – University of Utah - Co-Chair

Yeah. I can do that.

Steven Lane – Sutter Health - Co-Chair

Then we can add it into our HITAC presentation.

Kensaku Kawamoto – University of Utah - Co-Chair

Sounds good.

Steven Lane – Sutter Health - Co-Chair

Let's scroll up in the document. The next one was the RxNorm codes for discontinued drugs. That's the only recommendation we have in here so far specific to RxNorm. David, I think you agreed to try to phrase a broader recommendation around RxNorm codes or I guess you simply – I think you agreed to try to find us some contacts. So, maybe we can leave this one as it is for now but reserve the right to expand our commentary on RxNorm. Does that seem fair for now?

David McCallie – Individual - Public Member

Sure.

Steven Lane – Sutter Health - Co-Chair

Okay. Again, we've talked about medical benefit. We don't have time to go through this in great detail. I think the rest of these are pretty clear. Keep scrolling up. The prescription transfer transaction, I certainly was pleased when I discussed this with the folks from NCPDP to learn that this exists. It has not been broadly implemented. So, it's not something that we can weigh in on. Scroll up a little bit further.

The PDMP query – here, the comment is pretty limited. We haven't dug deeply into PDMP to make a lot of recommendations. A lot of people are working on this, but there is an NCPDP standard, which can be used here. Again, for people who are more involved in PDMP, does anyone feel this is particularly beneficial for us to comment on or perhaps that it should be removed?

In the adverse drug event space, we spent a fair bit of time at our last meeting talking about this in great detail. I tried to pull all that together into some specific observations and recommendations, which I very much want folks to review and weigh in on. I guess the other PDMP issue – maybe I'll just reorient these – had to do with the cost of accessing that data to the point that Ken has raised.

So, we are at the end of our time. I really want to appreciate and thank you all for your participation. A lot of folks were quiet today but some really contributed a lot. We are going to be providing a summary of these subdomains and where we're going to be weighing in to HITAC in a couple of days.

And then, as I say, over the next two weeks, we very much want people to dig into the spreadsheet to look at the very specific wording of the observations, the recommendations,

please make additions, comments, etc., in the document so that we can come back in two weeks and really start to formalize and move towards finalizing our recommendations in this domain.

Ken, anything to add before we sign off?

Kensaku Kawamoto – University of Utah - Co-Chair

No.

Steven Lane – Sutter Health - Co-Chair

Lauren?

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

Not for me. Thank you.

Steven Lane – Sutter Health - Co-Chair

Wonderful. Thank you all and we'll see you back on the 23rd of July.

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

Thanks, everyone.