PHARMACY INTEROPERABILITY AND EMERGING THERAPEUTICS TASK FORCE 2023 MEETING

August 30, 2023 10:30 AM – 12 PM ET

VIRTUAL

Speakers

Name	Organization	Role
Hans Buitendijk	**Oracle Health**	**Co-Chair**
Shelly Spiro	**Pharmacy Health Information Technology Collaborative**	**Co-Chair**
Pooja Babbrah	Point-of-Care Partners	Member
Chris Blackley	Prescryptive	Member
Shila Blend	North Dakota Health Information Network	Member
David Butler	Curatro, LLC	Member
Steven Eichner	Texas Department of State Health Services	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Member
Jim Jirjis	HCA Healthcare	Member
Summerpal Kahlon	Rocket Health Care	Member
Steven Lane	Health Gorilla	Member
Meg Marshall	Department of Veterans Health Affairs	Member
Anna McCollister	Individual	Member
Deven McGraw	Invitae Corporation	Member
Ketan Mehta	Micro Merchant Systems	Member
Justin Neal	Noble Health Services	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Naresh Sundar Rajan	CyncHealth	Member
Scott Robertson	Bear Health Tech Consulting	Member
Alexis Snyder	Individual	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Christian Tadrus	Community Pharmacy Owner	Member
Sheryl Turney	Elevance Health	Member
Afton Wagner	Walgreens	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Tricia Lee Rolle	Office of the National Coordinator for Health Information Technology	ONC Program Lead
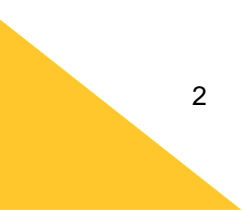
Call to Order/Roll Call (00:00:00)

Michael Berry
Good morning, everyone, and welcome to the Pharmacy Interoperability and Emerging Therapeutics Task Force. I am Mike Berry with ONC, and we are glad that you could be with us today. This Task Force meeting is open to the public, and your comments are welcome in Zoom chat throughout the meeting or during the public comment period that is going to be held around 11:15 Eastern Time this morning. I would like to begin roll call of our task force members, so when I call your name, let us know if you are here. I will start with our cochairs. Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Shelly Spiro?

Shelly Spiro
I am here.

Michael Berry
Pooja Babbrah?

Pooja Babbrah
Good morning, I am here.

Michael Berry
Chris Blackley?

Chris Blackley
Good morning.

Michael Berry
Shila Blend?

Shila Blend
Good morning.

Michael Berry
David Butler? Steve Eichner?

Steven Eichner
Present, good morning.

Michael Berry
Raj Godavarthi? Adi Gundlapalli? Jim Jirjis? Summer Kahlon?

Summerpal Kahlon
Good morning.

Michael Berry
Steven Lane?

Steven Lane
Good morning.

Michael Berry
Meg Marshall?

Meg Marshall
Hi, good morning.

Michael Berry
Anna McCollister?

Anna McCollister
Good morning.

Michael Berry
Deven McGraw?

Deven McGraw
Good morning.

Michael Berry
Ketan Mehta?

Ketan Mehta
Good morning.

Michael Berry
Justin Neal?

Justin Neal
Good morning.

Michael Berry
Eliel Oliveira?

Eliel Oliveira
Good morning.

Michael Berry
Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Michael Berry
Scott Robertson? Alexis Snyder?

Alexis Snyder
Good morning.

Michael Berry
Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
Christian Tadrus? Sheryl Turney is not able to join us today. Afton Wagner?

Afton Wagner
Good morning.

Opening Remarks (00:02:00)

Michael Berry
Good morning and thank you, everyone. Before we turn our meeting over to Hans and Shelly, Tricia Lee and I would like to just take a few moments to make a few comments. First of all, I want to thank everyone for participating on this Task Force. I appreciate the engaging discussions, and now, we are at the point where we need your help formulating draft recommendations. We realize that for many of you, this is the first HITAC Task Force you have participated in. Those of you who are not HITAC members were selected for this Task Force based on your individual expertise and not the organization you work for, so we are at the point where we need your help to finalize recommendations in the topic areas discussed today. I just want to say that the final recommendations are the consensus of the entire Task Force, so please feel free to contribute your input on those draft recommendations.

In fact, we really need your input in drafting those recommendations, and right now, we have a lot of good ideas and comments on the worksheet, but we want to take those comments and turn them into those draft recommendations. Hans is going to help us walk through how he does this. I just want to point out that even though Hans and Shelly, as our cochairs, are starting to do this process, they cannot do this work all by themselves, so I am encouraging all Task Force members to volunteer to help draft those recommendations. Not everyone needs to weigh in on every single line on the worksheet, but maybe you can volunteer to write up one or more. So, during today's call or afterwards, please let the cochairs know

which recommendations you are comfortable drafting for the Task Force to discuss at a future meeting. With that, I will turn it over to Tricia Lee to see if she would like to add anything additional.

Tricia Lee Rolle

Thanks, Mike. I will echo your thanks for everyone's participation so far. We are just about halfway through our task charges, and so, that is a pretty big milestone with a lot of great discussion, but one thing that has come to our attention is that at least one individual has expressed some hesitancy in participating in drafting recommendations, thinking that they need to be reflective of their organization's position on things, and we just want to remind you of what Mike just said, that you have been chosen not for your organization or company's position on any particular issue, but because of your expertise, your resume, and varied experiences.

The recommendations document that will be shared with the full HITAC and that comes back to ONC is really reflective of you as individuals. Your organizations are not signing off on any positions that are made. I hope that helps for anyone who might be feeling a bit hesitant. I will just give you a reminder that we are halfway through. We really want clear, concise recommendations. There has been a lot of great discussion, but ONC really cannot do much with discussion notes. What we need are your recommendations.

So, I am not going to say we are the genie in the bottle, but if you had the genie in the bottle, you would not just want to discuss things with the genie, you would actually want to tell the genie what you want. Now, your wish is not our every command, but we do take the recommendations very seriously. This is your opportunity to let us know within the scope of the things that we do, certification standards, coordination, policy work, what it is that can help advance pharmacy interoperability. So, I am not sure how much more emphasis Mike and I can put on this being your chance, so I do hope that there will not be as much inertia or hesitancy in really telling us specifically what your recommendations are, and again, we are halfway through, so we really wanted to emphasize that for you. Again, thank you for your time, and I am going to hand things over to Hans.

Recommendation Drafting Example Discussion (00:05:59)

Hans Buitendijk

All right. Thank you, and good morning. We are going to follow up on some of the comments that Tricia Lee and Mike just said. First of all, welcome today. We are switching to a new task. We are looking at the agenda right now, and we are moving into that. It will be introduced in a moment, and we will have a little bit more discussion around some of the drafting, how we started to go about that, and how we can collectively move that forward, so we are looking forward to that. I also want to welcome the audience from the public with a reminder that while you do not have the opportunity to join into the verbal discussion throughout, there will be an opportunity during public comment, and you are absolutely welcome to join in the chat and put your comments, questions, and otherwise in there. There has always been very lively discussion there, and there are a good number of points in there that will be included as part of the notes as well that we can tap into for thoughts and ideas also.

So, take advantage of that, and we will certainly have the public comment period later. With that, we will look at the agenda. We have Task 3. Shelly is going to get further into that in a moment with a presentation today by Pooja Babbrah and Justin Neal. We will discuss that further, we will have our public comment, and then, at the end, we will go back to planning next steps, what is coming up next week, as well as what we
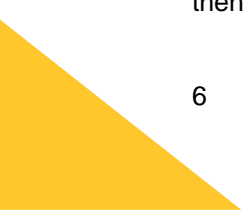
can do in parallel to move this all forward. So, I appreciate that. Shelly, why don't you pick it up from there, introduce Task 3, and then we will go back to the agenda on recommendation drafting?

Task 3 Introduction: Identify standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies (00:07:59)

<u>Shelly Spiro</u>
Thanks, Hans. I just want to keep our well wishes and safety to our colleagues in Florida. It looks like you have a pretty bad storm there, so, family and friends, have them in your prayers. I am sure they are going to need them today throughout the southeast and up the coast. Today, you can see our agenda. First, Hans is going to do the recommendation and drafting example discussion, and then we will go into Task 3, which is to identify standards needed to support prescribing and management of emerging therapeutics, including, but not limited to, specialty medications, digital therapeutics, and gene therapy. So, after Hans is done with his section, we are going to go into our presenters who, I will remind you, have five minutes. Also, remember that in the chat, make sure you are on everyone, not the panelists. With that, Hans, I am going to turn it back over to you. Can we pull up the spreadsheet?

<u>Hans Buitendijk</u>
All right, let's have a look at that. What we are going to step through is since we have gone through Tasks 1 and 2 and are now beginning to turn into final recommendations over the next couple weeks. We want to have a look at how we arrange that. Can we go to Topic 1 and scroll slightly to the right? It should be Column E that we should have a look at, though we can look at D as well. That is perfect. What we have done so far is collect a number of discussion points in the earlier column, and in D, we started to create some draft recommendations. You see in there that either somebody specifically or a couple people with red marks started to identify what that is.

What we are currently doing is going to the right-hand side to E, and where we see recommendations that relate to each other and there is opportunity to combine them, we are going to put them in there, pick up the language from various ones of those, and start to craft that as well. You still see a fair amount of red in there as well because a couple folks are already jumping in to provide some clarifications as well, but the structure that we see is that it starts with "Recommend that ONC," and that really is meant to clearly indicate that it is something that ONC can do. They can do it in whole or in part in collaboration with others, but it is something that ONC should pick up and do something, whether it is by themselves or with the community, as in the first example here with pharmacies and pharmacists, public health, and a number of areas.

Then, we provide a rationale, why we think it is important that it is being done, which can help prioritize and understand where it is going to be put on their roadmap, or they might say, "Well, that was a great rationale, but from our perspective, with the bandwidth that we have, other things are more important to tackle first." We are currently still using the organization of the topic at hand. In this case, if you go back to Column 1, the topic at hand was more technical standards, and we had some short-term and long-term questions around that. We have these around the public health emergent use cases and otherwise, so it is in that first area. So, we are looking for anything that attaches back to that.

Between Topics 1 and 2, there are some restarting topics that come up, and there needs to be continuity. We are still trying to figure out how we present that. We are not quite there yet, but we are clearly going to see that some comments, for example, around certification or certain standards to be used are not only relevant in the emergent scenarios, but also in normal operational times and otherwise. So, we still have to run through to make sure it is clearly organized as to what it applies to, to Task 1 only, Task 2 only, or something that cuts across anything we need to move forward with.

As you scroll down for a moment, the intent is that in Column E now, we are picking up from what is in draft recommendations, Column D. In this first example, we were pretty much able to pick everything up. As we go down, we might find some areas in Column D that have not yet been highlighted where we have a question around whether it is really within the scope or needs to be a bit more clarified and targeted. So, we are going to have some follow-up on that specifically, but where you have your name in here and looking at that, if you can take the examples on the right-hand side to look at what we are trying to get to, put your suggestion and recommendation more in that format. You may do that at this point in time in Column D, where Shelly and I are picking it up, copying it over into Column E, and starting there, and then we may have further discussion, like you can see here with some red marking in this particular case with Ike, going back and forth on some things to clarify.

If you can make your suggestions in Column D with enhanced, clarified statements there, we will move them over and do some further tuning as needed. After we have gone through upcoming topics, we can go through Column E and see if there is consent, if we have any concerns with what is stated here, if someone is strongly objecting or we are missing something as well, and just make sure we did not miss anything substantial from Column D that is supposed to be in scope. So, that is the way we are going to try to work through it offline in parallel. If you go further down, there are still placeholders there for a number of people, so we are particularly looking at those. Not to pick on Jim, but his happens to be the first one that popped up.

Where you see "placeholder," have a look at that because you may feel comfortable that this is it and we can remove "placeholder." We will know at that point in time that it is ready to start to move into the final recommendation column, where we need to make sure everybody is comfortable with that. I am going to stop there for a moment and see whether, Shelly, you have any additional comments before opening it up and making sure that we are all in sync on how we are trying to get from D to E. We have done an initial pass now, not meant to be totally complete, for Topic 1. We are going to be doing the same thing for Topic 2. If that is where you have most of your comments, please go ahead and make updates or put in recommendations that are not there yet, but that you are thinking of.

Shelly Spiro
Thanks, Hans. That is a great overview, and again, as Mike and Tricia Lee had said, we really encourage you to get those recommendations in place and look at Column E. I just want to alert Mike that there were several people who came in late, so make sure that they are captured. I think Pooja has a question.

Hans Buitendijk
Yes, go ahead.

Pooja Babbrah

Thanks, Shelly and Hans. I just want to make sure I am understanding. I know there are going to be some things where we are thinking we could wordsmith "recommendation" versus "clarification." Do you still want us to just work in Column D if we have some wordsmithing to the actual recommendation?

Hans Buitendijk
If you have wordsmithing to the actual recommendation, like you currently see, and there are clarifications that are not substantively changing, but enhancing, at this point in time, it is perfectly okay to do the same thing and mark it up in red, green, or whatever the color happens to be that is assigned to you, but red is the easiest to pick up. If it is a new recommendation that we have not really talked about or that is really a substantial change, put that in D and highlight it, say it is new in some fashion, just to make sure that we see it because that requires a little bit more discussion and making sure that we are all in agreement that it can move over.

The ones that we put in Column E are ones that have come up a number of times. It sounds like there is a fair amount of support for it. We might not be exactly in the same spot on how to phrase it best, or we may need to have some nuances in there to make sure it is not a one-sided perspective and we forgot about another perspective that needs to be brought in as well, so it is not meant to be final, but it is more of something that we are all in agreement on with the direction we are heading, and we just need to get it cleaned up and properly stated.

Pooja Babbrah
Perfect, thank you.

Hans Buitendijk
Any other questions? As you can see, a number of participants have already started…

Tricia Lee Rolle
Hi, Hans, just a quick point of clarification so it is not confusing. So, we do not all have to be in agreement on everything that is being recommended. If there is a new perspective or something that is a bit different, we can always note dissent or capture that there are other alternate ways to look at something, so that might be helpful, just because I know there are some issues where I know the Task Force is looking at it from a number of different perspectives. So, it is not 100% consensus. It is really just reflecting that this is what the group has brought forward.

Hans Buitendijk
Thank you for that clarification, and I completely agree, it can provide those different perspectives. For both of those, we would still then have to be very clear on what the intent is that then can be considered and weighed by ONC at that point in time. Any other questions at this point in time?

Shelly Spiro
Just a comment. Out of all the Task Forces, and Mike and Hans, you can correct me if I am wrong, but we have had some really good discussion, and the hardest part is going from a discussion into a recommendation, but we need to be thinking about this to complete our tasks for HITAC and for the November 9th meeting with HITAC. We have to have all of our recommendations done before the 1st of November, and that is why we are pushing this really hard. I think we have a really good general idea of

what is happening within the pharmacy world, and we will continue to have presenters, but it is really important for the task group members to get these recommendations in for Topics 1 and 2, which we have completed the discussions on, and as more discussions come within Topics 3 and 4, we might have to go back and tweak a little bit on Topics 1 and 2, but this is your time to shine. Christian, I think you have a question.

Christian Tadrus
Thanks, Shelly. I guess I am still trying to track here, too. So, in Column D, I have a recommendation there with "rationale." It is not directly moved over to final. There are versions of some of those comments in the final. Can you speak to how Column E recommendations relate to, say, my Column D, if that is what was intended?

Hans Buitendijk
Yes. What we are trying to do is that there are a couple of recommendations that have the same kind of related theme, so, rather than trying to have them as individual recommendations where possible, we are trying to combine them into one because it is also going to be a balancing between not getting too lengthy, and if you combine too much, it might get too lengthy in some areas, and in others, not too detailed, because there needs to be flexibility in how to go about implementing them, but there are good examples in there. So, in that context, you will see that, as a first pass, we are trying to combine a number of recommendations together and see whether that works. If there is something that is missing, then we can certainly add an additional recommendation to it or get clarification to the existing one to make that fit. That is why this is not meant to be the final one, but it is just the first pass in trying to collapse some of the first things together that really seem to be on the same theme.

Christian Tadrus
What I was clarifying and what I thought was happening is that some of these concepts in D have already been incorporated into E, but we have not marked in D where we have said we have moved it over, broadened, and refined it. So, as part of our process as we move stuff to E, can we somehow mark in D that that concept was captured in this other phrase over here so that we are not spinning our wheels figuring out how to push them back and forth? It may be more of a process.

Hans Buitendijk
That is a good point, though, and we have not done that yet, but that is a great suggestion. We have done it in prior ones, but did not have the time yet to mark everything in D that we think has been covered, so that is a good point to clarify. We have to make sure that I can do a good highlighting, that that is obvious. And then, you still might find that we think we reflected it, and in your case, we think we have gotten the essence of the recommendation that you made in D1 that we put in Column E and highlighted. You still might say we missed something. That is fair. Look at those and make sure that we did not miss something that is critical or that it still warrants a separate recommendation because we did not quite catch the intent.

Christian Tadrus
Thank you.

Hans Buitendijk
Other questions or comments?

Shelly Spiro

Anna, you had a question. You were not able to put recommendations of your use case. Do you need more time to do that?

Anna McCollister

I just got some not-awesome personal news about a family member this week, so I have been a bit distracted and have not had a chance to get back in and put in recommendations. based off use cases that I put in Section 2, so it was more of an apology than a question.

Shelly Spiro

No problem. Sorry about that.

Hans Buitendijk

We went through past ones for Topic 1. There still will be cleanouts and we will fine things. Next, we are going to do the same kind of thing with Topic 2 as well, so hopefully by next week, you will see a lot of adjustments there in whatever column it is, maybe E as well, although it is not exactly the same numbering, and to clarify, we are only looking at the tabs that have that green bar under them. You can use the ones in red for historical reference in our discussion and make sure we did not miss anything, but that is not where we are going to be looking to make sure that we pick up on draft recommendations. We are only looking at Topics 1 and 2, which have a green bar under them.

Shelly Spiro

The tabs have a green bar, so if you look all the way down, you will see a green bar. Those are the ones that we really want you to focus on. The other tabs that are red are more notes and discussion that led us to the recommendation. On our agenda, Hans, if you could wrap up, I just want to thank you personally for all the hard work you are doing on consolidating the discussion, and Tricia Lee, too, and making sure that we get these recommendations done, so thank you, Hans, for all the hard work you have put into this. I appreciate it.

Hans Buitendijk

You are welcome, and thank you to everybody who has started to put in updates and suggestions, because that is what we were looking for, to have that level of interaction to narrow it down to the final recommendation, so I really appreciate that.

Shelly Spiro

Hans, if you are okay, we can go to our next agenda item, which is Topic 3. Can we go back to the agenda?

Hans Buitendijk

Or the slides, yes.

Shelly Spiro

The slides, yes. Thank you. I will give them a second to pull it up. So, I read it before, but while we are pulling up the slides again, No. 1 is to identify standards/needs to support prescribing and management of emerging therapies. So, we are at the emerging therapies. Go to the next slide, please. Today, we have

two presenters, who will be focusing on specialty medications, and for those of you who are not familiar with pharmacy, specialty pharmacy focuses on high-cost drugs that are captured by certain plans or entities from a benefits standpoint, and so, I am excited to hear from Pooja, who is one of our Task Force members. She is the practice lead for pharmacy and PBM services at Point of Care Partners. We also have Justin Neal, who is also a Task Force member, who is vice president of patient support and data contract services for Noble Health Services. So, thank you to both of our presenters, and let's go on to our presentations. Next slide. Pooja, I think you are up first.

Presentation & Task 3 Discussion (00:27:22)

<u>Pooja Babbrah</u>
All right, thanks, Shelly. So, I know I have five minutes. I am going to buzz through a bunch of slides. There are quite a few slides in this deck, and a lot of them are more informational. Let's go to the next slide. Just quickly, I want to make sure we are all clear on what we are talking about when we say "specialty medication." I put this slide in as a definition. So, when we talk about specialty medications on the pharmacy side, what we are talking about are medications that, in general, are defined as high cost, more complex in delivery, handling, administration, and potentially in terms of patient management or restrictions on the medication. As a quick note for everyone, there is no single list or definition of specialty meds. All stakeholders define it a little bit differently, but like I said, in general, what we are talking about are the higher-cost, higher-touch in terms of patient management, and special handling of drugs. Let's go to the next slide.

The next two slides are more informational for the Task Force members. This talks about some general information on factors that may influence whether a medication or product is covered under the pharmacy benefit or the medical benefit. Let's go to the next slide. This is also just information as well. It is a little bit older data, but the numbers have not changed a lot. When you think about overall prescription volume and prescription spend, I would say about 45% of the drug spend right now is for medications that are covered under the medical benefit, and from a prescription volume standpoint, it is a little bit lower, probably about 35-38% of the prescriptions. Let's go to the next slide.

So, what is the real issue around specialty medications? Well, most of the standards that we have been talking about, whether it is the e-prescribing Script standard, ePA, and even real-time benefit check, really work for those prescriptions that are covered under the pharmacy benefit. So, the doctor has a lot of visibility into those, from prescribing all the way to dispensing. If a prescription or medication falls into the medical benefit, that is where it falls into a manual process oftentimes, and when you see about the stat where it takes two to three weeks for a patient to get on a medication, from a specialty med standpoint, that is really what we are talking about. So, let's skip forward two slides.

I want to put this in the context of a patient scenario. What I am going to walk through in the next three and a half minutes is this patient scenario. So, we have a 37-year-old female patient who has been diagnosed with rheumatoid arthritis. She has recently been having flareups after having it under control for many years, and she goes in to see her doctor. You can see a number of medications that are covered under the pharmacy benefit in blue and those that are covered under the medical benefit in orange. Let's skip ahead to see what happens to this patient. Let's move to the next slide.

So, the patient goes in to the doctor to talk about this. Eligibility checks are run, so the doctor knows that the patient is covered under a certain health plan and knows what the pharmacy benefit is, but the difference on the pharmacy benefit side is that we have this formulary and benefit information, which is pulled into the EHR. So, when the doctor goes to prescribe the medication, he can see what is covered under that patient pharmacy benefit. He cannot necessarily see what is covered under the medical benefit. So, in the next step, diagnosis, when he goes to prescribe this med, he will see, for example, that Humira is available under the pharmacy benefit, and there is also information that a PA is required, and maybe step therapy is required as well.

But, the provider knows that he has had similar patients who have had success on Remicade, where, even though you can see that that is covered under the medical benefit, the doctor does not necessarily know that, and that is where it falls into a manual process where the provider has two choices. They can either prescribe Humira or, knowing that Remicade is a great option, they can go ahead and prescribe that, and that will kick off this more manual process of getting the patient on this med. Usually, what will happen is that prescription will go to a specialty pharmacy, the specialty pharmacy starts working that prescription, or it could go to what we call a hub, and you can see the note here that hub services are services where manufacturers can use these vendors to do benefit investigation and all of that. So, I am running out of time here, but just know it is a very manual process, which is why it can take two to three weeks.

Shelly Spiro
Pooja, we had two minutes before, so I am going to give you another minute and a half.

Pooja Babbrah
Okay, perfect. So, this is what causes a lot of the pain points, and while we are waiting for benefit investigation to happen, while we are waiting for PAs to happen manually and for other things, the patient could end up in the ER because they are waiting to get on the specialty medication therapy. And so, this is oftentimes where we see where the downfall occurs. Unfortunately, if the patient ends up in the ER or something else, they may get on another drug, and it feels like the process has to start all over again. So, let's flip ahead to the next slide and go through ideal states. The real value here, the real issue I think we are trying to solve for, is that it would be great if, in the EHR, the doctor is able to see what medication is covered, whether it is under the pharmacy benefit or the medical benefit. They can see the restrictions, they can see what they can prescribe, and we will hopefully then gray out that adverse patient outcome of them ending up in the ER or having a bigger issue because they cannot get on the specialty medication.

Let's go to the next slide because I do want to quickly touch on standards. This is also for reference for the Task Force members. There are standards in place that could be solving for this. The one callout I will make is a lot of what is in red is HL7 FHIR IGs that are focused on prior authorization, things that we are already doing on the NCPDP side for the pharmacy benefit, so you see price cost transparency, you see prior auth support, and all of that, but the one caveat here is that at CMS, which I know is not under ONC's purview, when it came to the proposed rule for prior authorization and using some of these new standards, specialty medications unfortunately were not called out specifically. So, it is not something that we cannot overcome, but I just wanted to make that note. So, really, from a pain point standpoint, just in summary, we know there are things that can solve this, I think there are some opportunities for ONC, and thank you for the time.

Shelly Spiro

Thank you, Pooja. Ike, can you wait until we go through the next presentation, or do you want to address it now?

Steven Eichner

It is directly related to the presentation at hand.

Shelly Spiro

What do you think, Hans? Well, let's go ahead, Ike. We will just give Justin a little bit more time.

Steven Eichner

I will be quick. Another point that needs to be included here is that patient access to pricing information comes into play very much as well, especially as we are seeing more medications at substantially higher costs and how that factors into decision making as well. It is one thing if you are looking at a $20.00 copay, and quite another if you are looking at 10% of a $30,000.00 or $100,000.00 medication and a $4,000.00 out-of-pocket expense. So, that is another element that needs to get factored in somewhere.

Shelly Spiro

Go ahead, Pooja. Do you want to respond?

Pooja Babbrah

Yes. That is a great point, and I know we created an implementation guide under the CARIN Alliance for a consumer-facing real-time benefit check. I just realized I did not add that in here, but that is something that I think could be a great opportunity as well.

Shelly Spiro

Thank you, Pooja. Let's go on to the next slide, and Justin, I assume you are up.

Justin Neal

All right, thank you so much, Shelly. I want to go ahead and go to the next slide. Awesome job by Pooja. I am going to give an overview of some of the pharmacy impact and items that they really need as part of the data that is a little bit less direct prescriber-patient-facing, but still really coordinated as part of the continuum that happens in specialty pharmacy. So, from a high level, you are getting the prescription in, and Noble Health Services, where I work, is probably considered more of a midrange regional specialty. So, we are licensed and have patients in all 50 states, but we are not one of these large, vertically integrated specialty pharmacies that you might have attached to a PBM.

So, when the prescription comes in, as Pooja said, there is a lot of prior authorization and benefits investigation that is going on to get that patient set up and approved, and a lot of coordination with the provider. From there, once all that really hard work and information that Pooja talked through is done, that is when you are getting the bread and butter of what specialty has, and that is when you are getting a lot of clinical support, where you have a team of clinical pharmacists that are following this patient and collecting a lot of information that we are required to for a number of reasons that I will talk about on another slide here, but also making sure that that patient stays on therapy. That is the goal with a lot of why these barriers exist. That is essentially what specialty is, a lot of barriers from a lot of different stakeholders. The one that

matters the most, that is really up front, and is really the last piece before it is off to the patient, is that copay assistance, making sure the patient can afford it both in the short and long term, which is a hot topic right now in the specialty space.

Flipping over to the next slide, talking about barriers, essentially, that is what specialty revolves around, getting the patient on therapy. These are extremely high-cost medications. They could be $5,000.00 or $30,000.00 a month, and some could be upwards of $90,000.00 a month, and that is why the payers, in a lot of cases, are setting these barriers, and the pharmacy is helping to get through those, to get that patient covered for the product with the pay the provider needs, but at the same time, trying to make sure they are maximizing the value of that. Flipping over to the next slide, looking at some of the technology and data points that we have been talking through over the last couple months that the pharmacy needs, it really depends on the stakeholder that we are looking at.

So, from good pharmaceutical care, that demographic information like patient weight, height, and stuff like that to really figure out the appropriate dose of something that is needed every day with a lot of medications, and to really get that whole med list and make sure that it is an appropriate therapy and supports that PA, from there, it kind of goes into the payer barriers that exist, that they are collecting some information, both making sure that that utilization is maximized, patients are staying compliant, and getting reporting, because they do not let everyone fill these prescriptions, and they want to make sure they are getting the information to make sure that the patient is getting the most of this really expensive therapy.

From there, the part that I think a lot of folks might not be aware of is the accreditation barriers. In order to fill these, lots of organizations have to have external accreditations that also have additional information and requirements that require them to collect a lot of information that is from this patient's medical record, including tracking outcomes, and then really being measured on turnaround time to make sure how quickly they are getting patients on the therapy, and that is similar to what the manufacturers are looking as well to make sure that patient is really getting on therapy as quickly as possible.

Flipping over to the next slide, this is the part where I think when we are talking a lot about what we are looking at, when you have local solutions for information, when you are really dealing with a patient population that is not in your backyard, this is a really important part of having standardization that really transcends and goes into the pharmacy workflow across the country. From my perspective, it is really easy when you have patients in your backyard, but it is very difficult when you have patients that are across the country and trying to work through some of those challenges. Flipping over to the next slide, I know I am coming up on time here.

Shelly Spiro
I am going to give you another minute, to be fair.

Justin Neal
Sorry, I know I can talk fast.

Shelly Spiro
Two minutes for you.

Justin Neal

Awesome, all right. So, looking at a couple patient examples of what high-level stuff might be required, getting a patient, for instance, that is a hep C patient, to fill this and get it out the door, between the payer and the accreditation requirements, the pharmacy actually has to have all this information that we have been talking about as good pharmaceutical care, and we are measured on it by external auditors coming in and making sure that we did, so that includes the genotype of the therapy, the viral load, the cirrhosis status, and any prior treatment that they had. After they complete the therapy, the pharmacy is no longer seeing that patient. We have to get past VR12s to prove that they actually achieved a cure. I will skip that invoice piece.

For a Crohn's patient, we might need a TB test to actually justify the fact that they are going on a TNF inhibitor, and they need to confirm that they do not have TB, and that has to be confirmed annually. As a patient with Crohn's, following up on things like flareups, counseling on steroid use, having this information is something that, a lot of times, a specialty pharmacy is very manually gathering from the patient, but by having that integration directly with the EHR, having integration with the health systems, that goes a long, long way to making sure that we can capture this information. Flipping over to the last slide, we are also making sure that, as we capture information, regardless of quality of life, cure status, fill histories, compliance, and other drug-related problems that the pharmacy finds, we are sharing that back to the healthcare continuum to help improve the care across the board. I know it is really quick, but thank you very much.

Shelly Spiro

Great. Thank you, both Pooja and Justin. We really appreciate your input into this. I am going to take the first question for myself. So, both Pooja and Justin, we have heard, or at least I have, in relationship during transitions of care that some of the specialty pharmacies as the patient goes into the hospital or into a skilled nursing facility, where you have different medication dispensing aspects. Have you looked at those issues, or is it still a very manual process once those medications get to where the patient is in the hospital or skilled nursing facility?

Pooja Babbrah

Justin, I do not know if you want to take that. I have not dug into that piece of it as much, Shelly. I have been more on the ambulatory side for the work that I have done.

Justin Neal

I have not dug in as much, but what I will say, Shelly, is whenever you are having that patient transitioning between different care modalities, it gets inherently more complicated, and it is a little bit easier when you have therapies that maybe have more of a nursing component to them because there is already better communication along those lines, but it is more of a self-administered therapy. It leads to a lot more phone calls and manual intervention to understand what is going on with that patient.

Shelly Spiro

So, what I am hearing is it is a barrier in most situations, but what I would like to hear from is on the patient advocacy side. Have you run into these problems? Summer, we will let you go next.

Justin Neal

From the patient side, it really varies, and at the end of the day, trying to get stuff to the patient, the more they are ending up in different modalities, it definitely can complicate the situation. I guess that is the way I would summarize it as quickly as possible.

Shelly Spiro
Thank you, Justin. Summer?

Summerpal Kahlon
Thanks, Shelly. I want to go back a little bit to Pooja's presentation and tie it into this presentation as well. I am struggling a little bit to understand the problem to be solved here with standards because all the standards required to do this exist, so I would like to understand a little better where the barriers are. For example, with hepatitis C, health system pharmacists that are operating on integrated EMR platforms and have direct HL7 connections with their providers are getting most, if not all, of this information, and they are operating in an ideal state that was projected earlier in this slide deck. So, it seems like a little bit of what we are solving for is the specialty pharmacies that may not be part of a health system or directly engaged with some sort of provider network, but again, the standards seem to exist, so I want to make sure it is clear what the problem is to be solved here from a standard perspective.

Pooja Babbrah
I can address that. Yes, obviously, if you are in a health system, I think you have a lot more access to information. I think there is a lot of chat happening around this. I think the bigger thing is yes, the standards exist, but first of all, the question is if the information is being shared. Also, we have talked about the education piece of it on several calls. There should be access to all this information that is not necessarily happening today, so I think it ties into some of our prior recommendations. Do we need to educate? Do we need to do more about information blocking, EHI, and what needs to be shared, all of those things that we have been talking about?

Shelly, I had my hand up to also address your question as you were talking about if a patient moves to a SNF or another setting. In one project that we are working on more on the post-acute care side as Point of Care Partners, I did hear something which shocked me, and I would love to hear about it from some of the patient advocates on the phone. As a patient is getting transitioned from the hospital to a long-term post-acute care setting, oftentimes, the medication list or the medication prescriptions are being handed to the drivers that are driving the patients to these facilities as opposed to being sent electronically, and to me, I think I was a little bit in shock to hear that, and I am sure that is happening all over the place, so I think that is one thing that, to Summer's point, too, if standards are in place and we have this ability, how do we then make sure that that is being utilized and sent electronically versus handing papers to drivers who probably do not always necessarily hand them off? So, that is just another data point there.

Shelly Spiro
Thank you, Pooja. Afton?

Afton Wagner
Thank you both for the great presentations. I was thinking about specialty medications, and Pooja, I know you mentioned a lot of them are in the medical space and go through Medicare Part B. Some of them are now in Part D, especially the biosimilars, and the one thing I was thinking about is a lot of times, these

medications are processed not in the community pharmacy, but at a separate specialty pharmacy, and a lot of times, they are mailed to the patient, and so, I do not know if I have any recommendations, but should we think about making recommendations to make the communication process easier from the patient getting the medication at their house versus coming into the pharmacy to answer questions? Is there anything we need to think about there that could make it easier for the patient from the perspective of access or questions of data exchange?

Hans Buitendijk
I am curious about what Anna's reaction is to that from a patient perspective in particular, but generally, Afton, what would you be particularly thinking about that might be some gaps we would have to fill in that space from a pharmacist-patient communication perspective? What jumps out to you that we could advance better with ONC's help?

Afton Wagner
That is the million-dollar question, Hans. It just came to my mind right now. Let me put some thought into that. It would be great to hear from Anna, and I see she has her hand raised as well, so that would be fantastic. But, I know we need signatures, and it is a requirement that we get a signature every time we send something out. I do not know if that processed could be streamlined a little bit more. Not having the patient at the counter might be… I do not know. Let me think about it, but let's hear from Anna because she might have some good feedback on that.

Shelly Spiro
Anna, go ahead.

Anna McCollister
I have lots of thoughts and feedback, and I will try to channel them toward something that is specifically relevant to this. As somebody who takes four, sometimes five specialty medications, this whole process is so remarkably dysfunctional that it is difficult for me to imagine that it is anything but designed to be dysfunctional so that people do not finish the process, and therefore, the health plan does not have to pay for the medication. A lot of this stuff is data that exists somewhere, but the process of coordination between the lab, the physician, and the pharmacy or specialty pharmacy is remarkably difficult and manual, and all of that has to be mediated by the patient or somebody on behalf of the patient. For instance, if I can get it, I take an erythropoietin for my chronic kidney disease from diabetes, and it leads to anemia, and because of FDA's really crappy guidance, it gives the healthcare plans the ability to limit access to it for people who have a hemoglobin above 10, which is absurd, but that is what they have chosen to do and we will put that aside for now.

So, the health plan requires you to get lab values, and that is a whole process. You have to go into a lab, etc., which is a very demanding part of it. The data then has to be received from the lab to the physician, which weirdly takes longer than it should, though it has gotten better over time, and then the physician has to send the lab values, like hemoglobin, to the specialty pharmacy. Per the insurance plan, the specialty pharmacy only wants one discrete value from that lab test. So, for example, with hemoglobin, you could be dehydrated, and that impacts your level. If the pharmacy actually would receive more data from that CBC, then they might be able to say, "Hey, this person's serum creatinine was a little elevated, maybe they actually have a lower hemoglobin, but it is artificially inflated," and therefore, it would be possible for them

to make a slightly more nuanced decision about whether or not this patient should have access to the therapy. Whether or not they choose to do that would be different, but right now, they say that is not possible because they do not have the data because the data is not in prescribed fields or structured fields, etc.

So, that is one medication that just I take, but it is an example of the kinds of things… My mother is not well, and the number of things that she has to go through to get access to her specialty medication as somebody who is really suffering, in a lot of pain, and is having a really hard time managing all of this is just absurd. All of this data exists in certain places. Anyway, every case is different, every patient's capability is different, and every medication and the requirements by the pharmacy plan or health plan are different, but the crux of it is that a lot of this data exists, it is just that none of it flows from one place to the other, and as a result, it requires the patient to be the person who manages this entire process on behalf of their provider and on behalf of the specialty pharmacy and make sure that all of this stuff happens, and in addition, because of the way it works, there is no possibility that these specialty pharmacies could make a more nuanced decision about what is and is not appropriate for this individual patient.

Whether or not they intentionally choose to not look at other data fields, like the case that I gave you with hemoglobin and erythropoietin, versus whether or not having… If we can get them more ready access to additional information that would enable a nuanced decision making for individuals, then at least that would be one fewer thing that they could claim was the barrier to access. I could go on, but I will not. There is a lot of data dysfunction, and all of it has to be mediated by the patient.

Shelly Spiro
Anna, this is Shelly. As a follow-up question to you, which you do not have to answer if it is too much personal health information, have you ever been admitted to the hospital and had trouble getting your specialty medications?

Anna McCollister
The specialty medications that I take at home?

Shelly Spiro
Yes.

Anna McCollister
I usually just take them with me.

Shelly Spiro
Okay, so your solution from the patient side is to take those with you during transitions of care, not necessarily having them managed by either the hospital, long-term care facility, or another location that you might have to be admitted to.

Anna McCollister
That just sounds like torture to me, frankly. Fortunately, there have only been two times that I was admitted from the ER into an actual inpatient scenario, and in both cases, I had friends come to my apartment, just grab all my meds, and bring them.

Shelly Spiro
Interesting. Ike?

Steven Eichner
To back that up, I would not dream of relying on a hospital to replace a specialty drug. Thinking about the reapprovals for that on a medicine, it could literally be $1 million a year of authorizations. That would just be a nightmare. I do think it is important that we think about it from a patient-centered perspective as we look at duplicative questions. How do we keep the patient at the center of these exchanges so the patient is not overburdened with information or requests for duplicative information? I actually went through this myself in the last few days, and another place that seems to be a gap is looking at patient information about medications in terms of looking at the medication list that is available electronically from my pharmacy. It does not include educational links regarding any of the medicines. It would not be that difficult to have a link for each medicine back to the pharmaceutical manufacturer of that medication, or even a link back to the pharmacy to say, "Hey, if I have a question about this drug, who do I contact?"

Shelly Spiro
Justin or Pooja, do you want to comment on what Ike is talking about?

Justin Neal
I was just going to say that that technology absolutely exists today. I would say it depends on some of the platforms to be able to communicate that as part of the initial counseling with the pharmacist to add additional resources from the manufacturer to really aid in that process, especially if you are talking about a self-administered medication and its injection technique, and also making the patient aware, to your point, Ike, what type of question goes to whom, what should be a call to the manufacturer versus a call to the pharmacy or doctor.

Steven Eichner
Right, and that may be an opportunity here as we are looking at recommendations for standards or inclusion. Yes, the technology exists in practice, but does there need to be a push to incorporate that as potentially a certification criterion that says that if you, as a pharmacist, are using a certified technology, from a certification perspective, it needs to include this kind of functionality for the ability to get patient education material, the ability to connect the patient to the pharmacist on call or on duty, etc., and that is certainly within our wheelhouse as a Task Force.

Shelly Spiro
Thank you, Ike. Alexis?

Alexis Snyder
As I sit and listen, I am tacking on more comments, so I will try to be brief. I guess I want to go back first to your question, Shelly, about specialty medications during admission to the hospital. I have had that inpatient experience with my daughter on several occasions where a specialty medication is not available readily, and I have run into obstacles with being allowed to bring it in from the outside. So, that is a real obstacle that patients and caregivers face on a regular basis, and most of the time, when the hospital realizes that you are going to have to bring it in yourself for timely care, you cannot self-administer it, have a caregiver administer it, or keep it in your room. It needs to be under lock and key at a nurse's station within the floor

that you are on, and that is also really difficult for specialty medications with shortages and having comfort in handing over something and making sure you get that back or it does not get misplaced, etc. So, I just wanted to weigh in on that question. I also wanted to weigh in on your question about mail order and some other obstacles and use cases regarding that.

So, there are health plans that require that you only use mail order for certain specialty medications or medications in general as well, and even with those that have an opt-out component to that, that opt-out period takes time, and it is also sometimes not recorded correctly on the health plan side and runs into problems for weeks and weeks, having access to getting medication because you cannot get around the mail-order-only pharmacy, getting it more timely, and opting out.

The other point I wanted to make with that, too, is when you are dictated to only use mail order, it also becomes an obstacle for the patient and caregiver, whereas you may have secondary insurance, and your secondary insurance is not accepted at that mail-order pharmacy because really, your health plan is the one supplying the medication for mail order, so that creates a large burden for patients to pay out of pocket and then get reimbursed by their secondary provider, which most people cannot do with some of these specialty medications, so that is just another issue with mail order to be sorted out.

The last comment I wanted to make goes back to some of the flowchart from Pooja's presentation, and I had put this in a comment, so I will just briefly rehash what I had said there. A lot of the obstacles for patients start with that second step, where the decision-making process is done by the provider for what to prescribe, which is hopefully a shared decision with the patient. Once the determination has been made on what they are going to prescribe, the majority of the time, the provider just sends that off electronically or hands somebody a written prescription, and that is it.

They are not going into the system that is available in real time to see what the coverage is, see what the obstacles are, and see if there is a step plan that has to be gone through first, there has to be a generic instead, a different drug tried first, a PA process, or what have you, so it just goes back to the obstacles we have been talking about from the beginning of this Task Force, that it just stops right there. The pharmacy gets it, and it goes right back to the patient and caregiver to sort out all the obstacles, make the phone calls to the health plan, the provider, the pharmacy, or sometimes multiple pharmacies. Something needs to be done to move that forward. So, if this information is available to providers in the beginning, and while the patient is sitting there in their office, they can go through it together and figure it out, then great, but that is not happening in the real world.

Shelly Spiro
Thank you. Pooja?

Pooja Babbrah
I just want to make sure… The reason I wanted to start with that slide that said… I do not think we are ever going to land on a definition of "specialty." Everyone is going to cover differently, everyone is going to do all that, so I appreciate all the discussion around that, but I want to refocus our discussion around what we can actually do about this, and I see there is a lot of chat in the discussion on EHI, and I feel like there is an exercise for us or a recommendation that we can be making. I guess technically, in specialty pharmacies, everyone is covered under information blocking, so we can look at what is available today as part of that

EHI data set and what we should be able to share back and forth. So, I just wanted to make sure we are focused on what ONC can actually focus on.

Shelly Spiro
Thank you, Pooja. Hans?

Hans Buitendijk
Thank you. I really enjoyed the discussion here, both spoken and by chat. It emphasizes a number of themes that we have started to see, that specialty medications are contributing to extra arguments of why this is important, the sharing of EHI, the education, and other components that I think we can bolster suggestions to say it is across the board and highlight in specialty medications a variety of the examples that have that need even further.

At the same point in time, there are two points I want to bring up. One is related to one of the discussions around privacy and consent that is popping up in the chat for consideration, and the other one is more of a question, as we have talked a lot about EHI, to find out what other particular interactions, which we have a couple of, that are specific to specialty medication that make it particularly complex that we might not have touched upon yet. I think privacy and consent is somewhat in that in-between part that we have talked about a little bit, but I think today, it becomes clearer that having a better opportunity and ability to have computable consent mechanisms that certain data can and cannot be shared, that there are certain steps that you can and cannot take in the context of specialty medication.

That really highlights that that continues to be a big topic that we need to highlight to ONC. That needs to be tackled, and there are different perspectives from prior HITAC discussions on this in the Interoperability Standards Workgroup feedback to HTI-1, etc., that there is the standards part and tagging, which can only get you so far, but at some point in time, there needs to be a real infrastructure in place because just tagging the data and letting it flow through the system to all the parts is not necessarily going to be able to ensure that the data is properly recognized and that the most current rules are always being used.

As we make those suggestions, I would strongly recommend that we include not just looking at standards and adoption generally, but very specifically as well the infrastructure that would enable us to do that in real time so we do not need to chase down flags that may need to be changed across many different providers. It is a big topic that I would suggest including in our recommendations. The other part, back to specialty medications specifically, is what other areas do you see that are not more of what we have discussed, that are good examples, but that we have not covered yet? Are there interactions we just have not covered yet? On one of the slides, Pooja, you had quite a variety of price transparency, prior authorization, and otherwise. Is there anything that jumps out in that space that we need more focus on to advance for specialty medications?

Pooja Babbrah
Yes, and thanks for calling that out. I do think both those topics are important, but I think it was Ike that commented that we do have the standards in place for those. The question becomes adoption of those, and also the patient aspect. What is the opportunity here, and what are we really missing? It is the data flow back and forth and the visibility. I think it is bringing into not only the visibility, but really the consumer side. We do have an implementation guide that could be picked up that patient-facing apps could allow

patients to check. We know doctors are busy, and they are not necessarily going to have the time to check on pricing and things like that, so what is that opportunity for the consumer?

We clearly have folks on this call, too, that are very invested in their care, and I think having that visibility into where their drug is in the process in terms of the prior authorization, where it is on the benefit investigation side, and how much it is going to cost them out of pocket is a huge piece that is missing today. If pharmacists and providers do not have time, let the patient get more involved because these patients clearly have the ability to do this and want to do it, but it is just a matter of getting the information. If I had a wish list, I would say that is the first one we need to focus on.

Shelly Spiro
Thank you, Pooja and Hans. Summer?

Summerpal Kahlon
Thanks, Shelly. Just building on what Hans and Pooja were just mentioning, a lot of our discussion after Pooja's presentation really focused more on the clinical side of things, but I want to go back because there was a large chunk of her presentation that related more to the administrative transactions, the claims, and claims-related transactions, and it feels like one of the fundamental problems there is that we have two parallel standards for medical claims and pharmacy claims. I know there are commercial services that exist that map between the two different types of claims and the appropriate clearinghouses, and I think they are done in a more proprietary way, but they kind of map those transactions between networks and allow them to flow as an intermediary.

I know that at one point, NCPDP was looking at this issue and trying to figure out how to harmonize a little better with the WEDI standards, but I do not know where that landed. If there is a standards problem here, that may be one of the key issues, to understand that harmonization between the WEDI standard on the medical benefit and the NCPDP standard, not only for specialty medications, but also for vaccines, which are also often covered under a medical benefit. I would like to spend a little bit of time there, and I have to admit I am not exactly sure where NCPDP stands today on harmonizing that standard, so I would love to hear from someone who is more in the know there, but it feels like that might be a role for ONC as well, to help facilitate that mapping of the two standards so that data can flow between what are two distinct transaction-based clearinghouse networks today.

Shelly Spiro
Pooja, did you want to close?

Pooja Babbrah
Yes, I just put this in the chat. Thanks for that. A couple years ago at NCPDP, one of the specialty Task Forces put out a whitepaper that really highlighted this issue, saying there are all these separate, disparate systems that do not all tie together, so I know that task group, Margaret Weiker, and others at NCPDP reached out to several organizations in CAQH, and I think Margaret is on the line and can comment a little bit more on the actual work, but I do know that NCPDP is now working with CAQH on this topic and doing potential operating rules around this. So, I know they are just getting started. I did meet with CAQH a couple weeks ago to do a deeper dive, but that is something that is now being looked at across organizations, and I am hoping Margaret can just add more into the chat a little bit on the actual operating rules.

Shelly Spiro
Thank you, Pooja. Anna?

Anna McCollister
Pooja's earlier comment pretty much echoed exactly what I was going to say. Just trying to think about all of the myriad points of frustration throughout all these processes and the amount of time that I spend on them, one of the key points of frustration is that all of this information exists in one form or another, but much of the process information and status information is not visible to the patient, and it is as if we pretend the providers actually have time to do this stuff, and they do not. Even when they are awesome providers with great staff, they just do not have time to do it, and even if they really have a committed sense of urgency to serve their patients, it is not nearly as urgent as mine or mine for my mother's.

So, all of this information data elements have a status, and the ability to proactively move data or ping the specialty pharmacy that the lab data had arrived into the doctor's EHR portal, to be able to actively send and ping them and say it is there, should be given to the patient, both in terms of data about what the data is that is being considered, what the status is of whether it is considered, opened, or viewed by somebody there, pinging somebody through an informatics system, portal, or whatever to say, "Hey, it is sitting in your inbox, you need to take a look at this and process it…" All of that power should be given to the patient rather than pretending, as we like to do, that physicians are the only ones who can handle that process and that they actually have the time to do it. Preferably, the patient would not need to be involved, but that is the reality that we live in, so let's stop making the process more difficult by pretending things are what they are not.

Shelly Spiro
Thank you, Anna. Ike?

Steven Eichner
Just to counter that, I am not sure we need to put more burden on the patient to do an administrative task regarding pushing data back and forth. That is why we have spent an awful lot of resources developing technology to make data more accessible. Providers have concerns about creating administrative burdens. So do patients. I spend a lot of time just dealing with my pain. I do not need an extra burden of chasing down to see if a lab value came back from a laboratory to forward it along to a specialty pharmacy.

Anna McCollister
None of us need that, Ike. I would prefer to do the things that I used to do before I had to do all this stuff, but the reality is that is what I spend a lot of time doing, whether it is for my care or my mother's. That is where it stands. Nothing about this is ideal, but it would be great if I did not have to wait on hold to reach the doctor or the pharmacy to see who had opened what, only to find out that they had not. At least that would save hours of hold time for me.

Steven Eichner
I agree with you there. To mitigate that, something I put in the chat a few minutes ago was that potentially, what we need is a common workflow tool that is visible to all to understand where a particular medication is in the workflow from a physician recommending or issuing a script to it until the drug actually ends up in

the patient's hands for consumption so that there is a clear understanding, visible to all, about what the process is, what the workflow is for that particular medication, where it stands in the workflow, and who is responsible for taking the next action.

Shelly Spiro

Ike, I think you are right on on that, but I think what we really need to realize in terms of what you are talking about is a separate process for high-cost drugs for high-risk patients, but is that really what we should be doing? Shouldn't we be looking at the exchange of all medications and access to medications?

Steven Eichner

I would suggest that the same base process relates to a drug regardless of cost, whether it is out of stock, $100,000.00 a dose, or 20 cents a dose. Again, tracking that through is a simple tool for everybody to understand that the physician or clinician ordered a drug. Has it been sent to the pharmacy, yes or no? Is it in stock at the pharmacy, yes or no? Those kinds of questions are consistent throughout. For specialty or expensive drugs, there may be some additional steps, but I honestly do not think it is a different process. There may be some additional details or components, but I think the core workflow, steps, and communication are really the same regardless of what the medication is.

Anna McCollister

I agree with that. I now have to do this with generic medications in the middle of the market. It is the same process. I do not know why, but that is where we are.

Shelly Spiro

Thank you. We probably have less than two minutes left. Alexis, go ahead.

Alexis Snyder

I do not want to reiterate too much of what has gone back and forth, but I was just waiting to weigh in, and I put a lot of the comments in the chat, too. For one, for patients who are already stuck in the middle, even when transparency is better and if transparency gets more improved in the future, they are still always stuck in the middle because there is only so much the patient or caregiver can actually push forward or do, beyond making a bunch of phone calls to everybody involved and getting different answers from the pharmacy, the provider's office, and the insurer, and literally just passing information back and forth with no one pushing it through. Again, to Ike's point about being stuck in the middle and placing more burden, that is never the solution.

On top of all of it, and I have mentioned this in past meetings and will say it again, there are patients and caregivers who are not able or capable of doing these things. There are people that do not speak English, there are people that do not know what the channels are, there are people that do not know who to contact, and there are people that are very, very sick who literally physically cannot do it. So, to say that we should place the burden back on patients to help push the process along goes way back to before even having any of these processes available. So, patients do play a part, but they are not the be-all and end-all, and they are not in a position to be the be-all and end-all. They cannot move it forward. That is just not a solution.

Shelly Spiro

Thank you, Alexis. Pooja, can we wait until after public comment?

Pooja Babbrah
Sure.

Shelly Spiro
Okay. Mike, go ahead.

Public Comment (01:19:36)

Michael Berry
All right, thank you, Shelly. We are going to open up our meeting for verbal public comment. If you are on Zoom and would like to make a comment, please use the hand raise function located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. I see Margaret Weiker has her hand raised, so Margaret, please go ahead. You have three minutes. You are still on mute.

Margaret Weiker
Thanks. I am Margaret Weiker, the vice president of standards development at NCPDP. In August of 2018, NCPDP formed the Work Reported by Benefit Coverage Identification Task Group to address issues related to the identification of benefit coverage, specifically the challenges in determining if a specialty medication is covered under the medical or pharmacy benefit. The desired outcome of benefit identification is to provide a comprehensive benefit coverage overview electronically at the time the medication is selected and to improve a patient's ability to begin therapy without delay. The process should be easily accessible without multiple manual steps or duplication of efforts by providers, specialty pharmacies, and hubs. The task group published a whitepaper which addresses those challenges and potential electronic solutions that can be leveraged in the prescribing and dispensing process.

The task group also conducted a survey to identify which techniques are most commonly used today to determine benefit coverage. A key finding of this survey is the X-12 270/271 transactions can be more effective in communicating medical benefit coverage for drugs if additional granularity was included in the transactions, which is supported by the existing format. As the recognized operating rule authoring entity, NCPDP contacted CAQH CORE to discuss collaboration opportunities that would support the exchange of more granular eligibility information related to the medical benefit on the request and response between prescribers and payers. After LeAnn Stember, president and CEO of NCPDP, presented the opportunity to the CAQH CORE board, approval of the project was given, and NCPDP and CAQH CORE began their work. NCPDP and CORE would be happy to share more with the Task Force about this work effort and encourage all those interested to reach out to participate. I will put the information in the chat of how to join an NCPDP task group as well as a link to our specialty pharmacy resource guide. Thank you.

Shelly Spiro
Thank you, Margaret.

Michael Berry
Thank you, Margaret. Next up is Erin Weber. You have three minutes.

Erin Weber

Good morning, all. This is Erin Weber, vice president of the Committee on Operating Rules for Information Exchange, or CORE, at CAQH. For those who might not be familiar with CORE, we are a collaboration of more than a hundred industry stakeholders who lead the development of consensus-based business rules or operating rules that build on standards to improve interoperability and drive automation. CORE is designated by the Secretary of HHS as the national operating rule authoring entity under HIPAA. So, I just want to build on some of Margaret's comments. We are excited to update the Task Force on the joint work CORE is currently conducting with NCPDP to address this eligibility gap in the specialty pharmacy space. As Margaret mentioned, in a recent whitepaper, NCPDP identified challenges experienced by stakeholders in being able to timely and accurately identify the appropriate benefit coverage, whether medical or pharmacy benefit, for a specific medication being prescribed and potential out-of-pocket costs to the patient at the time of care.

So, NCPDP and CORE are collaborating to support the exchange of more granular information related to the medical benefit in the 270/271 eligibility request and response between providers and payers, including coverage and patient financial responsibility like copays, deductibles, and coinsurance, which can be supported by the current version of the X-12 standard, but is not required. So, right now, our organizations are conducting a joint environmental scan to better understand the current industry approaches to address this challenge, and we plan to launch a joint NCPDP and CORE eligibility and benefits task group in October to develop operating rule requirements for the X-12 270/271 to support the exchange of this coverage and benefit information or medications covered under the medical benefit, which can also include gene therapy.

Ultimately, our goal would be to bring these rules to NCVHS, the National Committee on Vital and Health Statistics, for consideration for federal mandate under HIPAA sometime next year, as currently, plans are not required to include this information in their eligibility response. Although health plans have not yet built out the systems and applications that can support **[inaudible] [01:24:50]** inquiry using existing and widely adopted standards like the 270/271 and building on a transaction that is already highly automated will make it more efficient, less costly, and faster to implement in the market, perhaps, than using a new standard or one-off process that would need to be developed from scratch. NCPDP and CORE are happy to share more with the Task Force about this work effort and encourage all those interested to reach out to participate. Thank you.

Michael Berry
Thank you, Erin. Next up, we have Mary Andrawis. You have three minutes.

Mary Andrawis
Hi there, everybody. I want…

Hans Buitendijk
I think we lost Mary.

Mary Andrawis
Can you hear me now?

Hans Buitendijk
Yes, go ahead.

Mary Andrawis

Thank you guys so much. I really appreciate it. I wanted to first thank you all for your work because I see this is a group of highly motivated and very skilled pharmacy and specialty industry experts, so I really appreciate everyone's insights and expertise. I actually have more of a question than a comment, which is when I looked at the charge that is given to this Task Force by ONC, the focus is really on public health and identifying what those standards and data needs are.

And so, I was curious to know… As we think about public health, I know the other listed short-term goal is related to public health emergency use cases, but then it goes on into the long-term vision, thinking about public health surveillance and reporting in public health interventions, and in my opinion, I encourage us to think about that so that we do not get stuck on some of the issues related to the standards and the data needs, but also the use cases, so that we can eventually get to the public health divisions and groups, CDC, and beyond to the state and local agencies to demonstrate to them how this data would be useful and helpful to them because I think there is work that needs to be done there.

So, I know it does not technically fit within this idea of standards and data needs, but from where I sit, there is a need to even just inform and educate the public health world, which is currently undergoing a modernization, and there is a lot of action there in trying to modernize the entire public health data system. So, this is a great time for pharmacy to be there at the table, and so, I do not know if we just append the short-term… Anyway, I just wanted to bring that long-term vision up and elevate that because I think it is so important and so timely in what we are seeing right now with all of the action and the HIEs in the public health space as well. Thank you so much.

Michael Berry

Thank you, Mary. Hans and Shelly, I am not seeing any other hands raised, so I will turn it back to you to close us out.

Task Force Work Planning (01:28:01)

Shelly Spiro

Thank you. I appreciate it. Thank you, everyone. Pooja, sorry about that. I hope you can put your question in the chat. Thank you, everyone, for getting us going on our first Topic 3 challenge. Remember to put your recommendations in. Hans, any last comments?

Hans Buitendijk

I have a general question. As we go through our notes on Topic 3, we have the tab for Topic 3, so please put them in there. It particularly focuses on standards gaps. If there are some examples from specialty medication, of which we had a number, that really bolster the recommendations in Topics 1 or 2, do not hesitate to add them there to really further underscore the importance of that recommendation across the board, and specialty medication in particular, so that we will figure out the balance between the two. I am looking forward to lots of red markup and additional recommendations over the next couple days.

Shelly Spiro

We are not meeting next week. I know we are at the top of the hour. I also will not be available on September 13, so Hans will be doing this with the help of ONC, which he is very capable of doing, so thank you, everyone. Have a safe Labor Day holiday, and we wish our colleagues in Florida well. Thank you, everyone.

Hans Buitendijk
Thank you.

Adjourn (01:29:35)