ONC | HealthIT ADVISORY COMMITTEE

Transcript

PHARMACY INTEROPERABILITY AND EMERGING THERAPEUTICS TASK FORCE 2023 MEETING

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VIRTUAL

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

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	Centers for Disease Control and Prevention	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	Harvard Medical School & Harvard Pilgrim Health Care Institute	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 will be held around 11:50 Eastern Time this morning. I would like to begin rollcall of our Task Force members, so when I call your name, please let us know if you are here, and I will begin with our cochairs. Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Shelly Spiro?

Shelly Spiro
Good morning.

Michael Berry
Pooja Babbrah?

Pooja Babbrah
Good morning, I am here.

Michael Berry
Chris Blackley is not able to join us. Shila Blend?

Shila Blend
Good morning.

Michael Berry
David Butler?

David Butler
Good morning.

Michael Berry
Steve Eichner?

Steven Eichner
Present.

Michael Berry
Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Michael Berry
Adi Gundlapalli is not joining us today. Jim Jirjis?

Afton Wagner
I am present, and I suggest changing my asterisk to two asterisks.

Michael Berry
Okay. If you have not heard, Jim has accepted and started a new position at the CDC, and he is actually going to be the CDC's federal representative on the HITAC, replacing Adi, so, congratulations, Jim. We will add your extra asterisk, thank you. Summer Kahlon? Steven Lane?

Steven Lane
Good morning, I am here, and special congratulations to Jim on your asterisk.

Michael Berry
Meg Marshall? I believe Anna McCollister is not able to join us today. Deven McGraw?

Deven McGraw
Present. Good morning, everyone.

Michael Berry
Ketan Mehta?

Ketan Mehta
Good morning.

Michael Berry
Justin Neal?

Justin Neal
Good morning, everyone.

Michael Berry
Eliel Oliveira?

Eliel Oliveira
Good morning.

Michael Berry
Naresh Sundar Rajan? Scott Robertson? Alexis Snyder is not able to join us today.

Scott Robertson
Sorry, this is Scott Robertson. I missed it.

Michael Berry
Thank you, Scott. Fil Southerland? Christian Tadrus? Sheryl Turney? Afton Wagner?

Afton Wagner
Good morning.

Michael Berry
Good morning, everyone. Thank you so much, and now, please join me in welcoming Hans and Shelly for their opening remarks.

Opening Remarks and Introduction to Topic 4 (00:02:50)

Hans Buitendijk
Good morning, everybody. We really appreciate everybody joining. Today, we will keep on going and start with Topic 4 in a moment, as Shelly and Tricia Lee provide further introductions, and after Topic 4, we are going to go back and keep on moving anything into the green as far as we can go today so that we can look at what we have done and what we still need to do at that point in time. As always, at the end, there will be public comment, which also means that along the way, for those who are from the public, please use chat if you want to to make comments and ask questions along the way, and then, at the end, you have the opportunity to either emphasize or provide additional comments verbally at that point in time. So, we are looking forward to that, and I will remind Task Force members to use "everyone" in the chat to get it on the record as well. With that, I am going to pass it to Shelly.

Shelly Spiro
Thank you, Hans, and welcome, everyone, to our weekly meeting. We are so glad that we were able to meet. Luckily, the ONC is available to be with us today and the government did not close this last weekend, so we are very thankful that we can continue our work. Our next topic is on the direct-to-consumer prescription services. We have not been able to secure a speaker or presenter for this section, so I asked Tricia Lee if she would be willing to explain ONC's reason that this particular topic was added to the discussion, so I am going to turn it over to Tricia Lee to provide some insight into that.

Tricia Lee Rolle
Thanks, Shelly, and congratulations to Jim. Welcome to civil service. So, we have reached our fourth topic. It is kind of hard to believe we have been at it for a while, but here we are. We have described this as direct-to-consumer prescription or prescribing services, and it is really an area of healthcare services that provide prescription medications based on an online assessment, which could be a questionnaire or some form that gets filled out, and possibly calls or video meetings with a physician or nurse practitioner. A lot of the prescribing for this area has been around acute infections and sexual/reproductive health issues, and medications can be delivered to your home or a prescription can be sent to your pharmacy. Payment can also range. It can be self-pay, HSA, or even a flex savings account, and there are some insurances that these companies are accepting as well. There are a number of these types of companies out there. We were advised that we probably do not want to specifically call them out, but if you google my description, you can probably find some of these.

And so, this is an area where ONC is interested in hearing your recommendations just because it is emerging, it is new, and while there are reasons why patients might want to circumvent or not use traditional channels to seek medical care and get prescriptions, we are just interested in the connectivity of it all and all the recommendations that the Task Force has for ONC on the area as far as standards technology or anything else we might do to be supportive or areas we need to look out and watch out for. I know that there are certainly a lot of privacy concerns and reasons why a patient might not want their primary care physician to know that they are receiving a certain treatment or have a certain condition. I do not think we want the Task Force to delve too deeply into that, but to really focus on any technical considerations or things that ONC should keep front of mind or top of line when thinking about this area. I hope that helps describe what we mean when we say "direct-to-consumer prescription services."

Shelly Spiro
Thank you, Tricia Lee. That was a great overview of what we are trying to have. So, we will continue the discussion on this until the top of the hour, so let's open it up for a discussion on what folks feel about this topic. It is pretty quiet out there.

Tricia Lee Rolle
Shelly, I will also add that these services can be accessed online. You can go to the websites, but you can also download apps that allow you to do this as well.

Shelly Spiro
So, what do folks feel about this? Pooja, thank you for stepping up.

Discussion: Topic 4 Direct to Consumer Prescription Services (00:08:07)

Pooja Babbrah
When I think about online pharmacies, there are a couple of things that come to mind in terms of recommendations. I know that earlier this year, NCPDP held a stakeholder action group that talked about digital therapeutics, and that was a topic last week, if I remember correctly. What we heard in that discussion was a lot of these digital therapeutics were using these online pharmacies, and they were faxing prescriptions or not using standard in order to get the prescription. To me, I think that is one thing we need to be thinking about in terms of if there is an opportunity for us to think about what kind of standards could be used to get prescriptions to these pharmacies. I am not saying that they have to use… With apps and things, there are probably lighter-weight standards, but there are APIs and things like that.

So, in my head, when I am thinking about recommendations we could make, it is how we make sure that prescriptions are being sent to online pharmacies using standards, but also, bringing it into the data fold, how are you capturing that intimate history? If someone is using an app to order it, is it being captured in the patient's medication history? We have been talking a lot about whether pharmacists can have access to the patient's clinical information and medication information when they are going to provide clinical services, so how do we make sure that those pharmacies are looped in just like any other pharmacy if they are dispensing medications? I guess that is the initial reaction when I think about these types of pharmacies.

Shelly Spiro
Thank you, Pooja. David?

David Butler
This is clearly a personal opinion on this, but my impression is that this is not an area that needs a technological solution as far as if there is too much or too little of this. This should be handled more on the patient care regulatory side rather than saying this technology should not be used for this or that. It sounds to me like we are opening our discussions here, so I am taking the direction that if the patient is benefiting from care wherever it comes from in the world, the technology becomes irrelevant with regard to controlling it. It may cause benefit, so we should not restrict it. If it is a deficiency, then the deficiency should be focused on how the patient is being harmed. I do not see this as a technology-based discussion. I think it is more practice and care.

Shelly Spiro
Thank you. Steven?

Steven Lane
I will once again echo David, as I tend to do in these meetings, to simply say that I think we want to hold these direct-to-consumer prescription services to the same standards to which we would hold any other provider, that we should make sure these systems, programs, and vendors are able to access the necessary clinical data to inform the care and services that they provide, and that those care and services are documented in a way that is then made available to everyone else on the care team with a valid need to know. The fact that they are direct-to-consumer notwithstanding, the rest of us on the care team need to know if the services **[inaudible] [00:12:36]** things have been provided, the dispense history, and all the same information as if they were going through a retail pharmacy or a clinic.

Shelly Spiro
Thank you, Steven. Sheryl?

Sheryl Turney
Can you hear me?

Shelly Spiro
Yes, we can.

Sheryl Turney
Okay, because it looks like I am muted on my computer. I got a new Windows system, and I do not know how to use everything yet. Thank you very much for that. I wanted to agree with some of the things that Steven just brought up, but also, I think it is important because from a clinical and a payer perspective, medication reconciliation, being aware of all the prescriptions and the adherence that a patient has, is very important, and today, we do not really have access to those things that are direct-to-consumer because they often do not go through insurance for various reasons, so I think it really is important that the adherence is the same standards that we have regardless of the payment method or how that prescription service is provided, but that clinical information, medication reconciliation, and all those abilities to share that data across the spectrum are going to be very important.

Shelly Spiro

Thank you. Scott?

Scott Robertson
Yes. In regard to the idea that they need to have access to pertinent information and that they should be provided that information back into the broader patient record, I think their basic model is a disincentive to participate because if their marketing is "Here are healthcare services you can get," nobody is going to know about it. If they follow standard of practice and provide that information back to the longitudinal health record, they are actually exposing that service, so the primary care provider's records will see it anyway. I think that is just sort of a fundamental problem. I do not think there is really any recommendation around that, but I just wanted to bring that up.

Shelly Spiro
Thank you. Christian, I would like to ask you if you can explain your comment because I know you are a member of the Missouri State Board of Pharmacy. From a state board of pharmacy standpoint, can you opine on that?

Christian Tadrus
I apologize, I joined after the question was asked, and I have been inferring what you are asking about, so if I am a little off topic, I apologize to everybody, that topic being informed standards. Kathy brought up the point around boards of pharmacy being involved in that conversation, and I would say that if we are going down this path, we do have to recognize that the states have the ultimate authority on prescriptive authority and how the practice is deployed in their state, so we have to recognize that, be accommodative in whatever map we lay out, and defer to a large degree around those allowances.

So, my comment really was that it is not just the pharmacy state laws and/or regulations that fall from them that might be the lens through which that state board of pharmacy expects care or dispensing of medications to happen from the standpoint of patient safety, there are also other laws and regulations that often appear on books that are really at the prescriptive end of the equation on the prescriber's side, such as non-steerage expectations, freedom of choice of pharmacy, and those concepts, but also this idea of what a valid patient relationship might have to constitute in order for a script to be considered valid, even if issued. In Missouri, we have some regs on the books around that as well, so that makes it incredibly hard for pharmacists to determine whether or not the prescription being issued had met all the thresholds for being considered a legal prescription for the purposes of dispensing.

So, there are some pros and cons of that because I think we could help with communication around some of these issues and definitions, the types of prescriptions, and the types of consultations that these prescriptions emanate from that would give some clarity to that so that pharmacies are not inadvertently filling scripts or that scripts are not being issued inappropriately under state laws, especially when they go across state borders for residents of different states. We have done some work with that NCPDP on codification and the script standard around whether it is a modifier subsequent to a telehealth visit or is an inpatient notification scenario, so I think those can be informative in our standards. With regard to mail order, I would argue and probably the support the concept that the model does not seem to replicate where this is heading at the moment, and is probably influenced largely by things outside of the professional care relationship, so it is a tough question to answer.

From a regulatory standpoint, just to close out, as a regulator, we would license a dispensing pharmacy as a dispensing pharmacy and hold them to whatever accountable expectations we have of a pharmacy, so they are not different in that respect. They may have some slight variations of allowances based on method of delivery and contact with the patient, but we would hold a mail-order accountable, just like we would a community or a long-term care, to whatever our regs were when operating in our state, so keep that in mind. I would say there is a regulatory conversation we have to talk about, probably even more of a state statutory conversation, if we are going to do this, but standards can help if they can follow and keep up with those changes, which I think the standards organizations do a good job of trying to accommodate.

Shelly Spiro
So, Christian, just as a follow-up question, do the prescribers have to get a license in order to do this online prescribing? I assume that it goes to a mail-order pharmacy, so that also needs to have a license. Is that correct?

Christian Tadrus
So, a mail-order pharmacy would have to have a license issued from the state they are, for example, shipping prescriptions into, and would have to comply with all the requirements of that license category that they get for that state, so those requirements will vary across the 50 states. From the prescribing end and the validity of an issued prescription, that is also going to vary by states, mostly based on the Medical Practice Act definitions that apply to the prescribing side of the equation of physicians, nurse practitioners, and so forth, and some of them are fairly specific about what threshold must be met to constitute a valid patient care relationship, and therefore, a prescription being issued. Now, the routing of those scripts is really more of an EHR function, and payer-incentivized directional flow, as well as patient choice, where appropriate for the pocketbook, I guess. I think there are different components there, Shelly. Does that answer the question?

Shelly Spiro
I just have one more follow-up. Are any of those prescribers required to use e-prescribing, as most of the states have adopted mandatory e-prescribing?

Christian Tadrus
I think we are in that weird transition phase of five to 10 years where, as those mandates are coming on board, either for reasons of patient safety or monitoring controlled substance flow, all the states that I am aware of have quite a few exception triggers that allow them to use paper, fax, and other things and say, “Look, if they do not have the technology in place, they can ask for an exemption or qualify those things.” We are still dealing with a lot of that, even though the states are moving rapidly through some directional flow in the e-prescribing standpoint of being made mandatory.

I think an e-prescribing switch would be able to give you a little more detail on how much adoption is there, but even in Missouri, for example, where this is something we have dealt with on our state board, many of our physicians still do not have electronic systems. There are country docs, there are people working in small hospitals that cannot afford systems, and surprisingly, there are still a few community pharmacies that do things without e-prescribing, and when you are in the model of a cash-based pharmacy, which is increasingly popular nowadays, other than e-prescribing, you are probably not buying a system to do

telecom processing of third-party insurances. Models are evolving, but I suppose it still is a bit of a wild west out there. From a regulatory and legislative standpoint, I think the problem is that it is not 100% mandatory.

Shelly Spiro
Thanks, Christian. Pooja?

Pooja Babbrah
I think Christian brings up some really good points. I never really thought about individual states. When I think of these online pharmacies, like Amazon Pharmacy, I do not know if they would fall under this umbrella. I am looking at Hans's recommendation of if we consider these as the same types of facility that should be under any of these rules, but then, when I think about all the models, this is such a new space that I wonder if it is too early to even make recommendations in this area. I think Christian brought up some good points, and I think we need to take them into consideration in terms of state regulations and what is considered an actual pharmacy.

Shelly Spiro
Scott?

Scott Robertson
Following up on Christian, Pooja, and others, these are providers. They need to abide by all state and/or federal regulations, and as such, I think they should be sharing information unless the patient actively states they do not want it to be shared because the patients have that choice, and again, to reiterate, it seems that would mainly be a state-level concern rather than a federal one, so I do not know if there could be a recommendation ONC or the federal agencies to say something in terms of those services abiding by all the rules for non-direct-to-consumer providers. I do not know if that can be a recommendation. Thank you.

Shelly Spiro
Hans?

Hans Buitendijk
Sorry, I was double muted. From the perspective of a recommendation to ONC, it sounds like we can treat this as another setting, another context, but based on state and other jurisdictional rules, one that effectively has to play by the same rules, but from an ONC perspective, I have not heard that there is a different kind of interoperability, a different kind of data set, or a different something else that we need to highlight with a specific recommendation, but rather that as things are being rolled out, going to a comment that Katie Russell is making around consent, whether it is opt in or opt out, whether it is explicit at that point in time, it needs to be a statement by the patient that yes, they are consenting to have this shared or not.

However it is done, it needs to be transparent to the patient, but I am not seeing anything unique to ONC that we can recommend that needs to be addressed differently or additionally. That is what I was trying to make with a comment in the chat, that we need to acknowledge that this is a space, that in many ways, they are interacting or potentially have a need to interact the same way, depending on what level the patient wants to have that data shared or not.

Hans Buitendijk

Thanks, Hans. Tricia Lee, maybe you can answer this. I have not seen it, but has ONC recognized this setting as following the rules of ONC, especially from the prescriber's standpoint?

Tricia Lee Rolle
I would say that the closest, or at least the catchall umbrella here, from an HHS perspective would be telehealth, but I think there are some unique aspects to the services that we are trying to describe here. This form right here is probably the most direct that we have come to at identifying this category of services, that you just download an app and run with it or go on a website, input your symptoms, and see what happens. I hope that is helpful.

Generally, we are working in the telehealth space, but this HITAC topic is our first real venture into understanding or exploring that specific workflow. The patient gets an app or goes online, puts in their symptoms, and maybe talks to a nurse practitioner or physician, who then sends or ships a prescription. There are other areas where the service might potentially request a lab or send off something to collect a sample, so, again, depending on what type of health concern there is, it can be a little bit more involved, but the questionnaire or video chat with a nurse practitioner or physician is pretty typical as far as the patient identifying their symptoms without a face-to-face visit in that prescription being delivered to them.

Shelly Spiro
So, what you are saying is it does fall under telehealth?

Tricia Lee Rolle
I would say that could be a catchall for it.

Shelly Spiro
Okay. Any other comments or questions? Thank you all for a great discussion. I think we got the gist of what we needed, Hans. I hope we have, and with that, I am going to turn it over to Hans to lead our discussion on Topics 1, 2, and 3 for the review of the recommendations.

Topics 1, 2 and 3: Review of Recommendations (00:29:21)

Hans Buitendijk
Sounds great. I just have one comment. As today, our patient advocate reps, Anna and Alexis, are not on, we probably will want to carve out some time next week as we talk about recommendations. Let's see how far we get, hopefully to Topic 4, so we can ensure there is nothing else we need to add to this. So, I think what we are going to do, then, is go to the spreadsheet, and if it is okay, it might be easiest for me to share my screen. Last time, we were a little bit challenged by having a couple of editors in the same cell at the same time, so what we are going to try to do today is have me edit in Column E for Topic 1 and Column F for Topic 2, if we get there, but I will be the only one.

I would ask that everybody stays out of Columns E or F in the respective topics. If you have any thoughts or suggestions you want to make, write them down quickly as a suggestion or alternative in a column to the right, if you can find one, and then, as needed, we can copy and paste over at this time or a later point in time, but please stay out of Column E. Even if you sit on top of it, that might already cause a challenge, so I would suggest not pointing at any cell, particularly in that regard, if you can. I am going to start sharing my

screen, and if it is correct, then you should see it right now. The first question, as always, is is this large enough or too large?

Shelly Spiro
It is too small.

Hans Buitendijk
Okay, I am going to increase it a little bit. Let me know when the text is large enough, and then I will adjust the column sizes accordingly. Is this good enough?

Shelly Spiro
It is better, but I think once you double-click the cell that you are interested in, we will be able to see it better.

Hans Buitendijk
Okeydoke. So, we will go with this. Let me know initially that we have it right, and let's start. So, since last week, a couple things have happened. On the left-hand side in Column D, you will see a slightly expanded reference when it says "covered" in Topic 1, and then, it would be E2, and since there are multiple recommendations, the recommendation is listed as well. So, as you go through your comments in Column D and see if they are addressed or not, they are fully indexed in Column D for Topic 1. We are almost done with Topic 2 to get to the bottom of that list. There are two or three left to make sure we get to that level of detail. That allows you to say, "Okay, I made my comment," and to double-check whether we have addressed it sufficiently or not. We believe it has been addressed in Topic 1, Column E, Row 2, and it is R2, so in this case, we think this one that Steven and I worked on is addressed by R2 on the right-hand side here.

At that point in time, if it is already in green, please do not edit it offline. Make a comment that we can recognize. I believe I found one from David Burgess in Column D, but if you can make it very clear that there needs to be an update that needs to be made there before we get to the Word document, that would be great. On the other hand, we are now going to go in, and if text in Column E is still in black, you will start to see that it has some level of red in it to indicate that something needs to happen, and today, we are going to look at everything that is not yet green, and we are trying to get as far as possible. We are trying to avoid wordsmithing. We just want to make sure that the general intent is there, and then, somebody who has a better way of phrasing it can pick up the wordsmithing afterwards. We will keep track of who that is, but we do not want to spend too much time wordsmithing during the call. With that, before jumping in, I need to get something over here so I can see if there is a hand raised.

Shelly Spiro
I will check that for you, Hans. There are no hands raised.

Hans Buitendijk
Great. Any questions before we dive in? All right. So, where we are at, then, is the first one, R3. Sorry, I need to highlight it this way. We were generally aligned with the recommendation, but we still had some open questions on clarity and rationale, and Scott and Afton were going to double-check, particularly in the second instance.

Shelly Spiro
Hans, Scott has raised his hand.

Scott Robertson
There was a bit of a mix-up. I do have a recommendation that I should put in that row, but in F or G.

Hans Buitendijk
Yes, put it in G on here or something like that, and then we can copy it over.

Scott Robertson
Actually, I did end up editing the… Wow, there are too many things here. There it is. I did end up editing the recommendation itself, just because when I took all of the changes out, I still had some changes in it, and it got a little confusing, so I just pasted it in G, although I do not see it now. Do you see it?

Hans Buitendijk
Let's find out. There. Let's move on. Could you highlight the changes you made so that we can hone in on the differences when we reread everything? We can move on to the next and come back once we wrap up, and you will be ready at that time as well.

Scott Robertson
Okay, let me do that.

Hans Buitendijk
Sounds good. So then, we come back to R3, which is the rest of E2 there. If somebody needs to resize columns, please do not do that, because at that point in time, as you can see here, it will not show as nicely on the screen that everybody is looking at, so please refrain from resizing so we have this all in one spot. Okay, we are back to where we were. That means we are going to go to the next one. Here, we are looking at R11. Alexis and Anna could not make it, but Christian, Afton, and others did join. They came up with an update that is highlighted in red, so there were quite a few updates made. I will show everything here. There was still a little bit of a follow-up by Alexis to clarify. She is not on the call today, but what I would like to do is at least look at the rest so we can see if everybody is okay with the direction, and then there will still be some fine-tuning based on Alexis's feedback.

So, it currently reads, "Recommend that ONC work with CMS, STLTs, and other relevant agencies to develop a value-based incentive structure using quality measures so that prescribing providers and patients can be timely and accurately informed at the point of e-prescribing care information regarding the availability whether a prescribed, recommended medication intervention is available or may be reasonable available at the pharmacy selected by the patient and to which the patient medication prescription has been or is being considered to be sent/referred."

This may still need to be chopped up into multiple sentences, but that is the first one. That is where that second comment from Alexis is coming in. "This should include data on the status of drug supplies, on the expected time of medication availability, and on detailed tracking data on shipments for medications with all actors in the process, including pharmacies, ordering providers, patients, and public health emergency systems. We suggest that a cross-sectional workshop with a focus on the patient, ordering providers, and

pharmacy go through a use case model to further inform existing standards, the necessary capabilities, and gaps, including those identified in the HITAC Intersection of Clinical and Administrative Data Task Force report, 'A Path Toward Further Clinical and Administrative Data Integration,' regarding transparency to patient as they apply to the pharmacy setting as well."

So, other than some of the adjustments that Alexis is looking at, is there any concern at this point in time that this generally moves forward as a recommendation? I will scroll down so you can look at the rationale that was updated and cleaned up as well so it can go with it, and then there will be more wordsmithing after that. Are there any concerns with moving this forward? We will work with Alexis to clean up any remaining pieces and make it flow a little bit easier.

Steven Eichner
Hans, this is Steve Eichner. One thing that came out of COVID-19 specifically was that in many jurisdictions, public health was providing COVID-19 vaccines to providers at specific locations. Some providers wanted to reallocate vaccines across their systems, and that was challenging. So, in this system, we are looking at how we account for distribution in that space and setting priorities for distribution.

Hans Buitendijk
Is that something that this recommendation can address, or is that a separate statement that needs to be inside allocations? What do you recommend?

Steven Eichner
I guess it relates because as we are talking about availability, who is determining what is available where?

Shelly Spiro
Ike, this is Shelly. I understand where you are coming from, and I think that was just a unique situation. Most medications go through a wholesaler.

Steven Eichner
I am not discounting that, but remember, a basic charge to the Task Force is coming out of the public health emergency, so I want to make sure that when those situations occur, we have a framework that supports those kinds of activities.

Shelly Spiro
Yes, and I think that would be up to… If the United States government were supplying providers, then it would be their responsibility to come up with a plan to reallocate because there is a chain of custody that has to occur when medications are under control of, say, the physician's office. Was it refrigerated appropriately? Was it kept appropriately? That reallocation has to be up to a policy process.

Steven Eichner
Right, so it may be good to call attention here with a consideration, though I will not call it an exception, in a public health emergency that there may be different processes adapted or adopted in those situations.

Hans Buitendijk

But is that necessary for the recommendation here, or is that in light of what we are recommending, that as that is being fleshed out, it would come up by having references to public health emergency systems here? Perhaps we should add public health in this statement as well because the supplies are distributed somewhere between providers, pharmacies, and public health.

Steven Eichner
Right.

Shelly Spiro
Hans, I think that should be a separate recommendation because it does not fall within the normal process. It is sort of like returns and reallocation of unused product with chain of custody. It is in a totally different process.

Steven Eichner
Right, but it fits in here, because if you are looking at availability, it kind of fits into this model or component as well. It may be different, but it is certainly related and is a factor here as well.

Shelly Spiro
I still think we will confuse this one because this one was more focused on engaging the patient. I understand that is still a portion of engaging the patient, but I think public health emergency should be a separate recommendation.

Hans Buitendijk
Shelly, would it be possible for you and Ike to work through and see how it can be phrased as a separate recommendation?

Steven Eichner
Sure.

Shelly Spiro
Yes.

Hans Buitendijk
With additional information, we might be able to say what we have here, as it is, is okay to move forward. We may either find something in addition, based on Ike's comment, or in a separate recommendation to address it in that way. Is that a reasonable way to move forward?

Shelly Spiro
I would like to call on Afton and Christian, who are part of the subgroup that worked on this. What are your thoughts on this?

Afton Wagner
Thanks, Shelly. I do think it is probably a second recommendation, just from the rationale that we built out last week. It does not quite fit under it, but I am happy to tease it out a little bit more, if that would be helpful.

Shelly Spiro
Yes, absolutely. Hans, what I am saying is I think we are going to lose the intent on R11 if we try to fit this into this recommendation because it does have a different intent on the recommendation in relation to public health emergencies.

Hans Buitendijk
So, to confirm, for now, we are okay with what is stated here, and Ike, Shelly, Afton, and perhaps Christian, Alexis, and Anna as well will work on the second one to address the reallocation part and how that can be stated from an ONC perspective.

Shelly Spiro
Yes.

Hans Buitendijk
Ike, would that work for you as well?

Shelly Spiro
Ike?

Steven Eichner
Yes. Sorry, I was muted.

Hans Buitendijk
No worries. So, with that, unless anybody has a concern as I go about this, I will indicate that we are okay with it. I am not going to turn it green quite yet, but at least we can say okay that we are okay with what we have updated so far, and I will do the rest later to get the strikeouts out of it. Before we move on, does anybody else have anything?

David Butler
I just have one minor thing. I seem to focus on this perhaps too much, but midway through that paragraph, we have a suggestion about all the actors in the process. We do not note pharmacists, but we note pharmacies.

Hans Buitendijk
Any concerns?

Shelly Spiro
The reason we noted pharmacies is because when we were talking about inventory control, we really felt it was the pharmacy that has control over the inventory.

David Butler
But it would be the pharmacist who is the authority in that pharmacy. It is not the pharmacy that has that authority. It is always a pharmacist. A pharmacy cannot do this on its own.

Shelly Spiro

Right, I understand that. I thought we had this discussion last time about looking at the difference between naming pharmacists and pharmacies and what the different functions were between the two.

Hans Buitendijk
One could argue that in the context of this, the pharmacist would like to know about this as much as the pharmacy, if you will, because they interact with the providers and the patients. So, if we say "all actors," then from a logistics perspective, the pharmacy has information to offer just as the entity moving the drugs, but the pharmacist, the provider, and the patient needs to know the ordering information, so it seems like we could add "pharmacist" to this to ensure that all perspectives are in play.

Shelly Spiro
I would agree with that, Hans.

Christian Tadrus
Shelly, this is Christian, and I would say that is a good addition too. I did not have a chance to step into this overall conversation, but earlier, you asked me about this. It is nuanced, as we mentioned on previous calls, and it is a very challenging situation, which I think is why we have come up with this compromise. We are going to have to have a working group to tease out this stuff because it is not just pinging a pharmacy from an automated standpoint, the pharmacy responds that it is in stock or out of stock, and the script goes flying all over the country in different directions because somebody responds, "Yes, in stock."

The pharmacist is probably making an informed judgment on that response in a lot of these cases. It may not be in stock at the moment of the ping, but there is a response that would be flexible enough to say that it would arrive in time before the patient runs out or some other scenario that would work in the communication stream. You are going to need some human intervention there, I would think, at least in the near term. I think having the human aspect of involved actors is important here. I would also call out that Kathy Graf called out a typo or omission in the rationale line when we say "drug distributor and sometimes manufacturer." I think that was meant to include pharmacy as well.

Hans Buitendijk
Where did you see that? Sorry.

Christian Tadrus
The first sentence in the rationale line. It goes, "Currently, there is no way to tell a prescribing provider or the patient if a drug distributor and sometimes manufacturer." That should say "pharmacy, drug distributor, and sometimes manufacturer has new drugs in supply."

Hans Buitendijk
"Pharmacy, drug distributor," like this?

Christian Tadrus
Yes, basically, capturing anybody in the distribution.

Afton Wagner

When Anna first wrote it up, she mentioned the manufacturer or distributor not having it in stock, and then we expanded the rationale to include all kinds of situations, but I guess we missed it.

Hans Buitendijk
Let me fix it so it is there. At this point in time, we are waiting for Alexis with a couple of additional tweaks here, and then, from there, I just need to keep this to make sure that Alexis stays in the loop there. And then, we are looking at a likely second additional recommendation that we will find out the name of later.

Shelly Spiro
I think you might want to put red in that sentence that we need to fix. It looks like a bit of a run-on.

Hans Buitendijk
That is the one here that we need to break up into more sentences because it is too long. Okeydoke, it can go green right after that. We will go in and then do further wordsmithing. Next is R12. This has a couple of updates from last week that we need to make sure we copied over and had the right ones, and we believe that this now represents what David was suggesting. "Recommend that ONC require full interoperability between EHRs, PBMs, and other TPAs that ensure that information about drug device, medical supplies, and services coverage terms of an insurer are immediately available to patients, practitioners, and appropriate personnel affected by that change, including providing full awareness of the therapeutic and cost impact of that formulary change, beginning at the start of any open enrollment period through the end of the patient's coverage."

So, the question is with these updates that were suggested initially, based on what is struck through here, it was considered that it would be out of scope because it was looking to intent to change here. It is now stating that when it has changed, everybody needs to be made aware, and we need to have the ability to inform everybody effectively. So, with that, are we comfortable that this is now in scope, and are we comfortable that this is phrased sufficiently clearly and we only need to look at wordsmithing after this?

Shelly Spiro
Hans, can you get rid of the blue column?

Hans Buitendijk
The one to the left?

Shelly Spiro
Yes, or move the bottom bar over so we are seeing…

Hans Buitendijk
Hold on. I am trying to shrink it, but someone is in it. Is this helping? Let me close that and go back. Mayb that is the reason why. Now I can shrink this. Can you see more of that?

Shelly Spiro
Yes, we can see it, but it still small. That is better. There you go.

Hans Buitendijk

Is this fine? Okay.

Shelly Spiro
That is good.

Hans Buitendijk
Okeydoke. So, we were at R12. Can we turn that green? And then, let's look at the rationale as well and see if there is anything that needs to be tweaked, but that needs to be tweaked later to make sure the rationale is complete. Otherwise, are we okay with the recommendation?

Pooja Babbrah
Hans, this is Pooja. I just have one small wording change. For "immediately available," should we say "available in real time," since that is the term that we use? Maybe "immediately available" is fine, but…

Hans Buitendijk
David, are you okay with that?

David Butler
I am fine with the change.

Hans Buitendijk
Okay. Any other comments? If not, then that sounds like I can turn this green after removing this, and then we will look at everything else here that can come along, and that then becomes wordsmithing. Great, the first green of the day. I like it. Have I selected the correct green? Yes.

Shelly Spiro
You can get rid of "David" at the top.

Hans Buitendijk
Yes, thank you. So, we got that, which means we have one more done.

David Butler
Shelly, you did not mean that literally, did you?

Shelly Spiro
No, not at all, David. I apologize.

Hans Buitendijk
By the way, I picked this one up already in the Word doc, so that is done, and I believe that we have 14, which was a small addition there. That was fixed, so that is done. That means we go on to the next one. We had R6, the recommendation that generally, we were going in the right direction, but there were a couple additions that Christian was going to look at some measures for. Christian, I am not sure whether you had the chance to do that or whether we needed to leave this here and come back to this next week.

Christian Tadrus

I would appreciate some extra time there, but the general thought here was whether or not we need to focus on different types of measures that are more descriptive of pharmacy quality outside dispensing of a product, which are the current ones, and I am probably going to need some input from others on viability there. So, I can suggest some different approaches, but some of them may end up being more proprietary and some more general, the idea being that the concept here is are there better measures to be looking at from the standpoint of pharmacies and their relationship to public health that the outcome measures are trying to address.

Hans Buitendijk
So, if you can provide some suggestions and put them in here, then others can look there as well, and next week, we can round it out.

Christian Tadrus
Okay, thanks.

Hans Buitendijk
Great. That concludes this particular cell. The next one was empty because we did not have anyone, which gets us to R15. It states, "Recommend that ONC recognize interactions between pharmacists and other providers as a critical component of Trusted Exchange Framework's treatment exchange purpose and address the barriers and encourage education for pharmacies and pharmacists to join the TEF as it is operationalized. This should address both the ability for pharmacists to query other providers, as well as other providers querying pharmacies for patient data." Any thoughts, or are we okay with that, as well as the rationale? If you have any immediate ones, you can drop them in. Are we okay with this? I am not seeing hands raised. Going once, going twice? I am taking the strikeout out. Okay, then this is going to become green.

The next one is "Recommend that ONC recognizes the pharmacists," and we may want to remove the dash, which gets confusing, "with public health interactions," and we need to add "health" there, "and reporting as a critical component of TEF's public health exchange purpose and address the barriers to consistent standardized data elements and formats across the public health community, including CDC and STLTs, considering reporting frameworks such as APL's case reporting approach. This not only applies to pharmacy interoperability, but all reporting to public health by all providers." Any thoughts or further major tweaks before we do the minor ones? I am not seeing any hands raised. Not hearing anybody else, this goes green.

Next, we have Recommendation 17, "Recommend that ONC collaborates with the pharmacies and other providers, including their HIT suppliers, to establish appropriate reporting mechanisms directly from the pharmacy to the care team members and vice versa, i.e., push messaging rather than solely relying on respective queries for information." Deven had a question. "It seems like there is a missing word or two." I think we did it. We did not add "trigger event," "vice versa," or "bidirectional," so there is still a little bit of work to be done. I missed that one. So, that still needs to be done. We will come back to that next week because that was not working and I totally skipped over it.

Shelly Spiro
I have a question on that, Hans. By "HIT suppliers," do you mean vendors?

Hans Buitendijk
Yes. Do we want to call them vendors?

Shelly Spiro
Is that a term that is used?

Hans Buitendijk
They are sometimes used interchangeably. I am okay with "vendors." So, we will fix that and come back to this next week and approach it. Is there anything else that jumps out that we missed, other than "triggered events" and "bidirectional"? Okay, next is Recommendation 18. By the way, I see a comment here that I have not seen yet. "Recommend ONC collaborates with pharmacists, clinical data, public health agencies, including CDC and STLTs, to identify a minimum data set within USCDI that pharmacists must be able to exchange with IIS registries, EHRs, and possibly other pharmacy information systems considering the various roles that pharmacists have in the test-to-treat process during normal times and emergency use interventions. The scope should consider not only prescription-related data, but also any non-prescription-related data where the pharmacist provides test-to-treat services such as assessments, tests, treatment, and/or advice rendered." Any thoughts here, other than that clinical data seems to be missing something, because they do not quite equate to pharmacists and public health agencies?

Shelly Spiro
David has his hand raised.

Hans Buitendijk
David?

David Butler
This is my set-based thought process here. With the sentence that is about the third line down where we talk about "may have in the test-to-treat process," I am wondering if anything after the word "process" is needed because the implication is there are times that are either not normal times or emergency use intervention times. I do not know why that phrase needs to be in there. I would remove it.

Hans Buitendijk
Any objections? That makes sense. Okay, it is gone. Thank you, David.

Shelly Spiro
Hans, I think Scott put his…

Hans Buitendijk
Let's come back to that after R18. "Clinical data" seems like it needs to be a different term to be on par with "pharmacists" and "public health agencies." Who should that be? Other providers? Who should be part of this, other than pharmacists and public health agencies? Otherwise, I might suggest striking this.

David Butler
What about "providers"?

Hans Buitendijk
Just “providers”?

David Butler
We are talking about entities, pharmacists and public health, which is misspelled, and then we talk about data in the middle. I think they mean provider data.

Hans Buitendijk
Okay, that makes sense. We will remove the H there.

Jim Jirjis
Is there any possibility that meant it was intended to be clinical data registries?

Hans Buitendijk
It could be, and if that makes sense, we can add that. I will put it in.

Jim Jirjis
I welcome other people’s thoughts.

Shelly Spiro
I agree, like with STC and some of the other intermediaries holding data on behalf of the providers.

Steven Eichner
The callout for IIS was specific to pharmacists, so I am not sure what other clinical data you are expecting from public health.

Hans Buitendijk
Do you want to be more specific, Ike, and specifically call it IIS instead of clinical data?

Steven Eichner
I think we may want to call attention to IIS and other pieces, but from a public health perspective, I am not sure what other data you are seeking from public health agencies in their role as public health agencies from a clinical care perspective.

Hans Buitendijk
David and Jim, regarding IIS and others in the context of Ike’s comment, are you okay if we focus on IIS registries here?

Jim Jirjis
I guess I was thinking of adverse drug effect monitoring and such, that VAERS and such might not be covered, and should be.

David Butler

It seems a little specific. Would it be better to have something broader, and then have IIS be an example? Because there may be other data sets in the future that are relevant. General or specific is the problem.

Jim Jirjis
I agree.

Steven Eichner
I am not trying to be limiting. I just know the history of the recommendation, which came out of the focus on IIS, and I do not want to lose the tree for the forest.

David Butler
That is why I think having the general and then parenthetically calling out IIS is important. I agree with you.

Hans Buitendijk
Are you okay with it this way, Ike? It is specifically called out, because that is the topic area, but we are not limited to them.

Steven Eichner
Yes.

Hans Buitendijk
Okay. Any others?

Shelly Spiro
Christian put in there that HID reporting is mandatory in some states, and pharmacists are doing prep…

Christian Tadrus
Test-to-treat.

Hans Buitendijk
Is there any other update that would need to be made? Sorry, I do not have my chat up quite yet.

Christian Tadrus
Shelly, I think that would go into public health agencies, and I think that is captured there.

Hans Buitendijk
Okay, sounds good. Anybody else? Going once, going twice?

Shelly Spiro
Maybe we should put "looking at use cases such as IIS, prep, test-to-treat, antibiotics, antibiotic stewardship" in the rationale.

Steven Eichner

This is Ike again. We should not be inventing new standards for exchange if we already have standards that meet criteria. In other words, if there already are methods for exchanging data with IISes, there does not necessarily need to be a different standard for pharmacists.

Hans Buitendijk
I would agree that that is fair, and by focusing on USCDI, we can establish the scope of the data, and where we do have existing standards, data should be used to exchange that. Where the existing standards are not covering everything of interest, then we need to either update or find a way it can be encompassed as well. In a way, by focusing on USCDI here, it leaves open which standards are going to be used, but in light of all the other recommendations, it would seem that we are first going to focus on standards already available and already used for that data. Is that reasonable, or do you want to have an additional statement here to make sure that the implementation and support of USCDI needs to take advantage of existing standards wherever possible? Ike, any particular thoughts on that, whether we should add something here or, given the rest of the recommendation set, by having USCDI for pharmacists and public health defined, if you will, that we know at that point in time that the next step looking for the standards will be addressed through those other recommendations?

Shelly Spiro
Let me ask you a question, Hans. In the example of IIS, they might want the lot number of the immunization or the vaccine that was given. That is not in USCDI. Is that what you are talking about?

Hans Buitendijk
Let's say that is a data element of interest, and an interesting one. It might not be in USCDI in this context, so it would either be a USCDI Plus or a USCDI element, wherever it ends up, but for now, it is somewhere in the USCDI umbrella. That would mean unless a standard already supports that, we would then have to look for enhancing or advancing a standard to ensure that lot number is included in a transaction to IIS. Now, today, I am pretty sure that is in the transactions VXU, but let's assume for a moment that it is not. Then, it would have to be added. If it is already there, then USCDI was just catching up with what is already out there, but now it is clearly stated that it is of interest. Does that help or confuse further?

Shelly Spiro
I was just trying to bring that forward. I think it does. Let's just go on and leave it.

Hans Buitendijk
Ike, is that enough clarification on the standard support, just to make sure? Are you okay with leaving it like these and leave the other recommendations to address the standards to be used there, or do you think it is critical to add something here as well? You may be on mute. I am not hearing from Ike. I am a little hesitant to go green here without getting confirmation there, so let's move on. We will come back and double-check with Ike that he is okay with that. You indicated that Scott had…

Shelly Spiro
R3.

Hans Buitendijk
Okeydoke. Go ahead, Scott. Why don't you describe what you did?

Scott Robertson
Well, there were a few things that I did in the recommendation part, mainly for clarification and consistency with other things we were saying, so those edits at the top are fairly insignificant, although the more I look through this, the more it seems like we really should have consistent… I see some phrasing occurring slightly differently in different recommendations, and it would be a tedious process to go through, like when we say "patients, caregivers, pharmacists, and other providers." We have little variations that it might be good to be consistent about, but those are really not anything.

The bigger change was the specific concerns in the rationale, and I put together what I thought was a better sentence or two. Patients may have different concerns about sharing data with different care team providers. They may want some care team members to have access to all information, like physicians, while others, like nurses and pharmacists, may have limited access. The patients must have a means to manage these consistently. It does address it, and the statement was there, but having typed this and read it over and over, I do not know if there is another recommendation in here that talks about access considerations generally because it seems like an overarching concept that a consistent means to permit patients to manage their information access…

Hans Buitendijk
Actually, later on, we get to R23, and that is all about consent management, so we ought to look there and see this aspect of it, this perspective of some more, some less, and see whether we can further reflect it in there. If you go in your own version to the bottom, the last row in this particular tab, this is documented. Have a look there.

Scott Robertson
Well, when we get to that, it might negate the need for that last sentence.

Hans Buitendijk
Or we could still have it here, but elaborate it there in the rationale. It is helpful to understand why.

Scott Robertson
It turns out that with some of the changes that I made, whoever edited R3 previously found the same edits that I ran across. There is some redundancy and some spelling and stuff.

Hans Buitendijk
All right, with these updates, does anybody object to turning this green after applying these updates? Not hearing any, I think I am going to try to do the following shortcut. I am just turning it green, and I will take care of the removal…

Scott Robertson
You may not want to do that.

Hans Buitendijk
Why not?

Scott Robertson
Okay, you can just take out the strikethroughs. I made the mistake of doing that, and I had to redo the whole thing.

Hans Buitendijk
I know that feeling. Let's go back to where we were. Thank you, Scott, for that. We were down here at 18, and Mike, I am not sure whether you can hear us now or you are still offline. We will come back to that. Let's go to 19. "Recommend that ONC work with CDC, ASPR, and STLTs in particular to identify a shared…" This is actually getting a little bit too big on the screen to go from left to right. Let me do it this way so it is a little bit less sideways. "Recommend that ONC work with CDC, ASPR, and STLTs in particular to identify a shared superset of key operational measures critical to situational awareness during declared emergencies across different data sources, such as hospitals, clinics, pharmacies, etc., include support for that set, which covers pharmacies as data sources as well, into the HELIOS Aggregate Data Initiative," if that is spelled right, "to ensure implementation guidance covers these measures." And then, there is the rationale, "Pharmacies play an important role," etc. Any concerns with this recommendation? I am not seeing any raised hands. Anything in the chat, Shelly?

Shelly Spiro
Nothing.

Hans Buitendijk
Green it is.

Shelly Spiro
I just want to warn you we have two minutes before public comment.

Hans Buitendijk
Let's see whether we can squeeze in R20, and then we will pick up with R21 after that. If there is going to be discussion on R20, we will stop that and go to public comment. "Recommend that ONC, in collaboration with FDA, CDC, and STLTs, further review FDA's Sentinel surveillance program on how pharmacy data sharing would be important for their surveillance during emergencies." Any comments or thoughts? Any concerns? If not, then, with 50 seconds to go, I will turn that green. The next one will likely have a little bit more conversation, so, Mike, I think we are ready to turn it over to you for public comment, and if we have time left, we will continue with R21.

Public Comment (01:18:42)

Michael Berry
Great, thank you, Hans. 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 are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. Let's pause for a moment and see if any members of the public would like to raise their hand. I am not seeing any hands raised yet, Hans, so I will turn it back to you to finish up. Thank you.

Hans Buitendijk

All right, thank you. While you might not have public comments you are still invited to make any comments in the chat. I will reshare my screen, and we should still be on that one. On to 21, which states, "Recommend that ONC consider including the capturing of race and ethnicity as part of e-prescribing certification and point to USCDI Version 4 that references the CDC Race and Ethnicity Code Set, Version 1.2, where alternative paths are not available or policies and measures require the sharing as part of e-prescribing." And then, there is the rationale of why it should go through e-prescribing, because there are no other paths available to share. Maybe this needs to be clarified a little bit more what "alternative paths" means, just by spelling out or sharing the data with…I believe it was around **[inaudible] [01:20:35]**.

Shelly Spiro
I agree.

Hans Buitendijk
Are there any additional comments or thoughts? Scott, you have your hand up.

Scott Robertson
I am concerned if this becomes a requirement for… Oh, "as part of e-prescribing certification." Having it within the e-prescription, I dislike the idea of it eventually becoming a requirement for the pharmacies to collect, just because of the workload in many pharmacies these days.

Hans Buitendijk
Christian?

Christian Tadrus
This one makes sense from a health equity focus standpoint and an SDOH standpoint, which is an emerging theme…no, not an emerging theme; it is upon us. So, being able to exchange not only race and ethnicity, but some other components there is important. So, I think that is going to support bidirectional work, even if a little bit of a burden on systems vendors to be able to exchange it, so I am generally in support of this recommendation for that reason. The patient does not need to be pinged five times for the same question. If a validated, credible source of a healthcare provider has collected that, which could include pharmacists, why should we burden patients with repetitive statements? Race and ethnicity typically does not change over a lifespan, as I recall.

Shelly Spiro
Pooja?

Pooja Babbrah
I think this makes sense. When I read this, we are not saying that the pharmacists have to capture it, it just being able to shared in the e-prescribing workload, which I think is the right way to go, because as long as we are stating it that way, I think this makes a lot of sense, and I would support this.

Shelly Spiro
Afton?

Afton Wagner

Yes, I think it was me who originally brought up the fact that we had a really hard time gathering this information in the early pandemic days, so it would be great to have it, and I agree. As long as it is not mandatory to have and collect it, being able to receive and exchange information would be super helpful from this standpoint.

Shelly Spiro
David?

David Butler
I have two comments. One, we note the word "capturing." We never note "exchange." Should that be changed to either include the exchanging of data regarding race and ethnicity, or should it be capturing and exchanging?

Hans Buitendijk
To clarify, on the USCDI side, I just need to double-check, somebody else might know for sure, but I believe that this information is already in USCDI Version 3. There might be a more current version in 4, but that would mean that on the certified software side, it is already starting to be included, as well as other SDOH information. On the non-pharmacist provider side is where the capturing as a result needs to be enabled as well to be able to exchange or receive it. It seems like as we do this, as we now say that it should be part of exchange as well with e-prescribing, at some point in time, I would agree with David's earlier point that if the pharmacist happens to be the first one in connection with the patient, they might be the one that is able to capture it. It is still a challenge for everybody to capture it, but if everybody is part of the care team and you are the first one in contact, you may be the best person to capture it. You might not get it for whatever reason, but you should have the opportunity to capture it if you can.

Shelly Spiro
Scott?

Hans Buitendijk
David would like to follow up because I responded to a comment that he made, so, David first, and then back to Scott.

David Butler
My second comment addresses some of what I think Scott was talking about. It sounds like this should then include the ability to capture an exchange, not actually the capturing, because that sounds much more forceful. It could even be the option to capture and change it, but I think that might be a little toothless, so I think "ability" works.

Hans Buitendijk
That sounds reasonable. Scott?

Scott Robertson
I actually was going along the same lines as this discussion. My only concern right now is that as far as the exchange, that works in as part of the e-prescribing certification. Capture is in the workflow, and I do not

have a problem with that. Mandating capture is going to be a workload consideration, but capture in itself, the ability to capture it, store it, and then exchange it… As long as we are of the ability, I think it is okay.

Hans Buitendijk
And therefore, if you cannot capture it, you cannot exchange it.

Scott Robertson
Yes, somebody has to obtain it first.

Hans Buitendijk
What we typically see in the standards that it is zero-dot-dot something because if you acknowledge that you cannot capture it, for whatever reason, what it typically means is that in order to be able to exchange it, you have to be able to capture it.

Scott Robertson
That is brought out in the rationale. I find it a little awkwardly stated, but I cannot think of a less awkward mechanism at this point. Thank you.

Hans Buitendijk
Are we then generally looking at the hands up and the discussion? With these adjustments, does it look like we have an acceptable recommendation, with the rationale to follow and further wordsmithing later? I am not hearing any objections, so I am going to turn this one green without removing that part. We will remove the strikethrough later because there may still be an opportunity to get us to R22 with two minutes to spare. There is 23, but that might be the introduction to next week. This one states, "Recommend that ONC collaborate with the pharmacy community and patients to develop guidance on best practices for data capture from patients in pharmacies." Thoughts? Scott?

Scott Robertson
I think that is a great overall thing to recommend. It is sort of nebulous in that it covers a lot of things, but anything that could be done to make it simpler for patients and pharmacies to interact for all this additional information that we are looking for would be a good thing.

Steven Eichner
This is Ike. I have a friendly amendment to include stakeholders and caregivers.

Hans Buitendijk
"Pharmacy community…" So, taking Scott's other comment in mind, would you put it like that, Ike?

Steven Eichner
And caregivers.

Hans Buitendijk
Oh, caregivers, sorry about that.

Steven Eichner

Instead of exclusively patients because you have parents and other folks involved.

Shelly Spiro
We are at the top of the hour, Christian. I think we need to stop this discussion.

Hans Buitendijk
We will not turn this one green yet, but we are close. We will pick it up next week at R22, and Ike, if you can consider whether R18 meets the additional thoughts that you have in here or other recommendations sufficiently cover the thought you had around R18, then we can resolve that one as well.

Task Force Work Planning (01:30:04)

Shelly Spiro
Okay, we are meeting on October 11th, and just as a reminder, if you want to attend the HITAC meetings on October 19th and November 9th, on October 19th, we will provide an update to the HITAC, and on November 9th, we will finish. Sorry, Mike. We went over a minute. Thank you, everyone.

Hans Buitendijk
Thank you.