

Transcript

PHARMACY INTEROPERABILITY AND EMERGING THERAPEUTICS TASK FORCE 2023 MEETING

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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	Prescriptive	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
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 Taskforce. I am Mike Berry with ONC, and we are very glad that you could join us today. This taskforce 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 11:50 Eastern Time. I would like to begin rollcall of our taskforce members, so when I call your name, please let us know if you are here. I will just note that Hans is off this week, so he will not be able to join us. I will start with Shelly Spiro.

Shelly Spiro

Good morning.

Michael Berry

Pooja Babbrah?

Pooja Babbrah

Good morning.

Michael Berry

Chris Blackley?

Chris Blackley

Good morning.

Michael Berry

Shila Blend is not able to join us. David Butler?

David Butler

Good morning.

Michael Berry

Steve Eichner? Raj Godavarthi?

Rajesh Godavarthi

Good morning.

Michael Berry

Jim Jirjis is not able to join us today. Summer Kahlon? Steven Lane?

Steven Lane

Good morning.

Michael Berry





Meg Marshall? Anna McCollister? Deven McGraw is not able to join us. Ketan Mehta? Justin Neal? Eliel Oliveira? Naresh Sundar Rajan?

Naresh Sundar Rajan

Good morning. Present.

Michael Berry

Scott Robertson?

Scott Robertson

Good morning.

Michael Berry

Alexis Snyder?

Alexis Snyder

Good morning.

Michael Berry

Fil Southerland?

Fillipe Southerland

Good morning.

Michael Berry

Christian Tadrus? Sheryl Turney? Afton Wagner?

Afton Wagner

Good morning.

Michael Berry

Good morning, everyone, and now, please join me in welcoming Shelly for her opening remarks.

Opening Remarks & Review of Draft Recommendation Report (00:02:10)

Shelly Spiro

Good morning, everyone. Wow, we are getting close to the end. Hans is not with us today. He is off today, so I will try to push through. I will definitely not do as good a job as Hans has, but Hans and I have been working closely on trying to bring everything to at least a document that we can review, which we will be going over today, and that will be our review of the draft recommendations and report. We will be giving an overview, and then focusing on the highlighted recommendations that we have not reviewed with the taskforce yet, but we believe that this new document will be very useful to us. Then, we will go to public comment, and then our next steps.

Just as a reminder to everyone, the HITAC meeting is tomorrow, and we will be doing the presentation there, so if you would like to join us, I am sure that our taskforce members on the HITAC will be there and





support the work that we are doing also. Then, with that, we will adjourn, and hopefully see if we need to meet next week. If we can get through this document, we will probably meet again, but we have to have everything done and ready to ONC on this document very soon. As another reminder, in your chat, especially for those who are attendees and part of the taskforce, make sure you change the chat to send to everyone. I want to thank the Accel team, Tricia Lee, and Mike Berry from ONC, who are helping us with all of this work. I just want to personally thank all of them. Let's go on.

Tricia Lee is going to help us today, since Hans is not with us, to review the document. As I said earlier, what we have done is move everything out of the spreadsheet, so we will no longer use the spreadsheet. If you have read your homework assignments, those homework assignments have given you instructions on how to access the spreadsheet. You will have comment-only access to this document. Hans has done just a fabulous job of structuring this. I have to give him full credit. He has done a really great job. Tricia Lee, if you could make it larger, that would be very helpful so we could get it large enough to actually see. Thank you.

So, as you can see, this is a draft of what will be presented on November 9th to the HITAC meeting. We felt it was very difficult to read all of the comments in the spreadsheet that we had, so Hans and I felt it was important to get it into a Word document to make it much easier to read and to respond to. So, I am just going to go through the beginning part so you can see the structure of the document. Some of this is a template that ONC uses, and so, there is a table of contents that will help with the structure. Keep coming down. And then, what Hans and I have done is put together a background, and in the background, of course, we have our charges. We have had several presentations which this was outlined in. Please feel free to make comments all throughout this area. This is just an overview of what we have done at the different meetings. Keep on coming down.

And then, we get into the recommendation portion. We put an introduction into the recommendation portion, and also, during the discussion, there are some bullet points as to what we have tried to convey on what has happened over the many weeks that we have been meeting. Stop there for a minute. What we have found with the presentations are some really general or overarching similarities in the recommendations, and so, instead of sticking strictly to the topics, we integrated the topics into a much more comprehensive workflow so that we can address especially those recommendations that crossed many of the different topics. As I said before, Hans has really done a great job of putting this together. Watch for the highlighted areas. This is going to be the important piece. Can you stop there and go back up to use cases?

As we had some discussion, we decided to put together some of the use cases that were related to the topics, and as you can see, they are definitely here, and they are all bullet-pointed. I would encourage you to go through those also and make recommendations. If you think the use cases are out of scope or not reflected as to what the taskforce has been trying to accomplish, please make your comments. I think there were instructions. You will not have editing capability. You will have comment-only capability where you can add comments to the side, I believe, and Excel team or Maggie, please correct me if I am wrong. Will they be able to also be in suggesting mode to make comments into this document? We will get that clarified for you, so watch the language in the homework assignments. This is the most important thing that you can do. If you have any questions, please reach out to Maggie, Mike, or Tricia Lee.





So, let's scroll down. These are the different use cases. Go back up. As you can see, we also separated out some of the use cases by topics, not the four topics that we went over, but overarching topics that came out, so we can sort of consolidate the recommendations into those topics so we are not losing the flow of what we are trying to accomplish, so you can see things like incorporating pharmacists into the care team, consumer engagement, data-driven, medication-related, population-level interventions, and so on. Keep coming down if you can. Pooja, I see you have entered some comments in there, so I am glad you are able to do that. Keep coming down.

What is important for us to do today is to really go through the highlighted recommendation areas because we want to make sure we can change these ones that are highlighted to things that we can remove, move forward, and say are our recommendations. As you can see, those recommendations listed below in yellow highlight have not yet been agreed to. They were not yet green in the spreadsheet, so please do not remove the highlight until we have spoken about those particular recommendations.

As you can see, we kept the coding, which is, as you can see here in the first one, Recommendation R3, which has already been reviewed and changed from green, and we did move it in, not in a highlighted area, but this will also help ONC to go back and look at the discussions in relationship to the spreadsheet. Basically, all that we did on the recommendation side of the lists of specific recommendations is to put them into the order that we felt were the category, so this category is general. These were general recommendations that sort of fit across all the different topics that ONC has given us as our charge. So, you can go down now. I think you have a general understanding of where we are at. I am going to stop there for a minute, Tricia Lee, if we can. Are there any questions or comments about the structure of the document? With that, we are going to move on, then.

Let's go down to our first highlighted recommendation area, which is this one, which is Recommendation 27, or R27, from the spreadsheet. This is to "Recommend that ONC identify the obstacles to sharing data between pharmacists, other pharmacists, and other provider treatment, care coordination, and other lawful processes beyond technology and standards, including addressing current contracting practices. Since pharmacies and pharmacists are actors under 21st Century CURES Act information-blocking provisions, ONC should consider how it can use information-blocking authorities to issue regulations or guidance to eliminate unnecessary or unreasonable contractual obstacles when encouraging the adoption of already available technology and standards, further harmonizing the advancing interoperability with and among the various pharmacy settings. ONC should provide additional guidance and identify approaches, including considering focused modular certification programs for pharmacy management systems to drive advancement of standards-based interoperability." I am not going to read the rationale, but it is there. Are there any comments on this one? Pooja, I see you have raised your hand.

Pooja Babbar

Yes. I just wonder about that first line. I do not know if we can address current contracting practices, if that is under ONC's authority. I think the rest makes sense, but I just wonder if we should take out those words. I would suggest we possibly take that out.

Shelly Spiro

Does anybody want to comment on that? I think the intent on this was more in terms of the work that is being done with TEFCA, the Trusted Exchange Framework and Common Agreements.



**Pooja Babbrah**

Oh, got it, okay.

Shelly Spiro

I do not know if you want to take that out again, but I think that was the intent in relationship to health information exchanges.

Steven Eichner

This is Ike. I think if you replace it with something around TEFCA, that would be fine, but saying “current contracting practices” is way too broad because most contracts are really within the state legal framework, not the federal framework.

Shelly Spiro

So, could you just put a comment in there, Tricia Lee? I would not remove the language, sorry. I think we need a comment on it. Could you strike it and put a comment there? Other than that, Ike or Pooja, since you have been commenting, is there anything else we can change in here in order to move from highlighted to another area? Afton, I think you have a comment.

Afton Wagner

Yes. Just looking at the first sentence, “identify the obstacles to sharing data between pharmacists, other pharmacists,” is that supposed to be “pharmacies and other pharmacists” or between pharmacists at the same site and other pharmacists outside that site?

Shelly Spiro

I think the idea of why it was other pharmacists is because sometimes we have a pharmacist in one location that was dealing with a pharmacist in another location.

Afton Wagner

Yes, but I think maybe a clarification... I am just trying to think of how I would word it. I get what you are saying, but when I look at it, it seems like it should be different.

Steven Eichner

This is Ike. If you change the word “between” to “among,” that might solve it.

Shelly Spiro

That sounds good, Tricia Lee.

Afton Wagner

Thanks, Ike. You guys are better at wordsmithing than I am.

Shelly Spiro

Maybe we should say “other pharmacists in different locations.”

David Butler



I got a different impression from this. I think it does need to be clarified, but I think the intent was to show that there are... We talked about the fact that there are pharmacists who are in dispensing roles, and there are pharmacists who are in clinical roles that may involve even prescribing, and so, the intent was to represent the fact that the pharmacist could be among the other providers. So, my suggestion would be to say, as it says "to share information between pharmacists and other providers," I would put in parentheses "including pharmacists," and that would represent the fact that they are among that class of other providers, who may not be in the dispensing role, but may be directing a pharmacist to take this action for a patient.

Shelly Spiro

So, it would be "among pharmacists and other providers (including other pharmacists)." Is that what you are saying?

David Butler

Yes. I would go back to the original text and just move "and pharmacists," the phrase that was there. Can you revert back to the original?

Shelly Spiro

So, it is "among pharmacists..."

David Butler

I would say "between pharmacists" is fine with me. I would take the "other pharmacists" phrase, cut it, and place it right after "other providers" in parentheses, and say "including," and then "other pharmacists."

Tricia Lee Rolle

That helps clarify for me, David.

Shelly Spiro

So, we want to keep "between" and not use "among," is that correct? Okay, outside of the contractual piece, can we turn this from highlighted to non-highlighted?

Steven Eichner

This is like. I have one other piece at the top of Page 12, the third line. "ONC should consider how it uses its regulatory authority," not its "information-blocking authority."

Shelly Spiro

Yes...?

Steven Eichner

Right now, the language says, "should consider how to use its information-blocking authority to issue regulations." It is just its regulatory authority.

Shelly Spiro

How would you like it written? Could you put a comment?

Steven Eichner





I think it should be “ONC should consider using its regulatory authority to issue regulations...”

Shelly Spiro

So, instead of “how,” “should consider using”?

Steven Eichner

In other words, it does not have the authority to block information. ONC has the authority to create regulations, but it is not the actor in blocking information.

Shelly Spiro

Are you following that, Tricia Lee? So, “ONC should consider how it can use its regulatory authority to issue regulations.” Is that fine?

Steven Eichner

Yes, that is great.

Shelly Spiro

Okay. Scott?

Scott Robertson

With that edit, I lost the thing I was looking at. If we are moving “addressing current contracting processes” at the top of that, “including” has to get out of there too as a comment. I thought I saw “contracting” somewhere else, but I cannot find it anywhere, so that is all I have. Actually, just get rid of “unnecessary” from the “or unreasonable contractual.” Just say “eliminate unnecessary obstacles.” Well, “unnecessary” is not really needed, either. Thank you.

Shelly Spiro

Is everybody okay with that? David?

David Butler

Back up in the first sentence, one other thing I see that I think might be missing where we say “for treatment, care coordination, and other lawful purposes,” a practice of pharmacists is to also assess patients, as any practitioner would, so I think where it says “for treatment,” it should begin with the real initiation of your practice, which is for “patient assessment, treatment.”

Shelly Spiro

Scott?

Scott Robertson

Looking at that sentence again now, “beyond technology and standards...” Because of the structure, that looks like somehow, technology and standards is part of “treatment, care coordination, and other lawful purposes.” Could we move “beyond technology and standards” somewhere with “identify the obstacles,” maybe “other than technology and standards”? Does that read any better? It felt backwards to me.

Shelly Spiro





Are we good to go with this one, then? We will leave the strikethrough and put some language in there to make it clearer that contracting will be more related to TEFCA's common agreements. David?

David Butler

I have two things. I like moving up the "beyond technology and standards," but I think it needs to say "including beyond technology and standards."

Shelly Spiro

"Recommend ONC identify obstacles..."

David Butler

"...including those beyond technology and standards." Basically, we need to remove all the obstacles, but that is how I would identify it, if we need that phrase in there.

Shelly Spiro

So, the first sentence in the recommendation is "Recommend ONC identify the obstacles, including..."

David Butler

"...including those beyond technology and standards." So, the phrase "including those" needs to be there in front of "beyond," on the first line of the highlighted paragraph. And then, the second aspect of this is I like the sentence, but I do not see a purpose to the sentence yet as to why we are doing this. It seems to me we need to say something closing off the end of the sentence with the reason we are saying to do this.

Shelly Spiro

Well, I think since pharmacists and pharmacies are actors in 21st Century CURES blocking provisions, ONC should consider how it can use regulatory authority. To me, that is the piece of this that gives the rationale.

David Butler

Is it possible, then, that we could take that last phrase of the sentence, where we say "for patient assessment, treatment, care coordination, and other lawful purposes"? Is there something there we could say about improving the interoperability among healthcare practitioners for patient assessment, treatment, and so forth? So, "for improving..."

Shelly Spiro

I know there is still wordsmithing that needs to be done on this one. I do not want to hold up because we have a lot to go through, so let's keep it yellow. It looks like there is still a lot. Do we want to form a subgroup, or do you just want to go in and start making comments so we can make this changed? I guess we will have to go ahead, meet next week, and try to finish this one. I am going to move us along if that is okay. Let's leave this one the way it is, and we will have to come back to that. So, let's go to Recommendation 37. "Recommend that ONC address a gap where PBMs and payers are not considered covered actors under the 21st Century CURES Act rules, yet have electronic health information that is relevant to pharmacists and other providers." What do we say about this one? Any comments?

Steven Lane





Hans had suggested combining this with the one above.

Shelly Spiro

What do you think about that?

Steven Lane

It seems like juxtaposing them like this makes as much sense. They are a little different.

Shelly Spiro

Pooja?

Pooja Babbrah

I would keep them separate.

Shelly Spiro

I agree with that, Steven. What we see is that especially pharmacists and pharmacies have a very close relationship with their payers, and there is a need for the payers to be involved in receiving and exchanging clinical information as part of care coordination or other aspects, and I would agree with Pooja that they should be separate. They are two different types of recommendations. We are recommending specifically that payers be brought into this, since they are consolidating and using clinical information. Okay, does anybody disagree with that, and can we turn this one from yellow into clear? Okay, let's make that clear, then. As we would use the term from the spreadsheet, changing it to green would be comparable to this.

Steven Lane

Shelly, as you can see, I have added a few minor editorial changes. You might just accept those as we go so that they are done, just what you are seeing there in red, strikethrough, etc.

Shelly Spiro

Does anybody have any problem with that? I think they are fine, so let's...

Steven Lane

People can do that after the fact, but I just think we should agree.

Shelly Spiro

Let's go on to Recommendation 38. This one is "Recommend ONC convene stakeholders, including pharmacists, other providers, patients, mail-order pharmacies, national associations and state boards of pharmacy to address the needs for and approach to sharing data captured with and by direct-to-consumer providers, as they interact with a patient and have the same needs to share data with and from the other care team members for that patient." Pooja?

Pooja Babbrah

I know we call out NABP here, but I think we suggest just using them as examples. Maybe we recommend ONC convene stakeholders, including pharmacists, other providers, patients... I guess mail-order pharmacy is fine to call out, but then we should possibly say "associations" and just put examples, as opposed to calling out NABP specifically, unless anyone felt there was a reason to. I think part of this came





because of the discussion we had about all the state rules, so maybe we should keep them in there, but that is just a suggestion of putting them in as more of an example.

Shelly Spiro

I agree. David?

David Butler

I agree as well. Personally, I would remove the word “mail-order.” I do not know why mail-order pharmacies are unique.

Shelly Spiro

Because the products are mailed. When you go to a direct-to-consumer situation, you are not going to a pharmacy to go pick it up, so you are really not interacting. It is more that the medications are being mailed to you.

David Butler

That is their function, yes, but any pharmacy can home-deliver or mail any prescription, so we have come up with a term “mail-order” to categorize a group that functions that as their sole task, but that doesn’t make them separate from the pharmacy because any pharmacy can do that same thing.

Pooja Babbrah

Should we say “online pharmacy,” David?

David Butler

That is different.

Pooja Babbrah

It is not necessarily mail-order, right?

David Butler

Online is a different beast.

Pooja Babbrah

But I think that is what we are referring to here, so I wonder if we could just edit it to say “online pharmacies” instead of “mail-order.”

Shelly Spiro

Since I wrote this one, I am fine with that.

David Butler

And what, again, would be the reason for having state boards listed?

Shelly Spiro

Because this is an area that they control, so we wanted to get their input because they are the ones that are regulating these DTC operations. Alexis?



**Alexis Snyder**

I think we just need to add “caregivers” after “patients,” or we can even put “patients/caregivers” because sometimes someone else is speaking for them, and we should do that again at the end of the recommendation, where it talks about patients, putting “interact with the patient/caregiver.”

David Butler

To come back to the question about the state board of pharmacy, because this is direct-to-consumer, wouldn't that also affect the prescriber practitioners for those providers and their state boards as well? I am not trying to make this into a great big huge organization to meet on this, but it seems like state boards of health would include state board of medicine.

Shelly Spiro

I do not know if Christian is on, but the way that the state boards are set up, David, is they oversee the prescribing even though it is regulated by the health departments that oversee the medical practices, so you have to still be licensed to prescribe. It is just the way that the state boards are structured, and that really falls under the purview of the state boards.

David Butler

So, the state board of medicine would not have any impact on the prescriber or the physician?

Shelly Spiro

They do within their practice act, but not specifically in terms of prescribing. Alexis?

Alexis Snyder

Oh, I did not lower my hand from before. I am good.

Shelly Spiro

Not a problem. Can we turn this one now to non-highlighted? Okay, let's make that one good to go, including the rationale. Just remember, if you think there is anything that you want to change in the rationale, then go ahead and put your comments in. Our main objective today is to go through the recommendations. I am going to leave this up to you to look at the rationale. Okay, let's go on.

This one, Recommendation 23, is very long. “Recommend that ONC further explore the potential of an interoperable privacy policy and consent infrastructure for helping to assure appropriate sharing of health information consistent with applicable law and patient preferences. In exploring the infrastructure, ONC should collaborate with other appropriate organizations, workgroups, and similar industry efforts (Example: HITAC, HL7, National Interoperability Collaborative, NIC, SHIFT, the Sequoia Project, WEDI, etc.) for this capability. Any such infrastructure should support a broad spectrum of entities or should be engaged in health information exchange to improve individual and population health, including, but not limited to, pharmacies and pharmacists.” Any comments on this one? Alexis?

Alexis Snyder

Where it says “In exploring this infrastructure, ONC should collaborate with other appropriate organizations,” maybe we should put “relevant” instead of “appropriate.”



**Shelly Spiro**

Okay. Does anybody disagree with changing it to “relevant”? Does anyone have any other comments? Okay, can we go ahead and turn this one non-highlighted? Okay, let’s do that, then. Let’s go on to Recommendation 31, that “ONC pharmacy-payer communications, as it advances privacy policy and patient consent directives, management addressing the ability to share medication fill information.” Pooja?

Pooja Babbrah

I am just wondering. I can go back and look, but throughout the document, do we need to call out PBMs? I think we need to be consistent if we are calling out PBMs or health plans. Can we just add a comment that we need to be consistent?

Shelly Spiro

I think we can do that. Okay, are there any other comments on this recommendation? Okay, let’s do that and go to the next recommendation, No. 28. “Recommend that ONC considers inclusion of the more specific prescription data change infrastructure (Example: Change or cancel prescription and fill status) as required interactions for both prescriber and pharmacies, the USCDI and ONC’s certification program. Consideration should be given to appropriate to inclusion of patient and caregiver for relevant notification and awareness.” David? David is not answering.

David Butler

Sorry, trying to think through the whole process is too intense here. I apologize, but I actually want to jump back to that last conversation we had on the previous one. When I was first thinking about it, I thought the idea of changing it from “payer” to “PBM” was fine, but it occurred to me that it is a growing area where pharmacies are dispensing more medical devices. It may not be through the PBM, and there are a number of pharmacies that are DME providers as well, and I do not know if they are regulated under that, but there is much more interaction now, and it may increase as we see this practice change in the advancing therapeutics, that the payer is an important part. So, maybe we should say both or leave it as “payer.” And, of course, we see the aggregation now of payer and PBM into one company, so I just think that might need a little bit more thought about which one to make it.

Pooja Babbrah

I would prefer that we say “health plan” and “payer.” I think that would help distinguish them, because I agree that it needs to be both. That way, you can distinguish the two.

Shelly Spiro

Any other spots on Recommendation 31? We will work on some language to make that clearer. Okay, going back to No. 28, can we go ahead and make this one non-highlighted? Okay, let’s move on to Recommendation 29. “Recommend that ONC explores the need and awareness for standards-based secure instant messaging capabilities in addition to the current messaging capabilities that use direct messaging and a variety of message paradigms through HL7 V.2, HL7 FHIR, and NCPDP Script.” Any comments? Can we change this one? Pooja, go ahead.

Pooja Babbrah

Actually, I am good with this one. Never mind.



**Shelly Spiro**

Okay. Anybody else? Let's go ahead and change that. Let's go to Recommendation 30. "Recommend that ONC event notification capabilities with pharmacies and pharmacists as part of a focused modular certification approach. Any comments on this one? Okay, can we go ahead and change this to non-highlighted? Okay, let's go on. Recommendation No. 32 is "Recommend that ONC and CMS convene an industry group, including pharmacies and pharmacists and relevant standards organizations, to identify an approach to making data available to ordering providers and patients regarding where they can fill that prescription the earliest." Any comments? David?

David Butler

This reminded me of a conversation we had in the previous meeting with Hans. We were trying to come up with something for when we use the word "pharmacy" in the second line of the highlight, and I was pressing the idea of "pharmacist" being separate from "pharmacy," but we needed something for "pharmacy," and the thought of putting in "pharmacy corporation" as a term was a little too specific. Hans asked me to go back and look for another term, and I came up with one that I thought might work here, and I apologize for not putting it in, but it is a long story. Could it be "pharmacy enterprises"? If you look up the term in OECD, "enterprises" represents organizations, corporations, projects, and every possible way an organization would meet. You could note that as "enterprises as designated by OECD."

Shelly Spiro

Afton?

Afton Wagner

Isn't this one very similar to the one that Christian, Alexis, Anna, and I worked on a couple weeks ago in that small, separate group? I cannot find it right now, but it is in the previous... I see Alexis's hand is raised. Alexis, did you think the same thing, or do you think this is different?

Alexis Snyder

No, I think this is the same thing. I think that we literally did work on 32, and this is the same recommendation, and it is completely rewritten. My comment was also that the convening group was not just an industry group, but included patients and caregivers as well.

Shelly Spiro

I am going to take "industry" out and come up with just "group"?

Tricia Lee Rolle

Sorry, I just want to make sure I capture David's suggestion. "Pharmacy enterprises as designated by" who?

Shelly Spiro

David?

David Butler

Could you say that again?



**Shelly Spiro**

Look at the bubble in the comment that she has highlighted.

Tricia Lee Rolle

Instead of “pharmacies,” you want “pharmacy enterprises as designated by” who?

David Butler

Just say “pharmacy enterprises.” Put a quote after “pharmacy enterprises.” I am wanting to use “pharmacy enterprises.” You can leave that. I want to leave that. Sorry, I did not mean to make you take that out. Here is the sentence I would put in.

Shelly Spiro

She wants the acronym. What is the acronym of the organization?

David Butler

Oh, it is OECD, Office of Economic...oh no, I have forgotten.

Shelly Spiro

Okay, we can look up the name of that.

David Butler

I will do that.

Tricia Lee Rolle

Thank you. Sorry to interrupt. I know Alexis and Afton were talking.

Shelly Spiro

I do not remember. Alexis or Afton, what do you want to change this to?

Afton Wagner

I was just thinking this is very similar to what we already have written. Do we need to have another one that has the same goals?

Alexis Snyder

I think it is that one. I think it has been changed. That is what I was saying, Afton.

Afton Wagner

I had thought it was already a separate one.

Alexis Snyder

I do not think what we have is going to show up somewhere else. I think it was 32.

Afton Wagner

Okay.



**Alexis Snyder**

I could be wrong, but that is what I was thinking.

Shelly Spiro

I am pretty sure that it was. That is what we tried to get to to talk about what we had talked about, of making information at the time of prescribing.

Alexis Snyder

I do not think it captures everything we were trying to capture before. I would have to pull it up and look at it, and I can make comments once we get our homework to go into the document and comment, but I think there is a lot missing, and the emphasis is not the same.

Shelly Spiro

Do we want to leave this one highlighted, then? Is that your recommendation?

Alexis Snyder

Yes, and patients and caregivers are missing from the convening group. It is not just an industry group.

Shelly Spiro

Yes. We need to look at the language on industry, so could you make some changes into that as your recommendation?

Alexis Snyder

Yes.

Shelly Spiro

Okay, we will leave No. 32 highlighted. Those who are interested in this one should go back and make sure we have captured everything in this one. Let's go down to emerging therapies. I am just trying to watch the clock. Mike, I am sort of multitasking here, so can you help me make sure we do not miss our public comment? Just chime in when it is time. Okay, Recommendation 36. "Recommend that ONC work with laboratories, device manufacturers, National Library of Medicine, LOINC, and SNOMED to address the mapping of pharmacogenomic lab testing and values from the device to industry standards encoding used in the test reporting akin to LVD, mapping initiatives under FDA SHIELD, and general laboratory beat testing. Additionally, alignment should be pursued to common terminology to relevant gene therapies that should be indicated based on the test results." Thank you. It is getting kind of small for me for some reason. Any changes in this one, or can we change this one from highlighted to non-highlighted? Okay, I am not hearing or seeing any comments. Oh, Scott?

Scott Robertson

Thank you, Shelly. Well, we do it in so many other places, but there are genomics groups that all just flew out of my head that are not exactly standards organizations, but close to them, so, should we include NLM, LOINC, SNOMED, and industry organizations or something?

Shelly Spiro



Are you thinking of the compendiums?

Scott Robertson

No, I am thinking of... Oh, I have been to their meetings, too.

Shelly Spiro

Are you talking about CPIC?

Scott Robertson

What is it? It is a big umbrella organization that is coordinating information exchange between all kinds of genomics projects. It is not just the laboratories and the device manufacturers. You want those organizations that laboratories and device manufacturers participate in so that they have common messaging, and they need to be included as well. That is all I am saying. What has just been added is fine.

Shelly Spiro

Okay. Any other comments? Can we go ahead and turn this one into non-highlighted? Okay, let's go on, then. Okay, we are at Recommendation 35. "Recommend that ONC include different pharmacy settings (Example: Specialty pharmacies and clinical pharmacy vendor systems) in any requirements related to certification of pharmacy vendor systems. ONC should ensure that these vendor types are called out specifically in any potential regulation." Any comments on this one? David?

David Butler

I have a question here. So, if I am a pharmacist who is rounding in a hospital with a physician on the surgery team, am I included in this, or is that under some other...? If that is all I do, and I do not spend time in the pharmacy for the institution, but my role is to do the pharmacokinetic calculations, assess the patient for adverse events, look for drug interactions, and things like that...

Shelly Spiro

I think that is the clinical pharmacy vendors, your clinical documentation systems.

David Butler

Okay, thanks.

Shelly Spiro

Pooja?

Pooja Babbrah

I was just going to say that. I think this refers to the actual vendors, not the pharmacists.

Shelly Spiro

Right, because that is where certification lies. Certification lies with the vendors. Okay, can we go ahead and change this from highlighted to non-highlighted? Okay, let's move on. We are getting there. This one is Recommendation 33. "Recommend ONC work with CMS to establish quality measures as part of a performance program aligned with an ONC-defined certification approach focusing on measures that advance the adoption of interoperability. Example measures for consideration would be 1). How many times





a patient needed to call a pharmacy and how many people they needed to speak with, 2). How much time patients spent communicating with pharmacies and payers for a provider to coordinate care, 3). How many bidirectional interactions were involved to finalize a prescription (See Recommendation 28, for example), or 4). Reducing the time from writing prescriptions to being filled for a patient.” Alexis?

Alexis Snyder

No. 4 would not be a measure, that would be an outcome, not reducing, but measuring the time it takes, which I think is already there in one of the previous ones.

Shelly Spiro

So, you want to change No. 4, which is the second-to-last line. Tricia Lee, you would change “reducing” to...?

Alexis Snyder

You are not reducing the measuring, you are reducing the time it takes.

Shelly Spiro

So, “measuring” instead of “reducing.” Thank you, Alexis. David?

David Butler

This seems to be directed toward operational performance, not so much their performance or outcomes performance. If we are going to have quality measures as part of a performance program, it ought to include healthcare quality and health outcomes performance as well.

Shelly Spiro

No, this is not total. This is for certification approaches.

David Butler

Yes, but it seems to be certifying only operational things. Items 1 through 4 are very operational. There is nothing about also reporting on adverse events prevented, interactions detected, therapeutic dosing changes, number of interactions with the physician... None of that is included in this.

Shelly Spiro

Well, I do not think example measures... These are examples, so if we want to write another example, No. 5, then maybe that is what we put in. Do you want to come up with some language for that, David?

David Butler

All right.

Shelly Spiro

Tricia Lee, put a comment in there that David Butler will add an example.

David Butler

Because I am taking it in a different direction from what is in there, I hope someone will speak up if they think what I am talking about adding does not seem appropriate.



**Shelly Spiro**

I am not hearing anything. Can we go ahead and change this one? We will address the comment, and David, you will add another.

David Butler

Okay.

Shelly Spiro

Can we go ahead and change this one from highlighted to non-highlighted? You missed one on the bottom there, Tricia Lee. Okay, let's go on. These are our parking lot considerations, and I think it is important that we go through them. We have had some topics that we felt were not quite in scope, and that is what this section was for. I will go ahead and read it. "Interaction with usability of technologies by users yield concerns whether more can or should be done to improve on consistent use of interactions, such as technologies and users use multiple different technologies. Some of the variations can lead to user errors that turn into impact patient safety, while others lead to inconsistent data across providers that challenge analytics. ONC HIT certification program includes criteria on the use of appropriate design guidelines in the development process." There is the link to 170.315 in the certification program.

"Safety-enhanced design and consumer-focused portals," another link to the certification, view, download, and transmit to third party. "The taskforce suggestions that ONC and HITAC should further explore opportunities to align health IT in terms of common terminologies, surveys, questions, and assessments that can further advance consistency and data quality, particularly across pharmacists and other providers, while maintaining flexibility to advance new and alternative approaches." Any comments on this one? Scott?

Scott Robertson

That first sentence seems very convoluted. I do not know if I can wordsmith it adequately on the fly, so I am just wondering... Actually, it may just be better if the last part of that sentence... Here, I will just put it as a suggestion so you can see what I am thinking about. If that was removed... That seems to be redundant, added on, and does not really improve the sentence.

Shelly Spiro

Pooja?

Pooja Babbrah

Is the question whether we want to make this recommendation? Is that the question that we are posing? I do feel like it is out of the scope of the charge, but I would rely on Steven and others that may have been on these kinds of taskforces in the past. What is your recommendation? Do we still add this in, even though we feel that it was out of scope? I am just curious to hear from others.

Shelly Spiro

Well, that was one reason why we had a parking lot section. We believe that this fell out of scope of our charges, and we wanted to bring it to the HITAC for further discussion and exploration.

Steven Lane



There is the option to refer items that are out of scope for a taskforce to the annual report workgroup for them to consider because that is really where things get captured that need to be followed up on, perhaps in other taskforces, so that is one consideration.

Shelly Spiro

Does anybody have any other comments? Should we go ahead and change this one from yellow to clear, with a little bit of wordsmithing? Okay, let's go ahead and change that to clear. Where are we at now in the document? I think we have gotten through all the recommendations. We did a good job. So, let's go back up, since we do have another 10 minutes. Let's see if we can at least get some more discussion in the last 12 minutes, especially on this one here. I know we had a lot of discussion on this. "Recommend that ONC identify the obstacles, including beyond technology and standards, to sharing data between pharmacists and other providers, including other pharmacists, to patient assessment, treatment, care coordination, other lawful purposes, and so on." Can we clean this up a little bit to get it to non-highlighted?

Steven Eichner

This is Ike. We know they are kind of fundamental. Do we want ONC just to identify, or do we want them to do something about it?

Shelly Spiro

That is a good point. Does anybody want to comment on that?

David Butler

I am in agreement with Ike. It should be stronger, maybe "identify and remove the obstacles."

Shelly Spiro

What do people think about that?

Steven Lane

Yes.

Shelly Spiro

Okay. Pooja?

Pooja Babbrah

We do kind of say that below, though. In the second sentence, we say ONC should consider how it can use its regulatory authority to address issues, so maybe we can just consolidate it a little bit so it is just not as long of a sentence. Maybe we should just have some editing. I am wondering if we can eliminate that second sentence if we put that up above.

Shelly Spiro

Okay, so, you are saying since pharmacies... Maybe that is rationale. Is that what you are saying?

Pooja Babbrah





Yes, “since pharmacies and pharmacists,” starting there, and then we say, “ONC should consider how it can use its regulatory authority to issue regulations and/or guidance to eliminate obstacles.” If we are saying it above, I just think it may be redundant, but there may just be some editing we can do.

Steven Eichner

This is Ike. Should patients be included in that list as well?

Shelly Spiro

So, do you want to add “patient/caregiver” to “sharing data between pharmacists, other providers, including other pharmacies”?

Steven Eichner

Right, because right now, it is focused exclusively on healthcare professionals. There is no **[audio cuts out]** **[01:09:34]** to patients.

Shelly Spiro

So, after the parentheses, you would want another comma, and then you would have a comma above where it says “and”? So, put a comma there, and then get rid of the “and.” “Other providers, including other pharmacists, and...”

Steven Lane

No, they did not include that.

Shelly Spiro

“...and patients/caregivers” or “patient assessment, treatment, care coordination, and other lawful purposes”? Are we okay with that, Ike?

Steven Eichner

I think we also might want to insert the word “monitoring” so it says “patient monitoring assessment.”

Shelly Spiro

Well, pharmacists do assess, so...

Steven Eichner

I am not taking it away. I am adding the word “monitor.”

Shelly Spiro

“Patient assessment, treatment, monitor care coordination...” Okay, there you go.

Steven Eichner

Right. So, that pharmacy asks me if I have taken my blood pressure medicine. That would be a monitor, in my mind.

Shelly Spiro

That is fine. David?



**David Butler**

I was just going to agree. I think Pooja said this as far as taking that second sentence and combining it with the first. That eliminates my concern about the first not having an action to it.

Shelly Spiro

So, do we want to take out “then” and “address”?

David Butler

I do not know. I am just saying if there is a way to combine the two, that might make it even stronger.

Shelly Spiro

It just makes it a longer thing. I am not quite sure how to fix it.

David Butler

Maybe since it is literally the second sentence, maybe it should just be a lead-in in the second sentence to tie the two together, saying “furthermore, ONC should consider” or “in addition, ONC should consider,” and opening the second sentence that way.

Shelly Spiro

So, the fourth line from the page you are on, Page 12, would have “furthermore” before “ONC,” right?

David Butler

Yes.

Shelly Spiro

Is that what you had in mind? Does that work for everyone? Can we go ahead and change this one now?

Tricia Lee Rolle

I have a quick question. Were you suggesting that this be added to the end of the first sentence? Were you making a comment on that, or do you actually want it moved?

Pooja Babbrah

Tricia Lee, I wonder if we should keep that, but as part of the rationale. It might make it a little bit cleaner.

Shelly Spiro

Maybe it should be in the first line of the rationale.

Pooja Babbrah

Yes.

Shelly Spiro

So, let’s go down to the rationale. That gets copied into the first sentence of the rationale, and then “several,” but you have to get rid of the strikethrough. You guys are so good.



**Tricia Lee Rolle**

We will still need to wordsmith this because the two do not really go together. They can go in the rationale, but we will still need to wordsmith it.

Shelly Spiro

Okay. Can you put a note on that to include that strikethrough somewhere in the rationale? Does anybody want to take a crack at that, or would you like Hans and me to do that? I am not seeing any hands go up. So, are we at a point now where we can turn this to non-highlighted? It looks like we can make this non-highlighted. So, we have four minutes left. Do we have one more highlighted area that we did not quite finish, or did we get them all? That would be so awesome. Oh, we have to work on 32. So, we have four minutes. Let's see if we can get this one done. "Recommend ONC and CMS convene an industry group..." Maybe we should say "stakeholder group" instead of "industry." Would that work in the first line of Recommendation 32? I know that was one of the concerns. So, change "industry" to "stakeholder," or get rid of "industry group" and just put "stakeholders."

David Butler

I like "stakeholders."

Shelly Spiro

You do not need the "and." It can be "convene a stakeholder group, including primary...relevant organizations to identify an approach to making available ordering providers." Can we change "ordering providers" to "prescribers"? Is that clearer, or do we want to keep "ordering providers"?

David Butler

Either one sounds fine.

Shelly Spiro

Okay, and I think we are using "patients/caregivers." Is that right, Alexis? I think that is appropriate. Get rid of the "and" and put a slash between "patients" and "caregivers," "regarding where they can fill their prescriptions the earliest." Can we go ahead? Are there any other comments on this one? Can we go ahead and change this from...? David?

David Butler

Sorry, I am a dog with a bone here. This seems very specific. If it is just talking about filling their prescriptions the earliest, are we dealing with refills? Is it strictly the earliest? Do we want to deal with what is safest? There seem to be a lot of questions that come to my mind with this, and things that ought to be considered.

Shelly Spiro

If you look at the rationale, David, I think it might help. Afton?

Afton Wagner

I cannot speak for Anna since she is not on, but I believe this came up when she was trying to get prescriptions filled, and it just took a very long time to find a pharmacy that would be able to fill them, and they just wanted to find out at the point of prescribing where they can go and get their prescription filled





immediately, if there are any issues with ordering, or anything like that, so I think that is where it stemmed from.

David Butler

I remember that conversation and her saying that, and I think she is absolutely right. That needs to be improved. I just do not want the safety to be dropped out.

Afton Wagner

Yes.

Steven Lane

There are clearly a lot of dimensions. There is convenience, there is safety, there is cost, and so many other things, but as I read through this, it seems to focus on my question of the urgency and the time factor. If we add everything else and pile onto this, we may lose the point here.

Shelly Spiro

Scott? You have one minute, by the way.

Scott Robertson

Okay. I did change “fill their prescriptions” to “fill urgent prescriptions,” and I wonder if we should just take out the “earliest.” If this is really meant for urgent prescriptions, focusing on the earliest is focusing on time, but as people are pointing out, we still need to have safe, soon, and close.

Shelly Spiro

Scott, I am going to stop you for a minute so we can go right into public comment, and we will come back to this before we close everything down. Go ahead, Mike.

Public Comment (01:19:24)

Michael Berry

All right, thanks, 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. Let’s pause for a moment to see if any members of the public would like to make a comment. I am not seeing any hands raised at the time, Shelly, so I will turn it back to you to finish us out.

Shelly Spiro

Okay, let’s go back to the spreadsheet. I apologize, Scott, for cutting you off.

Scott Robertson

I have changed the end of the recommendation to just be where they can fill urgent prescriptions. Do not focus on time with “earliest” because, as others have said, maybe one can be available the earliest, but you have to drive 15 miles to get there. So, location is important, as is safety. If a patient will not go to a particular pharmacy, it does not help. But where can they fill their urgent prescriptions?



**Shelly Spiro**

Well, I think a lot of the conversation was especially in relationship to high-risk medications that are being kept by a specialty pharmacy. They might not have the right dose. I am trying to channel Alexis and Anna, and neither are on the call, but they end up being the coordinator of where to obtain the medications. David?

David Butler

I have a way to possibly help with that. Could we end the sentence with the phrase “to optimize patient care”? So, they can fill their urgent prescriptions where they can fill their urgent prescriptions in a manner that optimizes patient care. Because then, we are considering the patient, and that is to be the focus.

Shelly Spiro

I think it is more that they get their prescription, they meet with their physician, and they want to know ahead of time. This is what we believe and why we want to convene a stakeholder group, so that there can be an electronic way to assure that that pharmacy has the inventory that is needed and they are not going around trying to search for it themselves. That was at least what I heard from the conversation. Does anybody else have any other comments? David, are you recommending adding “for care coordination” or “for safety”?

David Butler

I would say “where they can fill urgent prescriptions in a manner that optimizes patient care and convenience.”

Shelly Spiro

Can you make that red so we bring attention to it? What do people think about this? Can we go ahead and change this from highlighted and let you guys make comments as you need it? We have some red areas in there for people to go back and make their comments. Okay, I think we have gotten through all the recommendations. Tricia Lee, is that right? Is there anything else highlighted?

Fillipe Southerland

Shelly, this is Fil. I did add a couple of proposed cross-references to the HITAC HTI-1 recommendations. I added those late as suggestions.

Shelly Spiro

To which recommendation was that? Was it higher up?

Fillipe Southerland

Let's see here. One was to Recommendation 24.

Shelly Spiro

Can we go to Recommendation 24? They are not in order. Do you remember what page it was on, Fil?

Fillipe Southerland

Let's see here. Page 19.

Shelly Spiro



Okay, that is helpful, thank you. Fil says, “Can we consider...?” I cannot read that, sorry. It is too small for me. “Can we consider cross-reference to the HTI-1 PR taskforce?” What do folks think about that?

Fillipe Southerland

Just for context here, these recommendations are around creating a specialty EHR framework, so the intent here would just be to have ONC consider the pharmacy framework in relation to the overall specialty EHR framework, and also, the same with the incentive structures, making sure we are building incentive structures in alignment with CMS.

Shelly Spiro

Okay. Pooja, did you have a comment?

Pooja Babbar

Yes. I just want to make sure I understand what you are referring to here, Fil. Is this referring to the recommendations that the taskforce made to HITAC? Is that what you are referring to?

Fillipe Southerland

Right. So, these recommendations were from the HITAC HTI-1 taskforce to ONC.

Pooja Babbar

I think that is great, then, because those recommendations have already been made, and this is just bringing in pharmacy, so I think it is a good idea to have that.

Shelly Spiro

We have it in the comments. David?

David Butler

I just have a quick question on that. When you say “specialty practice,” could you give examples of a couple of the specialty practices this would be grouped with?

Fillipe Southerland

Sure. Other specialty EHR settings would be behavioral health, long-term post-acute care...

Shelly Spiro

Rehab, hospice...

Fillipe Southerland

Community services, community supports... We certainly need to have specialized pharmacy consideration, but we do not want to do something that is only specific to pharmacy, not considering this broader framework of other specialty settings. I think we have run into issues in the past where we want to make sure that this interfaces well with overall certification requirements and the interface with CMS.

Shelly Spiro

Right, and one thing that NCPDP did for pharmacy is reviewed the certification criteria and pulled out the areas that pharmacists’ clinical documentation systems, like EHR, would be able to focus on for that





specialty certification, and I know “specialty” is confusing to pharmacy because we have specialty pharmacy as a practice site. We are not talking about that. We are talking about other practice settings that do not quite fit into more of the enterprise EHR systems that we see for physicians and hospitals. Is that correct, Fil?

Fillipe Southerland

That is correct.

Task Force Work Planning (01:28:34)

Shelly Spiro

Okay. We have one minute left. Great work, everyone. I just want to draw your attention also to the references section of each of the comments. If you go down to those references, Hans has come back to give you an idea where it ties what we talked about back into our topic areas and what use cases it applies to. Keep that in mind as you are reviewing these comments because we want to make sure we are meeting the charges for ONC. We are at the top of the hour. Can we go to our last slide? Just as a reminder, so far, we will be meeting next week until Hans and I can meet with the ONC team to make sure we are at where we are, just to finalize the document. Maybe it will be a short meeting. We will go over some of the comments that you will be making into this document. And then, of course, tomorrow, there is the HITAC meeting, and I believe we have to have everything done by the end of the next meeting to make sure we are ready to give a final draft document to ONC for the November 9th HITAC meeting. We are a minute over. I apologize to Mike and others, but we will go ahead and adjourn. Great work, everyone. Thank you for all your help.

Michael Berry

Thank you.

Adjourn (01:30:15)

