Health Information Technology Advisory Committee

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Virtual Meeting

Meeting Notes | October 4, 2023, 10:30 AM – 12 PM ET

Executive Summary

The goal of the Pharmacy Interoperability and Emerging Therapeutics Task Force (PhIET) meeting on October 4 was to continue review of final recommendation draft wording and structure and introduce Topic 4: Direct to Consumer Prescriptions Services. A robust discussion followed.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	Opening Remarks and Introduction to Topic 4
10:40 AM	Discussion: Topic 4: Direct to Consumer Prescription Services
11:00 AM	Topics 1, 2 and 3: Review of Recommendations
11:50 AM	Public Comment
11:55 AM	Task Force Work Planning
12:00 PM	Adjourn

Call to Order

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:30 AM.

Roll Call

Members in Attendance

Hans Buitendijk, Oracle Health, Co-Chair
Shelly Spiro, Pharmacy Health Information Technology Collaborative, Co-Chair
Pooja Babbrah, Point-of-Care Partners
Shila Blend, North Dakota Health Information Network
David Butler, Curatro, LLC
Steven Eichner, Texas Department of State Health Services
Rajesh Godavarthi, MCG Health, part of the Hearst Health Network
Jim Jirjis, Centers for Disease Control and Prevention
Summerpal (Summer) Kahlon, Rocket Health Care
Steven Lane, Health Gorilla
Ketan Mehta, Micro Merchant Systems
Deven McGraw, Invitae Corporation
Justin Neal, Noble Health Services
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Scott Robertson, Bear Health Tech Consulting

Christian Tadrus, Community Pharmacy Owner
Sheryl Turney, Elevance Health
Afton Wagner, Walgreens

Members Not in Attendance

Chris Blackley, Prescryptive
Meg Marshall, Department of Veterans Health Affairs
Anna McCollister, Individual
Naresh Sundar Rajan, CyncHealth
Alexis Snyder, Individual
Fillipe (Fil) Southerland, Yardi Systems, Inc.

ONC Staff

Mike Berry, Designated Federal Officer, ONC
Tricia Lee Rolle, ONC

Key Points of Discussion

Opening Remarks and Introduction to Topic 4

PhIET Task Force Co-Chairs, Hans Buitendijk and Shelly Spiro, welcomed the Task Force and reviewed the Meeting Agenda. Shelly noted that they have been unable to secure a presenter on this topic and asked Tricia Lee Rolle to explain why ONC added Topic 4 to PhIET discussions. Tricia gave an overview of Topic 4: Direct to Consumer Prescription Services noting the types of medications commonly prescribed in this manner. She said that there are many online companies providing this service and informed the group that ONC is interested in hearing recommendations around these services because it is new. She added that ONC is interested in the connectivity of traditional healthcare channels and these emerging online only medical services. She requested the task force focus on technical considerations.

Discussion: Topic 4 Direct to Consumer Prescription Services

- Pooja Babbrah suggested making recommendations centered around standardizing the prescribing process with these direct to consumer websites and mobile applications. She asked how they can make sure that those online pharmacies are connected like traditional pharmacies.
- David Butler opined that this topic does not need a technical solution but should be handled from a patient regulatory perspective. He added that the technology becomes irrelevant if the patient is benefiting from the service. He said this is not a technology based discussion but one of practice and care.
- Steven Lane agreed with David and added that direct to consumer prescription services should be held to the same standards as any other provider. He said that the task force should work to ensure that these systems, programs, and vendors have access to necessary clinical care to inform the care and services they provide. He added that regardless of being “direct to consumer”, the patients care team needs to be able to see their dispensing history as with any traditional pharmacy.
- Sheryl Turney agreed with David and Steven and added that, from a clinical and payer perspective, medication reconciliation is important. She added that they do not have access to that information because they do not go through insurance. She noted that it is important they adhere to the same standards as other providers.

- Scott Robertson noted that the business model for these direct to consumer prescribers have a disincentive to participate in information sharing as they market themselves as healthcare services that a patient can receive without anyone knowing. He noted that if they followed standard practice and provided that information back to a patients care team then the primary care provider would know. He said he was unsure if there was any way around that.
- Shelly asked Christian Tadrus to clarify his comment in the chat.
    - Christian noted that ultimately it is the states that have the final say on prescriptive authority. He gave some information on the legality of prescribing and script standards and noted that they can help inform their recommendations. He opined that this is a regulatory conversation, from a state statutory perspective.
    - Shelly followed by asking how prescribers get licensed for online prescribing and if it is the same process for mail order pharmacies.
        - Christian answered that the mail order pharmacies have licenses issued from the states they are shipping into. The licensing requirements vary across state lines. He added that the validation of prescriptions will also vary across state lines and will trend toward the Medical Practice Act. The routing of those prescriptions is guided by Electronic Health Record (EHR).
        - Shelly followed up asking if any of the United States use e-prescribing as some of the state's mandate it.
        - Christian said they are currently in transition. He said that the mandates have begun to take rule but many pharmacies are not yet equipped to do so. He noted that in Missouri many physicians still have not adopted EHR. He said that cash pharmacies are becoming increasingly popular and noted that there is no incentive to adopt EHR. He said the problem is it is not 100% mandatory.
- Pooja said Christian's comments need to be considered and that it may be too soon for recommendation in this space. She asked if Amazon pharmacy would be included under this umbrella.
- Scott said that these prescribers are providers and need to comply with federal and state regulations. He added that these entities should be required to share their information unless the patient does not want their information shared. He reiterated that this would be a state regulatory concern.
- Hans summarized what he thought the group was saying. He noted that there should be some clear documentation of consent to share information by the patient. Beyond that, he does not see what more ONC can recommend.
- Shelly asked Tricia if the ONC has identified a legitimate space for direct to consumer prescribers.
    - Tricia said they would generally fall under the umbrella of "telehealth." However, there are some unique aspects to the direct to consumer environment they are looking to identify. She added that this is the ONC's first venture in researching the workflow of this patient-provider relationship and gave some examples of the types of interactions that take place in that relationship. She noted that these providers may also order laboratory work for a patient.
    - Shelly asked for confirmation they are considered "telehealth."
    - Tricia confirmed.
- Shelly asked for any additional questions or concerns. There were none.

Topic 1, 2 and 3: Review of Recommendations

Hans noted that Anna McCollister and Alexis Snyder were not present and said that time needs to be set aside during next week's meeting to discuss their recommendations. He instructed the group to refrain from working in the cells in column E and column F during active discussion and editing to avoid the technical

difficulties raised last week. He said if anyone had they should write it, say it, or note it in an empty column to transfer over afterward.

He said the comments in column D were now fully indexed for Topic 1 and gave an overview of the progress draft review. He asked if there were any questions or concerns.

Recommendation 3 (R3)

- Hans noted that discussions on R3 did begin but clarity was needed and noted that Scott Robertson and Afton Wagner were set to review it.
    - Scott noted that he had a recommendation he was putting it in column G, same row as R3. He continued to say that he could not see what he pasted into column G
    - Hans located it and asked Scott to highlight his changes so they can compare the differences and asked continued to the next recommendation.

Recommendation 11 (R11)

- Hans asked the group to refrain from resizing the columns in the spreadsheet. He reviewed changes made by Christian, Anna, Afton, and Alexis. He asked if there were any concerns.
    - Steven Eichner asked how priority of distribution can be accounted for.
    - Hans questioned if that was a question for this recommendation or if it is more aligned with reallocations.
    - Steven Eichner said it is related because it concerns availability. He noted some issues that arose during COVID-19 and asked who is determining what is available.
    - Shelly said she understood he was referencing and noted that it was a unique situation. She added that most medications go through a wholesaler.
    - Steven Eichner said that a basic charge of the task force comes from public health emergency and he wants to make sure there is a framework in place that would support an emergency should another arise.
    - Shelly said that the US government would have to decide on reallocation. She added that there is a chain of custody that is specific to the medication type, i.e., appropriate refrigeration so that allocation need to a policy process.
    - Steven Eichner said that public health emergency processes should be considered.
    - Hans asked if that was necessary for this recommendation or in light of it and suggested where it could be addressed.
    - Shelly said it is a separate recommendation because it would not fall under normal processes. She said reallocation is a different process.
    - Steven Eichner said it fits here because of availability. He said it may be different but it is related.
    - Shelly said adding it to this recommendation would confuse it.
    - Hans asked Shelly and Steven Eichner to draft a separate recommendation.
    - Shelly asked those who worked on this recommendation for their opinions.

- Afton agreed that it should be a separate recommendation based on the current rationale. She volunteered to help refine it.
- Shelly clarified that the intent of R11 would be lost if they tried to fit this into it as well.
- Hans summarized what was just discussed and asked if that was correct.
- Shelly said yes.
- Hans asked Steven Eichner if he agreed with that.
- Steven Eichner agreed.
- Hans said he will not change this recommendation to green yet but will note it as “ok” and asked for any additional thoughts.
- David Butler said that “pharmacist” is not noted in the recommendation.
- Shelly said they noted “pharmacist” and not “pharmacy” because the recommendation relates to inventory and the pharmacy is the entity that controls that not the “pharmacist.”
- David said that it is the pharmacist who has authority in this situation not the pharmacy.
- Shelly said she understood his point and noted that they had previously discussed the difference between “pharmacy” and “pharmacist.”
- Hans said that adding “pharmacist” would ensure all perspectives are included.
- Shelly agreed.
- Christian agreed that it would be a good addition. He added that this scenario is nuanced and noted that inventory is not just an automated system response but includes a human response confirming that things are or aren’t in stock. He also noted that Cathy Graft identified a typo.
- Hans asked where it was.
- Christian said it was in the first sentence of the rationale.
- Hans said they would fix it and added that he is waiting for Alexis to review it as well.
- Shelly suggested marking the sentence that needs to be fixed in red and said that it is too long.
- Hans agreed it is too long.

Recommendation 12 (R12)

- Hans reviewed the recommendation and asked if it can be turned green.
  - Pooja suggested adding “available in real time.”
  - Hans asked David if that was acceptable.
  - David agreed.
  - Hans turned the recommendation green and said it was done.

Recommendation (R6)

- Hans asked Christian if he was able to review and edit.
  - Christian asked for some extra time to do so and gave a general description of what he was looking to add to the recommendation.
  - Hans asked him to note those suggestions in the recommendation so that others can review and discuss them next week.
  - Christian agreed.

Recommendation 15 (R15)

- Hans reviewed the recommendation and asked for any questions or concerns. There were no comments so he changed it to green.

Recommendation 16 (R16)

- Hans reviewed the recommendation and asked for any questions or concerns. There were no comments so he changed it to green.

Recommendation 17 (R17)

- Hans reviewed the recommendation and noted that it still needs some editing. He added that they will review it again next week.
- Shelly asked if Health Information Technology (HIT) suppliers are vendors.
- Hans said the terms are used interchangeably and added that they will review this recommendation next week.

Recommendation 18 (R18)

- Hans reviewed the recommendation and asked for comments.
    - David suggested removing everything after the word “process” in the third line down.
    - Hans asked if there were any objections. There were none so he changed it. He then suggested adding another term to be on par with pharmacists.
    - Jim Jirjis suggested “provider.”
    - David asked if it is possible that it is referring to clinical data registries.
    - Hans said he could add that if it made sense.
    - Shelly agreed.
    - Steven Eichner said he was unsure what clinical data is expected from public health.
    - Hans asked if he wanted it to explicitly mention Immunization Information System (IIS) instead of “clinical data.”
    - Steven Eichner reiterated he was unsure was additional data would be expected from a clinical public health perspective.
    - Hans asked David and Jim if they agreed with that.
    - David said he was looking at it from the view of adverse drug effects monitoring and such.
    - Jim said it was too specific and suggested something broader and using IIS as an example. He added that there may be additional relevant data sets in the future.
    - David agreed.
    - Steven Eichner said he is not trying to be limiting.
    - Jim agreed with making it general and referencing IIS.
    - Hans asked Steven Eichner if he agreed.
    - Steven Eichner agreed.
    - Shelly read Christians comment that HIV reporting is mandatory in some states and pharmacists are doing prep and test to treat.
    - Christian said it was captured in the recommendation.
    - Hans asked for any additional updates.
    - Shelly suggested putting the use cases in the rationale.

    - Steven Eichner said they should not be inventing new standards as there are already methods for exchanging data with IIS. It does not need to be a different standard for pharmacists.
    - Hans agreed and added that suggested adding United States Core Data for Interoperability (USCDI) to leave it open. He asked Steven if that was sufficient or if additional wordage is needed.
    - Shelly asked Hans for clarification on USCDI as it does not capture all data necessary, i.e., vaccina lot number or vaccine given.
    - Hans clarified that unless the standard already supports that, an advancement would need to make sure the lot number is included in the transaction to IIS. He asked Steven Eichner if he agreed to leave it as is.
    - Steven Eichner did not respond so Hans left it as is until Steven Eichner could answer.

- Hans returned to R3 and asked Soctt to explain his suggestions.
- Scott said his edits were for clarification and insignificant and noted that the more he reads through the recommendation the more inconsistent the wording appears. He added that the biggest change was in rewriting the rationale. He said he does not think there is another recommendation that addresses access considerations.
- Hans said R23 addresses content management and access considerations is an aspect of that. He directed Scott to the bottom right, last row.
- Scott said it may negate the need for the last sentence.
- Hans said it is helpful in the rationale.
- Hans asked for any objections to turning R3 green. No objections made and he turned it green.

Recommendation 19 (R19)

- Hans reviewed the recommendation and asked for concerns. There were none and Hans turned it green.

Recommendation 20 (R20)

- Hans reviewed the recommendation and asked for concerns. There were none and Hans turned it green.

Recommendation 21 (R21)

- Hans reviewed the recommendation and noted some sections that needed additional clarification.
    - Shelly agreed.
    - Scott raised concerns with an e-prescribing requirement because of the burdensome workload already present in pharmacies.
    - Christian said he is in support of this recommendation as it will support bidirectional work.
    - Pooja asked for clarification on this recommendation centering on sharing information and not having the pharmacist capture information.

- Afton confirmed.
- David asked if it should then state “capturing and exchanging.”
- Hans clarified by explaining that this information is included in either R3 or R4. He added that providers should have the opportunity to capture it if they can.
- David said that this recommendation should include the ability to capture and exchange. He suggested “the ability to capture” instead of “capture.”
- Scott agreed and reiterated that mandating capture needs workload consideration.
- Hans asked for any objections on this recommendation. There were none and he turned it green.

Recommendation 22 (R22)

- Hans reviewed the recommendation and asked for comments.
  - Scott said this recommendation is great.
  - Steven Eichner suggested including “stakeholders” or “caregivers.”
  - Shelly noted that time was almost up.
  - Hans said they will pick up here next week and asked Steven Eichner to review R18.

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

None received.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Pooja Babbrah: Congratulations Jim!

Shila Blend: Congratulations Jim!

Deven McGraw: Him, that’s great news - thank you for your service!

Eliel Oliveira: Congrats Jim!!

Deven McGraw: Argh - Jim 🙄

Summerpal Kahlon: Good morning, just arrived at the meeting

Shelly Spiro: Congratulations Jim!

Jim Jirjis: Thank you

Mike Berry (ONC): Welcome to the Pharmacy Interoperability and Emerging Therapeutics Task Force.

Mike Berry (ONC): Please remember to select "Everyone" when using Zoom chat. All messages to "Everyone: are included in the meeting minutes. Thanks!

Catherine Graeff: Should the role of State Boards of Pharmacy related to online pharmacies and requirements be considered?

Summerpal Kahlon: A lot of the patient-related data is self-entered in these services through a series of Q&A, and they will often order their own labs when they want results

Katie Russell: I agree and I think when patients are using these online services, there is usually a reason why they aren’t going to traditional channels of physician prescription and pharmacy dispense. And the patient consent issue is too large

Summerpal Kahlon: Not sure these types of services are interested in health record interoperability

Justin Neal: I think to Pooja's point the biggest risk it about polypharmacy and being able to complete a true patient medlist that falls into our other operability discussions. There are regulatory conversations at numerous boards of pharmacies but I don't think they fall into the scope of our conversations.

Steven Lane: Just because a provider is not interested in providing well informed, safe, coordinated care doesn't mean that we should not support this goal through policy and standards.

Hans Buitendijk: Sounds like this is in effect another "setting" that we can reference in our recommendation where appropriate, but not requiring new recommendations.

Pooja Babbrah: +1 Hans

Sheryl Turney: @Hans I agree

Summerpal Kahlon: Agree with Scott. They are intentionally operating outside the system

Steven Lane: If the DTC providers are not interested in access to appropriate data, the patient themselves may well be interested in alerts / decision support that takes into account all of the services and medications they are receiving.

Kim Boyd: Are there perspectives this task force should gather from patient advocacy groups on this issue?

Katie Russell: Agree, looking a company right now and they say we can share the data with your PCP and they think it's a good idea but won't without your express permission.

Hans Buitendijk: @Scott: One can consider a form of patient consent directive to not share, which is then effectively granted given the channel. In reverse, when a patient does want it to be shared, then it would be helpful that it could be, unless we then depend on patient mediated interop.

Hans Buitendijk: And per Katie's comment, looks like at least one company indicates it can.

Katie Russell: And it says is my information safe with "company" and it says yes using industry standard encryption and stored in encrypted form on servers according to strict federal standards including HIPAA. So I think from that, they won't because it would violate HIPAA but they can if the consent is received

Pooja Babbrah: @kim boyd - good idea. And we do have a few patient advocates on the task force too

Summerpal Kahlon: Would tend to agree that these companies would have the ability, if they choose, to generate and share data via known standards. What's the role for ONC here? These services typically operate on a cash-pay basis so the payment-related policy levers aren't typically there

Kim Boyd: eRX - exemptions also depends on the control of the med.

Scott Robertson | BearHealthTech: If the patient chooses to not have their information shared, that is their choice. But that should be a choice. The DTC service should, by default, share information unless the patient directs otherwise

Katie Russell: I disagree, I think that's opt in patient consent instead of opt out.

Steven Lane: DTC services should be held to the same Information Sharing requirements as any other provider. Those that specifically provide treatment for potentially sensitive conditions may want to highlight patients' right to opt out of data sharing based on the Privacy Exception.

Katie Russell: I think when you are utilizing a service and not providing information of your insurance or provider, that they aren't bound to share it with those folks. The patient should be in control of their data

Kim Boyd: If they are a provider by definition then ONC's information blocking rules apply

Catherine Graeff: + Hans

Summerpal Kahlon: @Steven, I tend to agree with @Katie, if they're not participating in insurance/government programs, I don't think ONC has any mechanism to compel them to participate in interoperability programs

Deven McGraw: If they are HIPAA-covered (i.e., billing insurance), they are permitted to share for TPO (treatment, payment, operations) without the need to obtain prior consent, unless the Rx is for a sensitive condition where consent is required by state or federal law. Patient can request for information to be held confidential - but unless a state law mandates honoring that request, or the patient self-pays and requests such confidentiality, it doesn't have to be granted. Not all of the "sensitive" types of prescriptions serviced by the DTC market involve information specially protected by privacy laws (i.e., Viagra as an example).

Summerpal Kahlon: I could be wrong of course :)

Scott Robertson | BearHealthTech: @Katie - my comment was trying to deal with the double-negative: "opt-in to not sharing" or "opt-out in order to not share"

Kim Boyd: Many insurers do cover this type of service provider.

Richard Sage: Could everyone check their "Send to" setting to be sure that you have it set to "Everyone"? We are missing many comments in this chat…

Deven McGraw: And yes, a pharmacy (DTC or otherwise) could adopt a requirement for consent prior to sharing as a matter of institutional policy.

Scott Robertson | BearHealthTech: Should there be a default data sharing, i.e., "we will share medical information unless the patient requests otherwise". If different providers can choose defaults, the patient may not be aware if there information will be shared or not

Steven Lane: @Deven - Why would such an institutional policy not constitute Information Blocking?

Deven McGraw: @Steven, if it is a policy that is uniformly applied across all similarly situated requesters, and one that gives patients the choice, it would not be information blocking.

Deven McGraw: Happy to point you to the guidance (probably mostly in the preamble to the info blocking rules) that makes this more clear.

Steven Lane: Thank you, Deven.

Suzanne Gonzales-Webb, CPhT: R11, Last sentence in rationale: Delays are not only time consuming and frustrating for patients and other stakeholders but importantly may result in adverse patient health outcomes

Catherine Graeff: The first sentences refers to "distributor." Is that the wholesaler or the pharmacy?

Catherine Graeff: Coverage terms can vary by benefit plan (assigned to insured). The insurer can have many so may need to be more granular

Deven McGraw: Apologies - I need to drop a bit early — will listen to the recording of the last half hour and catch up on the homework offline 😊

Summerpal Kahlon: looks good

Jim Jirjis: concur

Catherine Graeff: R17 should say "pharmacists and other providers?"

Scott Robertson | BearHealthTech: R3 is available for your consideration

Pooja Babbrah: agree - providers

Christian Tadrus: HIV reporting is mandatory in some states and pharmacists are doing PEP and PrEP TtT requiring reporting and referral. Would that be a use case?

Suzanne Gonzales-Webb, CPhT: Agree with @Scott regarding collecting this data---pharmacies---may not have the capacity to do this. Exchange yes

Kim Boyd: Access, use, exchange and store

Kim Boyd: capture

Pooja Babbrah: agree with Scott on this one

Suzanne Gonzales-Webb, CPhT: Add to R22: as part of the collaboration create what 'should' (mandatory) be collected, and 'could be' (not-mandatory) collected

Christian Tadrus: Consider pharmacist care process in any guidance since it drives the engagement process

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

Task Force Work Planning

- Shelly reminded the group of upcoming meetings and noted that the HITAC update meeting is on October 19 should any task force member want to join.

Resources

Pharmacy Interoperability and Emerging Therapeutics 2023 Webpage
Pharmacy Interoperability and Emerging Therapeutics 2023 – October 4, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

The meeting adjourned at 12:01 PM.