Health Information Technology Advisory Committee

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Virtual Meeting

Meeting Notes | October 11, 2023, 10:30 AM – 12 PM ET

Executive Summary

The goal of the Pharmacy Interoperability and Emerging Therapeutics Task Force (PhIET) meeting on October 11 was to continue the review of final recommendation drafting and dialogue on 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
10:55 AM	Topics 1, 2 and 3 and 4: 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
David Butler, Curatro, LLC
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
Meg Marshall, Department of Veterans Health Affairs
Anna McCollister, Individual
Deven McGraw, Invitae Corporation
Justin Neal, Noble Health Services
Naresh Sundar Rajan, CyncHealth
Scott Robertson, Bear Health Tech Consulting
Alexis Snyder, Individual

Fillipe (Fil) Southerland, Yardi Systems, Inc.
Christian Tadrus, Community Pharmacy Owner
Sheryl Turney, Elevance Health
Afton Wagner, Walgreens

Members Not in Attendance
Chris Blackley, Prescryptive
Shila Blend, North Dakota Health Information Network
Steven Eichner, Texas Department of State Health Services
Ketan Mehta, Micro Merchant Systems
Eliel Oliveira, Dell Medical School, University of Texas at Austin

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 reiterated that they have been unable to secure a presenter on this topic and Hans noted that this is the last time they will be reviewing the spreadsheet.

Discussion: Topic 4 Direct to Consumer Prescription Services
- Anna McCollister asked for an overview of what ONC is looking for regarding Topic 4.
  - Tricia Lee Rolle gave an overview.
- Christian Tadrus asked if direct to consumer prescription services were being considered in the context of an initial prescription or around refills. He also asked if they are considering state law.
  - Tricia answered that the assumption is that this is happening legally. ONC is interested in knowing if there is a need for interoperability, and healthcare coordination, or if anything additional needs to be considered in this field. She said they are not responsible for reconciling laws across states or jurisdictions.
- Christian said he did not support patients outsourcing prescriptions for self-defined health needs [and then his audio connection was lost].
- Hans Buitendijk noted that they were discussing this topic today to account for the patient perspective brought by Anna and Alexis Snyder as they were not present at the last meeting. He asked them both for any consideration from the patient viewpoint.
- Anna asked if the focus should be concerning the informatics of how to make this work or policy around how to make it work.
- Shelly Spiro answered the former. She added that they cannot dictate policy in relation to wrong or right only leverage the technology to ensure information is flowing appropriately. She noted that it is like digital therapeutics (DTx) software but does not coordinate with primary care. She said these prescriptions need to be identified in a way that allows for sharing with the patient care team if a patient centered model of care is to be achieved.
- Anna gave a personal example of some prescription difficulties she has experienced related to

telehealth to clarify if she understood what ONC was asking for.

- Shelly said yes and explained the difference between the scenario she presented and what they are focusing on for this recommendation. The concern here is the lack of connectivity with the patient care team.
- Hans noted a recommendation draft that Shelly input on the spreadsheet that provided additional clarity on the goal of this topic.
- Shelly suggested that ONC do outreach with the National Association of Boards of Pharmacy (NABP) and added that if these prescribers are doing anything illegal it is for the state boards to deal with. She said the state boards should be involved because they can confirm whether the laws and regulations are being met. She asked Christian for comment.
- Christian said regulations sometimes inhibit what can be done. He suggested building the recommendation from the perspective of what the state authorizes pharmacies to do under their licensing. He added that the recommendation does not need to be around policy. He said that recommendations should not be written solely from the perspective of a consumer seeking a drug. Language needs to be included that says "subsequent to appropriate medical needs."
- Shelly asked David Butler to expand on his comment in the chat.
- David said there needs to be some recognition of the popular opinion that medication should not be controlled. He added that uncontrolled medication is risky and noted that the solutions mentioned in his chat comment are necessary for maintaining patient safety. He also suggested establishing a group to discuss how at-home ambulatory patients, and other at-home situations, would be able to assess, monitor, and report to a body that could assess a need and make recommendations.
- Shelly agreed and noted that this happens a lot with over-the-counter herbal medications. She noted that when patients do not disclose the use of these medications it inhibits the pharmacist's ability to assess potential adverse drug reactions.
- Alexis referred to David's chat comments regarding safety concerns. She noted that it is no different than a caregiver or patient keeping records on medications they are taking and added that sometimes people lie about their medications. She suggested building recommendations around safety and proposed using the initial survey to evaluate side effects or adverse reactions before refills are given.
- Justin Neal said that, from an interoperability standpoint, the more interconnection of medical information that exists the more regulation there will be. He added that it is important to collect the information to assess for possible adverse drug reactions and communicate those reactions to providers.
- Anna said that the Digital Medicine Society (DiMe), who work on DTx and digital biomarkers, created the Virtual First Medical Practice Collaboration (IMPACT), a trade group for virtual first care (V1C) companies. She suggested reaching out to the CEO for their perspective on data sharing and virtual care providers.
  - o Shelly asked Anna to put that into a recommendation.
  - o Hans told Anna she could put it in the tab for Topic 4 or wait until all is transferred to the document and address it there.
- Anna said she would.
- Shelly asked Anna to email the recommendation to her and Hans if she cannot get it into the spreadsheet.

Topic 1, 2, 3, and 4: Review of Recommendations

Hans reviewed the spreadsheet and flow of topics for review and instructed the group to make comments in columns F or G.

Recommendation 11 (R11)

- Hans asked Alexis if she had a moment to review.
  - Alexis said she did not agree with the word "reasonably" as it is not a definitive time period and does not solve the problem in the recommendation.
  - Hans said it would be transferred to the document as is and further edited when they shift to the document.
  - Alexis agreed and added that an appropriate length of time needs to be defined.
  - Hans suggested adding the need to define what is considered a reasonable amount of time in the recommendation. He noted that they would not have to define it but would identify that the definition is needed.
  - Alexis agreed.
  - Pooja Babbrah agreed as well.
  - Shelly noted that Scott Robertson recommended using "appropriate."
  - Alexis said it raises the same issue as "reasonable."
  - Shelly agreed it must be on a case-by-case basis.
  - Alexis reiterated that she agreed with Hans' rewording.
  - Hans said he would make that change.
  - Anna agreed with Alexis and suggested giving ONC guidance on the process for determining the appropriate length of time.
  - Hans asked Anna to draft wording to be added.
  - Anna agreed and added that she would ask Alexis to comment.
  - Hans split the second sentence into two and asked them if that was a reasonable starting point. The rest will be done in the document phase.
  - Alexis said it looked good and agreed to address it further in the document.
  - Hans asked for any further concerns, there were none and he turned the recommendation green.

The group skipped discussions on reallocation.

Recommendation 6 (R6)

- Hans reviewed the additions to the recommendation.
  - Scott suggested changing "ability to capture data from the level of analysis" to "appropriate level of analysis."
  - Christian agreed with Scott.
  - Hans asked for any further concerns, there were none and he turned the recommendation green.

Recommendation 34 (R34)

- Hans reviewed the recommendation.
  - A Task Force member suggested removing the second "provide."
  - Hans asked if there were any further concerns.
  - Shelly reminded the group that when a recommendation is made green that means it will go into the Google document.
  - There were no objections and Hans turned the recommendation green.

Recommendation 17 (R17)

- Hans reviewed the recommendation and asked Deven McGraw if it addressed her concerns.
  - Deven said yes.
  - Hans asked for any further concerns, there were none and he turned the recommendation green.

Recommendation 18 (R18)

- Hans said he reached out to Steven Eichner regarding this recommendation and suggested leaving it as is and making any needed changes in the document. He asked if there were any objections to it as written.
  - Shelly noted Melissa McClung's comment saying it should be Immunization Information Systems (IIS) or Immunization Registry, not both.
  - Steven Lane said only one is needed.
  - Shelly suggested "immunization registry."
  - Steven agreed and noted that there are other registries so it should be kept broad.
  - Hans noted that it is written that way for more inclusivity.
  - Shelly suggested changing to "have ability to access" from "need to access."
  - Scott said there is a reference to IIS registries in the third line down.
  - Hans said that could be clinical data registries.
  - Scott said it was under rationale.
  - Shelly asked Suzanne Gonzales-Webb's which line she was referencing in her comment.
  - Scott said pharmacies need the "ability to access."
  - Suzanne commented that Scott was correct.
  - Afton Wagner suggested changing "particular" to "particularly" in the rationale.
  - Steven suggested adding "and other relevant clinical data registries" to be more inclusive.
  - Hans asked for any further concerns, there were none and he turned the recommendation green.

Recommendation 22 (R22)

- Hans reviewed the recommendation and asked for any further concerns. There were none and he turned the recommendation green.

Recommendation 23 (R23)

- Hans reviewed the recommendation.
  - Deven said a single national infrastructure for consent registry is a big undertaking and needs further exploration before a recommendation can be made. She noted that it is complicated since consent is situational. She suggested using the term "actively explore" and setting up another task group to research it. It is premature to tell ONC to advance this.
  - Pooja agreed with Deven and noted that there is a lot of activity around it. She recommended removing "establish the national privacy policy and patient consent directives infrastructure," and leaving it at ONC.
  - Steven agreed and noted that the HTI-1 Task Force discussed this as well and suggested looking at how it was phrased there. He said they are not ready to recommend ONC to act on this. He added that Square Project will be launching a long-standing privacy workgroup in the beginning of next year and they should be included in any collaboration.
  - Shelly said there is some work being done on personal preferences and some software that are emerging ways to capture this information but overseen by the patient.

- o Anna agreed with everyone's comments. She said it is important to do, but not so quickly. She said she was interested in what is The Sequoia Project's opinion on this. She added that making hasty recommendations can have negative ramifications.
- o Hans agreed with everyone's comments and noted the need to address infrastructure in the recommendation. He added that current standards are lacking and something additional is needed.
- o Shelly noted that Deven suggested removing "national" and adding "interoperable."
- o Scott suggested, "explore the infrastructure needs for an interoperable privacy policy."
- o Hans said that made sense and asked Deven if she had any additional suggestions.
- o Deven said her suggestions were in the chat and noted that Shelly mentioned them. She opined that specificity around collaboration in combination with Health Level 7 (HL7) is too directive at this point and suggested changing it to "could consider collaboration."
- o Hans made the suggested changes.
- o Deven reiterated that this topic needs to be further explored before making any recommendations.
- o Hans reiterated what Deven said for clarity.
- o Deven confirmed that was what she was saying.
- o Pooja mentioned a listening session she attended that concluded in very general language for ONC about conducting research. She suggested noting that language for review is an example of language that can be used for this recommendation.
- o Hans said that would be great.
- o David agreed with Deven and added that the recommendation is very broad. He noted that companies following the General Data Protection Regulation (GDPR) and Health Insurance Portability and Accountability Act (HIPAA) requirements can build out a database that would allow for chart visibility but that opens the possibility of abuse in patient interaction with chart visibility. He added that patients and providers need to be involved in this exploration and more examples of what is being recommended are needed.
- o Hans asked for any additional comments.
- o Shelly said no.
- o Hans said Pooja, Deven and he would review the changes via email and asked if anyone else wanted to be part of the discussion.
- o Deven asked if there would be an opportunity to review any changes outside of the email chain.
- o Hans said yes.
- o Anna said she did not want to be part of the email chain but said she was available if her perspective was needed.

That concluded drafting recommendations for Topic 1 and the group moved on to Topic 2.

Recommendation 24 (R24)

- Hans reviewed the recommendation and asked for any additional comments.
  - o Scott mentioned a comment asking whether it is among "pharmacies" or "pharmacists."
  - o Hans asked if the focus should be on pharmacists or the pharmacy.
  - o Scott said they did not come to a decision of when we use "pharmacy" versus "pharmacist."
  - o Hans said that needs to be evaluated for each recommendation.
  - o Shelly said Cathy Graef also brought up licensed pharmacy technicians and noted that "pharmacy" would cover that.

- o Hans said previous recommendations need to be reviewed to ensure all appropriate terms are included.
- o Christian said if they are going to get granular, they need to consider other health professionals like nurses or public health entities who can also be part of a pharmacy health team.
- o Hans noted David's comments in the chat and added that for the time being it will stay as is. He did reiterate the need to review all recommendations for the usage of both terms.
- o Shelly added that a pharmacist can work independently while pharmacy technicians cannot and noted that she thinks "pharmacy" and "pharmacist" are appropriate.
- o Hans asked for any further concerns, there were none and he turned the recommendation green.

Recommendation 25 (R25)

- Hans reviewed the recommendation.
  - o David said he was unclear on what "pharmacy as an organization" meant.
  - o Shelly suggested using "entity" instead of "organization."
  - o David said that might work and asked if "pharmacy" is being referred to here as the profession or facility.
  - o Hans said "facility" can be used to describe a physical building or an organization. He said they used "organization" to be clear they are not referring to the building.
  - o David asked for an example of a pharmacy as an organization.
  - o Hans used CVS as an example.
  - o David said that CVS was a corporation.
  - o Shelly suggested using "business" or "entity."
  - o David suggested "taxable entity."
  - o Hans changed it to "taxable entity."
  - o David said that worked and asked if the recommendation was also addressing the commerce outside of the pharmacy area of the business.
  - o Hans said they were focusing on the pharmacy business unit managing pharmacy related capabilities.
  - o David then suggested borrowing from HIPAA and using "pharmacy component of a hybrid entity" as that is how HIPAA refers to it.
  - o Hans asked to what extent the recommendation needs to be refined. He said they need to be careful not to use too large an umbrella for "pharmacy." He asked David to follow up with this recommendation.
  - o David said he would and added that what he suggested may be too restrictive. He asked the group for additional perspectives as well.

Recommendation 26 (R26)

- Hans reviewed the recommendation.
  - o Shelly noted that Scott suggested "pharmacies" in the chat as it would include all staff.
  - o Scott said "record location services" does not fit with linking patients with the correct record.
  - o Hans said patient matching was being conducted by the pharmacists in conjunction with other care team members.
  - o Scott said that it may be unnecessary.
  - o Hans noted the changes.
  - o Scott suggested adding "after services."

- Shelly noted David's suggestion "in order to provide pharmacists the needed information for improving patient care."
- Hans added the suggestion.
- Pooja said she did not understand what "include the pharmacy community in the advancement" was asking.
- Shelly said the intent was to address the need to engage pharmacists in the national conversation around patient matching.
- Hans noted that there was a consensus on the recommendation and added that additional wordsmithing was needed. He then turned it green.

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

None received.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

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

Mike Berry (ONC): Please select "Everyone" when using Zoom chat. Chats to everyone are added to the meeting minutes.

Jim Jirjis: Jim Jirjis joined

Deven McGraw: Apologies for being late - am on now.

Steven Lane: Are there any international best practices here? In much of the world there are many fewer barriers to access to medications and an associated greater role for pharmacists to recommend such therapies.

Justin Neal: I would think that in an environment of DTC drug prescribing, interoperability would provide a more robust way of controlling the process and putting a largely cash patient into "the sunlight." Required interoperability where the full medical chart is available to providers makes the information available to other providers. Much like a PMP does for controls.

Hans Buitendijk: In those circumstances, pharmacists then still operate within their authority where certain medications are categorized closer, but not quite OTC. Where then a prescription/filling of medication occurs and the patient provides proper authorization to share this with other care team members.

Anna McCollister: Have we reached out to the DiME/IMPACT project? They are a digital first care/telehealth trade group. I am a founding member but haven't had time to be involved in many of the projects. They have worked on some of these issues, but I'm not sure of what they have done on specific data standards.

Steven Lane: While unlikely to be acceptable in our society, and imperfect in its view, it would seem useful if there were a list of OTC therapeutics which, when purchased, would provide an opportunity for patients to specify their PCP or the location of their primary medical record, so that the relevant data could be easily uploaded to their chart. Today patients can manually enter/report this information, though most do not. Making this easier could be beneficial.

Scott Robertson: "(e.g., 48 hours)"
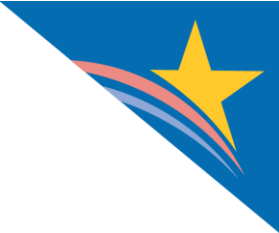
Deven McGraw: "Timely"? I get it's not specific but at least it recognizes it must be timely given the circumstances.

David Butler: "a time-period previously declared by each provider"

Deven McGraw: Can't just be up to the provider, with all due respect - ideally there needs to be incentives to do so faster but within capabilities.

Melissa McClung: For clarity, it should probably be either IIS or immunization registries

Suzanne Gonzales-Webb, CPhT: need access? " have ability to access" (R18)

Suzanne Gonzales-Webb, CPhT: under rationale

Suzanne Gonzales-Webb, CPhT: yes, thank you Scott... that was it

Steven Lane: Suggest "IIS and other relevant clinical registries"

Steven Lane: Add to the list of collaborators the upcoming Sequoia Project Privacy and Consent workgroup.

Steven Lane: National consent registries were also addressed in HITAC taskforce recommendations regarding HTI-1 NPRM.

Deven McGraw: I'm happy to help suggest some language that is geared more toward further exploration of these issues vs being more specific

Deven McGraw: +1 to Anna about the potential to lead to barriers.

Hans Buitendijk: Thank you Deven!

Deven McGraw: Take out the word "national" for now

Deven McGraw: Add the word "interoperable" instead?

Pooja Babbrah: +1 Deven

Steven Lane: Agree that this should warrant a dedicated HITAC taskforce.

Steven Lane: While related, this is not specific to Pharmacy Interoperability.

Deven McGraw: Would love to see that language, Pooja!

Cathy Graeff: Did we discuss removing pharmacies? Also consider licensed pharmacy technicians to be included

David Butler: Pharmacists are the authority, pharmacies are the facility, so I believe each should be included for specific, independent needs.

Melissa McClung: consider adjusting the wording to say "...that is common with the health IT used by the provider community that is being deployed...."

David Butler: Well said Shelly.

Shelly Spiro: @David thanks

Cathy Graeff: Maybe we are talking about information technolocy needs and not clinical needs

Cathy Graeff: Pharmacies are licensed. Seems like grocery stores, the rest of the business in not relevant

Deven McGraw: Do we need that kind of detail? Why not just an explanatory line or two at the top of the recommendation that we are talking about the pharmacy unit if within a larger entity? Plus hybridization is a judgement call that a larger pharmacy decides whether to make - they always have the option of following HIPAA throughout their entire enterprise.

Kim Boyd: Pharmacy - licensed establishment where prescription medications are prepared, dispensed, and sold to patients based on a medical prescription from a qualified healthcare professional

Scott Robertson: would include all staff

Scott Robertson: pharmacies

Suzanne Gonzales-Webb, CPhT: pharmacies - for patient matching

David Butler: could we add "in order to provide pharmacists the needed information for improvidng patient care."

David Butler: Excellent! Thank you.

Steven Lane: Kudos to the co-chairs for the tremendous work finalizing and pulling together our taskforce recommendations.

Pooja Babbrah: this looks great!! Thank you Hans and Shelly for all your hard work on this!

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL
No comments were received via email.

Task Force Work Planning
- Hans reviewed the draft document and updated the group on progress. He noted where comments can be made in the document and explained the layout, corresponding spreadsheet location, and where feedback needs to go.
- Shelly reviewed the remaining meeting dates on the calendar.

Resources
Pharmacy Interoperability and Emerging Therapeutics 2023 Webpage
Pharmacy Interoperability and Emerging Therapeutics 2023 – October 11, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment
The meeting adjourned at 12:01 PM.