ONC | HealthIT ADVISORY COMMITTEE

Health Information Technology Advisory Committee

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Virtual Meeting

Meeting Notes | September 27, 2023, 10:30 AM – 12 PM ET

Executive Summary

The goal of the Pharmacy Interoperability and Emerging Therapeutics Task Force (PhIET) meeting on September 27 was to continue the review of the final recommendation draft wording and structure. One guest speaker joined the meeting and presented information to further discussions around Topic 3. A robust discussion followed.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	Opening Remarks
10:40 AM	Task 3 Guest Presentation on Digital Therapeutics
11:00 AM	Task 1 and 2: 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
Adi Gundlapalli, Centers for Disease Control and Prevention (CDC)
Jim Jirjis, HCA Healthcare
Summerpal (Summer) Kahlon, Rocket Health Care
Steven Lane, Health Gorilla
Meg Marshall, Department of Veterans Health Affairs
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
Alexis Snyder, Individual
Fillipe (Fil) Southerland, Yardi Systems, Inc.
Christian Tadrus, Community Pharmacy Owner
Afton Wagner, Walgreens

Members Not in Attendance

Chris Blackley, Prescryptive
Anna McCollister, Individual
Ketan Mehta, Micro Merchant Systems
Naresh Sundar Rajan, CyncHealth
Sheryl Turney, Elevance Health

ONC Staff

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

Key Points of Discussion

Opening Remarks

PhIET Task Force Co-Chairs, Hans Buitendijk and Shelly Spiro, welcomed the Task Force and reviewed the Meeting Agenda. PhIET Task Force continued Task 1 and 2 draft recommendations review.

Task 3 Guest Presentations

Shelly introduced guest speaker Ibrar Ahmed, Software and Enterprise Architecture Manager, ZS.

Ibrar gave a presentation regarding digital therapeutics. He explained what digital therapeutics is and suggested several points for standardization consideration. He also gave an overview of Digital Therapeutics (DTx) software as well as the Prescription Digital Therapeutic (PDT) ecosystem and noted needs on the manufacturing side.

Discussion:

- Hans asked if there is a community already active that could identify the gaps in connectivity or is there still work to be done to progress in that area.
- Ibrar said he was unsure as he is not as involved in those communities. However, he did mention some groups that are starting to think about it, i.e., DTx Alliance, National Council for Prescriptions Drugs Program (NCPDP) task forces and noted that there are seven initiatives that have begun. He stressed the need for standardization and acceleration.
- Shelly noted that the Food and Drug Administration (FDA) has some requirements on DTx, including Clinical Decision Support (CDS) algorithms and the use of Artificial Intelligence (AI). She asked Ibrar to comment on how to ensure that there is some standardization process for patient safety, population bias, and other related areas.
- Ibrar said the CDC has had notable discussions around clinical decision support not being considered a DTx. CDS may in some cases be considered digital medicine. He added that his company often

recommends their clients spend time mapping data used to connect decisions with data sources. They also advise their customers to refrain from feeding information back to the algorithm as it would cause automatic retraining of the algorithm. These are the steps they are currently taking to leverage technology for their customers while safeguarded them from safety issues.

- Pooja Babbrah said there are already prescribing standards in place and there should be no difference in prescribing DTx if they are in the Electronic Health Record (EHR) workflow and asked if the recommendation should be centered around collecting patient data. She also asked Ibrar what would be his "wish list" of recommendations to progress these therapies forward.
    - Ibrar said that there need to be minimum standards that account for key differences. He added that there needs to be a standardized mechanism for EHRs to integrate new technologies with respect to PDTs, also, standardizing benefit verification.
    - Hans noted that there is a prescription aspect and result aspect. He asked Ibrar what are the biggest challenges that need to be addressed to move this beyond prescribing and getting results.
    - Ibrar said eligibility, benefits, and reimbursement is a large pain point from an incentivizing perspective. From a patient standpoint there needs to be circular data optimization and configurability of treatment plans so they can be changed accordingly. He added that data driven training for pharmacists would be beneficial.

Task 1 and 2: Review of Recommendations

- Hans asked the group to add any suggestions or recommendations for DTx to the Topic 3 recommendations tab. He reviewed the draft recommendations with the group noting that those in green note recommendations ready to move to the document phase. He reviewed the agenda and began reviewing the draft recommendations.

Recommendation 2 (R2)

- Hans reviewed the recommendation and asked if there were any recommended changes.
    - Steven Eichner said there was a typo.
    - Hans reviewed the recommendation for typos.
    - Scott Robertson said the second sentence in rationale was convoluted and needed editing.
    - Shelly asked him to specify which part.
    - Scott could not find it, he said he would raise his hand once he found it.
    - Steven Eichner said it should read public health "agencies" not "organizations."
    - Hans agreed and asked if it was fair to use "PHA" where needed.
    - Steve Eichner said yes.
    - Hans changed the recommendation to green.

Recommendation 3 (R3)

- Hans reviewed the recommendation and asked Alexis Snyder if they captured her comments completely in this iteration.
    - Alexis said it looks good for now.
    - Hans asked Deven McGraw about her comment in the chat regarding "PTO."
    - Deven said she has never seen it notated as PTO before, it should be spelled out.

- Hans asked for any additional comments on sentence flow and rationale.
- Steven Eichner said he wanted to make the disclosure components clear.
- Hans asked if what is written is sufficient or more needs to be stated.
- Steven Eichner said that is good.
- Scott asked if the parenthetical in rationale was referring to prescriptions from pharmacies/pharmacists or something else. He suggested adding "beyond what pharmacy has."
- Steven Eichner said the issue is that medication lists are incomplete in EHR.
- Scott referred to Afton Wagner's suggestion in the chat.
- Hans referred to a brief update he made in the spreadsheet and asked if that helped.
- Scott said he will look at further edits to see how it can be improved.
- Hans asked him to review it with Afton.
- Afton agreed.

Recommendation 10 (R10)

- Hans reviewed the recommendation and asked if Anna McCollister, Pooja, and Steven Eichner had an update on their follow up.
  - Pooja said she had not met to review.
  - Steven Eichner said he made changes in red.
  - Hans said they will skip it for now until Pooja and Anna can review the changes.
  - Pooja said she agreed with the changes.
  - Hans changed the recommendation to green.

Recommendation 11 (R11)

- Hans reviewed the recommendation and noted that Christian Tadrus, Afton Wagner, and Alexis need to review a change.
  - Afton said they are set to meet at 2 p.m. today to review it. She noted a need to focus on a use case scenario and said she agreed with cross-sectional workshops to see how it would work.
  - Hans said they will review it again next week after she and Christian have met.
  - Alexis said she wants to add something that goes beyond what is in stock and accounts for shortages, and ability to order. Those parts are missing here.
  - Steven Eichner explained the rationale and clarified his suggestion for wording being grounded in concern over the lack of connectivity of independent pharmacies.
  - Shelly noted that David Butler posted a question about the difference between pharmacy and pharmacist in the chat and asked if he wanted to speak on it.
  - David addressed Steven Eichner's concerns and noted that they typically do have access to networks that can inform them of product availability I the local distribution level.

- Hans referred to his original comments in the chat and asked if he was suggesting changing “pharmacy/pharmacist” to “pharmacist,” unless “pharmacy” needs to be explicitly mentioned.
- David answered yes and added that the pharmacist is responsible for patient care not the pharmacy.
- Hans asked if “pharmacies” would be appropriate when addressing issues of inventory, operations, and the like.
- David said for the purposes of storage and security yes, however, if the inventory affects patient care, then it is the pharmacist’s responsibility.
- Hans asked David to help identify when either term should be included.
- David noted that the pharmacist’s role can vary from dispenser to provider and that needs to be considered when categorizing pharmacists.
- Hans said he had a fair point and noted the need for terminology used to fall within the 21st Century Cures Act definitions.
- Steven Lane suggested approaching “pharmacy” and “pharmacist” the same as physicians. He explained that as a physician who works in a clinic both he and the clinic are considered independent entities with individual authority.
- Hans agreed and added that it should be made as clear as possible.
- Summerpal (Summer) Kahlon agreed with Steven Lane. He noted the importance of distinguishing between “pharmacist” and “pharmacy.” He added that any recommendations for standardization submitted should be at the pharmacy level and not pharmacist.
- Hans noted that they should never use “pharmacy/pharmacist” as they may both be needed but one more than the other.
- Steven Lane referred to Pooja’s question in the chat and answered that there is no single clear answer to whether pharmacists are providers or not. You get a different answer depending on whose definition you reference.
- Hans noted that this makes it challenging.

Recommendation 12 (R12)

- Hans reviewed the recommendation and noted that as it is currently written it is out of scope of ONC. He added that if no one has suggestions on rewording then it will be placed in the “out of scope” column.
    - David Butler said he made changes but cannot see them.
    - Hans said he will follow up on this one and check previous drafts to find if anything is missing.

After moving those recommendations to their next stages, the group continued with recommendations not yet discussed.

Recommendation 15 (R15)

- Hans reviewed the recommendation.
    - Steven Eichner suggested adding “ONC’s work with the Recognized Coordinating Entity (RCE).”
    - Hans said he will add it.
    - David said it should read “any provider” and not “other provider.”

- Hans asked if anyone had any issues with that wording change.
- Steven Eichner suggested “a pharmacist and another provider.”
- David said “other” is not a comprehensive term and does not include all types of providers.
- Hans agreed and noted the importance of using terms correctly in these recommendations because many of them overlap.
- Steven Eichner said it may not be every provider type, it can be another esoteric provider like durable medical equipment.
- David asked if it should say “healthcare provider.”
- Hans said he thought the term “provider” assumes “healthcare provider.”
- Pooja raised concerns for limits the term “healthcare provider” could create should public health move beyond just “test and treat.”
- Steven Lane agreed.

Recommendation 16 (R16)

- Hans reviewed the recommendation.
  - Summer suggested a more specific term as “public health” and “public health agency” are too broad.
  - Hans asked how to make it more specific.
  - Summer suggested “public health departments where there may be clinical services offered” as one component as well as “routine surveillance, reporting data, condition reporting, and disease registries.”
  - Steven Eichner said they want to be broad but agreed that the PHL line needs to be corrected.
  - Hans suggested adding wording that changes public health providers to public health agencies.
  - Summer said they it should be a combination of both.
  - Steven Eichner said public health agencies (PHA) include both.
  - Hans asked if both terms are needed.
  - Steven Eichner reiterated that “agencies” covers both.
  - Hans asked Summer if that was ok with him.
  - Summer answered yes and no. He suggested parsing it into “emergency management” versus “routine surveillance and management.”
  - Hans asked if there is anything specific to emergency use that goes above and beyond normal use?
  - Alexis suggested adding “reporting to public health by all providers” and “patient consent” at the end.
  - Steven Eichner noted that providers are authorized to report data to public health without patient consent.
  - Alexis said that is for some cases not all cases.
  - Hans made a change and asked them to review.

- Steven Eichner and Alexis said they could not see it.
- Alexis said if it is noted in the rationale then it needs to be in the recommendation. People often read the recommendation and not the rationale.
- Steven Eichner said it needs wordsmithing and asked if the recommendations can be moved to a new spreadsheet.
- Shelly said they are in the process of doing that now.

There were some technical issues with getting the changes to show in the spreadsheet so they moved on to R17 in the meantime.

Recommendation 17 (R17)

- Hans reviewed the recommendation.
    - Deven said the sentence is missing a verb making it confusing to read. She suggested adding “to establish” to clarify the recommendation.
    - Hans asked if that change works.
    - Steven Eichner said it is important to specify the type of reporting. What is being reported or exchanged here?
    - Hans said he thinks that is addressed in the use case for topic two.
    - Steven Eichner suggested saying “clinical data or something appropriate” so that it goes with the use case for topic two.
    - Hans said that was a fair point.
    - Steven Eichner asked if this is supposed to be bidirectional.
    - Hans said yes.
    - Steven Eichner said as written it is unclear what information would be pushed, where it would go, and from where it came.
    - Hans said that needs to be established, currently it is about data in general.
    - Steven Eichner suggested adding trigger conditions to reporting mechanisms.
    - Hans noted that he has been making changes in the spreadsheet and they are not updating.
    - Steven Eichner said different events may be relevant to different providers, i.e., lab test results, etc.
    - Hans said this can be worked out, we do not have an answer today.
    - Shelly said Admission, Discharge, Transfer (ADT) is a use case.
    - Hans said it is one where push messages are of interest, the other is “lab results become available.”
    - Steven Eichner reiterated his example for a trigger event.
    - Pooja suggested adding the ADT and lab result examples.
    - Hans said yes.
    - David suggested clinical diagnosis as well.
    - Steven Lane said sometimes it is indication and no formal International Statistical Classification of Diseases and Related Health Problems (ICD) diagnosis term is used.
    - Hans said R16 needs more work. He asked if R15 and R17 can be made green.
    - There were no objections.

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!

Mike Berry (ONC): Please tag "Everyone" when using Zoom chat so that your comment is included in the meeting notes. Thanks!

Cathy Graeff: NCPDP has a task group that has defined a use case where the PDT is prescribed and billed to the prescription benefit. Meet twice monthly.

Summerpal Kahlon: What's the role for a pharmacist in "dispensing" a digital therapeutic? Education/Training? Technical setup and configuration?

Cathy Graeff: The use case NCPDP worked on has the pharmacist providing the PDT "activation code" and provides training, etc.

Pooja Babbrah: Digital Therapuetic Alliance DTA is doing some of this work

Afton Wagner: Academy of Managed Care Pharmacy also has a DTx Advisory Group

Cathy Graeff: There is work going on regarding who should review the data generated by the DTx. Prescriber may not be the best choice in all use cases. May be a role for pharmacists. Lots of diversity in PDTs and standardization difficult at this time.

Hans Buitendijk: @Scott: Is there any activity on this with HL7 Rx as well and/or HL7 Devices that you are aware of? Particularly in the FHIR space.

Christian Tadrus: Pharmacists are involved in RPM as well as monitoring outcomes of therapies and may use Digital Medicine (devices) to do this work. If the pharmacist is a provider, they may also be are authorized to prescribe DTx under CPAs.

Summerpal Kahlon: Are these digital therapeutics intended to be prescribed for a finite amount of time? and refilled/renewed? will they be disabled for use if they are not renewed by the prescriber in a timely manner?

Cathy Graeff: Yes, some DTx can be similar to medications in that regard. Finite amount of time and renewals are possible.

Afton Wagner: AMCP held a partnership forum on DTx that identified challenges for payer needs. Proceedings can be found here: https://www.jmcp.org/doi/full/10.18553/jmcp.2022.22093

Deven McGraw: Would the FHIR APIs in certified EHR technology be the point of entry for digital therapeutic prescribing solutions?

Hans Buitendijk: FHIR based prescribing is not yet there. Prescribing would be a mix of HL7 v2 and NCPDP SCRIPT between EHR and pharmacy where internal it would be HL7 v2 and external NCPDP SCRIPT.

Cathy Graeff: USP is also exploring what should be standardized from the USP perspective.

Hans Buitendijk: I'm curious beyond prescribing and resulting, what other interactions with EHRs, payers, etc. would stand out to improve interactions with the devices.

Cathy Graeff: Compendia who provide info used by EHRs in e-prescribing have challenges related to devices. They are aware and working on how these devices show up when prescribing or dispensing from compendia perspective.

Scott Robertson: Another interaction may be if remote adjustments to the DTx parameters (therapy changes)

Cathy Graeff: Some DTx manufacturers are considering following a pathway similar to specialty pharmacy and Hubs.

Summerpal Kahlon: That raises a question - will settings in the digital therapeutic need to be part of the prescription? So they can be changed (like dosing/frequency in a medication) from time to time?

Pooja Babbrah: +1 Cathy - it seems that makes sense

Pooja Babbrah: Unfortunately others are giving up all together and going direct to consumer

Afton Wagner: It would be helpful for pharmacists to view changes in therapy based on clinician monitoring of DTx and also to help monitor adherence

Pooja Babbrah: And some of these DTx are also prescribed with another component which falls under DME. Seems like there are multiple paths these can take.

Cathy Graeff: There is a real role for pharmacists in analyzing the data and recommending changes in "dosing" etc.

Afton Wagner: Pharmacists could also enter any recommendations for therapy into DTx dashboard, etc. for consideration by the prescriber

David Butler: Steven, I'm not finding the text you entered for R6. I'm only finding the following " R6: need to identify the lead on pharmacy measures or other expert entity ..Christian to make this edit."

Deven McGraw: What is PTO?

Deven McGraw: Is it TPO? (Treatment, payment, operations?)

Steven Eichner: Payment, treatment, operations

Deven McGraw: I usually see it abbreviated as TPO but as long as we spell it out, it will be clear

Suzanne Gonzales-Webb, CPhT: typo - under R3 Recommend: - bi-directional line..... "pharmaciies...

Afton Wagner: As a pharmacist, I think that all medications are pertinent to review drug interactions, etc.

David Butler: As I'm reviewing these recommendations, I'm feeling even less comfortable with the terms "pharmacists" and "pharmacies" being used interchangeably (e.g., pharmacist/pharmacy). I don't believe we do this with physician/clinic or nurse/hospital. The pharmacist is the individual with legal authority over all information. The pharmacy is only a legal entity and corporate authority cannot override a pharmacist's decision regarding patient care. Thus, I recommend using "pharmacist" as the only term, unless there is a specific, facility-based need for "pharmacy" to be used.

Pooja Babbrah: Thanks, Ike for taking that on

Steven Eichner: My pleasure!

Pooja Babbrah: +1 David

Cathy Graeff: Agree with David

Shila Blend: SHILA Blend present my apologies for being late

Christian Tadrus: re: independents all being in wholesaler managed systems.   Over half use non-wholesaler controlled systems vendors.

Christian Tadrus: All have challenges managing inventory with 340b / LTC / retail / specialty all in play.

Pooja Babbrah: How does ONC define providers in other regulations, etc. Is it just covered under providers?

Pooja Babbrah: Sorry - are pharmacists covered under providers

Steven Lane: CMS definition of Provider (does not specifically mention pharmacists, except as they may fall under "non-physician provider"): https://www.cms.gov/glossary?items_per_page=10&term=provider&viewmode=grid&page=1. ONC references the Public Health Service Act, which does reference pharmacists: https://www.healthit.gov/sites/default/files/page2/2020-08/Health_Care_Provider_Definitions_v3.pdf

Pooja Babbrah: Should an overall recommendation to ONC be to work with HHS to try to synchronize definitions? Maybe too far out of scope?

Deven McGraw: Pooja, some of the definitions are in statute - beyond the ability of HHS to fix

Christian Tadrus: Healthcare provider would align with state level definitions

Deven McGraw: Agree with Ike that if the recommendation is broadly worded (as it is), it accommodates the different structures and authorities of public health throughout the country

Christian Tadrus: "… unless required by law or regulation"

Shila Blend: State or federal law

Christian Tadrus: ADT transactions?

Pooja Babbrah: +1 Christian

Steven Lane: Praise to the co-chairs and ONC staff for a tight task force.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

Task Force Work Planning

- Shelly reviewed upcoming tasks and dates noting October 19, 2023 as the date they will provide an update to HITAC.

Resources

Pharmacy Interoperability and Emerging Therapeutics 2023 Webpage
Pharmacy Interoperability and Emerging Therapeutics 2023 – September 27, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

The meeting adjourned at 12:00 PM.