Health Information Technology Advisory Committee

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Virtual Meeting

Meeting Notes | October 25, 2023, 10:30 AM – 12 PM ET

Executive Summary

The goal of the Pharmacy Interoperability and Emerging Therapeutics Task Force (PhIET) meeting on October 25 was to continue review of the Draft Recommendation Report. A robust discussion followed.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	Opening Remarks
10:40 AM	Review of Draft Recommendation Report
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
Summerpal (Summer) Kahlon, Rocket Health Care
Steven Lane, Health Gorilla
Anna McCollister, Individual
Justin Neal, Noble Health Services
Eliel Oliveira, Harvard Medical School & Harvard Pilgrim Health Care Institute
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
Jim Jirjis, Centers for Disease Control and Prevention
Meg Marshall, Department of Veterans Health Affairs
Deven McGraw, Invitae Corporation
Ketan Mehta, Micro Merchant Systems

ONC Staff

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

Key Points of Discussion

Opening Remarks

PhIET Task Force Co-Chair, Shelly Spiro, welcomed the Task Force and reviewed the Meeting Agenda. Hans informed the group that they are progressing on schedule. Shelly thanked Hans for his work in organizing the document and discussion commenced.

Review of Draft Recommendation Report

Hans reviewed the sections of the document and noted changes added as well as open comments. He asked Tricia Lee Rolle to review her comments added.

- Tricia Lee raised concerns over the term “direct-to-consumer (DTC) medication services” as the term could potentially invoke negative connotations associated with direct-to-consumer advertising. She noted that they are not assuming nefarious intentions but describing an aspect of prescribing that has little visibility. She added that they reached out to the Digital Medicine Society (DiME) as was suggested and they noted that Virtual First Care (V1C) is a more industry acceptable term to describe this area of health services. She then shared a document with the group explaining what V1C and its framework. Tricia Lee noted that she added some notes for consideration into the document for the group’s review. She noted that she did not want the group to publish a document that could be perceived as coining a term with negative connotations.
- Steven Lane asked for clarification on what aspect of the current wording contains any negative connotation.
- Tricia Lee clarified that the term “direct-to-consumer” reads as if they are coining a new phrase. And that the pharmaceutical industry has received negative press over direct-to-consumer advertising.
- Steven Lane said “direct-to-consumer” is a common phrase used in many different settings, i.e., “direct-to-consumer” advertising. He referenced his chat comment and added that the idea of V1C is very popular right now with many digital health companies beginning to provide these services. He added that he does not see that term as problematic or negative as written. He suggested discussing it further and developing a list of examples.
- Christian Tadrus noted that their recommendations have been centered on engaging the pharmacy and pharmacist more proactively in patient care and the word “direct” suggests a bypass of those pharmacies and pharmacists. He suggested coming up with a term that better encompasses the

pharmacist's role of dispensing and service provisions as prevent bypassing the pharmacist's roles.

- Hans informed the group that any notes related to this topic should be placed in R38 as that is the only recommendation that discussed "direct-to-consumer" issues and topic 4.
- Anna agreed that DTC is confusing and that it suggests that a provider is not needed. She noted that they were really discussing V1C. She suggested using the term V1C as it best describes the issue.
- Pooja Babbrah agreed and suggested using the term "online pharmacy," "online pharmacy services," or both since this about convening stakeholders.
    - Anna disagreed as they are not only pharmacies but doctors providing care, requesting labs, and providing counsel.
- Pooja asked if it would be appropriate to add them as stakeholders.
    - Hans noted that the original question included the term DTC and cannot be changed as it is part of the charge. He suggested adding "to include pharmacists," removing DTC from the rationale and explaining it further. He asked if that would help.
- Shelly reminded the group of the intent of these topics and recommendations. She noted that from an interoperability standpoint these entities need to be in the position to exchange information with other members of a patient's care team and added that that was the most important aspect of the recommendation. She said it was also important to note that these entities are different from the traditional pharmacy/pharmacist relationship and they need to be included in interoperability.
- Hans noted they had a lot of topics to discuss and asked if they could move on and return to this discussion later.
- Tricia Lee noted that at this stage it is too late to change the charge task itself. She suggested adding a footnote for clarification.
- Steven Eichner suggested adding patients when they return to this topic.
- Hans asked the group to add any suggestions as comments to R38 to be discussed later. He moved on to the "Additional Background" section and noted the addition of the term's "caregiver" and "patient advocates." He asked Alexis Snyder and Christian if they agreed with the additions.
- Alexis agreed.
- Christian agreed.
- Hans noted the addition of 42 U.S. Code § 300jj and wording from the 21st Century Cures Act Final Rule for clarification on the definition of the term's "provider" and "pharmacist." He asked for any questions or concerns.
- Steven Lane added the word "regulatory."
- Shelly said it made sense.
- Hans asked for any further questions or concerns regarding Christian's suggested additions to the definition of "pharmacist." There were none.
- Hans reviewed Alexis' suggestion to add "with transparency and communication to patients/caregivers" to the bidirectional use case section and suggested also adding it to the consumer engagement section. He asked if everyone agreed. There were no objections.
- Hans moved down to Consumer Engagement and asked the group if they agreed with the added bullet points.
    - Christian said there needs to be language that says information exchange needs to be robust enough to give a broader view of when a product will be available. He asked if that was captured.
    - Hans said it was captured in R11 and noted that the intent here was to capture various use cases.
    - Christian said he was content with that.
- Hans asked for any additional comments. There were none.
- Hans moved on to Pharmacy Quality Measures. He noted updates and summary of specific quality measures related to value based care (VBC) versus those relevant to the pharmacy setting.
- Christian said he had another example that may be added.

- Hans asked him to note it in the comments and asked if anyone had any concerns with those already added. There were no objections.
- Hans moved to R27 and noted suggestions for migrating text from the recommendation to the rationale. He also noted the addition of Fil Southerland's suggestion to reference Health Data, Technology, and Interoperability (HTI-1). He asked Fil if the addition was sufficient.
- Fil said it was.
- Hans asked if there were any questions or comments regarding the text moved to rationale. There were none.
- Hans noted that R12, 32, and 11 were discussed as part of topic 1 and defining quality measures. He reviewed the questions of whether all three recommendations were needed or if they would be better combined. He then noted that R11 was kept as is, R12 was focused on interoperability capabilities and kept where it was, and R32 would be merged with R11.
- Shelly asked if the subtopics would be included.
- Hans said all subtopics would be included. He noted that R11 and R32 would be merged and R12 would stay as is because it was not about quality measure but interoperability capabilities. He noted Steven Lane's update and asked if there were any additional concerns. There were none.
- He reviewed the suggestion to merge R13 and 14 and further suggested keeping them apart. He asked the group for comments.
    - Summer Kahlon said if both modes of communication addressed are freeform then they should be combined, if one is transactional and the other is freeform then they should stay separate.
    - Hans said he read the recommendations as related but different and thought it best they stay separate because they addressed different areas.
    - Summer said that as written, they should be combined.
    - Anna shared her personal challenges with getting her prescriptions filled and noted that she thinks the recommendations are related but distinct.
    - Christian said they should be separate but need refinement for clarity and detail.
    - Hans reiterated the opinions of the current discussion and noted that if the distinction can be made clearer between the two then they can be kept separate.
    - Alexis agreed that they can be kept separate as long as the language is rewritten for clarity and to reduce redundancy. She suggested wording that suggests a mandatory universal process for pharmacies to allow two-way communication on mobile apps.
- Shelly said she opposed the word "require" as ONC has no jurisdiction to place any regulatory requirement on pharmacies for this. She agreed with Alexis' suggestion. She was concerned with the word "require" from a regulatory standpoint.
    - Hans agreed that "required" may be too strong for a recommendation. He said there will be edits after this meeting and they will be shared immediately. It will not need to be discussed in the next meeting.
    - Shelly asked David Butler to explain his comments on R13 and 14.
    - David said the purpose of R14 is to accomplish R13 and suggested adding "in order to improve pharmacist, patient/caregiver interaction for such needs as…" to the end of the first sentence in R14 and creating a list of needs. The first on that list would be R13 because that is the end goal.
- Hans said it needed additional wordsmithing that will be shared with everyone once done for a final review.
- Shelly asked if most wanted it combined or separated.
- Hans said there was no clear preference for either as long as the purpose of each was made clear. He asked if anyone had any objections. There were none.
- Shelly asked which category R32 pertained to.
- Hans said specific interoperability capabilities of particular interest and R11 is about quality measures. He noted that the purple text in R11 were the additions lifted from R32. He then raised two

questions, did the purple text sufficiently reflect R32 and should the word “their” or “urgent” be used.

- Anna said she does not think “urgent” serves a purpose as the definition of what is urgent is relative.
- Hans asked if there were any objections to using the term “their.”
    - Christian said he was still struggling on how to further focus the recommendation. He said that it does not have the best wording and does not see it as a quality measure. He added that his issue is not with “urgent” but with putting a quality measure on convenience and he does not think it is appropriate for the recommendation.
    - Hans said it would be difficult to make that level of change now considering the discussions that took place.
    - David said there needs to be a way to capture and use data to improve all aspects of pharmacy. He suggested replacing “their/urgent” with “all prescriptions in a way that optimizes patient care and convenience.” That would be a more comprehensive recommendation.
    - Hans suggested using “fill prescriptions” to cover any kind of prescriptions.
    - David said that would be more succinct, “all” would encompass every aspect.
    - Hans asked if there were any objections to “all.”
    - Pooja Babbrah said there is a definition of “urgency” as used in electronic authorization and asked if anyone present had more insight on it. She noted the need to keep “urgent” in the recommendation.
    - David said that the inclusion of “all” would encompass the urgent, the routine, and anything in between and agreed with including “urgent” somewhere in the text.
    - Pooja suggested looking at the definition of urgent used for prior authorizations.
    - Christian agreed with “all” but suggested adding further clarification that it would be centered around increasing communication and medication management visibility for the patient and not the dispensing of the medication.
- Hans asked if adding “all prescriptions” and including “routine to urgent” would be satisfactory. There were no objections. He followed up by asking if there were any concerns with removing R32.
- Shelly noted Margaret Weiker’s chat comments referencing a Centers for Medicare and Medicaid Services (CMS) notice of proposal of rule regarding prior authorization time frames. She added that it may be a place to look for some definition of “urgency.”
- Alexis said she agreed with any word used though she noted that using “all” assumes a patient is getting all medications at one place. She added that whatever word is agreed on would need to be changed in the rationale as well.
- Hans asked if there were any additional comments. There were none and R32 was removed.
- Hans reviewed comments on R4 suggesting merging R4 and R9 as they are very similar. He directed the group to the new combined wording under R9 and asked for comments or concerns. There were none and the recommendations were combined.
- Hans reviewed suggestions added to reference HITAC recommendations four and six. He asked for any questions or concerns. There were none.
- Hans reviewed Alexis’ comment on R19 saying the rationale was not clear. He noted the edits and asked Alexis if it was now clear.
- Alexis said yes.
- Hans asked for any additional questions or concerns. There were none.
- Hans reviewed David’s note on R33 and asked if he had a list of examples.
- David added the list.
- Hans asked anyone with additional suggestions for the list to let him know.
- Hans returned to R38 and noted that he did not see any additional suggestions. He asked if adding a footnote that clarifies the charge and using the term DTC in conjunction with virtual care and telehealth and referencing only virtual telehealth in the rationale was sufficient to finalize this recommendation, or if Tricia Lee’s suggested text should be included.
    - Christian asked if siloed or disconnected care models were considered in this

recommendation. He asked if this was outside of the primary care arrangement or if it was broader. He suggested considering the distinction.
    - Hans answered both and noted that it was different in that the patient does not see the provider in person.
    - Christian said if this care is distinguished from traditional means of care than the distinction should be made.
    - Steven Lane said it is a new distinction, care separated from the established care team. He added that other terms reference only the technical aspect of providing care, i.e., location.
    - Hans asked if there was a definition of what providers can constitute a care team. In his opinion virtual health providers would be included.
    - Steven said it is a new area that has not been discussed.
    - Scott Robertson said they have had many discussions on the "patient care team" but have not defined it. He said that virtual health providers, and others, need access to a patient's medical history. Primary care providers need access to that information.
    - Alexis elaborated on Scott's comments and added that if a patient chose to see any provider, they should be considered a part of that patient's care team. She suggested adding wording that identifies virtual health as something that is outside of the traditionally accepted modes of delivering health care services.
    - Anna said she was not clear on the issue here. She noted this as an issue of modality and not care. She noted no difference in "virtual care provider" versus "traditional practitioner". She gave an example of a provider she has seen virtually since the pandemic and noted no difference in the care she received virtually as compared to the care she received from him in person.
- Shelly reminded the group that these providers may have different insurance payer models and do not have the same regulatory requirements to interact with providers as physical pharmacies do. That lack of regulation warrants a need to share patient information. She suggested adding "after the current network of providers."
- Hans asked for clarification on what is meant by "network." He still thinks they are part of the team.
- Anna suggested using "nontraditional care settings."
- Shelly said they were still missing the point of the patient interaction with a provider who is not sharing any pertinent medical data with any other provider.
- Hans agreed with Anna's suggestion. He added that although they may not be part of the insurance network, they are part of the patient care team and noted "nontraditional" as inappropriate. He suggested continuing wordsmithing offline. He asked for any additional comments or concerns.
- Anna noted that none of her traditional providers communicated with each other, and that it was a false distinction to make. She added that these services are covered by insurance.

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

None received.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Shila Blend: Shila Blend -Present

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

Mike Berry (ONC): Please remember to select "Everyone" when using the Zoom chat. Messages to "Everyone" will be included in the meeting notes. Thanks!

Christian Tadrus: "Other than the patient's primary care provider"?

Steven Lane: There are LOTS of virtual care providers doing some version of this.

Pooja Babbrah: should we say online pharmacies or online pharmacy services

Hans Buitendijk: Note we removed the acronym "DTC" and spelled it out everywhere.

Deanne Primozic: +1 Steven, agreed. Examples would be helpful

Afton Wagner: @pooja, I was thinking that as well but online pharmacies may also come with a negative connotation (Rogue online pharmacies, etc.)

Pooja Babbrah: Afton - if these pharmacies need to be certified, maybe we say certified online pharmacies?

Afton Wagner: That could be a good compromise

Summerpal Kahlon: Maybe the distinction here is that they are full online medical services, not just pharmacies

Steven Lane: One key point with DTC medication offerings is that the consumer often does not know what type of prescriber is approving their meds - a pharmacist or a physician. I think that it makes sense to encourage transparency in this regard.

Summerpal Kahlon: @steven, agree

Doug Mirsky: WRT the current edits in 38, from the perspective of DiMe, Telehealth is a subset of Virtual Care rather than an “or”.

David Butler: R12 is certainly about capability, but it is also addressing a current deficiency in our healthcare system where Payors - and the impact they have on care - has not been sufficiently included in healthcare interoperability. This should leader to greater evaluation of Payor quality measures as well regarding their impact on both the patient and the healthcare team for that patient.

Summerpal Kahlon: Seems with the description, we're saying they are distinct. Suggest we clarify the text in R13 to be clear they are standardized transactional responses based on NCPDP standards, but made available to the patient in addition to typical users of the standard

David Butler: I suggest combining by adding the following phrase tot he end of R14: in order to improve patient care through greater pharmacist-patient-caregiver interaction for such needs as:" R13 could be included with a list of examples.

Pooja Babbrah: I can’t seem to raise my hand. Isn’t there a concept of urgent with electronic prior auth?

Margaret Weiker: Yes, there is an indicator in the SCRIPT Standard. There is a CMS NPRM regarding PA and it includes timeframes.

Margaret Weiker: Under existing regulations for standard prior authorization decisions, MA organizations

> and applicable integrated plans must make a decision and send notice of that decision as
>
> expeditiously as the enrollee’s condition requires, but may not exceed 14 calendar days
>
> following receipt of the request for an item or service. Under certain circumstances, a plan may
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> extend this 14-calendar day timeframe consistent with the rules at § 422.568(b)(1)(i) or §

422.631(d)(2)(ii). Similarly, for standard prior authorization decisions, Medicaid managed care plans and CHIP managed care entities must make a decision and send notice of that decision as expeditiously as the beneficiary's condition requires within state-established time frames, but may also not exceed 14 calendar days following receipt of the request for an item or service.

Margaret Weiker:

> Under these programs, if a provider indicates or the payer determines that following the standard timeframe could seriously jeopardize the patient's life, health or ability to attain, maintain, or regain maximum function, the MA plan, applicable integrated plan, Medicaid managed care plan, or CHIP managed care entity must make an expedited authorization decision and provide notice as expeditiously as the beneficiary's health condition requires, but no later than 72 hours after receiving the request.

Doug Mirsky: For consideration by the panel "…to address the needs for and approach to sharing data captured through virtual first care interactions, that may include direct-to-consumer or telehealth, where pharmacists are included, as they interact…"

Alexis Snyder: Its not just modality, its care outside of a health system such as HIMS, providers who prescribe Ozempic or those who prescribe MH drugs outside the sytstem for example

Alexis Snyder: To Shelly, its more than outside the network, as many patients see multiple specialists across multiple networks

Alexis Snyder: "Offsite non-traditional provides outside non connected with a large health care system"

Alexis Snyder: *providers

Alexis Snyder: * and not connected with

Alexis Snyder: *the larger a large health care system

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

Task Force Work Planning

- Hans reviewed the tasks to be done offline and noted that changes would be sent out for review.

Resources

Pharmacy Interoperability and Emerging Therapeutics 2023 Webpage
Pharmacy Interoperability and Emerging Therapeutics 2023 – October 25, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

The meeting adjourned at 12:00 PM.