



Health Information Technology Advisory Committee

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Virtual Meeting

Meeting Notes | August 23, 2023, 10:30 AM – 12 PM ET

Executive Summary

The goal of the Pharmacy Interoperability and Emerging Therapeutics Task Force meeting on August 23 was to continue the discussion surrounding Task 2b and 2c and introduce Task 2d: What can ONC do to address drug inventory transparency for prescribers and consumers? A guest speaker joined the call and presented information to further the discussion regarding drug transparency. A robust discussion followed.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	Opening Remarks
10:40 AM	Task 2b Use Case Review and 2c Recommendation Discussion
10:55 AM	Task 2d Introduction: What can ONC do to address drug inventory transparency for
	prescribers and consumers?
11:00 AM	Guest Presentation
11:05 AM	Task 2d Discussion
11:50 AM	Public Comment
11:55 PM	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 Chris Blackley, Prescryptive 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 Anna McCollister, Individual Ketan Mehta, Micro Merchant Systems Alexis Synder, Individual Scott Robertson, Bear Health Tech Consulting Fillipe (Fil) Southerland, Yardi Systems, Inc. Christian Tadrus, Community Pharmacy Owner Sheryl Turney, Elevance Health Afton Wagner, Walgreens

Members Not in Attendance

Deven McGraw, Invitae Corporation Justin Neal, Noble Health Services Eliel Oliveira, Dell Medical School, University of Texas at Austin Naresh Sundar Rajan, CyncHealth

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 discussions on Task 2.

Task 2b Use Case Review and 2c Recommendation Discussion

- Hans Buitendijk reviewed the agenda. He reviewed Task 2b and 2c in detail while reorienting the task force with the new spreadsheet organization. He asked if the new layout is helpful for improved data organization.
- Steven Eichner noted that non-technological policies should be considered. He also suggested including the role of public health.
- Hans said Topic 1 includes public health emergency comments and wants to minimize overlap.
- Steven Eichner clarified that he was referring to topics not related to technology.
 - Hans asked if moving Steve Lane's comment regarding safety to the governance policy column would be a good example of what he meant.
 - Steven Eichner said yes.
 - Steven Lane had no objection to the move.
- Steven Eichner said his objective is to make the spreadsheet easier to navigate.
- Summerpal Kahlon said that much of their discussion around value-based care has been regarding data exchange between patient and provider.. He noted that focusing on fill data exchanged between the pharmacy and health plan can close gaps to meet quality measures.
- Shelly said there is an issue of connectivity and accessibility. She added that fill status was

added to United States Core Data for Interoperability (USCDI), but it is an optional field for eprescribing.

- Hans asked if there was a specific recommendation to advance sharing fill data with the payer.
- o Shelly answered, making it a mandatory requirement as part of certification.
- Hans asked for certification of whom.
- Shelly answered the certification of Electronic Health Record (EHR).
- Hans asked if certification would be solely on the provider's side.
- Shelly answered that it needs to be turned on and required on the prescriber side.
- Hans asked what would be helpful for understanding where gaps exist.
- Pooja Babbrah said there are standards in place, but stated data is not uploaded uniformly. There are issues accessing data for the uses it's need for. She suggested looking at how data is being accessed.
- Hans asked Pooja and Summer to add notes clarifying which parties would need to adhere to or implement those capabilities.
- Christian Tadrus referred to his comment in the chat. He added that recommendations focused on who needs access to what information to reduce transaction counts for payers.
- Chris Blackley said the fill transaction is not a required standard. He added that pharmacies must pay a fee to transmit a non-required transaction, making it a disincentive. Making it a required standard would solve that problem.
- Afton Wagner added that receiving the information in a readable format and prioritizing correctly is necessary for bidirectional facilitation. She asked how will the data get to the payer in an economical way?
- Summer said his additional comments were in the chat and added that it is important the provider not become an intermediary when closing these communication gaps.
- Hans asked everyone to note any additional comments in the spreadsheet.

Task 2d Introduction: What can ONC do to address drug inventory transparency for prescribers and consumers?

Shelly introduced Task 2d and the guest speaker, Phillip (Phil) Lettrich, RPh.

Guest Presentation

Phil gave a presentation regarding drug inventory transparency. He reviewed the purpose of the Pharmacy Product Locator Task Group and gave an update on their progress and status. He noted the task group is under the umbrella of the National Council for Prescription Durg Program's (NCPDP) Work Group 11. He also went into detail on their working parameters and discussed the benefit of drug transparency for patients, prescribers, and pharmacies. He noted that the task group is currently on hiatus.

Discussion:

• Anna McCollister noted that this issue is important to her personal pharmacy experience. She added that the current "just in time" inventory management system is exasperated by inventory shortages. She suggested the patient be able to see a full inventory stock and not just medication availability.

- Shelly asked Anna what she recommends the ONC does to increase pharmacist/pharmacy communication with the patient.
- Anna recommended making some data elements visible to patients. She said specific medication inventory information should be provided, i.e., varying denominations of medication, manufacturer information, and anything identified as a filter of what can and cannot be prescribed.
- Summer agreed with Anna. He noted the importance of including public health emergencies in recommendations made. He noted regional emergencies, like natural disasters, be included, as well as global health emergency events like the COVID-19 pandemic. He asked how standards would be constructed to include all applicable stakeholders.
- Shelly asked if there were any recommendations for that. She asked if a task force or educational session would be appropriate.
 - Summer suggested a transactional or registry standard should be considered for more stakeholders than just providers and patients.
- Scott Robertson raised concerns over open access to drug inventory and security. He suggested more specific use cases as they are still very general. He added that a query could be useful; however, it may become burdensome for pharmacies with a large volume of patients. He shared concerns that a registry is difficult to keep up to date since inventory is so dynamic and could be used by nefarious actors.
- Phil said they are taking a "crawl, walk, run" approach and noted the importance of focusing on today's solutions and building upon those for the future. He addressed Scott's concerns for inventory security and added that filtering inventory queries by inquiry type, i.e., physician, pharmacy, patient, could be a solution. He noted that corporations would be more open to making a query over creating a registry. He mentioned that the data elements needed for a query already exist in the standard.
- Anna recommended changing the discussion perspective from pharmacy-centered to patientcentered. She said that all points raised are valid, but each of those points inhibits a patient's ability to maintain their health independently. She reiterated the need for specific medication inventory data visibility. She said the solution needs to be patient centered.
- Alexis Snyder agreed with Anna and reviewed a use case based on her personal experience dealing with a lack of medication availability. She said when a medication cannot be filled, the burden falls to the patient and provider to find an alternative prescription, and it can be a lengthy and cumbersome process. Coordination of care needs to be improved, and solutions are needed.
- Steven Eichner noted that there was inventory control and accountability during the COVID-19 public health emergency and used Texas as an example. He asked if an automated phone inventory information system is in place at any health system. A fist step could be to use inventory management systems to populate automated voice response queries.
- Shelly said that would be complicated to do with multiple drugs and situations.
- Steven Eichner said this would be an initial steppingstone to build on.
- Shelly said a recommendation is needed to define a process that would work for all parties involved from patients to wholesalers.
- Hans said there may be an opportunity in targeted queries. He asked what ONC can do to assist in advancing the work of NCPDP's Pharmacy Product Locator Task Group.
 - Shelly asked if a playbook or a tool kit of some kind might be a good recommendation.
- Anna reiterated that data points already exist that can facilitate this process.
- Scott said inventory is electronically managed but is not as robust as perceived. He added the pharmacy can only share the information they have. He noted that it will take some time to implement a solution.



- Shelly agreed that it is a very complex issue. She referred to Summer's comment in the chat and asked Phil if he had any other comments or questions.
- Phil said this effort is driven by patient and consumer needs. He used the Amazon inventory management system as an example of consumer expectation and inventory management possibilities.
- Anna agreed it is possible.
- Steven Eichner reiterated that the solution needs to be patient-centered without burdening the workflow.
- Shelly agreed and said that the initial recommendation should be identifying several specific use case scenarios. She suggested forming a group that would identify these use cases.
- Hans reviewed the spreadsheet and asked if there were any comments that stood out. He also asked for any specific recommendations and agreed forming a group would be beneficial.

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

None received.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Michael Berry: Welcome to the Pharmacy Interoperability and Emerging Therapeutics Task Force.

Michael Berry: Please remember to tag "Everyone" when using Zoom chat. We welcome your feedback.

Alexis Snyder: Quality measures added from last meeting by Hans are noted as Jake's comments- they are actually mine from chat last meeting

Pooja Babbrah: agree

Afton Wagner: Yes, agree with separating any policy/non-tech related recommendations

Katie Russell: Agree on getting fill data to health plan

Pooja Babbrah: we also added some adherence related data elements to V4 of UCSDI

Alexis Snyder: If adherence data were to be added to USCDI V4 it would also need reasoning for nonadherence

Hans Buitendijk: So should we move Summer's comment to the Governance/Policy section?

Pooja Babbrah: I'll add that to the notes

Hans Buitendijk: Pooja: Thank you!

Summerpal Kahlon: To clarify my comment, it is about getting the data from pharmacy to health plan

Scott Robertson: there is a potential privacy issue with sending all dispenses. Some patients may not want a "psych" med known to the payer and thus the employer

Summerpal Kahlon: the use case to get the fill data to the provider is different, its more about effective prescribing and care processing

Kristol Chism: +1 Chris

Summerpal Kahlon: getting it to the health plan is about analytics and reporting



Pooja Babbrah: +1 Scott

Pooja Babbrah: This ties into patient eConsent

Summerpal Kahlon: forcing the fill data to flow through the provider to the health plan places a bottleneck and agdditional burden on the provider as the intermediary

Pooja Babbrah: patient consent

Alexis Snyder: +1 to Scott

Alexis Snyder: *if out of pocket able to not share data but all who use insurance to pay we will create a large disparity for those who may not want data shared but cannot afford out of pocket cost

Richard Sage: +1 to Summerpal

Summerpal Kahlon: There's a challenge holding health plans accountable for delivering quality, but then saying patients can choose not to share the data that indicates they are receiving quality care

Catherine Graeff: Clarify is this price transparency or pharmacy inventory transparency?

Alexis Snyder: Yese Ike I am aware-my point is if ONC sets a rule that coverage by insurer 100% gets reported but out of pocket does not need to be that will be a problem

Margaret Weiker: How to Join a Task Group:

If you are a current participant in the NCPDP Collaborative Workspace, just check the task group on your NCPDP Collaborative Workspace User Profile. (The User Profile is on the right.) You can join the NCPDP Collaborative Workspace for free; instructions on how to join the Collaborative Workspace can be found at the following link: https://standards.ncpdp.org/Standards/media/pdf/EmailToExistingTaskGroups.pdf

Hans Buitendijk: A recommendation for not sharing data where ONC could help out is that as part of its privacy and consent initiatives that the scope includes not only the provider side, but pharmacy-payer communication as well that needs to support whatever the resulting privacy and consent management infrastructure/standards end up being.

Shelly Spiro: @Hans+1

Hans Buitendijk: Are we on another slide?

Alexis Snyder: Patient needs to know where they can get the drug when not available and/or pharmacist work with provider and patient to decide on different dose or different drug if need be

Alexis Snyder: @Anna-yes! Most times cannot even get threw and delays care and outcomes

Summerpal Kahlon: Question for the pharmacists here - where is inventory data stored? Is it in the pharmacy management systems where the SCRIPT standard typically interacts?

David Butler: With DSCSA serving to create a national data warehouse of all product inventory, standards must consider the ability and need for pharmacists and software vendors to be able to track product unit-of-sale from manufacturer to patient. This will improve the quality of care, as well as allow the creation of analytics to help pharmacists predict and anticipate matching supply chain inventory with each patient's needs.



Scott Robertson: @Summerpal - usually inventory is managed, or at least replicated, in the same system as the prescription processing/dispensing system.

Summerpal Kahlon: Thanks @Scott

Alexis Snyder: Agree with Anna, the amount of time spent without solutions for patients and caregivers needs to be improved. Many delays in care and therfore poor outcomes

Afton Wagner: @summerpal we have an inventory management systems for this

Steven Lane: @Anna - Thank you for sharing your personal experience. It is SO important to bring this first person patient perspective to this discussion.

Alexis Snyder: Yup-monthly for injectables too

Pooja Babbrah: +1 Steven - thank you, Anna for the patient perspective

Katie Russell: The pharmacy world is still claim driven and providing their stocks and sending it to a place that isn't in their Chain, they do not receive reimbursement for that. To me this feels like a function that a health plan or PBM plan should provide as an adherence solution

Catherine Graeff: What about the common situation where the pharmacy dispensing system which received eRx is not connected to the inventory management system?

David Butler: Current reimbursement regulations encourage separation of drug product (e.g., insulin), from device (e.g., pump) in dispensing channels. Thus, patients are restricted to getting their drug only from the pharmacy and their necessary device only from a DME medical supplier and PBMs reimburse only the drug, while health insurers reimburse only the medical device. This creates many opportunities for lack of coordination and the resulting failure to provide a patient with proper care, plus creating frustration and anxiety for the patient as well. Standards should more closely align drug with all associated medical equipment and medical supplies.

Alexis Snyder: And its not only inventory many times there are shortages and can't be ordered and then patient and provider need to figure out substitute dose or drug and is that available etc, does pt need new PA etc

Pooja Babbrah: +1 Cathy G

Hans Buitendijk: This seems like an appointment slot query: is there enough to fill what I need? and hold it for a short time to actually route it to that pharmacy? Thus not providing a full inventory response.

Lisa Schwartz: Agree with Scott's comment that inventory is very dynamic and inconsistent ways people will use inventory info will lead to disappointment. It's just a point in time and what is in stock at noon may be gone twenty minutes later.

Afton Wagner: Agree with @Lisa, an inventory query is a snapshot in time and changes dynamically

Katie Russell: That's an interesting point, Scott. And unfortunately some of the meds that have had shortages like ADHD meds are controlled meds and are a good use case because of the shortage but also may be ones that people are looking to steal

Katie Russell: I also think that if were giving patients information it could cause much more frustration when it looks available but they aren't able to get it because the inventory change is so dynamic



Shelly Spiro: @Katie agree and not just steal but miss doses that can cause clinical problems.

Afton Wagner: @Katie - agree, it can also be ordered and reserved for a specific patient

Alexis Snyder: Real time access and solutions

David Butler: I agree with Scott regarding a registry. However, interoperable standards should allow real-time communication through the cloud to both a data center (data warehouse) and all data records along the edge. Registry should be replaced by machine learning-based trees that connect all data from suppliers and dispensers. Then the pharmacist's local system can join these records with their patient records.

Summerpal Kahlon: As a provider, I think a point transaction using SCRIPT in the context of epresribing makes a lot of sense

Alexis Snyder: Hear hear to Anna

Summerpal Kahlon: In a public health emergency, would using a SCRIPT standard require that a prescriber on behalf of the public health agency do the query?

Scott Robertson: Agree about access, but what is "access" really mean. One extreme - "do you have x tabs of y product". I'd support that (and it may be too strict). another extreme - "what products do you have" - something I would not support.

Hans Buitendijk: Not to go in the weeds here, but queries based on confirmed, trusted prescriptions may ease the concerns with responding to an availability request. Are those types of considerations part of the NCPDP's workgroup's scope?

Summerpal Kahlon: Would it need to be done 1 med, 1 patient at a time in that scenario? Is there maybe a batch HL7 transaction that fits that scenario? not necessarily to a registry, but to a workflow system like the pharmacy inventory management system

Scott Robertson: A variant to include: a "small broadcast" to local pharmacies asking "do you have x tabs of y product".

Summerpal Kahlon: @Scott,that makes sense

Mary Kay Owens: Pharmacies could assist patients and prescribers by having a dedicated number to send text messages to rather than having to call.

Shelly Spiro: @Alexis so are you saying someone should be a care coordinator for access to medication issues? Who will be paying for those services? Is this a health plan issue?

Scott Robertson: extension to the idea: "do you have x tabs" -> "yes; "please 'reserve' x tabs, eRx to follow" (scope creep)

Lisa Schwartz: @Scott - yes...query needs to be followed by an eRx, a paid claim, and timely pickup. Languishing in will call or being returned to stock is inefficient.

Alexis Snyder: @Shelly, yes-someone needs to champion threw the process and care coordination at provider level is billable and perhaps can be on pharmacy level.

David Butler: Keep in mind that all trading partners must now add to an electronic log when a unit-of-sale is transferred between the participants. All of this is electronic, all of it could be made available via the DSCSA-



mandated interoperable standards, so software vendors should be able to access these data for predictive and prescriptive analytics in real-time.

Alexis Snyder: It all goes back to the ineroperablility between pharmacy and provider taht also needs to be transparent to patient/caregiver. Provider needs access to availability and send to pharmacy where avail that patient is able to access. If then not avail when pharmacy gets rx pharmacy should have responsibility to let provider know and then provider or pharmacy champions the process of where to get or works together with patient to determine new drug/dose etc.

Lisa Schwartz: DSCSA is not a solution for tracking inventory. Dispensers use the serialized package ID primarily for purchase records and not dispensing. The supply chain is also concerned about the privacy of that data to guard against introducing fraudulent/counterfeit product.

Alexis Snyder: Just like the ICAD task force pushed for transparency of PA process along the line, transparency along the line of filling drug is needed

Summerpal Kahlon: For the provider query to pharmacy, I would suggest ONC could endorse a finalized SCRIPT standard as the method and establish a recommended workflow framework for effective adoption in the context of eprescribing

Summerpal Kahlon: would be up to industry stakeholders to then drive adoption and utilization

Lisa Schwartz: @christian +1

Summerpal Kahlon: for other stakeholders, I would suggest ONC could convene a dedicated session, perhaps just a 1 day (or less) meeting with a cross-sectional group of public health, pharmacy, and standards (NCPDP, HL7, etc) stakeholders to work through a use case model

Summerpal Kahlon: Not sure if there's an existing standards body/forum that could accommodate that sort of working session of stakeholders/users to establish the optimal workflow

Alexis Snyder: That convening would need patients/caregivers as well

David Butler: Yes, DSCSA is still imperfect. But is a good standard for ONC to take advantage of a build improved access to real-time product location and quality.

Shelly Spiro: @Summer +1 sounds like a good suggestion, but with this complex issue a day's stakeholder meeting should be a start

Alexis Snyder: @Phil-yes!

Scott Robertson: @ Phil +1

Lisa Schwartz: Patient is only sorta the buyer...third-party payers come into play as well.

Katie Russell: +1 Lisa, patients aren't the only consumers in the equation

David Butler: I agree with Phil, and I expand it with another example: Home Depot can tell me how many products are at each store and which aisle and bay where it is located, which I have verified multiple times ;). Keep in mind that retailers have a much larger set of data breadth, depth, and turnover than do suppliers of pharmacy and medical products.

Scott Robertson: a "problem" with the Amazon example: when I am shopping on Amazon, when I find the product and it's available, I create the order. This is what could happen for the prescriber, but the patient can't



initiate the order. If the patient is searching for the product, they have to relay the pharmacy info to the prescriber.

Pooja Babbrah: +1 Shelly

David Butler: I agree with forming a group. Most specific examples both pro an con simply point out that the much higher-level view is that there are potential opportunities to correct the deficiencies to today's system and these should be studied and potential solutions promoted.

Richard Sage: All great points and considerations. I agree that we need to further define Use Cases. The main reason that this task group went on hiatus is due to lack of participation. We need all parties involved in these discussions.

Shelly Spiro: @DavidB +1

Katie Russell: Isn't this problem an information blocking problem? ONC has named covered actors in this and aren't health plans left out of being covered actors?

Summerpal Kahlon: To me it's a bit if a business stakeholder problem. Whatever the correct forum is, the issue of adoption is driven by stakeholders with a vested interest

Summerpal Kahlon: In the public health scenario, the use cases are primarily driven by public health agencies and their need to deliver and effective service in times of emergency

Pooja Babbrah: I have to drop off a little early. Thanks all - great discussion!

Scott Robertson: There are factors in addition to inventory that impact whether the pharmacy can (or should) fill the script. Shelly mentioned REMS. But also insurance, hours of operation, etc. Not saying it can't be done, agreeing that this needs to be considered by a group focused on the patient-oriented use case. (should consider the prescribing process as the patient remains the focal point.)

Scott Robertson: @Christian - I agree. But knowing that the patient's first-choice pharmacy can't fill it will help the patient know where they need to go to pick up the script.

Richard Sage: @Scott - agree with all of your points, but I also agree with Phil's suggested pace... crawl, walk, run. Let's focus on "Yes", "No", "Yes with conditions" initially then build on this.

Scott Robertson: @Christian (on the "maybe we need ...) - I like that idea

Scott Robertson: @Rick - I'm all for "crawl, walk, run", as long as we're crawling in the right direction

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

Task Force Work Planning

- Hans reviewed comments and recommendations made in the spreadsheet and asked everyone to continue adding comments and review comments already made in case they were noted incorrectly. He also reviewed some comments made in the chat.
- Shelly reiterated that the complexity of the issue requires developing specific use cases.



- Anna asked Hans if he wanted them to note specific recommendations or give examples of use cases.
- Hans answered both.
- Shelly added that use cases are vital for technological solution development. She told Anna any use cases identified from a patient advocacy standpoint would be helpful.
- Hans asked if there were any additional examples than those already added.
- Shelly asked Anna if there was any patient consent issue regarding data sharing.
- Anna said not in this case. Inventory is not patient information, and the prescription has already been shared.
- Alexis noted the importance of considering any disparities that may be created regarding patients paying out-of-pocket. Patients who pay out-of-pocket for medications should have a say on who receives that information.
- Shelly also noted that provider burden needs to be considered as well.
- Anna said efforts must focus on individuals seeking care, not the system. She added that increasing relevant data element visibility and accessibility would also help providers.
- Alexis said it is not about shifting away from any patient/caregiver role but rather making it easier to work as a team.
- Shelly agreed and reviewed the Task 3 topic for next week's meeting.
- Hans asked everyone to continue to work on the spreadsheet.

Resources

<u>Pharmacy Interoperability and Emerging Therapeutics 2023 Webpage</u> <u>Pharmacy Interoperability and Emerging Therapeutics 2023 – August 23, 2023 Meeting Webpage</u> <u>HITAC Calendar Webpage</u>

Adjournment

The meeting adjourned at 12:01 PM.