Health Information Technology Advisory Committee

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Virtual Meeting

Meeting Notes | June 28, 2023, 10:30 AM – 12 PM ET

Executive Summary

The goal of the Pharmacy Interoperability and Emerging Therapeutics Task Force meeting on June 28 was to continue the discussion on Short-Term Public Health, Emergency Use Authorizations, and Prescribing Authorities. Six subject matter experts joined the call and provided their perspectives and suggestions to ONC regarding issues within the pharmacy ecosystem. A robust discussion followed.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	Opening Remarks
10:40 AM	SHORT-TERM Public Health, Emergency Use Authorizations, and Prescribing Authorities
11:05 AM	Discussion
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 10:32 AM.

Roll Call

Members in Attendance

Hans Buitendijk, Oracle Health, Co-Chair
Shelly Spiro, Pharmacy Health Information Technology Collaborative, Co-Chair
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)
Steven Lane, Health Gorilla
Jim Jirjis, HCA Healthcare
Summerpal (Summer) Kahlon, Rocket Health Care
Meg Marshall, Department of Veterans Health Affairs
Anna McCollister, Individual
Deven McGraw, Invitae Corporation

Ketan Mehta, Micro Merchant Systems
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Naresh Sundar Rajan, CyncHealth
Scott Robertson, Bear Health Tech Consulting
Fillipe (Fil) Southerland, Yardi Systems, Inc.
Alexis Synder, Individual
Christian Tadrus, Community Pharmacy Owner
Sheryl Turney, Elevance Health
Afton Wagner, Walgreens

Members Not in Attendance

Pooja Babbrah, Point-of-Care Partners
Justin Neal, Noble Health Services

ONC Staff

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

Key Points of Discussion

Opening Remarks

Pharmacy Interoperability and Emerging Therapeutics Task Force Co-Chairs, Hans Buitendijk and Shelly Spiro, welcomed the Task Force, reviewed the meeting agenda, and recapped the Charge. The Task Force members who were unable to join the first meeting, including Adi Gundlapalli, Christian Tadrus, Jim Jirjis, and Meg Marshall, introduced themselves.

SHORT-TERM Public Health, Emergency Use Authorizations, and Prescribing Authorities

Shelly Spiro introduced the subject matter experts.

RDML Pamela Schweitzer, Assistant Surgeon General and 10th Chief Pharmacist USPHS, discussed the public health experience for pharmacists, specifically pertaining to the COVID-19 pandemic. She noted throughout the height of the pandemic; there was an extreme lack of interoperability between pharmacy ecosystems. RDML Schweitzer expressed the crucial importance of data sharing within pharmacies.

Lisa Schwartz, Senior Director, Professional Affairs, National Community Pharmacists Association (NCPA), reviewed the Pharmacists Patient Care Process workflow, as well as a case study on COVID-19 and a Test-to-Treat workflow.

Darren Townzen, Senior Director Health and Wellness Billing and Reconciliation, Walmart, reviewed short-term challenges in pharmacy ecosystems, lessons learned from the COVID-19 pandemic, and suggestions for ONC on next steps.

Chad Worz, Executive Director and CEO, American Society of Consultant Pharmacists (ASCP), provided an overview of the Skilled Nursing Facilities Pharmacy workflow. The workflow was operationalized during the COVID-19 pandemic and has been successful in administering vaccinations in nursing homes. It is a closed-

loop vaccination process. He noted it is critical for ONC and Centers for Medicare and Medicaid (CMS) to understand the importance of vaccinating individuals regardless of their care setting.

Michael Popovich, CEO, and Jason Briscoe, Director of Pharmacy Operations, STC Health, reviewed COVID-19 vaccination efforts, interoperability lessons from past ONC initiatives, and steps for pharmacies to ensure readiness for day-to-day electronic data reporting and exchange. Jason provided suggestions to ONC on next steps regarding health records, refined queries, standards and IT modernization, and data use agreements.

Discussion

- Steven Lane said it would be helpful if pharmacies had access to previous vaccinations, clinical data, and contraindications so any individual can get their immunizations updated properly.
    - Jason Briscoe said he hopes that is the future for pharmacies. He noted pharmacies would ideally become an immunization destination.
    - Michael Popovich agreed with Jason. During the COVID-19 pandemic, pharmacies with two-way data exchange capabilities could assess what vaccinations patients were due for. He added traditional vaccines are beginning to be administered in pharmacies.
- Hans Buitendijk asked about the direction of immunization registries to medication lists and lab tests. What are the current obstacles to getting pharmacists connected? What are the barriers to connecting to health information exchanges (HIEs) and other networks? What are the key challenges to expand connections to IIS or improve data availability?
    - Michael said pharmacies that are partnered with electronic health record (EHR) vendors have success in connecting to HIEs and immunization records. It will be key for ONC to continually invest in modernizing systems to encourage interoperability and the use of frameworks.
- Hans asked about the capabilities to report inventory to different jurisdictions.
    - Lisa Schwartz said historically, inventory levels have been viewed as proprietary. During the COVID-19 pandemic, a lot of inventory was managed tightly. There were also shortages, both widespread and localized. This information might not be useful because it can change quickly, and organizations are usually not willing to present it.
    - Scott Robertson said there is a precedent in the emergency management space for service and inventory requests/response. That could be an example framework to build off.
- Jim Jirjis noted it is an issue that providers do not have readily available access to medication data (i.e. med history, med rec, immunization history) This information needs to be in the workflow.
- Hans asked how far are we on the ability to connect community pharmacists to data sources on med history, med rec, immunization data, clinical data?
    - RDML Schweitzer added that external data sharing should be a priority, especially in emergency situations. Pharmacists can share data within their own systems, but there's no interoperability outside or across systems.
    - Christian Tadrus said reporting access is two-fold. Pharmacist scope of practice changes depending on the state, and some pharmacists do not have access to medication lists. He noted it is a challenge to report to different sources and authorities. Reporting to states is different than federal programs. There are soe issued with business competition and then technical challenges with capabilities to access data.
- Chad Worz noted skilled nursing facilities typically have a smaller population. Nursing homes use a limited number of EHRs.
    - Christian agreed and noted intermediaries provide some access to exchange, but there is variation. Skilled nursing facilities and assisted living facilities have less capabilities and must connect to multiple intermediaries. It is expensive to connect to numerous intermediaries.
- Hans asked does the newer SCRIPT standard meet the interoperability needs of pharmacists? Are there more standards needed to support? What policy limitation exist that prevent pharmacists from using standards to access information?

- Christian also said communicating with the broader care team is crucial. Standardized communication between providers will aid interoperability and ensure alignment with the plan of care.
- Alexis Snyder noted some patients find their community pharmacist to be a retailer and not part of the care team. They may not want their private information shared with them.
    - Steven Lane agreed and said it is a tricky issue. However, if pharmacists are treating and administering medications, they need to be treated as providers and have access to comprehensive health data.
    - Alexis noted there are many people in the pharmacy who may have access to patient information other than the pharmacist. It is a slippery slope of how much is shared without consent.
- Scott said patients should make their own EHR privacy decisions, but they also need to be educated on the consequences of keeping information private.
- Christian noted pharmacy boards set standards of practice.
- David Butler added Alexis's concerns are also relevant in other care settings. The pharmacy industry has evolved. Where infrastructure was built and designed to separate the functions and work of physicians and pharmacists, today, we need to bring the pharmacist and provider together.
- Hans said consent is a recurring theme and was part of the HTI-1 Proposed Rule Task Force discussion and recommendations. It may be beneficial to revisit those recommendations within the context of this Task Force.

PUBLIC COMMENT

Mike Berry, Designated Federal Officer, ONC, opened the meeting up for public comment.

QUESTIONS AND COMMENTS RECEIVED VERBALLY

- Mary Kay Owens noted there are issues with intermediaries blocking pharmacists from information. She would like ONC to create a plan to address this issue. She added that currently, pharmacies do not have standardized patient consent.
- Kim Boyd thanked the Task Force for engaging subject matter experts in this effort. She noted it is crucial to have opportunities for pharmacy system certifications. Bidirectional data sharing is important to expand the role of the pharmacist in the care team. Incentives will also be something to consider as part of the certification process.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Meg Marshall: Good morning. Meg Marshall is here

Hans Buitendijk: @Pam Schweitzer: What reporting methods were used during COVID to share pharmacy "situational awareness" data such as stock, services, availability, etc.?

Pam Schweitzer: Many pharmacies have robust inventory management systems, but there needs to be a standardized way to share the data "outside" their system.

Deven McGraw: "Normalization of sharing information" - such a great comment. Gets at some of the culture/business issues that are so often the obstacle to interoperability…

Heidi Polek: I totally agree Deven. I loved that statement

Fillipe Southerland: Very helpful diagram Chad, thank you.

Hans Buitendijk: One of ONC's roles is maintaining an HIT certification program. Would there be benefits for various interoperability use cases that pharmacy IT would be certified to ease interactions?

Pam Schweitzer: @Hans - absolutely!

Pam Schweitzer: The pharmacy profession appreciates your comments...pharmacies would like to be known for being - community immunizers/destination.

Heidi Polek: Obtaining complete medication lists for patients is very difficult for dispensing pharmacies. How can we overcome barriers that are put into place by companies that manage access to repositories of prescription information?

Kim Boyd: Effective communication and exchange of data with other healthcare systems such as EHRs, PDMPs, HIEs, Hospitals systems could be very beneficial in enabling automated and efficient workflows, reduce manual entry and error. Med list/history is a great target area

Jim Jirjis: Med rec and immunization administration are often skipped in doctors offices due to time constraints and the costly and time intense efforts to find out med and immunization history. Smooth interoperability of both domains into the workflow will create tremendous personal and public health benefit

Kim Boyd: By receiving real-time patient data from EHRs or other sources, pharmacists can make more informed decisions about medication dispensing, minimizing the risk of adverse drug events and improving patient safety.

Jason Briscoe: Agreed, Kim Boyd.

Pam Schweitzer: Medication list - I feel pretty strongly that we need to have the patient engaged in deciding which medication information is shared.

Suzanne Gonzales-Webb: @Pam Schweitzer Absolutely agree.

Kim Boyd: Will TEFCA potentially help resolve the challenge of costs for pharmacist in connecting with HIEs and the cost of obtaining information from this source.

Heidi Polek: Agreed Kim Boyd. How the PMS systems get those connections to hundreds of EHRs will not come easily

Heidi Polek: With some many sources of patient data, how do we determine the source of truth? How do we handle inconsistencies across the various sources to ensure the pharmacy has the most up to date information on a patient?

Steven Lane: One could argue that the safe administration of immunizations requires bidirectional access to both state immunization registries as well as the existing nationwide interoperability framework and component networks/QHINS/HIEs. Such a patient safety standard would appropriately apply equally to physicians and pharmacists.

Kim Boyd: Agreed @Heidi Polek - NCPDP is strategically focused on many efforts to help solve and support a framework for interoperability on many fronts - including Value Based Care, PGx, DTx, Coordination of Care and the convergence between the pharmacy and medical community to solve for patient care challenges.

Mary Awuonda: Great presentations. The issue of buy-in, financial support, and training to advance interoperability issues from pharmacists on the ground -community, clinical pharmacists etc. is critical Any recommendations made from this group would go much further with buy-in from them.
A specific example: is that our college is a champion for our state designated HIE and there were some challenges with local pharmacy's willingness to contribute data to the HIE for various reasons. For the independents -particularly those serving minority communities (where chain pharmacy presence is limited) some of it boiled down to support financial and health IT infrastructural support. What thoughts does this group have to one extend buy-in to galvanize this group.
This is critical because the lack of pharmacy interoperability -if status quo does not improve- will lead to

significant health equity issues for minority/underserved patients as only data will be shared for some and not all.

Pam Schweitzer: Considerations for ONC - to better prepare for emergency response: Sandbox for vendors and pharmacies and public health ecosystem to do table top exercises - ensuring interoperability is working as expected. Communities need to have better training. Also, need human-centered design and minimize glitchy systems.

Deven McGraw: Please reset your chat settings to “everyone” for the discussion so the public can see your comments as well ☺

Heidi Polek: I totally agree Mary A. We need buy-in from other healthcare orgs/provider and their tech solution companies to want to share information with pharmacies

Kim Boyd: Data standardization is a big issue to solve for

Heidi Polek: Another good point Kim Boyd

Pam Schweitzer: Pharmacy needs to be at the table as machine learning and artificial intelligence are incorporated into emergency response preparation.

Mary Kay Owens: As to Heidi's comment this is a major issue where PBMs and other intermediaries are blocking access to dispensing and claims histories for pharmacists needed for test and treat and other clinical management.

Shila Blend: Pharmacy access to drugs which are to be filled would be beneficial. As an example, a pharmacy transfers a prescription for a nausea med to another pharmacy out of town for a patient needing an urgent refill. The next time the patient was filling all of their meds at the pharmacy, they couldn't fill the nausea med due to the prescription transfer and needed to go to a second pharmacy to fill that

Donna Doneski: Does TEFCA impact depend on how IISs are connected?

Deven McGraw: Would love to understand more about “blocking” by intermediaries.

Alexis Snyder: The patient needs to have control over what is shared and when. It cannot be a standard all or none process or “ as simple as sharing billing information"

Mary Kay Owens: Another issue for pharmacists is their lack of a wider patient consent that would inform patients that the pharmacy is accessing and participating in an HIE and will have access to their complete medication and medical data. This is very needed if we are going to practice in an expanded role and be able to communicate with other providers and care team members.

Steven Lane: We should also discuss the challenge of Immunization History Reconcilliation. As with Medication Reconciliation, we need a way for an appropriate professional, working with an individual and/or caregivers, to review and update the immunization history and then make that reconciled history available to all applicable members of the care team and treating providers.

Alexis Snyder: Pharmacies will also have the burden of how they keep shared data private and who in pharmacy can access-such as a tech vs. pharmacist who patient may not want to have access to their medical hx

Chad Worz: 1 in 6 deaths from Covid-19 were in skilled nursing homes and 3 in 4 deaths were in people over the age of 65. Risk factors combined with age combine to identify the most at risk people - whether it is access to inventory for priority populations or access to state IIS information - we have to ensure that RISK helps define the implementation and the compliance with systems pharmacies use to vaccinate.

Donna Doneski: @Chad Agree 100%

Alexis Snyder: @Steven Lane, even when the pt/caregove reconciles the med and/or vaccine hx it doesn't always get updated/reconciled on the EHR side

David Butler: I agree with Lisa's comments regarding shortages. DSCSA creates an infrastructure allowing pharmacist to provide better consulting to patients regarding drug availability. There should be improvements in practitioner access to this data in order to better help patients.

Hans Buitendijk: Do we have an understanding of how many pharmacies are connected to HIEs/networks to get access to a patient's record?

Pam Schweitzer: During emergencies - we need to know where product is.

Chad Worz: Long term care pharmacies have access to nursing home eHRs - for what it's worth. This helps with vaccinations and treatment assessment for things like Paxlovid and Tamiflu.

Heidi Polek: Hans-I don't think a lot of pharmacies currently take advantage of gaining access to HIE data. There is a need for patient consent to access it. I am working with a pharmacy in PA that is in a grant program that will involve utilization of HIE data for their patients.

Alexis Snyder: Agree with David. Providers need to know about availability before sending rx

Shila Blend: I agree with Heidi, our HIE has a few pharmacies we are working with and expanding but only have a minority participating so far

Chad Worz: SNF - Pharmacy relationships could be used as an example for the value of community pharmacies having access to HIEs and eHRs.

Kim Boyd: Relative to Pharmacy connectivity to HIEs, NIH put out a report a couple of years ago. I haven't been able to locate it yet.

Mary Kay Owens: Recommend that ONC investigate the information blocking regarding medication dispensing histories by claims processing entities and intermediaries.

Hans Buitendijk: @Heid - Regarding the need for consent, are pharmacists considered part of the Treatment use case, thus pharmacists could have access similar to other providers? I.e., how big is that consent challenge?

Michael Popovich: For immunizations - Pharmacies connected through HIEs: Not as many go through HIEs today as go direct to the Public Health Immunization Systems. A rough estimate is at most 5% connect through any HIE. Connecting through the HIE is not a problem simply another connectivity step. In general it is easier to connect directly to PH.

Pam Schweitzer: Federal programs should be included with information sharing....noticed during COVID-19 that patients move from VA, IHS, BOP to community.

Steven Lane: What is the situation with professional liability for pharmacists? As a PCP, I am responsible to meet the standard of care for assessing a patient's immunization needs, and safely determining, administering, and documenting the appropriate products. Are pharmacists held to similar standards?

Mary Awuonda: Hi @Hans it varies significantly I also echo Heidi's comments. In Maryland the designated HIE was able to get sharing via the legislature so all pharmacies share I believe. In DC its different there is no sharing. The HIE gets the Prescription data from Claims data. Which for some use cases like checking medication adherence may be 30 days too late

Heidi Polek: IMO, Pharmacists should be considered as part of the treatment team and therefore not need an additional level of patient consent to access HIE data. However, most of the pharmacies that I have worked with have needed patient consent before accessing

Shila Blend: It varies for HIEs as far as prescription info. NDHIN has Dr First with prescriptions as well as the PDMP access for our HIE participants

Alexis Snyder: @Heidi, even if pharmacist where considered part of care team patient/caregiver should be able to decide who sees and can access EHR as they can do now between facilities

Hans Buitendijk: @Heidi, @Mary: Do you see this more as a state, federal, or professional challenge to ease access to a patient's relevant data for a pharmacist?

Heidi Polek: @Hans, IMO, access issues are more related to data blocking by orgs that maintain large repositories of it. There is also a regulatory component to it as well.

Kim Boyd: @Hans I would offer that state policies do create challenges and even opportunities. Some is also long-standing infrastructure and business policy issues.

Hans Buitendijk: @Heidi: data blocking would assume there is a right that is not honored, yet it sounds like there are consent requirements that would indicate there no right (thus no information blocking) unless consent is provided by the patient.

Hans Buitendijk: How can consent requirements be eased?

Mary Awuonda: @Hans I agree with both Heidi and Kim. I also again repeat the issue of Buy-in. There is also a ROI question that comes up. Is it worth it for us to do so. So I feel incentives-broadly almost in the meaningful use context would certainly help

Kim Boyd: @Hans I and I am sure many other patients see my pharmacist as a provider of care and therefore should have access to information to help me make informed decisions about my care.

Heidi Polek: @Hans, at this time, there are orgs that manage large amounts of pharmacy medication history information that prohibit access by community pharmacies

David Butler: This may be larger than this initiative, but ONC should evaluate supporting the creation of general-practitioner partnerships between community physicians-community pharmacists. Building an IT and legal infrastructure supporting enhanced expertise by a combined physician (diagnosis)-pharmacist (therapy) partnership using a standardized, nationwide collaborative practice act would go a long way toward improving care and reducing costs by minimizing need for referrals to more expensive specialist care.

Alexis Snyder: And there are many patients who see the pharmacist as a retail supplier who does not need to know everything about them

Mary Kay Owens: Yes, Heidi is correct and this needs to be addressed by ONC as to why they are able to block access when patient consent has been granted. Pharmacists are part of the care team and need access to all data.

Kim Boyd: As the role of the pharmacist continues to evolve and expand into the clinical care arena, the need for information becomes critical. Consent will help solve for that.

Pam Schweitzer: In general, pharmacy systems are fragmented - it would be ideal to have some type of certification requirements (which incorporates interoperability) for those pharmacists involved in providing clinical services - would need to include financial incentives.

Mary Kay Owens: Consent for pharmacists is no different than that for any other medical provider.

Mary Kay Owens: Agree with Steven!

Alexis Snyder: Agree Steven, but share is still patient choice

Kim Boyd: Pharmacists are also “actors” under the information blocking rule

Scott Robertson: agree, everyone needs to be held to appropriate professional responsibilities, AND the patient is the ultimate arbiter of who gets to see what information

Steven Lane: These same issues or who has access to what information applies to community clinics and hospitals. All health data access is based on a Need to Know.

Suzanne Gonzales-Webb: Pharmacy Technicians are also obliged to follow HIPAA rules/Consent

Pam Schweitzer: @Alexis - I so agree; patient's prerogative.

Shila Blend: would an opt out system benefit in this

Steven Lane: Similarly, as HIPAA covered providers, pharmacists should have the responsibility to follow all requirements with regard to health information privacy and security.

Alexis Snyder: @shila, there is an opt out system between health facilities and should be same for pharmacy

Alexis Snyder: Setting standards and enforcing privacy: accidents and misuse happen and processes in place are for after the damage is done

Heidi Polek: @alexis there will always be some level of visibility into a patient's medical information by unlicensed pharmacy staff. everyone working in that pharmacy is bound by hipaa. as for more advanced clinical info, of course that should be limited to those who truly need it (ie an pharmacy intern or pharmacist)

Steven Lane: It sounds like there may be a need for additional education of both pharmacies/pharmacists and the public regarding the applicability of all HIPAA rules to pharmacy-based care.

Hans Buitendijk: +1 Steven

Alexis Snyder: @Heidi, that is my point. Just bc your help to HIPPA does not make it better if you don’t want that tech to know your medical info-even if they keep it private patient may not want them to know regardless

Hans Buitendijk: While at the same time understanding how already available technology and networks can be advanced, which is an investment/ROI/incentives challenge as there is already a lot of data potentially available.

Steven Lane: I there a history of HIPAA breach reporting by pharmacies? Have penalties been applied in a manner similar to other HIPAA-covered providers? Do pharmacies re-train their staff on HIPAA-related responsibilities annually in the manner that physician practices do?

Hans Buitendijk: Plus it ties back to our consent discussions on how to enable managing that so a patient can have further ability to indicate who can receive their data.

Heidi Polek: @steve yes there is history of violations and penalties. and yes, pharmacies do have policies that include retrain as well as dismissal depending on the level of violation

Deven McGraw: Thank you for more detailed comment, Mary Kay.

Heidi Polek: @steve pharmacies retrain all employees annually for hipaa as well as other topics like fraud, waste & abuse

Jason Briscoe: @Steven Lane. Answers to your questions re: HIPAA and Pharmacies - 3 Yes's.

David Butler: @Steve - yes, pharmacists are required to train by hipaa standards, and have been fined for failures

Shelly Spiro: @Steven OCR might have breach information. Pharmacies are regulated to follow HIPAA rules including policy and procedures for training new and current staff on a regular basis.

Steven Lane: Good to know that pharmacists are meeting their HIPAA requirements. There seems to be a need for public education, based on the comments here from our patient advocates.

Alexis Snyder: @Steven training on HIPPA is important, but again it is first about non-clinical staff not having access to begin with for patient privacy

Ketan Mehta: 100% agree with the certification process comment

Mary Kay Owens: Agree with Kim.

David Butler: @Alexis - non-clinical staff in a pharmacy are not allowed access to hipaa data, just as in a hospital or health insurer or physician office.

Kim Boyd: Thank you to ONC for convening. I look forward to the next call and next steps.

Heidi Polek: @alexis pharmacies typically have policies that limit access to PHI by ALL staff unless there is an active patient encounter. There are many examples of employee dismissal of pharmacy staff when a staff member views a patient profile outside of a prescription dispensing event.

Alexis Snyder: @Shelly @David, the computers are open and screens easily seen and accessed in the pharmacy by techs and others

Heidi Polek: many stories of pharmacy staff fired for looking at med history of celebrities

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

Resources

Pharmacy Interoperability and Emerging Therapeutics 2023 Webpage
Pharmacy Interoperability and Emerging Therapeutics 2023 – June 28, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

Mike Berry reminded Task Force members to add their recommendations into the Task Force Recommendations Planning Document. The Task Force will not be meeting next week, July 3-7. The next convening will be on July 12.

The meeting adjourned at 12:00 PM.