

Health Information Technology Advisory Committee

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Virtual Meeting

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

Executive Summary

The goal of the Pharmacy Interoperability and Emerging Therapeutics Task Force meeting on August 30 was to review the final recommendation draft formatting and introduce Task 3: Identify standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies. Two guest speakers joined the call and presented information to further the discussion regarding specialty medications. A robust discussion followed.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	Opening Remarks
10:40 AM	Recommendation Drafting Example Discussion
10:55 AM	Task 3 Introduction: Identify standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies.
11:00 AM	Presentations
11:10 AM	Task 3 Discussion
11:50 AM	Public Comment
11:55 PM	Task Force Work Planning
12:00 PM	Adjourn

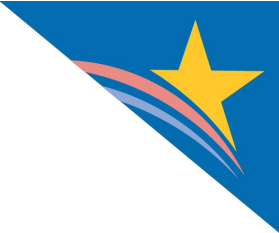
Call to Order

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, Prescriptive
Shila Blend, North Dakota Health Information Network
Steven Eichner, Texas Department of State Health Services
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
Deven McGraw, Invitae Corporation
Ketan Mehta, Micro Merchant Systems
Justin Neal, Noble Health Services
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Naresh Sundar Rajan, CyncHealth
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

David Butler, Curatro, LLC
Rajesh Godavarthi, MCG Health, part of the Hearst Health Network
Sheryl Turney, Elevance Health

ONC Staff

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

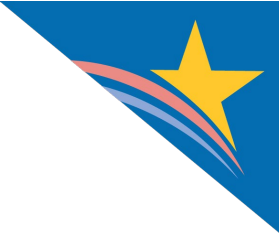
Key Points of Discussion

Opening Remarks

PHIET Task Force Co-Chairs, Hans Buitendijk and Shelly Spiro, welcomed the Task Force and reviewed the Meeting Agenda. PHIET Task Force reviewed recommendation drafting format requirements and began Topic 3 discussions.

Recommendation Drafting Example Discussion

- Mike Berry told the Task Force it is time to begin drafting final recommendations. He reminded Task Force members that they were chosen for their personal expertise and not to reflect the opinions of their respective employers.
- Tricia Rolle echoed Mike's comment regarding recommendation perspectives. She said this is an opportunity for the Task Force to enhance interoperability.
- Hans Buitendijk reviewed the agenda.
- Shelly also reviewed the agenda and reminded everyone to enter comments into the chat.
- Hans reviewed, in detail, topics 1 and 2. He guided the group through the spreadsheet notes and oriented them with the column for final recommendations. He also gave a detailed explanation of how to draft final recommendations.
- Shelly urged everyone to continue to enter recommendations into the worksheet.
- Pooja Babbar asked for clarification on which column to use to edit wording.
 - Hans said editing can be done in column E. He added that if there is a new recommendation or a recommendation is substantially changed, it should go in



column D.

- Tricia noted that consensus is not needed for recommendations.
- Hans agreed and asked if there were any more questions.
- Shelly Spiro noted that all recommendations need to be submitted before November 1, 2023. She urged the finalization of recommendations for Topics 1 and 2.
- Christian Tadrus asked for clarification on the recommendations currently drafted in column E.
- Hans said they are trying to combine similar recommendations to avoid repetitiveness and grammatical clumsiness. He noted that the comments currently in column E are a first pass and not final.
 - Christian asked if those combinations can be noted in column E.
 - Hans said that was a great idea, and he will do that.
- Shelly asked Anna if she needed more time to input her recommendations.
- Anna McCollister answered yes.
- Hans told the task force members to focus on the sections with the green bar for draft recommendations. The red tabs are for historical record.
- Shelly reiterated to everyone to focus on areas with green bar tabs on the spreadsheet. She thanked Hans for all his work organizing the information.

Task 3 Introduction: Identify standards needs to support prescribing and management of emerging therapies including, but not limited to specialty medications, digital therapeutics, and gene therapies

Shelly introduced the guest speakers Pooja Babbar, Task Force Member, Practice Lead, Pharmacy and PBM Services, Point-of-Care Partners, and Justin Neal, Task Force Member, Vice President of Patient Support and Data Contract Services Noble Health Services.

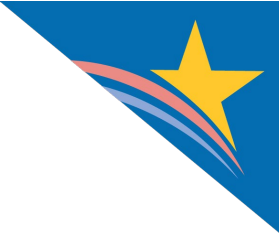
Presentation

- Pooja gave a presentation regarding specialty medications. She reviewed the criteria for defining a specialty medication; she compared medical and pharmacy benefit coverage, as well as specialty prescription volume and spending by coverage type. She presented a hypothetical prescription scenario that highlighted the challenges and unintended consequences of the current specialty pharmacy prescribing process and made suggestions for improvement.
 - Steven Eichner suggested adding patient access to pricing information.
 - Pooja agreed.
- Justin presented an overview of the specialty pharmacy workflow. He discussed technological barriers, opportunities for interoperability, the role of the specialty pharmacy, and national needs. He also presented two hypothetical use case scenarios and provided examples of what feedback specialty pharmacies should be providing.

Discussion:



- Shelly asked if medications are still manually processed at transitions of care and transfers to long-term/post-acute care facilities.
 - Pooja said she has not investigated it.
 - Justin said he has not investigated it either.
- Shelly asked if this is a barrier from a patient advocacy perspective.
 - Justin said it varies from patient to patient, but it can complicate the situation.
- Summer Kahlon asked for clarification on where exactly barriers exist from a standards perspective. He noted that current standards address all barriers mentioned.
 - Pooja agreed that standards exist; however, the information is not shared, and access is limited. She noted that there have been reports of physical medication lists handed to drivers being lost when patients are transferred and not retrieved.
- Afton Wagner asked if centering recommendations around the communication needs of patients to make the patient experience easier would be helpful.
 - Hans said he was curious about Anna's thoughts on that idea from a patient's perspective. He asked Afton if she had any specific thoughts on where gaps may exist in the communication chain.
 - Afton said she would give it some thought.
- Anna noted that currently, communication is mediated through the patient. She detailed her personal experience and the barriers she deals with when getting her prescriptions filled. She added that the crux of the issue is that all necessary data points exist, but there is no efficient data flow. She suggested enabling access to more information as part of the solution.
- Shelly asked Anna if she had ever had trouble getting medications during a hospitalization.
 - Anna said she brings her medication with her.
 - Shelly asked for clarification that her solution to medication access during hospitalization is to bring her own medication instead of letting the care team manage it during her hospital stay.
 - Anna said she would never rely on the hospital to get her necessary specialty medication.
- Steven Eichner agreed with Anna and added the importance of finding a patient-centered solution. He identified another gap in patient medication lists. He shared some personal challenges he has experienced with medication lists. He added that the medication lists do not include any patient education links or resources.
 - Justin said that those resources do exist, but availability is platform-dependent.
- Steven Eichner asked if there should be a certification criterion around functionality.
- Alexis Snyder shared some of the challenges she has also faced with accessing specialty medications during hospitalization. She noted that additional obstacles exist with payers who only cover mail-order pharmacies as well as financial burdens that come from those mail-order pharmacies, i.e., out-of-pocket expenses, data visibility, etc.
- Pooja said she appreciates all the discussion but urged focus on more tangible suggestions. She suggested looking at the information available today, especially within electronic health information (EHI), and building on that.
- Hans said privacy and consent are big topics of concern in the chat comments. He asked if there was any computable consent mechanism to help or if there was any area that needed more attention. He also asked what interactions, specific to specialty medication, contribute to current obstacles. Is there anything additional that has not been discussed yet?
- Pooja said both are important; however, the focus should be on adoption. She noted that data flow, workflow visibility, and price transparency are important, with the primary focus being on the patient. Standards exist but we need adoption and more focus on improving the consumer experience.



- Summer said a primary hurdle lies in parallel standards for processing medical claims and pharmacy claims. He noted that the National Council for Prescription Drug Programs (NCPDP) was looking into harmonizing this issue but is unsure how far they got in the process. He added that the lack of standards to translate between medical and pharmacy eligibility and claims is a concern.
- Pooja referred to her comment in the chat and added that the NCPDP has highlighted this issue and has been working with the Council for Affordable Quality Healthcare (CAQH) to find a solution. She asked Margaret Weiker for comment.
- Anna reiterated that the data points exist; they just need to be made visible to the patient. She suggested allowing patients to view prescription status, receive notifications, etc.
- Steven Eichner said notifications and workflow visibility would place an additional burden on the patient.
 - Anna said that it is not an ideal situation, but at least it reduces wait time.
- Steven suggested a common workflow, visible to all, to mitigate patient burden.
- Shelly said that was a good idea but asked for a separate suggestion for high-cost medications.
- Steven Eichner said pricing is irrelevant. A workflow tool should work for all medications.
 - Anna agreed.
- Alexis noted some additional obstacles facing patients, i.e., technology, language, education, and health barriers. She added that placing the burden back on patients is not a solution.

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT

- Margaret Weiker, Vice President of Standards Development for the NCPDP, discussed Work Group 45, the Benefit Coverage Identification Task Group, and reviewed some of their findings. She noted that a white paper was developed and published with those findings and added a link to a specialty pharmacy resource guide.
- Erin Weber, Vice President of the Committee on Operating Rules for Information Exchange (CORE) at CAQH, gave an overview of CAQH and what they do. She built upon Margaret's comments and noted that CORE has been working with NCPDP to exchange more granular data. She also discussed committee goals.
- Mary Andrawis reminded the group that the charge of this task group needs to cover public health and asked everyone to keep long-term goals in mind and not get stuck on data.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mary Andrawis: Hi everyone, first timer over here. Mary Andrawis, PharmD, MPH. Thanks for having me

Jim Jirjis: Jim Jirjis joined a tad late

Mike Berry (ONC): Welcome to the Pharmacy Interoperability and Emerging Therapeutics Task Force. We are glad you could join us!

Mike Berry (ONC): Please remember to tag "Everyone" when using Zoom chat. Chats to "Everyone" are made part of the meeting notes. Thanks!

Mary Andrawis: So so great seeing you Tricia, it has been FOREVER! I am so excited to be here!

Mary Andrawis: Question about this topic - there are already states which require medication dispense data be reported via legislation and we can use these states as a case study to inform the policy guidance mentioned in this recommendation.



Mary Andrawis: *not a question, just a comment.

Mike Berry (ONC): Slides for today's meeting can be found at:

<https://www.healthit.gov/hitac/events/pharmacy-interoperability-and-emerging-therapeutics-task-force-2023-7>

Mary Andrawis: @Pooja this is a very powerful use case, thank you for sharing.

Alexis Snyder: For many patients it becomes a Manuel process immediately during the prescribing decision as many providers do not check coverage details etc. In the real world most providers send an rx with blind info regarding coverage and then it gets kicked back to the patient from the pharmacy that its not covered, or needs a PA etc.

Christian Tadrus: Visibility to all pharmacies involved in patient dispensing or care services is essential given the routing of some scripts like Specialty to hubs and other dispensing providers. Ensuring all pharmacies know what the hub knows would be key to keeping collaborative care front and center and facilitate more pharmacies to to participate possibly reducing time to medicine in hand (even if it's not the originally ordered prescription).

Alexis Snyder: Adn the patient gets stuck in the middle trying to coordinate the processes needed

Pooja Babbrah: Thanks Ike - we do have an IG we created under the CARIN Alliance for a consumer-facing RTBC which would allow patient facing apps to have the same information on patient pricing that the doctor can see through their EHR

Summerpal Kahlon: It's important to remember that everything the pharmacist needs, the physician/prescriber needs as well. Need to ensure data flow is fully bilateral

Summerpal Kahlon: medication fill history, benefit coverage, pricing, prior authorization status, etc

Steven Lane: All that information captured by the specialty pharmacists constitutes EHI that should / needs to be available to the patient and other care team members to access, exchange and use upon request.

Pooja Babbrah: +1 Steven

Alexis Snyder: +2 to Steven

Kristol Chism: Also, keep in mind with specialty medications, many times this is a higher touch medication in terms of additional patient education/counseling/monitoring.

Hans Buitendijk: Ties into Topic 2 use cases to further underpin the need for bi-directional clinical data exchange.

Steven Lane: Are specialty pharmacies collecting adherence data in a format consistent with the new USCDI v4 data element? <https://www.healthit.gov/isa/taxonomy/term/3446/uscdi-v4>

Christian Tadrus: Community pharmacies often find themselves fielding questions from patients on specialty meds they don't dispense. Not having visibility into care plan / coverage diagnosis, etc. via some mechanism continues to undermine coordinated care. If industry is going to continue to allow for routing of meds to multiple pharmacies for various interests or concerns, we need to close the gap of information between those entities with rails so that bad actors don't leverage patient data inappropriately. So agree with Dr. Lane that access to info by all relevant providers for the patient is needed and probably a patient safety issue.



Hans Buitendijk: I am hearing that managing specialty medications underscore use cases discussed so far. Do you see, compared to what has been discussed so far, additional data requirements that have not been discussed that are unique to specialty medications?

Justin Neal: I think a great deal of the information already exists in the patient chart but to Poojas point this is shared across the spectrum with the health system but is much harder to obtain when you are not integrated into that health system.

Katie Russell: + 1 Justin

Richard Sage: +1 Justin

Christian Tadrus: Quickly catching up to a patient's medication / healthcare journey is challenging for sure. Portability of the medical chart, coverage history, benefits and pharmacies would likely reduce not only time to reestablish care but also minimize dangers inherent to transitions of care.

Mary Andrawis: My experience with some states is that pharmacies can/do have access to the full patient chart, but do not want to have that access or use the access because their workflow does not support it's usage.

Steven Lane: As a physician, I think that the clinical data needs of specialty pharmacists would be the same as retail and clinical pharmacists. They should have the same access to USCDI as any other member of the care team (and should be reciprocally sharing back all such data that they generate).

Pooja Babbrah: sharing patient consent electronically - could this be a certification requirement or wrapped into USCDI?

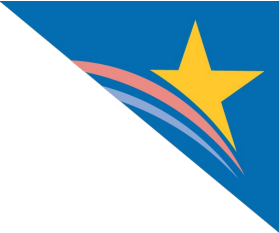
Steven Lane: Providers must have access to the full patient record (unless specific restrictions/exceptions apply). We ALSO have a responsibility, under HIPAA and good sense, to only access and use the minimum necessary information for the purpose that we are accessing the data. Pharmacists MUST have the training, processes, and oversight/auditing in place to assure that they are accessing and using clinical data appropriately. We should not try to support privacy at the expense of access to critical information.

Christian Tadrus: Interestingly, most of the processes of pharmacists managing specialty medications are the same underlying processes for managing less expensive / LDD or complex medications. Benefit investigations / knowledge of drug mechanisms of action, counseling on use and storage, assessment of drugs interactions, etc... all the same and all pharmacists are taught the same process. In that sense, any pharmacy could perform to specialty standards if they have access to data and the product to distribute. Many are already do have "specialty workflow processes" but don't have access to these drugs due to purchaser and mfg interests.

Hans Buitendijk: @Pooja - Consent is not yet part of USCDI, in part I suspect that enabling computable consent management has still some ways to go. Perhaps a recommendation in our Patient Engagement Use Case should include something on advancing the topic of privacy and consent management, using specialty medications as a particular example?

Steven Lane: @Pooja - The closest we have in USCDI is <https://www.healthit.gov/isa/uscdi-data-class/security-label#level-1>. Not Consent per se.

Pooja Babbrah: @hans - yes. I think that makes sense from a recommendation standpoint



Katie Russell: +1 Steven, Also while they need all the training & auditing on accessing the data appropriately but I also think there is a physician provider community that doesn't agree that they have the training to provide more services to the patient beyond filling a script.

Summerpal Kahlon: I feel strongly the solution here is a recommendation that ONC require specialty pharmacies to certify on the ability to send/receive HL7/FHIR data for problems, allergies, medications, and labs and also a requirement to provide a patient portal

Hans Buitendijk: Having computable consent directives based on data and specific sensitivity labels (not confidentiality labels as those are fairly temporal) is the goal/challenge we have to tackle generally, and in the pharmacy context it underscores that need.

Summerpal Kahlon: Similar to EMR system requirements for Meaningful Use/etc

Steven Lane: Recall that HTI-1 is anticipated to include standards for specifying an individual's request(s) for restrictions on the use/disclosure of their EHI under HIPAA. This is the flip side of Consent when it comes to data sharing.

Summerpal Kahlon: The standards exist, the issue seems to be lack of adoption by specialty pharmacies

Steven Lane: @Summer - I will again suggest that we NOT have separate data or format requirements for pharmacists, but to simply treat them like the Providers that they are with the same data access rights and responsibilities as any physician.

Hans Buitendijk: And as such restriction is agreed to, the infrastructure to handle it is the hard part. The current standards have insufficient guidance to yield consistent/scalable implementations, and requires an actual infrastructure to manage and access all applicable privacy rules and consent directives to be able to evaluate them real-time. Current data tagging is not enough.

Summerpal Kahlon: @Steven, we're saying the same thing. Providers are on HL7/FHIR

Kim Boyd: +1 Steven

Katie Russell: +1 Steven

Hans Buitendijk: Current data tagging guidance would leave real gaps that result in either data leakage, or under-sharing where more could/should be shared.

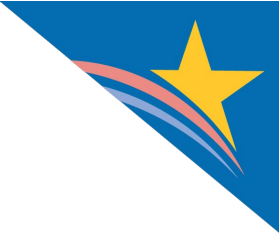
Pooja Babbrah: @summer There is definitely an opportunity for education around interoperability, standards, etc. for specialty pharmacies. There is an organization - National Association of Specialty Pharmacy and I'm on their technology committee. We did a survey and found a real need for education around these topics. We are starting to do some of that and could pull together some recommendations for ONC on where to do some additional education, etc.

Steven Lane: It seems that we are due for an ONC-sponsored workgroup to focus on health data privacy and consent management.

Summerpal Kahlon: @Pooja, I think that's a great place to start

Hans Buitendijk: +1 (or 10) Steven

Pooja Babbrah: @steven- agree. we can build on the consent day ONC hosted. That was wrapped around life stages. It's a good approach of how to look at consent



Summerpal Kahlon: @Steven, agree, the privacy issue is a much deeper topic for discussion, beyond simply moving data from point A to B. Privacy/consent is important to effectively set the rules around that data movement

Summerpal Kahlon: worth a dedicated assessment/discussion

Pooja Babbrah: <https://www.healthit.gov/news/events/discovery-workshop-econsent-birth-end-life>

Richard Sage: @steve, agree!

Hans Buitendijk: Such discussion should not be limited to the standards, but the essential infrastructure to actually make it work.

Alexis Snyder: Exactly Hans, the infrastructures need to be improved to make it wor

Alexis Snyder: work

Mary Andrawis: +1 Hans

Steven Lane: Perhaps the co-chairs could capture the key elements of this consent discussion and suggest this to the HITAC Annual Report Workgroup co-chairs.

Alexis Snyder: The other problem Christian which I'm sure you have seen, is the primary insurer will coverage one drug while the secondary will only cover another and vs. versa, and getting reconciliation to get it covered by both is daunting

Hans Buitendijk: @Ike Informed consent by patients on any topic is critical, which is a mix of all information/impacts clearly understood and patient's responsibility/awareness of the consequences of either choice. But once given, we need to be able then to manage that regardless of how data is being shared (SCRIPT, v2, CDA, FHIR, etc., and proprietary exchange as well).

Kim Boyd: The inclusion of administrative and coverage data into the workflow is key. If front office staff or I as the patient can get to that information via a plan portal or call then that information should be in workflow

Kim Boyd: Pharmacy standards facilitate this information in an immediately everyday

Pooja Babbrah: I know NCPDP is working with CAQH on potential operating rules around eligibility

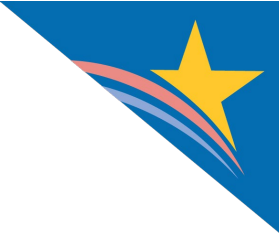
Margaret Weiker: There is not an issue with crosswalking/mapping a NCPDP real-time claim to a X12 837 Claim

Alexis Snyder: @Pooja, not all patients " have the ability " to be the coordinator, but more importantly the patient/caregivers is stuck in the middle trying to get the answers and then coordinate with all the players and there is only so much on that level the pt/cg can actually do to move it forward-so rallying patients to advocate and coordinate is not the answer

Hans Buitendijk: What discussions are currently occurring between NCPDP and HL7 Da Vinci particularly to align in areas where they relate as it seems to be an NCPDP-X12-HL7 relationship as new use cases are emerging where HL7 FHIR is being pursued?

Margaret Weiker: I'll provide more information about the collaboration between NCPDP and CAQH CORE during the public comments period

Pooja Babbrah: thank you Margaret!



Alexis Snyder: +1 to IKE!!!

Pooja Babbrah: Alexis and Ike - good points

Alexis Snyder: @Anna but not everyone is capable of doing it

Pooja Babbrah: I agree and I didn't mean that this burden should be on patient, but I do think if the data is there, patients can choose to look or have it available more informational

Pooja Babbrah: +1 Ike

Justin Neal: +1 Ike

Pooja Babbrah: agree - process should be the same across all medications

Katie Russell: Not only is it a burden to the patient, it assumes a high health literacy of the patient to act on the information.

Suzanne Gonzales-Webb: Agreed. While there may appear to have special considerations for certain drugs, the process should be the same.

Kristol Chism: +1 Katie

Alexis Snyder: @pooja-even if transparent to patient the patient does not have the ability to do much about it except make numerous calls to all involved who all provide different explanations for the problem and what needs to be done

Justin Neal: To Ike and Shelly's point. the reason why so many external resources are put into specialty drugs to get them covered is because there's more dollars to offset that work essentially. If technology could help better all that it absolutely is transferrable to all meds.

Summerpal Kahlon: Seems the first issue of patient transparency is a place to look for info. Do specialty pharmacies need to be required to offer a patient portal the way providers do?

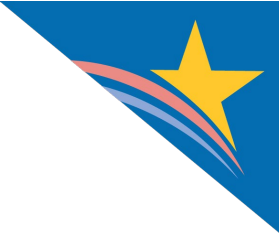
Summerpal Kahlon: At least that creates an electronic medium to begin to access data and information

Alexis Snyder: @Summerpal-we went threw this in the PA task force too and yes transparency and portal for communication would be helpful where all parties could see the same real time information so all are on the same page and no one can provide differing info/communication that continues to hold the process up

Pooja Babbrah: In case we run out of time, I just wanted to address Hans question about coordination between NCPDP - HL7 Da Vinci - WEDI - as it relates to specialty medications, we have several examples where there is coordination. Specifically one Implementation guide that was developed to share additional clinical information between EHR and pharmacy when a specialty prescription is sent over. This was an HL7 FHIR IG given the additional information that needed to be sent was clinical information. This is being used today. we continue to look at opportunities where there is overlap and opportunities to work together with other SDOs

Margaret Weiker: NCPDP task groups are open to any interested party. Information on how to join a task group is available at <https://standards.ncdp.org/Standards/media/pdf/EmailToExistingTaskGroups.pdf>

Steven Lane: Thank you @Margaret!



Margaret Weiker: NCPDP has published a Specialty Pharmacy Resource Guide at <https://ncpdp.org/NCPDP/media/pdf/Resources/Specialty.pdf?ext=.pdf>

The resource guide provides references to Implementation Guides, White Papers and Task Groups.

Suzanne Gonzales-Webb: apologies, need to drop early for another meeting

Margaret Weiker: +1 Pooja

Erin Weber: Information on CAQH CORE current initiatives is available here: <https://www.caqh.org/core/current-initiatives>

Pooja Babbrah: I did put my comment in chat!

Tricia Lee Rolle: No meeting next week!

Tricia Lee Rolle: Enjoy the time off :0)

Pooja Babbrah: thanks all - great discussion once again!

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

Task Force Work Planning

- Hans asked everyone to continue to work on the spreadsheet.

Resources

[Pharmacy Interoperability and Emerging Therapeutics 2023 Webpage](#)

[Pharmacy Interoperability and Emerging Therapeutics 2023 – August 30, 2023 Meeting Webpage](#)

[HITAC Calendar Webpage](#)

Adjournment

The meeting adjourned at 12:01 PM.