



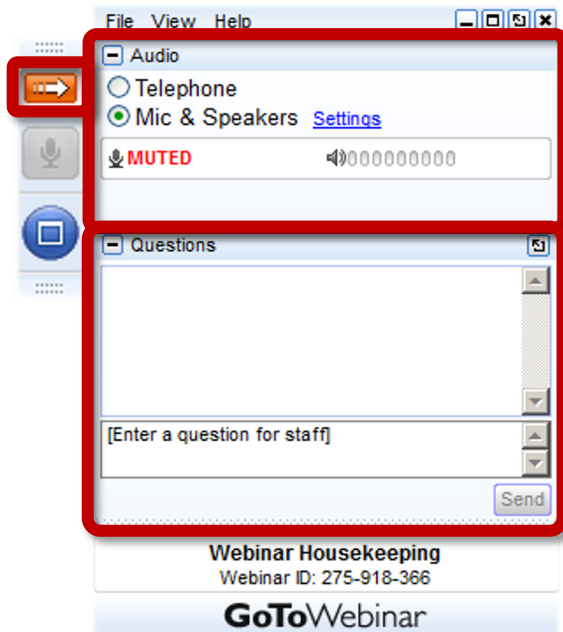
# Interoperability MATTERS

an initiative of The Sequoia Project

## Public Advisory Forum

July 20, 2021

# How to Participate Today



## Your Participation

Open and close your control panel

Join audio:

- Choose “Mic & Speakers” to use VoIP
- Choose “Telephone” and dial using the information provided

Submit questions and comments via the Questions panel

**Note:** Today’s presentation is being recorded and will be provided

Problems or Questions? Contact the Interoperability Matters Team at:

[interopmatters@sequoiaproject.org](mailto:interopmatters@sequoiaproject.org)

# Agenda

- Welcome and Agenda
- RCE Status Update
- Interoperability Matters Work Group Updates
  - Information Blocking Work Group and Subgroups
    - Suggested FAQs
  - Data Usability Work Group
  - Emergency Preparedness Information Work Group
- Discussion

## Leadership Council



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by ResMed



- Audacious Inquiry
- CA Emergency Medical Services Association
- Consensus Health
- Cureous Innovations
- CVS Health
- Hawaii HIE
- Health InfoNet
- Innovacer
- Mayo Clinic
- Virginia Health Information

# RCE Status Update

## TEFCA Timeline and Process

### Timeline to Operationalize TEFCA

#### Summer/Fall/Winter 2021

- Public engagement webinars.
- Common Agreement Work Group sessions.
- RCE and ONC use feedback to finalize Common Agreement V1 and QHIN Technical Framework (QTF) V1.

#### Calendar Q1 of 2022

- Release Final Trusted Exchange Framework, Common Agreement V1 Final, and QTF V1 Final.

#### During 2022

- QHINs begin signing Common Agreement.
- QHINs selected, onboarded, and begin sharing data on rolling basis.





# Clinical Connections: A 7 Week Intensive for Health Plans

## Program Overview

- 7-week course, with weekly Class and Office Hours
- Clinical interoperability focus
- Information Blocking compliance (if HIN); implications for data requestors
- Includes context of other rules (e.g. CMS interop, Transparency in Coverage)



## Class Topics

- Class #1: Information Blocking Overview
- Class #2: What is an Information Blocking Violation?
- Class #3: Exceptions
- Class #4: Exceptions continued
- Class #5: CMS Interoperability-related Rules
- Class #6: Enforcement Issues
- Class #7: Compliance, Organizing for Success, and Wrap up

# Work Groups in Progress

# Information Blocking Workgroup and Subgroups

## Information Blocking Workgroup: June Meeting

- CMS IPPS NPRM: Information Blocking Attestation
- Information Blocking Subgroups Update
- Reviewed and approved FAQs for ONC
  - Content and Manner (from Developers Subgroup)
  - What is “interference” with EHI access, exchange, or use?
- Post April 5: Around the Room

# Summary of HIT Developer Issues Discussed to Date

- **Designated Record Set**
  - How is this defined by HIPAA and in the definition of EHI? Can the definition vary across providers?
  - Can providers and developers have different definitions, based on what is available electronically?
  - How will this be operationalized after October 2022?
- **Content and Manner as Gateway Exception**
  - What if it takes time and back-and-forth to understand the request? When does the “clock start” on ability to use infeasibility exception if needed?
  - Can a negotiation move back and forth between “any manner” and an “alternative manner”?
  - Can a developer suggest a specific “alternative manner” without going through hierarchy in the rule?
  - Do PDFs qualify as EHI?
- **Apps and APIs**
  - Can have certified and non-certified APIs
  - Different approaches depending on end-user (patient-facing versus internal provider use)
  - Registration and vetting – what do providers want?
  - Need transparency and patient control of duration of app’s ability to access data and how often data can be accessed, what data can be accessed, how to terminate access, etc. Need granular controls.
  - Need tools to limit access to data withheld under harm and privacy exceptions
- **Clinical Notes**
  - Issues in mapping notes to UCSDI categories
  - Challenges aligning with variable state laws
  - Questions about how far back in time can be accommodated in portals and API
- **Balancing Access and Privacy/Security**
- **Certification and Information Blocking**

## Summary of HIN/HIE Issues Discussed to Date

- **Consumer Access**

- HINs starting from different places; some have patient portals, others do not
- Participation agreements and BAAs may determine whether/how information is shared upon patient request, but all HINs need to have a strategy
- Identity verification and authorization are key sticking points
- Important to have appropriate, non-discriminatory consumer education on how to access information and understanding the benefits and risks of sharing data with third-party apps

- **Compliance Practices**

- Must consider state laws, existing contractual frameworks, technology tools, participants to exchange
- Common practices include updating participant policies and procedures, amending participation agreements, etc.
- Need internal policies, ability to determine requester has the right to access data, documented processes to identify and management complaint responses; analysis and documentation to support use of exceptions, and dispute resolution process

- **Overlapping Privacy Rules**

- Many overlapping federal, state and local laws (HIPAA, SMAHSA 42 CFR Part 2, Common Rules, FERPA, etc) in existence and under development (particularly at state level)
- Limited resources to be able to monitor and analyze and adequately train workforce– key challenge
- Limited technical tools to segment data for privacy, so may need to use privacy and infeasibility exceptions
- Potential unintended consequence of less data sharing due to complexity



## Summary of Provider Issues Discussed to Date

- **Adolescent Access**

- Challenging issue that is hard to operationalize (identifying all sensitive data, providing education for teens and parents/guardians, working through consent and proxy access, etc.)
- Technology tools could help: segmentation, support for separate accounts for adolescents and parents/guardians as process, tools to prevent inappropriate proxy access to adolescent accounts
- Question of access to pre-teen information by adolescent

- **Communicating with Patients, Families and Caregivers about Information Sharing**

- Multiple modes of education being used (factsheets, FAQs, blog posts, video, presentations to patient advisory councils, etc.)
- Concern about useability of portals, given large volume of content and need for better consumer tools, such as search, filter, use of date ranges, etc.
- Limited tools for individuals to choose how to segment data (different access by provider; what is shared with HINs and other outside institutions, etc.)
- Need tools to support use of harm, privacy and other exceptions
- Unclear relationship between sharing of EHI using portals/API access and tradition HIM ROI
- Continued concern about potential harm from results being shared with patients before consultation with clinician; option for conversation about patient preferences before test is ordered

## Summary of Provider Issues Discussed to Date

- **Education for Patients, Families and Caregivers about APIs**
  - Experience to date is varied – some providers have seen apps connecting and are tracking volumes while others have seen little/no uptake (still early days, given April 5 Applicability Date)
  - Generally it is vendors, app developers and third parties that provide lists of apps, not providers
  - Education generally centers on benefits/risks of using apps and limitations on provider role after data shared
- **Preparing for the move to full definition of EHI in October 2022**
  - Full contents of Designated Record Set not in the EHR, API, or portal (for example, need to also accommodate billing data and images)
  - Limited technical tools to manage; may lead to greater use of Content and Manner and Infeasibility exceptions
  - Will need to combine portal/API access with highly responsive Health Information Management process
  - Better clarity and similar definitions across organizations would be helpful, particularly for entities with fewer resources

# FAQ Submissions

## Subgroups Are Identifying Outstanding Questions

- Developer Subgroup – Initial questions submitted
- HIN/HIE Subgroup – Initial questions identified and undergoing review
- Provider Subgroup – Initial questions under consideration

## FAQs Submitted to ONC: Content and Manner

1. The requests for the same EHI to be provided in the same manner could be handled under the Content and Manner exception in either “any manner requested” or “alternative manner” depending on how the initial request is framed by the requester. The use of one or the other initial paths could result in varying application of the licensing and fees exceptions and commercial terms requirements for the actor handling of the two requests for the same EHI that are ultimately provided with the same content and manner.
  - i. How does ONC view potential variation in fees or licensing terms for the two requests given the requirements for consistency on the Fees and Licensing exceptions and for when one or both exceptions apply?
  - ii. Can a data holder and a data requester move “back and forth” between “any manner” and “alternative manner”? For example, sometimes an initial data request is not fully specified and once fully specified, it could be fulfilled in “any manner requested”.
    1. Does ONC recognize that an initial “request” may be more of an inquiry rather than a request with an expectation of action by the actor/data holder, with such “inquiries” not triggering the regulatory requirements associated with requests?
2. Similarly, could you go back to “any manner” if the request can be handled, but not through the first two parts of the alternative manner hierarchy 71.301(b)(2)(i)(A) and (B) or would you need to go to the mutually agreeable machine-readable step in the hierarchy?
3. There can be issues where fulfilling a request would use a mix of certified and non-certified “proprietary” technology. What are the implications of such mixed technology for the use of this exception, if any (e.g., only part of the request could be met with step 1 in the alternative manner hierarchy)?
4. Similarly, a single request might be partially met by “any manner” and partially by “alternative manner” (e.g., some EHI in a single request might be available through an API as requested and other data in the same request only available via a C-CDA machine readable file); how should an actor use this exception in such instances?

## FAQs Submitted to ONC: Content and Manner

5. Could discussions with a requester take place outside of the focus on the three tiers in the alternative manner hierarchy? Do you have to stay within the three tiers in the specific order? Could you move directly to the second or third level if the requester wants to do that (or the actor would like to suggest that approach) or, for example, if a regulated actor offers its complete menu of “alternative manners” for the requestor’s consideration, which might span tiers 1, 2, and 3. Or, do you need to document an attempt to address each tier in the specified order?
6. Please clarify whether a PDF could qualify as “machine readable” if both parties agree to its use. We note that other HHS units, including the Office of the Secretary, OCR, and CMS have treated PDFs as machine readable.

## FAQs Submitted to ONC: Interference

1. Can a patient prospectively request of or agree with their clinician that the availability of test results or other EHI via a portal or API will be delayed until the clinician can review the EHI and/or discuss the EHI with the patient? For example, could such a documented agreement by the patient constitute a request for only some EHI consistent with this ONC FAQ <https://www.healthit.gov/curesrule/faq/actor-required-fulfill-request-for-access-exchange-or-use-ehi-all-ehi-they-have-for-patient-or>. Alternatively, would the Privacy Exception sub-exception (e)–*respecting an individual's request not to share information* enable such an approach if all applicable conditions for this sub-exception are met?
2. Can ONC provide policy and best practices guidance to healthcare organizations and clinicians (both provider actors) about how best to balance the ability of clinicians to specify limits on the release of specific EHI, consistent with the definition of information blocking and applicable exceptions and the responsibility of the health care organization that employs or contracts with the individual clinicians to exercise oversight of such individual clinician decisions to meet its own information blocking-related obligations and policy requirements?
3. If a provider (i) determines that only certain EHI will be made available through a portal or API (e.g., older clinical notes, notes developed by certain types of providers, or, after October 2022, types of EHI that are not in the USCDI), (ii) provides for an alternate path to access, exchange, or use for EHI that is not made available through the portal (or API), and (iii) informs patients via the portal on what EHI to expect to be available and what EHI is available through a specified alternate means (e.g., the HIM unit of the organization), would such an approach not constitute interference and be consistent with the requirements not to be engaged in information blocking?

# Data Usability Work Group



## Data Usability Workgroup

### PURPOSE

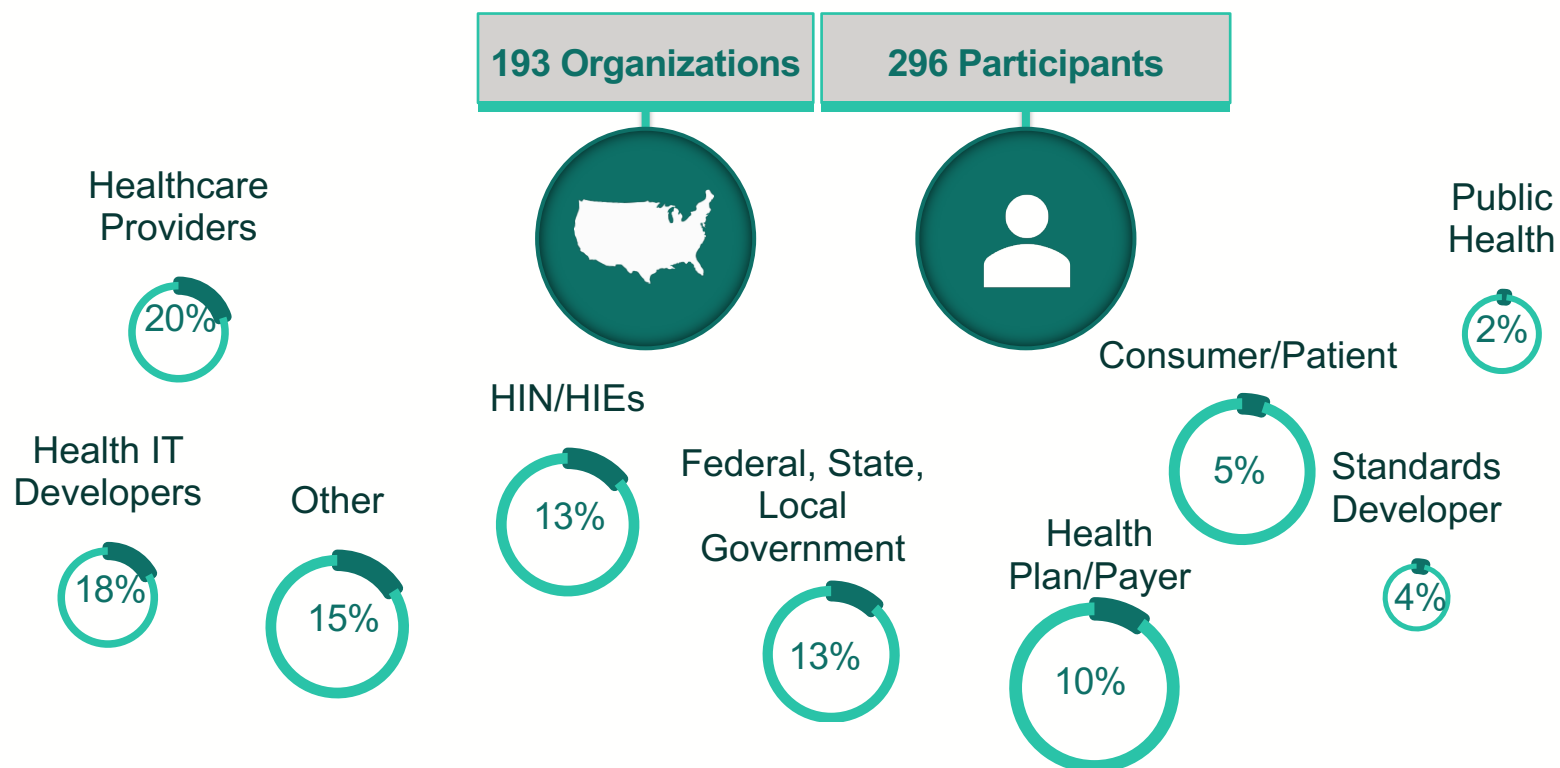
- Develop a specific and pragmatic implementation guide on clinical content for healthcare stakeholders to facilitate health information exchange.
- Cover identified priority use cases, that are readily adoptable by health information exchange vendors, implementers, networks, governance frameworks, and testing programs.
- Target improvements necessary to enable semantic interoperability of health information to improve the usability of data received by end users within their workflows.
- Build on existing work (e.g. C-CDA Templates, ONC, USCDI V1, joint Carequality-CommonWell Document Content Workgroup) and coordinate with related SDOs and industry initiatives

## Scope and Key Deliverables

Develop one implementation guide focused on data quality and addressing each of the following high-level use cases:

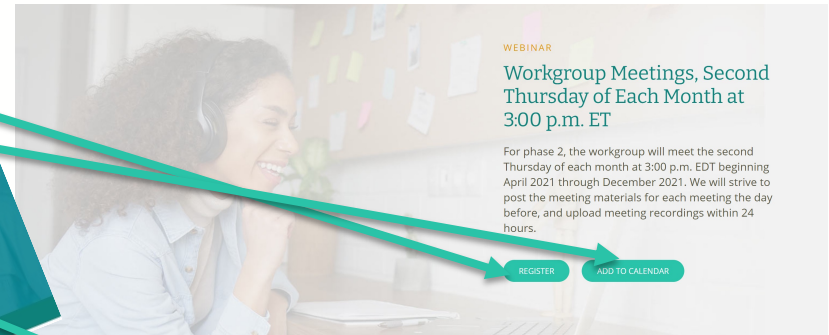
- Provider-to-provider health information exchange
- Provider-to-Public Health Agency information exchange
- Healthcare entity-to-consumer information exchange

## Data Usability Work Group Members



## Website, Meeting and Workgroup Logistics

- Register for the Workgroup
- Calendar Downloads
- Meeting Notes



### Four Work Phases

The Interoperability Matters **Leadership Council** chartered the Data Usability Workgroup to work in the following phases:

**PHASE 1**  
Administration and Prioritization (Current)  
October 2020-March 2021  
[View Meeting Notes](#)

**PHASE 2**  
Developing Initial Drafts  
April 2021-November 2021  
[View Meeting Notes](#)

**PHASE 3**  
Public Comment Period/ Recommended Next Steps  
TBD, based on end of Phase 2-60 days after start

**PHASE 4**  
Finalizing Implementation Guides  
TBD, based on end of Phase 3-[3 months after start]

### Meeting Materials and Recordings

#### Phase 2

June 10: Meeting Notes	<a href="#">View</a>
May 13: Meeting Notes	<a href="#">View</a>
Apr 15: Meeting Notes	<a href="#">View</a>
Apr 8: Meeting Notes	<a href="#">View</a>
Apr 1: Meeting Notes	<a href="#">View</a>

#### Phase 1

Mar 25: Meeting Notes	<a href="#">View</a>
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<https://sequoiaproject.org/interoperability-matters/data-usability-workgroup/>

## Phase 2 Implementation Guide Development Process

- Co-chairs and staff have started to organize and gather the content for the 8 topic areas developed in phase 1 activities – the following tasks will be completed monthly for each topic area by staff to review
- Topics will be addressed in priority order with one – two topics reviewed each month
  - This will be documented in the existing Google docs and/or the draft IG for the work items
    - Priority Work Items Spreadsheet:
      - <https://docs.google.com/spreadsheets/d/1eRbgoStsfhYzIK-wj4TIU9Wr4MEkxF3syOxsHWIPdg/edit#gid=0>
  - Staff will take a high level pass of existing recommendations from Commonwell IG
  - Integrate feedback from workshop(s) to the draft IG
  - Incorporate feedback from Data Usability Collaboration space / forum
    - <https://sequoiaproject.org/interoperability-matters/data-usability-workgroup/>
  - Go over problem statements from a more technical perspective
  - Document other aspects to be considered for the solution
  - Identify questions that still require clarification for all topics
  - Update the Draft IG for each topic category and use case

# Emergency Preparedness Information Workgroup Update

## Emergency Preparedness Information Workgroup

This workgroup provides a forum to learn about health information technology innovations impacting emergency preparedness. The workgroup will focus on concepts that create potential challenges for states in terms of interoperability and Health IT modernization in the emergency preparedness area.



**Policy and/or regulatory**

**Programmatic challenges**

**Data/data privacy and security**

**Funding and resources**

**Communications**

## Membership

- Membership currently includes representatives from several state agencies (Public Health, EMS, Medicaid and others) and HIEs who are experts in the emergency preparedness and response arena: Texas, Florida, California, Virginia, Colorado, Georgia, Tennessee and several others
- If you are interested in participating in this critical work, please contact [dcondrey@sequoiaproject.org](mailto:dcondrey@sequoiaproject.org)



## Key Deliverables

The workgroup's initial operating scope will be to discuss and prioritize topics in the emergency preparedness and response arena where we can potentially make recommendations for change or improvement. The group will focus on the following deliverables:

- Lessons learned from response to the current pandemic as it relates to interoperability and Health IT; this might include policy and regulatory challenges and data privacy
- Key concepts and items to consider to improve disaster response utilizing technology best practices across states, HIEs and partners
- Create a Community of Practice where public health and other state entities who respond to emergencies can discuss innovations and blockers to those innovations



## Updates

- The Workgroup has established a regular monthly meeting cadence and continues to build out membership
- A SWOT analysis was completed in order to address our first deliverable: gather insights and observations as it pertains to the response to the pandemic
- A white paper is in process and under review to document the findings from our SWOT analysis. This white paper will be posted on the Sequoia website and available to the public
- The Workgroup provided public comment/feedback to the Public Health Task Force – a subcommittee of HITAC

# Discussion

## Interoperability Matters Meeting Schedule

Meetings	Cadence	Day	Time	Upcoming Meetings
Leadership Council	Bimonthly	2nd Wednesday	1:00-2:00pm ET	8/18/2021
Public Advisory Forum	Quarterly	3rd Thursday	2:30-3:30pm ET	10/19/2021
<b>Work Groups</b>				
Information Blocking Compliance Work Group	Bimonthly	2nd Friday	12:00-1:30pm ET	8/20/2021
HIN/HIE Subgroup	Monthly	2nd Monday	2:00-3:30pm ET	<del>8/2/2021</del>
Health IT Developer Subgroup	Monthly	3rd Monday	3:30-5:00pm ET	<del>8/16/2021</del>
Healthcare Providers Subgroup	Monthly	4th Wednesday	12:00-1:30pm ET	7/28/2021
Emergency Preparedness Work Group	Monthly	3rd Monday	2:00-3:00pm ET	8/16/2021
Data Usability Work Group (Phase 2)	Monthly	2nd Thursday	3:00-4:00pm ET	8/10/2021

**Join Us and Get Involved!**

<https://sequoiaproject.org/about-us/membership/>

## Public Advisory Forum

### Contact Us

Thank you for your support of  
Interoperability Matters!

If you would like to get in touch you can  
reach us at:



(571) 327-3640



Interopmatters@sequoiaproject.org

# Work Group Members

# Information Blocking 2021 Work Group

## Associations and Orgs - Health IT Community

- Jeff Coughlin, HIMSS
- Lauren Riplinger, AHIMA
- Scott Stuewe, DirectTrust
- Samantha Burch, AHA
- Matt Reid, AMA
- Andrew Tomlinson, CHIME

## Consumers

- Ryan Howells, CARIN Alliance
- Deven McGraw, Ciiitizen

## Health Information Networks and

### Service Providers

- Melissa Soliz, Missouri Health Connect
- Alan Swenson, Carequality
- Ammon Fillmore, Indiana Health Information Exchange – Co-chair

## Healthcare Providers / Physicians

- David Camitta, CommonSpirit
- Eric Liederman, Kaiser Permanente
- Paul Uhrig, Bassett Health Network, Co-Chair

## Payers

- Nancy Beavin, Humana
- Danielle Lloyd, AHIP
- Matthew Schuller, BCBSA

## Developers

- Cherie Holmes-Henry, EHRA/NextGen
- Alya Sulaiman, Epic
- Josh Mast, Cerner
- Jennifer Stoll, OCHIN
- Rita Bowen, MROCorp
- Susan Kohler, Greenway Health

## Federal Government

- Steve Bounds, SSA

## Information Blocking Subgroup – Health IT Developers

### Developer Organizations

- Leigh Burchell, Allscripts
- Alex Desilets, eClinicalWorks
- Peggy Frizzell, Flatiron Health
- Cherie Holmes-Henry, NextGen
- Anu Nakkana, Greenway Health
- Josh Mast, Cerner (Chair)
- Alya Sulaiman, Epic
- Jay Starr, Health Catalyst

### Data Requestors

- Deven McGraw, Ciitizen
- Matt Becker, Kno2

### Health Care Providers

- Sid Thornton, Intermountain Health Care
- Suzanne Srebnik, Montefiore IT

### Health Information Exchange

- Dan Paoletti, The Ohio Health Information Partnership/CliniSync



## Information Blocking Subgroup – Health Care Providers

### Providers Across the Continuum

- Jana Aagaard, CommonSpirit
- Roberta Baranda, Valley Children's Healthcare
- Rene Cabral-Daniels, Cenevia
- Matthew Eisenberg, MD, Stanford Health Care (Chair)
- Jim Jirjis, MD, HCA Healthcare
- Joule Adler, MD, Sutter Health
- Bridget Léon, Mayo Clinic
- Eric Liederman, MD, Kaiser Permanente
- Virginia Lorenzi, New York-Presbyterian Hospital
- Cynthia Morton, National Association for the Support of Long Term Care
- Matt Reid, American Medical Association
- Matthew Shafiroff, MD, White Plains Hospital
- Michael Storlie, Skagit Regional Health
- Paul Uhrig, Bassett Healthcare Network

### Data Requestor

- Jennifer Blumenthal, OneRecord
- Leslie Kelly Hall, Engaging Patient Strategy

### Vendor

- Alya Sulaiman, Epic

### Health Information Exchange

- Kevin Conway, CyncHealth

## Information Blocking Subgroup – HIEs/HINs

### Health Information Exchanges / Health Information Networks

- Zoe Barber, New York eHealth Collaborative
- Meghan Chaffee, CyncHealth
- Ammon Fillmore, Indiana Health Information Exchange (Chair)
- Daniel Kim, Surescripts
- Pam Matthews, GeorgiaHIE
- Jay Nakashima, eHealth Exchange
- Shreya Patel, MiHIN
- AJ Peterson, NetSmart
- Pat Russell, eHealth Exchange
- Melissa Soliz, SHIEC
- Jen Stoll, OCHIN
- Scott Stuewe, DirectTrust
- Wylie van den Akker, Collective Medical
- Paul Wilder, Commonwell

### Data Requestor

- Rick Howard, Apervita
- Deven McGraw, Ciitizen

### Vendor

- Kory Mertz, Audacious Inquiry