



California Health & Human Services Agency Center for Data Insights and Innovation Data Exchange Framework Data Sharing Agreement Policies & Procedures Subcommittee Meeting Summary Wednesday, September 23, 2022, 9:30 a.m. to 12:00 p.m.

Attendance

Subcommittee Members in attendance: William Barcellona, Michelle (Shelley) Brown, Jason Buckner, Yvonne Choong, Louis Cretaro, Matthew Eisenberg, Elaine Ekpo, John Helvey, Sanjay Jain, Bryan Johnson, Diana Kaempfer-Tong, Helen Kim, Steven Lane, Deven McGraw, Leo Pak, Mark Savage, Tom Schwaninger, Morgan Staines, Belinda Waltman

Subcommittee Staff and Presenters in attendance: Cindy Bero (Manatt Health Strategies), Barbara Clopton (CalHHS/CDII), Rim Cothren (Independent HIE Consultant to CDII), Lammot du Pont (Manatt Health Strategies), Jonah Frohlich (Manatt Health Strategies), Courtney Hansen (CalHHS/CDII), Kevin McAvey (Manatt Health Strategies), Juliette Mullin (Manatt Health Strategies), John Ohanian (CalHHS/CDII), Helen Pfister (Manatt Health Strategies), Elaine Scordakis (CalHHS/CDII), Jocelyn Torrez (CalHHS/CDII)

Public in attendance: approximately 72 public attendees joined this meeting via Zoom video conference or through call-in functionality.

Meeting Notes

Meeting notes elevate points made by presenters, Subcommittee Members, and public commenters during the Data Exchange Framework (DxF) Data Sharing Agreement (DSA) Policies and Procedures (P&Ps) Subcommittee meeting. Notes may be revised to reflect public comment received in advance of the next DSA P&P Subcommittee meeting. Meeting materials, full video recording, transcription, and public comments may be found on the Center for Data Insights & Innovation (CDII) <u>Data Exchange</u> <u>Framework website</u>.

Welcome and Roll Call

Courtney Hansen, Assistant Chief Counsel, CalHHS Center for Data Insights and Innovation (CDII), welcomed attendees to the first meeting of the DSA P&P Subcommittee. Courtney reviewed the meeting agenda and introduced Subcommittee Members via roll call.

Vision and Meeting Objectives

Courtney Hansen thanked Subcommittee Members for their engagement and reviewed the vision for data exchange in California, along with the meeting objectives.





Data Exchange Framework Background and Implementation Roadmap

Jonah Frohlich, Senior Managing Director, Manatt Health Strategies, provided an overview of Assembly Bill 133, the DxF and its DSA, P&Ps (both published and in development), required signatory types, and the statutory timeline for implementation.

Comments from Subcommittee Members included:

• Definitions of required signatory types should be aligned with definitions used in federal and state law (e.g., federal information blocking rule, legislation establishing California's Office of Health Care Affordability).

Data Sharing Agreement and Policies and Procedures Subcommittee

Courtney Hansen provided an overview of the DSA P&P Subcommittee Charter, including discussion of the Subcommittee's role and responsibilities, relationship to the Implementation Advisory Committee (IAC), Member expectations, and meeting timeline. Courtney noted that the DSA P&P Subcommittee will advise on the development of, and modifications to, the DSA and its P&Ps and that Members will be expected to act as ambassadors to their networks, sharing and collecting input on DSA P&P development and related topics.

Comments from Subcommittee Members included:

- General support for the content and language of the Subcommittee Charter.
- Request to align timing of Subcommittee milestones with timing of finalization of federal regulations in development.
- A request for clarification on the Subcommittee's decision-making processes.

Jonah Frohlich noted that the DSA P&P Subcommittee will advise on DSA and P&P topics but does not have decision-making authority. Jonah also stated that the Subcommittee would develop recommendations using a consensus-driven approach, where possible.

Courtney requested any additional feedback on the Subcommittee Charter by Monday, September 26, 2022, prior to document finalization.

Prioritization of Next Set of P&Ps

Helen Pfister, Partner, Manatt Health Strategies, provided an overview of P&Ps planned for development and led discussion on a proposed prioritization of P&P topics. Topics of P&Ps prioritized for near-term development include:

- 1. Information Blocking
- 2. Monitoring and Auditing
- 3. Required Transaction Patterns
- 4. Real-Time Data Exchange
- 5. Technical Requirements for Exchange
- 6. Qualified Health Information Organization (HIO) Designation Process





Other potential P&P topics include: dispute resolution, authorizations, consent management, enforcement, rules-based access, implementation and onboarding, data quality, and obligations to cooperate with respect to the DxF.

Comments from Subcommittee Members included:

- Development of P&Ps on "Consent Management" and "Authorization" should be prioritized.
 - Strong understanding of consent management and authorization among signatories is integral to the appropriate exchange of specially protected data, including data protected by 42 CFR Part II.
 - Note: Parties may exchange sensitive information, including Part II data, if the appropriate authorization is obtained.
 - A major challenge to data exchange is the lack of a system to manage consents between entities.
- A new P&P should be created (or an existing one revised) to further clarify requirements for signatories to support individual access (e.g., considerations for providing access to an individual's family members or caregivers).
- Consensus around the importance of the six P&Ps that have been prioritized for near-term development.
- The Data Quality P&P should, if developed, align with initiatives being led by the Department of Health Care Access and Information (HCAI), including any regulations related to the Healthcare Payments Data Program.
- It would be helpful to develop a central glossary of key definitions in a standalone document (separate from the P&Ps) to support signatory understanding and DxF implementation.
- In addition to new P&Ps, signatories, particularly community-based organizations, will require technical assistance to build data exchange capacity and required workflows.

Public Comment

Courtney Hansen opened the meeting to public comment, which included¹:

- Lucy Johns supported the idea of raising the priority of an "Authorization" P&P to ensure protection of patient privacy.
- Rachel McLean, California Department of Public Health, requested the inclusion of local public health departments throughout discussions.
- Harry Martin, County of Santa Clara, requested additional background information on the DxF to support implementation by counties and other stakeholders
 - Note: Members of the public are invited to participate in the DxF webinar series for more information on DxF implementation. More information on

¹ Name spelling approximated based on verbal statements.





the webinar series is available on the CDII <u>Data Exchange Framework</u> <u>website</u>.

Content for P&Ps in Development

Courtney Hansen named the three P&Ps in development that would be the subject of the day's discussion. These three P&Ps address:

- Information Blocking
- Monitoring and Auditing
- Required Transaction Patterns

Information Blocking

Helen Pfister introduced draft content for the Information Blocking P&P. Helen noted that the draft content generally aligns with the federal information blocking rule while expanding the list of impacted actors to include all signatories and expanding the type of information involved from electronic health information (EHI) to health and social services information (HSSI).

Comments from Subcommittee Members included:

- The Information Blocking P&P should align with federal information blocking rules to minimize complexity and reduce the number of new requirements, especially for potential signatories that are not required to the sign the DSA.
- Subcommittee Members shared background information on federal information blocking rules:
 - <u>An FAQ released by The Office of the National Coordinator for Health</u> <u>Information Technology (ONC)</u>
 - An ONC fact sheet with statistics on information blocking claims
 - A link to the Sequoia Project's Information Blocking Compliance Resource Center
- This P&P should consider an approach in which Electronic Medical Record (EMR) vendors, and not Participants themselves, are held responsible for complying with information blocking requirements.
- Depending on its scope, the DSA's prohibition against charging fees to other Participants (aside from by Qualified Health Information Organizations or QHIOs) may raise concerns from signatories about their ability to pay for costs related to complying with the DSA and potential reductions to available signatory revenue streams (e.g., the California Department of Public Health's vital records service).
- Signatories, especially those not subject to the federal information blocking rule, will require technical assistance to be able to understand and comply with DxF requirements.

Monitoring and Auditing

Helen introduced draft content for the Monitoring and Auditing P&P. Helen noted that this P&P would be high-level and provides the DxF Governance Entity with the ability to monitor and audit.





Comments from Subcommittee Members included:

- This P&P should be expanded to also include content on enforcement.
 - Courtney clarified that CalHHS does not yet have independent statutory authority for enforcement.
- CalHHS could defer to federal enforcement authorities if the DSA and its P&Ps align with federal policy (e.g., by referring complainants to federal information blocking reporting processes).
- General agreement that attestation, required reporting, and auditing are appropriate methods for monitoring and auditing.
- A QHIO should be able to attest to requirements on another signatory's behalf.
- A request for more information on the topics/requirements that will be subject to monitoring and auditing.
- It would be helpful to have additional materials (e.g., a readiness checklist, implementation and onboarding policy) to support signatories in implementing the DxF and preparing for monitoring and auditing.
- General agreement that it is critical to ensure appropriate protections for private/sensitive data (to prevent exposing trade secrets or revealing internal vulnerabilities).

Required Transaction Patterns

Rim Cothren introduced draft content for the Required Transaction Patterns P&P. Rim introduced four patterns, described below, noting that the first three are supported by the Trusted Exchange Framework and Common Agreement (TEFCA). Rim also acknowledged that though the discussion scenarios presented a provider-centric perspective, the transaction patterns described were meant to be applicable to all DSA signatories (e.g., social services organizations, counties, public health organizations).

Comments from Subcommittee Members included:

- 1. Targeted Request for Health Information
 - Individual participants may face technical challenges in responding to the high expected volume of queries.
 - There should be clear guidance on whether the responsibility to respond to queries falls on the Participant versus the QHIO/EHR vendor.
 - A participant registry may be required to support Participants' ability to send targeted requests for health information.
 - While this transaction pattern focuses on how Participants will respond to requests from other Participants, future discussion on requirements to respond should include discussion of how Participants are expected to respond to requests from *individuals*.
- 2. Broadcast Request for Health Information





- Requiring Participants to support the Broadcast Request transaction pattern could lead to an unmanageable volume of traffic that would be difficult for Participants to respond to. This issue could be mitigated by supporting *targeted* broadcast requests e.g., by supporting requests within a discrete geographic region or by limiting the types of Participants that can make this kind of request.
- The entity requesting data should clearly specify the scope of the broadcast request to minimize burden for responding Participants.
- Varying perspectives on whether this transaction pattern should be prioritized. Some Members felt this was a critical transaction pattern to support clinical care while others felt there it was too challenging to support now with given technology and resources.
- Given the connectedness of the various proposed transaction patterns, it may be helpful to first identify priority use cases then determine what transaction patterns are required to support them.
- 3. Targeted Health Information Delivery
 - There is an opportunity to improve the delivery of admission, discharge, and transfer (ADT) notifications from hospitals to provider organizations.
 - This transaction pattern has implications for the way individuals interact with DxF Participants e.g., situations where an individual requests that their health information be send to a third party or in which patient-generated health data gets added to an individual's health record.
 - It will be important that the full care team, and not just individual providers, receive information about individuals under its care.
- 4. Request for Notification
 - General agreement that this transaction pattern is important though opinions differed on whether it should be made mandatory.
 - It may be easier to implement an approach in which Participants are required to select and support a minimum number of transaction patterns drawn from a longer list of prioritized patterns.
 - A state-supported directory service with the ability to facilitate publishsubscribe transactions would make implementation of this pattern more feasible.

Next Steps and Closing Remarks

Courtney Hansen reviewed next steps and thanked Members for their engagement. She noted the following upcoming meetings:

- DSA P&P SC Meeting #2 October 25, 2022, 10:00 AM to 12:30 PM
- DSA P&P SC Meeting #3 December 15, 2022, 9:00 AM to 11:30 AM
- DSA P&P SC Meeting #4 January 26, 2023, 9:00 AM to 11:30 AM
- DSA P&P SC Meeting #5 March 9, 2023, 9:00 AM to 11:30 AM





Appendix 1. Data Exchange Framework Data Sharing Agreement and Policies & Procedures Subcommittee - Meeting Attendance (Sept 23, 2022)

Last Name	First Name	Title	Organization	Present
Barcellona	William	Executive Vice President for Government Affairs	America's Physician Groups	Yes
Brown	Michelle (Shelley)	Attorney	Private Practice	Yes
Buckner	Jason	Chief Information Officer & Chief Technology Officer	Manifest Medex	Yes
Choong	Yvonne	Director of Government Affairs	California Association of Health Facilities	Yes
Cretaro	Louis	Leady County Consultant	County Welfare Directors Association of California	Yes
Eisenberg	Matthew	Medical Informatics Director for Analytics and Innovation	Stanford Health	Yes
Ekpo	Elaine	Attorney	California Department of State Hospitals	Yes
Helvey	John	Executive Director	SacValley MedShare	Yes
Jain	Sanjay	Manager, Data Analytics	Health Net	Yes
Johnson	Bryan	Chief Information Security Officer	California Department of Developmental Services	Yes
Kaempfer- Tong	Diana	Attorney	California Department of Public Health	Yes
Kim	Helen	Senior Counsel	Kaiser Permanente	Yes
Lane	Steven	Clinical Informatics Director Familly Physician	Sutter Health Palo Alto Medical Foundation	Yes
Matsubara	Lisa	General Counsel & VP of Policy	Planned Parenthood Affiliates of California	No
McGraw	Deven	Lead, Data Stewardship and Data Sharing, Ciitizen Platform	Invitae	Yes
Pak	Leo	Chief Technology Officer	Los Angeles Network for Enhanced Services	Yes
Savage	Mark	Managing Director, Digital Health Strategy and Policy	Savage & Savage LLC	Yes
Schwaning er	Tom	Senior Executive Advisor, Digital Ecosystem Interoperability	Los Angeles Care	Yes
Staines	Morgan	Privacy Officer & Asst. Chief Counsel	California Department of Health Care Services	Yes





Last Name	First Name	Title	Organization	Present
Steffen	Elizabeth	Chief Information Officer	Plumas District Hospital	No
Tien	Lee	Legislative Director and Adams Chair for Internet Rights	Electronic Frontier Foundation	No
Waltman	Belinda	Acting Director, Whole Person Care LA	Los Angeles County Department of Health Services	Yes