

**California Health & Human Services Agency
Center for Data Insights and Innovation
Data Exchange Framework Stakeholder Advisory Group
Data Sharing Agreement Subcommittee
Meeting Summary (v1)
Tuesday, April 26, 2022, 12:00 p.m. to 2:30 p.m.**

Attendance

Data Sharing Agreement Subcommittee Members in attendance: Chair John Ohanian, Ashish Atreja, William (Bill) Barcellona, Jenn Behrens, Michelle (Shelley) Brown, Louis Cretaro, Elaine Ekpo, Sanjay Jain, Diana Kaempfer-Tong, Elizabeth Killingsworth, Helen Kim, Carrie Kurtural, Steven Lane, Lisa Matsubara, Deven McGraw, Eric Raffin, Morgan Staines, Ryan Stewart, Lee Tien, Belinda Waltman, Terry Wilcox.

Data Sharing Agreement Subcommittee Staff and Presenters in attendance: Rim Cothren (HIE Consultant to CalHHS/CDII), Lammot du Pont (Manatt Health Strategies), Kevin McAvey (Manatt Health Strategies), Helen Pfister (Manatt Health), Elaine Scordakis (CalHHS/CalOHII), Nikhil Sethi (Manatt Health), Khoua Vang (CalHHS/CDII), Justin Yoo (Manatt Health Strategies).

Members of the Public in attendance: Approximately 55 public attendees joined this meeting via Zoom video conference or through call-in functionality.

Meeting Notes

Meeting notes elevate points made by presenters, Data Sharing Agreement Subcommittee Members, and public commenters during the Data Sharing Agreement Subcommittee meeting. Notes may be revised to reflect public comment received in the period following the Subcommittee meeting. Meeting materials, full video recording, transcription, and public comments may be found at: <https://www.chhs.ca.gov/data-exchange-framework/>.

Welcome and Roll Call

John Ohanian, Chief Data Officer, California Health & Human Services (CalHHS), welcomed attendees to the sixth and final meeting of the Data Exchange Framework (DxF) Stakeholder Advisory Group Data Sharing Agreement (DSA) Subcommittee. DSA Subcommittee Members were named and introduced via roll call.

Vision and Meeting Objectives

John Ohanian read the DxF vision statement developed by CalHHS and the Stakeholder Advisory Group and shared the meeting objectives.

Data Sharing Agreement (DSA)

Helen Pfister, Partner, Manatt Health, stated that the DxF DSA and its Policies and Procedures (P&Ps) are mutually reinforcing documents that will govern and require the exchange of health information. Pfister stated that the DxF DSA and an initial set of P&Ps will be released by July 1, 2022.

Pfister shared the DxF DSA table of contents and noted that the language in the DSA is based on the language shared with DSA Subcommittee Members in prior Subcommittee meetings. Pfister noted the tight coupling of the DxF DSA and the P&Ps with, for instance, some topics being introduced in the DSA and further detailed in the P&Ps.¹

Section 1. Parties and Section 2. Purpose and Intent

Pfister introduced the sections of the DxF DSA on parties and purpose and intent. Pfister affirmed that the DxF DSA is meant to be technology agnostic and does not create a single entity that exchanges information nor creates a single repository of data.

Section 4. Use of Health and Social Services Information

Pfister introduced the section on use of health and social services information and noted that this topic would be further expanded upon in the corresponding P&P.

Section 5. Policies and Procedures and Specifications

Pfister introduced the section on policies and procedures and specifications and stated that the P&Ps and specifications are meant to be flexible and may be added to or modified over time.

Section 6. Authorizations

Pfister introduced the section on authorizations.

Comments from DSA Subcommittee Members included:

- It is unclear how organizations will operationalize this section's provisions which describe the sharing and evaluating of authorizations by and among participants.
- This section as written may not adequately support the sharing of data subject to 42 CFR Part 2 as many organizations would face significant challenges sharing authorizations and/or verifying authorizations received from potential exchange partners.
- It would be beneficial to include explicit mention and consideration of 42 CFR Part 2 data in the DxF DSA or a related P&P.

¹ Discussion of the terms defined in *Section 3. Definitions* was incorporated into the review of sections relevant to each term.

- Some data sharing initiatives require data requesters to obtain consent for all data types, regardless of whether the involved data is subject to 42 CFR Part 2.
- Government entities may face special challenges in sharing some types of data given State and federal rules.
- Ensuring exchange of data subject to 42 CFR Part 2 could be prioritized for a future phase of DxF DSA implementation if barriers to exchange are unable to be addressed prior to DxF DSA finalization.
- Requiring an authorization when it is not otherwise required by law could be considered information blocking for entities covered by the Cures Act final rule.
- Authorizations should be sought and received at initial or early contact points with individuals (e.g., at time of enrollment into programs providing health care or social services).
- Independent from the DxF DSA, open data exchange would be supported by:
 - Use of a 'universal' authorization form
 - Availability and use of a consent registry
 - Broader awareness of the State Health Information Guidance (SHIG)
 - Improved alignment of various state and federal laws

Section 7. Requirement to Exchange Health and Social Services Information

Pfister introduced the section on requirement to exchange health and social services information.

Comments from DSA Subcommittee Members included:

- There should be a P&P that describes an approach for developing a qualifying list of acceptable solutions or intermediaries that signatories can use to facilitate data exchange and satisfy the conditions of the DxF and the DxF DSA.
- Organizations should be encouraged or required to not only use qualifying solutions or intermediaries, but also to make their digital contact information available to potential exchange partners, potentially through an electronic directory.
- Government entities may face challenges with implementing a single locus of data exchange for the entire entity as such entities are often comprised of separate programs, each with its own digital contact information and points of contact.

Section 8. Privacy and Security

Pfister introduced the section on privacy and security.

Comments from DSA Subcommittee Members included:

- The specifics of the content on safeguards would be more appropriately placed in a P&P or specifications.
- General agreement that the provision on malicious software is not necessary as the DxF DSA does not establish a single network that will be used by signatories.

Section 9. Special Compliance Provisions and Applicability of HIPAA

Pfister introduced the section on special compliance provisions and applicability of HIPAA.

Comments from DSA Subcommittee Members included:

- General support for extending HIPAA requirements to other participants that may not be covered entities or business associates. Doing so would support improved data privacy and security among all DxF participants.
- Organizations not generally subject to HIPAA should be provided with support to be able to meet this baseline expectation.
- Creating a contractual requirement for entities to comply with HIPAA would not give the Office of Civil Rights the right to investigate an organization that is otherwise not subject to HIPAA.

Section 10. Minimum Necessary

Pfister introduced the section on minimum necessary.

Section 11. Individual Access Services

Pfister introduced the section on individual access services.

Comments from DSA Subcommittee Members included:

- The specifics of individual access services would be more appropriately placed in a P&P.
- Organizations should be expected to share the data in their systems, but should not be expected to access data from other organizations to fulfill requirements related to individual access services.
- Other sections of the DxF DSA would benefit from clarification on allowable fees as described in this section.
- This section should align with federal statutes and rules (e.g., the 21st Century Cures Act), once the implications of such statutes and rules become clearer and additional federal guidance becomes available.
- This section should align with other policy and programs that pertain to an individual's right to access data (e.g., vital records, Medi-Cal's concept of an authorized representative).

Section 12. Cooperation and Non-Discrimination

Pfister introduced the section on cooperation and non-discrimination.

Comments from DSA Subcommittee Members included:

- Some of the provisions on cooperation and non-discrimination would be more appropriately placed in a P&P.

Section 13. Information Blocking

Pfister introduced the section on information blocking.

Comments from DSA Subcommittee Members included:

- References to the 21st Century Cures Act and its associated regulations may be unintentionally limiting as their information blocking provisions only apply to a subset of the actors that are expected to sign the DxF DSA.
- The DxF DSA serves as a contractual approach to prevent information blocking, separate from the provisions detailed in federal law.

Section 14. Legal Requirements

Pfister introduced the section on legal requirements.

Comments from DSA Subcommittee Members included:

- General agreement that the section is appropriate as written.

Section 15. Representations and Warranties

Pfister introduced the section on representations and warranties.

Comments from DSA Subcommittee Members included:

- This section could extend its provision specific to government participants to apply to all participants.

Section 16. Term, Suspension and Termination

Pfister introduced the section on term, suspension and termination.

Comments from DSA Subcommittee Members included:

- Ability of the entity or entities governing the DxF DSA to take enforcement actions (e.g., against organizations who are required to sign the DxF DSA but do not) should be clarified. Such responsibilities may need to be granted to the governing entity via statute.
- Even if an organization's participation in exchange is governed by the DxF DSA is terminated (e.g., as part of an enforcement action), the organization would be free to exchange data outside of the DxF DSA, though they wouldn't benefit from DSA provisions (e.g., requirement to respond) and services (e.g., a potential participant directory).
- It may be unreasonable to include an expectation that organizations destroy relevant data if their participation in exchange under the DxF DSA is terminated.

Section 17. Participant Liability

Pfister introduced the section on participant liability.

Comments from DSA Subcommittee Members included:

- An organization should not be held responsible for data accuracy if it is not the creator of said data.
- It should be clarified what entity or organization is responsible for determining liability.
- This section may be overly broad in its assignment of liability on organizations causing harm.
- Language should be clarified to ensure that this section is not considered an indemnity clause for participants.
- Language could be clarified to note that third party beneficiaries are indemnified from liability.
- Participants could be encouraged or required to obtain and maintain cyber-liability insurance. However, doing so would be difficult for many organizations including government entities and social services organizations.
- This section could potentially include reference to a required arbitration process, overseen by the governance entity.
- The DxF DSA should not create new liabilities for signatories.
- This section should include provisions on standard limitations for liability, with some carve outs.

Section 18. Miscellaneous/General Provisions

Pfister introduced the section on miscellaneous and general provisions.

Public Comment

John Ohanian opened the meeting for spoken public comment. There were no public comments given.

Policies and Procedures (P&Ps)

Dr. Rim Cothren, HIE Consultant to CalHHS/CDII, named the six P&Ps that are planned for release by July 1, 2022.

1. Amendment of DSA

Cothren introduced the Amendment of DSA P&P.

Comments from DSA Subcommittee Members included:

- The DxF DSA amendment process could be streamlined by allowing amendments to go into effect without requiring signatories to re-execute the full agreement.
- Involving a stakeholder advisory group or other similar entities may slow down the process for DxF DSA amendment review, comment, and implementation.
- The allowed timeframe for implementing amendments should be extended.

2. Amendment of Policies and Procedures

Cothren introduced the Amendment of Policies and Procedures P&P.

Comments from DSA Subcommittee Members included:

- Complying with changes to P&Ps within 30 days would be difficult for many organizations. The timeframe should be extended.
- Organizations that are unable to comply with amendments within the allowable timeframe should be provided extensions on an as needed basis.
- This P&P should include a provision permitting for the allowed timeframe to be shortened, if required (e.g., to ensure timely compliance with new law).

3. Data Elements to Be Exchanged

Cothren introduced the Data Elements to be Exchanged P&P.

Comments from DSA Subcommittee Members included:

- The language in this section should clarify that organizations will only be required to share the specified data elements if those elements are already in the organization's possession.
- Organizations should not be expected to invest an unreasonable amount of effort to correct or otherwise "clean" data prior to sharing with exchange partners.
- Data exchange intermediaries could be incentivized to become signatories of the DxF DSA.
- Data exchange intermediaries could sign a separate agreement, if needed, for the purposes of becoming a 'qualified' intermediary.
- Provisions of this P&P may be specified to apply only to covered entities as some organizations, including some social services organizations, may have difficulty complying with the provisions as written.
- Organizations may have challenges exchanging data according to the most recent United States Core Data for Interoperability (USCDI) standards as there is a time lag between the time when the standards are finalized and when health information technology is able to support their collection and exchange.

4. Breach Notification

Jonah Frohlich, Senior Managing Director, Manatt Health, introduced the Breach Notification P&P.

Comments from DSA Subcommittee Members included:

- Many organizations would find it challenging to provide a breach notification within two calendar days. This allowed timeframe should be extended.
- The requirements in this P&P should align with existing laws that also require entities to submit breach notifications.
- It is important for government entities to receive breach notifications promptly.

- The timeframes in this P&P should balance the goal of allowing organizations to promptly address potential security incidents with the goal of limiting undue burden on reporting organizations.

5. Permitted, Required, and Prohibited Purposes

DSA Subcommittee members provided comments on the Permitted, Required and Prohibited Purposes P&P.

Comments from DSA Subcommittee Members included:

- Organizations could be required to proactively ‘push’ data, (i.e., not just in response to a request) though many provider organizations may have concerns with expanding notification requirements beyond what is required by existing federal rules.
- The ‘operations’ purpose may no longer need to be parsed down into its sub-purposes as the federal Trusted Exchange Framework and Common Agreement – to which the DxF DSA should align – has gone in a different direction.
- Data types designated as being ‘required’ by this P&P should be required of all DxF DSA signatories regardless of whether an individual signatory requests or does not request a specific data type.
- This P&P should explicitly name 42 CFR Part 2 data and other specially protected data types.

Note: The DSA Subcommittee did not discuss the final P&P (Requirement to Exchange Health & Social Services Information). This P&P will be addressed at the next Stakeholder Advisory Group meeting on May 18th, 2022.

Next Steps and Closing Remarks

John Ohanian thanked DSA Subcommittee Members and the public for their participation and engagement at this meeting as well as at all of the prior DSA Subcommittee meetings. Ohanian reviewed project next steps and noted that the revised versions of the DxF DSA and P&Ps would be discussed at the next meeting of the Stakeholder Advisory Group on May 18th, 2022. More information about this meeting is available at: <https://www.chhs.ca.gov/data-exchange-framework/>).

Appendix 1. Data Exchange Framework Data Sharing Subcommittee Members - Meeting Attendance (April 26, 2022)

Last Name	First Name	Title	Organization	Present
Ohanian	John	Chief Data Officer (Chair)	CalHHS	Yes
Atreja	Ashish	CIO and Chief Digital Health Officer	UC Davis Health	Yes
Barcellona	William (Bill)	Executive Vice President for Government Affairs	America's Physician Groups (APG)	Yes
Behrens	Jenn	Chief Information Security Officer	LANES	Yes
Brown	Michelle (Shelley)	Attorney	Private Practice	Yes
Cretaro	Louis	Lead County Consultant	County Welfare Directors Association of California	Yes
Ekpo	Elaine	Attorney	CA Dept. of State Hospitals	Yes
Jain	Sanjay	Sr. Business Analyst	Health Net	Yes
Kaempfer-Tong	Diana	Attorney	CA Dept. of Public Health	Yes
Killingsworth	Elizabeth	General Counsel & Chief Privacy Officer	Manifest Medex	Yes
Kim	Helen	Senior Counsel	Kaiser Permanente	Yes
Kurlej	Patrick	Director, Electronic Medical Records & Health Information Exchange	Health Net	In Memoriam
Kurtural	Carrie	Attorney & Privacy Officer	CA Dept. of Developmental Services	Yes
Lane	Steven	Clinical Informatics Director Family Physician	Sutter Health Palo Alto Medical Foundation	Yes
Matsubara	Lisa	General Counsel & VP of Policy	Planned Parenthood Affiliates of California	Yes
McGraw	Deven	Lead, Data Stewardship and Data Sharing, Ciitizen Platform	Invitae	Yes

Last Name	First Name	Title	Organization	Present
Raffin	Eric	Chief Information Officer	San Francisco Department of Health	Yes
Staines	Morgan	Privacy Officer & Asst. Chief Counsel	CA Dept. of Health Care Services	Yes
Stewart	Ryan	System VP, Data Interoperability and Compliance	CommonSpirit Health	Yes
Tien	Lee	Legislative Director and Adams Chair for Internet Rights	Electronic Frontier Foundation	Yes
Waltman	Belinda	Acting Director, Whole Person Care LA	Los Angeles County Department of Health Services	Yes
Wilcox	Terry	Director of Health Information Technology/Privacy & Security Officer	Health Center Partners	Yes