

**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, January 18, 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, Elizabeth Killingsworth, Helen Kim, Patrick Kurlej, 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), Jonah Frohlich (Manatt Health Strategies), Kevin McAvey (Manatt Health Strategies), Jennifer Schwartz (CalHHS/CDII), Elaine Scordakis (CalHHS/CalOHII), Khoua Vang (CalHHS/CDII), Justin Yoo (Manatt Health Strategies).

Members of the Public in attendance: Approximately 33 public attendees joined this meeting via Zoom video conference or through call-in functionality.

Meeting Notes

Meeting notes elevate points made by presenters, the 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 advance of the next Data Sharing Agreement 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) and Chair of the Data Sharing Agreement (DSA) Subcommittee welcomed attendees to the third meeting of the Data Exchange Framework (DxF) Stakeholder Advisory Group DSA Subcommittee. DSA Subcommittee Members were named and introduced via roll call.

Meeting Objectives

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

Public Comment

John Ohanian opened the meeting for spoken public comment, which included:

- David Ford, Vice President of Health Information Technology, California Medical Association, who noted the recent release of the federal [Trusted Exchange Framework and Common Agreement \(TEFCA\)](#) and characterized it as an important resource for the DSA Subcommittee to consider as it develops the DxF DSA.
 - Jennifer Schwartz, Chief Counsel, CalHHS CDII, acknowledged the release of TEFCA and stated that DxF DSA staff would analyze its contents and bring pertinent considerations to future meetings, as needed.

(For written public comment submitted through the Zoom interface, see the Q&A log at <https://www.chhs.ca.gov/data-exchange-framework/>).

Threshold Questions for the Data Exchange Framework (DxF) Data Sharing Agreement (DSA)

Jennifer Schwartz introduced two threshold questions for the development of the DxF DSA on the topics of: (1) requirement for individual and proxy access; and (2) social service organizations as business associates.

Requirement for Individual and Proxy Access

Schwartz reviewed existing policy pertaining to individual and proxy access of information and asked how the DxF DSA should address the topic.

Comments from DSA Subcommittee Members included:

- The DxF DSA should facilitate individual and proxy access to their data as envisioned by the Stakeholder Advisory Group and as required by applicable laws.
- The DxF DSA could draw on approaches described in other existing data sharing agreements. For example, TEFCA includes individual access among its guiding principles and notes individual access services as an authorized exchange purpose.
- Individual and proxy access policies should balance the goal of easy access to one's own information with the goals of privacy and data security (e.g., robust authentication).
- General agreement that the DxF DSA should accommodate an approach in which a proxy may have access to some information, but not necessarily all information e.g., potentially sensitive information on sexual or adolescent health.
 - There are existing efforts (e.g., Protecting Privacy to Promote Interoperability) to develop standards for an access model that would allow individuals and proxies to granularly control access to their health information.
- While the DxF DSA should facilitate data access for individuals and their legal proxies, the DSA Subcommittee should carefully consider whether access should be expanded to other parties (e.g., executors or administrators for the deceased), given the legal and operational complexities.

- The approach for providing individual and proxy access should be rooted in a conceptual consent framework and, potentially, a consent registry.
- Individual and proxy access is a complex issue and should be dealt with at a high-level in the DxF DSA by including language requiring compliance with applicable law. Additional details can be provided in policy and procedures or other guidance.

Social Service Organizations as Business Associates

Schwartz asked how the DxF DSA can support an approach that would build trust among network participants for entities, including many social services organizations, that do not meet the definition of a business associate and therefore are not beholden to the privacy and security requirements of HIPAA.

Comments from DSA Subcommittee Members regarding the application of HIPAA to social service organizations included:

- General agreement that social service organizations should not be required to execute business associate agreements (BAAs) unless they meet the HIPAA definition of a business associate.
- Some existing data sharing agreements include privacy and security policies similar to those described in HIPAA and other law to build trust among the diverse participants of a given network that includes organizations that are not covered entities.
- To help build trust, the DxF DSA could include exhibits on security standards or require entities to perform security risk assessments to provide transparency on expectations for organizations that are not covered entities.
- Social service organizations can be incentivized to share data in conformance with privacy and security requirements if the DxF DSA includes provisions that entities must provide data if they wish to receive it (i.e., the principle that “to get data, you must give data”).

Comments from DSA Subcommittee Members regarding privacy and security considerations included:

- The DxF DSA should leverage a data sharing model rooted in individual-level authorization from the individual which would ensure express consent and support data sharing of specially protected data types (e.g., HIV test results, data governed by 42 CFR Part 2).
- The DxF DSA should ensure accountability processes (e.g., availability of an audit trail) are in place in case of security incidents or other issues.

DxF DSA Outline

Jennifer Schwartz shared a draft outline of the DxF DSA, noting that included topics were subject to change.

Comments from DSA Subcommittee Members included:

- The DxF DSA should seek a balance between a comprehensive approach to address the needs of signatories that may not participate in any other data sharing agreements and the goal to minimize redundancy with requirements from other applicable laws, regulations, and rules.
- The structure and content of the DxF DSA should draw upon and consider related data sharing frameworks and resources including TEFCA and the CalAIM Data Sharing Authorization Guidance.
- The DxF DSA should support a minimum level of interoperability via required adherence to widely recognized technical standards.
- The DxF DSA should maintain the statutorily mandated focus on technological agnosticism.

DxF DSA Content: First Set of Topics

Jennifer Schwartz introduced draft language for the first set of DxF DSA topics which included:

1. Breach, Privacy, and Security
2. Technology Agnostic
3. Exchange Purposes
4. Requirement to Respond
5. Authorizations

(The document with draft language is available at <https://www.chhs.ca.gov/data-exchange-framework/>).

Breach, Privacy, and Security

Schwartz introduced draft language for breach, privacy, and security.

Comments from DSA Subcommittee Members included:

- California has existing laws pertaining to breach, but these laws are complex and varyingly apply to different organization types and have differing requirements.
- The DxF DSA should include breach and security expectations that do not require a level of compliance and technical capability that would create barriers to participation.
- Requirements mandating breach reporting within hours of the incident may not be reasonable.
- The definition of breach should be standardized for all entities, to the extent possible.
- Lawful data exchange should not be considered a breach.
- A landscape analysis of law and policy governing breach requirements (e.g., HIPAA, CCPA) would be helpful to inform the development of the DxF DSA.
- Social service organizations and resource-limited organizations would benefit from additional information and technical assistance on privacy and security law and their pertinent obligations.

Technology Agnostic

Schwartz introduced draft language for the concept of technological agnosticism.

Comments from DSA Subcommittee Members included:

- The DxF DSA should define what is meant by the terms ‘meaningful exchange’ and ‘technologically ready and able’ and what process will assess and determine whether the terms apply for a given organization or scenario.
- General support for allowing organizations to work with health information intermediaries to meet the requirements of the DxF DSA.
- While the DxF DSA is required to be technologically agnostic, it should support signatory adoption and use of recognized data standards to ensure meaningful exchange.

Exchange Purposes

Schwartz introduced draft language for exchange purposes.

Comments from DSA Subcommittee Members included:

- The DxF DSA should include a list of the required exchange purposes and not attempt to define all the possible permitted purposes; in practice, most participants in data exchange network focus on adherence to required exchanges rather than permitted exchanges.
- However, including language on permitted purposes in the DxF DSA could send important signals to the market and stimulate exchange beyond the required uses.
- The definition for the treatment exchange purpose should be expanded to include:
 - 1) care coordination, clarifying that care coordination is considered to be treatment regardless of the entity providing services; and/or
 - 2) services provided by social service organizations.
- The DxF DSA should have a detailed definition of the health care operations exchange purpose, requiring or limiting sub-purposes as appropriate.
- The DxF DSA should include research as an exchange purpose.

The ‘Requirement to Respond’ and ‘Authorizations’ topics were not covered and will be addressed in future meetings.

Next Steps and Closing Remarks

John Ohanian thanked DSA Subcommittee Members and the public for their engagement. Ohanian reviewed project next steps and noted that the next meeting will take place on February 23, 2022.

Appendix 1. Data Exchange Framework Data Sharing Subcommittee Members - Meeting Attendance (January 18, 2021)

Last Name	First Name	Title	Organization	Present
Ohanian	John	Chief Data Officer (Chair)	California Health & Human Services Agency	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
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	Yes
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
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

Last Name	First Name	Title	Organization	Present
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