

Data Exchange Framework

Data Sharing Agreement (DSA) Policies & Procedures (P&P) Subcommittee Meeting #10

Wednesday, October 31, 2023

9:00 a.m. – 11:00 a.m.



Meeting Participation Options Written Comments

- Participants may submit comments and questions through the Zoom Q&A box; all comments will be recorded and reviewed by CDII staff.
- Participants may also submit comments and questions as well as requests to receive Data Exchange Framework updates – to CDII@chhs.ca.gov.
- Questions that require follow up should be sent to <u>CDII@chhs.ca.gov</u>



Meeting Participation Options Spoken Comments

• **Members of the public and DSA P&P Subcommittee Members** must "raise their hand" for Zoom facilitators to unmute them to share comments; the Chair will notify participants of appropriate time to volunteer feedback.

Logged into Zoom	Phone Only
If you logged on via <u>Zoom</u>	lf you logged on
<u>interface</u>	via <u>phone-only</u>
Press "Raise Hand" in the	Press "*9" on your phone to
"Reactions" button on the	"raise your hand"
screen	Listen for your <u>phone number</u>
If selected to share your	to be called by moderator
comment, you will receive a	If selected to share your
request to "unmute;" please	comment, please ensure you
ensure you accept before	are "unmuted' on your phone
speaking	by pressing "*6"



Public Comment Opportunities

- Public comment will be taken during the meeting at designated times.
- Public comment will be limited to the total amount of time allocated for public comment on particular issues.
- The Chair will call on individuals in the order in which their hands were raised.
- Individuals will be recognized for up to two minutes and are asked to state their name and organizational affiliation at the top of their statements.
- Participants are encouraged to use the comment box to ensure all feedback is captured or email their comments to <u>CDII@chhs.ca.gov</u>.



Agenda

9:00 AM Welcome and Roll Call

9:05 AM Informational Item: Vision & Meeting Objectives

9:10 AM Informational Item: Policies & Procedures (P&Ps) Development Status

9:30 AM Discussion Item: Proposed Updates to Existing P&Ps

10:05 AM Discussion Item: Participant Directory P&P

10:35 AM Public Comment

10:50 AM Informational Item: Next Steps and Closing Remarks



Welcome and Roll Call

DSA P&P Subcommittee Members (1 of 2)

Name	Title	Organization
DeeAnne McCallin (Chair)	Deputy Director, Data Exchange Framework	CDII
Courtney Hansen	Assistant Chief Counsel	CDII
Ashish Atreja	CIO and Chief Digital Health Officer	UC Davis Health
William (Bill) Barcellona	Executive Vice President for Government Affairs	America's Physician Groups (APG)
Michelle (Shelley) Brown	Attorney	Private Practice
Jason Buckner	Chief Information Officer & Chief Technology Officer	Manifest Medex
Louis Cretaro	Lead County Consultant	County Welfare Directors Association of California
Matthew Eisenberg	Associate Chief Medical Informatics Officer	Stanford Health
John Helvey	Executive Director	SacValley MedShare
Sanjay Jain	Manager, Data Analysis	Health Net
Bryan Johnson	Chief Information Security Officer	CA Dept. of Developmental Services
Diana Kaempfer-Tong	Attorney	CA Dept. of Public Health
Justin Kaltenbach	Interim Chief Technology Officer	Los Angeles Network for Enhanced Services



DSA P&P Subcommittee Members (2 of 2)

Name	Title	Organization
Helen Kim	Senior Counsel	Kaiser Permanente
Steven Lane	Chief Medical Officer	Health Gorilla
Sunny Lowell	Acting Chief Privacy Officer	CA Dept. Of State Hospitals
Lisa Matsubara	General Counsel & VP of Policy	Planned Parenthood Affiliates of California
Deven McGraw	Lead, Data Stewardship and Data Sharing, Ciitizen Platform	Invitae
Jackie Nordhoff	Director of Regulatory Affairs	PointClickCare
Eric Raffin	Chief Information Officer	San Francisco Department of Public Health
Mark Savage	Managing Director, Digital Health Strategy and Policy	Savage & Savage LLC
Tom Schwaninger	Senior Executive Advisor, Digital Ecosystem Interoperability	LA Care
Morgan Staines	Privacy Officer & Asst. Chief Counsel	CA Dept. of Health Care Services
Elizabeth Steffen	Chief Information Officer	Plumas District Hospital
Lee Tien	Legislative Director and Adams Chair for Internet Rights	Electronic Frontier Foundation
Belinda Waltman	Director of Analytics Integration	Los Angeles County Department of Health Services
Terry Wilcox	Director of Health Information Technology/ Privacy & Security Officer	Health Center Partners



Speaker Introductions

DeeAnne McCallin

Deputy Director, CDII

Courtney Hansen

Assistant Chief Counsel, CDII

Rim Cothren

Independent HIE Consultant, CDII



Vision & Meeting Objectives

The Vision for Data Exchange in California

Once implemented across California, the Data Exchange Framework (DxF) will create new connections and efficiencies between health and social services providers, improving whole-person care.

The DxF is California's first-ever statewide Data Sharing Agreement (DSA) that requires the secure and appropriate exchange of health and human services information to enable providers to work together and improve an individual's health and wellbeing.





Meeting Objectives

Review status of P&Ps in development

2 Discuss proposed policy for charging fees under the DxF

3 Discuss draft language for the Participant Directory P&P



Policies and Procedures (P&Ps): Development Status

P&P Status Summary

CDII continues to develop and solicit feedback on draft P&Ps.

P&P Topic	Status	To Be Covered Today
Early Exchange	Finalized, pending release	
Privacy Standards and Security Safeguards (Amendment)	Under Development (being finalized)	\checkmark
Requirement to Exchange HSSI (Amendment)	Under Development (being finalized)	\checkmark
Individual Access Services (Administrative Modification)	Under Development (post-public input)	\checkmark
Breach Notification (Administrative Modification)	Released with Notification of Intended Administrative Changes (objections due Nov 27)	\checkmark
Data Elements to Be Exchanged (Amendment)	Released for Public Comment (due Nov 20)	\checkmark
Participant Directory	Under Development	\checkmark
[New] Fees	Under Development	\mathbf{X}







Public Comment Period

CDII is soliciting public comments on proposed amendments to the <u>Data Elements to</u> <u>Be Exchanged P&P</u> through November 20, 2023.

Substantive changes to the proposed amended draft include revisions to:

- Clarify that Participants are not required to Exchange abortion or abortion related services information as part of data listed in this P&P, in alignment with the newly signed AB 352.
- Establish a precedence for data element, terminology, and data format standards, and thereby clarifying the
 requirements for Participants and addressing gaps in the ability of the HL7 Messaging Standard Version 2.5.1 and the
 HL7 Clinical Document Architecture (CDA®) Release 2 standards to represent all of the data elements that must be
 exchanged if Maintained by Participants as required by the Data Elements to Be Exchanged P&P.
- Replace the term "regulation" with the clause "law or the Policies and Procedures" to clarify the intent of the language.

The amended draft also includes <u>administrative</u> changes to, among other things, align the P&P with the Glossary of Defined Terms and language used in other P&Ps, especially those drafted after the initial publication of the Data Elements to Be Exchanged P&P in July 2022.

Further detail can be found on the DxF website.



Notice of Intended Administrative Changes *Breach Notification P&P*

CDII is proposing to make certain <u>administrative changes</u> to the Breach Notification P&P.

- CDII is revising this P&P to ensure consistency with the DxF Glossary of Defined Terms and to clarify the use of certain terms. These revisions should not result in any change to the meaning of the P&P, or to CDII's expectations for Participants, and are otherwise not considered to be substantive.
- CDII is seeking public comment <u>only with respect to these administrative modifications</u> through a simplified process (previously used for the Individual Access Services P&P).
- Participants that object to CDII's determination that these changes are administrative may submit an objection through an <u>online form</u> provided on the <u>DxF website</u>. Objections are due by 5pm PT on November 27, 2023.

Please see Section III.5. of the <u>Development of and Modification to Policies and Procedures P&P</u> for more information on the Administrative Modification Process.



Notice of Intended Administrative Changes Individual Access Services P&P

On September 22, 2023, CDII released a notice of intended administrative changes to the <u>Individual Access Services P&P</u>.

- CDII is revising this P&P to ensure consistency with the DxF Glossary of Defined Terms and to clarify the use of certain terms.
- Through October 23, 2023, CDII provided opportunity for the public to object to the characterization of the proposed modifications as administrative.
- Feedback received included a request for confirmation that replacing references in the P&P to PHI or PII with references to Health and Social Services Information is an administrative change (as opposed to a material change). CDII maintains that this modification is an administrative change because the terms "PHI" and "PII" are substantively the same as the definition of "Health and Social Services Information" under the DxF.
- Upon review of objections received, CDII maintains that all proposed modifications are administrative and will move forward with finalizing the revised P&P, consistent with the process described in the Development of & Modifications to Policies and Procedures P&P.

Please see Section III.5. of the <u>Development of and Modification to Policies and Procedures P&P</u> for more information on the Administrative Modification Process.



Privacy Standards & Security Safeguards (1 of 2)

Being revised post-public comment

Overview

The purpose of this P&P is to help maintain the privacy, security and integrity of protected health information (PHI) or personally identifiable information (PII) and to promote trust among Participants of the DxF. It sets forth the procedure by which Participants fulfill obligations to use appropriate safeguards to protect the privacy of PHI and PII, and to maintain the secure environment that supports the exchange of it.

<u>Updates Post-Stakeholder Feedback Include (subject to change prior to finalization):</u>

- 1. Selling De-Identified Data Additional language clarifies that Participants may not sell de-identified Health and Social Services Information (HSSI) when that de-identified HSSI includes information received from another Participant.
- 2. Data on Gender-Affirming Care Additional language stipulates that Participants shall only Exchange abortion or abortion-related services information or gender affirming care information in compliance with Applicable Law.
- 3. Non-Covered Entities Revised language refers Participants who are not Covered Entities, a covered component of a Hybrid Entity, or a Business Associate, to the Permitted, Required and Prohibited Purposes P&P to guide the Exchange of PHI.
- 4. Specially Protected Information Additional language clarifies that Participants must comply with all Applicable Law that applies to specially protected HSSI.
- 5. Securely Destroy Additional language to the definition of Securely Destroy refers Participants to guidance from the U.S. Department of Health & Human Services for how to Securely Destroy HSSI.
- 6. Business Associate Agreements Additional language clarifies that the P&P does not require a Participant to execute a BAA if a BAA is not otherwise required under Applicable Law.

Next Step

Finalize and publish the P&P.

Privacy Standards & Security Safeguards (2 of 2)

Being revised post-public comment

Background

Section 111.4.a of the version of the Privacy Standards & Security Safeguards P&P released for comment reads as follows:

Policies and Procedures. Participants shall have written privacy and security policies and procedures to support Access, Use and Disclosure of Health and Social Services Information and prevent Loss, Destruction, Disruption, or unauthorized Disclosure, Access, Use, modification, or Exchange of Health and Social Services Information that are consistent with and satisfy the requirements set forth in Applicable Law and/or this policy.

Feedback Received

CDII received feedback suggesting that it **require Participants to periodically review and update the written privacy and security policies and procedures** required in Section III.4.a. The feedback did not specify a recommended frequency for review and updates to the privacy and security policies and procedures.

For Discussion

How frequently should Participants be required to review and update their written privacy and security policies and procedures?



Requirement to Exchange HSSI

Being revised post-public comment

Overview

The purpose of this P&P is to establish the responsibilities of Participants to respond to requests for Health and Social Services Information (HSSI) under the DxF.

<u>Updates Post-Stakeholder Feedback Include (subject to change prior to finalization)</u>:

- 1. Push Exchange Additional language specifies that Participants are required to provide HSSI to other Participants according to methods outlined in the Technical Requirements for Exchange P&P. In response to stakeholder concern regarding the receipt of unsolicited information, additional language specifies circumstances in which a Participant is not required to provide HSSI.
- 2. Partial Data Additional language clarifies that the recipient of a request is only responsible for providing HSSI requested that is already in its possession; this covers cases in which a recipient of the request may only have some or partial elements of the information requested.
- **3.** Information Blocking Exceptions Additional language clarifies that using the California Information Blocking Prohibitions P&P exceptions is permissive.
- 4. Requested Restriction Additional language clarifies that this P&P does not require a Participant to grant an Individual's request for a restriction on the Access, Use, or Disclosure of their HSSI.

Next Step

Finalize and release P&P.

Proposed Updates to Existing P&Ps

Current P&P Language Related to Fees

DSA Policies & Procedures contain language that requires more specificity and consistency regarding Participants' charging fees for data exchange.

Permitted, Required, and Prohibited Purposes P&P

Section III.5

"Participants are prohibited from charging fees to other Participants for any exchange of Health and Social Services Information under the DSA; provided that the foregoing shall not prohibit a Qualified HIO from charging fees to Participants who engage in data-sharing activities through the Qualified HIO."

Individual Access Services P&P

Section III.4

"A Participant may not charge another Participant any fees for PHI or PII exchanged in furtherance of this section."

California Information Blocking Prohibitions P&P

Section III.1.a.i

"Notwithstanding the fees exception in the Federal Information Blocking Regulations (45 C.F.R. § 171.302) ("Fees Exception"), a Participant may not charge another Participant fees for the Access, Exchange, or Use of Health and Social Services Information for a Required Purpose. However, a Participant that is a Health Information Exchange, Health Information Network, or Health IT Developer of Certified Health IT may charge other Participants fees for its services, provided that such fees are established consistent with the Fees Exception in the Federal Information Blocking Regulations, the Individual Access Services Policy and Procedure, and the Permitted, Required, and Prohibited Purposes Policy and Procedure."



Recommended Approach

- Eliminate references to charging fees for required DxF transactions with an administrative amendment to existing P&Ps, including the following:
 - Permitted, Required and Prohibited Purposes
 - Individual Access Services
 - California Information Blocking Prohibitions
- Publish a P&P dedicated to the topic of charging fees to consolidate the requirements associated with charging fees for data exchange under the DxF.
 - ✤ Release for public comment in Q4 2023
 - Target publication by January 31, 2024



Proposed Concepts (1 of 2)

Required Purposes

A Participant may not charge fees to another Participant for data exchange for a Required Purpose EXCEPT a Participant who is also an Intermediary may charge another Participant with whom they have a contract for exchange services in place to help that Participant meet their DSA obligation.

Permitted Purposes

A Participant may charge fees to another Participant for data exchange for a Permitted Purpose to the extent permissible under Applicable Law and the California Information Blocking Prohibitions Policy and Procedure.



Proposed Concepts (2 of 2)

Individual Access

- A Participant, including an Intermediary, may charge fees to an Individual for access to their data to the extent permissible under Applicable Law.
- A Participant may not charge fees to another Participant in support of Individual Access EXCEPT a Participant who is also an Intermediary may charge another Participant with whom they have a contract in place to help that Participant meet their DSA obligations.

Participant Directory P&P

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Participant Directory P&P (1 of 4) What we heard in our last meeting

The purpose of the Participant Directory is to communicate Participant <u>choices</u> in the networks, HIOs, or technologies they will use to provide Access to and Exchange HSSI.

Who enters choices

• Participants should be authoritative for their own choices.

What information on choices must be entered

- While most Participants may choose an Intermediary, they must be allowed to specify their choice of point-to-point connections using their own technology.
- Participants must be allowed to choose different entities for different types of exchange.
- Participants need not specify different entities for different Required Purposes.
- Participants should not include technical details (e.g., endpoint URLs, certificates).
- Given the lack of required detail, should not be necessary to delegate entry of their choices.
- May require technical contacts in some cases.

Who may access information on choices

- Some concern that access to the information by non-Participants may present a security risk.
- However, the information comprises only business choices and business information.

Participant Directory P&P (2 of 4)

The Participant Directory comprises:

- 1. A listing of Participants and their choices
- 2. An application that Participants use to enter their choices leveraging the DSA signing portal

The Participant Directory P&P establishes:

- What information is included in the Participant Directory listing:
 - Names of Participants and unique IDs assigned by the Participant Directory
 - Choices for how to submit (1) Requests for Information, (2) Information Delivery, and
 (3) rosters for Notification of ADT Events
 - Technical contacts (if the choice is to use Participant's own technology)
 - Whether the Participant is: (1) exercising its option to delay exchange until 1/31/2026;
 (2) a Voluntary Signatory and is choosing to terminate the DSA; or (3) ceasing operations
- Who can access the application and the listing, and how often the listing is updated
- Who must enter choices in the Participant Directory application, what information on choices must be entered, and by when
- Obligations to update choices



Participant Directory P&P (3 of 4)

Review of language in the P&P

DATA EXCHANGE

FRAMEWORK

CalHHS Data Exchange Framework Policy and Procedure

Subject: Participant Directory	
Status: Draft	Policy: OPP-X
Publication Date: TBD	Version: Draft

Purpose

I.

California Health and Safety Code (HSC) § 130290 was enacted in 2021 and establishes the creation of the California Health & Human Services Data Exchange Framework ("Data Exchange Framework") to enable and require real-time access to or exchange of Health and Social Services Information among Participants "through any health information exchange network, health information organization, or technology that adheres to specified standards and policies." The purpose of this Policy and Procedure is to establish obligations of Participants and the Center for Data Insights and Innovation (CDII) for providing, updating, storing, and communicating certain information concerning the network(s), health information organization(s), or technology(ies) Participants choose to use to Exchange Health and Social Services Information.

II. Policy

1. ESTABLISHING THE PARTICIPANT DIRECTORY

a. CDII shall establish a Participant Directory that allows Participants to:

i. Enter information concerning the Intermediary(ies) and/or technology(ies) the Participant chooses to use to provide Access to or Exchange of Health and Social Services Information under the Data Exchange Framework;

ii. Update and correct information on their choice(s) to maintain accuracy of the information in the Participant Directory; and

iii. Discover the Intermediary(ies) and/or technology(ies) other Participants have chosen to use to provide Access to or Exchange of Health and Social Services Information.

b. The Participant Directory shall make available to Participants the following information:



Participant Directory P&P (4 of 4)

Expected Next Steps

- 1. CDII may refine the draft Participant Directory P&P based on today's discussion.
- 2. The refined draft will be posted for public comment in November.
- 3. Issues raised in public comment that might benefit from further discussion may be brought to the DSA P&P Subcommittee for discussion at the December 5, 2023, meeting.
- 4. CDII will finalize and publish the Phase I version of the P&P.



Public Comment Period

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Next Steps and Closing Remarks

Next Steps for P&Ps - Summary

P&P	Tentative Next Steps
Early Exchange	Release (simultaneously with amended Privacy Standards and Security Safeguards P&P)
Privacy Standards and Security Safeguards (Amended)	Finalize P&P and release
Requirement to Exchange HSSI (Amended)	Finalize P&P and release
Individual Access Services (Administrative Modification)	Finalize P&P and release
Breach Notification (Administrative Modification)	Upon conclusion of the objection period, finalize P&P and release
Data Elements to be Exchanged (Amended)	Upon conclusion of the public comment period, finalize P&P and release
Participant Directory	Refine and release for public comment
Fees	Develop and release for public comment

*Posting timeline contingent upon feedback received during public input/comment which may require alternative next steps





CalHHS will:

- Consider the feedback provided by the DSA P&P Subcommittee
- Continue to advance P&Ps in development and, where applicable, solicit public comment
- Post a summary of today's meeting

DSA P&P Subcommittee Members and Members of the Public may:

 Provide any feedback on proposed changes to P&P language following instructions on the DxF <u>website</u>



Meeting Schedule

IAC Meetings	Date
IAC Meeting #11	November 16, 2023, 9:00 AM – 11:30 AM
IAC Meeting #12	December 19, 2023, 2:00 PM – 4:30 PM

DSA P&P Subcommittee Meetings	Date
DSA P&P SC Meeting #11	December 5, 2023, 9:00 AM – 11:30 AM

For more information or questions on DSA P&P Subcommittee meeting logistics, please email CDII.



DxF Webinar Schedule

DxF Information is Power Webinar Series*	Date
DxF Webinar #13	November 7, 2023, 2:00 PM – 3:00 PM
DxF Webinar #14	December 13, 2023, 1:00 PM – 2:00 PM

*Future webinars may be released at CDII's discretion.

