



Data Exchange Framework

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

Wednesday, March 6, 2024

1:30 p.m. – 4:00 p.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 DxF@chhs.ca.gov.
- Questions that require follow up should be sent to DxF@chhs.ca.gov.

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

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 DxF@chhs.ca.gov.

Agenda



1:30 PM
Welcome and Roll Call

1:35 PM Informational Item:
Vision & Meeting Objectives

1:40 PM Informational Item:
Policies & Procedures (P&Ps)
Status Update

1:50 PM Informational Item:
Update on Publication of the
Federal Part 2 Final Rule

2:00 PM Discussion Item:
Overview of Process for Modification of
the Data Sharing Agreement (DSA) or
Development or Modification of P&Ps

2:10 PM Discussion Item:
Potential P&P Concepts for
2024 Advancement

3:00 PM
Public Comment

3:15 PM 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
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
Diana Kaempfer-Tong	Attorney	CA Dept. of Public Health
Mark Knee	Acting Division Director, Interoperability Division	Office of Policy, Office of the National Coordinator for Health IT (ONC)

DSA P&P Subcommittee Members (2 of 2)

Name	Title	Organization
Steven Lane	Chief Medical Officer	Health Gorilla
Kelby Lind	Vice President of Regulatory Affairs	Planned Parenthood Affiliates of California
Sunny Lowell	Acting Chief Privacy Officer	CA Dept. Of State Hospitals
Belinda Luu	Senior Counsel	Kaiser Permanente
Deven McGraw	Chief Regulatory and Privacy Officer	Citizen
Jackie Nordhoff	Director of Regulatory Affairs	PointClickCare
Mark Savage	Managing Director, Digital Health Strategy and Policy	Savage & Savage LLC
Tom Schwaninger	Senior Executive Advisor, Digital Ecosystem Interoperability	LA Care
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

Speaker Introductions

DeeAnne McCallin

Deputy Director, CDII

Rim Cothren

Independent HIE
Consultant, CDII

Jonah Frohlich

Senior Managing
Director, Manatt
Health Strategies

Helen Pfister

Partner, Manatt
Health Strategies

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.



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Meeting Objectives

- 1** Review status of **P&Ps undergoing administrative modification**
- 2** Review the **newly published Part 2 Final Rule's impact to the DxF**
- 3** Discuss process and timeline for **modifying the DSA or developing or modifying P&Ps**
- 4** Discuss **potential new P&P concepts to advance in 2024**

Policies and Procedures (P&Ps): Status Update



P&P Status Summary

CDII is in the process of making modifications to P&Ps based on feedback received.

Status	P&P Topic	To Be Covered Today
Published	California Information Blocking Prohibitions	Informational Item
New Notification of Intended Administrative Modifications	Participant Directory	Informational Item
	Technical Requirements for Exchange	Informational Item

Notice of Intended Administrative Modifications

Technical Requirements for Exchange + Participant Directory

CDII is proposing to make administrative modifications to the Technical Requirements for Exchange P&P and the Participant Directory P&P. *CDII will accept objections to CDII's characterization of these changes as administrative until early April.*



- ❖ CDII is revising the Technical Requirements for Exchange P&P to align with the requirements of the Participant Directory P&P. This is an administrative change to limit the requirement to respond to queries to those organizations that Maintain HSSI. As this proposed change aligns with other P&Ps, CDII does not consider the proposed modification to be substantive.
- ❖ CDII is revising the Participant Directory P&P to align all deadlines to 10 'business' days (one occurrence previously referred to 'calendar' days). This is an administrative change that 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 revising both P&Ps to update language regarding the effective date of the policy. This is an administrative change that reflects that policies are now effective upon publication, rather than the past DxP implementation date of January 31, 2024.
- ❖ Participants that object to CDII's determination that these changes are administrative may submit an objection for the applicable P&P through an online form available on the [DxF webpage](#). The deadline for objectives will be updated in the "Notice of Intended Administrative Changes to P&Ps" section.

Update on Publication of the Federal Part 2 Final Rule



Part 2 Program Overview

The final rule applies to Part 2 Programs. A Part 2 Program is a federally assisted entity that:

1

Is an **individual or entity** (other than a general medical facility) that holds itself out as providing, and provides, substance use disorder diagnosis, treatment or referral for treatment; or

2

Is an **identified unit within a general medical facility** that holds itself out as providing, and provides, substance use disorder diagnosis, treatment or referral for treatment; or

3

Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.

Federal assistance is defined broadly, and includes programs that are conducted by any department or agency of the United States, that are carried out under a license, certification, registration or other authorization granted by any department or agency of the United States, that are supported by funds provided by any department or agency of the United States, or that have federal tax-exempt status.

Publication of the Final Rule on Part 2 (1 of 3)

Implications for sharing Part 2 data

In February 2024, the US Department of Health and Human Services (HHS) released a final rule on changes to 42 CFR Part 2, which has implications for the sharing of data under the DxF, namely regarding the form of consent and permissible redisclosures.

❖ Flexibility regarding patient consent

- ❖ The streamlined consent provisions are designed to better align Part 2 authorizations with those permitted under HIPAA.
- ❖ Consent forms will now permit a patient to consent to disclosures for all future “treatment, payment and health care operations” using a single form, with an allowed exception date of “none”.
 - ❖ *Note: the California Confidentiality of Medical Information Act requires that a patient authorization to release health information must have an expiration date or event that “limit[s] the duration of the authorization to one year or less, unless the person signing the authorization requests a specific date beyond a year or unless the authorization is related to an approved clinical trial... or medical research study...”*
- ❖ Consent forms may now use a description of a class of persons who may receive the information (rather than specifying each individual recipients).

❖ Flexibility regarding redisclosure

- ❖ The final rule also allows HIPAA covered entities and business associates that receive Part 2 records under the new consent framework to redisclose patient records without a new authorization, as long as such disclosure is in accordance with HIPAA.

Publication of the Final Rule on Part 2 (2 of 3)

Implications for sharing Part 2 data

The Final Rule's provisions regarding "intermediaries" are of particular relevance to DxF Participants.

❖ Intermediaries

- ❖ Clarity on the definition of "intermediary" as pertains to the Final Rule (vs the DxF)
 - ❖ The Final Rule defines "intermediaries" as "[a] person, other than a part 2 program, covered entity, or business associate, who has received records under a general designation in a written patient consent to be disclosed to one or more of its member participant(s) who has a treating provider relationship with the patient."
 - ❖ These may include research institutions and care coordination organizations that are not always subject to HIPAA.
 - ❖ The "member participants" of an intermediary may or may not be covered entities.
- ❖ DxF Participants who have signed a DSA but are not covered entities or business associates should consider evaluating whether they would constitute intermediaries under this definition. It appears that health information exchanges (HIEs) and health information networks (HINs) providing services to a Part 2 program that is not a covered entity would also be considered intermediaries.

Note: the definition of "intermediary" in Part 2 differs from the definition of the same term under the DxF.

Publication of the Final Rule on Part 2 (3 of 3)

Implications for sharing Part 2 data

❖ Intermediaries (*continued*)

- ❖ Intermediaries (*as defined in this final rule*) will be required to provide a list of disclosures for the previous three years upon patient request.
 - ❖ When disclosures are to an intermediary and the intermediary does *not* have a treating provider relationship with the patient, written consent must include the name of the intermediary and the names of its member participants.
 - ❖ If the intermediary *does* have a treating provider relationship with the patient, a general designation of the participants or class or participants is sufficient.

Looking Ahead

- ❖ Reminder that CDII is providing this update as an informational item and no action is required at this time; CDII does not anticipate changes to the DxP DSA/P&Ps as a result of this rule.
- ❖ While aspects of Part 2 have been changed, California law has not. Participants are still required to comply with applicable CA law, including HSC 11845.5 or CMIA.

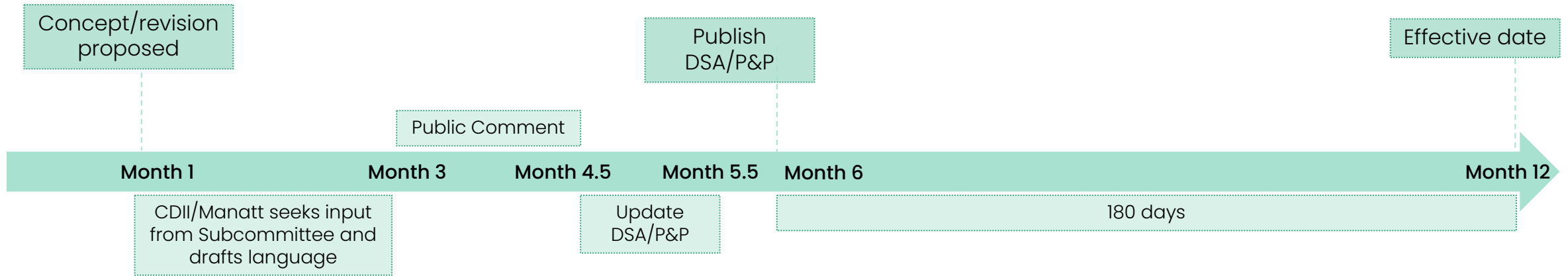
Overview of Process for Modification of the DSA or Development or Modification of P&Ps



DSA/P&Ps: Development and Revision Process

An illustrative timeline for DSA modification and P&P development or modification

The below timeline illustrates the process for how DxF DSA/P&Ps may be developed or revised following the implementation date of January 31, 2024.



Total time for development/modification: 11-15 months

Please see Section III.5. of the [Development of and Modification to Policies and Procedures P&P](#) for more information on the Administrative Modification Process (not shown in slide).

Potential P&P Concepts for 2024 Advancement



P&Ps: Looking Forward (1 of 2)

Potential Concepts to Address in 2024

Throughout 2023, CDII maintained a log of topics that may warrant consideration for development of or modification to current P&Ps. Today, we would like to discuss what Subcommittee Members recommend as topics to be considered.

Topics that have been proposed in meetings and public comment periods include:

❖ Exchange Method Conflict

- ❖ How Participants looking to exchange with each other resolve disagreement on preferred exchange methods
- ❖ CDII recommends Members refer to the **Manner Exception** in the [California Information Blocking Prohibitions P&P](#) on the [DxF webpage](#), which refers to the revised federal rule **45 CFR 171.301**.

❖ Non-Participant Intermediaries

- ❖ Should we require Participants who use Intermediaries who are not also Participants to include contractual flowdowns that they comply with the DxF?

❖ ONC's February 2024 Removal of USCDI v2 from SVAP

- ❖ ONC has removed USCDI v2 from SVAP, removing it from our definition of "National and Federally Adopted Standards", which is used in multiple P&Ps.

P&Ps: Looking Forward (2 of 2)

Potential Concepts to Address: Soliciting Input

What other topics do
Members feel should be
prioritized by CDII for 2024
development?

Public Comment Period



Next Steps and Closing Remarks



Next Steps

CalHHS will:

- Consider the feedback provided by the DSA P&P Subcommittee
- Continue to advance refinement of P&Ps through administrative changes underway 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 feedback on any potential P&P priority topics for 2024 development

Meeting Schedule

DSA P&P Subcommittee Meetings	Date
DSA P&P SC Meeting #14	April 10, 2024, 1:30 PM – 4:00 PM
DSA P&P SC Meeting #15	June 7, 2024, 11:00 AM – 1:30 PM

IAC Meetings	Date
IAC Meeting #14	March 19, 2024, 12:00 PM – 2:30 PM
IAC Meeting #15	May 22, 2024, 12:00 PM – 2:30 PM

For more information or questions on DSA P&P Subcommittee meeting logistics, please [email CDII](#).