Data Exchange Framework Stakeholder Advisory Group Meeting #8

California Health & Human Services Agency

Wednesday, May 18, 2022 10:00 a.m. to 1:00 pm



Meeting Participation Options Onsite

- Members who are onsite are encouraged to log in through their panelist link on Zoom.
 - Members are asked to <u>keep their laptop's video, microphone, and audio</u> <u>off</u> for the duration of the meeting.
 - The room's cameras and microphones will broadcast the video and audio for the meeting.
- Instructions for connecting to the conference room's Wi-Fi are posted in the room.
- Please email (<u>khoua.vang@chhs.ca.gov</u>) Khoua Vang with any technical or logistical questions about onsite meeting participation



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 Advisory Group staff.
- Participants may also submit comments and questions as well as requests to receive Data Exchange Framework updates – to <u>CDII@chhs.ca.gov</u>.



Meeting Participation Options Spoken Comments

 Participants and Advisory Group Members must "raise their hand" for Zoom facilitators to unmute them to share comments; the Chair will notify participants/Members of appropriate time to volunteer feedback.

If you are <u>onsite</u> and <u>not</u> <u>using Zoom</u>

Physically raise your hand, and the chair will recognize you when it is your turn to speak

If you logged on <u>onsite</u> via <u>Zoom interface</u>

Press "Raise Hand" in the "Reactions" button on the screen or physically raise your hand

If selected to share your comment, please begin speaking and <u>do not</u> <u>unmute your laptop</u>. The room's microphones will broadcast audio

If you logged on from <u>offsite</u> via <u>Zoom interface</u>

Press "Raise Hand" in the "Reactions" button on the screen

If selected to share your comment, you will receive a request to "unmute;" please ensure you accept before speaking

If you logged on via phone-only

Press "*9" on your phone to "raise your hand"

Listen for your <u>phone</u> <u>number</u> to be called by moderator

If selected to share your comment, please ensure you are "unmuted' on your phone 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, beginning with those in the room and followed by those dialed in or connected remotely through Zoom.
- 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>.





| 10:00 AM | Welcome and Roll Call John Ohanian, Chief Data Officer, California Health and Human Services |
|----------|--|
| 10:05 AM | Vision and Meeting Objectives Dr. Mark Ghaly, Secretary, California Health and Human Services |
| 10:15 AM | Data Sharing Agreement and Policy and Procedures Helen Pfister, Partner, Manatt Health Strategies |
| 12:20 PM | Public Comment |
| 12:35 AM | Data Exchange Framework Component Documents Jonah Frohlich, Senior Managing Director, Manatt Health |
| 12:45 PM | Digital Identity Strategy Update Dr. Rim Cothren, Independent HIE Consultant to CDII |
| 12:50 PM | Governance and Budget Update Marko Mijic, Undersecretary, California Health and Human Services |



Welcome and Roll Call



Advisory Group Members *Stakeholder Organizations (1 of 3)*

| Name | Title | Organization |
|--|--|--|
| Mark Ghaly (Chair) | Secretary | California Health and Human Services Agency |
| Jamie Almanza | CEO | Bay Area Community Services |
| Charles Bacchi | President and CEO | California Association of Health Plans |
| Andrew Bindman designated by Greg A. Adams | Executive Vice President; Chief Medical Officer | Kaiser Permanente |
| Michelle Doty Cabrera | Executive Director | County Behavioral Health Directors Association of California |
| Carmela Coyle | President and CEO | California Hospital Association |
| Rahul Dhawan designated by Don Crane | Associate Medical Director | MedPoint Management (representing America's Physician Groups) |
| Joe Diaz designated by Craig Cornett | Senior Policy Director and Regional Director | California Association of Health Facilities |
| David Ford designated by Dustin Corcoran | Vice President, Health Information Technology | California Medical Association |
| Liz Gibboney | CEO | Partnership HealthPlan of California |

Note: Complete bios for each member are available in a publicly posted biography listing; updated on Sept. 30th at 5pm PT



Advisory Group Members *Stakeholder Organizations (2 of 3)*

| Name | Title | Organization |
|--|--|---|
| Michelle Gibbons designated by Colleen Chawla | Executive Director | County Health Executives Association of California |
| Lori Hack | Interim Executive Director | California Association of Health Information Exchanges |
| Matt Legé delegate for Tia Orr | Government Relations Advocate | Service Employees International Union California |
| Sandra Hernández | President and CEO | California Health Care Foundation |
| Cameron Kaiser designated by Karen Relucio | Deputy Public Health Officer | County of San Diego (representing the California Conference of Local Health Officers) |
| Andrew Kiefer designated by Paul Markovich | Vice President, State Government Affairs | Blue Shield of California |
| Linnea Koopmans | CEO | Local Health Plans of California |
| David Lindeman | Director, CITRIS Health | UC Center for Information Technology Research in the Interest of Society |
| Amanda McAllister- Wallner designated by Anthony E. Wright | Deputy Director | Health Access California |



Advisory Group Members *Stakeholder Organizations (3 of 3)*

| Name | Title | Organization |
|---|--|---|
| DeeAnne McCallin designated by Robert Beaudry | Director of Health Information Technology | California Primary Care Association |
| Ali Modaressi | CEO | Los Angeles Network for Enhanced Services |
| Erica Murray | President and CEO | California Association of Public Hospitals & Health Systems |
| Eduardo Martinez designated by Art Pulaski | Legislative Director | California Labor Federation |
| Mark Savage | Managing Director, Digital Health Strategy and Policy | Savage & Savage LLC |
| Kiran Savage-Sangwan | Executive Director | California Pan-Ethnic Health Network |
| Cathy Senderling- McDonald | Executive Director | County Welfare Directors Association |
| Claudia Williams | CEO | Manifest MedEx |
| William York | President and CEO | San Diego Community Information Exchange |



Advisory Group Members State Departments (1 of 2)

| Name | Title | Organization |
|--|-----------------------------------|---|
| Ashrith Amarnath | Medical Director | California Health Benefit Exchange |
| Jim Switzgable designated by Nancy Bargmann | Deputy Director | Department of Developmental Services |
| Mark Beckley | Chief Deputy Director | Department of Aging |
| Scott Christman | Chief Deputy Director | Department of Health Care Access and Information |
| David Cowling | Chief, Center for Information | California Public Employees' Retirement System |
| Kayte Fisher | Attorney | Department of Insurance |
| Brent Houser | Chief Deputy Director, Operations | Department of State Hospitals |
| Julie Lo | Executive Officer | Business, Consumer Services & Housing Agency |



Advisory Group Members State Departments (2 of 2)

| Name | Title | Organization |
|--|---|--|
| Dana E. Moore | Deputy Director, State Registrar, & Chief Data Officer | Department of Public Health |
| Nathan Nau | Deputy Director, Office of Plan Monitoring | Department of Managed Health Care |
| Linette Scott | Chief Data Officer | Department of Health Care Services |
| Cheryl Larson Designated by Diana Toche | Director & CIO | Department of Corrections and Rehabilitation |
| Julianna Vignalats | Assistant Deputy Director | Department of Social Services |
| Leslie Witten-Rood | Chief, Office of Health Information Exchange | Emergency Medical Services Authority |



Vision & Meeting Objectives



Vision for Data Exchange in CA

Every Californian, and the health and human service providers and organizations that care for them, will have timely and secure access to usable electronic information that is needed to address their health and social needs and enable the effective and equitable delivery of services to improve their lives and wellbeing.



Meeting #8 Objectives

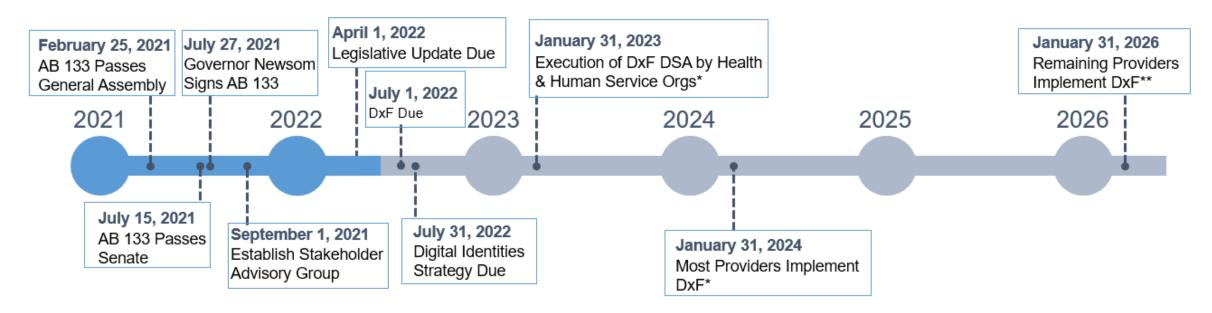
- Discuss drafts of the Data Sharing Agreement and initial set of Policies and Procedures
- 2. Provide an overview of the draft **Data Exchange Framework Component Documents** that have been released for public comment
- 3. Provide an update on the Strategy for Digital Identities
- 4. Provide an update on **DxF Governance** and funding allocation proposals in the **Governor's Budget May Revision**



Statutory Requirements & Timeline

AB 133 put California on the path to building a Health and Human Services Data Exchange Framework (DxF) that will advance and govern the exchange of electronic health information across the state.

AB 133 Implementation Timeline



*General acute care hospitals, physician organizations and medical groups, skilled nursing facilities, health service plans and disability insurers, Medi-Cal managed care plans, clinical laboratories, and acute psychiatric hospitals. County health, public health, and social services providers are <u>encouraged</u> to connect to the DxF.



**Physician practices of <25 physicians, rehabilitation hospitals, long-term acute care hospitals, acute psychiatric hospitals, critical access hospitals, and rural general acute care hospitals with <100 acute care beds, state-run acute psychiatric hospitals, and nonprofit clinics with <10 providers

Data Sharing Agreement and Policy and Procedures



DSA and Policies and Procedures (P&Ps) Development

By July 1, 2022, AB 133 requires the establishment of a single data sharing agreement and a common set of policies and procedures that govern and require the exchange of health information.

Data Sharing Agreement (DSA)

A legal agreement that a broad spectrum of health organizations execute by January 31, 2023

DSA Overview

- Streamlined document that focuses on the key legal requirements
- Aligns with and avoids duplication or conflicts with other data sharing agreements

Policies and Procedures (P&Ps)

Rules and guidance to support "on the ground" implementation

P&Ps Overview

- □ P&Ps provide details on implementation requirements
- □ P&Ps will be released in phases
 - On July 1, 2022, CalHHS will release an initial set of P&Ps.
 - After July 1st, additional P&Ps will be developed through stakeholder feedback and the DxF governance process.



Draft DSA and Draft P&Ps

Data Sharing Agreement (DSA)

DSA Table of Contents

- 1. Parties
- 2. Purpose and Intent
- 3. Definitions
- 4. Use of Health & Social Services Information
- 5. Policies & Procedures and Specifications
- 6. Authorizations
- 7. Requirement to Exchange Health & Social Services Information
- 8. Privacy and Security -
- 9. Minimum Necessary
- **10. Individual Access Services**
- 11. Cooperation and Non-Discrimination
- 12. Information Blocking -----
- 13. Legal Requirements
- 14. Representation and Warranties
- 15. Term, Suspension, and Termination
- 16. Participant Liability
- 17. Miscellaneous/General Provisions

Color Key

Red = DSA topics that are described in detail in the P&Ps

Policies & Procedures (P&Ps)

Initial P&Ps (to be released on July 1st)

- 1. Amendment of DSA
- 2. Amendment of Policies & Procedures
- 3. Breach Notification
- 4. Permitted, Required, and Prohibited Purposes
- 5. Requirement to Exchange Health & Social Services Information
- 6. Privacy and Security Safeguards
- 7. Individual Access Services
- 8. Data Elements to Be Exchanged

Future P&Ps (to be released after July 1st)*

- 1. Information Blocking
- 2. Monitoring and Auditing
- 3. Enforcement
- 4. Qualified HIO Designation
- 5. Technical Requirements for Exchange

* After July 1st, additional P&Ps will be developed through stakeholder feedback and the DxF governance process.

Sec 1. Parties

Overview

The DSA will be executed by the California Health and Human Services Agency (CalHHS) and Participants who are required to
or elect to exchange <u>Health and Social Services Information</u> pursuant to the DSA.

Key Definitions

- 1. Health and Social Services Information: Any and all information received, stored, processed, generated, used, transferred, disclosed, made accessible, or shared pursuant to the DSA, including but not limited to:
 - (a) Data Elements as set forth in the applicable Policy and Procedure;
 - (b) Information related to the provision of health care services, including but not limited to Protected Health Information (PHI); and
 - (c) Information related to the provision of social services.

Health and Social Services Information may include PHI, Personally Identifiable Information (PII), de-identified data (as defined in the HIPAA Regulations at 45 C.F.R. §164.514), pseudonymized data, metadata, digital identities, and schema.



Sec 2. Purpose and Intent

- The DSA sets forth a common set of terms, conditions, and obligations to support secure, real-time access to, or exchange of, Health and Social Services Information between and among the Participants.
- The DSA is <u>intended</u> to facilitate data exchange between the Participants in compliance with all applicable federal, state, and local laws, regulations, and policies.
- The DSA is <u>not intended or designed</u> to:
 - mandate or require a specific technology
 - o create a single entity that exchanges Health and Social Services Information
 - o create a single repository of data



Sec 4. Use of Health & Social Services Information

<u>Overview</u>

- The purposes for which Participants may exchange information under the DSA are set forth in the <u>Permitted</u>, <u>Required</u>, <u>and</u> <u>Prohibited Purposes P&P</u>.
- As described in more detail in the <u>Permitted</u>, <u>Required</u>, <u>and Prohibited Purposes P&P</u>, Participants may not use information they acquire under the DSA for their own indirect or direct financial benefit.



Sec 5. Policies & Procedures and Specifications

Overview

- The P&Ps and Specifications are incorporated into the DSA.
- The P&Ps and Specifications may be amended from time to time as described in the P&Ps.

Sec 6. Authorizations

<u>Overview</u>

- Except for disclosures that may be made without an authorization under applicable law, Participants may not disclose PHI or PII without a legally valid authorization.
- Any disclosure of Health and Social Services Information by a Participant shall be deemed an express representation that the Participant has complied with this section and unless the Participant receiving such information has actual knowledge to the contrary, the Participant receiving such information may reasonably and justifiably rely upon such representation.



Sec 7. Requirement to Exchange Health & Social Services Information

<u>Overview</u>

- Participants will engage in the exchange of Health and Social Services Information either:
 - 1. Through execution of an agreement with a Qualified HIO,
 - 2. Through execution of an agreement with another entity that provides data exchange, or
 - 3. Through use of the Participant's own technology
- If a Participant elects not to execute an agreement with a Qualified HIO and instead to use its own technology (or to
 execute an agreement with another entity that provides data exchange), the Participant must comply with (or ensure that
 the other entity enables it to comply with) the minimum requirements for data exchange set forth in the Policies and
 Procedures or Specifications.
- Additional details are provided in the <u>Requirement to Exchange Health & Social Services Info</u> P&P and include:
 - o Duty to respond
 - The intent for DxF to be technology agnostic

Key Definitions

 Qualified Health Information Organization: Qualified Health Information Organization" or "Qualified HIO" shall mean a state-designated data exchange intermediary that facilitates the exchange of Health and Social Services Information between Participants.

Sec 8. Privacy and Security

- Participants will fully comply with all Applicable Law relating to the DSA and the use of Health and Social Services Information.
- Each Participant shall be responsible for maintaining a secure environment that supports the exchange of PHI or PII as set forth in the Policies and Procedures.



Sec 9. Minimum Necessary

Overview

- Any use or disclosure of PHI or PII pursuant to the DSA will be limited to the minimum PHI or PII necessary to achieve the purpose for which the information is shared.
- <u>Except</u> where limiting such use or disclosure to the minimum necessary:
 - 1. is not feasible
 - 2. is not required under the HIPAA Regulations (such as for Treatment) or any other Applicable Law
 - 3. is a disclosure to an Individual User or Individual User's Personal Representative
 - 4. is a disclosure pursuant to an Individual User's Authorization, or
 - 5. is a disclosure required by Applicable Law.

Sec 10. Individual Access Services

Overview

 An Individual User or an Individual User's Personal Representative shall have the right to inspect and obtain a copy of PHI or PII about the Individual User as set forth in the Policies and Procedures.



Sec 11. Cooperation & Non-Discrimination

- The DSA contains various provisions relating to cooperation and non-discrimination, including the following:
 - 1. Each Participant shall cooperate in good faith with the Governance Entity and each other Participant to implement the provisions of the DSA;
 - 2. Each Participant shall provide such non-privileged information to the Governance Entity and any other Participant as reasonably requested for purposes of performing activities related to the DSA;
 - 3. Each Participant shall devote such time as may reasonably be requested by the Governance Entity to review information, meet with, respond to, and advise the Governance Entity or other Participants with respect to activities as they relate to the DSA;
 - 4. Each Participant shall provide such reasonable assistance as may be requested by the Governance Entity when performing activities as they relate to the DSA;
 - 5. Each Participant shall provide information and assistance to the Governance Entity or other Participants in the investigation of breaches and disputes, subject to a Participant's right to restrict or condition its cooperation or disclosure of information in the interest of preserving privileges in any foreseeable dispute or litigation;
 - 6. In seeking another Participant's cooperation, each Participant shall make all reasonable efforts to accommodate the other Participant's schedules and reasonable operational concerns; and
 - 7. A Participant may not require exclusivity or otherwise prohibit (or attempt to prohibit) any other individual or entity from joining or exchanging Health and Social Services Information under the DSA.



Sec 12. Information Blocking

Overview

Participants shall comply with any information blocking provisions set forth in the Policies and Procedures.

Sec 13. Legal Requirements

Overview

- The Governance Entity shall have the right but not the obligation to monitor and audit Participants' compliance with their obligations under the DSA.
- Unless prohibited by Applicable Law, Participants are required to cooperate with the Governance Entity in monitoring and auditing activities, including by providing complete and accurate information in furtherance of such activities.
- To the extent that any such information constitutes Confidential Participant Information, the Governance Entity will hold such information in confidence and not redisclose it except as required by Applicable Law.

Key Definitions

1. Confidential Participant Information: Proprietary or confidential materials or information of a Participant in any medium or format that a Participant labels as such upon disclosure or that given the nature of the information or the circumstances surrounding its disclosure, reasonably should be considered confidential. Notwithstanding any label to the contrary, Confidential Participant Information does not include any information which is or becomes known publicly through no fault of the party to which such information is disclosed (a "Receiving Party"); is learned of by a Receiving Party from a third party entitled to disclose it; is already known to a Receiving Party before receipt from the disclosing Participant as documented by the Receiving Party's written records; or is independently developed by a Receiving Party without reference to, reliance on, or use of the disclosing Participant's Confidential Participant Information.

Sec 14. Representations & Warranties

Overview

- This section contains representations and warranties of the Participants with respect to:
 - Authority to execute the DSA
 - Compliance with the DSA
 - Accuracy of Health and Social Services Information exchanged under the DSA
 - Authority to disclose the Health and Social Services Information that the Participant discloses under the DSA
 - Third-party technology utilized by the Participants to support the exchange of Health and Social Services Information under the DSA

Sec 15. Term, Suspension and Termination

- This section provides that a Participant that is not legally required to sign the DSA may terminate the DSA by giving the Governance Entity at least 10 business days' prior written notice.
- This section also states that Participants grant the Governance Entity the power to enforce any portion of the DSA through measures set forth in the Policies and Procedures and that such measures may include suspension or termination of a Participant's right to exchange Health and Social Services Information under the DSA.



Sec 16. Participant Liability

- Each Participant shall be responsible for its acts and omissions and not for the acts or omissions of any other Participant.
- Notwithstanding any provision in the DSA to the contrary, Participant shall not be liable for any act or omission if a cause of action for such act or omission is otherwise prohibited.



Sec 17. Miscellaneous/General Provisions

Overview (a) Governing Law (b) Assignment (c) Survival (d) Waiver (e) Caption (f) Entire Agreement (g) Validity of Provisions (h) Priority Counterparts (i) **Third-Party Beneficiaries** (j) (k) Force Majeure Time Periods (I)



Policies & Procedures

Initial P&Ps (to be released on July 1st)

- 1. Amendment of DSA
- 2. Amendment of Policies & Procedures
- 3. Breach Notification
- 4. Permitted, Required, and Prohibited Purposes
- 5. Requirement to Exchange Health & Social Services Information
- 6. Privacy and Security Safeguards
- 7. Individual Access Services
- 8. Data Elements to be Exchanged





P&Ps #1. Amendment of DSA

- Any member of the Governance Entity, any Participant or any other stakeholder that the Governance Entity deems appropriate may submit a written request for an amendment to the DSA. The Governance Entity may also solicit requests for amendments from all Participants and other interested stakeholders.
- If a request for a proposed amendment satisfies the criteria established by the Governance Entity, the Governance Entity will forward the request to legal counsel for an initial legal review. Following this initial legal review, a task force established by the Governance Entity will, in consultation with local partners and a stakeholder advisory group appointed by the Secretary of CalHHS, determine how to address the request.
- Prior to approving any amendments to the DSA, the task force will solicit and consider comments from the Participants on the amendments. To promote openness and transparency, the task force may post proposed changes to the DSA to a publicly accessible location.
- Following the task force's approval of an amendment, the Participants will be given at least 45 calendar days to review the approved amendment and register an objection if a Participant believes the amendment will have a significant adverse operational or financial impact on the Participant.
- Upon approval of an amendment, the Governance Entity will circulate the amendment to all of the Participants for signature at least 45 calendar days prior to the effective date of the amendment, except in the event that a shorter time period is necessary in order to comply with Applicable Law.
- The Governance Entity shall maintain in a publicly accessible location:
 - the DSA, and all amendments
 - a list of the current and prior Participants, as well as a list of individuals and entities that are required to execute the DSA but have not yet done so

P&Ps #2. Amendment of P&Ps

- Any Participant or other stakeholder that the Governance Entity deems appropriate may submit in writing to the Governance Entity a request for the development of a new Policy, or a request for the amendment or repeal of an existing Policy. Any member of the Governance Entity may also bring forth any concern or question regarding the Policies.
- The Governance Entity will consider any requests that meet the submission criteria set forth above at its next regularly scheduled meeting following receipt of such request.
- The Governance Entity will (a) prioritize requests; (b) consider the merits of the request, as well as the impact on Participants and individuals whose Health and Social Services Information is transmitted through the Data Exchange Framework; and (c) communicate actions taken with the requestor.
- Prior to approving any new, amended, repealed or replaced Policy, the Governance Entity will solicit and consider comments from the Participants on the new, amended, repealed or replaced Policy. To promote openness and transparency, the Governance Entity shall post proposed changes to the Policies to a publicly accessible location.
- Following the Governance Entity's approval of the new, amended, repealed or replaced Policy, the Participants shall be given at least 45 calendar days to review the approved Policy and provide written comments to the Governance Entity, except in the event that a shorter time period is necessary in order to comply with Applicable Law.





P&Ps #2. Amendment of P&Ps... continued

- If the Governance Entity receives no comments from Participants during the comment period, the new, amended, repealed or replaced Policy shall go into effect as approved by the Governance Entity and on the date identified by the Governance Entity, unless the Governance Entity withdraws the new, amended, repealed or replaced Policy prior to such date.
- If the Governance Entity receives comments from Participants during the comment period, the Governance Entity shall review the new, amended, repealed or replaced Policy in light of the comments and make a determination as to how to modify the new, amended, repealed or replaced Policy, if at all.
- Once the Governance Entity finalizes its determination, it shall provide at least 180 calendar days prior to notice of the effective date of the new, amended, repealed or replaced Policy, except in the event that a shorter time period is necessary in order to comply with Applicable Law.
- The Governance Entity shall maintain in a publicly accessible location all current Policies as well as originals of all amended, repealed and replaced Policies





P&Ps #3. Breach Notification

- "Breach" means the unauthorized acquisition, access, disclosure, or use of Health and Social Services Information not
 permitted by the DSA or Applicable Law, with certain exceptions listed in the DSA.
- Each Participant has the obligation to identify, notify, investigate and mitigate any known Breach or potential Breach, and when detection of a potential Breach has occurred, to notify the Governance Entity and any affected Participants of the potential Breach, as follows:
 - As soon as reasonably practicable, but no later than 72 hours after discovering a Breach has occurred, a Participant shall notify the Governance Entity and all affected Participants.
 - As soon as reasonably practicable, but no later than ten calendar days after discovering a Breach has occurred, a
 Participant shall provide a written report of the Breach to the Governance Entity and all affected Participants.
 - Notwithstanding the foregoing, within 24 hours following the discovery of a Breach that may involve a Governmental Participant, a Participant shall provide notification to all Governmental Participants that are likely impacted by the Breach.
 - Policy provides for exceptions with respect to requests for delays in Breach notification by law enforcement.





P&Ps #4. Permitted, Required, and Prohibited Purposes

- Required Purposes: Participants are <u>required</u> to exchange Health and Social Services Information or provide access to Health and Social Services Information for the following purposes:
 - Treatment
 - Payment
 - Health Care Operations (which for purposes of the DSA is limited to quality assessment and improvement activities and to certain population-based activities)
 - Public Health Activities
- Participants may only disclose Health and Social Services Information to another Participant for Health Care Operations if each entity either has or had a relationship with the Individual User who is the subject of the Health and Social Services Information being requested and the Health and Social Services Information pertains to such relationship.
- Permitted Purposes: Participants are <u>permitted</u> to exchange Health and Social Services Information or provide access to Health and Social Services Information they have obtained for <u>any other purpose (including, but not limited to social service</u> <u>activities and research activities</u>), provided appropriate Authorizations are made, if necessary, and the disclosure or use of Health and Social Services Information is permissible under Applicable Law.





P&Ps #4. Permitted, Required, and Prohibited Purposes ... continued

- **Prohibited Purposes**: Unless otherwise permitted by Applicable Law, Participants shall not:
 - Re-use, re-disclose, aggregate, de-identify, re-identify, or engage in the sale of Health and Social Services Information received through the DSA for their own indirect or direct financial benefit without explicit written authority to do so from the appropriate party. A Participant shall not be considered to be acting for its own benefit if:
 - The Participant is a Business Associate and has a legally enforceable written agreement authorizing the reuse, re-disclosure, aggregation, de-identification or re-identification of such Health and Social Services Information. This does not include the sale of Health and Social Services Information;
 - The Participant is performing Individual Access Services at the direction of an Individual User or an Individual User's Personal Representative; or
 - The Participant is a Social Services Organization and has a legally enforceable written agreement authorizing the re-use, re-disclosure, aggregation, de-identification or re-identification of such Health and Social Services Information with a government entity, Government Participant or other Social Services Organization. This shall not include the sale of Health and Social Services Information.
 - Be required to exchange or provide access to any information subject to 42 C.F.R. Part 2
- Specifications: Once specifications for a directory that sets forth how to exchange Health and Social Services
 Information among Participants has been developed, Participants will be required to provide the information set forth in
 those specifications.
- Fees: Participants are prohibited from charging fees to other Participants for any exchange of Health and Social Services Information under the DSA.

P&Ps #5. Requirement to Exchange Health & Social Services Info

- Duty to Respond
 - All Participants shall respond to requests for Health and Social Services Information made by other Participants and shall share Health and Social Services Information when required under the Required, Permitted and Prohibited Purposes Policy
- Technology Agnostic
 - The DxF is intended to be technology agnostic, meaning that no particular technology or method to exchange data is preferred.
 - Each Participant agrees to exchange Health and Social Services Information in accordance with the DxF to the extent the Participant is technologically ready and able and as set forth in the Policies and Procedures.
 - Participants that are not technologically ready and able shall not use such classification as a justification for failure to engage in the Meaningful Exchange of Health and Social Services Information under the DxF. Participants must engage in Meaningful Exchange of Health and Social Services Information.
 - Notwithstanding the requirements on the following page, or any applicable Policies and Procedures, a Social Services Organization is not required to exchange Health and Social Services Information or contract with another entity that provides data exchange services.





P&Ps #5. Requirement to Exchange Health & Social Services Info

Overview

Timing Considerations

- Starting January 31, 2024, the following Participants shall be considered technologically ready and able and shall exchange information under the DxF:
 - Healthcare organizations as set forth in California Health and Safety Code § 130290(f), except for physician
 practices of fewer than 25 physicians, rehabilitation hospitals, long-term acute care hospitals, acute psychiatric
 hospitals, critical access hospitals, rural general acute care hospitals with fewer than 100 acute care beds,
 state-run acute psychiatric hospitals, and any nonprofit clinic with fewer than 10 health care providers; and
 - Health information networks, health information organizations, health information service providers, and electronic health records technology providers.
- Starting January 31, 2024, the following Participants may access Health and Social Services Information under the DxF but are not required to disclose information until they are technologically ready and able:
 - Any healthcare provider, organization, group, facility, hospital, clinic, laboratory, health care service plan, health insurer or disability insurer exempted from the compliance date set forth in Section (2)(c) above;
 - Governmental Participants; and
 - Social Services Organizations.
- Starting January 31, 2026, physician practices of fewer than 25 physicians, rehabilitation hospitals, long term acute care hospitals, acute psychiatric hospitals, critical access hospitals, rural general acute care hospitals with fewer than 100 acute care beds, state-run acute psychiatric hospitals, and any nonprofit clinic with fewer than 10 health care providers shall be considered technologically ready and able and shall exchange information under the Data Exchange Framework.

P&Ps #6. Privacy and Security Safeguards

- Unless otherwise prohibited by Applicable Law, if a Participant is not a Covered Entity, a covered component of a Hybrid Entity or a Business Associate, the Participant shall, as a contractual standard, at all times, at a minimum, comply with the provisions of the HIPAA Regulations at 45 C.F.R. part 164, subparts C and E, as if it were acting in the capacity of a Business Associate.
- Each Participant shall be responsible for maintaining a secure environment that supports the exchange of PHI or PII
 pursuant to the DSA. Each Participant, regardless of whether it, pursuant to federal law, is subject to the HIPAA Regulations,
 shall use appropriate safeguards to prevent unauthorized use or disclosure of PHI or PII in a manner consistent with HIPAA
 Regulations, including implementing appropriate administrative, physical, and technical safeguards that protect the
 confidentiality, integrity, and availability of PHI or PII.
- Participants shall also be required to comply with any Specifications or other applicable Policies and Procedures that define requirements and expectations for Participants with respect to enterprise privacy and security.
- Each Participant acknowledges a Participant does not become a Business Associate of another Participant by virtue of signing the DSA or exchanging PHI or PII pursuant to the DSA.





P&Ps #7. Individual Access Services

- Participants shall provide an Individual User or an Individual User's Personal Representative access to inspect and obtain a copy of PHI or PII about the Individual User in a Designated Record Set (as defined in the HIPAA regulations).
 - Notwithstanding the foregoing, if permitted under Applicable Law, a Participant shall have the authority to deny right of access to inspect or obtain a copy of PHI or PII.
 - A Participant may require the Individual User or the Individual User's Personal Representative to assert their right to access the Individual User's PHI or PII in accordance with the HIPAA Regulations.
 - A Participant shall provide the Individual User or the Individual User's Personal Representative with the option of using electronic means (e.g., email or secure web portal) or other such means as determined by the Governance Entity to assert their rights for Individual Access Services to PHI or PII
- Prior to providing such access, the Participant shall be required to verify the identity of the Individual User or the Individual User's Personal Representative using standards and methods consistent with 45 C.F.R. § 164.514(h).
- Participants may not charge another Participant any fees for PHI or PII exchanged in furtherance of this P&P.



P&Ps #8. Data Elements to be Exchanged

- Participants shall make available or exchange, at a minimum, data based on their organizational categories:
 - Health Care Providers: Data required to be shared by actors under information blocking, expanding to USCDI v2:
 - Until October 6, 2022, data elements in the United States Core Data for Interoperability (USCDI) Version 1 and held by the entity.
 - After October 6, 2022, all Electronic Health Information (EHI) as defined under federal regulation in Section 171.102 of Title 45 of the Code of Federal Regulations, including data elements in the USCDI Version 2, and held by the entity.
 - **County health facilities and public health agencies**: The same data required of Health Care Providers, as allowed by Applicable Law.
 - *Health Plans*: Data required to be shared under the Centers for Medicare and Medicaid Services Interoperability and Patient Access regulations for public programs, expanding to USCDI v2:
 - For Individual Access Services, adjudicated claims and encounter information shall include cost information.
 - For Participants and Purposes other than Individual Access Services, cost information may be omitted.
 - o After October 6, 2022, clinical data shall include data elements in the USCDI Version 2 if held by the entity.
 - **Intermediaries**: The same data that is required to be shared by the organizations for whom the intermediary is facilitating exchange.
 - Participants not listed, including but not limited to Social Services Organizations shall provide access to or exchange Health and Social Services Information as defined broadly in the DSA. Data to be exchanged by other Participants may be the subject of a future revision to this policy.

P&Ps #8. Data Elements to be Exchanged...continued

- Participants shall use standardized data element formats, terminologies, and code sets identified in USCDI Version 2.
- For data elements not included in USCDI Version 2, Participants shall use standardized data element formats, terminologies, and code sets identified in applicable nationally recognized standards.
- Participants shall use nationally recognized data standard formats, which shall include one the following:
 - HL7 Messaging Standard Version 2.5.1 or greater
 - HL7 Clinical Document Architecture (CDA®) Release 2, HL7 Companion Guide to Consolidated Clinical Document Architecture (C-CDA®) 2.1 preferred if applicable
 - HL7 Fast Health Interoperability Resources (FHIR®) Release 4.0.1, US Core Implementation Guide 4.0.0 STU4 or greater preferred.



Public Comment Period



Data Exchange Framework Component Documents



DxF Component Documents

The six DxF Component Documents were shared with the AG on May 12th. Written comments will be accepted <u>through June 1st</u>.

| Document | Description |
|--|---|
| (1) DxF Development Process | An overview of the development process for the DxF document as well as the DSA, P&Ps, and Strategy for Digital Identities. |
| (2) DxF Guiding Principles | Documentation of the Data Exchange Framework Guiding Principles. |
| (3) CA Data Exchange Landscape | A review of the history of federal and CA initiatives to advance data exchange and of the current landscape of data exchange in CA. |
| (4) Data Exchange Scenarios | Updates to the six data exchange "scenarios" that were presented to the AG. |
| (5) DxF Governance | The proposed DxF governance model. |
| (6) CA Data Exchange Gaps and Opportunities | Description of the identified data gaps and opportunities. |



Digital Identity Strategy Update



Summary of Comments Received

CDII Presented a Draft Strategy for Digital Identities at the April 7th DxF Stakeholder Advisory Group Meeting

Comments Received

Attributes of Digital Identities

- 1. General support for attributes
- 2. Local identifiers should be included as appropriate
- 3. Should exchange unique statewide identifiers
- 4. Do not limit attributes (e.g., include gender)
- 5. Consumers should have control over elements

Purposes for Use

- 6. Should not exclude population health research Statewide Index
 - 7. Little value since interstate exchange is needed

Action Taken

Attributes of Digital Identities

- 1. Attributes unchanged
- 2. Local identifiers retained
- 3. Deferred until tokenization can be implemented
- 4. Limitations retrained for privacy per focus groups
- 5. Will explore within statewide index

Purposes for Use

6. Exclusion is only for attributes in digital identities <u>Statewide Index</u>

7. Retained for in-state matching per focus groups



Next Steps

The draft Strategy for Digital Identities will be released for public comment next week

The public comment period for the draft Strategy for Digital Identities will close approximately 10 business days after it is released. CDII is particularly interested in feedback around:

- 1. Attributes included in digital identities.
- 2. The use of digital identities in population health research, noting that the only restriction is that demographics in digital identities not be used as search criteria or to stratify populations.
- 3. Purposes for use, given considering the draft DSA and P&Ps.
- 4. The utility of a statewide index.



Governance & Budget Update



Governance and Budget Update

Governance

- CDII will begin developing the required infrastructure at CalHHS and CDII on to support and oversee DxF compliance on July 1st.
- CDII will continue to work with stakeholders in the summer and fall around the formation of a HIE Policy Board, which is planned to be established in January 2023 with the Governor's Budget.

Governor's Budget May Revision

- The Governor is proposing to establish a:
 - \$50M grant program at CDII to provide technical assistance to small or under-resourced providers.
 - \$200M practice transformation grant program at DHCS for small physician practices to upgrade their clinical infrastructure, such as expanding EHRs, data collection and reporting capabilities, implementation of care management systems, and other activities that will allow the adoption of the DxF.



Material Review Timeline

| Status | Step |
|--------------|--|
| \checkmark | Convene DxF Stakeholder Advisory Group (AG) |
| \checkmark | Convene AG Data Sharing Agreement Subcommittee |
| \checkmark | Identify key barriers to data exchange across technical infrastructure and standards, financing and business operations, and regulatory and policy domains |
| \checkmark | Establish guiding principles for health and human services data exchange in California |
| \checkmark | Provide feedback on options for resolving infrastructure gaps (HIT) |
| \checkmark | Provide feedback on resolution options for standards and consumer access gaps |
| \checkmark | Provide feedback on a potential governance model |
| \checkmark | Provide feedback on a potential governance model and for resolving regulatory and policy gaps |
| \checkmark | Provide feedback on elements of draft DxF and DSA |
| 6/23 | Review updates to the draft DxF and DSA based on submitted feedback |

For more information or questions on Stakeholder Advisory Group meeting scheduling and logistics, please email Khoua Vang (<u>khoua.vang@chhs.ca.gov</u>).

Next Steps: Material Review & Finalization

| Date | Step |
|--|---|
| May 18 | AG Meeting #8 Draft DxF, DSA, and P&Ps posted for public comment |
| Week of May 23 | Draft Strategy for Digital Identities posted for public comment |
| June 1, End-of-day | Comments due on draft DxF, DSA, and P&Ps |
| Draft Strategy for Digital Identities posted + 10 business days | Comments due on draft Strategy for Digital Identities |
| June 23 | Updates to all draft materials discussed at AG Meeting #9 |
| July 1 | Final versions of DxF, DSA, and P&Ps released |
| July 31 | Final version of Strategy for Digital Identities released |

